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CENTRE FOR MILITARY & VETERANS' HEALTH

The Middle East Area of Operations (MEAO) Health Study:

Prospective Study Report

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THE UNIVERSITY OF ADELAIDE AUSTRALIA

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MIHOP

Appendices – Volume Two

Appendix A

Chapter Five

Preliminary Study Report

Middle East Area of Operations (MEAO) Health Study

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Abbreviations

Abbreviation	Description
ADF	Australian Defence Force
CMVH	Centre for Military and Veterans' Health
DCO	Defence Community Organisation
DHSD	Defence Health Services Division
DHSP	Deployment Health Surveillance Program
DSTO	Defence Science and Technology Organisation
DVA	Department of Veterans' Affairs
ESO	Ex-Service Organisation
JOC	Joint Operations Command
MEAO	Middle East Area of Operations
NNAI	Near North Areas of Influence
PMB	Program Management Board
PMO	Program Management Office
PTSD	Post Traumatic Stress Disorder
RAAF	Royal Australian Air Force
RAN	Royal Australian Navy
RSL	Returned Services League
SAC	Scientific Advisory Committee
SRT	Scientific Research Team
UA	University of Adelaide
UQ	University of Queensland

Executive Summary

Introduction

1. This report describes the activities and outcomes of the Middle East Area of Operations (MEAO) Health Study preliminary study. This planning stage undertaken during 2009 included meetings with stakeholders, focus groups and piloting testing the study questionnaire with the target population.

2. The objective of the preliminary study was to conduct pre-testing of the survey instrument by gaining broad stakeholder and consumer input to the development of the study instruments and mode of data collection.

Methods

3. The preliminary study involved three activities: meetings with stakeholders, focus groups with serving and ex-serving Defence Force personnel, and pilot testing of the questionnaire.

4. Meetings with stakeholders occurred both formally and informally to gain feedback on the proposed study design and assessments. These included ongoing input and support from Defence through the Deployment Health Surveillance Program Management Office, as well as input from:

- Defence Force Units
- Other Federal Government Departments
- Ex-service organisations and veteran advocacy groups (both formal and informal)
- DVA advocates
- International military and veterans' health research centres

5. Twenty-five focus groups were held between 28 April 2009 and 13 August 2009 at eight bases hosting Force Units that have deployed to the MEAO. Several focus groups were offered at each base to accommodate different types of veterans (commissioned and non commissioned Officers, combat and combat-support personnel) and special groups such as medical staff and women. Two focus groups were held with MEAO veterans who had separated from the ADF. In all, 130 individuals participated in these 25 focus groups, which were run by CMVH staff with training and experience in the conduct of focus groups. The initial analysis of focus group discussions utilised an abridged transcript that was created from the audio record and observer/scribe notes.

6. Findings from the focus group discussions were mapped to the draft questionnaire. Suggestions to amend the questionnaire were made and reviewed by a working group at the University of Adelaide. All participants who took part in a focus group (n=130) were subsequently provided with a hard copy of the amended questionnaire for pilot testing.

Results

7. Stakeholder meetings informed the development of the draft questionnaire and refinement of study protocols and procedures as presented in the Detailed Research Plan of May 2009.

8. Focus groups then enabled direct input to the selection of health hazards and health concerns for health surveillance. The focus group outcomes reported here focus on three key topics: 1) identification of health hazards, 2) identification of health concerns, and 3) conducting the study.

9. Health hazards fell into two broad areas – major stressors and physical hazards. Major stressors included: Working in a combat zone; Operational and organisational stress; Families and returning to Australia and; Life on deployment. A wide range of physical hazards of concern were reported by MEAO veterans during the focus group discussions. Together, the stressors and

physical hazards were mapped to the draft questionnaire. This revealed where an issue of concern to veterans was not assessed, or where fuller assessment of pertinent issues was required.

10. A similar approach was taken in the mapping of health concerns. These were grouped into those that were of concern on deployment (Annex 4), and those that were of concern to veterans now and looking toward the future (Annex 5).

11. Participants also discussed how the main study could be conducted to maximise recruitment and completion of the study questionnaires and procedures.

12. Amendments were made to the draft questionnaire based on the outcomes of the focus group discussions. The questionnaire was then mailed to these participants. Thirty questionnaires were returned. Each of the returned questionnaires was independently reviewed by two UA Node staff, Dr Christopher Barton and Miss Jenelle Baur. Participant comments were noted along with missing items, entry of data in incorrect areas and any other problems with structure, flow and the organisation of items as indicated by the participant. A table of proposed amendments was developed and reviewed by the wider DHSP Project Team. The questionnaire was then refined based on these discussions.

Conclusions

13. The preliminary study complements the activities already undertaken in the development of the MEAO study protocol to identify health problems and health hazards for surveillance. This has included funded activities conducted as part of Phase 1a (review of the literature and review of health hazards) and Phase 1b (Detailed Research Plan). These previous activities drew on the published and grey scientific and medical literature, experience of the investigators and the input of the Defence-appointed SAC and PMB. The preliminary study complements this by incorporating the views of stakeholders (e.g. veterans' advocacy groups) and consumers (e.g. the veterans themselves).

14. The stakeholder meetings and focus groups largely confirmed the initial selection of health issues for surveillance and the priority attached to these issues. Where discrepancies were identified the questionnaire was amended such that veterans' concerns would be appropriately addressed. Pilot testing of the questionnaire enabled the checking of content, structure and flow issues, which were then able to be resolved.

15. The outcomes of the preliminary study engender confidence that the MEAO Health Study survey has strong face validity (i.e. measures what is important to stakeholders and consumers to measure) and will produce data that can be analysed confidently to answer the MEAO Health Study research questions.

Introduction

1. The Middle East Area of Operation (MEAO) Health study is the next study to be initiated within the Deployment Health Surveillance Program (DHSP). This program has recruited ADF personnel and comparison groups for health studies focussed on deployments to the Solomon Islands, East Timor, and Bougainville (collectively referred to as the Near North Area of Influence (NNAI) studies). The MEAO Health Study will add ADF personnel who participated in Operations in Afghanistan, Iraq, and areas supporting Operations in these countries. As the MEAO study was initiated at a time when the earlier DHSP studies were at advanced stages of implementation, it has been possible to incorporate lessons learnt from these studies.

2. The MEAO Health Study forms part of a coherent program of health surveillance of deployed ADF personnel and, as such, it is desirable that data collected on the MEAO deployed cohort are comparable to that collected in the previous DHSP studies. However, it is recognised that the MEAO deployments have been undertaken under very different conditions and largely different circumstances from most of the NNAI deployments that were the focus of the earlier DHSP studies. Hence, different exposures need to be assessed and the health issues for surveillance may be different to those assessed in the earlier studies.

3. The MEAO deployments are anticipated to be the greater source of risk, in terms of both the burden of disease and the cost of entitlements, compared to the other ADF deployments within the DHSP.

4. A preliminary study was initiated to conduct pre-testing of instruments for data collection. Pre-testing involves a series of activities that are designed to evaluate a survey instrument's capacity to collect the desired data, the capabilities of the selected mode of data collection, and the overall adequacy of the mode of data collection.

5. This report describes the activities and outcomes of the preliminary study. This planning stage undertaken during 2009 included meetings with stakeholders, focus groups and pilot testing the study questionnaire with the target population.

Objective

6. The objective of the preliminary study was to pre-test the survey instrument by gaining broad stakeholder and consumer input to the development of the study instruments and mode of data collection.

Aims

7. Focus groups with veterans of the MEAO were held to:

- Capture qualitative data on the experiences and health concerns of MEAO veterans that could be mapped to the health and exposure questionnaire to check the validity and relevance of items to be assessed; and,
- Begin the process of engaging ADF and ex-serving members in the MEAO Health Study.

8. The subsequent aim was to refine the draft study questionnaire based on the input of focus group participants and to pilot test it as a check of face validity and to identify potential content, structure or flow problems.

Methods

Study Design

9. The preliminary study focused on pre-testing the survey instrument. It involved three primary activities: meetings with stakeholders, focus groups with serving and ex-serving Defence Force personnel, and pilot testing of the questionnaire.

Participants

10. Meetings with stakeholders were conducted throughout 2008 and 2009 to gain feedback on the proposed study design and assessments. These included ongoing input and support from Defence through the PMO, as well as input from:

- Defence Force Units
- Other Federal Government Departments
- Ex-service organisations and veteran advocacy groups (both formal and informal)
- DVA advocates
- International military and veterans health research centres

11. Focus group participants were drawn from eight bases hosting Force Units that have deployed to the MEAO. Several focus groups were offered at each base to accommodate different types of veterans (commissioned and non commissioned personnel) and special groups such as medical staff, Commanding Officers and women. Two focus groups were held with MEAO veterans who had separated from the ADF.

12. All participants who took part in a focus group were invited to pilot test the study questionnaire.

Focus Group Method

13. The focus group method was selected to obtain information about the health and exposure experiences and concerns of the veterans. This approach enabled the research team to gain a broad understanding of the health issues and concerns of a variety of Service personnel in a short period of time and provided guidance on why these groups think and act the way that they do.

14. The focus groups were conducted according to the protocol and approach recommended by Kreuger and Casey[1], and Morgan and Kreuger[2].

15. Command endorsement was obtained from each of the Single Service Chiefs. A CMVH Liaison Officer from each of the three services identified Commanding Officers and initiated contact to arrange access to personnel and suitable facilities. A point of contact was assigned at each of the military bases, which provided local promotion and coordination of the focus group. LTCOL Peter Nasveld, CMVH Research Manager, was instrumental in identifying points of contact and arranging Defence liaison for focus groups.

Selection of participants for focus groups

16. Stratified purposive sampling and quota sampling were used to select the characteristics of potential participants for the focus groups. Purposive sampling involved selecting individuals because they had particular features or characteristics that enabled exploration and understanding of issues of concern to a broad range of MEAO veterans.

17. Quota sampling was also applied to ensure that a wide range of sub-groups were included in the final sample; particularly those smaller groups of interest in Defence (e.g. women) were included in the final sample. Quota sampling is common in qualitative research and involves selecting sub-populations of interest and the proportion of those sub-populations that will make up the final sample.

18. Quota was applied to gender (with one focus group restricted to female participants only), rank (Officer/other rank), role (Combat/Combat Support or Aircrew/non-aircrew/health) and Service.

19. Two of the focus groups (one in Adelaide and one in Brisbane) were restricted to MEAO veterans who had separated from the ADF. These ex-serving members were encouraged to participate through advertisements in the general media, veterans' publications, and personal contacts.

Focus Group Procedure

20. Focus group sessions were facilitated by Dr Christopher Barton, SQNLDR Michel Devine, or Ms Freya Goodhew. A/Prof Susan Treloar assisted in facilitating two focus groups. University facilitators were experienced in the conduct of focus groups.

21. Consent to record the session (either as notes or a digital audio recording) was sought at the beginning of each focus group. If verbal consent to take an audio record was not provided, the second investigator/research associate was instructed to take notes and to observe and note additional non-verbal information during the focus group.

22. Each focus group, other than four groups with Special Forces elements, was digitally recorded.

23. An interview guide was developed according to the protocol of Morgan and Kreuger[2], and used by the moderator to guide the discussion. Questions covered four broad areas including:

- Health concerns
- Positive and negative aspects of the deployment
- Experiences after returning from deployment
- Strategies for recruitment to the study and the use of incentives

Analysis of information gained from focus groups

24. Initially, in order to finalise the study questionnaire for pilot testing and meet the deadline for reporting, key themes and key issues were identified from the notes of the observer/scribe and from a review of the audio record. The latter involved listening to the audio file and making an abridged transcript to supplement the written notes of the observer. Thorough qualitative analysis of focus group transcripts will be conducted subsequently to fully explore the data provided.

25. The key themes and issues that were identified in this manner were mapped to the battery of assessments planned for the MEAO Health Study as a check that the key health and exposure concerns of personnel were assessed in the questionnaire.

26. Suggestions to amend the questionnaire were compiled. These were then reviewed and discussed by a working group at the CMVH UA Node. This group comprised Professor Alexander McFarlane, Dr Christopher Barton, SQNLDR Michel Devine, Miss Jenelle Baur and Mr Daniel Barnes.

27. Each item within the questionnaire was discussed until consensus was reached as to whether the item would be retained, amended or deleted. At this point, the questionnaire was considered 'print ready', in preparation for pilot testing.

Pilot Testing the Study Questionnaire

28. At the conclusion of each focus group, participants were asked if they would be willing to pilot test the study questionnaire once the preliminary analysis of the focus group data had been undertaken and changes to the study questionnaire arising from the focus groups had been made.

29. On 21 July 2009, the first 118 focus group participants were emailed to advise them that shortly they would receive a hard copy of the questionnaire in the mail, and that they should complete this questionnaire and provide additional written feedback to the study investigators.

30. The questionnaire was mailed to participants the following day. Participants were advised that responses were required by 31 July 2009.

Analysis of pilot study data

31. Each of the returned questionnaires was independently reviewed by two UA Node staff, Dr Christopher Barton and Miss Jenelle Baur. Participant comments were noted along with missing items, entry of data in incorrect areas and any other problems with the structure, flow and organisation of items as indicated by the participant.

32. A table of proposed amendments was developed and reviewed by the wider DHSP Project Team (including staff from both UA and UQ Nodes). The questionnaire was then refined based on these discussions.

33. Five focus groups were unable to be organised in time to meet the deadlines noted above. These focus groups involving Navy personnel at HMAS Kuttabul and Army personnel from 5 Aviation Regiment were held on 21 July 2009 and 13 August 2009 respectively. The revised questionnaire was provided to these focus group participants on 13 August 2009.

Results

34. The results are presented in three parts: I) Stakeholder meetings, II) Focus group outcomes, and III) Pilot Study outcomes.

Results Part I: Stakeholder meetings

35. Stakeholder meetings targeting key Defence and veteran stakeholders were conducted to gain feedback on the proposed study design and assessments, in addition to the ongoing input and support from Defence through the PMO.

36. These meetings included both formal (e.g. planned meetings with agenda and official representation) and informal discussion (including phone, email, or face to face meetings without agenda or official representation).

37. These discussions informed the development of the draft questionnaire and refinement of study protocols and procedures as presented in the Detailed Research Plan of May 2009.

Table 1.1: Stakeholder meetings held with individuals and organisations

Formal meeting	*Informal discussion*
1. Department of Defence, Joint Health Command, Program Management Board	1. Joint Operations Command (JOC)
2. Defence appointed Scientific Advisory Committee to the DHSP	2. Aviation Medicine Unit at RAAF Base Edinburgh
3. Department of Veterans' Affairs	3. Defence Science and Technology Organisation (DSTO)
4. National Younger Veterans' Consultative Forum (CMVH has a standing agenda item)	4. Australian Defence Association
5. Defence Force Units including: · 1 Psychology Unit	5. Returned Services League (RSL)
6. Millennium Cohort Group	6. Young Diggers
7. Professor Simon Wessely, Kings College London	7. Australian Peacekeepers and Peacemakers Veterans' Association
8. Mental Health Research Unit of the Dutch Armed Services	8. DVA Advocates
	9. Directorate of Mental Health, Canadian Armed Forces
	10. Defence Force Units including · SAS-R

Results Part II - Focus Group Outcomes

38. Twenty-five focus groups were completed between 28 April 2009 and 13 August 2009 (Table 1.2). These involved discussions with 130 MEAO veterans. The number of participants in each group ranged from 1 to 10. The majority of participants were still members of the ADF (n = 123), while seven ex-serving MEAO veterans participated in a focus group held in either Adelaide (n = 3) or Brisbane (n = 4). Only one focus group that was targeted at Navy sailors failed to attract any participants (Table 1.2), although this focus group could only be held at a time when no ships were alongside at HMAS Kuttabul.

39. All focus groups were digitally recorded except for groups with Special Forces elements (SAS-R and 4RAR). A total of 21 hours of audio was collected. When the group was not recorded, detailed notes were taken by an observer/scribe.

40. No adverse incidents occurred during the focus group discussions and all but one individual consented to participate after discussing the study with the research team. The individual who did not participate after hearing more about the study did not specify a reason for non-participation.

Table 1.2: Focus groups offered and the number of participants attending each group

Service	*Date*	*Group type offered*	*No. Attending*	*Facilitator and Scribe*
Royal Australian Navy				
Fleet Base East, Potts Point, Sydney	21/7/2009	Officers Sailors Medical Women	1 0 1 2	CB and FG (FG facilitated women's only group)
Australian Regular Army				
1st BDE, Robertson Barracks, NT	4/6/2009	Officers Combat Combat Support Medics	7 6 6 3	CB and FG
3rd BDE, Townsville, QLD	17/6/2009 and 13/8/2009	Officers Combat Combat Support Medics 5 AVN air crew 5AVN non-aircrew	2 10 10 4 7 5	CB and MVH CB and ST
7th BDE, Enoggera, QLD	NA	Officers Combat Combat Support Women	On exercises during study period.	NA
SAS-R, Perth	4/6/2009	Officers Other Ranks	5 9	MD and CC
4RAR, Holsworthy, Sydney	26/6/2009	Officers Other Ranks	4 10	MD and CC
Royal Australian Air Force				
Edinburgh, Adelaide	28/4/2009 21/5/2009	Aircrew Non Aircrew Medical	6 6 4	CB and DB
Richmond, Sydney	27/4/2009	Aircrew Non Aircrew Medical	3 1 10	CB and DB
Ex Serving				
Brisbane	25/6/2009	Ex-serving	4	CB and ST
Adelaide	28/9/2009	Ex-serving	3	CB

Focus Group Findings

41. The initial analysis of focus group discussions utilised an abridged transcript that was created from the audio record and observer/scribe notes as described in the methods. The outcomes reported here focus on three key topics: 1) identification of health hazards, 2) identification of health concerns, and 3) conducting the study. These were chosen as the first topics to investigate as they could be used to enhance the study protocol and, in particular, the study questionnaire. A more complete analysis utilising the verbatim transcript will be conducted later in 2009.

Health Hazards

42. Health hazards fell into two broad areas – major stressors and physical hazards.

43. Major stressors fell into four broad thematic areas which were labelled:

- Theme 1: Working in a combat zone
- Theme 2: Operational and organisational stress
- Theme 3: Families and returning to Australia
- Theme 4: Life on deployment

44. Within each thematic area there were a number of sub-categories contributing to the broader theme. The themes and sub-categories within each theme are detailed in Annex 2. For each sub-category the issue of concern is noted, as well as the group who raised the issue (individuals are not identified), an example of the issue using quotations taken from the focus group audio recording, how this issue is currently assessed in the draft study questionnaire, and a suggestion for how it could be assessed differently or more fully (as appropriate).

45. The physical hazards reported during focus group discussions are presented in Annex 3. It can be seen that they are organised alphabetically rather than thematically. Organising identified hazards this way was done for pragmatic reasons and facilitated the mapping process for these issues. The information is presented in a table that includes the issue identified, the group identifying the issue, an example from the audio recording, how this is currently assessed in the questionnaire and finally a suggestion for how it could be assessed differently or more fully (as appropriate).

Health concerns

46. Health concerns were grouped into those that were of concern on deployment (Annex 4), and those that were of concern to veterans now and looking toward the future (Annex 5).

47. For the mapping exercise, these were listed alphabetically rather than thematically. As can be seen in the tables presented in the annexes, only minor amendments were suggested to ensure that health concerns on deployment and in the long term were being assessed in the survey instruments.

Conducting the study

48. Participants were asked how the study could be conducted to maximise recruitment and completion of the study questionnaires and procedures. The outcomes of this aspect of the focus group discussion are summarised below in Table 1.3 and Table 1.4, and have been reported as ‘do’s’ and ‘don’ts’.

Table 1.3: Focus group participants' views on the style of the survey instrument

Do	*Don't*
• Keep it short • Provide opportunity for respondents to tell their story (e.g. use open ended questions) • Make the survey relevant to the role of the member (e.g. dead bodies rarely seen by support staff) • Include families • Use pre and post assessments	• Make it too long > 5 minutes 10-20 minutes max > 30 minutes • Assume one size fits all

Table 1.4: Focus group participants' views on promoting the study and recruiting veterans

Do	*Don't*
Use financial incentives (except for one combat-support group who were against) • Offer motor vehicle • offer $10,000 (i.e. significant amount) • offer leave • offer travel to exotic location • offer time off of work • offer movie vouchers • raffle	Email. Email is often deleted if optional • too busy • too many other things to do
Use chain of command. Get support of CO's/Flight Commanders. The CO must order 'do not touch this person' so they can complete the questionnaire.	Link survey to medical or psychology health checks. Members want to deploy and will avoid anything that threatens deployability.
Serving ADF personnel need to be "voluntold"	Promote it as a 'health study'. Health does not appeal as ADF members already do so many health related checks/questionnaires.
Provide an opportunity to complete the survey on base	Make it a burden (on time). A lot of hoops to jump through pre-deployment – minimise additional burden.
Use RAAF/RAN/Army Newspapers	Convey perception that a health problem is a weakness.
Consider promoting study participation into pre-deployment briefings. • Pre-deployment Environmental Health Lecture • Family nights • Pre-deployment psychology briefing	Use a 'brand' name like MilHOP or another acronym to name the study. Don't care what it is called. Just state clearly what the key objectives and key outcomes are going to be.
Consider link to AHA pre/post medical exam	Don't assume all individuals in the ADF will have access to a computer.
Respondents want to know that Defence/others understand the pressures they face	
Focus recruitment on individuals while they are in the ADF. Once out of Defence system they will be lost	

Respondents want to know that Defence take the research seriously.	
Respondents want to know that if there are issues, they will be identified and acted on	
Use RAR associations	
Emphasise independence from the ADF. Respondents need to be sure confidentiality is maintained, as they do not want to risk not being deployed. Sceptical of hidden agendas through the organisation.	
Respondents want good feedback and results to be applicable to the individual or at a local level (tangible outcomes from participation)	
Use Def Web and DRN pop ups.	

Pilot Study Outcomes

49. The questionnaire presented to the PMO and SAC in the Detailed Research Plan of May 2009 formed the draft questionnaire, which was the starting point for the development of the questionnaire that was ultimately pilot tested.

50. The issues identified by focus group participants were mapped to this questionnaire by the Research Fellow as described above as part of the focus group study. At that point, the focus group study was considered to have concluded and the pilot testing of the study questionnaire to have begun.

51. The mapping exercise revealed where there was a lack of assessment of a health concern or hazard, or where a higher priority was placed on an issue than was comparable to the level of assessment in the questionnaire. Potential alternative questions were identified by the Research Fellow.

52. A working group was formed to review the suggested amendments and make a final decision on what questions would be included for pilot testing. This working group was led by Professor McFarlane and included Dr Christopher Barton (Research Fellow), SQNLDR Michel Devine (CMVH liaison officer with RAAF nursing background), Mr Daniel Barnes (research officer) and Miss Jenelle Baur (research officer), who were each involved in the development of the questionnaire or the conduct of the focus groups.

53. Each of the suggested changes to the questionnaire were debated in the context of the overall aims of the DHSP and the MEAO Health Study and requirements to maintain contemporary standards of scientific quality and annotations made against the items for review in the questionnaire (Annex 6).

54. Further, the phrasing and wording of instructions and questions was reviewed and amended to reflect the colloquial use of language by sailors, soldiers, and airmen, as much as possible. Wording of instructions to validated scales and the questions within validated scales was never altered.

55. These changes were incorporated into the questionnaire and a hard copy in teleform format was created for pilot testing. This version of the questionnaire was mailed to the first 118 focus group participants on 21 July 2009 (focus group participants from the RAN and 5AVN Regiment were not included at this stage).

56. In completing the pilot questionnaire these participants were asked to comment on:

- The questions: do they address your health and exposure concerns?
- Do the questions address the health and exposure concerns of your mates and colleagues, who were not able to participate in a focus group?
- How long did it take you to complete the questionnaire? Is it too long, or about right?
- What else can we do to ensure any health concerns or exposure concerns you or your colleagues have are picked up on?

57. Feedback was requested by the 31 July 2009. However, it was apparent that some individuals did not receive the questionnaire until the first week of August. A reminder was emailed on 12 August 2009. Thirty-two participants returned the questionnaire (to 20 August 2009), six questionnaires were 'returned to sender' and three individuals had deployed before receiving the questionnaire. Excluding those who did not receive the questionnaire, the response rate was 29%.

58. On 3 August 2009, the returned questionnaires were reviewed by Dr Barton and Miss Baur. They reviewed hand-written comments made by the participants in the questionnaire and identified issues apparent in the structure and flow of the questions. These problems are listed in Table 1.5 below, together with the list of suggested amendments to remedy the issue and the rationale for the amendment.

Table 1.5: Problems with the pilot questionnaire and rationale for each change to the instrument

Section / Question Number	*Question*	*Suggested Amendment*	*Rationale*
Part I - Deployment History Section			
Pre-Deployment History	Other Deployments – OP RESOLUTE	Add 2006, 2007 and 2008.	As indicated by one participant
Part II - Health Section			
Section 2, 2.3	Medically diagnosed conditions	Add asthma	Dr diagnosed asthma was removed from section 5 and added here.
Section 2, 2.7	Medically diagnosed conditions	Add malaria	Several cases of malaria were reported during focus group and so this has been added as an option here.
Section 2	Medically diagnosed conditions	Add 'any other condition?'	Currently no option for any other conditions so this has been corrected here.
Section 2		Underline 'medical doctor'	
Section 3, 3.7	Was your smoking pattern different on deployment?	Add option for "I began/restarted smoking on deployment"	This addresses a gap in the current questions were smoking is only considered active prior to deployment.
Section 4, 4.21	Is there any other event that has caused you to have similar reactions?	Underline 'other'	
Section 5	Respiratory Health	Delete 5.3, 5.4, 5.7, 5.8, 5.9, 5.10, 5.11, 5.12	Questions amended so that they are identical to the ECRHS screening

			questions.
Section 6, 6.3	Have you had problems with infertility?	Move to 6.1	Individuals are missing this question. It also makes sense to ask it at the beginning as may explain no children.
Section 6, 6.2	How many weeks were you pregnant for?	CHANGE TO 'how many weeks was the pregnancy'	Majority of individuals will be male and some not answering this question as not themselves pregnant
Section 6	All	Underline key words	Clarify key issues to answer
Section 6	How many weeks pregnant '37 or more'?	Add words '37 or more (full term)'	Clarify meaning
Section 8 Background demographics	All	Move to end of questionnaire	Currently sits in middle of questionnaire, which is inappropriate. Moved to beginning of questionnaire.
Section 8	New Question	Add today's date	For calculation of age and data checking
Section 8, 8.14	What year did you discharge?	Add option for discharge to the Reserves	Some participants will discharge from regular to reserve service, so not out of ADF entirely
Section 8, 8.17	Specify what health problems led to unemployment?	Add more area for participants to respond	Allows for multiple health problems to be identified.
Section 8, 8.9	How many hours per week do you work?	CHANGE TO 'how many hours per week are you in paid employment	This is a question about under-employment. 1 participant raised issue of how to report retirement and volunteer work.
Part III - Deployment Experiences			
Instructions on front cover	New Question	Add – deployment to supporting regions	Two participants did not complete experiences form indicating they were in other areas supporting operations in Afghanistan.
Free text fields		ADD 'Please write clearly in capital letters'	Some handwriting illegible.
Section 10, 10.2 Section 17, 17.2	Main Duties	Add - Oil Platform protection	Navy exposure
Section 11, 11.24 Section 18, 18.24	Did you have sex with locals?	Delete	Uncertain if this is going to generate valid result due to Australian cultural attitudes.
Section 11, 11.62	Any additional	Make this box bigger	

Section 18, 18.62	experiences		
Section 12, 12.7 Section 19, 19.7	'During your deployment did you?'	Make it more obvious that if answer yes to any of these activities than must indicate if this benefitted the local community	Some individuals indicated activities but did not report if they perceived a benefit to community of this activity.
Section 15, 15.7 and 15.8 Section 22, 22.7 and 22.8	Scanning the environment for risk	Add an option 'Immediately'	Need to have a 0 time point.
Section 13, 13.2 Section 20, 20.2	Were you temporarily not fit for duty?	Delete	Participants not completing this series of questions correctly. If attended sick parade will now be able to indicate the reason. If medically not fit will indicate this by recording time out of role.
Section 13, 13.2 If Yes (i) Section 20, 20.2 If Yes (i)	Respiratory Illness	Add If yes 'did you experience a fever'	This will discriminate against flu and cold.
Section 15, 15.14 Section 22, 22.14	Quality of marriage and relationships	Add numbers to boxes	To provide an indicator of scale.

59. The changes indicated above were incorporated into the questionnaire to produce the 'print ready' questionnaire (MEAO Study Deliverable 4) (Annex 7). As a final check, this print ready questionnaire was mailed to focus group participants from the RAN and 5 Aviation Regiment on the 13 August 2009.

Discussion

60. As part of the planning phases of the MEAO Health Study, a preliminary study that involved pre-testing of the survey instruments was conducted. This comprised formal and informal meetings and discussion with stakeholders, focus groups with veterans of the MEAO, and pilot testing the study questionnaire.

61. The preliminary study complements the activities already undertaken in the development of the MEAO study protocol to identify health problems and health hazards for surveillance. This has included funded activities conducted as part of Phase 1a (review of the literature and review of health hazards) and Phase 1b (Detailed Research Plan). These previous activities drew on the published and grey scientific and medical literature, experience of the investigators and the input of the Defence-appointed Scientific Advisory Committee and DHSP Program Management Office and Board. The preliminary study complements this by incorporating the views of stakeholders (e.g. veterans' advocacy groups) and consumers (e.g. the veterans themselves).

62. The stakeholder meetings and focus groups largely confirmed the initial selection of health issues for surveillance and the priority attached to these issues. In particular, focus group participants revealed concerns about long-term mental health issues (especially depression, PTSD and alcohol abuse), medically unexplained symptoms (especially irritable bowel-like symptoms), and the long-term effects of dust on the respiratory system.

63. Health concerns in theatre were also mostly consistent with the literature and those identified in ADF Hazard Assessment Team reports. These included viral conditions associated with living in dense accommodation (e.g. diarrhoea and respiratory infections), as well as combat and non-combat related injuries, in particular musculoskeletal injuries. Importantly, the latter was often attributed to the weight of issued body armour and some individuals reported either not wearing assigned armour as directed, or alternatively, purchasing their own lighter weight armour from local (non-ADF) sources.

64. The assessment of health hazards (including psychological stressors and physical hazards) has always been a priority of the DHSP[3], more so than in comparable international studies (e.g. Millennium Cohort Study, King's College Gulf War Research group). The investigators initially based decisions on the inclusion of exposures on reports by ADF Hazards Assessment Teams, hazards assessed in the NNAI studies, hazards assessed in the 1990/91 Australian Gulf War Veterans' Health Study, and hazards assessed in international studies from the King's College group, Millennium Cohort group and the Deployment Risk and Resilience Inventory. The focus groups revealed that the exposures assessed in these studies are not directly equivalent to the Australian experience of exposure to health hazards in the MEAO. For example, refinement to the questionnaire was made in the area of roles and responsibilities in the MEAO and we have been able to better tailor the questionnaire to the specific experiences of the Australian deployed cohorts.

65. The focus groups were also able to clarify the relative priority that should be placed on the assessment of various exposures. For example, the focus groups clarified which hazards were context, location, time or role dependent. One example is the risk (psychological and physical) from indirect fire. Indirect fire has persisted throughout the campaign and is a common exposure to personnel located in both Iraq and Afghanistan, but not supporting areas outside of these countries (e.g. .2, .4). The fear associated with indirect fire was significant and negatively affected some individuals; however, this fear tended to diminish over the length of the deployment and focus group participants reported becoming blasé to the threat by the end of the deployment.

66. Stress associated with separation and re-integration with family and re-establishing relationships on return to deployment was a more significant area of concern than initially envisaged by the research team. Similarly, the impact of organisational factors was of higher

priority to MEAO veterans than originally anticipated and consequently the assessment of these factors was enhanced.

67. The hard copy questionnaire was then pre-tested using an approach similar to one mode of response that will be used in the main surveillance program, that is, self-report. It is important to pre-test in this fashion to ensure that participants understand the questions, are provided with suitable response options and that they are able to navigate skip patterns. It will be important to 'process pilot' test the questionnaire in each mode that it is to be delivered (i.e. web-based and hard copy), but the current testing has enabled issues of language, content and flow to be refined.

Future Directions

68. This preliminary study report describes activities undertaken as part of development that are best described as "pre-testing" of the survey instrument. Pre-testing is distinct from pilot testing, which involves testing all the procedures and materials involved in data collection. Pilot testing of the full MEAO protocol is scheduled for the first half of 2010.

69. The focus groups were wide-ranging and provide opportunities for more detailed analysis of content. At a later date, the audio files obtained from focus groups will be transcribed verbatim. The transcript will be prepared such that future analysis may be facilitated by the use of the qualitative data management program NVivo 8 (QSR International). This information can then be accessed by researchers according to standard protocols for requesting access to DHSP data.

70. One example that has already been identified for further investigation is the provision of support to families of deployed personnel, which was an issue of special concern highlighted during the focus group discussions. A brief report on these issues was provided to the Defence Community Organisation (31 July 2009) to facilitate a review of their policies in relation to activities with families of deployed personnel (Annex 8). Further thematic analysis of the focus group discussions will explore this and other issues in greater depth, leading to the submission of manuscripts to peer reviewed general, military and veterans' health journals.

Conclusion

71. Pre-testing is an important activity in the development of survey instruments. The three pre-testing strategies utilised in the MEAO preliminary study have provided important consumer input to the content and language of the survey tools. Combining pre-testing techniques in this fashion provided a more comprehensive design then undertaking just one of these activities. Similarly, pre-testing of the survey tools at this stage, rather than the whole study protocol, meant that content, structure and flow issues could be investigated more thoroughly and these problems fixed prior to pilot testing of study procedures.

72. The outcomes of the preliminary study engender confidence that the MEAO Health Study survey has strong face validity (i.e. measures what is important to stakeholders and consumers to measure) and will produce data that can be analysed confidently to answer the MEAO Health Study research questions.

Annexes

Annex 1 – Interview Guide

Annex 2 – Identification and Mapping of Major Stresses

Annex 3 – Identification and Mapping of Health Threats

Annex 4 – Identification and Mapping of Health Concerns on Deployment

Annex 5 – Identification and Mapping of Current and Long Term Health Concerns

Annex 6 – Examples of annotations made to the pilot questionnaire during review by a questionnaire working group

Annex 7 – Final Print Ready Questionnaire

Annex 8 – Information provided to Defence Community Organisations about MEAO veterans concerns about deployment

References

1. Kreuger R, Casey M. Focus Groups: a practical guide for applied research. Sage: Thousand Oaks, Ca. 2000.

2. Morgan D, Kreuger R. The focus group kit. Sage: Thousand Oaks, Ca. 1998.

3. Barton C**,** Treloar S, Dobson A, McClintock C, McFarlane AC. The Deployment Health Surveillance Program: Vision and challenges of health surveillance for Australian military cohorts. ANZJPH. 2008; 32(6): 529-34.

Appendix B

Detailed Research Plan

CMVH
CENTRE FOR MILITARY & VETERANS' HEALTH

Detailed Research Plan - Revised

Middle East Area of Operations (MEAO) Health Study

Deliverable Item 5 (Phase 2b)
Financial Year 2009/10

June 2010

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Australian Government
Department of Defence
Department of Veterans' Affairs

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Innovation in Education

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CONTENTS

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Approvals

This document requires the following approvals:

Name	Position	Signature	Date	Version
Prof Alexander McFarlane	Principal Investigator			
Prof Michael Moore	Scientific Advisory Committee			
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Executive Summary

1. The Detailed Research Plan presented here updates the previous Detailed Research Plan submitted December 2009. The various updates to the plan build on the initial Design Options paper that was submitted during Phase 1a and incorporate methodological developments achieved through experience gained during the Near North Area of Influence (NNAI) Studies, outcomes of the Middle East Area of Operations (MEAO) Preliminary Study conducted by CMVH in 2009, and ongoing consultation with the Department of Defence and Department of Veterans' Affairs (DVA) and other partners and collaborators.

2. The MEAO Health Study is part of the Deployment Health Surveillance Program (DHSP). The CMVH UA has also been contracted by the Defence Directorate of Mental Health to conduct a study of the Health and Wellbeing of Australian Defence Force (ADF) members who have not deployed to the MEAO. Collectively, the MEAO Health Study and the Health and Wellbeing Study are promoted under a common banner known as the Military Health Outcomes Program (MilHOP).

3. The specific objectives of the MEAO Health Study include identifying:

a. links between specific chemical, physical, biological and psychological exposures potentially encountered during the MEAO deployment and physical and psychological health outcomes;

b. short-term and long-term physical and psychological health effects associated with MEAO deployment;

c. means of increasing the utility of ADF health records for monitoring of the physical and psychological health of serving members;

d. protective (resilience) factors for psychological health outcomes; trajectory and pattern of psychological morbidity and its somatic manifestations and antecedents;

e. potential emergence of any post-deployment syndrome(s); patterns of health care utilisation by personnel deployed to the MEAO;

f. health indicators that are predictive of disability and where early intervention or program change may minimise disability in ADF members and veterans

4. The Detailed Research Plan is divided into two elements: Part 1 describes the research methods and Part 2 outlines the project management plan.

5. The MEAO Health Study will comprise three studies:

- **Prospective Study** (Study 1) - All Defence personnel who are scheduled to deploy to the MEAO after June 2010 and return to Australia by December 2011 will be invited to participate in the MEAO Prospective Study. Data (self-report questionnaire, physical assessments, blood and saliva samples, and neurocognitive assessments) will be collected approximately three months prior to and four months post-deployment. Electronic health records may also be collected in the future.
- **Census Study** (Study 2) - All Defence personnel who have deployed to the MEAO (between October 2001 and December 2009) will be invited to participate in the MEAO Census Study. Self-report questionnaire data, psychological screening data and future electronic health records will be collected. No blood samples will be collected and no other testing (e.g. physical tests or neurocognitive assessments) will be conducted as part of the Census study.
- **Mortality and Cancer Incidence Study** (Study 3) - This study will include all personnel who have deployed to the MEAO.

6. For each study we describe the study design, the recruitment plan and data collection approach, and provide an overview of the data analysis plan. The recently completed Preliminary Study has identified exposure and health concerns amongst serving and ex-serving personnel deployed to the MEAO as well as strategies to maximise recruitment of participants for Studies 1 and 2.

7. Part 2 of the Detailed Research Plan addresses project management issues. It is divided into five elements – a data management plan, a communication plan, a risk management plan, a quality assurance plan and the governance plan.

Introduction

1. This document updates the Detailed Research Plan submitted December 2009 for a health study of Australian Defence Force (ADF) personnel deploying to the Middle East Area of Operations (MEAO) during or after June 2010 and returning from deployment by December 2011 and MEAO veterans who deployed between 2001 and 2009. The plan builds on a Literature Review, Review of Health Hazards and Evaluation of Design Options that were prepared in Phase 1a.

2. The MEAO Health Study flows on from earlier CMVH Deployment Health Studies. These projects include the InterFET (International Force in East Timor) Pilot Project, the Solomon Islands Health Study, the Bougainville Health Study, and the East Timor Health Study (collectively referred to as the Near North Area of Influence (NNAI) Health Studies).

3. These projects involved one group of personnel who deployed on specific Operations and a comparison group of frequency-matched non-deployed ADF personnel. Because of the large numbers who have deployed to the MEAO, this design required review for the MEAO Health Study.

4. DHSP projects to date have collected both cross-sectional and retrospective data. The MEAO Health Study aims for the first time to incorporate a prospective component, collecting baseline data where possible both before and after deployment.

5. The MEAO Health Study will consist of three major components: a prospective study (Study 1), a census study (Study 2) and a mortality and cancer incidence study (Study 3).

6. As for previous DHSP studies, data sources for the MEAO Health Study will include hazard assessments, the National Death Index and the National Cancer Statistics Clearing House, self-report questionnaires, and routinely collected Defence psychological screening information. Unlike previous DHSP studies, hard copies of defence medical records will not be extracted, although potentially, future electronic health records may be accessed. Also Study 1 will collect blood and saliva samples and conduct specific physical and neurocognitive assessments with consenting personnel in identified sub-groups.

7. Provision has been made in the study design for follow-up cancer and mortality linkage for members of the NNAI study cohorts. Further longitudinal follow-up of members of the DHSP health study cohorts will be required in order to identify longer term health trends.

8. The Detailed Research Plan is divided into two substantive parts: Part 1 describes the research method and Part 2 outlines the project management plan.

PART 1 – PROJECT METHODOLOGY

Aims and Objectives

Aims

9. The MEAO Health Study is part of the Deployment Health Surveillance Program (DHSP). The DHSP aims to establish and maintain an integrated data system for monitoring the physical and mental health of deployed ADF personnel and to conduct specific studies to:

a. Increase understanding of:
   i. Chemical and physical environmental factors
   ii. Biological factors (including health countermeasures) such as vaccines and infections
   iii. Psychological stressors that lead to physical and mental health problems associated with deployment;

b. Investigate and increase understanding of the short, medium and longer-term physical and mental health effects of exposure to the factors described above (in a.) with specific deployments;

c. Provide advice to Defence on measures to improve health programs.

10. The MEAO Health Study will contribute to the overall aim of the DHSP by:

a. Ascertaining the health status of ADF personnel who have deployed to the MEAO;

b. Investigating changes in health outcomes between pre- and post-deployment in a subgroup of ADF personnel scheduled to deploy to the MEAO from June 2010 and returning from deployment by December 2011;

c. Investigating exposures and other risk factors where changes in health outcomes are found;

d. Establishing a framework for ongoing monitoring of the health of MEAO veterans, throughout their military career and after they separate from the ADF;

e. Being an important building block in the development of a comprehensive health surveillance system for ADF personnel.

11. The MEAO Health Study has been designed to address the following **broad research objectives**, by investigating whether there are:

a. Specific physical or psychological disorders or symptom clusters that are associated with particular features of deployment to the MEAO in different locations or roles;

b. Gender differences in any health impact of MEAO deployment;

c. Exposures associated with increased risk of morbidity and mortality for the group as a whole, and for specific MEAO subgroups with identified health disorders;

d. Changes in health outcomes between the pre- and post-deployment phases that may be associated with specific exposures;

e. Screening tools and tests which may enable the early detection of disorders so as to instigate treatment earlier and minimise disability in veterans;

f. Changes in ADF health and exposure records and recording practice that will facilitate future health surveillance at group level as well as providing ADF clinicians with quality data for clinical purposes.

12. The MEAO Health Study will provide data to describe the health of ADF personnel who have deployed to the MEAO and this information has the potential to enhance the future force capability of ADF personnel.

Specific objectives

13. Within the broad aims outlined above, the MEAO Health Study has the following specific objectives:

a. To investigate links between specific chemical, physical, biological and psychological exposures potentially encountered during the MEAO deployment and physical and psychological health outcomes;

b. To understand the interrelationships between short-term and long-term physical and psychological health effects associated with deployment;

c. To increase the utility of ADF health records for monitoring of the physical and psychological health of serving members;

d. To identify protective (resilience) factors for psychological health outcomes;

e. To determine the trajectory and pattern of psychological morbidity and its somatic manifestations and antecedents;

f. To investigate the potential emergence of any post-deployment syndrome(s);

g. To identify patterns of health care utilisation by personnel deployed to the MEAO;

h. To investigate relationships between deployment, exposures and non-specific symptoms and specific health problems;

i. To identify health indicators that are predictive of disability and where early intervention or program change may minimise disability in ADF members and veterans.

Preliminary Study and Pilot Work

Study Design

14. This planning stage during 2009 included meetings with stakeholders, focus groups and piloting instruments with the target population.

Stakeholder meetings

15. Stakeholder meetings targeting key Defence and veteran stakeholders were conducted to gain feedback on the proposed study design and assessments, in addition to the ongoing input and support from Defence and DVA directly. These included:

- National Younger Veterans' Consultative Forum (CMVH has a standing agenda item)
- Defence Force Units such as 1 Psychology Unit
- Ex-service organisations such as RSL, Australian Defence Association
- Other veterans groups (e.g. Young Diggers, Australian Peacekeepers and Peacemakers Veterans' Association).

Focus Groups

16. Focus groups were conducted to add to and complement the process already undertaken to select instruments for the study questionnaire and assign priority to the measures proposed. This process incorporated a review of the literature and a review of health hazards (MEAO Phase 1a), experience of the investigators, input from the Scientific Research Team (SRT) and the input of the Scientific Advisory Committee (SAC) and the Program Management Board (PMB).

17. Specifically, focus groups were used to: 1) capture qualitative data on the experiences and health concerns of MEAO veterans that will be mapped to the health and exposure questionnaire to check the validity and relevance of items to be assessed and 2) engage serving ADF and ex-serving members in the project.

18. Up to 10 individuals participated in any one focus group. Stratified purposive sampling and quota sampling were used to select participants for the focus groups. Quotas were applied to gender (with one focus group restricted to female participants only), rank and Service.

19. The procedure for identification of participants within each Service was advised by the Chain of Command and coordinated by a delegated Officer assigned by each Service in liaison with CMVH ADF liaison personnel.

20. The focus groups were conducted according to the protocol and approach recommended by Kreuger and Casey[1], and Morgan and Kreuger[2].

[1] Kreuger R and Casey M. Focus Groups: a practical guide for applied research. Sage: Thousand Oaks, Ca. 2000.
[2] Morgan D and Kreuger R. The focus group kit. Sage: Thousand Oaks, Ca. 1998.

21. In total, 27 focus groups were held with currently serving Defence Force members as outlined in Table 1. Holding focus groups in each of these Units provided an opportunity for different Service groups and members with different roles to take part.

22. Two focus groups (one in Adelaide and one in Brisbane) were held with MEAO veterans who had separated from the ADF. CMVH liaised with ex-serving organisations to promote the focus groups to ex-serving members. Additional advertisements in the general media and veterans' publications were used to widely publicise the focus groups.

23. Venues on ADF bases were used when focus groups included serving members, and CMVH offices in Brisbane or Adelaide were used for focus groups with ex-serving participants.

24. Each focus group session lasted between 1 and 1.5 hours and was facilitated in a consistent way by a group moderator who used a semi-structured interview guide. The interview guide covered topics including:

- Health concerns
- Positive and negative aspects of the deployment
- Experiences after returning from deployment
- Strategies for recruitment to the study and the use of incentives.

25. The focus groups were tape recorded using a digital recorder with the consent of participants. Initially, in order to meet the deadline for reporting to the PMO (29 May 2009) and finalisation of the study questionnaire for pilot testing (in July 2009), key themes and key issues were identified from the notes of the observer/scribe and from a review of the audio record. The latter involved creating an abridged transcript by listening to the audio file and making notes to supplement the written record.

26. The key themes and key issues identified in this manner were mapped to the battery of assessments planned for the MEAO Health Study to ensure that key health and exposure concerns of personnel were incorporated into the study protocols for pilot testing.

27. Later, the audio files obtained from focus groups were transcribed verbatim by CMVH staff with appropriate security clearances and an external transcription company. The transcripts were prepared such that future analysis may be facilitated by the use of the qualitative data management program NVivo 8 (QSR International).

Table 1: Defence Force personnel invited to participate in a focus group

Army		Navy		Air Force	
1st Bde - Darwin		**Fleet Base East**		**RAAF Edinburgh**	
Officer Rank	**Other Rank**	**Officer Rank**	**Other Rank**	**Officer Rank**	**Other Rank**
FG1	FG2 Combat	FG1	FG2 (sailors)	FG 1 Aircrew	
	FG3 Combat Support	FG3 Medical		FG2 Non-Aircrew	
FG4 Medical		FG4 Women		FG3 Medical	
3rd Bde - Townsville				**RAAF Richmond**	
FG1	FG3 Combat				
FG2 Aviation Air Crew	FG4 Combat Support			FG1 Aircrew	
	FG5 Aviation Non Air Crew			FG2 Non-aircrew	
FG6 Medical				FG3 Medical	
7th Bde - Enoggera					
FG1					
FG2 Medical					
FG3 Women					
SASR - Perth					
FG1	FG2				
4RAR - Holsworthy					
FG1	FG2				

FG = Focus Group

Pilot study

28. Information derived from the focus groups was mapped to the draft questionnaire, which was then amended to address any weakness or omission identified from the focus groups.

29. Focus group participants who consented to being contacted for future follow-up were asked to pilot test the questionnaire.

30. These participants were mailed a hard copy of the questionnaire to complete and return to the CMVH.

31. Any problems with questions, structure, flow or organisation of items identified by participants were noted by a CMVH research officer, and then all feedback was collated and reviewed by the SRT prior to development of the final version of the questionnaire.

Process Pilots

32. Process piloting of the recruitment process and the web-based questionnaire is described in the Study 1 and Study 2 Recruitment Plan sections.

Study 1: Prospective Study

Study Design

33. Currently serving ADF personnel will be invited to participate in the study approximately four months prior to deployment to the MEAO **(Time 1)** and followed up three months after returning from deployment **(Time 2).**

34. At each time point, participants will be asked to complete a self-administered questionnaire**.** A subset of eligible ADF members (~n=750) will also be asked to take part in a brief physical assessment and provide a saliva and blood sample. A smaller group of these participants (~n=400) will also be asked to undertake a neurocognitive assessment

35. CMVH researchers will seek consent to access and link post-deployment psychological screening records (RtAPS and POPS).

Recruitment Plan

Participants

36. In order to be eligible to participate in the MEAO Prospective Study individuals must :

a) Be members of the ADF and deploying to the Middle East Area of Operations after the 1st June 2010, and return to Australia from deployment by December 2011; and

b) Individuals who are eligible to participate in this study, but were not given the opportunity, or who did not respond to the pre deployment invitation, will still be eligible and therefore invited to participate at the post-deployment follow up.

These inclusion criteria apply regardless of:

- service type (navy, army or air force),
- rank,
- gender
- the length of deployment,
- the country where most time is spent (i.e. may be in Iraq/Afghanistan or in an area/country (outside Australia) supporting these operations),
- the role (combat, support, technical etc); and/or
- whether the ADF member has previously deployed to the MEAO.

Exclusion criteria

37. The following criteria will exclude individuals from being invited to participate in the MEAO Prospective Study questionnaire:

- Individuals who are NOT members of the Australian Defence Force including:
  - Members of foreign militaries seconded to the ADF;
  - Civilian contractors (whether bound to Defence Force Discipline Act or not);
  - Government officials (e.g. Department of Foreign Affairs and Trade (DFAT));
  - Aid workers (including Australian Government officials);
  - Civilians contracted to Defence Science Technology Organisation (DSTO);
  - Public Servants; and
  - Australian Federal Police;
- ADF personnel accompanying government officials or representatives not technically required for conduct of operations

38. Recruitment will be staggered to coincide with deployment schedules for different deploying groups.

39. All ADF personnel meeting the inclusion criteria will be invited to participate. Based on current deployment commitments, it is estimated there will be approximately 2,100 ADF personnel eligible to participate in the MEAO Prospective Study. Of this number we expect that approximately 1000 would consent and provide data pre- and post-deployment.

40. Individuals who complete Study 2 measures but are then subsequently selected for deployment will also be invited to participate in Study 1. These individuals will have multiple data points, which is consistent with the vision for the DHSP as a longitudinal health surveillance program.

Sample Size and Power

41. From ADFPAY data it is estimated that approximately 3,000 personnel deployed on Operation SLIPPER in 2008 (up to 12 November 2008). Defence have estimated that during the study data collection period approximately 2,100 eligible ADF personnel will be deploying to the MEAO. Of the these personnel, we estimate that 1,000 will be recruited to the MEAO Prospective Study, and that with this number the study will have good power to detect within-person differences between measurements taken pre- and post-deployment.

42. To detect small effects in categorical health outcomes (for example, 2.5% reporting improved health and 5% reporting a deterioration in health) a minimum sample of over 1000 participants responding at both time points would be required to achieve

80% power. However, for outcomes with clearer trends of an increase in prevalence, the number of participants required to achieve an 80% power is less.

43. For continuous outcomes the standardised mean difference (mean difference / standard deviation) was used to determine the sample size required to achieve good statistical power. These calculations assumed a correlation of 0.3 between the measures taken before and after deployment. Based on these assumptions the MEAO Prospective Study should have high power to detect standardised differences as small as 0.15 if the sample size participating is greater than 600. The retention rate from pre to post deployment is anticipated to be greater than 80%. Therefore, small effects in continuous outcomes will be possible to detect.

44. For biological measures the sample size required varies depending on the anticipated difference between the pre- and post-deployment measures. Given the anticipated higher response rate in the MEAO Prospective Study there is some potential for sub-studies using smaller samples to test specific research questions.

MEAO Prospective Pilot Study

45. A small pilot test of the MEAO Prospective Study protocol was conducted by the beginning of June 2010.

46. Approximately 50 Aircrew from RAAF Base Edinburgh who routinely deployed to the MEAO were invited to participate in the pilot test. Thirty-three individuals responded to the invitation.

47. The first 13 respondents agreed to participate in a pilot test of the MEAO Prospective Study physical testing protocol.

48. Pilot testing of the following instruments was undertaken:

a. Self administered questionnaire.

b. Physical testing sub protocol:

- Blood and Saliva collection
- Physical tests
- Transportation of biological samples to laboratories for testing

c. Data transfer and data analysis.

General Promotion of MEAO Prospective Study

49. For the MEAO Prospective Study to be effective and achieve desired outcomes, participation by ADF personnel is paramount. To encourage maximum participation and to best utilise personnel and resources, robust engagement plans to inform, recruit and involve participants have been developed. A series of advertisements will be followed by a Ministerial Launch. In addition to further media releases, promotional posters, web

pages and editorials, a 1800 number and study email address will be available to answer any Study questions.

50. Prior to the initial direct contact with potentially eligible ADF members the following strategies will be used to promote the MEAO Prospective Study:

a. Once deploying groups have been identified, and DIRLAUTH has been approved, CMVH posted ADF Liaison Officers will brief Commanding Officers (COs), Officers Commanding (OC), Executive Officers (XOs) and Senior Non-Commissioned Officers (SNCOs) of target units to gain support for the project
b. Permission will be sought to incorporate generic information about the MEAO Prospective Study into the pre deployment briefings with the support of JOC.

Pre-deployment Communication

51. Different strategies will be used to promote the MEAO Prospective Study, contact individuals and then follow up non-responders depending on whether they are members of the Special Forces (SF) or other ADF elements.

Communicating with eligible ADF members who are NOT part of the SF

52. Defence Force members posted to the CMVH will be responsible for identifying all deploying ADF personnel who are eligible for this study and are not members of the SF. This information will be provided to the research team who have been cleared to a restricted status. These research staff will then be responsible for sending warm up letters and invitation packs. The invitation pack will be sent both by email and hardcopy and will contain the study free-call (1800) number and an email address so that recipients can advise CMVH researchers if they would prefer the invitation pack to be sent to a different email or mailing address.

53. Non-SF respondents can nominate to take part in the study by returning the signed consent forms to CMVH researchers, or by logging on to the secure study website to complete the consent form and questionnaires online.

Communicating with eligible ADF members who are a part of the SF

54. A Special Operations Command (SOC) Administration Officer will liaise with the SF personnel eligible to participate in the MEAO Prospective Study. This will include obtaining lists of deploying SF members and sending out warm up letters and invitation packs to these individuals. The SF members' invitation pack will be sent by hardcopy only and will contain an SF-specific study free-call number and email address so that recipients can advise the SOC Administration Officer if they would prefer the invitation pack to be sent to a different mailing address.

55. SF respondents can only nominate to take part in the study by returning the signed consent forms to the SOC Administration Officer.

Recruitment to the MEAO Prospective Study

56. A personalised study invitation pack will be sent to all potential eligible participants approximately three months prior to the scheduled date for overseas deployment.

57. Members of SF will receive a modified invitation package to meet the special privacy and security requirements of this group.

Materials included with the SF Invitation Pack include:

a. A letter from the Principal Investigator
b. A letter of support from the Chief of the Defence Force and the Repatriation Commissioner
c. An instruction sheet describing how to take part in the study or decline the invitation to participate
d. The study consent form and duplicate participant copy
e. A basic information sheet for SF members who are eligible to take part in physical tests and neurocognitive assessments identifying procedures and requirements related to participation in the study
f. A supplementary information sheet for SF members eligible for the physical tests and neurocognitive assessments
g. A contact form to aid tracking for future longitudinal follow-up
h. A copy of the ADHREC guidelines for volunteers
i. The pre-deployment study questionnaires
j. A reply paid envelope

58. Other eligible ADF members (non-SF) will be sent an email containing a link to the study website where individuals can view the following documents:

a. A letter from the Principal Investigator
b. A letter of support from the Chief of the Defence Force and the Repatriation Commissioner
c. An instruction sheet describing how to take part in the study or decline the invitation to participate
d. EITHER
    a. A basic information sheet for those eligible to take part in the questionnaire component of the study only

        OR

    b. A basic information sheet for ADF members who are not SF and are eligible to take part in physical tests and neurocognitive assessments. These individuals will also be provided with a supplementary information sheet describing the physical testing and neurocognitive assessment measures in detail
e. A contact form to aid tracking for future longitudinal follow-up
f. A copy of the ADHREC guidelines for volunteers
g. A reply paid envelope.

59. Non-SF members can choose to complete the study consent form and the pre-deployment study questionnaires over the internet or in hardcopy. SF members will only be able to complete the hardcopy version.

60. A hard copy of the invitation pack will be sent concurrently to the member's Unit address, or to a nominated address advised by the invitee upon receipt of the warm up letter, that will contain each of the documents described above that are relevant to the individual.

61. A free-call study information phone number and dedicated study email address will also be available for refusals or queries from invitees.

62. The strategies detailed above have been revised based upon lessons learnt from the NNAI Health studies and the MEAO Preliminary Study completed in 2009.

Pre Deployment Follow-up of Non-SF Non-Responders

63. Follow-up of individuals who have not responded to the invitation package will be managed by the research team.

64. These non-responders will be followed-up with a reminder email within two weeks of the first invitation package being sent. If a response is still not received within one week of the reminder, a research staff member with appropriate security clearance will follow-up non-responders with a telephone call. If requested, information will be resent by email or mail. A further follow-up call will be placed one week later if no response has been received.

65. Up to ten attempts to contact non-responders prior to the scheduled date for deployment will be made.

66. In Formed Units where there is minimal response, the Officer Commanding will be contacted by CMVH staff and asked to promote the study further amongst personnel under their command.

Pre Deployment Follow-up of SF Non-Responders

67. Follow-up of SF members who have not responded to the invitation package will be managed by a SOC Administration Officer.

68. The SOC Administration Officer will follow up non-responders from the SOTGs by hard copy reminder letter within two weeks of the first invitation package being sent. If a response is still not received within one week of the reminder, the SOC Administration Officer will follow-up non-responders with a telephone call and re-send information by mail if requested. A further follow-up call will be placed one week later if no response has been received.

69. Up to ten attempts to contact non-responders prior to the scheduled date for deployment will be made.

70. In SF Units where there is minimal response, the Officer Commanding will be contacted by CMVH staff and asked to promote the study further amongst personnel under their command.

Recruitment at the post-deployment follow-up

71. Pre deployment questionnaires, physical tests, biological samples and neurocognitive assessments must be completed prior to deployment. However, eligible participants who wish to participate but who deploy at short notice, or who are unable to complete the consent procedure or questionnaire prior to deployment, will remain eligible and still be invited to participate in the post deployment component. These individuals will receive a post-deployment warm up letter one week prior to receiving the remainder of the invitation package as described above.

Selection of a sample of participants for the physical and neurocognitive assessments

72. Individuals from SOTG, the MTF and RAN sailors deploying to the MEAO, may be invited to participate in a physical test, provide a sample of saliva and blood and undertake a neurocognitive assessment pre- and post-deployment.

73. These participants will be provided with a supplementary information sheet describing the physical tests, the biological sampling process and the neurocognitive assessment to be performed.

74. These individuals will be able to consent to completing just the questionnaire component or all questionnaire, physical testing and/or neurocognitive assessment components.

75. Non-SF members from these groups who consent to completing the physical tests and/or neurocognitive assessments will be contacted by a CMVH research officer to schedule an appointment.

76. SF members who consent to completing the physical test and/or neurocognitive assessments will be contacted by the SOC Administration Officer.

77. Different selection criteria apply to the physical tests and neurocognitive assessment components. These are:

Physical Test Inclusion Criteria

78. In order to be eligible to participate in the MEAO Prospective Study physical testing, individuals must:

a. be eligible to participate in the MEAO Prospective Study questionnaire (see inclusion and exclusion criteria above),
b. have completed a pre deployment questionnaire,
c. be assigned to either:
    i. Special Operations Task Group (SOTG);
    ii. Mentoring Task Force (MTF); or
    iii. A RAN ship selected by Defence.

Physical Test Exclusion Criteria

79. There are no specific exclusion criteria applicable to the MEAO Prospective Study physical testing.

Neurocognitive Assessment Inclusion Criteria

80. In order to be eligible to participate in the MEAO Prospective Study neurocognitive assessment, individuals must

a. be eligible to participate in the MEAO Prospective Study questionnaire
b. have completed a pre deployment questionnaire,
c. be assigned to:
    i. Special Operations Task Group (SOTG);
    ii. Mentoring Task Force (MTF); or
    iii. a RAN ship selected by Defence.

Neurocognitive Assessment Exclusion Criteria

81. There are no specific exclusion criteria applicable to the MEAO Prospective Study neurocognitive assessments.

Data Collection Plan

Overview

82. Data will be collected at two time points. At Time 1 data collection will occur just after recruitment to the study, approximately three months prior to deployment.

83. Time 2 measures will be administered approximately four months after completion of Return to Australia processing.

84. The data collection is divided into four components:

a. A self-administered questionnaire (all)
b. Extracting data from health records including ADF psychological screening records
c. A physical test, saliva and blood samples (sample only n~750).
d. A neurocognitive assessment (sample only n~400)

Self administered questionnaire

85. The self-administered questionnaire will be administered at the pre-deployment assessment and at the post-deployment assessment.

86. The pre-deployment questionnaire (Annex 1.1) consists of:

- A brief deployment history questionnaire;
- A health questionnaire; and
- Personality and resilience insert

The post-deployment questionnaire (Annex 1.2) consists of:

- A health questionnaire; and
- A deployment experiences questionnaire completed at the post-deployment assessment. Specific deployment experiences questions are asked for Afghanistan and Iraq separately.

87. Details of the questions and scales within each component of the survey are provided later in the section entitled Data Collection Tools.

88. Pilot testing of the questionnaire has indicated that it will take participants between 30 and 60 minutes to complete at each assessment and options for completing will include:

a. Internet, using a web-based questionnaire (access by ID number and password provided with invitation package) (available for non-SF only); and

b. A mailed (hard copy) questionnaire on a scannable tele-form (available for non-SF and SF).

89. Experience from the NNAI Health Studies suggests that the majority of participants preferred the web-based version. The data from questionnaires completed on the web automatically populates the DHSP database (see Data Management Plan), removing the need to enter data by hand.

90. Non-SF participants who opt to complete the paper questionnaire will be able to return the questionnaires in a supplied reply paid envelope to CMVH. Following processing and checking of the completed forms, returned hard copy questionnaires will be uploaded to the Defence Health Research System database as described in the Data Management Plan.

91. SF participants will be provided with a reply paid envelope to return the completed questionnaire to the SOC Administration Officer. Once the SOC Administration Officer has checked to ensure that there is no identifying information on the questionnaire, they will send it to the CMVH, who will scan the forms using a tele-form scanner. This de identified data will also be used to populate the DHSP database.

92. 'Drop-in centres' conducted by CMVH staff at selected bases will also provide an additional opportunity for ADF members eligible for the MEAO Prospective Study to complete the questionnaire.

Health Records Data

Psychological Screens (RtAPS and POPS)

93. On returning to Australia, ADF personnel complete a paper-based screening tool, the Return to Australia Psychological Screen (RtAPS). Personnel complete a further screen—the Post Operational Psychological Screen (POPS)—three to six months later. These instruments are administered by Defence Force psychologists. The information collected during these screens is stored electronically and will be provided to the research team.

Physical Tests, saliva and blood samples

94. A rigorous and thorough examination of serving personnel has clear scientific benefits and the potential to define future risks that can be modified for individuals. Further, it communicates a concern and conviction about the wish to protect individuals by the ADF. Defining these health characteristics and their impact on performance also has a major capacity to sustain and develop the capability of the ADF.

95. Consequently, participants from SOTG, MTF and the Navy will be invited to take part in a series of physical tests, provide saliva samples and have blood samples taken.

96. CMVH will subcontract physical tests and biological collection and analysis to Healthscope.

97. ADF Liaison Officers will negotiate with a Point of Contact at each location for physical testing and neurocognitive assessment and facilitate access to suitable facilities at the home barracks of the groups who will participate in these assessments.

98. CMVH will provide training to Healthscope staff in the procedures and use of equipment for physical tests. CMVH will provide staff to oversee data collection at each location and monitor quality, providing continuous quality improvement feedback directly to Healthscope staff.

99. The CMVH staff (in the case of non-SF participants), or the SOC Administration Officer (for SF participants) will provide participants with salivette tubes for collection of saliva samples the day before the physical testing appointment. Three samples will be collected by participants in their home. One sample approximately 30 minutes after awakening in the morning, and two further samples collected at 8pm in the evening. Participants will then be asked to store the samples in their refrigerator at home and bring it with them the following day when they are required to present for the physical testing. An automated SMS reminder will be sent to participants 30 minutes before each sample is due to be collected, to remind them to collect the saliva sample.

100. During the physical tests, specifically trained research staff from Healthscope will measure height, weight and waist and hip circumference, conduct a step (fitness) test and measure blood pressure. Lung function will be assessed by spirometry.

101. Photographs will be taken of participants' backs, palms of their hands, soles of their feet and side views of the cheek, lower nose and lips. This is done in order to assess dermatological conditions that develop on deployment.

102. The collection of blood samples, coordination of pathology tests, reporting of results to CMVH and storage of samples will be sub-contracted to Healthscope.

103. Approximately 40ml of blood will be collected in vacuette tubes.

104. Following collection, the bloods will be prepared for transport and storage on site by Healthscope staff. This will involve centrifugation, where appropriate, using a portable centrifuge, of the whole blood to separate serum. Healthscope will coordinate delivery of the saliva and blood samples to laboratories for testing.

105. Two aliquots of serum will initially be stored for up to 10 years.

106. The complete list of pathology tests to be undertaken is provided with the description of data collection tools.

107. De-identified, linkable, results of laboratory tests will be provided electronically to populate the Defence Health Data Management System.

108. The results of each of the pathology tests will be reviewed by a medical doctor. A plain language summary of the outcomes of pathology tests will be prepared and provided as part of feedback directly to the participants that complete this aspect of the study, if requested by the participant. In addition, participants will be advised when any of the test results indicate the need for a medical consultation. In this case, participants will also be provided with a copy of the original pathology results for review by their doctor.

Neurocognitive Testing

109. Personnel from SOTG, MTF and the Navy may also be invited for neurocognitive testing utilising the computerised Brain Resource Company (BRC) QuickCap. Neurocognitive testing will occur on a subgroup of approximately 400 individuals who meet the eligibility criteria for neurocognitive testing. This testing will provide pre- and post-deployment assessment of the effects of stress and mild traumatic brain injury on neurocognitive function.

110. Neurocognitive assessments will involve direct measurement of brain function in response to particular tasks using event related potentials, quantitative electroencephalogram (qEEG) and startle response. Consenting participants will be fitted with a QuickCap and EDA electrodes and receive pre-recorded task instructions. The testing environment is standardised and the measurement of performance is computerised, which limits confounding due to the impact of the environment and human interaction on participant performance. An extensive database of normative data exists for this test against which results can be matched.

111. The battery of tests assess the following domains of cognitive function:

- Resting Electric Brain Function (qEEG)
- Working memory
- Startle Response
- Emotion processing
- A Go/No Go Task to measure the capacity of the individual to suppress a natural tendency to respond.

Data Analysis Plan

Overview

112. The MEAO Prospective Study is an important building block in the establishment of a long-term health of ADF personnel. The data collected as part of this study will contribute to establishing a framework for ongoing monitoring of the health of MEAO veterans, throughout their military career and after they leave the ADF, and provides information to answer the following specific research questions:

a. Are there changes in health outcomes between pre- and post-deployment in ADF personnel deploying to the MEAO?
b. What exposures and other risk factors are associated with changes in health outcomes?
c. What are the protective (resilience) factors for psychological health outcomes?
d. What are the specific physical or psychological disorders or symptom clusters that are associated with particular features of deployment to the MEAO in different locations or roles?
e. Are there relationships between deployment exposures and non-specific symptoms and specific health problems?
f. What is the trajectory and pattern of psychological morbidity and its somatic manifestations and antecedents?

g. What role do biological measures play as mediating variables between exposure and symptom formation?
h. Are there gender differences in any health impact of MEAO deployment?
i. What is the value of measures utilised in the study as screening tools and tests which may enable the early detection of disorders so as to instigate treatment earlier and minimise disability in veterans?
j. What role do these biological measures play as screens?
k. How can the utility of ADF health records for monitoring of the physical and psychological health of serving members be increased?

Exploratory Data Analysis

113. An analysis of questionnaire response rates will be performed to assess response bias by comparing the demographic characteristics of people who took part in the prospective study and people who refused to take part. Response quality will also be assessed by examining proportion of survey questions completed and the biological outcomes recorded. The baseline demographics of the personnel in the prospective study will also be described.

Primary Analyses

114. For the prospective component of the study, the data from the self-administered questionnaire as well as any assessments will give information on the baseline level of health of Defence personnel before deployment to the MEAO.

115. The self-administered questionnaire will be repeated approximately four months after return from the deployment.

116. Health outcomes measured before and after deployment will be compared to assess whether deployment to the MEAO has had an effect on the health of Defence personnel. Paired t-tests will be used to compare normally distributed continuous variables, and the Wilcoxon signed rank test for non-normally distributed continuous variables. For categorical variables, McNemar's Test (for 2 by 2 category comparisons) and the test for symmetry (where the number of categories is greater than 2) will be utilised.

117. Multiple Regression models can also be used to compare the before and after deployment health measures. In these models the baseline measurement (pre-deployment) is treated as an independent variable (with other exposures and confounders) and the post-deployment measurement is treated as the dependent variable in the model.

118. As further follow-up data is collected from the same participants, the repeated measures data will be analysed using Multi-Level Modelling.

Study 2: Census Study

Study Design

119. Study 2 will involve a **cross-sectional census** of **all** serving and ex-serving ADF members who deployed to the MEAO between 1 October 2001 and 31 December 2009.

120. These individuals will be invited to complete a self-administered questionnaire about their deployment experiences and health outcomes.

121. ADF-held electronic psychology records and future electronic health record data will be obtained for analysis. Linkage between these and questionnaire data will only be possible where specific individual consent is provided.

Recruitment Plan

Participants

122. All current and former members of the ADF from the Royal Australian Navy, Australian Army or Royal Australian Air Force who deployed

- to Afghanistan or areas supporting operations in Afghanistan between 2001 and 2009; and/or
- to Iraq or areas supporting operations in Iraq between 2002 and 2009

will be invited to participate in the study. This definition encompasses only force assigned personnel and excludes visitors/secondments to the ADF from other military and civilian organisations. It includes personnel attached to foreign militaries or the United Nations.

Generation of Sampling Frame

123. A nominal roll will be constructed of personnel deployed to the Middle East Area of Operations. The initial sources used to generate the nominal roll are PMKeyS, ADFPAY and Deployment Orders (DEPORDS).

124. CMVH is working in consultation with the PMKeyS Remediation Project currently undertaken by Defence to verify and clean the datasets from each source and to best ascertain the most accurate deployment records for each person.

125. All individuals identified as having deployed to the MEAO between 1 October 2001 and 31 December 2009 will be invited to participate in the study. No comparison group is planned for the census study. Due to the large number deployed to the MEAO, identifying an appropriate comparison group who did not deploy to the MEAO, but who were fit to deploy over the same time period in similar roles, was not feasible. Rather, comparisons will be made between subgroups of interest within the full nominal roll.

Sample size and Power

126. Sample size and power calculations have been conducted for outcomes assessed in the questionnaire.

127. The nominal roll compiled includes a total of 26,915 persons, so around 27,000 are eligible to participate in the census study. A comparison of different subgroups (for example, gender, Service, time of deployment and Operation) and a response rate of 45% (based on responses to the Near North Area of Influence studies) would yield good statistical power to detect relative differences greater than 50% in conditions with a prevalence of over 5% in a comparison group. However, there is little power to detect relative differences of less than 20% in rarer conditions (less than 10% prevalence).

128. The statistical power to detect differences between continuous measures between the main subgroups is good, except for instances when the standardised absolute difference is less than 0.01.

Process Piloting

129. Procedures for contacting individuals and access to the web-based questionnaire for Study 2 will be developed and refined as part of process piloting.

130. A small number of known individuals (approximately 20) will be selected for preliminary testing of the web-based questionnaire. These individuals will be CMVH staff.

131. A sample of approximately 20 individuals will then be invited to test the web-based questionnaire. These individuals will include current ADF personnel.

132. Information for logging on to the web-based form and providing electronic consent will be provided by email. Participants will be asked to complete the web-based protocol to ensure smooth technical operation of consent procedures and the online forms. Testing will occur both within and external to the DRN environment. Extraction of data from web-based systems will also be tested for both participant tracking and data quality.

Promotion of the study and contacting veterans

133. Study 2 will initially be promoted through various media outlets and Defence organisations as described in the Communications Plan. The study will then be launched for serving personnel. This will involve intense promotion of the study throughout internal Defence channels. A launch of the study focusing on ex-Serving personnel will follow, utilising ex-Service organisations and media to promote the study and encourage participation, as described in the communication plan.

134. Prior to distributing any study information, vital status will be checked with the National Death Index (NDI). Approval from the Australian Institute of Health and Welfare (AIHW) Ethics Committee will be required to match names on the nominal roll to those on the NDI.

135. The Directorate of Strategic Personnel Policy Research (DSPPR) will assist with the recruitment of participants, based on an assessment of DSPPR's capacity and

capability to achieve scientific objectives. It is proposed that a project officer be employed within DSPPR to facilitate the process. However, all telephone follow-up will be conducted in-house at CMVH.

136. The Defence Health and Wellbeing Survey funded by the Directorate of Mental Health will also be run concurrently with Study 2.

Contacting Currently Serving Members

137. Initial contact will be made with participants via mail distribution of a 'warm-up letter', advising members that they will be invited to participate in the study and the importance of participation. The letter will contain the study freecall number and email address so that recipients can advise CMVH if they would prefer the invitation pack to be sent to a particular email or mailing address.

138. Seven days from the warm-up mailed letter being sent, a personalised study invitation pack will be sent by email to all individuals on the nominal roll, except those known to be deceased. The email will include an overview of the project and its significance, and links to a web-based package that will include more detailed information about the study, the information sheet, consent forms and questionnaires.

139. Where requested, or in the absence of an email address, a hard copy of the invitation pack will be sent by internal Defence Force mail to the member's Unit address, or to a nominated address advised by the invitee upon receipt of the warm-up letter.

140. The invitation package will include:

a. A comprehensive information sheet identifying procedures and requirements related to participation in the study;
b. A letter of support from the Chief of the Defence Force and the Repatriation Commissioner;
c. A contact letter from the Principal Investigator;
d. A copy of Australian Defence Force Human Research Ethics Committee Guidelines for Volunteers;
e. An instruction sheet for participation (including the URL and loin information for the online questionnaire, if relevant) and a form to register refusal, if desired;
f. A consent form with duplicate participant copy, covering individual components of the study (enabling consent to some or all components);
g. A contact form to aid tracking for future longitudinal follow up;
h. Health and Deployment Questionnaire booklets (hard copy invitation packs only); and
i. A reply paid envelope.

141. 'Drop-in centres' conducted by CMVH staff at selected bases will provide an additional opportunity for currently serving members wishing to participate in the study to obtain an invitation pack and complete the questionnaire. These centres will operate for four to five days in each location.

Contacting ex-serving members

142. For ex-serving members, a warm-up letter will be mailed to the individuals' last known home address obtained from their PMKeyS record.

143. As many ex-serving personnel can be expected to have changed address since leaving the Defence Force, 30 days will be allowed for 'return to sender' mail.

144. When the warm-up letter is not 'returned to sender', a mailed invitation package will be sent to this address.

Follow-up of non-responders

Invitations

145. It is assumed that an initial response rate of 30% will be achieved with currently serving personnel and 5% with ex-serving personnel (based on DSPPR advice and NNAI results).

146. Where a warm-up letter or invitation is returned undeliverable, telephone follow-up and tracing, as described below, will commence immediately.

147. In other cases, if there is no response to the invitation package within two weeks (emailed invitations) or three weeks (mailed invitations) a reminder will be sent to the same email or mailing address.

148. If there is still no response within a further two weeks (emailed reminder) or three weeks (mailed reminder), appropriately trained staff will follow up non-responders by telephone. A maximum of 10 attempts will be made, on various days of the week and various times of day to contact non-responders at the ADF or private telephone numbers obtained from their PMKeyS record.

149. Where telephone contact is made, the invitation package may be resent to the email or mailing address supplied by the invitee at their request, or alternatively refusal can be registered, if desired by the invitee. If no contact is made, but a telephone message service is available, a reminder message will be left, along with the study freecall number and email address.

150. Where telephone contact attempts have been unsuccessful, the individual's name, date of birth and last known private address will be provided to ComSuper who will assist researchers by checking their databases for current addresses. In cases where new addresses are found, ComSuper will forward the invitation package with a covering letter. In the event that this process is unsuccessful, a similar procedure will be undertaken in conjunction with the Department of Veterans' Affairs (DVA). Protocols have been developed by CMVH in collaboration with both ComSuper and DVA as part of the NNAI studies to facilitate this process.

Questionnaires

151. Where an individual registers his or her intention to complete the online questionnaire, but does not do so within two weeks of registering this intention, an email will be sent to the email address nominated on the individual's contact form, reminding him or her to complete the questionnaire within the next 14 days.

152. Where a mailed questionnaire is still outstanding three weeks after being sent, a reminder card will mailed.

153. Telephone follow-up of outstanding questionnaires will follow the same protocol as the follow-up of invitations described above. Questionnaires may be re-mailed or re-emailed, if requested by the respondent.

Data Collection Plan

Overview

154. Data collection for Study 2 will involve a survey of all personnel who have deployed to the MEAO and accessing health records including ADF electronic psychological screening records and the electronic (medical) health record as this becomes available.

Self administered questionnaire

155. The self-administered questionnaire is comprised of a:

- Brief Deployment History questionnaire
- Health Questionnaire
- Deployment Experiences Questionnaire.

156. The questionnaire is designed to take between 30 and 60 minutes for participants to complete and options for completing will include:

a. Internet, using a web-based questionnaire (access by study ID number and password provided with invitation package) or;
b. Paper questionnaire on a scannable tele-form completed privately or;
c. Telephone interview, if requested by the participant.

157. Experience from the NNAI Health Studies suggests that the majority of participants preferred the web-based version. The data from questionnaires completed on the web automatically populates the DHSP database (see Data Management Plan).

158. Participants who request to complete the paper questionnaire will be provided with a reply paid envelope to return the completed questionnaire to CMVH. Following tracking and checking the completed forms will be uploaded to the DHSP database as described in the Data Management Plan.

159. Serving members will be encouraged to complete the questionnaire in work time.

Health Records Data

Psychological Screening Records

160. On returning to Australia from overseas deployment, ADF personnel complete a paper-based screening tool, the Return to Australia Psychological Screen (RtAPS). Personnel complete a further screen—the Post Operational Psychological Screen (POPS)—three to six months later. These instruments are administered by Defence Force psychologists. The information collected during these screens is stored electronically and will be accessed by the research team in collaboration with Defence staff and according to protocols established for previous DHSP studies.

Electronic Health Records

161. Access to health records forms part of the vision for the DHSP, as described in the DHSP Road Map and Mandate. However, experience from the NNAI studies demonstrated that it is impractical to obtain hard copies of Unit Medical Records for large numbers of personnel. Consequently, the MEAO Health Study will seek to obtain electronic health records of MEAO veterans as they become available through 2010 as the electronic record replaces the paper record but it is recognised that in the life of this project representative analysis of health outcomes using this data source is unlikely to be possible.

Data Analysis Plan

Overview

162. The data collected as part of this study aims to answer the following specific research questions:

a. Are there links between specific chemical, physical, biological and psychological exposures encountered during the MEAO deployment and physical and psychological health outcomes?
b. What exposures are associated with increased risk of morbidity for the group as a whole and for specific MEAO subgroups with identified health disorders?
c. Are there gender differences in any health impact of MEAO deployment?
d. What are the protective (resilience) factors for psychological health outcomes?
e. Are there relationships between deployment, exposures and non-specific symptoms and specific health problems?
f. What is the pattern of psychological morbidity and its somatic manifestations?
g. Is there a post-deployment syndrome(s) common to the MEAO deployments?
h. What are the patterns of health care utilisation in personnel deployed to the MEAO and do these differ between groups?
i. What is the value of measures utilised in the study as screening tools and tests which may enable the early detection of disorders so as to instigate treatment earlier and minimise disability in veterans?

j. How can the utility of ADF health records for monitoring of the physical and psychological health of serving members be increased?

Exploratory Data Analysis

163. An analysis of questionnaire response rates will be performed to assess response bias. The response rate by age, sex, Service, service type, rank and current status (serving or ex-serving) will be assessed to identify sources of response bias and whether the study participants are representative of the full nominal roll. The level of response will be compared between the different subgroups of the nominal roll (for example gender, Service, time of deployment and Operation). Response quality will also be assessed by examining proportion of survey questions completed.

164. There are likely to be veterans of deployments to the Near North Area of Influence (and other deployments not considered to date in the DHSP) on the nominal roll. The previous deployment history of MEAO veterans will be compared between the subgroups of the MEAO nominal roll to assess whether specific subgroups were more likely to have deployed on other Operations. Likewise the number of MEAO deployments for each person will be calculated and compared between the exposure groups of interest.

Primary Analyses

165. The health outcomes in the self-administered questionnaire will be cross-tabulated by deployment and exposure subgroups. Differences in the distribution of responses between the different Operations, periods of deployment, deployment locations, services and other defined exposure subgroups will be examined using the chi-squared test for categorical variables, the t-test for normally distributed continuous variables, and the Mann-Whitney test for non-normally distributed continuous variables. Continuous measure may also be analysed using ordinary linear regression with demographics or confounder variables built into the model to account for differences between the exposure groups.

166. Odds ratios associated with different exposures with 95% confidence intervals will be calculated for binary outcomes using logistic regression to control for potential confounders.

167. Appropriate models for count data (for example Poisson or Negative Binomial Models) will be used to assess whether there are differences in the number of events (for example, the total number of symptoms recorded for each person). These models will also control for potential confounders.

168. Within-person comparisons will be performed between measures taken at different time points. In particular, measures of the K10 and PCL-C scales measured on Defence psychological screening records can be compared between the Return to Australia Psychological Screen (RtAPS) and the Post Operation Psychological Screen (POPS). McNemar's Test (for 2 by 2 category comparisons) and the test for symmetry (where the number of categories is greater than 2) will be used to compare categorical variables, and the paired t-test or the Wilcoxon signed rank test will be used as

appropriate to compare the scale original scores between these screens. Similar methods can be used to compare measures of psychological distress taken at the RtAPS or POPS with those recorded on the self report questionnaire.

Secondary / Subgroup Analyses

169. The responses from the general symptoms checklist can be used to investigate patterns of symptoms. There is also potential to investigate the existence of any post-deployment syndrome by looking at clusters of symptoms using factor analysis techniques if required.

170. More specific definitions of exposure will be investigated. For example, particular forms of combat, locations or other specific operational/occupational exposures such as sub-element task groups may be explored to define additional subgroups for comparison and analysis. Stratifications used in previous DHSP studies include Service, service type, gender, rank and period of deployment. Given the significant heterogeneity of the deployments (and therefore exposures) and the design based on internal comparisons within the cohort, the large sampling frame will allow these stratifications to be made while retaining acceptable cell size.

Study 3: Mortality and Cancer Incidence Study

Study Design

171. Study 3 will involve acquisition of data from the National Death Index and the State/Territory Cancer Registries (via the National Cancer Statistics Clearing House).

172. Defence personnel records (from PMKeyS) will be accessed to obtain information on personnel who were serving Australian Defence Force (ADF) members or separated from the ADF at three separate time points (1 January 2001, 1 January 2006 and 1 January 2011).

173. These personnel will be separated into four key groups:

- ADF personnel never deployed to the Middle East Area of Operations (MEAO);
- ADF personnel deployed to the MEAO between 2001 and 2005 inclusive, but not between 2006 and 2010 inclusive;
- ADF personnel deployed to the MEAO between 2006 and 2010 inclusive, but not between 2001 and 2005 inclusive;
- ADF personnel deployed to the MEAO between 2001 and 2005 inclusive, and also between 2006 and 2010 inclusive.

These groups have been defined to allow for the cohort deployed between 2001 and 2005 inclusive to be analysed at specific time points (such as 10-year follow-up) earlier. Five-year groups have been selected based on retention figures for the Australian Defence Force during the timeframe being considered [3].

In addition, this design allows for changes in prevalence of specific conditions among personnel deployed at different times to be detected [4,5]. Further subgroups will be defined based on individuals' dates of joining and separating from the ADF, to ensure that comparisons are made between contemporaneously serving groups of individuals.

Mortality Registry Data

174. Increased deaths from external causes have been found in studies of deployments to the 1990/91 Gulf War. Therefore, investigating patterns of mortality in veterans is an important focus of this study.

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[3] J Reich, J Hearps, A Cohn, J Temple, P McDonald. 2006. Defence Personnel Environment Scan 2025, p42. Department of Defence, Canberra. http://www.defence.gov.au/dpe/dpe_site/publications/DPES2025, accessed 5 May, 2010.

[4] JF Kelly, AE Ritenour, DF McLaughlin, KA Bagg, AN Apodaca, CT Mallak, L Pearse, MM Lawnick, HR Champion, CE Wade, JB Holcomb. 2008. Injury severity and causes of death from Operation Iraqi Freedom and Operation Enduring Freedom: 2003-2004 versus 2006. J Trauma, 64(2 Suppl): S21-26.

[5] O Horn, A Sloggett, GB Ploubidis, L Hull, M Hotopf, S Wessely, RJ Rona. 2010. Upwards trends in symptom reporting in the UK Armed Forces. Eur J Epidemiol, 25(2), 87-94.

175. The MEAO Health Study will utilise similar protocol and procedures as developed by CMVH for the NNAI studies. The mortality study will be conducted by linkage with the National Death Index which is managed by the Australian Institute of Health and Welfare (AIHW), and is a compilation of the data held by the various registries of death in the Australian States and Territories.

176. The timing of this study will have to take into account that the National Registry takes approximately two years to compile mortality information from the State and Territory Registries. For example, an analysis of mortality data conducted in 2011 would include only data compiled at that time, which would be as of 2009.

Cancer Registry Data

177. All forms of cancer (with the exception of non-melanocytic skin cancer) are the subject of compulsory registration in all States and Territories of Australia. While studies of cancer in veterans of the first Gulf War have not shown elevated rates, studies of Korean War veterans have shown excess rates of cancer decades after the end of the war. Cancer remains a significant concern of many veterans.

178. CMVH has established protocols for the extraction of data from the cancer registries and these protocols will be applied to the MEAO Health Study. Briefly, this will involve extraction and cleaning of data from the National Cancer Statistics Clearing House, which contains data derived from the eight State and Territory Cancer Registries.

179. Linkage to health registries formed one of the consent options in Study 2 (Census) of the Middle East Area of Operations Health Study. Cancer incidence data for the subset participants who give their consent to this linkage will be able to be linked to their responses to MEAO Study 2, in order to explore possible associations with specific roles or exposures during deployment.

180. The timing of this study will have to take into account that the National Cancer Statistics Clearing House takes approximately three to four years to compile cancer incidence information from the State and Territory Registries. For example, an analysis of cancer incidence data conducted in 2011 would only include State data compiled at that time, which would be as at 2007.

Analysis of cancer and mortality incidence

181. A subject's person-years of follow-up will be estimated from the end of the deployment to their death or follow-up date. The person-years will be used to calculate rates of mortality and cancer incidence in each arm of the study. Survival analysis techniques such as Life Tables, Survival curves as well as Poisson and Cox models can be used to analyse this time-to-event data. Long-term follow-up (10, 20 or 30 years post-deployment) is expected to provide the most informative results on mortality and cancer incidence.

Design options and power

182. Tables A-J present the estimated statistical power after 10 and 15 years follow-up for different effect sizes associated with cancer and mortality outcomes. Projections of mortality and cancer incidence rates are based on the most current Australian national estimates available (2005 for cancer and 2006 for mortality) and derived by applying these rates to a lexis expansion of the data assuming 10 and 15 years follow-up.

183. It is estimated that the mortality study will have a good statistical power (0.86) to detect relative differences of 30% in all-cause mortality after 10 years follow-up using a comparison group two thirds the size of the nominal roll and accounting for a healthy soldier effect (Table A). Using the same comparison group, after 15 years follow-up there is good statistical power (0.81) to detect a 20% difference in mortality (Table B) and a relative difference of 30% could be detected in the cancer incidence rates between the veterans and comparisons with 96% power after 10 years follow-up (Table C).

Longer follow-up would be required to be able to detect differences in cancer mortality and external cause mortality and detect relative differences of less than 20% in some of the comparisons of those deployed in the early period of the deployment and those deployed later (Tables E-J).

Hypothesis 1 – Is there an association between MEAO deployment and cancer/mortality?

Table A: All cause mortality power based on 10 years follow-up (estimated number in veterans arm 379 deaths (N = 26915))

All cause mortality	Comparison group size			Comparison group size with correction#		
Relative Risk	N = 26915	N=17943	N= 13458	N = 26915	N=17943	N= 13458
1.2	0.74	0.64	0.55	0.64	0.54	0.46
1.3	0.97	0.93	0.87	0.93	0.86	0.79
1.4	>0.99	>0.99	0.98	0.99	0.98	0.95

Rates in the cohort assumed to be 20% less than the general population

Table B: All cause mortality power based on 15 years follow-up (estimated number in veterans arm 693 deaths (N = 26915))

All cause mortality	Comparison group size			Comparison group size with correction#		
Relative Risk	N = 26915	N=17943	N= 13458	N = 26915	N=17943	N= 13458
1.1	0.44	0.36	0.31	0.36	0.30	0.25
1.2	0.95	0.89	0.82	0.89	0.81	0.73
1.3	>0.99	>0.99	>0.99	>0.99	0.99	0.97

Rates in the cohort assumed to be 20% less than the general population

Table C: All types cancer incidence power based on 10 years follow-up (estimated number in veterans arm 447 cancers (N = 26915))

All cause mortality	Comparison group size		
Relative Risk	N = 26915	N=17943	N= 13458
1.1	0.30	0.24	0.21
1.2	0.81	0.71	0.63
1.3	0.99	0.96	0.93

Table D: All types cancer incidence power based on 15 years follow-up (estimated number in veterans arm 889 cancers (N = 26915))

All cause mortality	Comparison group size		
Relative Risk	N = 26915	N=17943	N= 13458
1.1	0.54	0.45	0.38
1.2	0.98	0.95	0.91
1.3	>0.99	>0.99	>0.99

Hypothesis 2 – Is there an association between early MEAO deployment and cancer/mortality?

Table E: All cause mortality power based on 10 years follow-up (estimated number in veterans arm 111 deaths (N = 8581))

All cause mortality	Comparison group size			Comparison group size with correction#		
Relative Risk	N = 4291	N=8581	N= 17162	N = 4291	N=8581	N= 17162
1.2	0.18	0.28	0.37	0.15	0.23	0.31
1.3	0.35	0.53	0.67	0.28	0.44	0.57
1.4	0.56	0.76	0.88	0.46	0.66	0.80
1.5	0.75	0.91	0.97	0.64	0.83	0.93

Rates in the cohort assumed to be 20% less than the general population

Table F: All types cancer incidence power based on 15 years follow-up (estimated number in veterans arm 255 cancer (N = 8581))

All cause mortality	Comparison group size		
Relative Risk	N = 4291	N=8581	N= 17162
1.2	0.40	0.57	0.71
1.3	0.72	0.89	0.96
1.4	0.92	0.99	>0.99
1.5	0.99	>0.99	>0.99

Hypothesis 3 – Is there an association between late MEAO deployment and cancer/mortality?

Table G: All cause mortality power based on 10 years follow-up (estimated number in veterans arm 201 deaths (N = 13978))

All cause mortality	Comparison group size			Comparison group size with correction#		
Relative Risk	N = 7000	N=13978	N= 21000	N = 7000	N=13978	N= 21000
1.2	0.32	0.47	0.55	0.26	0.38	0.46
1.3	0.60	0.79	0.87	0.50	0.70	0.78
1.4	0.84	0.95	0.98	0.74	0.90	0.95
1.5	0.95	0.99	>0.99	0.90	0.98	0.99

Rates in the cohort assumed to be 20% less than the general population

Table H: All types cancer incidence power based on 15 years follow-up (estimated number in veterans arm 474 cancer (N = 13978))

All cause mortality	Comparison group size		
Relative Risk	N = 7000	N=13978	N= 21000
1.2	0.66	0.84	0.90
1.3	0.94	0.99	>0.99
1.4	>0.99	>0.99	>0.99

Hypothesis 4– Is there an additional effect of 'early' MEAO deployment on cancer/mortality among ADF personnel deployed 'late' MEAO?

Hypothesis 5- Is there an additional effect of late MEAO deployment on cancer/mortality among ADF personnel deployed 'early' MEAO?

Table I: All cause mortality power based on 15 years follow-up (estimated number in veterans arm 129 deaths (N = 4056))

All cause mortality	Comparison group size			Comparison group size with correction#		
Relative Risk	N = 4056	N=8112	N= 12168*	N = 4056	N=8112	N= 12168*
1.2	0.32	0.43	0.47	0.27	0.36	0.41
1.3	0.60	0.74	0.79	0.50	0.64	0.69
1.4	0.83	0.93	0.95	0.73	0.85	0.89
1.5	0.95	0.99	0.99	0.89	0.96	0.97

Rates in the cohort assumed to be 20% less than the general population
*Not possible for Hypothesis 5

Table J: All types cancer incidence power based on 15 years follow-up (estimated number in veterans arm 171 cancers (N = 4056))

All cause mortality	Comparison group size		
Relative Risk	N = 4056	N=8112	N= 12168*
1.2	0.42	0.54	0.60
1.3	0.74	0.86	0.90
1.4	0.93	0.98	0.99
1.5	0.99	>0.99	>0.99

*Not possible for Hypothesis 5

Data Collection Tools

184. The MEAO Health Study will utilise data collected from a number of different sources including self-report questionnaires, physical tests, biological tests, neurocognitive assessments and routinely collected electronic health data.

185. In order for data to be linked between the different sources, specific consent must be obtained from participants for that data linkage to occur.

186. Individual studies will utilise data sources as described below:

187. Study 1: the Prospective Study will utilise data collected from:

- Self-administered questionnaires;
- Physical tests including saliva and blood samples;
- Neurocognitive assessment;
- Electronic health records held by the ADF; and
- RtAPS and POPS.

188. Study 2: the Census Study will utilise data collected from:

- Self-administered questionnaires;
- Electronic health records held by the ADF; and
- RtAPS and POPS.

189. Study 3: the Mortality and Cancer Incidence Study will involve:

- Linkage with State and Territory cancer registries; and
- Linkage with the National Death Index.

190. The data to be collected from each of these sources are described in detail below.

Self-Administered Questionnaire

191. All participants will be asked to complete a self-administered questionnaire. This questionnaire will be the primary method used to determine where individuals deployed and for how long, deployment experiences, and health and wellbeing outcomes.

192. The questionnaire (Annex 1) is divided into three major components: 1) Brief Deployment History; 2) Health Questionnaire; 3) Deployment Experiences Questionnaire. These sections are described in more detail below.

193. Participants in Study 1 (Prospective Study) will complete an additional Personality and Resilience Insert (Annex 1.6) at the pre-deployment assessment.

Brief Deployment History

194. This questionnaire will be used in the following studies:

- Study 1 – MEAO Prospective Study (Pre-Deployment only)
- Study 2 – MEAO Census Study

195. All participants will be asked to indicate participation in active deployments. The questions and format were designed in-house after experience with the NNAI Health Studies.

196. Participants recruited to the MEAO Prospective Study will be asked to complete this history prior to deployment only. The census study participants will complete this questionnaire at the same time as they complete the Health Questionnaire and the Deployment Experiences Questionnaires.

197. The list of operations includes warlike, non-warlike, UN peacekeeping and peacemaking operations, and humanitarian aid and assistance operations.

198. Participants are asked to indicate the country they deployed to, the Operation name, the year the deployment started, the number of times deployed in that year and the total time (in months) deployed. Major recent operations are provided in boxes and space is provided for participants to nominate additional deployments at the end of the questionnaire. Following the question about history of deployments to the MEAO, three questions are asked about feelings of pressure to deploy and if they deployed with their home Unit. Questions about deploying with one's home Unit were identified during the Preliminary Study focus group as an important source of (di)stress. The items themselves were sourced from the Kings College Gulf War study questionnaire.

199. In addition to formal ADF deployments, a question is asked about work in the Middle East in a role outside of the ADF, such as working as a security contractor. The inclusion of this item was based on anecdotal reports of ADF members working in these roles, and which may contribute to the cumulative stress associated with working in the MEAO environment.

Personality and Resilience Insert

200. The Personality and Resilience Insert will be completed by participants in the following study:

- Study 1: MEAO Prospective Study (Pre-Deployment only)

201. This section consists of questions that will be completed at the pre-deployment assessment in place of the Deployment Experiences Questionnaire, which is only required at the post-deployment assessment.

202. The questions are drawn from a number of sources including the Ten Item Personality Inventory, Schuster Social Support Scale, a single item each for negative life events and prior psychiatric history, Symptom Interpretation Questionnaire, pre-existing traumatic exposures, and the Toronto Alexithymia Scale.

Ten Item Personality Inventory (TIPI)

203. The TIPI is a very brief personality inventory that provides a measure of the 'big' five personality domains[6].

[6] Gosling SD, Rentfrow PJ, Swann WB. A very brief measure of the big five personality domains. J Res Person. 2003; 37:504-528

204. The ten items ask directly about descriptors of each of the big five dimensions, thus optimising content validity, and focuses on breadth of coverage, removal of redundant and negation items. Each item represents each pole (extreme) of the big five personality dimensions (e.g. extraversion vs. introversion).

205. While having somewhat inferior psychometric properties to standard multi-item personality inventories, the TIPI is suitable for situations where personality is not the primary topic of interest and/or where time and resources to conduct a more extensive assessment for personality is not feasible.

Schuster Social Support Scale

206. The Schuster Social Support Scale is a ten item measure of social support that was developed to enable investigation of the effects of social relationships on emotional functioning[7]

207. This scale has been used extensively in community samples and is also used in the LASERR Study (Longitudinal ADF Study Evaluating Retention and Resilience).

Negative Life Events

208. Negative life events and problems in childhood are an important predictor of mental health and social problems.

209. The single item used here is intended to provide an indicator of 'good enough' childhood. It is also used in the Longitudinal ADF Study Evaluating Retention and Resilience (LASERR) study.

Prior Psychiatric History

210. Prior psychiatric history is an indicator of future mental health problems. Professor Alexander McFarlane developed the single item used.

Symptom Interpretation Questionnaire

211. The Symptom Interpretation Questionnaire (SIQ) is a 13-item scale used to determine attributional style, which is important for understanding self-report of symptoms and distress[8]. It comprises three scales providing an indication of 3 different attributional styles: psychologiser, somatiser, and normaliser.

Preexisting Traumatic Exposures

212. This set of 18 questions are adapted from the Composite International Diagnostic Interview (CIDI) and modified by McFarlane et al.

213. The questions ask about exposure to a number of traumatic experiences, the number of times exposed and the age of first and last exposure to the event. Experiences considered are taken from both potential traumatic exposures encountered in the ADF (e.g. direct combat) and events that may have occurred outside the ADF in adulthood (e.g. serious assault, terrorism) or in childhood (e.g. child physical abuse).

[7] Schuster T, Kessler R, Aseltine R. Supportive interactions, negative interactions and depressed mood. Am J Community Psychol. 1990; 18:423-38

[8] Robbins JM, Kirmayer LJ. Attributions of common somatic symptoms. Psychological Medicine. 1991; 21:1029.

214. The questions are used in the ADF LASERR study and also form part of the CIDI which is a widely used structured interview for mental health disorder.

Toronto Alexithymia Scale

215. Alexithymia is a cognitive-affective disturbance related to a reduced ability to recognise and verbalise internal emotions, and thoughts that tend to be fixated on external events. The Toronto Alexithymia Scale is a validated and reliable 20-item scale that has been used in studies of general community and clinical populations to provide a measure of the degree of alexithymia[9].

Health Questionnaire

216. The health questionnaire will be used in the following studies:

- Study 1: MEAO Prospective Study
- Study 2: MEAO Census Study

217. The cohort recruited to Study 1 will be asked to complete this questionnaire both prior to deployment and then on return from deployment. The cohort recruited to Study 2 will complete this questionnaire at the same time that they complete the Deployment Experiences Questionnaire.

218. The questions are derived from a number of different sources and will provide information about the major physical health, mental health, social function, and health risk factors identified by the review of literature, consultation with stakeholders and focus groups with serving and ex-serving personnel.

219. The questions are grouped into sections each with a common theme. The sections and the questions that make up each section are described in detail below.

Section 1: Background Details

1. This section is divided into two parts. All participants complete the first part that asks 13 questions providing important demographic and social information. The second part is only completed by Reservists and individuals who have left the ADF, who are asked a further five questions about their income and employment outside of the ADF.

2. The first part asks participants their gender, date of birth and marital/relationship status, which are used as confirmatory items to ensure information from PMKeyS is correct as these are essential covariates for assessment of health risk. Further questions are then asked about education, satisfaction with significant relationships, change in relationship status and the impact of military commitments on relationships and children.

3. A series of questions are also asked about workload and rank to provide confirmatory information against the PMKeyS data.

[9] Taylor GJ, Bagby RM, Parker JD. The 20-item Toronto Alexithymia Scale. Reliability and factorial validity in different languages and cultures. J of Psychosom Res. 2003;55(3): 277-83.

Section 2: Recent Health Symptoms

4. This section comprises 2 measures: a health symptom checklist and questions screening for mild traumatic brain injury.

Health Symptom Checklist

5. The 67-item self-report symptom questionnaire asks about recent (in the past month) respiratory, cardiovascular, musculoskeletal, dermatological, gastrointestinal, genitourinary, neurological, neuropsychological or cognitive, and psychological symptoms.

6. The questions build on the 63 item symptom questionnaire used in the Australian Gulf War Veterans' Health Study, which in turn was adapted from the symptom questionnaire developed and used by the King's College Gulf War Illness Research Unit[10] and which was based on the Hopkins Symptom Checklist[11].

7. The items can be analysed individually or using factor analysis to identify clusters of symptoms that might be indicative of 'syndromes'.

8. The questionnaire enables internal comparisons of self-reported symptoms within the study cohort, but importantly, use of the questionnaire allows comparisons with the results of international studies as well as the earlier 1990/91 Australian Gulf War Veterans' Health Study and the NNAI studies.

Mild Traumatic Brain Injury Questions

9. The mild traumatic brain injury (TBI) screener is used to provide an indication of mild traumatic brain injury. This screening tool comprises four questions and was adapted from Pietrzak et al.[12]. It was originally developed for use in Veteran's Administration medical facilities, and was based on a tool developed by the United States Defense and Veterans Brain Injury Center. It has been implemented at selected U.S. military bases to screen for TBI among returning OEF/OIF service members.

Section 3: Your Health Now

10. This section comprises 51 questions that have been drawn from instruments including the Short Form 12 (SF-12)[13], the 45 and Up Study[14] , the Kessler 10 Plus

[10] Unwin C, Blatchley N, Coker W, *et al.* Health of UK servicemen who served in Persian Gulf War. *Lancet* 1999;353:169–78

[11] Derogatis LR, Lipman RS, Rickels K, et al. The Hopkins Symptom Checklist (HSL): A self-report symptom inventory. *Behav. Sci.* 1974;19:1-15.

[12] Pietrzak RH, Johnson DC, Goldstein MB, Malley JC, Southwick SM: Posttraumatic stress disorder mediates the relationship between mild traumatic brain injury and health and psychosocial functioning in veterans of Operations Enduring Freedom and Iraqi Freedom. *J Nerv Ment Dis* 2009; 197(10): 748-53.

[13] Ware JE, Sherbourne CD. The MOS 36-item Short-Form Health Survey (SF-36). Conceptual framework and item selection. *Med. Care* 1992;30:473-483.

[14](www.45andup.org.au)

(K10+)[15], a question from the LASERR study, and medically diagnosed conditions from the Solomon Island Health Study and the Australian Gulf War Veterans' Health Study.

The Short Form 12 (SF-12)

11. The SF-12 is a multipurpose short form with only 12 questions, all selected from the SF-36 Health Survey[16]. Like the SF-36, it is a generic measure of health status and quality of life. Only a subset of questions from the SF-36 are utilised that enable scores to be calculated for general health, physical health, and mental function. The SF-12v2 to be utilised in the MEAO Health Study can also be scored as an eight scale health profile.

Questions from the 45 and Up Study

12. A series of questions relating to general health and wellbeing have been incorporated from those used in the 45 and Up Study (www.45andup.org.au). These questions ask participants to rate, in general, their overall health, quality of life, eyesight (with glasses or contact lenses), hearing, memory, and teeth and gums on a 5-point Likert scale.

Kessler 10 Plus (K10+)

13. The Kessler 10 Plus (K10+) is a widely used and validated 14-item questionnaire that is used as a general measure of psychological distress. Scores are calculated to provide a measure of risk of mental health problems. The scales were designed to be sensitive around the threshold for the clinically significant range of the distribution of non-specific distress in an effort to maximise the ability to discriminate cases of serious mental illness from non-cases. The K10 is used in the Australian Mental Health and Wellbeing Survey enabling comparison with general community norms. Additionally, it is currently used by the Australian Defence Force as part of the Return to Australia Psychological Screen (RtAPS) and Post Operational Psychological Screen (POPS). It was also used as a measure of psychological distress in the NNAI Health Studies.

Questions from the LASERR Study

14. This question provides a short measure of coping ability using one question with two subparts taken from the LASERR study. This item asks to what extent participants agree with statements relating to adopting to change and 'bouncing back' from illness or hardship.

Doctor Diagnosed Medical Conditions

15. A 23-item medical conditions questionnaire is incorporated here as an indicator of medical problems or conditions that have been diagnosed or treated by a doctor. This list is shortened from that used in the Australian Gulf War Veterans' Health Study and Solomon Islands Health Study such that it only incorporates the most common medical conditions identified in those studies.

[15] Kessler R, Mroczek D. Final Versions of our Non-Specific Psychological Distress Scale [memo dated 10/3/94]. Ann Arbor (Michigan): Survey Research Centre of the Institute for Social Research, University of Michigan; 1994

[16] Ware JE, Sherbourne CD. The MOS 36-item Short-Form Health Survey (SF-36). Conceptual framework and item selection. *Med. Care* 1992;30:473-483.

16. The questions are based on the medical conditions questionnaire originally developed and used by the King's College Gulf War Illness Research Unit and adapted for use in the Australian Gulf War Veterans' Health Study to include several conditions considered relevant to Australian veterans.

17. The term 'medical doctor' is used to qualify the person who diagnosed or treated the problem or condition and the time frame is 'last 12 months' when the questionnaire is completed pre-deployment, or since returning from the last deployment to the MEAO when the questionnaire is completed post-deployment in order to standardise the reference point and context for that diagnosis or treatment.

Section 4: Lifestyle behaviours

18. This section comprises 22 items to determine history of cigarette smoking, frequency of alcohol use and current alcohol use disorders, and use of dietary and energy supplements.

Cigarette smoking and tobacco use

19. History of cigarette smoking is assessed using a brief set of questions developed for use in the Millennium Cohort Study. Participants are asked about smoking in the past year (current smoking), ever smoking at least 100 cigarettes (ever smoking), age when started smoking, how much is smoked and if they have tried quitting. Two additional questions taken from the Kings College Study ask about smoking pattern on deployment.

Alcohol Use Disorders Identification Test (AUDIT)

20. The Alcohol Use Disorders Identification Test (AUDIT) questionnaire will be used to quantify current alcohol use and detect alcohol disorders. The scale was developed for the identification of currently active, hazardous and harmful alcohol consumption[17] . The AUDIT is used extensively in military research including the NNAI studies and the Australian Gulf War Veterans' Health Study. It is used by ADF psychologists in the POPS.

Questions about dietary supplements

21. Three questions developed for use in the Millennium Cohort study will be used here to assess whether participants currently use any body building supplements, energy supplements, or weight loss supplements. These questions are all asked in the deployment experiences questionnaire in relation to the use of supplements while on deployment.

Section 5: Life Experiences

22. This section comprises 60 items drawn from five separate questionnaires to assess anxiety and affective disorders including post traumatic stress disorder (PTSD), panic attacks, generalised anxiety disorder, major depression as well as anger and suicidality.

[17] Babor T, Fuente J, Saunders J, et al. The Alcohol Use Disorders Identification Test: Guidelines for use in primary health care. Geneva: Division of Mental Health, World Health Organisation, 1989

PTSD Check List (PCL)

23. Post traumatic stress symptoms will be assessed using the post traumatic stress disorder checklist (PCL). The PCL is a widely used, 17 item self-administered questionnaire for assessing symptoms of PTSD. The PCL-C to be used here is a civilian version of the instrument that can be referenced to any specific traumatic event (hence the C in the acronym). It has excellent test-retest reliability and internal consistency is very high. It has been used extensively for population-based research and is also used by Defence Force psychologists as part of the RtAPS and POPS, and was used in the NNAI studies.

Anger

24. Items from the Dimensions of Anger Scale[18] and two additional items from the AG21 questionnaire addressing anger and use of force are used. Items from the Dimensions of Anger Scale were also used in the LASERR study providing comparison to this study. Questions from the AG21 have not been published but are used by the US Military and were used in the East Timor and Bougainville Health Studies.

Questions from the Patient Health Questionnaire (PHQ)

25. The PHQ is the self report version of the PRIME-MD (Primary Care Evaluation of Mental Disorders) which was the first instrument designed for use in primary care that specifically diagnoses mental health disorders using diagnostic criteria from the Diagnostic and Statistical Manual of Mental Disorders, Revised Third Edition (DSM-III-R) and Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV). The full PHQ screens for five of the most common groups of disorders in primary care: depressive, anxiety, alcohol, somatoform, and eating disorders. Just the items from the anxiety and depression modules are used here.

Anxiety Module

26. Panic attacks and other anxiety disorders will be assessed by 22 items from the Brief PHQ. The first 15 items are questions for panic attack and the final seven items screen for other anxiety disorders.

27. The PHQ anxiety module has high sensitivity and specificity for detection of anxiety disorders in primary care and medical settings[19] and superior psychometric properties to other screening instruments such as the Hospital Anxiety and Depression Scale (HADS) for detection of panic attack.

Depression module

28. Depression is assessed from nine items from the Brief PHQ. Each item in the PHQ9 evaluates the presence and severity (frequency) of one of the nine DSM-IV criteria of major depression.

[18] Novaco, R. (1975). *Dimensions of anger reactions*. Irvine, CA: University of California.
[19] Spitzer RL, Kroenke K, Williams J. Validation and utility of a self-report version of PRIME-MD. JAMA 1999; 282: 1737-1744.

29. The nine item depression module has been validated against clinical diagnosis from a medical professional[20] and found to have superior operating characteristics to the Hospital Anxiety and Depression Scale and WHO5 instruments. In addition, a depressive symptom severity score can be obtained.

Suicidality

30. Suicidality is assessed using four items relating to ideation, planning and attempts in the previous 12 months.

Section 6: Respiratory Health

31. Respiratory symptoms are assessed using the European Community Respiratory Health Survey screening questionnaire. This questionnaire comprises seven main dichotomous items and two further items conditional on a positive answer to item

32. These nine items are drawn from the longer European Community Respiratory Health Survey (ECRHS), which in turn is derived from the International Union against Tuberculosis and Lung Disease (IUATLD) questionnaire.

33. Items within the screening questionnaire are weighted to produce a total score indicating the seriousness of asthma like symptoms[21] such as wheeze, shortness of breath and cough. A single question is included on allergy and hay fever which does not contribute to the calculation of the total score, but may be used as an indicator of allergy.

Section 7: Reproductive History

34. Reproductive health items were developed in-house by CAPT (RAN) Sonya Bennett. Participants are asked if they have ever had problems with fertility and if they have ever been pregnant or fathered a pregnancy. If they have fathered a pregnancy/become pregnant, detail is asked for each pregnancy including what the outcome of the pregnancy was, whether the pregnancy resulted in a live birth, gestation, gender of baby, weight of baby, and the presence of any birth defects or cancer.

Section 8: Recreation and Social Activities

35. Eleven questions are asked about current recreational and social activities. These were adapted from a DVA instrument but have not been published in the scientific literature. The questions were used in the NNAI Health Studies.

[20] Kroenke K, Spitzer RL, Williams JBW. The PHQ-9: Validity of a brief depression severity measure. J Gen Intern Med 2001; 16:606-613.
[21] Grassi M, Rezzani C, Biino G, Marinoni A. Asthma-like symptoms assessment through ECRHS screening questionnaire scoring. J Clin Epidemiol.2003; 56:238-247.

Section 9: Evaluation Questions

36. These two items ask the participant if there are any other important health concerns that were not addressed in the questionnaire or if they would like to add any other comments.

Deployment Experiences Questionnaire

37. This questionnaire is used to identify health hazards and threats both real and perceived, health on deployment, and experience returning to Australia. Questions are answered in relation to the *last deployment* to the MEAO.

38. The questionnaire is presented with forms specific for Iraq-based operations (Part A), and Afghanistan-based operations (Part B). Having two separate forms is designed to make participants feel that they are being asked questions specific to their experience in the MEAO and enables tailoring of the questionnaire to exclude questions not relevant to the experiences of personnel at some locations.

39. Participants are asked about a range of experiences they may have encountered on deployment to the MEAO including their exposure and frequency of exposure to hazards including airborne (e.g. dust, smoke), exhaust emissions/fumes/toxic industrial chemicals, noise, vector borne and communicable disease, animals, ionising and non-ionising radiation, combat, and perceived threats.

40. The items selected cover each of the major hazards personnel face in the MEAO as identified by the review of literature and review of Hazard Assessment Team reports conducted during Phase 1a. In addition, hazards reported by serving and ex-serving personnel during the Preliminary Study focus groups have also been incorporated.

41. The items addressing these hazards are derived from multiple sources including the Australian Gulf War Veterans' Health Study, ADF post-deployment health screen, Traumatic Stress Exposure Scale Revised (TSES-R), the Deployment Risk and Resilience Inventory (DRRI), and the Kings College Phase 2 questionnaire. Additional questions developed by the investigators to address health hazards identified during the preliminary study process that are not covered by pre-existing items include "Were you exposed to an environment where you inhaled fine dust or fibres?", "Were you exposed to others' cigarette smoke on base in a recreational or work context?", "Did you come into contact with body fluids or blood?", "Did you receive a blood transfusion?", "Did you use an NBC suit (not for training purposes)?" and "Did you use a respirator (not for training purposes)?"

Assessment of Physical Measures in a sub-group of participants enrolled in Study 1

Standardised measurement of height, weight, hip and waist circumference

42. Height will be measured in centimeters to one decimal place using a stadiometer, as the maximum distance from the floor to the vertex of the head with shoes removed.

43. Weight will be measured in kilograms, to one decimal place, in light clothing and without shoes using electronic scales.

44. Waist and hip circumference will be measured using a tape measure, in centimeters to one decimal place at the smallest circumference below the rib cage and above the umbilicus taken at the end of normal expiration. Hip circumference will be measured, in centimetres to one decimal place, at the largest circumference at the posterior section of the buttocks.

Blood Pressure

45. Blood pressure (BP) will be taken by a trained research nurse using a calibrated and validated digital sphygmomanometer with appropriate sized cuffs.

46. BP will be measured with the participant in a seated position and the arm supported at heart level, after five minutes' rest, and abstinence from food (including nutritional supplements) and caffeinated beverages for a minimum of 30 minutes prior to BP measurement. BP will be measured from the left arm of all participants unless there is some contraindication (e.g. lymphoedema).

47. BP will be recorded as three serial measurements at intervals of at least one minute. An additional three serial measures will be taken, if the difference between the SBP and DBP readings is more than 8 mm Hg for SBP and more than 5 mm Hg for DBP. The mean of three acceptable BP measurements will be used in the analysis.

Spirometry

48. Lung function testing will be conducted by a nurse using spirometry. The nurses will be provided with training on how to perform spirometry following the TSANZ/ANZSRS position paper on spirometry training.

49. Participants are asked to avoid using bronchodilators on the day of screening. Height and age will be recorded in order to calculate predicted lung function, and patients will then undergo spirometry using an Easy One^{TM} spirometer and following American Thoracic Society (ATS) guidelines for conducting spirometry.

50. Briefly this involves:

- Participants are seated for the testing
- The forced expiratory manoeuvre is performed with maximum effort immediately following a maximum inspiration
- Participants are required to perform a minimum of three technically acceptable blows with acceptability defined as:
  - Satisfactory start of test
  - Minimum exhalation Forced Vital Capacity (FVC) time of 6 seconds
  - End of test criteria met
- Participant manoeuvres are required to meet ATS criteria for reproducibility.

51. Quality of spirometry will be monitored routinely by a respiratory physiologist associated with CMVH, who will review spirometry results and provide feedback directly to the nurses.

52. The EasyOne™ spirometer will be used due to its ease of use, portability, and superior reliability. The EasyOne™ spirometer utilises digital ultrasonic flow measurement technology. Ultrasonic flow measurement eliminates problems associated with traditional methods of flow measurement and has no moving parts thus does not require repeated calibration or maintenance.

The Step Test

53. The step test is a standardised assessment of an individual's fitness and capacity to sustain effort. Measurement of heart rate in recovery from a standardised step test is an objective and efficient way to classify participants in terms of their aerobic fitness and is a measure of fatigability.

54. The method of McArdle[22] as applied in the Australian Gulf War Veterans' Health Study will be used. The test involves stepping at a designated cadence using a digital metronome, up and back from a 41.3 centimetre platform for three minutes. Women are required to complete 22 step ups per minute whilst men complete 24 step ups per minute. Participants are timed using a stop watch. Pulse rate is measured at five seconds and 20 seconds after completion of stepping using a heart rate monitor. The two measures are then averaged to give a single recovery heart rate in beats per minute for each participant, with lower rates indicating greater aerobic capacity.

Assessment of dermatological conditions

55. Photographs will be taken of participants' backs, palms of their hands, soles of their feet and side views of the cheek, lower nose and lips. This is done in order to assess dermatological conditions that develop on deployment.

[22] McArdle WD, Katch FI, Katch VL, Exercise physiology: energy, nutrition, and human performance. 2nd ed. 1986, Philadelphia: Lea & Febiger. 696.

Laboratory Investigations

56. Saliva and blood samples will be collected for the purpose of determining:

- Exposure to toxins;
- Exposure to infections known to be ubiquitous in the environment of the deployment;
- Direct physiological and immunological changes as a consequence of the stress to which the individual has been exposed in the course of the deployment;
- Direct effects of being exposed to a militant environment where there may be limitations on an individual's diet, combined with physical demands and potentially high altitude environments.

57. The measures proposed to be collected are based on the experience of the investigators in the Australian Gulf War Veterans' Health Study which provided probably the most detailed examination to date of a veterans' cohort in terms of their physical health and the current scientific literature.

58. The investigations to be undertaken are listed in Table 2 below.

Table 2 Summary of proposed assessments of biological samples collected pre and post deployment during the MEAO prospective Health Study

Assessment Purpose	What is assessed
Exposure to Toxins	*Blood chemistry and liver function* specifically: Sodium, Potassium, Chloride, Bicarbonate, Anion Gap, Glucose, Urea, Creatinine, total Cholesterol, Osmolarity, Urate, Phosphate, calcium, Ionised calcium, Albumin, Globulins, Total Protein, Bilirubin, GGT, ALP, ALT, AST, LD, CK, Magnesium, Amylase, Lipase, and C-Reactive Protein. *Heavy metal exposure* specifically: Lead *Organophosphate exposure* specifically: red blood cell cholinesterase
Exposure to Infections	*Total Cell Count (CBE)* specifically: haemoglobin, red cell count, packed cell volume, mean corpuscular volume, mean corpuscular haemoglobin, mean corpuscular haemoglobin concentration, red cell distribution width, total white cell count and white cell differentiation counts and percentages (neutrophils, lymphocytes, monocytes, eosinophils, basophils and platelets). *Erythrocyte Sedimentation Rate (ESR)* as part of CBE

	Viral infections specifically: o Epstein-Barr, o Cytomegalovirus, o Herpes Simplex, o Hepatitis C *Bacterial infections* specifically: o Mycoplasma, o Chlamydia (serology) o Helicobacter pylori (serology) *Parasitic infections* specifically: Leishmaniasis
Physiological and Immunological changes arising from stress	*Inflammatory mediators* specifically: Interleukin 1, Interleukin 4, Interleukin 6, C-Reactive Protein, and TNF Alpha, *Stress hormones* specifically: cortisol, nor-adrenaline, adrenaline
Effects of the deployed environment	*Cardiovascular Risk Factors* specifically: Total cholesterol and High Density Lipoproteins, Glycated Haemoglobin (HbA1C) *Dietary Components* specifically: B12 and Folate

Storage of biological samples

59. Two aliquots of serum will be stored at -70° Centigrade for a period of up to 10 years in order to conduct investigations in the future as new diagnostic technologies become available and/or as unexpected health concerns emerge among veterans.

Neurocognitive function

60. In addition to the measures listed above, neurocognitive assessments will occur on a subgroup of 400 individuals who meet the eligibility criteria for neurocognitive assessment. This testing will provide pre- and post-deployment assessment of the effects of stress and mild traumatic brain injury on neurocognitive function.

61. Consenting participants will be fitted with a QuickCap and EDA electrodes and receive pre-recorded task instructions. The testing environment is standardised and the measurement of performance is computerised, which limits confounding due to the impact of the environment and human interaction on participant performance. An extensive database of normative data exists for this test against which results can be matched.

62. The battery of tests assess the following domains of cognitive function:

- Resting Electric Brain Function assessment allows for the measurement of cortical arousal in the resting state, which reflects the priming of the individual to deal with environmental challenge.
- The verbal working memory task taps into a domain of function that is known to be abnormal in mild traumatic brain injury and psychiatric disorders and allows the measurement of reaction times.
- Startle response assessment involves a measure of arousal modulation and orientation to the environment that is known to change in PTSD. It is also a symptomatic marker, the objective measurement of which may have the capacity to be used as a screen of psychological symptoms independent of self-report.
- The emotion processing task measures the processing of unconscious facial expression providing information about the fear networks in the brain. Important significant differences have been found in the processing of facial emotion in individuals with post-traumatic stress disorder.
- The Go/No Go Task is a measure of the capacity of the individual to suppress a natural tendency to respond to visual stimuli. This particularly captures frontal inhibition of response by using both speed and accuracy of responses as well as the ability to inhibit inappropriate automotive responses.

Health Records

63. Data from a number of existing health record databases will be collected including psychological screening records, and future ADF electronic health records.

Psychology screening records

64. The Australian Defence Force conducts routine psychological screening for all personnel returning from overseas deployment. These screens are known as the Return to Australia Psychological Screen (RtAPS) and the Post Operational Psychological Screen (POPS).

65. RtAPS is usually conducted in theatre immediately prior to returning to Australia, while POPS is completed between three and six months post-deployment.

66. RtAPS and POPS are completed on paper and entered into a statistical package (SPSS) by the Psychology Research and Technology Group (PRTG). This SPSS file can then be accessed by the MEAO Health Study research team.

67. De-identified data will be requested for every individual deployed to the MEAO from October 2001 and returning from the MEAO by December 2011. Some individuals will have deployed more than once and will have multiple RtAPS and POPS files. Individual consent is required to link this information with data from other sources.

68. The following information will be requested for RtAPS and POPS:

RtAPS

- Major Stressors questionnaire

POPS

- Kessler 10 (K10)

- Traumatic Stress Experiences Scale (TSES-R)
- Kessler 10 (K10)
- Posttraumatic Stress Disorder Checklist (PCL)
- Posttraumatic Stress Disorder Checklist (PCL)
- Alcohol Use Disorders Identification Test (AUDIT)

ADF Electronic Health Records

69. The ADF is currently pursuing a standard electronic health record. It is unclear at this point what information this record will contain. When the electronic record becomes available CMVH will review the available data and access relevant information for all personnel deployed to the MEAO from October 2001 to December 2009.

70. As with psychological screening records, participants are required to consent to allowing the research team to link this information with other data sources.

Consent for data linkage

71. Privacy guidelines dictate that information provided by individuals can only be used for the purposes for which it was collected.

72. De-identified data can be obtained from each of the data sources nominated in this research plan; however, in order to link data, that is to match individual outcomes from one data source to another, written consent is required from the individual concerned.

73. Written consent will be sought from each individual in order to conduct data linkage for:

- ADF psychological screening records
- ADF-held medical records.

PART 2 - PROJECT MANAGEMENT

Data Management Plan

1. Data management for the MEAO Health Study is being handled by three data systems and data are transferred between systems on a needs basis. A Memorandum of Understanding between UA and UQ for data transfer is being developed for the sharing of MEAO Health Study data.

2. UA has established the Defence Health Research System at the Data Management and Analysis Centre (DMAC) University of Adelaide. This facility is a member of the Defence Industry Security Program (DISP) and is accredited as a restricted facility by the Department of Defence Information Communications Technology Development Division. Certificates of accreditation are included in Annex 2.

3. CMVH UQ has established a Research Data Management System (RDMS). CMVH UQ has DISP accreditation for the Defence Restricted Network (DRN) and RDMS server facility and Department of Defence Information Communications Technology Development Division accreditation at restricted level for its DRN system. Certificates of accreditation are included in Annex 2.

4. Health data for the MEAO Health Study will be obtained from four sources:

- Self-reported questionnaire data (Studies 1 and 2)

  The health and deployment questionnaire data may be completed online, in hard copy or, if required by the respondent, telephone interview. Online questionnaire data for Study 1 will be collected and managed by the Defence Health Research System. Online questionnaire data for Study 2 will be collected by a contractor to the Defence Directorate of Strategic Personnel Policy and Research (DSPPR) and then transferred to the Defence Health Research System. At the same time, participant tracking data will also be transferred to the UQ Research Data Management System. Data provided on hard copy questionnaires will be scanned and transferred electronically to the Defence Health Research System.

- Clinical and biological data (Study 1)

  Capture of this data will be performed by CMVH staff and Healthscope Clinical personnel. Data will be collected on hard copy case report forms, downloaded from testing equipment and direct electronic downloads from Healthscope laboratories for download into the Defence Health Research System at DMAC.

- Defence-owned psychological data (Study 1 and 2)

  Data from ADF psychological screening records will be requested when consent is obtained and transmitted electronically via the DRN or secure network to the Defence Health Research System.

- National routinely collected data (Study 3)

  Data for the Cancer and Mortality studies (Study 3) will be sourced from National Death Index and State Cancer Registry data provided by the Australian Institute of Health and Welfare (AIHW). These data will be provided electronically, either on disk or by the establishment of a secure web portal and transferred into the Defence Health Research System.

5. Databases will operate at CMVH UQ and the Data Management and Analysis Centre (DMAC) at the University of Adelaide, and DSPPR contractor. Routine data handling regarding participation will occur at each site.

6. Data from Study 1 will be held at the Defence Health Research System which in accordance with the directions of SAC and PMB will be the primary database.

7. Study 2 data will be collected by DSPPR and will be transmitted to the Defence Health Research System in a format compatible with the Defence Health Research System. Downloads of the Study 2 data will be made available to CMVH UQ by DMAC for analysis. The Defence Health Research System has been accredited to a restricted status. At a minimum, all activities associated with and any data transferred to and from the Defence Health Research System will be maintained in accordance with the System Security Design Document approved by Department of Defence Information Communications Technology Development Division.

8. Any other data maintained by the Research Data Management System (based at UQ) will be maintained in accordance with the following specifications:

- Nominal rolls - maintained on DRN or DSN;
- The key linking allocated Study ID numbers to individuals' identifying information - maintained on DRN;
- Participant contact information and service data sourced from PMKeyS - maintained on DRN or DSN;
- Participant management data to track the participation status of eligible individuals, including all contacts or attempted contacts made by CMVH or by other agencies assisting in data collection.

9. Datasets will be exported for statistical analysis in an appropriate format. All related datasets created for the study will be linked by Study ID numbers.

10. A protocol has been developed and implemented by CMVH for management of requests for data for DHSP sub-studies or follow-up studies. All such requests will need approval of the Investigator Committee in addition to ethical approval from the relevant ethics committees.

11. A protocol for providing access to de-identified data obtained in the DHSP studies has been established. Eligibility to apply for data access is restricted to CMVH Research Staff, investigators and associate investigators. Approval to access data must be sought from the Investigator Committee. All data requests and data sets provided are documented.

12. A Data Manager at each node will have responsibility for:

- Checking and maintaining data quality
- Developing and maintaining the consistency of data dictionaries
- Importing data from relevant sources
- Exporting datasets for analysis
- Ensuring compatibility and comparability of data collected at different sites
- Transfer of data between sites.

13. The Defence Health Research System operates at a minimum in accordance with the security requirements as described System Security Design Document approved by Department of Defence Information Communications Technology Development Division.

14. In addition to the above, CMVH UQ has approved Standard Operating Procedures for data management and data security.

Communication Plan

15. The MEAO Health Study communication plan is congruent with the CMVH Communications Strategy.

16. The CMVH Research Manager, WGCDR Merilyn White, chairs the Communications Working Group and coordinates Defence Liaison for the studies.

17. A detailed communication implementation plan outlines the form and timing of communication to engage all parties and stakeholders associated with the project.

18. The Research Manager provides regular reporting against key Communications Performance Indicators.

19. The MEAO Health Study Communications Plan is stored on the CMVH Project in a Box (PIAB) project management system.

Organisational Structure

20. The Chief Investigators of the MEAO Health Study are Professor Alexander McFarlane (First Chief Investigator), Associate Professor Susan Treloar, Professor Annette Dobson, Professor Malcolm Sim, Dr Keith Horsley, and COL Stephanie Hodson.

21. Described below are the roles and responsibilities of the key entities and positions within CMVH.

Director CMVH

22. Professor Peter Warfe is the senior supplier to Defence, has overall responsibility for the contract and he or the acting Director represents CMVH on the DHSP Program Management Board. Professor Warfe is the primary point of contact with the Commander, Joint Health Command in matters other than the MEAO study.

23. Professor Alexander McFarlane the first Chief Investigator, will be the primary point of contact with Defence for major scientific, contractual, management and budget issues pertaining to meeting the deliverables of the MEAO contract.

Investigator Committee

The Investigator Committee comprises:

- **Professor Alexander McFarlane** (Psychiatrist), **CMVH**. first Chief Investigator of the MEAO Health Study and Head University of Adelaide Node CMVH. Responsible for overall scientific leadership of the MEAO Health Study, and leading the University of Adelaide components of the MEAO Prospective Study. First point of contact for Defence on scientific issues for the MEAO Health Study.
- **Professor Annette Dobson** (Biostatistician and Epidemiologist), **CMVH**. Chair of Research, CMVH & School of Population Health, University of Queensland. Responsible for providing overall scientific leadership to the DHSP and statistical and epidemiological advice.
- **Associate Professor Susan Treloar** (Epidemiologist and Principal Research Fellow), **CMVH**. Head University of Queensland Node and First Chief Investigator of the East Timor and Bougainville Defence Deployed Health Studies. Responsible for leading the University of Queensland components of the MEAO Health Study (MEAO Census Study and Mortality and Cancer Incidence Studies).
- **Professor Malcolm Sim** (Occupational Physician and Epidemiologist), **Monash University**. Professor Sim's key contributions are as lead investigator on the Australian Gulf War Veterans' Health Study and in hazard assessment and occupational risks.

- **Dr Keith Horsley** (Medical Consultant) adjunct Associate Professor University of Queensland and Australian National University, formerly Department of Veterans' Affairs and Australian Institute of Health and Welfare. Dr Horsley's contribution is extensive experience in veterans' health research.
- **COL (Dr) Stephanie Hodson**, Directorate of Mental Health, **Department of Defence**. LTCOL Hodson has extensive mental health screening experience in a Defence context.

Investigator Committee Terms of Reference

Terms of reference are as follows.

1. Title

The name of the working group will be the MilHOP Investigators Committee**.**

2. Purpose

To ensure the scientific design, rigour, quality, and integrity of the MEAO Health Study and to facilitate the distribution of research findings.

3. Members

Members to include but not limited to:

- Professor McFarlane (First Chief Investigator)
- Professor Annette Dobson (Chief Investigator)
- Associate Professor Susan Treloar (Chief Investigator)
- Professor Malcolm Sim (Chief Investigator)
- Dr Keith Horsley (Chief Investigator)
- COL Stephanie Hodson (Chief Investigator)

As observers:

- Program Manager, Program Management Office (Ms Maxine Baban)
- Project Manager for UQ
- Study Manager for UA
- Study Manager Mental Health Prevalence Study

4. Chairperson

The Chief Investigator, Professor McFarlane will act as chair.

The responsibilities of the Chair include:

- scheduling meetings and notifying members,
- inviting specialists to attend meetings when required by the Investigators Committee; and
- reviewing and approving key points and recommendations from each meeting before distribution to members.

5. Frequency of Meetings

Meetings are held fortnightly or as required.

6. Functions

The function of the Investigator Committee is to ensure:

a) the scientific design, rigour, quality, and integrity of the individual components of the MEAO Health Study, including compliance with the NHMRC Guidelines for Ethical Conduct for Human Research, Australian Regulatory Authorities Regulation and Guidelines (eg privacy) and those of other appropriate approving bodies,

b) the primary MEAO Health Study is conducted in accordance with the Detailed Research Plan and the Statement of Works,

c) engagement with Defence and DVA to address emerging research questions that are relevant to the Defence Deployed MEAO Health Study and/or its various component studies,

d) the results from the MEAO Health Study are published in high quality scholarly journal articles, reports, book chapters, monographs, and texts,

e) that the research is presented at relevant conferences and other professional community forums,

f) regular correspondence and reports on scientific aspects of the MEAO Health study are provided to the PMB; and

g) the performance of the study is monitored against key deliverables (including financial aspects and timelines). Where significant changes to budget may be required or a potential impact on the performance of the study is noted, they are to discuss this with the Director CMVH. If the MEAO Investigator Committee and the Director CMVH cannot agree on the required actions to be taken, the Director CMVH will seek the advice of the Executive Deans UQ and UA if necessary to progress a satisfactory outcome.

7. Amendments

24. The Investigator group are listed in the acknowledgements in all research outputs but are only authors on publications where they meet the Vancouver Protocol criteria. The terms of reference are able to be reviewed as required so that the Investigators Committee remains responsive to the MEAO Health Study implementation requirements.

Other key CMVH positions in the organisational structure

25. The following positions within CMVH have specific roles in the MEAO Health Study:

- University of Adelaide MEAO Study Manager and Research Fellow (Dr Carol Davy)
- University of Queensland Project Officer (Finance and Contracts) (Anil Naidu)
- CMVH Business Manager (Geoff Wickham)
- CMVH Chief of Operations (GPCAPT Geoff Robinson)
- CMVH Research Manager (WCDR Merilyn White)
- CMVH e-health Officer (LCDR Steve Pullman)
- CMVH Professional Development Officer (CAPT Mat Carroll)
- CMVH Communications Officer (Alan Pinsker)

Other key entities in the organisational structure

26. The following entities and individuals within CMVH have a specific role in the MEAO Health Study:

Associate Investigators

27. Current Associate Investigators and their particular contribution to the study are:

- Dr Christopher Barton, CMVH, University of Adelaide (Research Fellow)
- Professor Philip Ryan, University of Adelaide (Data management and statistical consultant)
- Professor Catherine D'Este, University of Newcastle (Biostatistician, First Chief Investigator Solomon Islands Health Study, Investigator SHOAMP study)
- Professor John Spencer, University of Adelaide (Oral Health Epidemiology)
- Professor Justin Beilby, University of Adelaide (Health Services Research)
- Dr Carol Davy, CMVH, University of Adelaide (Research Fellow)

University of Queensland MEAO Health Study Research Team

28. Key personnel in the University of Queensland DHSP Research team are:

- Mr Michael Waller, statistician
- Dr Katherine Kirk – Senior Research Fellow
- Mrs Colleen Loos, Senior Research Assistant
- Mr Gore Chen -- Data Manager

- Ms Kara Pasmore, Research Assistant
- Ms Jeeva Kanesarajah, Research Assistant (Statistics)
- Mrs Fiona Grieve, Research Assistant (p/t)
- Ms Sarah McMullen, Project management assistant (p/t)
- Mrs Nadine Mammone, Administrative Assistant

University of Adelaide MEAO Health Study Research Team

29. Key personnel in the University of Adelaide DHSP Research team are:

- Ms Miranda van Hooff, Research Fellow
- Mr Roger Glenny, Adelaide Liaison Officer
- Flight Sergeant Yvette Davies, SOC Administration Officer
- Mr Chris Davies, Statistician
- Ms Michelle Lorimer, Statistician
- Ms Jenelle Baur, Data Manager
- Mr Daniel Barnes, Research Officer
- Ms Maria Abrahams, Research Officer
- Ms Freya Goodhew, Research Officer
- Mr Derek Browne, Research Officer
- Ms Laura Jones, Research Officer
- Matthew Robinson, Research Officer
- Elizabeth Saccone, Research Officer
- Ashleigh Kenny, Senior Administration Officer

30. Curricula Vitae for staff are available on request.

Other Project Support

Data management and Data Management Working Group

31. Data management services will be provided by the Data Management and Analysis Centre (DMAC) at the University of Adelaide and the University of Queensland CMVH Data Management System. The Defence Health Research System and the Defence Directorate of Strategic Personnel Policy Research will facilitate data collection.

32. A Data Management Working Group has been established and working to implement data management protocols in accordance with Program Management Board and Scientific Advisory Committee requirements.

33. A separate Data Analysis Working Group has been established for the MEAO Health Study.

34. Agendas and Minutes of the Data Management Working Group are held on the CMVH Project in a Box (PIAB) project management system.

MEAO Operations and Communications Working Groups

35. A working group to include key contacts in the Department of Defence and DVA has been established to implement and coordinate the logistics of operationalising the studies. Core membership will include the following:

- Mrs Maxine Baban (Program Management Office) (Chair, Operations Working Group);
- WGCDR Merilyn White, CMVH Research Manager (Chair, Communications Working Group);
- MAJOR Peter Collins (Joint Operational Command);
- Single Service representatives; and

- CMVH MEAO Research Team Study 1 and Study 2 representatives.

Other members will include but not be limited to:

- Ms Belinda Mitchell (Directorate of Strategic Personnel Policy Research)
- Ms Helen Benassi or other representative (Directorate of Mental Health)

36. Agendas and Minutes of the OpsComms Working Group are held on the CMVH Project in a Box (PIAB) project management system.

Stakeholders Group

37. A Stakeholders Group will be formed to ensure regular input and communication for relevant parties. Membership of this group will include: Study Investigators, Defence Personnel, Veterans / Ex-Service Organisations and DVA.

Australian Institute of Health and Welfare

38. The Australian Institute of Health and Welfare (AIHW) will conduct the linkage to the National Cancer Statistics Clearing House and the National Death Index for the Cancer Incidence and Mortality Study, and provide linked data directly to the DHSP.

Risk Plan

Identification of risks

39. Risk logs for each Study (1, 2 and 3) and for the MEAO Health Study overall have been developed and will be updated on a monthly basis by the UQ MEAO Project Manager and UA Study Manager. Current risks logs are stored on the CMVH Project in a Box (PIAB) project management system. The Investigator Committee and the PMO will be alerted to changes in risk after each review and update.

Classification of risk

40. The risk strategy for Phase 2b of the MEAO Health Study uses a conventional approach. Each risk is assessed against the Likelihood and Consequence Matrix below. Some of these risks were identified during planning and conduct of the Near North Area of Influence projects. For each risk appropriate responses will be determined in relation to avoidance, mitigation, acceptance or transfer.

Likelihood and Consequence Matrix ***(***L Low, M Moderate, H High and VH Very High)

Likelihood	Consequence				
	1 Insignificant	2 Minor	3 Moderate	4 Major	5 Catastrophic
A Almost Certain	M	H	H	VH	VH
B Likely	M	M	H	H	VH
C Possible	L	M	H	H	H
D Unlikely	L	L	M	M	H
E Rare	L	L	M	M	H

Risk Level is then determined according to the following table.

Unacceptable Risks	VH	Very High Risk	Management and resources required
	H	High Risk	Significant management attention required
Acceptable Risks	M	Moderate Risk	Some management attention required
	L	Low Risk	Manage by routine procedures

41. CMVH are committed to a comprehensive and systematic approach directed towards the effective risk management of opportunities and adverse impacts. Responsibility for risk management of each identified risk will be assigned to a specific risk owner. The University of Queensland carries overall responsibility for coordination of risk management.

42. All risk management decisions and practices will be in accordance with the values, ethics, leadership and behaviours of the University of Queensland and where appropriate the University of Adelaide. The study will be conducted in accordance with The National Statement on Ethical Human Research (NHMRC 2007). The investigators will endeavour to ensure that identified risks are managed through the application of control measures that provide the best outcomes for all stakeholders, ensuring that material risks are monitored through formal documentation and review with mitigation controls being implemented.

Quality Plan

43. This Quality Plan is part of the CMVH Quality Management System and should be considered relative to that framework. CMVH applies a systematic process of checking to ensure products and/or services are being developed to meet specified requirements. The MEAO Health Study will be conducted in compliance with the following corporate and nationally recognised research quality standards:

Corporate Quality Standards

- Centre for Military and Veterans' Health, Quality Manual
- Centre for Military and Veterans' Health, Research Standard Operating Procedures
- Centre for Military and Veterans' Health, Head Agreement
- University of Adelaide Guidelines and Rules for Responsible Practice in Research http://www.adelaide.edu.au/rb/policies/resprac.html
- University of Queensland Handbook of Policies and Procedures, (http://www.uq.edu.au/hupp/ - last accessed, 24 June 2010)
- Australian Defence Human Research Ethics Committee (ADHREC) approval
- Department of Veterans' Affairs Human Research Ethics Committee approval

- Australian Institute of Health and Welfare (AIHW) Ethics Committee approval
- All eight State and Territory Cancer Registry Ethics Committees
- The University of Adelaide Human Research Ethics Committee
- University of Queensland Medical Research Ethics Committee (UQ MREC) approval.

National Research Quality Standards

- National Statement on Ethical Conduct in Research Involving Humans, National Health and Medical Research Council and the Australian Vice-Chancellors' Committee, 2007 (http://www.nhmrc.gov.au/publications/ethics/2007_humans/contents.htm - last accessed 24th June 2010)
- National Privacy Principles, The Privacy Amendment (Private Sector) Act 2000, AGPS, February 2008 (http://www.privacy.gov.au/publications/npps01.pdf - last accessed 6th May 2009).

Customer's Quality Expectations

44. The Study Protocol has been designed to meet contemporary scientific and ethical standards in epidemiological research and governance standards as set by the Program Management Board. The aim is:

a. to facilitate a study design capable of obtaining data useful in answering questions of interest to Defence

b. assist in the validation and development of policy to address the health needs of personnel.

Customer Acceptance Criteria

Performance Reporting

45. Contract performance is to be assessed against the contract deliverables. Exception reports are to be submitted to the PMO for resolution.

Deliverables

46. Where appropriate, the supplier shall provide two (2) hardcopies and one (1) softcopy (in Microsoft products and in PDF format) of deliverable items. Notification of other deliverables will be provided within each interim report.

Quality Management Approaches

47. Quality management of the MEAO Health Study incorporates project management (planning and coordination of the operational aspects of the project) and management of the scientific components of the project (the research aspects of the project). These two aspects are considered below.

Project Management

48. Research projects conducted by CMVH for the Department of Defence comply with the "Projects IN Controlled Environments Version 2" (PRINCE2) project management methodology. Performance, risk and quality are specifically addressed through the use of the PRINCE2 system.

49. The management of the MEAO study will be undertaken in accordance with the PRINCE2 Project Management Methodology which aims to ensure the optimum risk reduction in achieving project objectives, within the prescribed quality, time and cost criteria.

50. Day-to-day management of the project will be the responsibility of the MEAO Health Study Manager at the University of Adelaide and the Project Manager at the University of Queensland.

Document Management - Quality Specifications for CMVH Research Manuscripts,

Reports and other Written Documents

51. Activity Statements being submitted to Defence are to be prepared in consultation with PMO to ensure that relevant information is presented in the format required by Defence. An Activity Statement Template will be used as the basis of these reports.

52. Final versions of documents must be scientifically accurate, organised in a logical fashion, comprehensible to the target reader, formatted consistently throughout and of a high standard of presentation.

53. Manuscripts prepared for submission to a journal must comply with the DHSP Policy & Procedures for Data Access, Analysis, Presentation & Publication and the respective journal 'Guidelines for Authors'.

54. Quality Assurance of written documents:

- Review and approval by supervisor
- Review and approval by the first Chief Investigator
- Review and clearance by Department of Defence.

55. Documents will be stored on the CMVH Project in a Box (PIAB) project management system.

Scientific Quality

56. Quality checks will be undertaken for all products produced by the MEAO Health Study. These checks will include reviews by the Investigator Committee and where appropriate review by individuals with specific expertise, including Defence and DVA personnel. Further quality checks will be provided by peer-reviewed assessment when results are submitted for publishing and presented at scientific meetings.

57. For the MEAO Health Study the following specific data quality checks will be implemented:

- For data collected by the self-report questionnaire, the investigators have checked the reliability and validity of the instruments, and where possible have only used instruments validated in military samples
- The quality and accuracy of the database will be a consequence of Data Management Systems operations and activities. The use of trained and experienced staff, the development of SOPs for activities and data checking as outlined above will ensure data of the highest quality possible given the study design.

Quality control and audit processes

58. Quality controls are developed for each of the primary MEAO Health Study Activities and are documented within the study protocols.

59. Audits and reviews against these Quality Controls will be undertaken by the Project Manager at the University of Queensland and the Study Manager at the University of Adelaide, to ensure variations to acceptable criteria are reported and resolved. Quality assurance activity and audit report outcomes will be reported to the Investigator Committee and PMO.

Problem Reporting and corrective action

60. The PRINCE2 methodology and template tools associated with Project In A Box (PIAB) project management system will be utilised to document quality issues and actions. Issues logs, quality logs, and project exception reporting will be reviewed quarterly reports to Defence.

Change Control Procedures

61. Because of the dynamic nature of the research environment, the inherent uncertainty in conducting research and the importance of being able to react to events and restructure the research protocol accordingly it is necessary to develop principles for project changes.

62. For changes resulting in deviations from the agreed products, project scope, timeframes, quality or budget originally approved by the Program Board, a Contract Change Proposal must be raised by CMVH. Changes to the protocol once approved by the relevant Human Research Ethics Committees will be submitted as amendments to those committees as per the instructions in the Australian Defence Force Protocol ADFP 1.2.5.3. (Health & Human Performance Research in Defence: Manual for Researchers).

Configuration Management Plan

63. Configuration management will be put in place to ensure that the version of products, their status, date of submission and location is clearly recorded.

Governance Plan

64. This Governance Plan provides details of the study deliverables, timelines, budget, and change management strategies for the study.

Timelines - MEAO Health Study Phase 2

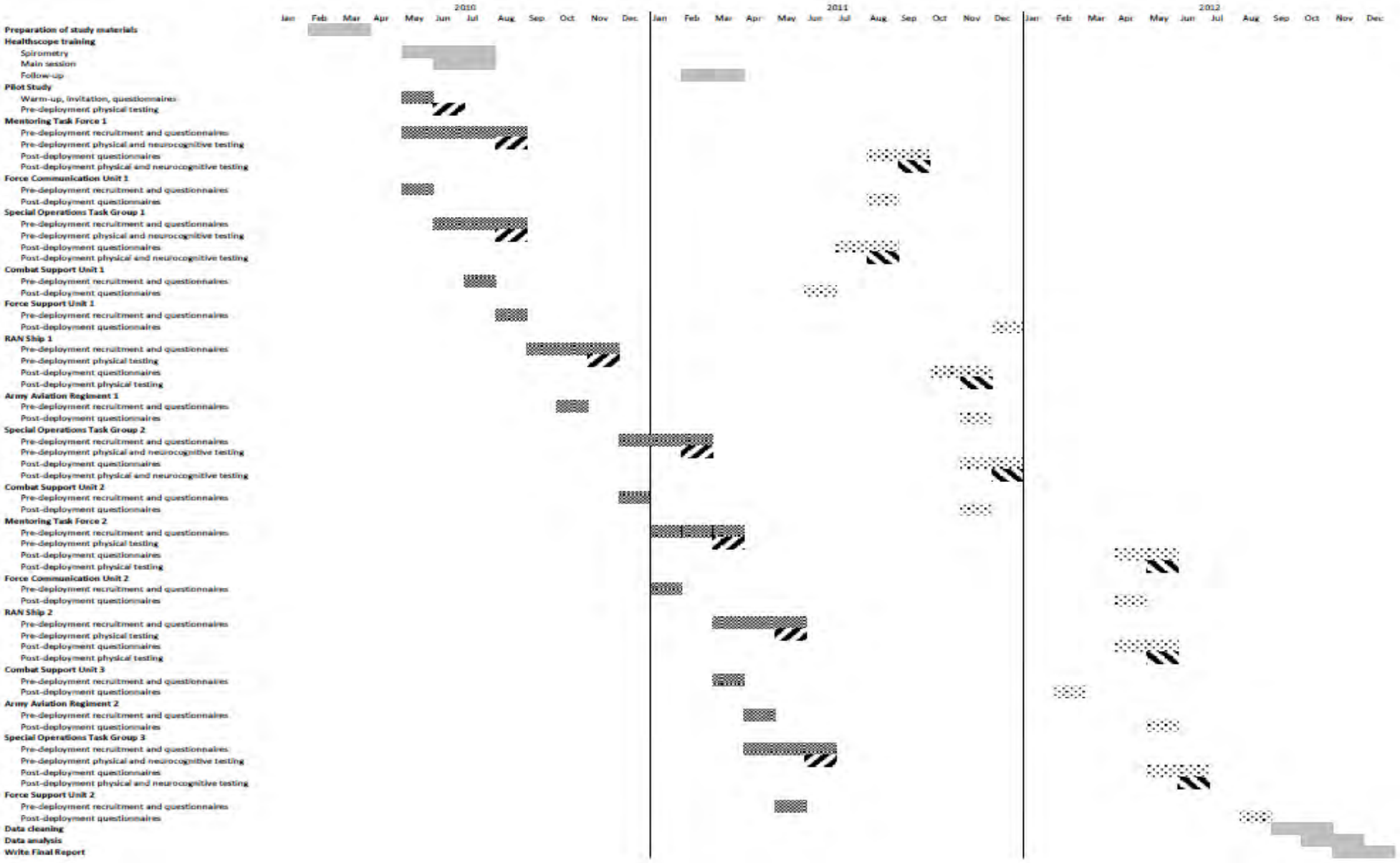
65. The proposed timelines for Phase 2 of the MEAO Health Study are January 2008 to June 2012. These timelines have been set to take into account the timing of:

- establishment of a robust secure data management system for participant contact and data collection tracking
- future deployments (for Study 1)
- time frames for ethics approvals
- time required to gain access to Defence-held data (for development of nominal rolls and health and psychological data)
- time required for adequate recruitment of study participants
- availability of data for appropriate reference years for linkage (mortality and cancer registry data).

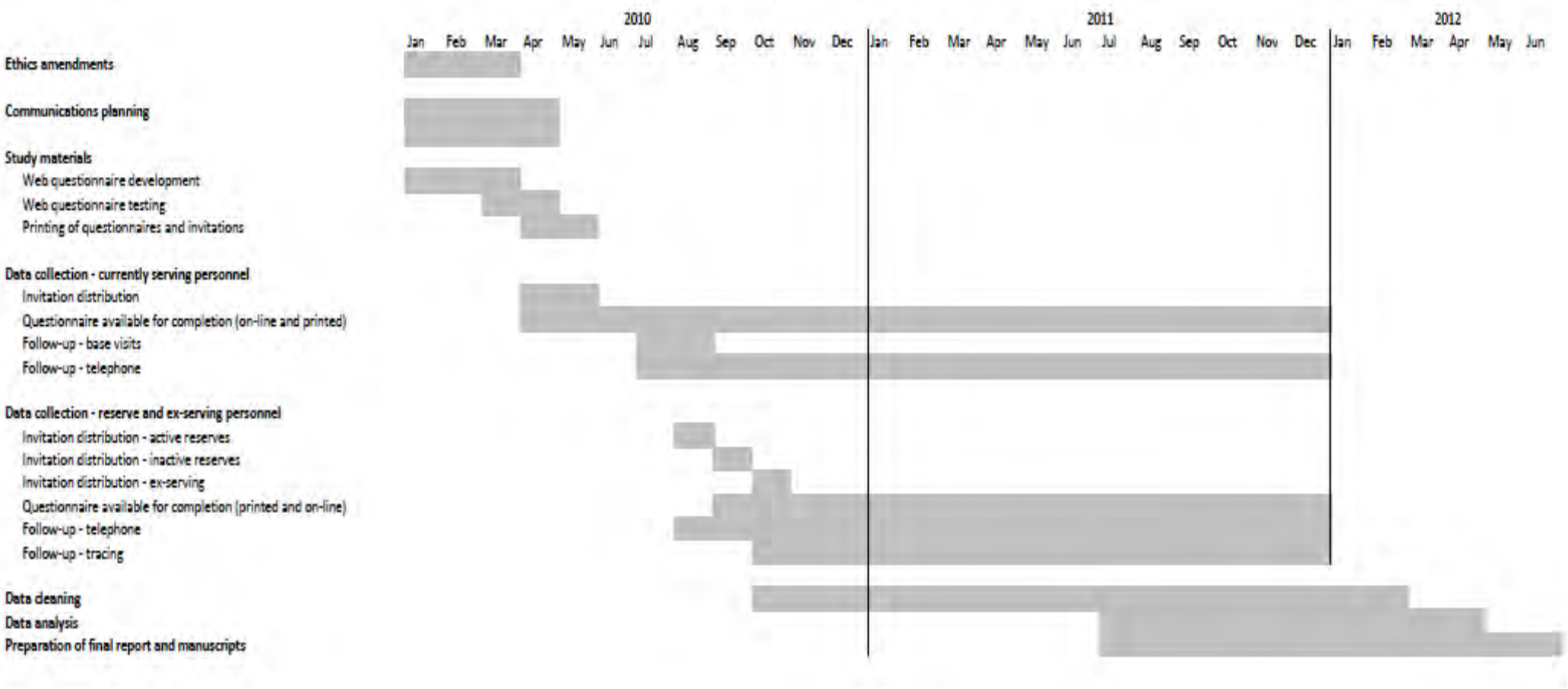
66. Some of these parameters are outside the control of CMVH such as ethical approval, provision of data from Defence, DVA contact tracing and data linkage by AIHW and will require ongoing monitoring. This schedule is also contingent on the timing of funding. These timelines have also been coordinated to achieve efficiencies in the recruitment of staff.

67. Gantt charts showing summaries of the timelines for Studies 1 and 2 are included below.

Gantt chart for Study 1 (Prospective)



Gantt chart for Study 2 (Census)



Deliverables / Milestones

68. The agreed deliverables/milestones for the MEAO Health Study Phase 2b are documented in each Financial Year's Statement of Works.

69. Each Statement of Works is stored on the CMVH Project in a Box (PIAB) project management system.

Key Performance Indicators (KPIs)

70. Key Performance Indicators are reported against Quarterly to Defence, for each Financial Year's Statement of Works.

71. KPIs as well as Milestones and Deliverables have to be met before invoicing can take place by the Universities.

72. Milestones and Deliverables as well as KPIs will vary between Financial Years.

73. Agreed KPIs are stored on the CMVH Project in a Box (PIAB) project management system for the Program Management Office (PMO) and both the University of Queensland and the University of Adelaide nodes to access.

74. CMVH reports against KPIs are stored on PIAB and will be provided to the PMO.

Budget

75. The budget for Phase 2 of the MEAO Health Study has been adjusted following revisions to the research protocols and changes in payment protocols.

76. Defence will pay salaries and travel costs on acquittal, but other operational costs will be paid quarterly on completion of deliverables, milestones and Key Performance Indicators as specified in the Statements of Works for each financial year.

77. The budgets for each of the studies are stored on the CMVH Project in a Box (PIAB) project management system. The budgets are appended to this plan (Annex 3).

Former contributors to MEAO Health Study

University of Adelaide

The late Professor Konrad Jamrozik (Chief Investigator)
SQNLDR Michel Devine (ADF Liaison Officer)
SQNLDR Jenny Dowling
Dr Nancy Briggs (Statistician)
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Dr Christine McClintock (Deployment Health Surveillance Program Manager)
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Appendix C

Questionnaire Protocol

CMVH
CENTRE FOR MILITARY & VETERANS' HEALTH

MIDDLE EAST AREA OF OPERATIONS (MEAO) PROSPECTIVE STUDY:

SELF-ADMINISTERED QUESTIONNAIRE PROTOCOL

Author: Maria Abraham and Carol Davy

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Australian Government
Department of Defence
Department of Veterans' Affairs

THE UNIVERSITY OF QUEENSLAND
AUSTRALIA

Charles Darwin
UNIVERSITY
Innovation in Education

THE UNIVERSITY OF ADELAIDE
AUSTRALIA

CONTENTS

Document Administration

Document Location

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Revision History

Date	Version	Description	Track Changes
09/03/2011	1.0 to 16.00	Internal Development of Plan	No
16/6/2011	17.00	Alter post deployment section to reflect agreed procedures	

Approvals

This document requires the following approvals:

Name	Position	Signature	Date	Version
Prof Annette Dobson	Principal Investigator			
Prof Michael Moore	Scientific Advisory Committee			
BRIG Stephen Rudzki	Program Management Board			

1. INTRODUCTION

Currently serving ADF personnel will be recruited into the MEAO Prospective Study no more than four months prior to their deployment and complete the study measures (Time 1). They will then be followed up no more than four months after returning from deployment (Time 2) and complete the study measures again. At each time point, participants will be asked to complete a Self Report Questionnaire, one of the three primary components of the study.

Pilot testing of the questionnaire has indicated that it will take participants between 30 and 60 minutes to complete at each assessment. Options for completing the Pre Deployment Questionnaire include:

a) A hard-copy briefing pack questionnaire on a scannable Tele-form (for eligible Special Forces (SF) and non SF participants).

Options for completing the Post Deployment Questionnaire include:

a) A hard-copy briefing questionnaire on a scannable Tele-form (for eligible Special Forces (SF) and non SF participants).
b) A web-based questionnaire (accessible via study ID number and password provided with the invitation package: for non Special Forces participants only)
c) A mailed hard-copy questionnaire on a scannable Tele-form (for eligible SF and non SF eligible participants).

Participants who complete a hardcopy briefing questionnaire will be able to return it directly to the research staff member providing the briefing or mail it back to CMVH in the supplied pre paid envelope. The data from questionnaires completed via the web will automatically populate the DMAC database, removing the need to enter data by hand. Participants who complete a hard copy version of the questionnaire will be able to return it to CMVH via the supplied reply paid envelope. Following the processing and checking of completed forms, returned hard copy questionnaires will be uploaded to the DMAC database as described in the Data Management Plan.

2. PRIMARY ROLES AND RESPONSIBILITIES OF STUDY TEAM MEMBERS

Three primary roles will be responsible for the management of self-report questionnaires:

1. The Project Officer will primarily be responsible for sending hardcopy self-report questionnaires completed by non Special Forces Personnel and receiving returned questionnaires from briefings or via postal mail to CMVH (UA). Duties will include:
    a. Printing invitation packs for non SF personnel
    b. Sending out invitation packs to non SF personnel if required
    c. Recording receipt of returned information packs on the DMAC Management Information System (DMAC MIS),
    d. Providing the completed self-report questionnaires to the CMVH Data Managers for scanning,
    e. Filing the returned hardcopy questionnaires once all information has been processed. and
    f. Providing the returned hardcopy consent forms to the SOC Administration Officer

2. The SOC Administration Officer with a „Secret" clearance will primarily be responsible for ensuring that the identifying information pertaining to SF personnel is not provided to any other member of the research team. For the questionnaire component of the study, this will involve:
    a. Printing invitation packs to SF personnel,
    b. Sending out invitation packs to SF personnel if required
    c. Receiving completed invitation packs from SF personnel,
    d. Recording receipt of returned information packs on the standalone SF Management Information System (SF MIS),
    e. Recording receipt of returned information packs by ID only on the DMAC MIS,
    f. Forwarding de-identified self-report questionnaires to the Data manager for scanning,
    g. Filing all SF identifiable documents such as consent forms etc within a secure location.
    h. Manning the SF 1800 freecall number
    i. Filing all non SF consent forms within a secure location.

3. CMVH Data Managers will primarily be responsible for the extraction of data from the hardcopy self report questionnaires. This will involve:
    a. Scanning returned hardcopy self-report questionnaires; and
    b. Electronically forwarding self-report questionnaire data to DMAC.

    Research Officers and administration staff will be available to support the above roles as required. The following information provides greater detail on the procedures associated with these roles.

4. Participant Liaison Officers will primarily be responsible for providing information to eligible non SF participants who have contacted CMVH UA through the 1800 number and/or CMVH email.

3. PRE-DEPLOYMENT SELF-ADMINISTERED QUESTIONNAIRE

The pre-deployment self-administered questionnaire (Appendix 2O) comprises:

1) A Brief Deployment History Questionnaire
2) A Personality and Resilience Questionnaire
3) A Health Questionnaire.

3.1 Contents of the Pre-deployment Invitation Package

Pre-deployment Invitation Packages will primarily be distributed to eligible personnel during face to face briefings conducted with either a deploying unit or alternatively during 39PSB briefings

Non Special Forces Personnel: The briefing invitation package will contain-

- A letter of support from the Chief of the Defence Force and the Repatriation Commissioner (Appendix 2A);
- A letter from the Principal Investigator (Appendix 2B);
- Duplicate copies of the study consent form enabling eligible participants to consent to some or all components of the study (Appendix 2E- for members not eligible to participate in physical and neurocognitive tests; Appendix 2F- for members eligible to participate in physical and neurocognitive tests);
- A comprehensive information brochure identifying procedures and requirements related to participation in the study (Appendix 2I- for members not eligible to participate in physical and neurocognitive tests; Appendix 2J- for members eligible to participate in physical and neurocognitive tests);
- A supplementary information sheet –only to be sent to members eligible to participate in physical and neurocognitive tests (Appendix 2K);
- A contact form to aid tracking for future longitudinal follow-up (Appendix 2M);
- A Pre-Deployment Study Questionnaire (Appendix 2O);
- A study investigators sheet (Appendix 2N); and
- A reply-paid envelope (return address CMVH (UA node).

SF Personnel: The invitation package will include-

- A letter of support from the Chief of the Defence Force and the Repatriation Commissioner (Appendix 2A);
- A letter from the Principal Investigator (Appendix 2B);
- An SF specific instruction sheet including a section for participants to register their refusal to participate (Appendix 2D);
- Duplicate copies of the study consent form enabling consent to some or all components of the study including participation in the physical and neurocognitive tests (Appendix 2G);

- A comprehensive information brochure identifying procedures and requirements related to participation in the study (including information about the physical and neurocognitive tests-Appendix 2J);
- A supplementary information sheet containing specific information about the physical and neurocognitive tests (Appendix 2L);
- A contact form to aid tracking for future longitudinal follow-up (Appendix 2M);
- The Pre-Deployment Study Questionnaires (Appendix 2O);
- A study investigators sheet (Appendix 2N); and
- A reply-paid envelope (SOC Administration Officer return address).

3.2 Preparation and Distribution Pre-deployment Invitation Package

3.2.1 Hardcopy Pre-deployment Briefing Package

Pre-deployment questionnaires will primarily be distributed to eligible participants via a face to face briefing conducted at a place and time negotiated with the deploying unit.

Non SF Personnel: The Study Manager and the Defence Liaison Officer will meet with identified non SF deploying units and 39PSB as soon as practicable to schedule an appropriate time for the questionnaire briefing. Please note: for all MTF units and ships, times will also be identified for physical testing and Neurocognitive assessments. For Non SF eligible participants including 39PSB, the Study Manager will request the Project Officer to make up the appropriate number of invitation packs (refer section 3.1) and arrange for them to be transported to the place of briefing. Where possible at least two weeks notice will be provided.

The Project Officer will facilitate the hard copy versions of the study invitation packs following the process outlined below:

- Obtain relevant pre-printed information brochure (physical testing vs. non-physical testing participant)
- Print the letter of support from the Chief of the Defence Force and the Repatriation Commissioner
- Print the contact letter from the Principal Investigator
- Print the study investigators sheet
- Print the relevant instruction sheet
- If applicable, print the supplementary information sheet for members eligible to participate in physical and neurocognitive tests
- Print duplicate copies of the relevant study consent form
- Print the future contact form
- Print the tele-form pre-deployment questionnaire
- Obtain a large reply-paid envelope and write participant‟s ID on the back
- Collate all of the components of the invitation package in the order listed above and place into a University of Adelaide envelope

SF Personnel: The Study Manager and the Defence Liaison Officer will meet with identified SF deploying units as soon as practicable to schedule an appropriate time for the questionnaire briefing as well as times to conduct physical testing and Neurocognitive assessments. For SF eligible participants, the Study Manager will request the SOC Administration Officer to make up the required number of invitations packs (refer section 3.1) and arrange for them to be transported to the place of briefing. Where possible, at least two weeks notice will be provided.

The SOC Administration Officer will prepare the hard copy versions of the study invitation packs following the process outlined below:

- Obtain relevant pre-printed information brochure containing information about the physical and neurocognitive tests
- Print the letter of support from the Chief of the Defence Force and the Repatriation Commissioner
- Print the contact letter from the Principal Investigator
- Print the study investigators sheet
- Print the SF instruction sheet
- Print the physical and neurocognitive testing supplementary information sheet
- Print duplicate copies of the SF study consent form
- Print the future contact form
- Obtain pre-deployment questionnaire
- Obtain a large reply-paid envelope addressed to the SOC Administration Officer
- Collate all of the components of the invitation package in the order listed above and place into a blank envelope
- Secure the SOC Administration Officer‟s return address label to the back of the blank envelope
- Seal the blank envelope securely with sticky tape

3.2.2 Hardcopy Invitation Package

Non SF Personnel: DMAC will create an online invitation pack and upload it to the study website. They will then send a personalised email to each deploying member, which will contain information about the study, as well as a link to the online invitation pack (same contents as hard copy invitation package). Participants will be able to access the online invitation pack by clicking on the link and entering their username and password (which will appear on the email).

SF Personnel: SF personnel are not being provided access to a web-based invitation package and questionnaire.

3.3 Procedure for Registering Consent in the Study

Non SF Personnel: Respondents can nominate to take part in the study by signing and returning one of the hard copy consent forms to CMVH (UA node).

When a consent form is received by the CMVH (UA node), the participant will be considered enrolled in the study. The Project Officer will be responsible for entering consent information from non SF Personnel onto the DMAC MIS.

SF Personnel: SF personnel can nominate to take part in study by signing and returning the hard copy consent form to the SOC Administration Officer. When a consent form is returned, the participant will be considered enrolled in the study. The SOC Administration Officer will be responsible for entering consent information for SF Personnel onto the SF MIS and unidentified information onto the DMAC MIS.

(Section 3.7 details the process for registering returned consent forms)

3.4 Procedure for Registering Alternative Contact Details

Non SF Personnel: Accompanying the consent forms in the invitation package is a form that requests participants‟ current contact information and the contact information of two alternative contacts. The Project Officer will be responsible for entering information obtained from this form into the DMAC MIS and will then file the contact details form in the participant‟s file.

SF Personnel: Any new or additional contact information obtained from SF personnel will be entered into the standalone Special Forces Management Information System (SFMIS) by the SOC Administration Officer. The SOC Administration Officer will then file their contact forms in a secure area.

3.5 Procedure for Opting Out of the Study

Non SF Personnel: Participants can opt out of the study by:

- Calling the CMVH research team on the toll free number 1800 232 904 – this phone will be answered by the Participant Liaison Officers between 9am and 5pm, Mondays to Fridays (the Protocol for answering telephone calls in contained in Appendix 6A and the list of FAQs to be used by Participant Liaison Officers is contained in Appendix 6B)
- Sending an email to cmvh@adelaide.edu.au registering their refusal to participate
- Completing the refusal form contained in their hardcopy information pack and posting it to CMVH (UA node) using the supplied reply-paid envelope

If a participant rings/emails/posts through their “refusal to participate” to CMVH (UA Node), the Participant Liaison Officer will record their refusal on the DMAC MIS so as to ensure that no further follow-up contact is made. Participant Liaison Officers will then file a hardcopy of all records in the participant‟s file.

SF Personnel: Participants can opt out of the study by-

- Calling the SOC Administration Officer on (SOC phone number TBA) and registering their refusal
- Sending an email to the SOC Administration Officer at (SOC email address TBA) and registering their refusal to participate
- Completing the refusal form contained in their information pack and posting it to the SOC Administration Officer using the supplied reply-paid envelope.

If a participant rings/emails/posts through their "refusal to participate", the SOC Administration Officer will record their refusal on the SF MIS so as to ensure that no further follow up contact is made. The SOC Administration Officer will also record, by study ID number only, their refusal to participate on the DMAC MIS. The SOC Administration Officer will then file a hardcopy of all records in a secure area.

3.6 Procedure for Answering Participants' Telephone Queries

Non SF Personnel: If a participant rings the toll-free number with a general enquiry about the study, questions regarding the individual study components, technical queries, complaints etc., the Participant Liaison Officers will refer to the Protocol for telephone enquires in Appendix 6A or the list of FAQs contained in Appendix 6B in order to best address their concern.

SF Personnel: If a participant rings the SOC Administration Officer with a general enquiry about the study, questions regarding the individual study components, technical queries, complaints etc., the SOC Administration Officer will refer to the Protocol for telephone enquires in Appendix 6A or the list of FAQs contained in Appendix 6B in order to best address the participant"s concern.

3.7 Procedure for Processing Returned Study Consent Forms

Non SF Personnel: All hard-copy consent forms that arrive at CMVH (UA node) will be forwarded to the Project Officer who will log their receipt and process them as follows:

- Record date of receiving hard-copy consent form on DMAC MIS
- Record the type of consent the participant has provided on the DMAC MIS, to ensure that no unauthorised follow-up is made
- Identify the correct Study ID from the DMAC MIS
- Record the Study ID on the top of the consent form
- Provide the consent form to the SOC Administration Officer who will file it in a secure area.

SF Personnel: All SF consent forms will be posted directly to the SOC Administration Officer who will log their receipt and process them as follows:

- Record the date of receiving consent form on the standalone SF MIS and the DMAC MIS (using the study ID only)
- Record the type or types of consent the participant has provided on the standalone SF MIS and the DMAC MIS (using the study ID only) to ensure that no unauthorised follow-up is made

- Assign a new study ID to the participant
- Record the new study ID on the consent form
- File the consent form in the participant‟s file which is held within a secure area.

3.8 Procedure for Processing Returned Pre-deployment Questionnaires

Non SF Personnel: Pre Deployment hardcopy questionnaires returned to CMVH (UA) by non SF participants will be managed in the first instance by Project Officer who will:

- Date stamp the questionnaire with the date it was received
- Log receipt of the questionnaire on the DMAC MIS
- Check the questionnaires for completeness

If a non SF participant answers “Yes” to any of the suicide questions in the Health Questionnaire, the Project Officer will immediately notify the Study Manager (refer to Appendix 8).

The Project Officer will then pass on the hardcopy questionnaires to the Data Manager who will:

- Record the Study ID on the front cover of the questionnaire (as per consent form see section 3.7)
- Scan complete tele-form questionnaires (refer to Appendix 7 for Teleform scanning instructions) which will automatically populate a CSV file
- Transfer data to DMAC via a secure FileTransfer Protocol (FTP)
- File the hard-copy tele-formed questionnaires in the participants files

SF Personnel: All SF personnel will provide their completed hardcopy questionnaire directly to the SOC Administration Officer, who will:

- Write the newly assigned Study ID on the front cover of the questionnaire
- Date stamp the questionnaire with the date it was received
- Log receipt of the questionnaire on the standalone SF MIS
- Record receipt of questionnaire by study ID number only on the DMAC MIS (as per consent form see section 3.7)

If a SF participant answers “Yes” to any of the suicide questions in the Health Questionnaire, the SOC Administration Officer will immediately notify the Study Manager (refer Appendix 8).

The SOC Administration Officer will then pass on only the hardcopy questionnaires identified by study ID only to the Data Manager, who will:

- Scan complete tele-form questionnaires (Teleform scanning procedure is described in Appendix 7) which will automatically populate a CSV file
- Transfer data to DMAC via a secure FileTransfer Protocol (FTP)
- Ensure the safe storage of hard-copy teleform questionnaires in the participant‟s file identified by study ID only.

3.9 Procedure for Checking for Missing or Discrepant Data

When a participant ticks two or more boxes on the same question, the following rules will be adhered to:

1. If two responses contradict each other then leave the response blank. For example, if someone ticks both „yes" and „no" in response to a single question, then leave the answer blank.
2. Take the highest value to questions where someone has ticked two boxes and the responses to the question may be ordered from lowest to highest. For example, if someone is answering a question about qualifications or income and they have ticked two boxes then take the highest value.
3. For scales (PCL-C, K10, AUDIT), or symptoms/conditions checklists, take the highest scoring of the boxes that they have ticked. For example if someone ticked that they had not experienced dizziness in the last month and also ticked that they had experienced moderate dizziness in the last month, then we would record „moderate".

When a participant intentionally or unintentionally leaves an item or section blank, leave the item or section blank.

3.10 Follow-up of Non-Responders

Given that the primary means of collecting pre deployment questionnaires is via face to face briefings, there will be no need for pre deployment follow up.

4. POST-DEPLOYMENT SELF-ADMINISTERED QUESTIONNAIRE

The post-deployment self-administered questionnaire (Appendix 5B) comprises:

1) A Health Questionnaire
2) A Deployment Experiences Questionnaire

Only participants who completed a pre deployment questionnaire will be invited to complete a post deployment questionnaire.

As per the pre-deployment phase of the study, SF personnel will be sent a different information package to non Special Forces personnel.

Post-deployment questionnaires can be completed by participants in one of three ways:

1) Via a hardcopy questionnaire mailed to the participant"s postal address

2) Via a web-based survey

3) Via a face to face briefing

4.1 Contents of the Invitation Package

Non SF Personnel: The invitation package will include:

- A covering letter from the Chief Investigator (Appendix 5A);
- A comprehensive information brochure identifying procedures and requirements related to participation in the study (Appendix 2H - for members not eligible to participate in physical and neurocognitive tests; Appendix 2I- for members eligible to participate in physical and neurocognitive tests);
- A supplementary information sheet – only to be sent to members eligible to participate in physical and neurocognitive tests (Appendix 2K);
- A contact form to aid tracking for future longitudinal follow-up (Appendix 2M);
- A Post-Deployment Study Questionnaire (Appendix 5B);
- A study investigators sheet (Appendix 2N); and
- A reply-paid envelope (return address CMVH (UA node) for those completing a hardcopy questionnaire.

SF Personnel: The invitation package will include:

- A covering letter from the Chief Investigator (Appendix 5A);

- A comprehensive information brochure identifying procedures and requirements related to participation in the study (including information about the physical and neurocognitive tests-Appendix 2J for those that did participate in the physical and/or neurocognitive tests)
- A supplementary information sheet containing specific information about the physical and neurocognitive tests (Appendix 2L for those that did participate in pre deployment physical and/or neurocognitive testing);
- A contact form to aid tracking for future longitudinal follow-up (Appendix 2M);
- A Post-Deployment Study Questionnaire (Appendix 5B);
- A study investigators sheet (Appendix 2N); and
- A reply-paid envelope (SOC Administration Officer return address).

4.2 Identifying Post Deployment Eligible Participants

The SOC Administration Officer is primarily responsible for identifying when eligible participants return from deployment (see SOP Appendix 9). Definition of eligible participant are those personnel who at least partially completed a self report questionnaire at pre deployment and have subsequently returned from that deployment.

4.3 Preparation and Distribution of the Post-deployment Invitation Package

4.3.1 Welcome Home Email/Letter

Non SF Personnel: Approximately one week after being identified by the SOC Administration Officer as returning from deployment, the Participant Liaison Officer will send a generic „welcome home" letter to all those personnel who did not participate in a pre deployment physical test or neurocognitive assessment Prospective Study advising them of the upcoming post-deployment components (Appendix 4A). As participants who completed a neurocognitive assessment and/or physical test (MTF, Ship and SF units) will be targeted through face to face briefs at various time points, they will not receive a welcome home letter.

If at all practicable, face to face briefings will be provided to other formed units where there are sufficient numbers of pre deployment participants in the one location. Where face to face briefings are not possible, ADF members eligible to participate in the post deployment questionnaire component will be contacted via email (see below) and sent a hardcopy invitation pack in the post.

4.3.2 Hard-Copy Invitation Package

Questionnaires will be delivered to MTF, Ship and SF participants via face to face briefings between 2 and 4 months post deployment. All eligible personnel, will receive a hardcopy post deployment invitation pack in this way

Non SF Personnel: The Defence Liaison Officer will contact MTF units and the Ship as soon as is practical to schedule an appropriate time for the post deployment questionnaire briefing. Please note: times will also be identified for physical testing and where applicable Neurocognitive assessments. The Study Manager will then request that the Project Officer make up the appropriate number of invitation packs and arrange for them to be transported to briefing location. Wherever possible, at least two weeks notice will be provided.

SF Personnel: The Defence Liaison Officer will contact the identified SF deploying units as soon as is practical to schedule an appropriate time for the questionnaire briefing as well as times to conduct physical testing and Neurocognitive assessments. The Study Manager will then request that the SOC Administration Officer to make up the required number of invitations packs (refer section 3.1) and arrange for them to be transported to the briefing location. Where possible, at least two weeks notice will be provided.

4.3.3 Web-Based Invitation

Non SF Personnel: DMAC will create two post-deployment online invitation packs (one for ADF members who completed the pre deployment questionnaire and one for ADF members who didn‟t) and upload it to the study website.

Approximately three months post-deployment, DMAC will send a personalised email to each member who has returned from deployment and is unable to participate in a face to face briefing. The email will contain information about the study as well as a link to the online post-deployment invitation pack (same contents as hard copy invitation package). As per the pre-deployment phase of the study, participants will be able to access the online invitation pack by clicking on the link and entering their username and password (which will appear in the email) (refer Appendix 10)

SF Personnel: SF personnel will not be provided access to a web-based invitation package and questionnaire.

4.3.4 Hardcopy Invitation Pack

Approximately three months post-deployment, Participant Liaison Officer will send a personalised invitation to each member who has returned from deployment and is unable to participate in a face to face briefing. The hardcopy invitation pack will contain information about the study as well as a contact details form and post deployment questionnaire (refer Appendix 10).

4.4 Procedure for Registering Consent in the Study

ADF members who consented to the pre deployment phase will assume to have consented to the post deployment phase.

4.5 Procedure for Registering Alternative Contact Details

If a participant wishes to register alternative contact details, they can do so by following the process outlined in section 3.4 of this protocol. Contact information provided as part of the post deployment phase will take precedence over contact information provided as part of the pre deployment phase.

4.6 Procedure for Opting Out of the Study

If a participant wishes to opt out of the study, they can do so by following the process outlined in section 3.5 of this protocol.

4.7 Procedure for Processing Returned Post-deployment Questionnaires

The procedure for processing returned post-deployment questionnaires is the same as that for processing pre-deployment questionnaires – refer to section 3.8 of this protocol

4.8 Procedure for Checking for Missing or Discrepant Data

Refer to section 3.9 of this protocol for how to check for missing or discrepant data.

4.9 Follow-Up of Post-deployment Non-responders

- Participants who do not respond at all to the hardcopy of email post deployment invitation will be followed up in the following manner (see also Appendix 11). If not responded within two weeks of receiving hardcopy pack, participant will receive an email from DMAC.
- If not responded within three weeks of receiving hardcopy pack, participant will receive a telephone follow up from CMVH research staff.
- The participant will continue to be followed up by telephone for up to ten times until either the
    - participant signals their intention not to participate;
    - Requests no further follow up; or
    - Completes the questionnaire.

Participants who only partially complete an online post deployment invitation will be followed up in the following manner (see also Appendix 11).

- If no further action within previous two weeks and the questionnaire is not submitted, the participant will receive a telephone follow up.
- The participant will continue to be followed up by telephone for up to ten times until either the
    - participant signals their intention not to participate;
    - Requests no further follow up; or
    - Completes the questionnaire.

5. QUALITY MANAGEMENT PLAN

Quality Management Plan for the Self Administered Questionnaire

Ensure Safety of Study Participants

Action	Responsible Party	Timeline
Support line numbers are provided on the 3rd page of the hardcopy pre and post questionnaire	Study Manager	Prior to commencement of the study
Support line numbers are provided at the beginning of the web based pre and post questionnaire	DMAC	Prior to commencement of web based pre questionnaire
Reference to support line numbers are provided immediately following the Life Experiences section of the hardcopy pre and post questionnaire	Study Manager	Prior to commencement of the study
Reference to support line numbers are provided immediately following the Life Experience section of the pre and post web based questionnaire	DMAC	Prior to commencement of web based post questionnaire
Brief the ADF Support line about the study and potential for callers	Joint Health Command	Prior to commencement of study
Offer support in accordance with Protocol (see Appendix B) to members who answer "Yes" to suicide questions	Research staff trained in ASIST	As soon as identified on returned questionnaire

Ensure that security and confidentiality requirements are adhered to

Action	Responsible Party	Timeline
All non SF Hardcopy Information Packs are distributed only by the CMVH UA staff	Study Manager	At all times
Web based questionnaires are developed within and administered by a fully accredited data management facility which has been audited by Defence	DMAC	Prior to commencing web based interface
A reply paid envelope is provided to ensure that non SF hardcopy questionnaire responses are sent directly to CMVH UA	Study Manager	At all times
All CMVH UA staff associated with the study are cleared to restricted status	CMVH Security Officer	At all times
All returned hardcopy questionnaires, consent and contact forms are stored in a room cleared to restricted status	Study Manager	At all times
All SF hardcopy information packs are distributed by a SOC Administration Officer cleared to secret level	Study Manager	At all times
Ensure that SF participants are not be provided with the web based	SOC Administration Officer	At all times

option		

Ensure consistency of all data collection

Action	Responsible Party	Timeline
Questionnaire protocol is developed	Study Manager	Prior to commencing study
Questionnaire protocol is adhered to	All CMVH UA staff	At all times
Standard set of questionnaires are approved by ethics	Research Fellow	Prior to use
Questionnaires contain version numbers for tracking purposes	Research Fellow	Prior to use
Information packs are checked against nominal roll prior to sending to ensure that correct names, addresses and Study IDs	Participant Liaison Officer or SOC Administration Officer	Prior to mailing
Returned hardcopy questionnaires are checked for obvious errors and oversights	Data Manager	Within one week of receiving
A Participant Liaison Officer Protocol is developed to answer questions from participants	Study Manager	Prior to commencing study
A SOP for cleaning data is developed	Statisticians	Prior to analysis
Imputation rules are agreed	Statisticians	Prior to analysis

Ensure that all Protocol Deviations (see definition below) are recorded and followed up appropriately

Action	Responsible Party	Timeline
Record any errors or omissions to the protocol on the Protocol Deviation Log	Any CMVH UA staff member	As soon as the deviation is identified
Collect and collate the Protocol Deviation Reports	Study Manager	Once per week
Take any action required to reduce the likelihood of any further Protocol Deviations	Study Manager	At all times

Definition of a Protocol Deviation

A protocol deviation is defined as any action or inaction which digresses from the Questionnaire Protocol and which compromises the integrity of any questionnaire data.

APPENDIX 1: PRE-DEPLOYMENT WARM UP

Appendix 1A: Warm-up Letter for Participants Eligible for the Prospective Study Who Have Not Completed Another MILHOP Study Survey

<<date>>

<<Name>>
<<Address>>>

Dear <<Name>>

The **Middle East Area of Operations (MEAO)** ***Prospective*** **Health Study** is an important research initiative being conducted for Defence by the Centre for Military and Veterans' Health. This study is a comprehensive large-scale program aimed at assessing the impact of deployment to the MEAO on the physical and mental health of ADF personnel. Your involvement will be important to the overall results independent of whether you have any adverse health outcomes or not.

The program builds on the recent Health Studies concerning the Near North Area of Influence. This ongoing body of research is called the Military Health Outcomes Program (MilHOP).

Shortly you will receive an email inviting you to participate in this MilHOP study. At the same time you will also receive a hardcopy invitation and information pack which will be sent to your internal Defence mailing address. Your chain of command has been informed of this initiative and will assist in ensuring you have adequate time to complete the study.

All ADF members deploying to the MEAO between September 2010 and returning from deployment before December 2011 are being invited to participate in this important initiative.

If you have any questions or comments about this program please contact
the Centre for Military and Veterans' Health
by email at cmvh@adelaide.edu.au
or by telephone on 1800 232 904 (freecall number).

Yours sincerely,

(INSERT SIGNATURE)

Professor Annette Dobson
First Chief Investigator, Military Health Outcomes Program (MilHOP)
Centre for Military and Veterans' Health
The University of Queensland

Appendix 1B: Warm-up Letter for Non-SF Participants Who Have Already Completed a MILHOP Survey

30 August 2011

<<Name>>
<<Address>>

Dear <<Name>>

Re: MilHOP *Prospective* Health Study

Thank you for your recent participation in the [Military Health Outcomes Program (MilHOP) Middle East Area of Operations Health Study OR MilHOP Health and Wellbeing Study]. Your participation in the MilHOP has contributed to our understanding of the health and wellbeing of Australia's military men and women. We are currently analysing the group results and preparing to present the findings to effect real change in the ADF.

The Department of Defence has advised the Centre for Military and Veterans' Health that you are scheduled for deployment to the MEAO in the near future. This letter is to advise you that as part of your deployment you will be eligible to volunteer to participate in the MEAO ***Prospective*** Health Study. The Prospective Health Study is a component of the MilHOP that seeks to identify any changes that occur in your health and wellbeing after deployment to the MEAO compared with your health and wellbeing from before you deployed.

Shortly you will receive an email inviting you to participate in the MEAO Prospective Health Study. At the same time you will also receive a hardcopy invitation and information pack which will be sent to your internal Defence mailing address. Your chain of command has been informed of this initiative and will assist in ensuring you have adequate time to complete the study.

All ADF members deploying to the MEAO from September 2010 and returning from deployment before December 2011 are being invited to participate in this important initiative.

If you have any questions or comments about the MilHOP program please contact the Centre for Military and Veterans' Health
by email at cmvh@adelaide.edu.au
or by telephone on 1800 232 904 (free-call number).

Yours sincerely,

(INSERT SIGNATURE)

Professor Annette Dobson
First Chief Investigator, Military Health Outcomes Program (MilHOP)
Centre for Military and Veterans' Health
The University of Queensland

Appendix 1C: Warm-up Letter for SF Participants Who Have Not Completed Another MILHOP Study Survey

<<date>>

<<Name>>
<<Address>>>

Dear <<Name>>

The **Middle East Area of Operations (MEAO)** ***Prospective*** **Health Study** is an important research initiative being conducted for Defence by the Centre for Military and Veterans' Health. This study is a comprehensive large-scale program aimed at assessing the impact of deployment to the MEAO on the physical and mental health of ADF personnel. Your involvement will be important to the overall results independent of whether you have any adverse health outcomes or not.

The program builds on the recent Health Studies concerning the Near North Area of Influence. This ongoing body of research is called the Military Health Outcomes Program (MilHOP).

Shortly you will receive a hardcopy invitation and information pack which will be sent to your internal Defence mailing address. Your chain of command has been informed of this initiative and will assist in ensuring you have adequate time to complete the study.

All ADF members deploying to the MEAO between September 2010 and returning from deployment before December 2011 are being invited to participate in this important initiative.

If you have any questions or comments about this program please contact
the Centre for Military and Veterans' Health
by email at MILHOP.SpecialForces@defence.gov.au
or by telephone on 1800 755 078 (freecall number).

Yours sincerely,

(INSERT SIGNATURE)

Professor Annette Dobson
First Chief Investigator, Military Health Outcomes Program (MilHOP)
Centre for Military and Veterans' Health
The University of Queensland

Appendix 1D: Warm-up Letter for SF Particiapnts Who Have Already Completed a MILHOP Survey

30 August 2011

<<Name>>
<<Address>>

Dear <<Name>>

Re: MilHOP *Prospective* Health Study

Thank you for your recent participation in the [Military Health Outcomes Program (MilHOP) Middle East Area of Operations Health Study OR MilHOP Health and Wellbeing Study]. Your participation in the MilHOP has contributed to our understanding of the health and wellbeing of Australia's military men and women. We are currently analysing the group results and preparing to present the findings to effect real change in the ADF.

The Department of Defence has advised the Centre for Military and Veterans' Health that you are scheduled for deployment to the MEAO in the near future. This letter is to advise you that as part of your deployment you will be eligible to volunteer to participate in the MEAO ***Prospective*** Health Study. The Prospective Health Study is a component of the MilHOP that seeks to identify any changes that occur in your health and wellbeing after deployment to the MEAO compared with your health and wellbeing from before you deployed.

Shortly you will receive letter inviting you to participate in the MEAO Prospective Health Study which will be sent to your internal Defence mailing address. Your chain of command has been informed of this initiative and will assist in ensuring you have adequate time to complete the study.

All ADF members deploying to the MEAO from September 2010 and returning from deployment before December 2011 are being invited to participate in this important initiative.

If you have any questions or comments about the MilHOP program please contact the Centre for Military and Veterans' Health
by email at MILHOP.SpecialForces@defence.gov.au
or by telephone on 1800 755 078 (freecall number).

Yours sincerely

Professor Annette Dobson
First Chief Investigator, Military Health Outcomes Program (MilHOP)
Centre for Military and Veterans' Health
The University of Queensland

APPENDIX 2: PRE-DEPLOYMENT INVITATION PACK

Appendix 2A: Pre-deployment Letter of Support from the Chief of Defence Force and Repatriation Commissioner

Australian Government
Department of Defence

Australian Government
Department of Veterans' Affairs

Dear Participant

We are writing to strongly encourage you to participate in a Health Study of Australian Defence Force (ADF) personnel who have deployed, or are about to deploy, to the Middle East Area of Operations.

The health of serving and ex-serving members of the ADF is of great importance to both the ADF and the Department of Veterans' Affairs (DVA). It is vital that the ADF possesses the best deployment-related health information available so that it can effectively monitor, prepare for, and lessen any adverse effects that operational deployments might have on its people.

The Department of Defence has previously commissioned studies into the long-term health and future well-being of ADF personnel who have taken part in recent deployments to Timor, Bougainville, and the Solomon islands. You and more than 25,000 other serving and ex-serving personnel are now being invited to participate in the Middle East Area of Operations Health Study. This study will include personnel who have deployed to Iraq or Afghanistan since 2001, and those who will deploy in 2010 and 2011. This includes Operations SLIPPER, BASTILLE, CATALYST, FALCONER and KRUGER.

Your support will assist the ADF in understanding the various health effects of operational deployments, now and into the future. With that knowledge, the ADF will be able to better protect the health of ADF members preparing for and undertaking future deployments. Clearly, the greater the response rates to the study survey, the more useful the results for us all.

The study will be conducted by the Centre for Military and Veterans' Health (CMVH), a consortium of Universities including the University of Queensland and the University of Adelaide, jointly supported by Defence and DVA.

Study participants' information will be used only for the purposes of the deployment studies unless otherwise indicated, and will be protected under the provisions of the Privacy Act 1988. Your response will not in any way affect your current status or future prospects within the ADF, or any pension, benefits or health services you are entitled to receive from the Department of Veterans' Affairs. Time will be made available during normal work hours for serving ADF members to complete the survey.

I encourage you to participate for your own benefit and that of your colleagues, as well as for the benefit of the broader ADF in carrying out our important work for the nation. A high participation rate is critical to the quality of the findings from this study.

Yours sincerely

Angus Houston
Air Chief Marshal
Chief of the Defence Force

3 March 10

Bill Rolfe
Brigadier (Rtd)
Repatriation Commissioner

8 March 10

Appendix 2B: Pre-deployment Cover Letter from the Chief Investigator

<<date>>

<<Name>>
<<Address>>>

Dear <<Name>>

As Chief Investigator of the Middle East Area of Operations (MEAO) research program conducted by the Centre for Military and Veterans' Health (CMVH), I would personally like to invite you to participate in this important research program. The program consists of a series of studies which will provide invaluable information about the detailed impact of deployment to the MEAO, and highlight steps that might be available to improve the performance and capability of you and your fellow ADF members in future deployments.

I understand that your health may not be a concern right now but as with elite athletes, we can learn a lot by understanding the impact of deployment on your physical and mental wellbeing. The results from this research will help individuals prepare for deployment. It will also give Defence the best opportunity to develop better ways of ensuring the best possible health and wellbeing outcomes for ADF service personnel.

CMVH would like you to consider participating in the Prospective Health Study of the MEAO research program. The Prospective Health Study will investigate the impact of deployment on your health by assessing this before you go on deployment and then again when you return. Please read the enclosed information brochure or log onto our website www.cmvh.org.au for more information.

Confidentiality of your personal information is of utmost concern. As CMVH is independent from Defence we can assure you that any individually identifiable information you choose to provide us will not be accessible by Defence. Neither will any party outside of the immediate research team have access to your identifiable information.

I appreciate your time is valuable. However, the participation of as many people as possible is critical to making sure our findings are representative of the ADF community. Even if you do not believe that your deployment will have any adverse consequences on your health, your contribution is still important. Your participation is a way of helping your mates now and into the future.

Yours sincerely,

Annette Dobson

Professor Annette Dobson
First Chief Investigator, Military Health Outcomes Program (MilHOP)
Centre for Military and Veterans' Health
The University of Queensland

Appendix 2C: Pre-deployment Instruction Sheet including Study URL and Login Information for the Online Questionnaire and Tear Off Slip to Decline the Invitation to Participate

CMVH
CENTRE FOR MILITARY & VETERANS' HEALTH

Middle East Area of Operations (MEAO) Prospective Health Study

➢ If you **wish to participate**, you can complete the study in two ways:

(1) Complete and return the **enclosed questionnaires** and **consent booklet** in the reply paid envelope provided.

OR

(2) Complete the questionnaire on the **internet**, by logging on to the website shown below, using the unique user name and password provided:

[Website address]

Your Username/Study ID: **[Username/Study ID]**

Your Password: **[Password]**

Please note: If you participate online you do **not** need to return any paper forms.

➢ If **you do not wish to participate**, you can decline this invitation in any of these ways:

- Call the study team on toll free number **1800 232 904**
- Send an email to cmvh@adelaide.edu.au with your Study ID and "Declined" in the subject line
- Complete and return the form below

(Declining the invitation will prevent you from getting reminders about the study)

✂- -

Middle East Area of Operations (MEAO) Prospective Health Study

To Decline the Invitation

☐ I DO NOT wish to participate in the Middle East Area of Operations (MEAO) Prospective Health Study

[Study ID]

Appendix 2D: Pre-deployment Instruction Sheet for Special Forces including a Tear Off Slip to Decline the Invitation to Participate

Middle East Area of Operations (MEAO) Prospective Health Study

➢ If you **wish to participate**, please:

- Complete and return the **enclosed questionnaires** and **consent booklet** in the reply paid envelope provided.

➢ If **you do not wish to participate**, you can decline this invitation in any of these ways:

- Call the study team on toll free number **1800 XXX XXX**
- Send an email to XXXX@adelaide.edu.au with your Study ID and "Declined" in the subject line
- Complete and return the form below

(Declining the invitation will prevent you from getting reminders about the study)

✂----------

Middle East Area of Operations (MEAO) Prospective Health Study

To Decline the Invitation

☐ I DO NOT wish to participate in the Middle East Area of Operations (MEAO) Prospective Health Study

[Study ID]

Appendix 2E: Consent Form for Non-SF Participants who are Not Eligible for Participation in the Physical, Biological and Neurocognitive Tests

MEAO Prospective Health Study Questionnaire Consent Form

I .....give my consent to participate in:
(please circle below the parts of the study you wish to consent to)

➢ ***ALL PARTS OF THE STUDY*** including all procedures and linking of personal information as described below — **Yes / No**

OR

➢ ***THE FOLLOWING PARTS ONLY:***

- Completing the Middle East Area of Operations (MEAO) Prospective Health Study Questionnaire approximately 3 months before my deployment and again 4 months after my deployment. — **Yes / No**
- Allowing linkage of information contained in electronic ADF health records (e.g. Health-Keys) with the study data — **Yes / No**
- Allowing linkage of information contained in my electronic ADF psychological screening records with the study data — **Yes / No**
- Allowing linkage to information held in other health registries including cancer registries and other health registry systems as outlined in the information sheet — **Yes / No**
- Being contacted for follow-up studies — **Yes / No**
- Allowing CMVH to obtain ADF contact details of any listed partner/spouse so that they may be invited to participate in a family study — **Yes / No**

My consent is provided on the following basis:

- I have read the MEAO Prospective Health Study Questionnaire information sheet provided to me about the aims of this research, how it will be conducted and my role in it.
- I understand the risks involved as described in the information sheet.
- I am cooperating in this project on the condition that:
  - My personal information and details will be kept confidential.
  - The information that is collected for this study will only be used for the Military Health Outcomes Program (MilHOP) research.
  - My participation will be from the commencement date to the end date specified on this form, or to the end of this project (June 2012). I can elect to withdraw from the project at any time.
- I can discuss my participation at any time with the Principal Investigator, a Research Team Member or a representative of one of the relevant Ethics Committees.
- I understand that Defence and DVA are interested in understanding the impacts of deployments and service life. Further studies may include: telephone interviews and family studies.
  - I understand that CMVH is conducting a family study this year and I allow CMVH to use family contact information held by the ADF to invite my family to participate if selected. My family will be able to decide whether they wish to participate at the time of contact.

Continued over page

I understand that:

- There is no obligation to take part in this study.
- I understand that this project is/may be ongoing, unless I am otherwise notified. In the event that the project exceeds the five year maximum period of consent, the project will be required to obtain a new consent form signed by me.
- If I choose not to participate there will be no detriment to my career, future health care, service pension, DVA pension or compensation claims.
- I am free to withdraw from the study at any time. If I do, there is no detriment to my career, future health care, service pension, DVA pension or compensation claims.
- My answers will be completely confidential and any personal details, which may identify me in any way, will not be passed to the Department of Veterans' Affairs or the Department of Defence. My answers will not in any way affect my pension, benefits or any health services I am entitled to from DVA.
- I can, at any time, withdraw my consent to participate in the project. Should I withdraw my consent, I can do so by contacting the study team at the Centre for Military and Veterans' Health on 1800 232 904 (free call) or cmvh@adelaide.edu.au

✓ I have kept a copy of the information and consent sheet, signed by me for my records.
✓ I have also been given a copy of Australian Defence Human Research Ethics Committee's (ADHREC) *Guidelines for Volunteers*.
✓ The study report will be made available to me at my request and any published reports of this study will preserve my anonymity.

Please forward results and findings to:

❒ My email address

❒ My home address

Participant Signature: _____

Name in Full: _____

Date: _____

Please sign and return to the Centre for Military and Veterans' Health

Participant Copy

MEAO Prospective Health Study Questionnaire Consent Form

I .....give my consent to participate in:
(please circle below the parts of the study you wish to consent to)

➢ ***ALL PARTS OF THE STUDY*** including all procedures and linking of personal information as described below — **Yes / No**

OR

➢ ***THE FOLLOWING PARTS ONLY:***

- Completing the Middle East Area of Operations (MEAO) Prospective Health Study Questionnaire approximately 3 months before my deployment and again 4 months after my deployment. — **Yes / No**
- Allowing linkage of information contained in electronic ADF health records (e.g. Health-Keys) with the study data — **Yes / No**
- Allowing linkage of information contained in my electronic ADF psychological screening records with the study data — **Yes / No**
- Allowing linkage to information held in other health registries including cancer registries and other health registry systems as outlined in the information — **Yes / No**
- Being contacted for follow-up studies — **Yes / No**
- Allowing CMVH to obtain ADF contact details of any listed partner/spouse so that they may be invited to participate in a family study — **Yes / No**

My consent is provided on the following basis:

- I have read the information sheet provided to me about the aims of this research, how it will be conducted and my role in it.
- I understand the risks involved as described in the information sheet.
- I am cooperating in this project on the condition that:
  - My personal information and details will be kept confidential.
  - The information that is collected for this study will only be used for the Military Health Outcomes Program (MilHOP) research.
  - My participation will be from the commencement date to the end date specified on this form, or to the end of this project (June 2012). I can elect to withdraw from the project at any time.
- I can discuss my participation at any time with the Principal Investigator, a Research Team Member or a representative of one of the relevant Ethics Committees.
- I understand that Defence and DVA are interested in understanding the impacts of deployments and service life. Further studies may include: telephone interviews and family studies.
  - I understand that CMVH is conducting a family study this year and I allow CMVH to use family contact information held by the ADF to invite my family to participate if selected. My family will be able to decide whether they wish to participate at the time of contact.

Continued over page

I understand that:

- There is no obligation to take part in this study.
- If I choose not to participate there will be no detriment to my career, future health care, service pension, DVA pension or compensation claims.
- I am free to withdraw from the study at any time. If I do, there is no detriment to my career, future health care, service pension, DVA pension or compensation claims.
- My answers will be completely confidential and any personal details, which may identify me in any way, will not be passed to the Department of Veterans' Affairs or the Department of Defence.
  My answers will not in any way affect my pension, benefits or any health services I am entitled to from DVA.
- I can, at any time, withdraw my consent to participate in the project. Should I withdraw my consent, I can do so by contacting the study team at the Centre for Military and Veterans' Health on 1800 232 904 (free call) or cmvh@adelaide.edu.au

✓ I have kept a copy of the information and consent sheet, signed by me for my records.
✓ I have also been given a copy of Australian Defence Human Research Ethics Committee's (ADHREC) *Guidelines for Volunteers*.
✓ The study report will be made available to me at my request and any published reports of this study will preserve my anonymity.

Please forward results and findings to:

❒ My email address

❒ My home address

Participant Signature: _____

Name in Full: _____

Date: _____

Please detach and retain for your records

Appendix 2F: Consent Form for Non-SF Participants Eligible for Participation in the MEAO Prospective Physical and Neurocognitive Tests

MEAO Prospective Health Study Questionnaire, Physical and Neurocognitive Testing Consent Form

I .....give my consent to participate in:
(please circle below the parts of the study you wish to consent to)

➢ ***ALL PARTS OF THE STUDY*** including all procedures and linking of personal information as described below — **Yes / No**

OR

➢ ***THE FOLLOWING PARTS ONLY:***

- Completing the Middle East Area of Operations (MEAO) Prospective Health Study Questionnaire approximately 3 months before my deployment and again 4 months after my deployment — **Yes / No**
- Allowing linkage of information contained in electronic ADF health records (e.g. Health-Keys) with the study data — **Yes / No**
- Allowing linkage of information contained in my electronic ADF psychological screening records with the study data — **Yes / No**
- Allowing linkage to information held in other health registries including cancer registries and other health registry systems as outlined in the information sheet — **Yes / No**
- A physical assessment 3 months before deployment and again 4 months after deployment as described in the information sheet — **Yes / No**
- Providing a blood and saliva sample 3 months before deployment and again 4 months after deployment as described in the information sheet — **Yes / No**
- Performing a neurocognitive test 3 months before deployment and again 4 months after deployment as described in the information sheet — **Yes / No**
- Being contacted for follow-up studies — **Yes / No**
- Allowing CMVH to obtain ADF contact details of any listed partner/spouse so that they may be invited to participate in a family study — **Yes / No**

Prospective Study Physical Test Consent Form-CB-20100421-V4.docx

My consent is provided on the following basis:

- I have read the MEAO Prospective Health Study Questionnaire, Physical and Neurocognitive Testing information sheet provided to me about the aims of this research, how it will be conducted and my role in it AND the supplementary information sheet for physical and neurocognitive testing that details the testing to be conducted.
- I understand the risks involved as described in the information sheet.
- I am cooperating in this project on the condition that:
    - My personal information and details will be kept confidential.
    - The information that is collected for this study will only be used for the Military Health Outcomes Program or MilHOP research.
    - My participation will be from the commencement date to the end date specified on this form, or to the end of this project (June 2012). I can elect to withdraw from the project at any time.
- I can discuss my participation at any time with the Principal Investigator, a Research Team Member or a representative of one of the relevant Ethics Committees.
- I understand that Defence and DVA are interested in understanding the impacts of deployments and service life. Further studies may include: telephone interviews and family studies.
    - I understand that CMVH is conducting a family study this year and I allow CMVH to use family contact information held by the ADF to invite my family to participate if selected. My family will be able to decide whether they wish to participate at the time of contact.

I understand that:

- There is no obligation to take part in this study.
- If I choose not to participate there will be no detriment to my career, future health care, service pension, DVA pension or compensation claims.
- I am free to withdraw from the study at any time. If I do, there is no detriment to my career, future health care, service pension, DVA pension or compensation claims.
- My answers will be completely confidential and any personal details, which may identify me in any way, will not be passed to the Department of Veterans' Affairs or the Department of Defence.
  My answers will not in any way affect my pension, benefits or any health services I am entitled to from DVA.
- I can, at any time, withdraw my consent to participate in the project. Should I withdraw my consent, I can do so by contacting the study team at the Centre for Military and Veterans' Health on 1800 232 904 (free call) or cmvh@adelaide.edu.au

✓ I have kept a copy of the information and consent sheet, signed by me for my records.
✓ I have also been given a copy of Australian Defence Human Research Ethics Committee's (ADHREC) *Guidelines for Volunteers*.
✓ The study report will be made available to me at my request and any published reports of this study will preserve my anonymity.

Please forward results and findings to:

❒ My email address

❒ My home address

Participant Signature: _____

Name in Full: _____

Date: _____

Please sign and return to the Centre for Military and Veterans' Health

MEAO Prospective Health Study Questionnaire, Physical and Neurocognitive Testing Consent Form

I .....give my consent to participate in:
(please circle below the parts of the study you wish to consent to)

➢ ***ALL PARTS OF THE STUDY*** including all procedures and linking of personal information as described below — **Yes / No**

OR

➢ ***THE FOLLOWING PARTS ONLY:***

- Completing the Middle East Area of Operations (MEAO) Prospective Health Study Questionnaire approximately 3 months before my deployment and again 4 months after my deployment — **Yes / No**
- Allowing linkage of information contained in electronic ADF health records (e.g. Health-Keys) with the study data — **Yes / No**
- Allowing linkage of information contained in my electronic ADF psychological screening records with the study data — **Yes / No**
- Allowing linkage to information held in other health registries including cancer registries and other health registry systems as outlined in the information sheet — **Yes / No**
- A physical assessment 3 months before deployment and again 4 months after deployment as described in the information sheet — **Yes / No**
- Providing a blood and saliva sample 3 months before deployment and again 4 months after deployment as described in the information sheet — **Yes / No**
- Performing a neurocognitive test 3 months before deployment and again 4 months after deployment as described in the information sheet — **Yes / No**
- Being contacted for follow-up studies — **Yes / No**
- Allowing CMVH to obtain ADF contact details of any listed partner/spouse so that they may be invited to participate in a family study — **Yes / No**

My consent is provided on the following basis:

- I have read the MEAO Prospective Health Study Questionnaire, Physical and Neurocognitive Testing information sheet provided to me about the aims of this research, how it will be conducted and my role in it AND the supplementary information sheet for physical and neurocognitive testing that details the testing to be conducted.
- I understand the risks involved as described in the information sheet.
- I am cooperating in this project on the condition that:
    - My personal information and details will be kept confidential.
    - The information that is collected for this study will only be used for the Military Health Outcomes Program (MilHOP) research.
    - My participation will be from the commencement date to the end date specified on this form, or to the end of this project (June 2012). I can elect to withdraw from the project at any time.
- I can discuss my participation at any time with the Principal Investigator, a Research Team Member or a representative of one of the relevant Ethics Committees.
- I understand that Defence and DVA are interested in understanding the impacts of deployments and service life. Further studies may include: telephone interviews and family studies.
    - I understand that CMVH is conducting a family study this year and I allow CMVH to use family contact information held by the ADF to invite my family to participate if selected. My family will be able to decide whether they wish to participate at the time of contact.

I understand that:

- There is no obligation to take part in this study.
- If I choose not to participate there will be no detriment to my career, future health care, service pension, DVA pension or compensation claims.
- I am free to withdraw from the study at any time. If I do, there is no detriment to my career, future health care, service pension, DVA pension or compensation claims.
- My answers will be completely confidential and any personal details, which may identify me in any way, will not be passed to the Department of Veterans' Affairs or the Department of Defence. My answers will not in any way affect my pension, benefits or any health services I am entitled to from DVA.
- I can, at any time, withdraw my consent to participate in the project. Should I withdraw my consent, I can do so by contacting the study team at the Centre for Military and Veterans' Health on 1800 232 904 (free call) or cmvh@adelaide.edu.au

✓ I have kept a copy of the information and consent sheet, signed by me for my records.
✓ I have also been given a copy of Australian Defence Human Research Ethics Committee's (ADHREC) *Guidelines for Volunteers*.
✓ The study report will be made available to me at my request and any published reports of this study will preserve my anonymity.

Please forward results and findings to:

❒ My email address

❒ My home address

Participant Signature: _____

Name in Full: _____

Date: _____

Please detach and retain for your records

Appendix 2G: Consent Form for SF Personnel Eligible for Participation in the MEAO Prospective Study Physical and Neurocognitive Tests

MEAO Prospective Health Study Questionnaire, Physical and Neurocognitive Testing Consent Form

I .....give my consent to participate in:
(please circle below the parts of the study you wish to consent to)

➢ ***ALL PARTS OF THE STUDY*** including all procedures and linking of personal information as described below **Yes / No**

OR

➢ ***THE FOLLOWING PARTS ONLY:***

- Completing the Middle East Area of Operations (MEAO) Prospective Health Study Questionnaire approximately 3 months before my deployment and again 4 months after my deployment **Yes / No**
- Allowing linkage of information contained in electronic ADF health records (e.g. Health-Keys) with the study data **Yes / No**
- Allowing linkage of information contained in my electronic ADF psychological screening records with the study data **Yes / No**
- Allowing linkage to information held in other health registries including cancer registries and other health registry systems as outlined in the information sheet **Yes / No**
- A physical assessment 3 months before deployment and again 4 months after deployment as described in the information sheet **Yes / No**
- Providing a blood and saliva sample 3 months before deployment and again 4 months after deployment as described in the information sheet **Yes / No**
- Performing a neurocognitive test 3 months before deployment and again 4 months after deployment as described in the information sheet **Yes / No**
- Being contacted for follow-up studies **Yes / No**
- Allowing CMVH to obtain ADF contact details of any listed partner/spouse so that they may be invited to participate in a family study **Yes / No**

SF Prospective Study Physical Test Consent Form-CB-20100421-V3.docx

My consent is provided on the following basis:

- I have read the MEAO Prospective Health Study Questionnaire, Physical and Neurocognitive Testing information sheet provided to me about the aims of this research, how it will be conducted and my role in it AND the supplementary information sheet for physical and neurocognitive testing that details the testing to be conducted.
- I understand the risks involved as described in the information sheet.
- I am cooperating in this project on the condition that:
  - My personal information and details will be kept confidential.
  - The information that is collected for this study will only be used for the Military Health Outcomes Program (MilHOP) research.
  - My participation will be from the commencement date to the end date specified on this form, or to the end of this project (June 2012). I can elect to withdraw from the project at any time.
- I can discuss my participation at any time with the Principal Investigator, a Research Team Member or a representative of one of the relevant Ethics Committees.
- I understand that Defence and DVA are interested in understanding the impacts of deployments and service life. Further studies may include: telephone interviews and family studies.
  - I understand that CMVH is conducting a family study this year and I allow CMVH to use family contact information held by the ADF to invite my family to participate if selected. My family will be able to decide whether they wish to participate at the time of contact.

I understand that:

- There is no obligation to take part in this study.
- If I choose not to participate there will be no detriment to my career, future health care, service pension, DVA pension or compensation claims.
- I am free to withdraw from the study at any time. If I do, there is no detriment to my career, future health care, service pension, DVA pension or compensation claims.
- My answers will be completely confidential and any personal details, which may identify me in any way, will not be passed to the Department of Veterans' Affairs or the Department of Defence. My answers will not in any way affect my pension, benefits or any health services I am entitled to from DVA.
- I can, at any time, withdraw my consent to participate in the project. Should I withdraw my consent, I can do so by contacting the study team at the Centre for Military and Veterans' Health on 1800 XXX XXX (free call) or XXXX@adelaide.edu.au

✓ I have kept a copy of the information and consent sheet, signed by me for my records.
✓ I have also been given a copy of Australian Defence Human Research Ethics Committee's (ADHREC) *Guidelines for Volunteers*.
✓ The study report will be made available to me at my request and any published reports of this study will preserve my anonymity.

Please forward results and findings to:

❒ My email address

❒ My home address

Participant Signature: _____

Name in Full: _____

Date: _____

Please sign and return in the reply paid envelope provided

SF Prospective Study Physical Test Consent Form-CB-20100421-V3.docx

Participant Copy

MEAO Prospective Health Study Questionnaire, Physical and Neurocognitive Testing Consent Form

I .....give my consent to participate in:
(please circle below the parts of the study you wish to consent to)

- ***ALL PARTS OF THE STUDY*** including all procedures and linking of personal information as described below — **Yes / No**

OR

- ***THE FOLLOWING PARTS ONLY:***
  - Completing the Middle East Area of Operations (MEAO) Prospective Health Study Questionnaire approximately 3 months before my deployment and again 4 months after my deployment — **Yes / No**
  - Allowing linkage of information contained in electronic ADF health records (e.g. Health-Keys) with the study data — **Yes / No**
  - Allowing linkage of information contained in my electronic ADF psychological screening records with the study data — **Yes / No**
  - Allowing linkage to information held in other health registries including cancer registries and other health registry systems as outlined in the information sheet — **Yes / No**
  - A physical assessment 3 months before deployment and again 4 months after deployment as described in the information sheet — **Yes / No**
  - Providing a blood and saliva sample 3 months before deployment and again 4 months after deployment as described in the information sheet — **Yes / No**
  - Performing a neurocognitive test 3 months before deployment and again 4 months after deployment as described in the information sheet — **Yes / No**
  - Being contacted for follow-up studies — **Yes / No**
  - Allowing CMVH to obtain ADF contact details of any listed partner/spouse so that they may be invited to participate in a family study — **Yes / No**

My consent is provided on the following basis:

- I have read the MEAO Prospective Health Study Questionnaire, Physical and Neurocognitive Testing information sheet provided to me about the aims of this research, how it will be conducted and my role in it AND the supplementary information sheet for Physical and Neurocognitive testing that details the testing to be conducted.
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- I am cooperating in this project on the condition that:
  - My personal information and details will be kept confidential.
  - The information that is collected for this study will only be used for the Military Health Outcomes Program (MilHOP) research.
  - My participation will be from the commencement date to the end date specified on this form, or to the end of this project (June 2012). I can elect to withdraw from the project at any time.
- I can discuss my participation at any time with the Principal Investigator, a Research Team Member or a representative of one of the relevant Ethics Committees.
- I understand that Defence and DVA are interested in understanding the impacts of deployments and service life. Further studies may include: telephone interviews and family studies.
  - I understand that CMVH is conducting a family study this year and I allow CMVH to use family contact information held by the ADF to invite my family to participate if selected. My family will be able to decide whether they wish to participate at the time of contact.

I understand that:

- There is no obligation to take part in this study.
- If I choose not to participate there will be no detriment to my career, future health care, service pension, DVA pension or compensation claims.
- I am free to withdraw from the study at any time. If I do, there is no detriment to my career, future health care, service pension, DVA pension or compensation claims.
- My answers will be completely confidential and any personal details, which may identify me in any way, will not be passed to the Department of Veterans' Affairs or the Department of Defence. My answers will not in any way affect my pension, benefits or any health services I am entitled to from DVA.
- I can, at any time, withdraw my consent to participate in the project. Should I withdraw my consent, I can do so by contacting the study team at the Centre for Military and Veterans' Health on 1800 XXX XXX (free call) or XXXX@adelaide.edu.au

✓ I have kept a copy of the information and consent sheet, signed by me for my records.
✓ I have also been given a copy of Australian Defence Human Research Ethics Committee's (ADHREC) *Guidelines for Volunteers*.
✓ The study report will be made available to me at my request and any published reports of this study will preserve my anonymity.

Please forward results and findings to:

❒ My email address

❒ My home address

Participant Signature: _____

Name in Full: _____

Date: _____

Please detach and retain for your records

SF Prospective Study Physical Test Consent Form-CB-20100421-V3.docx

Appendix 2H: Information Sheet for Non-SF Members Eligible only for the MEAO Prospective Health Study Questionnaire

YOUR PRIVACY

Your contact details have been obtained from the Department of Defence. Your details will not be forwarded to any other individual or agency, and will only be used for the purposes of the CMVH MilHOP studies and no other, without your express permission and subject to separate consent.

+ To ensure your privacy you have been given a study number
+ You will not be personally identified in any reports or articles
+ Information you provide is de-identified, and only re-identifiable by the research staff. Individual information is not passed on to the Departments of Defence or Veterans' Affairs, except by court order
+ Your data is only accessed by personnel with the appropriate security clearance, and is stored in secured facilities at the CMVH

ACCESSING YOUR INFORMATION

You have the right to access the information that is collected from you to assist with your medical care in the future by contacting the study team.

For questions, problems or concerns, or to have your name removed from the mailing list please contact the following:

+ **The Study Team**
  The Centre for Military and Veterans' Health
  1800 232 904; cmvh@adelaide.edu.au
+ **Principal Investigator: Prof Alexander McFarlane**
  University of Adelaide
  (08) 83035364;
  alexander.mcfarlane@adelaide.edu.au

SUPPORT FOR MEAO VETERANS

ALL HOURS SUPPORT LINE

A confidential telephone triage support service for ADF members and their families.
1800 628 036; Outside Australia: +61 2 9425 3878

+ **Lifeline** 13 11 14
+ **Veterans and Veterans' Family Counselling Service** 1800 011 046
+ **Veterans' Affairs Network (VAN)** 1300 551 918; Non-metro: 1800 555 254
+ **National Office for the Military Compensation and Rehabilitation Service** 1300 550 461
+ **Department of Veterans' Affairs** 13 32 54

If you prefer to speak to an independent University or Defence Force representative not involved in the study contact an Ethics Officer:

+ **The Australian Defence Human Research Ethics Committee**
  Executive Secretary
  (02) 6266 3837; ADHREC@defence.gov.au
+ **The University of Adelaide Research Branch**
  Secretary Human Research Ethics Committee
  (08) 8303 6028
+ **The Department of Veterans' Affairs Human Research Ethics Committee**
  HREC Coordinator
  (02) 6289 6204; ethics.committee@dva.gov.au

INFORMATION SHEET FOR THE MEAO PROSPECTIVE HEALTH STUDY QUESTIONNAIRE

CMVH
CENTRE FOR MILITARY & VETERANS' HEALTH

MilHOP
Military Health Outcomes Program

THE AIM OF THIS STUDY

You are invited to participate in a health study. This study is being conducted to better understand the health of members deployed to the Middle East. It forms part of the Federal Government's commitment to conduct health reviews of deployed personnel.

Responses will be analysed to determine how deployment and roles in the military impact on health and military careers.

WARFARE HAS CHANGED
We need YOU to give us a better understanding of the pressures and what you've been through

PARTICIPATION IS ENTIRELY VOLUNTARY

Your participation or non-participation will not be notified to the Department of Defence or the Department of Veterans' Affairs.

If you're in receipt of a Service-related pension, a decision not to participate, or to withdraw, will not lead to any detriment to your career or future health care or entitlements.

If you have a claim for compensation or are in receipt of a pension from the Department of Veterans' Affairs, a decision not to participate will not in any way affect your pension or compensation.

If you do choose to participate, you may withdraw from the study at any time.

You may choose which parts of the study you wish to participate in on the consent form.

BENEFITS AND RISKS OF PARTICIPATING

Your information will contribute to increased knowledge about Service-related health and ill-health. It may also assist the ADF in developing the most appropriate supportive and protective measures against future health threats. We cannot predict how the results of this study will impact to the advantage or disadvantage of veterans collectively in any future unknown context where issues of service-related ill health might arise. This survey is an opportunity for your own experience to contribute to the overall results.

We have many stringent processes in place to protect the confidentiality of the information you give us (see under "Your Privacy").

While there are not expected to be any risks associated with the study, there may be some questions you find distressing. Should you feel distressed, you may wish to discuss this with someone. A list of services is provided in this information sheet in case you require them.

STUDY FINDINGS

The study results will be fed back to you and made available on our website (www.cmvh.org.au).

Any reports prepared for Joint Health Command are presented as group data only, not individual data which identifies you. Group results will also be published in the medical and scientific literature.

WHO IS CONDUCTING THE STUDY?

The Centre for Military and Veterans' Health (CMVH) is a collaborative centre of the University of Queensland, University of Adelaide and Charles Darwin University. CMVH has been contracted by the Department of Defence to conduct this study. The study forms part of the Military Health Outcomes Program (MilHOP), an ongoing program aimed at assessing the physical and mental health status of currently serving and ex-serving ADF personnel. This program builds on recent CMVH Health Studies which looked at deployments to the Near North Area of influence.

WHAT'S INVOLVED?

To participate please complete the consent form where you will be given the opportunity to select each element of the study you wish to take part in. These include:

COMPLETE A QUESTIONNAIRE

You will be asked to complete a questionnaire 3 months before you deploy and 4 months after you return, about:

+ your previous deployments;
+ your health now, and;
+ your deployment experiences.

This will take between 30 minutes and 60 minutes to complete, and can be completed on the web or in hard copy format.

CONSENT TO LINK TO HEALTH RECORDS

If you participate, you will also be asked to let CMVH researchers link your study data to:

a. ADF health and psychological records.

b. Special disease or treatment registration systems, including diabetes and cancer registers; infectious diseases notification; disability information; radiotherapy, injury, midwives and birth defects data; and dialysis and transplant register.

BE CONTACTED FOR FOLLOW-UP STUDIES

We would like your permission to contact you in the future to invite you for other voluntary studies such as:

+ a telephone interview about your health and wellbeing;
+ family studies;
+ longer term health outcomes that may become apparent as veterans age.

This study has the full support of the CDF and serving ADF members may complete the questionnaire during work hours.

Appendix 2I: Information Sheet for Non-SF Participants Eligible for MEAO Prospective Health Study Questionnaire, Physical Testing and Neurocognitive Testing

YOUR PRIVACY

Your contact details have been obtained from the Department of Defence. Your details will not be forwarded to any other individual or agency, and will only be used for the purposes of the CMVH MilHOP studies and no other, without your express permission and subject to separate consent.

+ To ensure your privacy you have been given a study number
+ You will not be personally identified in any reports or articles
+ Information you provide is de-identified, and only re-identifiable by the research staff. Individual information is not passed on to the Departments of Defence or Veterans' Affairs, except by court order
+ Your data is only accessed by personnel with the appropriate security clearance, and is stored in secured facilities at the CMVH
+ Data we collect about your physical health including biological samples is stored in a de-identifed manner and only reidentifiable by the research staff.

ACCESSING YOUR INFORMATION

You have the right to access the information that is collected from you to assist with your medical care in the future by contacting the study team.

For questions, problems or concerns, or to have your name removed from the mailing list please contact the following:

+ **The Study Team**
  The Centre for Military and Veterans' Health
  Freecall: 1800 232 904
  Email: cmvh@adelaide.edu.au
+ **Principal Investigator: Prof Alexander McFarlane,**
  University of Adelaide (08) 83035364
  Email: alexander.mcfarlane@adelaide.edu.au

SUPPORT FOR MEAO VETERANS

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A confidential telephone triage support service for ADF members and their families. 1800 628 036; Outside Australia: +61 2 9425 3878

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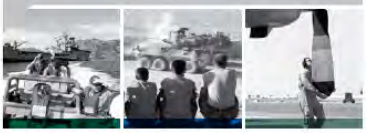
+ **Veterans and Veterans' Family Counselling Service** 1800 011 046
+ **Veterans' Affairs Network (VAN)** 1300 551 918; Non-metro: 1800 555 254
+ **National Office for the Military Compensation and Rehabilitation Service** 1300 550 461
+ **Department of Veterans' Affairs** 13 32 54

If you prefer to speak to an independent University or Defence Force representative not involved in the study contact an Ethics Officer:

+ **The Australian Defence Human Research Ethics Committee**
  Executive Secretary
  (02) 6266 3837; ADHREC@defence.gov.au
+ **The University of Adelaide Research Branch**
  Secretary Human Research Ethics Committee
  (08) 8303 6028
+ **The Department of Veterans' Affairs Human Research Ethics Committee**
  HREC Coordinator
  (02) 6289 6204; ethics.committee@dva.gov.au

INFORMATION SHEET FOR THE MEAO PROSPECTIVE HEALTH STUDY QUESTIONNAIRE, PHYSICAL, AND NEUROCOGNITIVE TESTS

CMVH



MilHOP
Military Health Outcomes Program

Information Sheet-MeaoPros-PT-CD-20110615-V18

THE AIM OF THIS STUDY

You are invited to participate in a health study. This study is being conducted to better understand the health of members deployed to the Middle East. It forms part of the Federal Government's commitment to conduct health reviews of deployed personnel.

Responses will be analysed to determine how deployment and roles in the military impact on health and military careers.

WARFARE HAS CHANGED
We need YOU to give us a better understanding of the pressures and what you've been through

PARTICIPATION IS ENTIRELY VOLUNTARY

Your participation or non-participation will not be notified to the Department of Defence or the Department of Veterans' Affairs.

If you're in receipt of a Service-related pension, a decision not to participate, or to withdraw, will not lead to any detriment to your career or future health care or entitlements.

If you have a claim for compensation or are in receipt of a pension from the Department of Veterans' Affairs, a decision not to participate will not in any way affect your pension or compensation.

If you do choose to participate, you may withdraw from the study at any time.

You may choose which parts of the study you wish to participate in on the consent form.

BENEFITS AND RISKS OF PARTICIPATING

Your information will contribute to increased knowledge about Service-related health and ill-health. It may also assist the ADF in developing the most appropriate supportive and protective measures against future health threats. We cannot predict how the results of this study will impact to the advantage or disadvantage of veterans collectively in any future unknown context where issues of service-related ill health might arise. This survey is an opportunity for your own experience to contribute to the overall results.

We have many stringent processes in place to protect the confidentiality of the information you give us (see under "Your Privacy").

While there are not expected to be any risks associated with the study, there may be some questions you find distressing. Should you feel distressed, you may wish to discuss this with someone. A list of services is provided in this information sheet in case you require them.

STUDY FINDINGS

The study results will be fed back to you and made available on our website (www.cmvh.org.au).

Any reports prepared for Joint Health Command are presented as group data only, not individual data which identifies you. Group results will also be published in the medical and scientific literature.

WHO IS CONDUCTING THE STUDY?

The Centre for Military and Veterans' Health (CMVH) is a collaborative centre of the University of Queensland, University of Adelaide and Charles Darwin University. CMVH has been contracted by the Department of Defence to conduct this study. The study forms part of the Military Health Outcomes Program (MilHOP), an ongoing program aimed at assessing the physical and mental health status of currently serving and ex-serving ADF personnel. This program builds on recent CMVH Health Studies which looked at deployments to the Near North Area of Influence.

WHAT'S INVOLVED?

To participate please complete the consent form where you will be given the opportunity to select each element of the study you wish to take part in. These include:

COMPLETE A QUESTIONNAIRE

You will be asked to complete a questionnaire 3 months before you deploy and 4 months after you return, about:

+ your previous deployments;
+ your health now, and;
+ your deployment experiences.

This will take between 30 minutes and 60 minutes to complete, and can be completed on the web or in hard copy format.

PHYSICAL ASSESSMENT

The research team will contact you to schedule an appointment approximately 3 months before you deploy and 4 months after you return to:

+ Measure height weight and blood pressure.
+ Assess fitness by a step test.
+ Assess lung function by spirometry.
+ Collect 40ml of blood to assess blood cells, chemistry, and infections (blood will be stored for up to 10 years).
+ Provide a saliva sample.
+ Undertake a cognitive test.
+ Photograph back, hand, feet and cheek to assess skin conditions that develop on deployment.

This testing will take about 2 hours and will be completed at your base. Detailed information is provided on the attached physical assessment information sheet. Any abnormal results will be reported directly to you.

CONSENT TO LINK TO HEALTH RECORDS

If you participate, you will also be asked to let CMVH researchers link your study data to:

a. ADF health and psychological records.

b. Special disease or treatment registration systems, including diabetes and cancer registers; infectious diseases notification; disability information; radiotherapy, injury, midwives and birth defects data; and dialysis and transplant register.

BE CONTACTED FOR FOLLOW-UP STUDIES

We would like your permission to contact you in the future to invite you for other voluntary studies such as:

+ a telephone interview about your health and wellbeing;
+ family studies;
+ longer term health outcomes that may become apparent as veterans age.

Appendix 2J: Information Sheet for SF Personnel Eligible for MEAO Prospective Study Questionnaire, Physical Testing and Neurocognitive Testing

YOUR PRIVACY

Your contact details have been obtained from the Department of Defence. Your details will not be forwarded to any other individual or agency, and will only be used for the purposes of the CMVH MilHOP studies and no other, without your express permission and subject to separate consent.

+ To ensure your privacy you have been given a study number
+ You will not be personally identified in any reports or articles
+ Information you provide is de-identified, and only re-identifiable by the research staff. Individual information is not passed on to the Departments of Defence or Veterans' Affairs, except by court order
+ Your data is only accessed by personnel with the appropriate security clearance, and is stored in secured facilities at the CMVH
+ Data we collect about your physical health including biological samples is stored in a de-identified manner and only reidentifiable by the research staff.

ACCESSING YOUR INFORMATION

You have the right to access the information that is collected from you to assist with your medical care in the future by contacting the study team.

For questions, problems or concerns, or to have your name removed from the mailing list please contact the following:

+ **The Study Team**
  The Centre for Military and Veterans' Health
  Freecall: 1800 ??? ???
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+ **Principal Investigator: Prof Alexander McFarlane,**
  University of Adelaide (08) 83035364
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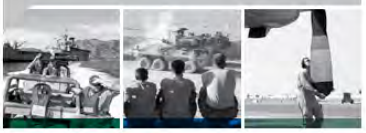
  Executive Secretary
  (02) 6266 3837; ADHREC@defence.gov.au
+ **The University of Adelaide Research Branch**
  Secretary Human Research Ethics Committee
  (08) 8303 6028
+ **The Department of Veterans' Affairs Human Research Ethics Committee**
  HREC Coordinator
  (02) 6289 6204; ethics.committee@dva.gov.au

INFORMATION SHEET FOR THE MEAO PROSPECTIVE HEALTH STUDY QUESTIONNAIRE, PHYSICAL, AND NEUROCOGNITIVE TESTS

CMVH
CENTRE FOR MILITARY & VETERANS' HEALTH



MilHOP
Military Health Outcomes Program

Information Sheet-MeaoPros-PT-CD-20110615-V18

THE AIM OF THIS STUDY

You are invited to participate in a health study. This study is being conducted to better understand the health of members deployed to the Middle East. It forms part of the Federal Government's commitment to conduct health reviews of deployed personnel.

Responses will be analysed to determine how deployment and roles in the military impact on health and military careers.

WARFARE HAS CHANGED
We need YOU to give us a better understanding of the pressures and what you've been through

PARTICIPATION IS ENTIRELY VOLUNTARY

Your participation or non-participation will not be notified to the Department of Defence or the Department of Veterans' Affairs.

If you're in receipt of a Service-related pension, a decision not to participate, or to withdraw, will not lead to any detriment to your career or future health care or entitlements.

If you have a claim for compensation or are in receipt of a pension from the Department of Veterans' Affairs, a decision not to participate will not in any way affect your pension or compensation.

If you do choose to participate, you may withdraw from the study at any time.

You may choose which parts of the study you wish to participate in on the consent form.

BENEFITS AND RISKS OF PARTICIPATING

Your information will contribute to increased knowledge about Service-related health and ill-health. It may also assist the ADF in developing the most appropriate supportive and protective measures against future health threats. We cannot predict how the results of this study will impact to the advantage or disadvantage of veterans collectively in any future unknown context where issues of service-related ill health might arise. This survey is an opportunity for your own experience to contribute to the overall results.

We have many stringent processes in place to protect the confidentiality of the information you give us (see under "Your Privacy").

While there are not expected to be any risks associated with the study, there may be some questions you find distressing. Should you feel distressed, you may wish to discuss this with someone. A list of services is provided in this information sheet in case you require them.

STUDY FINDINGS

The study results will be fed back to you and made available on our website (www.cmvh.org.au).

Any reports prepared for Joint Health Command are presented as group data only, not individual data which identifies you. Group results will also be published in the medical and scientific literature.

WHO IS CONDUCTING THE STUDY?

The Centre for Military and Veterans' Health (CMVH) is a collaborative centre of the University of Queensland, University of Adelaide and Charles Darwin University. CMVH has been contracted by the Department of Defence to conduct this study. The study forms part of the Military Health Outcomes Program (MilHOP), an ongoing program aimed at assessing the physical and mental health status of currently serving and ex-serving ADF personnel. This program builds on recent CMVH Health Studies which looked at deployments to the Near North Area of Influence.

WHAT'S INVOLVED?

To participate please complete the consent form where you will be given the opportunity to select each element of the study you wish to take part in. These include:

COMPLETE A QUESTIONNAIRE

You will be asked to complete a questionnaire 3 months before you deploy and 4 months after you return, about:

+ your previous deployments;
+ your health now, and;
+ your deployment experiences.

This will take between 30 minutes and 60 minutes to complete, and can be completed on the web or in hard copy format.

PHYSICAL ASSESSMENT

The research team will contact you to schedule an appointment to:

+ Measure height weight and blood pressure.
+ Assess fitness by a step test.
+ Assess lung function by spirometry.
+ Collect 40ml of blood to assess blood cells, chemistry, and infections (blood will be stored for up to 10 years).
+ Provide a saliva sample.
+ Undertake a cognitive test.
+ Photograph back, hand, feet and cheek to assess skin conditions that develop on deployment.

This testing will take about 2 hours and will be completed at your base. Detailed information is provided on the attached physical assessment information sheet. Any abnormal results will be reported directly to you.

CONSENT TO LINK TO HEALTH RECORDS

If you participate, you will also be asked to let CMVH researchers link your study data to:

a. ADF health and psychological records.

b. Special disease or treatment registration systems, including diabetes and cancer registers; infectious diseases notification; disability information; radiotherapy, injury, midwives and birth defects data; and dialysis and transplant register.

BE CONTACTED FOR FOLLOW-UP STUDIES

We would like your permission to contact you in the future to invite you for other voluntary studies such as:

+ a telephone interview about your health and wellbeing;
+ family studies;
+ longer term health outcomes that may become apparent as veterans age.

Appendix 2K: Supplementary Information Sheet for Non-SF Members Eligible to Take Part in the Physical and Neurocognitive Test

Physical and Neurocognitive Testing Supplementary Information Sheet

Why have I been given this information sheet?

This sheet provides information about the physical, blood and neurocognitive testing components of the MEAO Prospective Health Study. You are one of approximately 750 individuals who have been invited to take part in one or more of these tests. The tests will occur approximately 3 months before your deployment to the MEAO and then again approximately 4 months after you have returned to Australia.

Why are we doing this?

Deployment in the Middle East involves the risk of exposure to a range of infectious, biological and environmental hazards. This suite of tests has been chosen to detect important exposures. The tests also measure a range of baseline blood and biochemical parameters that tell us about the effects of stress on your body. We are interested in measuring these dimensions of your system before you deploy so we can more accurately determine if they have been altered by your deployment and the exposures that you may have faced. We have aimed to make these tests comprehensive for the most probable exposures you face.

What do I need to do?

If you are interested in taking part in one or more of these tests, please indicate this on the attached consent form. A research officer from CMVH will then contact you and your Officer Commanding to schedule a suitable time.

What does physical and blood testing involve?

The physical test will take approximately 2 hours to complete and comprise of:

Lung Function Test

Lung function testing will be conducted by a nurse using spirometry. You will be asked to avoid asthma medication (eg bronchodilators) on the day of screening. Briefly, spirometry involves attaching a nose clip and then making a forced expiratory manoeuvre with maximum effort. You will be asked to perform a minimum of three technically acceptable blows.

Saliva and blood sample

The day before testing you will be given instructions on how to collect a saliva sample in the morning and again in the evening at your home in a special collection tube. You will need to bring this with you the following day when you undertake the physical testing.

During the physical testing, a 40ml blood sample will be collected by a research nurse.

Storage of samples

A sample of your serum will be stored for a period of 10 years. Any additional tests to those listed over the page will only occur with your written consent. You will be notified prior to the sample being discarded after 10 years.

Standardised measurement of height, weight, hip and waist circumference

Your height will be measured using a stadiometer. Weight is measured in kilograms while wearing light clothing and without shoes using electronic scales. Waist and hip circumference will be measured using a tape measure.

Assessment of changes to skin condition

A photograph will be taken of your back, the palms of your hand, the soles of your feet, and your cheek. This is done to determine any dermatological (skin) changes during deployment. You will not be able to be identified from these photographs.

Blood Pressure

Your blood pressure will be taken by a trained research nurse using a calibrated and validated digital sphygmomanometer. It is measured while in a seated position, after 5 minutes rest. BP will be measured from your left arm (unless there is some contraindication (e.g. lymphoedema).

Step test:

The step test is a standardised assessment of your fitness and capacity to sustain effort. Measurement of heart rate in recovery from this test is an objective and efficient way to classify your aerobic fitness and fatigability. You will be asked to step up and back from a 40cm platform for 1 minute.

Pathology testing to be conducted as part of the MEAO Prospective Health Study

Assessment Purpose	What is Assessed
Exposure to Toxins	• *Blood chemistry and liver function* specifically: Sodium, Potassium, Chloride, Bicarbonate, Anion Gap, Glucose, Urea, Creatinine, total Cholesterol, Osmolarity, Urate, Phosphate, calcium, Ionised calcium, Albumin, Globulins, Total Protein, Bilirubin, GGT, ALP, ALT, AST, LD, CK, Magnesium, Amylase, Lipase, and C-Reactive Protein. • *Heavy metal exposure* specifically: Lead • *Organophosphate exposure* specifically: red blood cell cholinesterase
Exposure to Infections	• *Total Cell Count (CBE)* specifically: haemoglobin, red cell count, packed cell volume, mean corpuscular volume, mean corpuscular haemoglobin, mean corpuscular haemoglobin concentration, red cell distribution width, total white cell count and white cell differentiation counts and percentages (neutrophils, lymphocytes, monocytes, eosinophils, basophils and platelets), *Erythrocyte Sedimentation Rate (ESR)* • *Viral infections* specifically: o Epstein-Barr o Cytomegalovirus o Herpes Simplex o Hepatitis C *Bacterial infections* specifically o Mycoplasma o Chlamydia (serology) o Helicobacter pylori (serology) • *Parasitic infections* specifically: Leishmaniasis
Physiological and Immunological changes arising from stress	• *Inflammatory mediators* specifically: Interleukin 1, Interleukin 4 Interleukin 6, C-Reactive Protein, TNF Alpha • *Stress hormones* specifically: cortisol, nor-adrenaline, adrenaline
Effects of the deployed environment	• *Cardiovascular Risk Factors* specifically: Total cholesterol and High Density Lipoproteins, Glycated Haemoglobin • *Dietary Components* specifically: B12 and Folate

What does neurocognitive testing involve?

This test involves being fitted with a cap that measures electrical activity from the brain. The test takes approximately 60 minutes to complete (including instructions and practice time) and includes measuring resting electrical activity, emotion recognition, response inhibition, a measure of target detection and your reaction to a loud sound. These tests are a standard assessment in clinical settings and provide information about the neurophysiology of responses to challenges. At no time will you experience any pain or distress as a result of these tests.

Who do I contact if I have any questions?

Any member of the MEAO Prospective Health Study team can assist you if you have questions. A study team member can be contacted on (free call) 1800 232 904 or email: cmvh@adelaide.edu.au.

The Principal Investigator of the MEAO Health Study is GPCAPT/Professor Alexander (Sandy) McFarlane. Professor McFarlane can be contacted on (08) 8303 5200 or email: alexander.mcfarlane@adelaide.edu.au.

Appendix 2L: Supplementary Information Sheet for SF Members Eligible to Take Part in the Physical and Neurocognitive Tests

Physical and Neurocognitive Testing Supplementary Information Sheet

Why have I been given this information sheet?

This sheet provides information about the physical, blood and neurocognitive testing components of the MEAO Prospective Health Study. You are one of approximately 750 individuals who have been invited to take part in one or more of these tests. The tests will occur approximately 3 months before your deployment to the MEAO and then again approximately 4 months after you have returned to Australia.

Why are we doing this?

Deployment in the Middle East involves the risk of exposure to a range of infectious, biological and environmental hazards. This suite of tests has been chosen to detect important exposures. The tests also measure a range of baseline blood and biochemical parameters that tell us about the effects of stress on your body. We are interested in measuring these dimensions of your system before you deploy so we can more accurately determine if they have been altered by your deployment and the exposures that you may have faced. We have aimed to make these tests comprehensive for the most probable exposures you face.

What do I need to do?

If you are interested in taking part in one or more of these tests, please indicate this on the attached consent form. A research officer from CMVH will then contact you and your Officer Commanding to schedule a suitable time.

What does physical and blood testing involve?

The physical test will take approximately 2 hours to complete and comprise of:

Lung Function Test

Lung function testing will be conducted by a nurse using spirometry. You will be asked to avoid asthma medication (eg bronchodilators) on the day of screening. Briefly, spirometry involves attaching a nose clip and then making a forced expiratory manoeuvre with maximum effort. You will be asked to perform a minimum of three technically acceptable blows.

Saliva and blood sample

The day before testing you will be given instructions on how to collect a saliva sample in the morning and again in the evening at your home in a special collection tube. You will need to bring this with you the following day when you undertake the physical testing.

During the physical testing, a 40ml blood sample will be collected by a research nurse.

Storage of samples

A sample of your serum will be stored for a period of 10 years. Any additional tests to those listed over the page will only occur with your written consent. You will be notified prior to the sample being discarded after 10 years.

Standardised measurement of height, weight, hip and waist circumference

Your height will be measured using a stadiometer. Weight is measured in kilograms while wearing light clothing and without shoes using electronic scales. Waist and hip circumference will be measured using a tape measure.

Assessment of changes to skin condition

A photograph will be taken of your back, the palms of your hand, the soles of your feet, and your cheek. This is done to determine any dermatological (skin) changes during deployment. You will not be able to be identified from these photographs.

Blood Pressure

Your blood pressure will be taken by a trained research nurse using a calibrated and validated digital sphygmomanometer. It is measured while in a seated position, after 5 minutes rest. BP will be measured from your left arm (unless there is some contraindication (e.g. lymphoedema).

Step test:

The step test is a standardised assessment of your fitness and capacity to sustain effort. Measurement of heart rate in recovery from this test is an objective and efficient way to classify your aerobic fitness and fatigability. You will be asked to step up and back from a 40cm platform for 3 minutes.

SF Supplementary Information Physical Test-CB-20100512-v4.docx

Pathology testing to be conducted as part of the MEAO Prospective Health Study

Assessment Purpose	What is assessed
Exposure to Toxins	• *Blood chemistry and liver function* specifically: Sodium, Potassium, Chloride, Bicarbonate, Anion Gap, Glucose, Urea, Creatinine, total Cholesterol, Osmolarity, Urate, Phosphate, calcium, Ionised calcium, Albumin, Globulins, Total Protein, Bilirubin, GGT, ALP, ALT, AST, LD, CK, Magnesium, Amylase, Lipase, and C-Reactive Protein. • *Heavy metal exposure* specifically: Lead • *Organophosphate exposure* specifically: red blood cell cholinesterase
Exposure to Infections	• *Total Cell Count (CBE)* specifically: haemoglobin, red cell count, packed cell volume, mean corpuscular volume, mean corpuscular haemoglobin, mean corpuscular haemoglobin concentration, red cell distribution width, total white cell count and white cell differentiation counts and percentages (neutrophils, lymphocytes, monocytes, eosinophils, basophils and platelets), *Erythrocyte Sedimentation Rate (ESR),* • *Viral infections* specifically: o Epstein-Barr o Cytomegalovirus o Herpes Simplex o Hepatitis C *Bacterial infections* specifically o Mycoplasma o Chlamydia (serology) o Helicobacter pylori (serology) • *Parasitic infections* specifically: Leishmaniasis
Physiological and Immunological changes arising from stress	• *Inflammatory mediators* specifically: Interleukin 1, Interleukin 4, Interleukin 6, C-Reactive Protein, TNF Alpha • *Stress hormones* specifically: cortisol, nor-adrenaline, adrenaline
Effects of the deployed environment	• *Cardiovascular Risk Factors* specifically: Total cholesterol and High Density Lipoproteins, *Glycated Haemoglobin* • *Dietary Components* specifically: B12 and Folate

What does neurocognitive testing involve?

This test involves being fitted with a cap that measures electrical activity from the brain. The test takes approximately 60 minutes to complete (including instructions and practice time) and includes measuring resting electrical activity, emotion recognition, response inhibition, a measure of target detection and your reaction to a loud sound. These tests are a standard assessment in clinical settings and provide information about the neurophysiology of responses to challenges. At no time will you experience any pain or distress as a result of these tests.

Who do I contact if I have any questions?

The study SOC administration team member can be contacted on (free call) 1800 XXX XXX or email: XXXX@adelaide.edu.au

The Principal Investigator of the MEAO Health Study is GPCAPT/Professor Alexander (Sandy) McFarlane. Professor McFarlane can be contacted on (08) 8303 5200 or email: alexander.mcfarlane@adelaide.edu.au.

Appendix 2M: Contact Details Form to Aid Tracking for Future Follow-up Studies

YOUR CONTACT DETAILS

To ensure that we have your correct contact details, please provide your current residential address. Note: to ensure confidentiality of your information, these pages will be removed by the Study team and stored separately from your questionnaire responses. Your questionnaire will be identified by a unique study number only.

If you have changed your name, please provide details here

Previous surname

Given names if different

Please give your current address, contact numbers and email address

Number and Street _____

Suburb / Town _____

State _____ Postcode _____

Mobile phone _____

Home phone _____ Work phone _____

Email _____

Please complete and return in the reply paid envelope provided

ALTERNATIVE CONTACT DETAILS (OPTIONAL)

In case you move and we lose contact with you, please give us the names of up to two relatives or friends who may be able to tell us where you are. These should be people who are at long term addresses but who are not living with you. We would only use these alternative contacts in the event that we could not contact you at the address you have provided on the previous page.

Contact 1

Surname

All given names

Number and Street _____

Suburb / Town _____

State _____ Postcode _____

Mobile phone _____

Home phone _____ Work phone _____

Email _____

Contact 2

Surname

All given names

Number and Street _____

Suburb / Town _____

State _____ Postcode _____

Mobile phone _____

Home phone _____ Work phone _____

Email _____

Appendix 2N: Study Investigators Sheet

STUDY INVESTIGATORS:

Principal Investigator:
Professor Annette Dobson
CMVH, University of Queensland
Ph: (07) 3365 5346
Email: a.dobson@sph.uq.edu.au

Associate Professor Susan Treloar
CMVH, University of Queensland
Ph: (07) 3346 4904
Email: s.treloar@uq.edu.au

Dr Keith Horsley
Medibank HSA
Ph: 0411 264 666
Email: keith.horsley@hasgroup.com.au

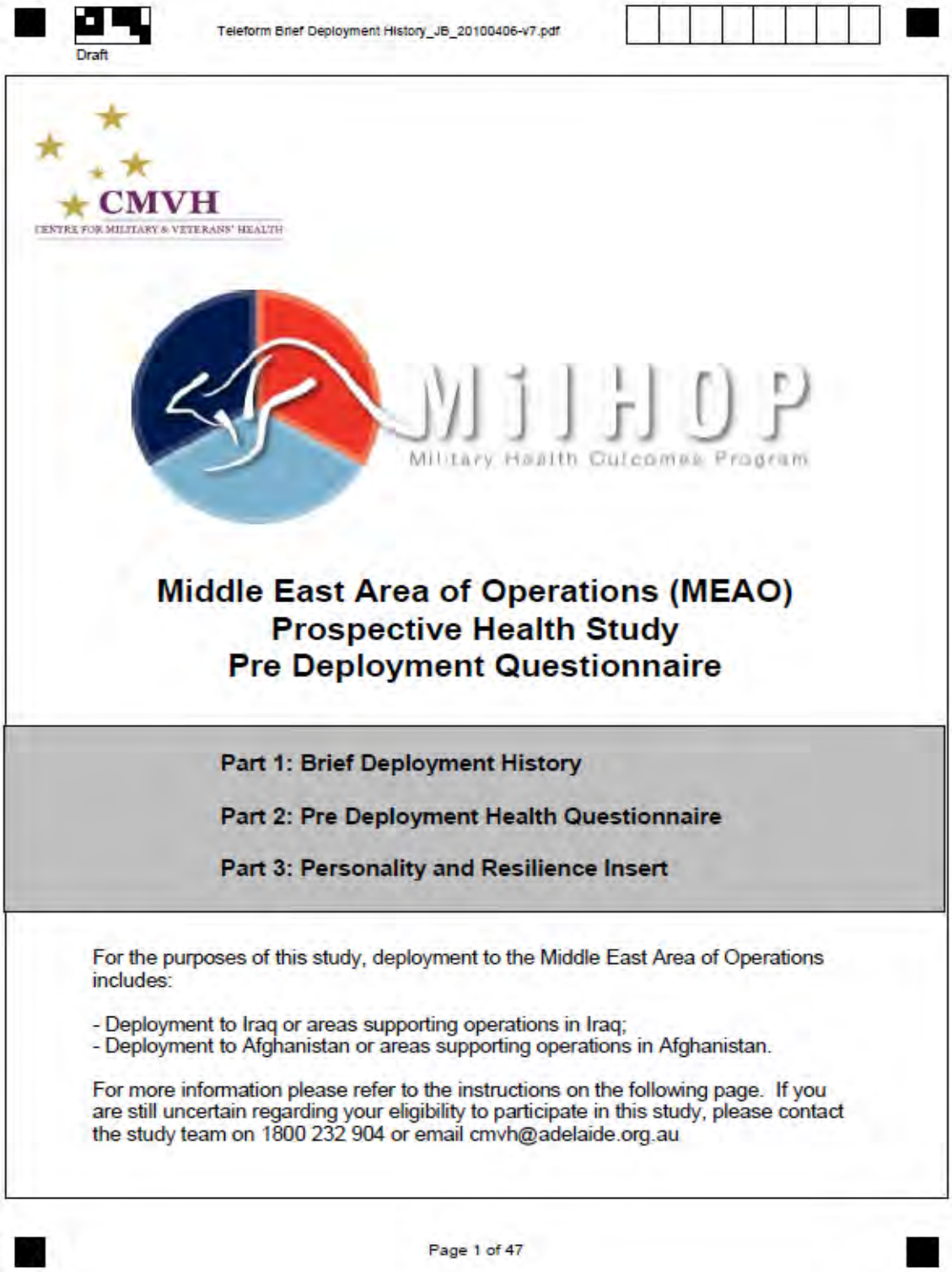
COL/Dr Stephanie Hodson
Directorate of Mental Health, Australian Defence Force
Ph: (02) 6127 2180
Email: stephanie.hodson@defence.gov.au

Professor Harvey Whiteford
Kratzmann Professor of Psychiatry and Population Health
Queensland Centre for Mental Health Research, The University of Queensland
Ph: (07) 3271 8684
Email: h.whiteford@uq.edu.au

Professor Philip Ryan
Director Data Management and Analysis Centre
Ph: (08) 83033570
Email: philip.ryan@adelaide.edu.au

Dr. Carol Davy
Research Fellow Centre for Military and Veterans' Health
Ph: (08) 83130676
Email: carol.davy@adelaide.edu.au

Appendix 2O: MEAO Prospective Health Study Pre-deployment Questionnaire



Instructions to complete this questionnaire:

This questionnaire asks about your physical and mental health. All information you provide in this questionnaire will be de-identified and will not be linked to other data we have collected about your health without your consent.

Please complete all sections by following the instructions at the beginning of each question. Please **shade circles**, rather than ticking or crossing them, and write clearly and in **capital letters**.

Shade Circles Like This--> ●

Not Like This--> ⊗ ✓

A	B	C	D	E	F	G	H	I	J	K	L	M
N	O	P	Q	R	S	T	U	V	W	X	Y	Z

If you make a mistake and wish to change your answer, simply cross out your mistake and choose the answer that is right for you.

Please use **blue or black pen**, not pencil.

Some questions may seem repetitive, but this is necessary due to the questions being grouped into scales.

If you have any questions, please call us on 1800 232 904.

SUPPORT

If you require support in regards to anything in this questionnaire, please refer to the contacts provided below:

ALL HOURS SUPPORT LINE (a confidential telephone triage support service for ADF members and their families)
1800 628 036; outside Australia +61 2 9425 3878

LIFELINE
13 11 14

VETERANS AND VETERANS' FAMILY COUNSELLING SERVICE
1800 011 046

VETERANS' AFFAIRS NETWORK (VAN)
1300 551 918; non-metro 1800 555 254

DEPARTMENT OF VETERANS' AFFAIRS
13 32 54

NATIONAL OFFICE FOR THE MILITARY COMPENSATION AND REHABILITATION SERVICE
1300 550 461

For questions, problems or concerns, or to have your name removed from the mailing list please contact:

THE STUDY TEAM: The Centre for Military and Veterans' Health
Freecall 1800 232 904; cmvh@adelaide.edu.au

PRINCIPAL INVESTIGATOR: Professor Alexander McFarlane, University of Adelaide
(08) 8303 5364; alexander.mcfarlane@adelaide.edu.au

If you prefer to speak to an independent officer of the Universities or Defence Force not involved in the study, you may contact an ethics officer on the numbers listed below:

THE AUSTRALIAN DEFENCE HUMAN RESEARCH ETHICS COMMITTEE
Executive Secretary: (02) 6266 3837; ADHREC@defence.gov.au

THE UNIVERSITY OF ADELAIDE RESEARCH BRANCH
Secretary, Human Research Ethics Committee: (08) 8303 6028

THE UNIVERSITY OF QUEENSLAND BEHAVIOURAL AND SOCIAL SCIENCES ETHICAL REVIEW COMMITTEE
Ethics Officer: (07) 3365 3942; humanethics@research.uq.edu.au

THE DEPARTMENT OF VETERANS' AFFAIRS HUMAN RESEARCH ETHICS COMMITTEE
HREC Coordinator: (02) 6289 6204; ethics.committee@dva.gov.au

Part 1:
Brief Deployment History

Draft

Brief Deployment History - MEAO

1.1 Have you been on an ADF operational deployment? (war-like, peacekeeping, peace-monitoring or humanitarian support)

○ Yes ○ No - **please skip to question 1.7**

Instructions: Please indicate which of the following major operations you have been deployed on (*please complete as much of this information as you can*).

1.2 Deployments to MEAO

COUNTRY	OPERATION NAME	YEAR(S) DEPLOYMENT(S) STARTED	NO. OF TIMES DEPLOYED IN YEAR	TOTAL TIME DEPLOYED (MONTHS)
○ Afghanistan or areas supporting operations in Afghanistan	○ OP SLIPPER	○ 2001		
		○ 2002		
		○ 2003		
		○ 2004		
		○ 2005		
		○ 2006		
		○ 2007		
		○ 2008		
		○ 2009		
		○ 2010		

Draft

Brief Deployment History - MEAO

COUNTRY	OPERATION NAME	YEAR(S) DEPLOYMENT(S) STARTED	NO. OF TIMES DEPLOYED IN YEAR	TOTAL TIME DEPLOYED (MONTHS)
○ Iraq or areas supporting operations in Iraq	○ OP BASTILLE	○ 2002 ○ 2003		
	○ OP FALCONER	○ 2003		
	○ OP CATALYST	○ 2003 ○ 2004 ○ 2005 ○ 2006 ○ 2007 ○ 2008 ○ 2009		
	○ OP KRUGER	○ 2009 ○ 2010		

Thinking about your most recent deployment to the MEAO:

1.3 Did you feel pressure from your unit to volunteer for this deployment?

- ○ Yes, formal chain of command
- ○ Yes, mates within Unit
- ○ No
- ○ Not applicable

1.4 When you deployed, did you deploy with your parent unit?

- ○ Yes
- ○ No, but I deployed with some members from my Unit
- ○ No, I didn't know anyone I deployed with
- ○ Not applicable, did not have a parent unit

If NO:

a) Did you feel you were treated any differently than members of the host unit?

- ○ No, I was treated the same as the members of the host Unit
- ○ Yes, I was treated better than the members of the host Unit
- ○ Yes, I was treated worse than the members of the host Unit

Brief Deployment History - Other Deployments

1.5 Other Deployments:

COUNTRY	OPERATION NAME	YEAR(S) DEPLOYMENT(S) STARTED	NO. OF TIMES DEPLOYED IN YEAR	TOTAL TIME DEPLOYED (MONTHS)
○ Solomon Islands	○ OP ANODE	○ 2003		
		○ 2004		
		○ 2005		
		○ 2006		
		○ 2007		
		○ 2008		
		○ 2009		
		○ 2010		

Brief Deployment History - Other Deployments

COUNTRY	OPERATION NAME	YEAR(S) DEPLOYMENT(S) STARTED	NO. OF TIMES DEPLOYED IN YEAR	TOTAL TIME DEPLOYED (MONTHS)
○ East Timor	○ InterFET, OP FABER, OP SPITFIRE, OP WARDEN	○ 1999 ○ 2000		
	○ OP TANAGER	○ 2000 ○ 2001 ○ 2002		
	○ OP CITADEL	○ 2002 ○ 2003 ○ 2004		
	○ OP SPIRE	○ 2004 ○ 2005 ○ 2006 ○ 2007		
	○ OP ASTUTE, OP CHIRON, OP TOWER	○ 2005 ○ 2006 ○ 2007 ○ 2008 ○ 2009 ○ 2010		

Brief Deployment History - Other Deployments

COUNTRY	OPERATION NAME	YEAR(S) DEPLOYMENT(S) STARTED	NO. OF TIMES DEPLOYED IN YEAR	TOTAL TIME DEPLOYED (MONTHS)
○ Bougainville	○ OP BEL ISI I	○ 1997		
		○ 1998		
	○ OP BEL ISI II	○ 1999		
		○ 2000		
		○ 2001		
		○ 2002		
		○ 2003		

1.6 What other Operations have you been deployed on (war like, peacekeeping, peace-monitoring or humanitarian support), including UN missions (e.g. OP Palate, OP Riverbank), Humanitarian Missions (e.g. OP Pakistan Assist, OP Sumatra Assist), secondments to foreign militaries (e.g. OP Enduring Freedom, OP Herrick), and border protection (e.g. Op Resolute)?

COUNTRY	OPERATION NAME	YEAR(S) DEPLOYMENT(S) STARTED	NO. OF TIMES DEPLOYED IN YEAR	TOTAL TIME DEPLOYED (MONTHS)

Brief Deployment History

1.7 Have you worked in the Middle East in a role outside of the ADF (e.g. as a security contractor or for an NGO)?	○ Yes ○ No

If YES:

COUNTRY (If you do not remember or do not wish to report this please write NA)	COMPANY NAME (If you do not remember or do not wish to report this please write NA)	YEAR(S) STARTED	NO. OF TIMES WORKED IN THIS LOCATION IN YEAR	TOTAL TIME WORKED IN THIS LOCATION (MONTHS)

Part 2: Pre-deployment Health Questionnaire

Draft

Section One: Background Details

1.1 What is today's date? (dd/mm/yyyy) / /

1.2 Are you male or female? ○ Male ○ Female

1.3 What is your date of birth? (dd/mm/yyyy) / /

1.4 Are you currently in a significant intimate relationship?
○ Yes - go to question 1.4a
○ No - go to question 1.4b

1.4a Are you:
○ Married and living together
○ Married with unaccompanied spouse (i.e. married partner currently lives elsewhere)
○ Living with partner (ADF recognised)
○ Living with partner (not ADF recognised)
○ In a long term relationship but not living together

1.4b Are you:
○ Never married
○ Previously married but now divorced
○ Previously married but now separated
○ Other, please specify:

1.5 Were you in a significant intimate relationship ONE YEAR AGO?
○ Yes - go to question 1.5a
○ No - go to question 1.5b

1.5a Were you:
○ Married and living together
○ Married with unaccompanied spouse (i.e. married partner currently lives elsewhere)
○ Living with partner (ADF recognised)
○ Living with partner (not ADF recognised)
○ In a long term relationship but not living together

1.5b Were you:
○ Never married
○ Previously married but now divorced
○ Previously married but now separated
○ Other, please specify:

1.6 How satisfied are you with your marriage / relationship?
○ Extremely satisfied
○ Satisfied
○ Neither satisfied or dissatisfied
○ Dissatisfied
○ Extremely dissatisfied
○ Not applicable

1.7 Have you or your spouse / partner ever seriously suggested the idea of divorce or permanent separation within the LAST YEAR? ○ Yes ○ No ○ Not applicable

Section One: Background Details

1.8 Overall, what impact have your military commitments (now, or in the past if you have left the military) had on your:

a) Marriage / relationship?
- ○ No impact
- ○ Positive impact
- ○ Negative impact
- ○ Not applicable

b) Children?
- ○ No impact
- ○ Positive impact
- ○ Negative impact
- ○ Not applicable

1.9 Which category best describes the highest educational qualification you have completed? Choose one.
- ○ Primary school
- ○ Secondary school up to grade 10
- ○ Secondary school grades 11-12
- ○ Certificate (trade, apprenticeship, technicians etc)
- ○ Diploma (associate, undergraduate)
- ○ Bachelor degree
- ○ Post-graduate qualification

1.10 How many hours per week are you in paid employment, when you are not on deployment? ☐☐☐ hours

1.11 To the nearest year, how long have / had you served with the Australian Defence Force: (if less than 1 year, please enter 1)

a) As a regular? ☐☐ years *or* ○ Not applicable

b) As a reservist? ☐☐ years *or* ○ Not applicable

1.12 What is your CURRENT rank or what WAS your rank when you left the military?
- ○ Senior Commissioned Officer (CMDR / LTCOL / WGCDR and above)
- ○ Commissioned Officer (LCDR / MAJ / SQNLDR and below)
- ○ Senior Non-Commissioned Officer (PO / SGT and above)
- ○ Junior Non-Commissioned Officer (LS / CPL and below)
- ○ Other ranks (AB / SMN / PTE / LAC / AC or equivalent)

1.13 In the past THREE YEARS, roughly how many months in total have you been away on Operational deployment? (if less than 1 month, please enter 1) ☐☐ months

If you are still a member of the regular Australian Defence Force, please go to Section Two.

If you are a Reservist or have discharged from the regular Australian Defence Force, please complete the following questions.

Section One: Background Details

1.14 What year did you discharge from the Regular Australian Defence Force?

or

○ Not applicable, I am a Reservist

1.15 Did you discharge to the Reserves or out of the ADF completely? ○ Reserves ○ Out of ADF ○ Not applicable, I have always been a reservist

1.16 What is your current employment status?

○ Paid employment full-time
○ Paid employment part-time / casual
○ Volunteer / community work
○ Student
○ Home Duties
○ Retired
○ Not working due to ill-health / TPI
○ Unemployed
○ Other, please specify:

1.17 Since you separated from the ADF, have you had a period of unemployment greater than 3 months? ○ Yes ○ No ○ Not applicable

If YES, was this period of unemployment primarily due to health problems? ○ Yes ○ No

If YES, please specify type:

1.18 What is your main source of income now? Choose one.

○ Wage or salary
○ Own business or share in a partnership
○ Age Service pension
○ Invalidity Service Pension
○ Compensation benefit under the VEA
○ Compensation benefit under the SRCA
○ Compensation benefit under the MRCA
○ Other government pension / allowance / benefit
○ Child allowance
○ Superannuation / annuity
○ Dividends / interest / income from investments
○ Other, please specify:

Section Two: Recent Health Symptoms

We would like to know about your health in the past month. Please indicate whether or not you have suffered any of the following symptoms in the past month, and if so, please indicate whether your symptoms were mild, moderate or severe in nature.

In the past month have you suffered from:	NO	YES		
2.1 Chest pain	O No	O Mild	O Moderate	O Severe
2.2 Headaches	O No	O Mild	O Moderate	O Severe
2.3 Rapid heartbeat	O No	O Mild	O Moderate	O Severe
2.4 Irritability / outbursts of anger	O No	O Mild	O Moderate	O Severe
2.5. Unable to breathe deeply enough	O No	O Mild	O Moderate	O Severe
2.6 Faster breathing than normal	O No	O Mild	O Moderate	O Severe
2.7 Feeling short of breath at rest	O No	O Mild	O Moderate	O Severe
2.8 Wheezing	O No	O Mild	O Moderate	O Severe
2.9 Sleeping difficulties	O No	O Mild	O Moderate	O Severe
2.10 Feeling jumpy / easily startled	O No	O Mild	O Moderate	O Severe
2.11 Feeling unrefreshed after sleep	O No	O Mild	O Moderate	O Severe
2.12 Fatigue	O No	O Mild	O Moderate	O Severe
2.13 Double vision	O No	O Mild	O Moderate	O Severe
2.14 Intolerance to alcohol	O No	O Mild	O Moderate	O Severe
2.15 Itchy or painful eyes	O No	O Mild	O Moderate	O Severe
2.16 Rash or skin irritation	O No	O Mild	O Moderate	O Severe
2.17 Skin infections e.g. boils	O No	O Mild	O Moderate	O Severe
2.18 Skin ulcers	O No	O Mild	O Moderate	O Severe
2.19 Shaking	O No	O Mild	O Moderate	O Severe
2.20 Tingling in fingers and arms	O No	O Mild	O Moderate	O Severe
2.21 Tingling in legs and toes	O No	O Mild	O Moderate	O Severe
2.22 Numbness in fingers / toes	O No	O Mild	O Moderate	O Severe
2.23 Feeling distant or cut off from others	O No	O Mild	O Moderate	O Severe
2.24 Constipation	O No	O Mild	O Moderate	O Severe
2.25 Flatulence or burping	O No	O Mild	O Moderate	O Severe

Section Two: Recent Health Symptoms

In the past month have you suffered from:	NO	YES		
2.26 Stomach cramps	O No	O Mild	O Moderate	O Severe
2.27 Diarrhoea	O No	O Mild	O Moderate	O Severe
2.28 Indigestion	O No	O Mild	O Moderate	O Severe
2.29 Dry mouth	O No	O Mild	O Moderate	O Severe
2.30 Pain in the face, jaw, in front of the ear, or in the ear	O No	O Mild	O Moderate	O Severe
2.31 Persistent cough	O No	O Mild	O Moderate	O Severe
2.32 Lump in throat	O No	O Mild	O Moderate	O Severe
2.33 Sore throat	O No	O Mild	O Moderate	O Severe
2.34 Forgetfulness	O No	O Mild	O Moderate	O Severe
2.35 Dizziness, fainting or blackouts	O No	O Mild	O Moderate	O Severe
2.36 Seizures or convulsions	O No	O Mild	O Moderate	O Severe
2.37 Feeling disorientated	O No	O Mild	O Moderate	O Severe
2.38 Loss of concentration	O No	O Mild	O Moderate	O Severe
2.39 Difficulty finding the right word	O No	O Mild	O Moderate	O Severe
2.40 Pain on passing urine	O No	O Mild	O Moderate	O Severe
2.41 Passing urine more often	O No	O Mild	O Moderate	O Severe
2.42 Burning sensation in the sex organs	O No	O Mild	O Moderate	O Severe
2.43 Loss of interest in sex	O No	O Mild	O Moderate	O Severe
2.44 Problems with sexual functioning	O No	O Mild	O Moderate	O Severe
2.45 Increased sensitivity to noise	O No	O Mild	O Moderate	O Severe
2.46 Increased sensitivity to light	O No	O Mild	O Moderate	O Severe
2.47 Increased sensitivity to smells or odours	O No	O Mild	O Moderate	O Severe
2.48 Ringing in the ears	O No	O Mild	O Moderate	O Severe
2.49 Avoiding doing things or situations	O No	O Mild	O Moderate	O Severe
2.50 Pain, without swelling or redness, in several joints	O No	O Mild	O Moderate	O Severe
2.51 Joint stiffness	O No	O Mild	O Moderate	O Severe
2.52 Feeling that your bowel movement is not finished	O No	O Mild	O Moderate	O Severe

Section Two: Recent Health Symptoms

In the past month have you suffered from:	NO	YES		
2.53 Changeable bowel function (mixture of diarrhoea / constipation)	O No	O Mild	O Moderate	O Severe
2.54 General muscle aches or pains	O No	O Mild	O Moderate	O Severe
2.55 Loss of balance or coordination	O No	O Mild	O Moderate	O Severe
2.56 Difficulty speaking	O No	O Mild	O Moderate	O Severe
2.57 Low back pain	O No	O Mild	O Moderate	O Severe
2.58 Night sweats which soak the bed sheets	O No	O Mild	O Moderate	O Severe
2.59 Feeling feverish	O No	O Mild	O Moderate	O Severe
2.60 Tender or painful swelling of lymph glands in neck, armpit or groin	O No	O Mild	O Moderate	O Severe
2.61 Loss of, or decrease in, appetite	O No	O Mild	O Moderate	O Severe
2.62 Nausea	O No	O Mild	O Moderate	O Severe
2.63 Vomiting	O No	O Mild	O Moderate	O Severe
2.64 Distressing dreams	O No	O Mild	O Moderate	O Severe
2.65 Stomach bloating	O No	O Mild	O Moderate	O Severe
2.66 Unintended weight gain greater than 4kg	O No	O Mild	O Moderate	O Severe
2.67 Unintended weight loss greater than 4kg	O No	O Mild	O Moderate	O Severe

Section Two: Recent Health Symptoms

2.68 During your lifetime, did you experience any of the following events?		
Blast or Explosion IED (improvised explosive device)	○ No	○ Yes
RPG (rocket propelled grenade), Land Mine, Grenade, etc.	○ No	○ Yes
Vehicular accident / crash (any vehicle, including aircraft)	○ No	○ Yes
Fragment wound or bullet wound above the shoulders	○ No	○ Yes
Fall	○ No	○ Yes

If NO to all events in 2.68: please skip to question 3.1. Otherwise, continue.

2.69 How many times in total have you experienced each of the following symptoms immediately after any of the events listed above?		
Loss of consciousness / "knocked out"		times
Being dazed, confused, or "seeing stars"		times
Not remembering the event		times
Concussion		times
Head injury		times

2.70 Did any of the following problems begin or get worse after any of the events listed above?					
Memory problems or lapses	○ No	○ Yes	Irritability	○ No	○ Yes
Balance problems or dizziness	○ No	○ Yes	Headaches	○ No	○ Yes
Sensitivity to bright light	○ No	○ Yes	Sleep problems	○ No	○ Yes

2.71 In the past week, have you had any of these symptoms?					
Memory problems or lapses	○ No	○ Yes	Irritability	○ No	○ Yes
Balance problems or dizziness	○ No	○ Yes	Headaches	○ No	○ Yes
Sensitivity to bright light	○ No	○ Yes	Sleep problems	○ No	○ Yes

Section Three: Your Health Now

This next set of questions ask for your views about your health. This information will help you to keep track of how you feel and how well you are able to do your usual activities.

For each of the following questions, please shade the circle that best describes your answer.

3.1 In general, how would you say your health is? ○ Excellent ○ Very good ○ Good ○ Fair ○ Poor

3.2 The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf?	○ Yes, limited a lot	○ Yes, limited a little	○ No, not limited at all
Climbing several flights of stairs?	○ Yes, limited a lot	○ Yes, limited a little	○ No, not limited at all

3.3 During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	ALL OF THE TIME	MOST OF THE TIME	SOME OF THE TIME	A LITTLE OF THE TIME	NONE OF THE TIME
Accomplished less than you would like	○	○	○	○	○
Were limited in the kind of work or other activities	○	○	○	○	○

3.4 During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	ALL OF THE TIME	MOST OF THE TIME	SOME OF THE TIME	A LITTLE OF THE TIME	NONE OF THE TIME
Accomplished less than you would like	○	○	○	○	○
Did work or other activities less carefully than usual	○	○	○	○	○

3.5 During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

○ Not at all ○ A little bit ○ Moderately ○ Quite a bit ○ Extremely

3.6 These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

	ALL OF THE TIME	MOST OF THE TIME	SOME OF THE TIME	A LITTLE OF THE TIME	NONE OF THE TIME
Have you felt calm and peaceful?	○	○	○	○	○
Did you have a lot of energy?	○	○	○	○	○
Have you felt downhearted and depressed?	○	○	○	○	○

3.7 During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives etc.)?

○ All of the time ○ Most of the time ○ Some of the time ○ A little of the time ○ None of the time

Section Three: Your Health Now

In general, how would you rate your:	EXCELL-ENT	VERY GOOD	GOOD	FAIR	POOR
3.8 Overall health?	○	○	○	○	○
3.9 Quality of life?	○	○	○	○	○
3.10 Eyesight (with glasses or contact lenses, if you wear them)?	○	○	○	○	○
3.11 Hearing?	○	○	○	○	○
3.12 Memory?	○	○	○	○	○
3.13 Teeth and gums?	○	○	○	○	○

The following questions inquire about how you have been feeling over the last four (4) weeks. Please read each question carefully and then indicate, by shading the circle, the response that best describes how you have been feeling.	ALL OF THE TIME	MOST OF THE TIME	SOME OF THE TIME	A LITTLE OF THE TIME	NONE OF THE TIME
3.14 In the past four (4) weeks, about how often did you feel tired for no good reason?	○	○	○	○	○
3.15 In the past four (4) weeks, about how often did you feel nervous?	○	○	○	○	○
3.16 In the past four (4) weeks, about how often did you feel so nervous that nothing could calm you down?	○	○	○	○	○
3.17 In the past four (4) weeks, about how often did you feel hopeless?	○	○	○	○	○
3.18 In the past four (4) weeks, about how often did you feel restless or fidgety?	○	○	○	○	○
3.19 In the past four (4) weeks, about how often did you feel so restless that you could not sit still?	○	○	○	○	○
3.20 In the past four (4) weeks, about how often did you feel depressed?	○	○	○	○	○
3.21 In the past four (4) weeks, about how often did you feel that everything was an effort?	○	○	○	○	○
3.22 In the past four (4) weeks, about how often did you feel so sad that nothing could cheer you up?	○	○	○	○	○
3.23 In the past four (4) weeks, about how often did you feel worthless?	○	○	○	○	○

Section Three: Your Health Now

The next few questions are about how these feelings may have affected you in the past four (4) weeks. You need not answer these questions if you answered 'None of the time' to all of the previous ten questions about your feelings.

3.24 In the past four (4) weeks, how many days were you TOTALLY UNABLE to work, study or manage your day to day activities because of these feelings? ☐☐ days

3.25 [Aside from those days], in the past four (4) weeks, HOW MANY DAYS were you able to work or study or manage your day to day activities, but had to CUT DOWN on what you did because of these feelings? ☐☐ days

3.26 In the past four (4) weeks, how many times have you seen a doctor or any other health professional about these feelings? ☐☐ times

3.27 In the past four (4) weeks, how often have physical health problems been the main cause of these feelings?

○ None of the time ○ A little of the time ○ Some of the time ○ Most of the time ○ All of the time

3.28 Please rate the following statements based on how you have felt in the <u>past 30 days</u> using the scale below.

	NOT TRUE AT ALL	RARELY TRUE	SOME-TIMES TRUE	OFTEN TRUE	TRUE NEARLY ALL THE TIME
a) I am able to adapt to change	○	○	○	○	○
b) I tend to bounce back after illness or hardship	○	○	○	○	○

Section Three: Your Health Now

Since returning from your last MEAO deployment, has a medical doctor diagnosed you with, or treated you for any of the following medical problems or conditions?

	YES	NO
3.29 High blood pressure	O	O
3.30 Migraines	O	O
3.31 Bowel disorder e.g. diarrhoea, constipation, bleeding	O	O
3.32 Eye or vision problems e.g. glaucoma	O	O
3.33 Hearing loss	O	O
3.34 Malaria	O	O
3.35 Any other significant infections, please specify type:	O	O
3.36 Arthritis or rheumatism	O	O
3.37 Back or neck problems	O	O
3.38 Joint problems	O	O
3.39 Asthma	O	O
3.40 Bronchitis	O	O
3.41 Sinus problems	O	O
3.42 Hay fever	O	O
3.43 Ear infection	O	O
3.44 Dermatitis	O	O
3.45 Any other skin problem, please specify type:	O	O
3.46 Skin cancer e.g. squamous cell or basal cell skin cancers	O	O
3.47 Any other kind of cancer, tumour or malignancy, please specify type:	O	O
3.48 Anxiety, stress or depression	O	O
3.49 Post traumatic stress disorder	O	O

Section Three: Your Health Now

	YES	NO
3.50 Other psychiatric or psychological condition needing treatment or counselling, please specify type:	○	○
3.51 Any other medical condition, please specify type:	○	○

Section Four: Lifestyle Behaviours

4.1 In the past year, have you used any of the following tobacco products?

	NO	YES
a. Cigarettes	○	○
b. Cigars	○	○
c. Pipes	○	○
d. Smokeless tobacco (e.g. chew, dip, snuff)	○	○

4.2 In your lifetime, have you smoked at least 100 cigarettes (5 packs)?

○ No - **please skip to question 4.9**

○ Yes - **continue to next question**

4.3 At what age did you start smoking? ☐☐ years old

4.4 How many years have you, or did you, smoke an average of at least 3 cigarettes per day (or one pack per week)? ☐☐ years

4.5 When smoking, how many packs per day did you, or do you, smoke?

○ Less than half a pack per day
○ Half to 1 pack per day
○ 1 to 2 packs per day
○ More than 2 packs per day

4.6 Have you ever tried to quit smoking?

○ Yes, and succeeded
○ Yes, but not successfully
○ No

4.7 If you have ever deployed, was your smoking pattern different while on deployment?

○ I have never deployed
○ I did not smoke on deployment
○ I smoked less than usual while on deployment
○ I smoked the same amount on deployment as when not deployed
○ I smoked more than usual while on deployment
○ I began / restarted smoking on deployment

4.8 If your smoking pattern changed during your deployment, what was the main reason?

Section Four: Lifestyle Behaviours

4.9. How often do you have a drink containing alcohol?	Never	Monthly or Less	2 to 4 times a month	2 to 3 times a week	4 or more times a week
	○	○	○	○	○

In answering the following questions, please remember that a standard drink contains 10g of pure alcohol

Standard Drinks Guide

4.10 How many 'standard' drinks (see above) containing alcohol do you have on a typical day when you are drinking?	1 or 2	3 or 4	5 or 6	7 to 9	10 or more	N/A
	○	○	○	○	○	○

	NEVER	LESS THAN MONTHLY	MONTHLY	WEEKLY	DAILY OR ALMOST DAILY
4.11 How often do you have six or more drinks on one occasion?	○	○	○	○	○
4.12 How often during the last 12 months have you found that you were not able to stop drinking once you had started?	○	○	○	○	○
4.13 How often during the last 12 months have you failed to do what was normally expected from you because of drinking?	○	○	○	○	○

Section Four: Lifestyle Behaviours

	NEVER	LESS THAN ONCE A MONTH	MONTHLY	WEEKLY	DAILY OR ALMOST DAILY
4.14 How often during the last 12 months have you needed a drink in the morning to get yourself going after a heavy drinking session?	○	○	○	○	○
4.15 How often during the last 12 months have you had a feeling of guilt or remorse after drinking?	○	○	○	○	○
4.16 How often during the last 12 months have you been unable to remember what happened the night before because you had been drinking?	○	○	○	○	○

4.17 Have you or someone else been injured as a result of your drinking?	No ○	Yes, but not in the last 12 months ○	Yes, during the last 12 months ○
4.18 Has a relative, a friend, a doctor or other health professional been concerned about your drinking or suggested you cut down?	No ○	Yes, but not in the last 12 months ○	Yes, during the last 12 months ○

4.19 Do you presently have a problem with drinking?	No ○	Probably not ○	Unsure ○	Possibly ○	Definitely ○

4.20 In the next 3 months, how difficult would you find it to cut down or stop drinking?	Very easy ○	Fairly easy ○	Neither difficult nor easy ○	Fairly difficult ○	Very difficult ○	N/A ○

4.21 On an average day, how many 250 - 375ml beverages containing caffeine do you drink (such as caffeine containing energy drinks, coffee, tea, coca-cola)?

○ None ○ 1-2 per day ○ 3-5 per day ○ 6-10 per day ○ 11 or more per day

Section Four: Lifestyle Behaviours

4.22 Do you currently take any of the following supplements?

a) Body building supplements (such as amino acids, weight gain products, creatine, etc.)

O Never O Less than once a month O Monthly O Weekly O Daily or almost daily

If YES, what was the name (generic or brand name) of the supplement that you used?

b) Energy supplements (such as energy drinks, pills, or energy enhancing herbs)

O Never O Less than once a month O Monthly O Weekly O Daily or almost daily

If YES, what was the name (generic or brand name) of the supplement that you used?

c) Weight loss supplements

O Never O Less than once a month O Monthly O Weekly O Daily or almost daily

If YES, what was the name (generic or brand name) of the supplement that you used?

In the last 12 months...

	NEVER	SOMETIMES	MOST OF THE TIME	ALMOST ALWAYS
4.23 Have you bet more than you could really afford to lose?	O	O	O	O
4.24 Have you needed to gamble with larger amounts of money to get the same feeling of excitement?	O	O	O	O
4.25 When you gambled, did you go back another day to try to win back the money you lost?	O	O	O	O
4.26 Have you borrowed money or sold anything to get money to gamble?	O	O	O	O
4.27 Have you felt that you might have a problem with gambling?	O	O	O	O
4.28 Has gambling caused you any health problems, including stress or anxiety?	O	O	O	O
4.29 Have people criticized your betting or told you that you had a gambling problem, regardless of whether or not you thought it was true?	O	O	O	O
4.30 Has your gambling caused any financial problems for you or your household?	O	O	O	O
4.31 Have you felt guilty about the way you gamble or what happens when you gamble?	O	O	O	O

Section Five: Life Experiences

Below is a list of problems and complaints that people sometimes have in response to stressful life experiences. Please read each one carefully, then shade the circle to the right to indicate how much you have been bothered by that problem in the past month.

	NOT AT ALL	A LITTLE BIT	MODERA-TELY	QUITE A BIT	EXTREM-ELY
5.1 Repeated, disturbing memories, thoughts or images of a stressful experience from the past?	○	○	○	○	○
5.2 Repeated, disturbing dreams of a stressful experience from the past?	○	○	○	○	○
5.3 Suddenly acting or feeling as if a stressful experience from the past were happening again (as if you were reliving it)?	○	○	○	○	○
5.4 Feeling very upset when something reminded you of a stressful experience from the past?	○	○	○	○	○
5.5 Having physical reactions (e.g. heart pounding, trouble breathing, sweating) when something reminded you of a stressful experience from the past?	○	○	○	○	○
5.6 Avoiding thinking about or talking about a stressful experience from the past or avoiding having feelings related to it?	○	○	○	○	○
5.7 Avoiding activities or situations because they reminded you of a stressful experience from the past?	○	○	○	○	○
5.8 Trouble remembering important parts of a stressful experience from the past?	○	○	○	○	○
5.9 Loss of interest in activities that you used to enjoy?	○	○	○	○	○
5.10 Feeling distant or cut off from other people?	○	○	○	○	○
5.11 Feeling emotionally numb or being unable to have loving feelings for those close to you?	○	○	○	○	○
5.12 Feeling as if your future somehow will be cut short?	○	○	○	○	○
5.13 Trouble falling or staying asleep?	○	○	○	○	○
5.14 Feeling irritable or having angry outbursts?	○	○	○	○	○
5.15 Having difficulty concentrating?	○	○	○	○	○
5.16 Being "superalert" or watchful or on guard?	○	○	○	○	○
5.17 Feeling jumpy or easily startled?	○	○	○	○	○

Section Five: Life Experiences

Below is a list of problems and complaints that people sometimes have in response to stressful life experiences. Please read each one carefully, then shade the circle to the right to indicate how much you have been bothered by that problem in the past month.

	NOT AT ALL	A LITTLE BIT	MODERA-TELY	QUITE A BIT	EXTREM-ELY
5.17a Having strong negative beliefs about yourself, other people, or the world (for example, having thoughts such as: I am bad, there is something seriously wrong with me, no one can be trusted, the world is completely dangerous)?	O	O	O	O	O
5.17b Blaming yourself or someone else severely for the stressful experience or what happened after it?	O	O	O	O	O
5.17c Having strong negative feelings such as fear, horror, anger, guilt, or shame?	O	O	O	O	O
5.17d Taking too many risks or doing things that cause you harm?	O	O	O	O	O

5.18 Thinking of the event(s) that you used to answer questions 5.1 - 5.17d, please list these events and the years they occurred below.

	Event description	Year
1		
2		
3		

5.19 Did this occur while deployed to the MEAO? O Yes O No

5.20 **If NO**, did this occur during another overseas deployment? O Yes O No

5.21 Is there any other event that has caused you to have similar reactions?

O No
O Yes - while deployed
O Yes - while NOT deployed

If yes, what was that event?

Year of event

Section Five: Life Experiences

5.22 Thinking over the past 4 weeks, shade the circle that best describes the amount of time you felt that way.	NONE OF THE TIME	A LITTLE OF THE TIME	SOME OF THE TIME	MOST OF THE TIME	ALL OF THE TIME
a) I found myself getting angry at people or situations	O	O	O	O	O
b) When I got angry, I got really mad	O	O	O	O	O
c) When I got angry, I stayed angry	O	O	O	O	O
d) When I got angry at someone, I wanted to hit them	O	O	O	O	O
e) My anger interfered with my ability to get my work, study or other productive activity done	O	O	O	O	O
f) My anger prevented me from getting along with people as well as I'd have liked to	O	O	O	O	O
g) I became angry at myself when I did not perform as well or achieve what I wanted	O	O	O	O	O
h) I became angry at myself when I did not handle social situations as well as I wanted	O	O	O	O	O
i) My anger had a bad effect on my health	O	O	O	O	O

5.23 How often over the last month did you get into a fight with someone and hit the person?

O Never O One time O Two times O Three or four times O Five or more times

5.24 How often over the last month did you threaten someone with physical violence?

O Never O One time O Two times O Three or four times O Five or more times

Section Five: Life Experiences

Over the last 2 weeks, how often have you been bothered by any of the following problems?

	NOT AT ALL	SEVERAL DAYS	MORE THAN HALF THE DAYS	NEARLY EVERY DAY
5.25 Little interest or pleasure in doing things	○	○	○	○
5.26 Feeling down, depressed, or hopeless	○	○	○	○
5.27 Trouble falling or staying asleep, or sleeping too much	○	○	○	○
5.28 Feeling tired or having little energy	○	○	○	○
5.29 Poor appetite or overeating	○	○	○	○
5.30 Feeling bad about yourself, or that you are a failure, or have let yourself or your family down	○	○	○	○
5.31 Trouble concentrating on things, such as reading the newspaper or watching television	○	○	○	○
5.32 Moving or speaking so slowly that other people could have noticed? Or the opposite - being so fidgety or restless that you have been moving around a lot more than usual	○	○	○	○
5.33 Thoughts that you would be better off dead or of hurting yourself in some way	○	○	○	○

5.34 If you checked off any of these problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

○ Not difficult at all ○ Somewhat difficult ○ Very difficult ○ Extremely difficult

The next group of questions are about anxiety.

	NO	YES
5.35 In the last 4 weeks, have you had an anxiety attack - suddenly feeling fear or panic?	○	○
If NO: please skip to question 5.50		
5.36 Has this ever happened before?	○	○
5.37 Do some of these attacks come suddenly out of the blue - that is, in situations where you don't expect to be nervous or uncomfortable?	○	○
5.38 Do these attacks bother you a lot or are you worried about having another attack?	○	○

Section Five: Life Experiences

Think about your last bad anxiety attack.		
	NO	YES
5.39 Were you short of breath?	○	○
5.40 Did your heart race, pound, or skip?	○	○
5.41 Did you have chest pain or pressure?	○	○
5.42 Did you sweat?	○	○
5.43 Did you feel as if you were choking?	○	○
5.44 Did you have hot flushes or chills?	○	○
5.45 Did you have nausea or an upset stomach, or the feeling that you were going to have diarrhoea?	○	○
5.46 Did you feel dizzy, unsteady, or faint?	○	○
5.47 Did you have tingling or numbness in parts of your body?	○	○
5.48 Did you tremble or shake?	○	○
5.49 Were you afraid you were dying?	○	○

Over the last 4 weeks, how often have you been bothered by any of the following problems?			
	NOT AT ALL	SEVERAL DAYS	MORE THAN HALF THE DAYS
5.50 Feeling nervous, anxious, on edge, or worrying a lot about different things	○	○	○
If NOT AT ALL: please skip to question 5.57			
5.51 Feeling restless so that it is hard to sit still	○	○	○
5.52 Getting tired very easily	○	○	○
5.53 Muscle tension, aches, or soreness	○	○	○
5.54 Trouble falling asleep or staying asleep	○	○	○
5.55 Trouble concentrating on things, such as reading a book or watching TV	○	○	○
5.56 Becoming easily annoyed or irritable	○	○	○

Section Five: Life Experiences

Please shade the circles that best describe your experience.		
5.57 In the last 12 months, have you ever felt that life was not worth living?	○ No	○ Yes
5.58 In the last 12 months, have you ever felt so low that you thought about committing suicide?	○ No	○ Yes
5.59 In the last 12 months, have you made a suicide plan?	○ No	○ Yes
5.60 In the last 12 months, have you attempted suicide?	○ No	○ Yes

If you require support in relation to any issues you have identified in this survey, we encourage you to refer to the contacts provided on Page 3.

Section Six: Your Respiratory Health

The following questions ask you about any respiratory symptoms you may have experienced in the past 12 months.		
	NO	**YES**
6.1 Have you had wheezing or whistling in your chest at any time in the last 12 months?	○	○
If YES:		
a. Have you been at all breathless when the wheezing noise was present?	○	○
b. Have you had this wheezing or whistling when you did not have a cold?	○	○
6.2 Have you woken up with a feeling of tightness in your chest at any time in the last 12 months?	○	○
6.3 Have you been woken by an attack of shortness of breath at any time in the last 12 months?	○	○
6.4 Have you been woken by an attack of coughing at any time in the last 12 months?	○	○
6.5 Have you had an attack of asthma in the last 12 months?	○	○
6.6 Are you currently taking any medicine for asthma (including inhalers, aerosols, or tablets)?	○	○
6.7 Do you have any nasal allergies including hay fever?	○	○

Section Seven: Your Reproductive History

7.1 Have you and your partner (current or previous) ever had problems with infertility (tried to get pregnant for more than 12 consecutive months without success)?

- O Never tried to get pregnant - **please skip to Section Eight**
- O No problem with infertility - **please skip to question 7.3**
- O Yes

If YES:

7.2 In what year did you recognise you had infertility problems? ☐☐☐☐

7.3 Have you ever been pregnant or fathered a pregnancy (including miscarriages, ectopics or terminations)?

- O Yes
- O No - **please skip to Section Eight**

If YES:

7.4 Please answer the following questions for each of your pregnancies (if you have had more than 4 pregnancies, please phone the study team on 1800 232 904). For pregnancies involving twins, triplets or more, use a separate column for each baby.

		1st Pregnancy	2nd Pregnancy	3rd Pregnancy	4th Pregnancy
What was the outcome of this pregnancy?	Live birth	O	O	O	O
	Live birth but baby died within 28 days of birth	O	O	O	O
	Still birth	O	O	O	O
	Ectopic pregnancy	O	O	O	O
	Miscarriage	O	O	O	O
	Termination (abortion)	O	O	O	O
	Currently pregnant	O	O	O	O
Approximate date of pregnancy outcome		☐☐☐☐☐☐ d d m m y y	☐☐☐☐☐☐ d d m m y y	☐☐☐☐☐☐ d d m m y y	☐☐☐☐☐☐ d d m m y y
How many weeks was the pregnancy? (Full term = 40 wks)	Less than 20	O	O	O	O
	20 or more but less than 37	O	O	O	O
	37 or more (inc. full term)	O	O	O	O

Section Seven: Your Reproductive History

		1st Pregnancy	2nd Pregnancy	3rd Pregnancy	4th Pregnancy
If this pregnancy resulted in a birth, what was your baby's sex?	Male	○	○	○	○
	Female	○	○	○	○
	Not applicable	○	○	○	○
If this pregnancy resulted in a birth, what was your baby's birth weight?		lbs oz *or* g *or:* ○ Can't remember ○ Not applicable	lbs oz *or* g *or:* ○ Can't remember ○ Not applicable	lbs oz *or* g *or:* ○ Can't remember ○ Not applicable	lbs oz *or* g *or:* ○ Can't remember ○ Not applicable
Did the baby have any birth defects?	Yes	○	○	○	○
	No	○	○	○	○
	Not applicable	○	○	○	○
If this pregnancy resulted in a live birth, has the child ever suffered from cancer?	Yes	○	○	○	○
	No	○	○	○	○
	Not applicable	○	○	○	○

Section Eight: Recreation and Social Activities

Please answer the following questions regarding your recreation and social activities.

How often do you...

	EVERY DAY	SEVERAL TIMES PER WEEK	WEEKLY OR FORT-NIGHTLY	MONTHLY	RARELY OR ON SPECIAL OCCASIONS	NEVER
8.1 Have contact with an ex-service organisation?	O	O	O	O	O	O
8.2 Have social contact with other veterans?	O	O	O	O	O	O
8.3 Have contact with friends or relatives?	O	O	O	O	O	O
8.4 Attend social activities such as watching sport, eating meals or watching movies?	O	O	O	O	O	O
8.5 Play sport (e.g. golf, fishing, exercise)?	O	O	O	O	O	O
8.6 Set aside time to do a hobby (e.g. wood work, craft, music)?	O	O	O	O	O	O
8.7 Set aside time to relax (e.g. watch TV, read, listen to music)?	O	O	O	O	O	O
8.8 Do voluntary work?	O	O	O	O	O	O

8.9 Do you commemorate significant military-related occasions such as attend ANZAC Day services, participate in marches or attend dawn services?	O Yes	O No
8.10 Do you know of other service veterans living near you?	O Yes	O No
8.11 Are any of your close relatives (parents, siblings) military veterans?	O Yes	O No

Section Nine: Evaluation Questions

9.1 Are there other important health concerns we have not asked you about? ○ Yes ○ No

If **YES**: please give details in the space provided

9.2 Do you have any additional comments you would like to add? ○ Yes ○ No

If **YES**: please give details in the space provided

You are 2/3 of the way through. Keep going!

Part 3: Pre-deployment Personality and Resilience Insert

Section One: Personality

Here are a number of personality traits that may or may not apply to you. For each statement, shade the circle that indicates the extent to which you agree or disagree with that statement.

Rate the extent to which the pair of traits applies to you, even if one characteristic applies more strongly than the other.

	DISAGREE			NEITHER AGREE NOR DISAGREE	AGREE		
	STRONGLY	MODERATELY	A LITTLE		A LITTLE	MODERATELY	STRONGLY
1.1 Extraverted, enthusiastic	○	○	○	○	○	○	○
1.2 Critical, quarrelsome	○	○	○	○	○	○	○
1.3 Dependable, self-disciplined	○	○	○	○	○	○	○
1.4 Anxious, easily upset	○	○	○	○	○	○	○
1.5 Open to new experiences, complex	○	○	○	○	○	○	○
1.6 Reserved, quiet	○	○	○	○	○	○	○
1.7 Sympathetic, warm	○	○	○	○	○	○	○
1.8 Disorganised, careless	○	○	○	○	○	○	○
1.9 Calm, emotionally stable	○	○	○	○	○	○	○
1.10 Conventional, uncreative	○	○	○	○	○	○	○

Section Two: Social Support

The next group of questions are about your relationships with people.

	OFTEN	SOMETIMES	RARELY	NEVER
2.1 How often do friends make you feel cared for?	O	O	O	O
2.2 How often do they express interest in how you are doing?	O	O	O	O
2.3 How often do friends make too many demands on you?	O	O	O	O
2.4 How often do they criticise you?	O	O	O	O
2.5 How often do friends create tensions or arguments with you?	O	O	O	O
	OFTEN	SOMETIMES	RARELY	NEVER
2.6 How often do family make you feel cared for?	O	O	O	O
2.7 How often do family express interest in how you are doing?	O	O	O	O
2.8 How often do they make too many demands on you?	O	O	O	O
2.9 How often do family criticise you?	O	O	O	O
2.10 How often do they create tensions or arguments with you?	O	O	O	O

Section Three and Four: Negative Life Events

For each of these next questions, shade the circle that best describes your response.

3. Overall, I had a happy childhood.

O Strongly disagree O Disagree O Neither agree nor disagree O Agree O Strongly agree

4. I have needed professional help to deal with emotional problems in the past.

O Not at all O To a small extent O To a moderate extent O To a large extent O Totally

Section Five: Symptom Interpretation

Listed below are conditions you may or may not have ever experienced. For each condition, please shade the circle next to each reason or group of reasons that corresponds to how much that might explain your condition. Please check every item for each question. Also, answer whether you have had the condition in the last 3 months by shading the 'Yes' or 'No' circle as appropriate.

	NOT AT ALL	SOME-WHAT	QUITE A BIT	A GREAT DEAL
5.1 If I had a prolonged headache, I would probably think that it is because:				
I am emotionally upset	○	○	○	○
There is something wrong with my muscles, nerves or brain	○	○	○	○
A loud noise, bright light or something else has irritated me	○	○	○	○
Have you had a prolonged headache in the last 3 months?		○ Yes	○ No	

	NOT AT ALL	SOME-WHAT	QUITE A BIT	A GREAT DEAL
5.2. If I was sweating a lot, I would probably think that it is because:				
I must have a fever or infection	○	○	○	○
I'm anxious or nervous	○	○	○	○
The room is too warm, I'm overdressed or working too hard	○	○	○	○
Have you noticed yourself sweating a lot in the last 3 months?		○ Yes	○ No	

	NOT AT ALL	SOME-WHAT	QUITE A BIT	A GREAT DEAL
5.3 If I got dizzy all of a sudden, I would probably think it is because:				
There is something wrong with my heart or blood pressure	○	○	○	○
I am not eating enough or I got up too quickly	○	○	○	○
I must be under alot of stress	○	○	○	○
Have you felt dizzy in the last 3 months?		○ Yes	○ No	

	NOT AT ALL	SOME-WHAT	QUITE A BIT	A GREAT DEAL
5.4 If I noticed my mouth was dry, I would probably think that is because:				
I must be scared or anxious about something	○	○	○	○
I need to drink more liquids	○	○	○	○
There is something wrong with my salivary glands	○	○	○	○
Have you had a dry mouth in the last 3 months?		○ Yes	○ No	

Section Five: Symptom Interpretation

	NOT AT ALL	SOME-WHAT	QUITE A BIT	A GREAT DEAL
5.5 If I felt my heart pounding in my chest, I would probably think that this is because:				
I've exerted myself or drunk a lot of coffee	○	○	○	○
I must be really excited or afraid	○	○	○	○
There must be something wrong with my heart	○	○	○	○
Have you noticed your heart pounding in the last 3 months?		○ Yes	○ No	

	NOT AT ALL	SOME-WHAT	QUITE A BIT	A GREAT DEAL
5.6 If I felt fatigued, I would probably think that it is because:				
I'm emotionally exhausted or discouraged	○	○	○	○
I've been over exerting myself or not exercising enough	○	○	○	○
I'm anaemic or my blood is weak	○	○	○	○
Have you felt fatigued in the last 3 months?		○ Yes	○ No	

	NOT AT ALL	SOME-WHAT	QUITE A BIT	A GREAT DEAL
5.7 If I noticed my hand trembling, I would probably think that it is because:				
I might have some sort of neurological problem	○	○	○	○
I'm very nervous	○	○	○	○
I've tired the muscle in my hand	○	○	○	○
Have you noticed your hands trembling in the last 3 months?		○ Yes	○ No	

	NOT AT ALL	SOME-WHAT	QUITE A BIT	A GREAT DEAL
5.8 If I had trouble sleeping, I would probably think that it is because:				
Some kind of pain or physical discomfort is keeping me awake	○	○	○	○
I'm not tired or I had too much coffee	○	○	○	○
I'm worrying too much or I must be nervous about something	○	○	○	○
Have you had trouble sleeping in the last 3 months?		○ Yes	○ No	

Section Five: Symptom Interpretation

	NOT AT ALL	SOME-WHAT	QUITE A BIT	A GREAT DEAL
5.9 If my stomach was upset, I would probably think that it is because:				
I've worried myself sick	○	○	○	○
I have the flu or stomach irritation	○	○	○	○
I've had something to eat that did not agree with me	○	○	○	○
Have you had an upset stomach in the last 3 months?		○ Yes	○ No	

	NOT AT ALL	SOME-WHAT	QUITE A BIT	A GREAT DEAL
5.10 If I lost my appetite, I would probably think that it is because:				
I've been eating too much or my body doesn't need as much food as before	○	○	○	○
I'm worrying so much that food just doesn't taste good anymore	○	○	○	○
I have some stomach or intestinal problem	○	○	○	○
Have you lost your appetite in the last 3 months?		○ Yes	○ No	

	NOT AT ALL	SOME-WHAT	QUITE A BIT	A GREAT DEAL
5.11 If I had a hard time catching my breath, I would probably think that it is because:				
My lungs are congested from infection, irritation or heart trouble	○	○	○	○
The room is stuffy or there is too much pollution in the air	○	○	○	○
I'm over excited or anxious	○	○	○	○
Have you had a hard time catching your breath in the last 3 months?		○ Yes	○ No	

	NOT AT ALL	SOME-WHAT	QUITE A BIT	A GREAT DEAL
5.12 If I noticed numbness or tingling in my hands or feet, I would probably think that it is because:				
I'm under emotional stress	○	○	○	○
There is something wrong with my nerves or blood circulation	○	○	○	○
I am cold or my hand or foot went to sleep	○	○	○	○
Have you had numbness or tingling in your hands or feet in the last 3 months?		○ Yes	○ No	

Section Five: Symptom Interpretation

	NOT AT ALL	SOME-WHAT	QUITE A BIT	A GREAT DEAL
5.13 If I was constipated or irregular, I would probably think that it is because:				
There is not enough fruit or fibre in my diet	○	○	○	○
Nervous tension is keeping me from being regular	○	○	○	○
There is something wrong with my bowels or intestine	○	○	○	○
Have you been constipated in the last 3 months?		○ Yes	○ No	

Section Six: Pre-existing Traumatic Exposures

Please indicate if you have ever in your lifetime experienced any of the following events:

	EXPERIENCED EVENT	NO. OF TIMES	AGE FIRST TIME	AGE LAST TIME
6.1 Direct combat	O No O Yes			
6.2 Life-threatening accident	O No O Yes			
6.3 Fire, flood, or other natural disaster	O No O Yes			
6.4 Witness someone badly injured or killed	O No O Yes			
6.5 Rape	O No O Yes			
6.6 Sexual molestation	O No O Yes			
6.7 Serious physical attack or assault	O No O Yes			
6.8 Threatened / harassed without weapon	O No O Yes			
6.9 Threatened with weapon / held captive / kidnapped	O No O Yes			
6.10 Tortured or victim of terrorists	O No O Yes			
6.11 Domestic violence	O No O Yes			
6.12 Witnessed domestic violence	O No O Yes			
6.13 Finding dead body	O No O Yes			
6.14 Witnessed someone suicide or attempt suicide	O No O Yes			
6.15 Child abuse - physical	O No O Yes			
6.16 Child abuse - emotional	O No O Yes			
6.17 Any other stressful event, please specify:	O No O Yes			
6.18 Did you ever suffer a great shock because one of these events happened to someone close to you? Please specify event type.	O No O Yes			

Section Seven: Alexithymia

Using the scale provided as a guide, indicate how much you agree or disagree with each of the following statements by shading the corresponding circle. Give only one answer for each statement.

	STRONGLY DISAGREE	MODERATELY DISAGREE	NEITHER DISAGREE NOR AGREE	MODERATELY AGREE	STRONGLY AGREE
7.1 I am often confused about what emotion I am feeling.	○	○	○	○	○
7.2 It is difficult for me to find the right words for my feelings.	○	○	○	○	○
7.3 I have physical sensations that even doctors don't understand.	○	○	○	○	○
7.4 I am able to describe my feelings easily.	○	○	○	○	○
7.5 I prefer to analyse problems rather than just describe them.	○	○	○	○	○
7.6 When I am upset, I don't know if I am sad, frightened, or angry.	○	○	○	○	○
7.7 I am often puzzled by sensations in my body.	○	○	○	○	○
7.8 I prefer to just let things happen rather than to understand why they turned out that way.	○	○	○	○	○
7.9 I have feelings that I can't quite identify.	○	○	○	○	○
7.10 Being in touch with emotions is essential.	○	○	○	○	○
7.11 I find it hard to describe how I feel about people.	○	○	○	○	○
7.12 People tell me to describe my feelings more.	○	○	○	○	○
7.13 I don't know what's going on inside me.	○	○	○	○	○
7.14 I often don't know why I am angry.	○	○	○	○	○
7.15 I prefer talking to people about their daily activities rather than their feelings.	○	○	○	○	○
7.16 I prefer to watch "light" entertainment shows rather than psychological dramas.	○	○	○	○	○
7.17 It is difficult for me to reveal my innermost feelings, even to close friends.	○	○	○	○	○
7.18 I can feel close to someone, even in moments of silence.	○	○	○	○	○
7.19 I find examination of my feelings useful in solving personal problems.	○	○	○	○	○
7.20 Looking for hidden meanings in movies or plays distracts from their enjoyment.	○	○	○	○	○

APPENDIX 3: REMINDER LETTERS

Appendix 3A: MEAO Prospective Health Study Non-SF Reminder Email Content

Middle East Area of Operations Prospective Study

(part of the Military Health Outcomes Program – MilHOP)

Reminder

Dear [name],

We recently emailed you an invitation to participate in the Middle East Area of Operations (MEAO) *Prospective* Study. The Study is investigating changes to the health of ADF personnel arising from their deployment to the MEAO.

If you have already logged on to the internet, or contacted the Centre for Military and Veterans' Health, thank you! If you have not yet participated in this study but would like to, we would be grateful if you would do so in the next 14 days.

For more information on the study, or to complete the consent forms and questionnaire on the **Internet**, please go to the following website:

[website address]

Your Username/Study ID: **[Username/Study ID]**

Your Password: **[Password]**

If you would like this information and the questionnaire mailed to you in hard copy, please **request a mail out package** by emailing cmvh@adelaide.edu.au and including your Study ID and preferred mailing address.

If you wish to decline the invitation (this will prevent you from getting further reminders) you can do so via the website, by phoning the Study team on **1800 232 904** or by emailing cmvh@adelaide.edu.au and putting "Declined" in the subject line.

DO NOT REPLY TO THIS EMAIL

We would appreciate your participation. Thank you.

Yours sincerely,

(INSERT SIGNATURE)

Professor Annette Dobson
First Chief Investigator, Military Health Outcomes Program (MilHOP)
Centre for Military and Veterans' Health
The University of Queensland

Appendix 3B: MEAO Prospective Health Study SF Reminder Letter Content

Middle East Area of Operations Prospective Health Study

(part of the Military Health Outcomes Program – MilHOP)

Reminder

Dear [name],

We recently sent you an invitation to participate in the Middle East Area of Operations (MEAO) *Prospective* Health Study. The Study is investigating changes to the health of ADF personnel arising from deployment to the MEAO.

If you have already sent back your consent form and questionnaire, or contacted the Centre for Military and Veterans' Health, thank you! If you have not yet participated in this study but would like to, we would be grateful if you would do so in the next 14 days.

For more information on the study you can visit our website

www.cmvh.org.au

OR

Contact a member of the Study Team on 1800 755 078

If you would like this information and the questionnaire mailed to you again in hard copy, please **request a mail out package** by emailing MILHOP.SpecialForces@defence.gov.au and including your Study ID and preferred mailing address.

If you wish to decline the invitation (this will prevent you from getting further reminders) you can do so via the website, by phoning the Study team on **1800 755 078** or by emailing MILHOP.Special Forces@defence.gov.au and putting "Declined" in the subject line.

We would appreciate your participation. Thank you.

Yours sincerely,

(INSERT SIGNATURE)

Professor Annette Dobson
Principal Investigator, MEAO Health Study

APPENDIX 4: POST-DEPLOYMENT WELCOME HOME

Appendix 4A: Post-deployment Welcome Home Letter for Non-SF Pre-deployment Participants

<<date>>

<<Name>>
<<Address>>

Dear <<Name>>

Re: MEAO Prospective Study

I would like to take this opportunity to welcome you home from your recent deployment to the Middle East and to thank you for your participation in the pre-deployment phase of the MEAO Prospective Study. Your involvement has greatly contributed to our understanding of the health and wellbeing of the men and women who serve with the Australian Defence Force.

Shortly you will receive a letter inviting you to participate in the post deployment phase of the study. Your chain of command has been informed of this initiative and will assist in ensuring you have adequate time to participate.

If you have any questions or comments, in the meantime, please contact the Centre for Military and Veterans' Health via email at cmvh@adelaide.edu.au or via telephone on 1800 232 904 (free-call number).

Yours sincerely,

Professor Annette Dobson
First Chief Investigator, Military Health Outcomes Program (MilHOP)
Centre for Military and Veterans' Health
The University of Queensland

Appendix 4B: Post-deployment Welcome Home Letter for SF Pre-deployment Participants

<<date>>

<<Name>>
<<Address>>

Dear <<Name>>

Re: MEAO Prospective Study

I would like to take this opportunity to welcome you home from your recent deployment to the Middle East and to thank you for your participation in the pre-deployment phase of the MEAO Prospective Study. Your involvement has greatly contributed to our understanding of the health and wellbeing of the men and women who serve with the Australian Defence Force

In approximately four months time, you will receive a letter inviting you to participate in the post deployment phase of the study. Your chain of command has been informed of this initiative and will assist in ensuring you have adequate time to participate.

If you have any questions or comments, in the meantime, please contact the Centre for Military and Veterans' Health via email at MILHOP.SpecialForces@defence.gov.au or via telephone on 1800 755 078 (free-call number).

Yours sincerely,

Professor Annette Dobson
Chief Investigator, Military Health Outcomes Program (MilHOP)
Centre for Military and Veterans' Health
The University of Queensland

APPENDIX 5: POST-DEPLOYMENT INVITATION PACKAGE – ADDITIONAL MATERIALS (TO PRE DEPLOYMENT PACK) ONLY

Appendix 5A: Post-deployment Letter from the Chief Investigators for Participants Who Did Complete Pre-deployment Assessment

<<DATE>>

<<NAME>>
<<ADDRESS>>

Dear <<NAME>>

Thank you for your participation in the pre deployment phase of the Middle East Area of Operations (MEAO) Prospective Study. However, in order to better understand the impact of deployment on your physical and mental wellbeing, we now need you to complete the post deployment phase of this study.

The results from this research will help in the future to better prepare individuals for deployment. It will also provide Defence and the Department of Veteran Affairs with the best possible advice on how to support the mental and physical health needs of Australian Defence Force service personnel.

Confidentiality of your personal information is of utmost concern. As CMVH is independent from Defence we can assure you that any individually identifiable information you choose to provide us with, will not be accessible by Defence. Neither will any party outside of the immediate research team have access to your identifiable information.

Even if you do not believe that your deployment will have any adverse consequences on your health, your contribution to the post deployment phase is still important.

Yours sincerely,

Annette Dobson

Professor Annette Dobson
First Chief Investigator, Military Health Outcomes Program (MilHOP)
Centre for Military and Veterans' Health
The University of Queensland

Appendix 5B: MEAO Prospective Health Study Post-deployment Questionnaire

Draft

ID:

CMVH

MIHOP

Middle East Area of Operations (MEAO) Prospective Health Study Post Deployment Questionnaire

Part 1: Post Deployment Health Questionnaire

Part 2: Deployment Experiences Questionnaire

For the purposes of this study, deployment to the Middle East Area of Operations includes:

- Deployment to Iraq or areas supporting operations in Iraq;
- Deployment to Afghanistan or areas supporting operations in Afghanistan.

For more information please refer to the instructions on the following page. If you are still uncertain regarding your eligibility to participate in this study, please contact the study team on 1800 232 904 or email cmvh@adelaide.org.au

Page 1 of 48

Instructions to complete this questionnaire:

This questionnaire asks about your physical and mental health. All information you provide in this questionnaire will be de-identified and will not be linked to other data we have collected about your health without your consent.

Please complete all sections by following the instructions at the beginning of each question. Please **shade circles** rather than ticking or crossing them, and write clearly and in **capital letters.**

Shade Circles Like This--> ●

Not Like This-->

If you make a mistake and wish to change your answer, simply cross out your mistake and choose the answer that is right for you.

Please use **blue or black pen**, not pencil.

Some questions may seem repetitive, but this is necessary due to the questions being grouped into scales.

If you have any questions, please call us on 1800 232 904.

SUPPORT

If you require support in regards to anything in this questionnaire, please refer to the contacts provided below:

ALL HOURS SUPPORT LINE (a confidential telephone triage support service for ADF members and their families)
1800 628 036; outside Australia +61 2 9425 3878

LIFELINE
13 11 14

VETERANS AND VETERANS' FAMILY COUNSELLING SERVICE
1800 011 046

VETERANS' AFFAIRS NETWORK (VAN)
1300 551 918; non-metro 1800 555 254

DEPARTMENT OF VETERANS' AFFAIRS
13 32 54

NATIONAL OFFICE FOR THE MILITARY COMPENSATION AND REHABILITATION SERVICE
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Part 1: Post-deployment Health Questionnaire

Draft

ID:

Section One: Background Details

1.1 What is today's date? (dd/mm/yyyy) / /

1.2 Are you male or female? O Male O Female

1.3 What is your date of birth? (dd/mm/yyyy) / /

1.4 Are you currently in a significant intimate relationship?
O Yes - go to question 1.4a
O No - go to question 1.4b

1.4a Are you:
O Married and living together
O Married with unaccompanied spouse (i.e. married partner currently lives elsewhere)
O Living with partner (ADF recognised)
O Living with partner (not ADF recognised)
O In a long term relationship but not living together

1.4b Are you:
O Never married - go to question 1.8
O Previously married but now divorced - go to question 1.8
O Previously married but now separated - go to question 1.8
O Other, please specify: - go to question 1.8

1.5 Were you in a significant intimate relationship before the beginning of your last deployment to the MEAO
O Yes - go to question 1.5a
O No - go to question 1.5b

1.5a Were you:
O Married and living together
O Married with unaccompanied spouse (i.e. married partner currently lives elsewhere)
O Living with partner (ADF recognised)
O Living with partner (not ADF recognised)
O In a long term relationship but not living together

1.5b Were you:
O Never married - go to question 1.8
O Previously married but now divorced - go to question 1.8
O Previously married but now separated - go to question 1.8
O Other, please specify: - go to question 1.8

1.6 How satisfied are you with your current marriage / relationship?
O Extremely satisfied
O Satisfied
O Neither satisfied or dissatisfied
O Dissatisfied
O Extremely dissatisfied
O Not applicable

1.7 Have you or your spouse / partner seriously suggested the idea of divorce or permanent separation since the beginning of your last deployment to the MEAO? O Yes O No O Not applicable

Draft

ID: | | | | | | | | |

Section One: Background Details

1.8 Overall, what impact have your military commitments (now, or in the past if you have left the military) had on your:

a) Marriage / relationship?
- O No impact
- O Positive impact
- O Negative impact
- O Not applicable

b) Children?
- O No impact
- O Positive impact
- O Negative impact
- O Not applicable

1.9 Which category best describes the highest educational qualification you have completed? Choose one.
- O Primary school
- O Secondary school up to grade 10
- O Secondary school grades 11-12
- O Certificate (trade, apprenticeship, technicians etc)
- O Diploma (associate, undergraduate)
- O Bachelor degree
- O Post-graduate qualification

1.10 How many hours per week do you usually work, when you are not on deployment? | | | | hours

1.11 To the nearest year, how long have you served with the Australian Defence Force: (if more than 0, but less than 1 year, please enter 1)

a) As a regular? | | years or O Not applicable

b) As a reservist? | | years or O Not applicable

1.12 What is your CURRENT rank or what WAS your rank when you left the military?
- O Senior Commissioned Officer (CMDR / LTCOL / WGCDR and above)
- O Commissioned Officer (LCDR / MAJ / SQNLDR and below)
- O Senior Non-Commissioned Officer (PO / SGT and above)
- O Junior Non-Commissioned Officer (LS / CPL and below)
- O Other ranks (AB / SMN / PTE / LAC / AC or equivalent)

1.13 In the past THREE YEARS, roughly how many months in total have you been away on Operational deployment? (if more than 0, but less than 1 month, please enter 1) | | months

If you are still a member of the regular Australian Defence Force, please go to Section Two.

If you are a Reservist or have discharged from the regular Australian Defence Force, please complete the following questions.

Draft

ID:

Section One: Background Details

1.14 What year did you discharge from the Regular Australian Defence Force?

or

O Not applicable, I am a Reservist

1.15 Did you discharge to the Reserves or out of the ADF completely? O Reserves O Out of ADF O Not applicable, I have always been a reservist

1.16 What is your current employment status?

O Paid employment full-time
O Paid employment part-time / casual
O Volunteer / community work
O Student
O Home Duties
O Retired
O Not working due to ill-health / TPI
O Unemployed
O Other, please specify:

1.17 Since you separated from the ADF, have you had a period of unemployment greater than 3 months? O Yes O No O Not applicable

If YES, was this period of unemployment primarily due to health problems? O Yes O No

If YES, please specify type:

1.18 What is your main source of income now? Choose one.

O Wage or salary
O Own business or share in a partnership
O Age Service pension
O Invalidity Service Pension
O Compensation benefit under the VEA
O Compensation benefit under the SRCA
O Compensation benefit under the MRCA
O Other government pension / allowance / benefit
O Child allowance
O Superannuation / annuity
O Dividends / interest / income from investments
O Other, please specify:

Section Two: Recent Health Symptoms

We would like to know about your health in the past month. Please indicate whether or not you have suffered any of the following symptoms in the past month, and if so, please indicate whether your symptoms were mild, moderate or severe in nature.

In the past month have you suffered from:	NO	YES		
2.1 Chest pain	O No	O Mild	O Moderate	O Severe
2.2 Headaches	O No	O Mild	O Moderate	O Severe
2.3 Rapid heartbeat	O No	O Mild	O Moderate	O Severe
2.4 Irritability / outbursts of anger	O No	O Mild	O Moderate	O Severe
2.5. Unable to breathe deeply enough	O No	O Mild	O Moderate	O Severe
2.6 Faster breathing than normal	O No	O Mild	O Moderate	O Severe
2.7 Feeling short of breath at rest	O No	O Mild	O Moderate	O Severe
2.8 Wheezing	O No	O Mild	O Moderate	O Severe
2.9 Sleeping difficulties	O No	O Mild	O Moderate	O Severe
2.10 Feeling jumpy / easily startled	O No	O Mild	O Moderate	O Severe
2.11 Feeling unrefreshed after sleep	O No	O Mild	O Moderate	O Severe
2.12 Fatigue	O No	O Mild	O Moderate	O Severe
2.13 Double vision	O No	O Mild	O Moderate	O Severe
2.14 Intolerance to alcohol	O No	O Mild	O Moderate	O Severe
2.15 Itchy or painful eyes	O No	O Mild	O Moderate	O Severe
2.16 Rash or skin irritation	O No	O Mild	O Moderate	O Severe
2.17 Skin infections e.g. boils	O No	O Mild	O Moderate	O Severe
2.18 Skin ulcers	O No	O Mild	O Moderate	O Severe
2.19 Shaking	O No	O Mild	O Moderate	O Severe
2.20 Tingling in fingers and arms	O No	O Mild	O Moderate	O Severe
2.21 Tingling in legs and toes	O No	O Mild	O Moderate	O Severe
2.22 Numbness in fingers / toes	O No	O Mild	O Moderate	O Severe
2.23 Feeling distant or cut off from others	O No	O Mild	O Moderate	O Severe
2.24 Constipation	O No	O Mild	O Moderate	O Severe
2.25 Flatulence or burping	O No	O Mild	O Moderate	O Severe

Section Two: Recent Health Symptoms

In the past month have you suffered from:	NO	YES		
2.26 Stomach cramps	O No	O Mild	O Moderate	O Severe
2.27 Diarrhoea	O No	O Mild	O Moderate	O Severe
2.28 Indigestion	O No	O Mild	O Moderate	O Severe
2.29 Dry mouth	O No	O Mild	O Moderate	O Severe
2.30 Pain in the face, jaw, in front of the ear, or in the ear	O No	O Mild	O Moderate	O Severe
2.31 Persistent cough	O No	O Mild	O Moderate	O Severe
2.32 Lump in throat	O No	O Mild	O Moderate	O Severe
2.33 Sore throat	O No	O Mild	O Moderate	O Severe
2.34 Forgetfulness	O No	O Mild	O Moderate	O Severe
2.35 Dizziness, fainting or blackouts	O No	O Mild	O Moderate	O Severe
2.36 Seizures or convulsions	O No	O Mild	O Moderate	O Severe
2.37 Feeling disorientated	O No	O Mild	O Moderate	O Severe
2.38 Loss of concentration	O No	O Mild	O Moderate	O Severe
2.39 Difficulty finding the right word	O No	O Mild	O Moderate	O Severe
2.40 Pain on passing urine	O No	O Mild	O Moderate	O Severe
2.41 Passing urine more often	O No	O Mild	O Moderate	O Severe
2.42 Burning sensation in the sex organs	O No	O Mild	O Moderate	O Severe
2.43 Loss of interest in sex	O No	O Mild	O Moderate	O Severe
2.44 Problems with sexual functioning	O No	O Mild	O Moderate	O Severe
2.45 Increased sensitivity to noise	O No	O Mild	O Moderate	O Severe
2.46 Increased sensitivity to light	O No	O Mild	O Moderate	O Severe
2.47 Increased sensitivity to smells or odours	O No	O Mild	O Moderate	O Severe
2.48 Ringing in the ears	O No	O Mild	O Moderate	O Severe
2.49 Avoiding doing things or situations	O No	O Mild	O Moderate	O Severe
2.50 Pain, without swelling or redness, in several joints	O No	O Mild	O Moderate	O Severe
2.51 Joint stiffness	O No	O Mild	O Moderate	O Severe
2.52 Feeling that your bowel movement is not finished	O No	O Mild	O Moderate	O Severe

Section Two: Recent Health Symptoms

In the past month have you suffered from:	NO	YES		
2.53 Changeable bowel function (mixture of diarrhoea / constipation)	O No	O Mild	O Moderate	O Severe
2.54 General muscle aches or pains	O No	O Mild	O Moderate	O Severe
2.55 Loss of balance or coordination	O No	O Mild	O Moderate	O Severe
2.56 Difficulty speaking	O No	O Mild	O Moderate	O Severe
2.57 Low back pain	O No	O Mild	O Moderate	O Severe
2.58 Night sweats which soak the bed sheets	O No	O Mild	O Moderate	O Severe
2.59 Feeling feverish	O No	O Mild	O Moderate	O Severe
2.60 Tender or painful swelling of lymph glands in neck, armpit or groin	O No	O Mild	O Moderate	O Severe
2.61 Loss of, or decrease in, appetite	O No	O Mild	O Moderate	O Severe
2.62 Nausea	O No	O Mild	O Moderate	O Severe
2.63 Vomiting	O No	O Mild	O Moderate	O Severe
2.64 Distressing dreams	O No	O Mild	O Moderate	O Severe
2.65 Stomach bloating	O No	O Mild	O Moderate	O Severe
2.66 Unintended weight gain greater than 4kg	O No	O Mild	O Moderate	O Severe
2.67 Unintended weight loss greater than 4kg	O No	O Mild	O Moderate	O Severe

Section Two: Recent Health Symptoms

2.68 Since the beginning of your last deployment, have you experienced any of the following events?		
Blast or Explosion IED (improvised explosive device)	O No	O Yes
RPG (rocket propelled grenade), Land Mine, Grenade, etc.	O No	O Yes
Vehicular accident / crash (any vehicle, including aircraft)	O No	O Yes
Fragment wound or bullet wound above the shoulders	O No	O Yes
Fall	O No	O Yes

If NO to all events in 2.68: please skip to question 3.1. Otherwise, continue.

2.69 How many times in total have you experienced each of the following symptoms immediately after any of the events listed above?		
Loss of consciousness / "knocked out"		times
Being dazed, confused, or "seeing stars"		times
Not remembering the event		times
Concussion		times
Head injury		times

2.70 Did any of the following problems begin or get worse after any of the events listed above?					
Memory problems or lapses	O No	O Yes	Irritability	O No	O Yes
Balance problems or dizziness	O No	O Yes	Headaches	O No	O Yes
Sensitivity to bright light	O No	O Yes	Sleep problems	O No	O Yes

2.71 In the past week, have you had any of these symptoms?					
Memory problems or lapses	O No	O Yes	Irritability	O No	O Yes
Balance problems or dizziness	O No	O Yes	Headaches	O No	O Yes
Sensitivity to bright light	O No	O Yes	Sleep problems	O No	O Yes

Section Three: Your Health Now

This next set of questions ask for your views about your health. This information will help you to keep track of how you feel and how well you are able to do your usual activities.

For each of the following questions, please shade the circle that best describes your answer.

3.1 In general, how would you say your health is? O Excellent O Very good O Good O Fair O Poor

3.2 The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf?	O Yes, limited a lot	O Yes, limited a little	O No, not limited at all
Climbing several flights of stairs?	O Yes, limited a lot	O Yes, limited a little	O No, not limited at all

3.3 During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	ALL OF THE TIME	MOST OF THE TIME	SOME OF THE TIME	A LITTLE OF THE TIME	NONE OF THE TIME
Accomplished less than you would like	O	O	O	O	O
Were limited in the kind of work or other activities	O	O	O	O	O

3.4 During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	ALL OF THE TIME	MOST OF THE TIME	SOME OF THE TIME	A LITTLE OF THE TIME	NONE OF THE TIME
Accomplished less than you would like	O	O	O	O	O
Did work or other activities less carefully than usual	O	O	O	O	O

3.5 During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

O Not at all O A little bit O Moderately O Quite a bit O Extremely

3.6 These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks…

	ALL OF THE TIME	MOST OF THE TIME	SOME OF THE TIME	A LITTLE OF THE TIME	NONE OF THE TIME
Have you felt calm and peaceful?	O	O	O	O	O
Did you have a lot of energy?	O	O	O	O	O
Have you felt downhearted and depressed?	O	O	O	O	O

3.7 During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives etc.)?

O All of the time O Most of the time O Some of the time O A little of the time O None of the time

Section Three: Your Health Now

In general, how would you rate your:	EXCELL-ENT	VERY GOOD	GOOD	FAIR	POOR
3.8 Overall health?	O	O	O	O	O
3.9 Quality of life?	O	O	O	O	O
3.10 Eyesight (with glasses or contact lenses, if you wear them)?	O	O	O	O	O
3.11 Hearing?	O	O	O	O	O
3.12 Memory?	O	O	O	O	O
3.13 Teeth and gums?	O	O	O	O	O

The following questions inquire about how you have been feeling over the last four (4) weeks. Please read each question carefully and then indicate, by shading the circle, the response that best describes how you have been feeling.	ALL OF THE TIME	MOST OF THE TIME	SOME OF THE TIME	A LITTLE OF THE TIME	NONE OF THE TIME
3.14 In the past four (4) weeks, about how often did you feel tired for no good reason?	O	O	O	O	O
3.15 In the past four (4) weeks, about how often did you feel nervous?	O	O	O	O	O
3.16 In the past four (4) weeks, about how often did you feel so nervous that nothing could calm you down?	O	O	O	O	O
3.17 In the past four (4) weeks, about how often did you feel hopeless?	O	O	O	O	O
3.18 In the past four (4) weeks, about how often did you feel restless or fidgety?	O	O	O	O	O
3.19 In the past four (4) weeks, about how often did you feel so restless that you could not sit still?	O	O	O	O	O
3.20 In the past four (4) weeks, about how often did you feel depressed?	O	O	O	O	O
3.21 In the past four (4) weeks, about how often did you feel that everything was an effort?	O	O	O	O	O
3.22 In the past four (4) weeks, about how often did you feel so sad that nothing could cheer you up?	O	O	O	O	O
3.23 In the past four (4) weeks, about how often did you feel worthless?	O	O	O	O	O

Section Three: Your Health Now

The next few questions are about how these feelings may have affected you in the past four (4) weeks. You need not answer these questions if you answered 'None of the time' to all of the previous ten questions about your feelings.

3.24 In the past four (4) weeks, how many days were you TOTALLY UNABLE to work, study or manage your day to day activities because of these feelings? | | days

3.25 [Aside from those days], in the past four (4) weeks, HOW MANY DAYS were you able to work or study or manage your day to day activities, but had to CUT DOWN on what you did because of these feelings? | | days

3.26 In the past four (4) weeks, how many times have you seen a doctor or any other health professional about these feelings? | | times

3.27 In the past four (4) weeks, how often have physical health problems been the main cause of these feelings?

O None of the time O A little of the time O Some of the time O Most of the time O All of the time

3.28 Please rate the following statements based on how you have felt in the past 30 days using the scale below.

	NOT TRUE AT ALL	RARELY TRUE	SOME-TIMES TRUE	OFTEN TRUE	TRUE NEARLY ALL THE TIME
a) I am able to adapt to change	O	O	O	O	O
b) I tend to bounce back after illness or hardship	O	O	O	O	O

Section Three: Your Health Now

Since returning from your last MEAO deployment, has a medical doctor diagnosed you with, or treated you for any of the following medical problems or conditions?

	YES	NO
3.29 High blood pressure	O	O
3.30 Migraines	O	O
3.31 Bowel disorder e.g. diarrhoea, constipation, bleeding	O	O
3.32 Eye or vision problems e.g. glaucoma	O	O
3.33 Hearing loss	O	O
3.34 Malaria	O	O
3.35 Any other significant infections, please specify type:	O	O
3.36 Arthritis or rheumatism	O	O
3.37 Back or neck problems	O	O
3.38 Joint problems	O	O
3.39 Asthma	O	O
3.40 Bronchitis	O	O
3.41 Sinus problems	O	O
3.42 Hay fever	O	O
3.43 Ear infection	O	O
3.44 Dermatitis	O	O
3.45 Any other skin problem, please specify type:	O	O
3.46 Skin cancer e.g. squamous cell or basal cell skin cancers	O	O
3.47 Any other kind of cancer, tumour or malignancy, please specify type:	O	O
3.48 Anxiety, stress or depression	O	O
3.49 Post traumatic stress disorder	O	O

Section Three: Your Health Now

	YES	NO
3.50 Other psychiatric or psychological condition needing treatment or counselling, please specify type:	○	○
3.51 Any other medical condition, please specify type:	○	○

Section Four: Lifestyle Behaviours

4.1 Since the beginning of your last deployment to the MEAO, have you used any of the following tobacco products?

	NO	YES
a. Cigarettes	O	O
b. Cigars	O	O
c. Pipes	O	O
d. Smokeless tobacco (e.g. chew, dip, snuff)	O	O

4.2 In your lifetime, have you smoked at least 100 cigarettes (5 packs)?

O No - **please skip to question 4.9**

O Yes - **continue to next question**

4.3 At what age did you start smoking? ☐☐ years old

4.4 How many years have you, or did you, smoke an average of at least 3 cigarettes per day (or one pack per week)? ☐☐ years

4.5 When smoking, how many packs (25 cigarettes) per day did you, or do you, smoke?

O Less than half a pack per day
O Half to 1 pack per day
O 1 to 2 packs per day
O More than 2 packs per day

4.6 Have you ever tried to quit smoking?

O Yes, and succeeded
O Yes, but not successfully
O No

4.7 Was your smoking pattern different while on your last deployment to the MEAO?

O I did not smoke on deployment
O I smoked less than usual while on deployment
O I smoked the same amount on deployment as when not deployed
O I smoked more than usual while on deployment
O I began / restarted smoking on deployment

4.8 If your smoking pattern changed during your deployment, what was the main reason?

Section Four: Lifestyle Behaviours

4.9 How often do you have a drink containing alcohol?	Never	Monthly or Less	2 to 4 times a month	2 to 3 times a week	4 or more times a week
	O	O	O	O	O

In answering the following questions, please remember that a standard drink contains 10g of pure alcohol

4.10 How many 'standard' drinks (see above) containing alcohol do you have on a typical day when you are drinking?	1 or 2	3 or 4	5 to 6	7 to 9	10 or more	N/A
	O	O	O	O	O	O

	NEVER	LESS THAN MONTHLY	MONTHLY	WEEKLY	DAILY OR ALMOST DAILY
4.11 How often do you have six or more drinks on one occasion?	O	O	O	O	O
4.12 How often since the beginning of your last deployment have you found that you were not able to stop drinking once you had started?	O	O	O	O	O
4.13 How often since the beginning of your last deployment have you failed to do what was normally expected from you because of drinking?	O	O	O	O	O

Section Four: Lifestyle Behaviours

	NEVER	LESS THAN ONCE A MONTH	MONTHLY	WEEKLY	DAILY OR ALMOST DAILY
4.14 How often since the beginning of your last deployment have you needed a drink in the morning to get yourself going after a heavy drinking session?	O	O	O	O	O
4.15 How often since the beginning of your last deployment have you had a feeling of guilt or remorse after drinking?	O	O	O	O	O
4.16 How often since the beginning of your last deployment have you been unable to remember what happened the night before because you had been drinking?	O	O	O	O	O

4.17 Have you or someone else been injured as a result of your drinking?	No O	Yes, but not since the beginning of my last deployment O	Yes, since the beginning of my last deployment O
4.18 Has a relative, a friend, a doctor or other health professional been concerned about your drinking or suggested you cut down?	No O	Yes, but not since the beginning of my last deployment O	Yes, since the beginning of my last deployment O

4.19 Do you presently have a problem with drinking?	No O	Probably not O	Unsure O	Possibly O	Definitely O

4.20 In the next 3 months, how difficult would you find it to cut down or stop drinking?	Very easy O	Fairly easy O	Neither difficult nor easy O	Fairly difficult O	Very difficult O	N/A O

4.21 On an average day, how many 250 - 375ml beverages containing caffeine do you drink (such as caffeine containing energy drinks, coffee, tea, coca-cola)?

O None O 1-2 per day O 3-5 per day O 6-10 per day O 11 or more per day

Section Four: Lifestyle Behaviours

4.22 Do you currently take any of the following supplements?

a) Body building supplements (such as amino acids, weight gain products, creatine, etc.)

O Never O Less than once a month O Monthly O Weekly O Daily or almost daily

If YES, what was the name (generic or brand name) of the supplement(s) that you used?

b) Energy supplements (such as energy drinks, pills, or energy enhancing herbs)

O Never O Less than once a month O Monthly O Weekly O Daily or almost daily

If YES, what was the name (generic or brand name) of the supplement(s) that you used?

c) Weight loss supplements

O Never O Less than once a month O Monthly O Weekly O Daily or almost daily

If YES, what was the name (generic or brand name) of the supplement(s) that you used?

Since the beginning of your last deployment...

	NEVER	SOMETIMES	MOST OF THE TIME	ALMOST ALWAYS
4.23 Have you bet more than you could really afford to lose?	O	O	O	O
4.24 Have you needed to gamble with larger amounts of money to get the same feeling of excitement?	O	O	O	O
4.25 When you gambled, did you go back another day to try to win back the money you lost?	O	O	O	O
4.26 Have you borrowed money or sold anything to get money to gamble?	O	O	O	O
4.27 Have you felt that you might have a problem with gambling?	O	O	O	O
4.28 Has gambling caused you any health problems, including stress or anxiety?	O	O	O	O
4.29 Have people criticized your betting or told you that you had a gambling problem, regardless of whether or not you thought it was true?	O	O	O	O
4.30 Has your gambling caused any financial problems for you or your household?	O	O	O	O
4.31 Have you felt guilty about the way you gamble or what happens when you gamble?	O	O	O	O

Section Five: Life Experiences

Below is a list of problems and complaints that people sometimes have in response to stressful life experiences. Please read each one carefully, then shade the circle to the right to indicate how much you have been bothered by that problem in the past month.

	NOT AT ALL	A LITTLE BIT	MODERA-TELY	QUITE A BIT	EXTREM-ELY
5.1 Repeated, disturbing memories, thoughts or images of a stressful experience from the past?	O	O	O	O	O
5.2 Repeated, disturbing dreams of a stressful experience from the past?	O	O	O	O	O
5.3 Suddenly acting or feeling as if a stressful experience from the past were happening again (as if you were reliving it)?	O	O	O	O	O
5.4 Feeling very upset when something reminded you of a stressful experience from the past?	O	O	O	O	O
5.5 Having physical reactions (e.g. heart pounding, trouble breathing, sweating) when something reminded you of a stressful experience from the past?	O	O	O	O	O
5.6 Avoiding thinking about or talking about a stressful experience from the past or avoiding having feelings related to it?	O	O	O	O	O
5.7 Avoiding activities or situations because they reminded you of a stressful experience from the past?	O	O	O	O	O
5.8 Trouble remembering important parts of a stressful experience from the past?	O	O	O	O	O
5.9 Loss of interest in activities that you used to enjoy?	O	O	O	O	O
5.10 Feeling distant or cut off from other people?	O	O	O	O	O
5.11 Feeling emotionally numb or being unable to have loving feelings for those close to you?	O	O	O	O	O
5.12 Feeling as if your future somehow will be cut short?	O	O	O	O	O
5.13 Trouble falling or staying asleep?	O	O	O	O	O
5.14 Feeling irritable or having angry outbursts?	O	O	O	O	O
5.15 Having difficulty concentrating?	O	O	O	O	O
5.16 Being "superalert" or watchful or on guard?	O	O	O	O	O
5.17 Feeling jumpy or easily startled?	O	O	O	O	O

Section Five: Life Experiences

Below is a list of problems and complaints that people sometimes have in response to stressful life experiences. Please read each one carefully, then shade the circle to the right to indicate how much you have been bothered by that problem in the past month.

	NOT AT ALL	A LITTLE BIT	MODERA-TELY	QUITE A BIT	EXTREM-ELY
5.17a Having strong negative beliefs about yourself, other people, or the world (for example, having thoughts such as: I am bad, there is something seriously wrong with me, no one can be trusted, the world is completely dangerous)?	O	O	O	O	O
5.17b Blaming yourself or someone else severely for the stressful experience or what happened after it?	O	O	O	O	O
5.17c Having strong negative feelings such as fear, horror, anger, guilt, or shame?	O	O	O	O	O
5.17d Taking too many risks or doing things that cause you harm?	O	O	O	O	O

5.18 Thinking of the event(s) that you used to answer questions 5.1 - 5.17d, please list these events and the years they occurred below.

	Event description	Year
1		
2		
3		

5.19 Did any of these occur while on your deployment to the MEAO? O Yes O No

5.20 Did any of these occur during another overseas deployment? O Yes O No

5.21 Is there any other event that has caused you to have similar reactions?
O No
O Yes - while deployed
O Yes - while NOT deployed

If yes, what was that event?

Year of event

Section Five: Life Experiences

5.22 Thinking over the past 4 weeks, shade the circle that best describes the amount of time you felt that way.

	NONE OF THE TIME	A LITTLE OF THE TIME	SOME OF THE TIME	MOST OF THE TIME	ALL OF THE TIME
a) I found myself getting angry at people or situations	O	O	O	O	O
b) When I got angry, I got really mad	O	O	O	O	O
c) When I got angry, I stayed angry	O	O	O	O	O
d) When I got angry at someone, I wanted to hit them	O	O	O	O	O
e) My anger interfered with my ability to get my work, study or other productive activity done	O	O	O	O	O
f) My anger prevented me from getting along with people as well as I'd have liked to	O	O	O	O	O
g) I became angry at myself when I did not perform as well or achieve what I wanted	O	O	O	O	O
h) I became angry at myself when I did not handle social situations as well as I wanted	O	O	O	O	O
i) My anger had a bad effect on my health	O	O	O	O	O

5.23 How often over the last month did you get into a fight with someone and hit the person?

O Never O One time O Two times O Three or four times O Five or more times

5.24 How often over the last month did you threaten someone with physical violence?

O Never O One time O Two times O Three or four times O Five or more times

Section Five: Life Experiences

Over the last 2 weeks, how often have you been bothered by any of the following problems?	NOT AT ALL	SEVERAL DAYS	MORE THAN HALF THE DAYS	NEARLY EVERY DAY
5.25 Little interest or pleasure in doing things	O	O	O	O
5.26 Feeling down, depressed, or hopeless	O	O	O	O
5.27 Trouble falling or staying asleep, or sleeping too much	O	O	O	O
5.28 Feeling tired or having little energy	O	O	O	O
5.29 Poor appetite or overeating	O	O	O	O
5.30 Feeling bad about yourself, or that you are a failure, or have let yourself or your family down	O	O	O	O
5.31 Trouble concentrating on things, such as reading the newspaper or watching television	O	O	O	O
5.32 Moving or speaking so slowly that other people could have noticed? Or the opposite - being so fidgety or restless that you have been moving around a lot more than usual	O	O	O	O
5.33 Thoughts that you would be better off dead or of hurting yourself in some way	O	O	O	O

5.34 If you checked off any of these problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

O Not difficult at all O Somewhat difficult O Very difficult O Extremely difficult

The next group of questions are about anxiety.	NO	YES
5.35 In the last 4 weeks, have you had an anxiety attack - suddenly feeling fear or panic?	O	O
If NO: please skip to question 5.50		
5.36 Has this ever happened before?	O	O
5.37 Do some of these attacks come suddenly out of the blue - that is, in situations where you don't expect to be nervous or uncomfortable?	O	O
5.38 Do these attacks bother you a lot or are you worried about having another attack?	O	O

Section Five: Life Experiences

Think about your last bad anxiety attack.		
	NO	YES
5.39 Were you short of breath?	O	O
5.40 Did your heart race, pound, or skip?	O	O
5.41 Did you have chest pain or pressure?	O	O
5.42 Did you sweat?	O	O
5.43 Did you feel as if you were choking?	O	O
5.44 Did you have hot flushes or chills?	O	O
5.45 Did you have nausea or an upset stomach, or the feeling that you were going to have diarrhoea?	O	O
5.46 Did you feel dizzy, unsteady, or faint?	O	O
5.47 Did you have tingling or numbness in parts of your body?	O	O
5.48 Did you tremble or shake?	O	O
5.49 Were you afraid you were dying?	O	O

Over the last 4 weeks, how often have you been bothered by any of the following problems?			
	NOT AT ALL	SEVERAL DAYS	MORE THAN HALF THE DAYS
5.50 Feeling nervous, anxious, on edge, or worrying a lot about different things	O	O	O
If NOT AT ALL: please skip to question 5.57			
5.51 Feeling restless so that it is hard to sit still	O	O	O
5.52 Getting tired very easily	O	O	O
5.53 Muscle tension, aches, or soreness	O	O	O
5.54 Trouble falling asleep or staying asleep	O	O	O
5.55 Trouble concentrating on things, such as reading a book or watching TV	O	O	O
5.56 Becoming easily annoyed or irritable	O	O	O

Section Five: Life Experiences

Please shade the circles that best describe your experience.		
5.57 Since the beginning of your last deployment, have you ever felt that life was not worth living?	O No	O Yes
5.58 Since the beginning of your last deployment, have you ever felt so low that you thought about committing suicide?	O No	O Yes
5.59 Since the beginning of your last deployment, have you made a suicide plan?	O No	O Yes
5.60 Since the beginning of your last deployment, have you attempted suicide?	O No	O Yes

If you require support in relation to any issues you have identified in this survey, we encourage you to refer to the contacts provided on Page 3

Section Six: Your Respiratory Health

The following questions ask you about any respiratory symptoms you may have experienced since the beginning of your last deployment.

	NO	YES
6.1 Have you had wheezing or whistling in your chest at any time since the beginning of your last deployment?	O	O
If YES:		
a. Have you been at all breathless when the wheezing noise was present?	O	O
b. Have you had this wheezing or whistling when you did not have a cold?	O	O
6.2 Have you woken up with a feeling of tightness in your chest at any time since the beginning of your last deployment?	O	O
6.3 Have you been woken by an attack of shortness of breath at any time since the beginning of your last deployment?	O	O
6.4 Have you been woken by an attack of coughing at any time since the beginning of your last deployment?	O	O
6.5 Have you had an attack of asthma since the beginning of your last deployment?	O	O
6.6 Are you currently taking any medicine for asthma (including inhalers, aerosols, or tablets)?	O	O
6.7 Do you have any nasal allergies including hay fever?	O	O

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Section Seven: Recreation and Social Activities

Please answer the following questions regarding your recreation and social activities. How often do you…

	EVERY DAY	SEVERAL TIMES PER WEEK	WEEKLY OR FORT-NIGHTLY	MONTHLY	RARELY OR ON SPECIAL OCCASIONS	NEVER
7.1 Have contact with an ex-service organisation?	O	O	O	O	O	O
7.2 Have social contact with other veterans?	O	O	O	O	O	O
7.3 Have contact with friends or relatives?	O	O	O	O	O	O
7.4 Attend social activities such as watching sport, eating meals or watching movies?	O	O	O	O	O	O
7.5 Play sport (e.g. golf, fishing, exercise)?	O	O	O	O	O	O
7.6 Set aside time to do a hobby (e.g. wood work, craft, music)?	O	O	O	O	O	O
7.7 Set aside time to relax (e.g. watch TV, read, listen to music)?	O	O	O	O	O	O
7.8 Do voluntary work?	O	O	O	O	O	O

7.9 Do you commemorate significant military-related occasions such as attend ANZAC Day services, participate in marches or attend dawn services? O Yes O No

7.10 Do you know of other service veterans living near you? O Yes O No

7.11 Do you have any siblings?
O No - please skip to question 7.13
O Yes - continue to next question

7.12 Please answer the following questions for each of your siblings.

GENDER	DATE OF BIRTH	CURRENTLY MEMBER OF THE ADF
O Male O Female	/ /	O Yes O No
O Male O Female	/ /	O Yes O No
O Male O Female	/ /	O Yes O No
O Male O Female	/ /	O Yes O No
O Male O Female	/ /	O Yes O No

7.13 Are any of your close relatives (other than siblings) military veterans? O Yes O No

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Section Eight: Evaluation Questions

8.1 Are there other important health concerns we have not asked you about? ○ Yes ○ No

If **YES**: please give details in the space provided

8.2 Do you have any additional comments you would like to add? ○ Yes ○ No

If **YES**: please give details in the space provided

You are 2/3 of the way through. Keep going!

Part 2:
Deployment Questionnaire

Instructions to complete:

Please answer these questions in relation to your LAST deployment to the Middle East Area of Operations.

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Section One: Deployment Details

1.1 On your MOST RECENT deployment to the MEAO, were you mainly based in: (please shade all that apply)

- O Tarin Kowt
- O Kandahar
- O Kabul
- O Other areas in Afghanistan
- O Other areas supporting Afghanistan
- O Iraq
- O Other areas supporting Iraq
- O Attachment to foreign militaries or UN

1.2 How many weeks lead time were you given prior to your last deployment to the MEAO? (if more then 0, but less than 1 week, please enter 1) | | weeks

1.3 During your last deployment to the MEAO, what were your MAIN duties? (please shade all that apply)

- O Combat (e.g. Infantry, Artillery, etc.)
- O Medical (e.g. RMO, Environmental or Preventive Health, Nurses, Medics)
- O Security
- O EOD (Bomb Disposal, IED Technician)
- O Training Local Police / Army
- O Engineering
- O Logistics / Supply
- O Force Protection
- O Driver
- O Welfare (e.g. Chaplain, Psychologist)
- O Trades (e.g. Fitter, Mechanic)
- O Air Crew - Rotary Wing
- O Air Crew - Fixed Wing
- O Flight Operations Cell
- O Oil Platform Protection
- O Maritime Operations - Between Deck
- O Maritime Operations - Above Deck
- O Clearance Diver
- O Boarding Party
- O Administrative
- O Headquarters
- O CIMIC (Civil Military Co-operation)
- O Peacekeeping
- O Catering
- O Intelligence
- O Communications
- O Military Police
- O Other, please specify:

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

1.4 Were you required to work mixed duty cycles (ie. day - night - day shifts)? O Often O Sometimes O Rarely O Never

1.5 Were you permanently on night shifts during your last deployment to the MEAO? O Yes O No

1.6 About how many hours per day, on average, were you considered 'on duty'? | | hours

1.7 How many days per month did you not work on your last deployment to the MEAO? (if more then 0, but less than 1 day, please enter 1) | | days per month

Section One: Deployment Details

1.8 What was your rank during your last deployment to the MEAO?

- O Senior Commissioned Officer (CMDR / LTCOL / WGCDR and above)
- O Commissioned Officer (LCDR / MAJ / SQNLDR and below)
- O Senior Non-Commissioned Officer (PO / SGT and above)
- O Junior Non-Commissioned Officer (LS / CPL and below)
- O Other ranks (AB / SMN / PTE / LAC / AC or equivalent)

1.9 Please indicate your service status during your last deployment to the MEAO.

O Reservist on full time service O Full time member O Other, please specify:

Section Two: Chemical and Environmental Exposures

During your last deployment to the MEAO, how often…?	NEVER	ONCE	2-4 TIMES	5-9 TIMES	10+ TIMES
2.1 Were you exposed to smoke from fires / smoke from waste incineration / oil fire smoke?	O	O	O	O	O
2.2 Were you exposed to dust storms?	O	O	O	O	O
2.3 Were you exposed to an environment where you inhaled fine dust or fibres (e.g. driving vehicles, near operating aircraft, damaged building)?	O	O	O	O	O
2.4 Were you exposed to others' cigarette smoke in an enclosed recreational or work environment?	O	O	O	O	O
2.5 Were you exposed to diesel exhaust?	O	O	O	O	O
2.6 Were you exposed to aviation, marine or automotive fuels?	O	O	O	O	O
2.7 Were you exposed to aircraft fumes?	O	O	O	O	O
2.8 Were you exposed to toxic industrial chemicals?	O	O	O	O	O
2.9 Were you exposed to solvents (e.g. thinners, sealer, paints)?	O	O	O	O	O
2.10 Did you live in an area recently sprayed or fogged with chemicals?	O	O	O	O	O
2.11 Did you dip your cams to prevent insect bites?	O	O	O	O	O
2.12 Did you take medication to prevent or suppress malaria (e.g. Doxycycline, Primaquine)?	O	O	O	O	O
2.13 Were you close to loud noises and did not have hearing protection (e.g. explosions, weapon fire)?	O	O	O	O	O
2.14 Were you exposed to noise for extended periods of time without hearing protection (e.g. machinery, aircraft operations)?	O	O	O	O	O
2.15 Were you bitten by flies, sand flies, fleas, mosquitoes or other insects that required medical attention?	O	O	O	O	O
2.16 Did you have close contact with local animals (dogs, cats, rats, etc.)?	O	O	O	O	O
2.17 Did you come into contact with body fluids or blood?	O	O	O	O	O
2.18 Did you receive a blood transfusion?	O	O	O	O	O
2.19 Did you drink from local taps or wells?	O	O	O	O	O
2.20 Did you eat local food?	O	O	O	O	O
2.21 Did the food available have a negative effect on your performance?	O	O	O	O	O

Section Two: Chemical and Environmental Exposures

During your last deployment to the MEAO, how often…?

	NEVER	ONCE	2-4 TIMES	5-9 TIMES	10+
2.22 Did you swim or bath in local lakes, rivers or the sea?	O	O	O	O	O
2.23 Did you have contact with the local population?	O	O	O	O	O
2.24 Did you get sunburnt?	O	O	O	O	O
2.25 Were you close to sources of non-ionising radiation (e.g. radar or microwave, or EOD countermeasures)?	O	O	O	O	O
2.26 Did you have contact with any chemical or biological weapons?	O	O	O	O	O
2.27 Did you have contact with depleted uranium shell casings?	O	O	O	O	O
2.28 Did you enter or come in close proximity to recently destroyed vehicles?	O	O	O	O	O
2.29 Did you enter or come in close proximity to recently destroyed structures (e.g. buildings, bunkers, etc.)?	O	O	O	O	O
2.30 Were you exposed to ionising radiation or radioactive material?	O	O	O	O	O
2.31 Did you use an NBC suit (not for training purposes)?	O	O	O	O	O
2.32 Did you use a respirator (not for training purposes)?	O	O	O	O	O
2.33 Did you clear / search buildings?	O	O	O	O	O
2.34 Did you clear / search caves?	O	O	O	O	O
2.35 Did you come under small arms or anti-aircraft fire?	O	O	O	O	O
2.36 Did you come under guided or directed mortar / artillery fire or missile attack?	O	O	O	O	O
2.37 Did you experience in-direct fire (e.g. rocket attack)?	O	O	O	O	O
2.38 Did you seriously fear you would encounter an IED?	O	O	O	O	O
2.39 Did you experience an IED / EOD that detonated?	O	O	O	O	O
2.40 Did you experience a suicide bombing?	O	O	O	O	O
2.41 Did you experience a landmine strike?	O	O	O	O	O
2.42 Did you encounter small arms fire from an unknown enemy combatant (e.g. sniper, civilian with weapon)?	O	O	O	O	O
2.43 Did you discharge your weapon in direct combat?	O	O	O	O	O

Section Two: Chemical and Environmental Exposures

During your last deployment to the MEAO, how often...?	NEVER	ONCE	2-4 TIMES	5-9 TIMES	10+
2.44 Did you experience a threatening situation where you were unable to respond due to the rules of engagement?	O	O	O	O	O
2.45 Did you go on combat patrols or missions?	O	O	O	O	O
2.46 Did you participate in support convoys (eg. re-supply, VIP escort)?	O	O	O	O	O
2.47 Were you concerned about yourself or others (including allies) having an unauthorised discharge of a weapon?	O	O	O	O	O
2.48 Were you in danger of being killed? e.g. combat, motor vehicle accident (MVA), assault, hostage situation	O	O	O	O	O
2.49 Were you in danger of being injured? e.g. combat, MVA, assault, hostage situation	O	O	O	O	O
2.50 Did you handle dead bodies? e.g. combat, civilian casualties	O	O	O	O	O
2.51 Did you see dead bodies? e.g. combat, civilian casualties	O	O	O	O	O
2.52 Did you hear of a close friend or co-worker who had been injured or killed? e.g. combat, MVA, disaster situation	O	O	O	O	O
2.53 Were you present when a close friend or co-worker was injured or killed? e.g. combat, MVA, disaster situation	O	O	O	O	O
2.54 Did you fear that you had been exposed to a contagious disease, toxic agent or injury? e.g. radioactivity, HIV, chemical warfare	O	O	O	O	O
2.55 Were you witness to human degradation and misery on a large scale? e.g. refugee camps, starvation	O	O	O	O	O
2.56 Did you hear of a loved one who had been injured or killed?	O	O	O	O	O
2.57 Were you present when a loved one was injured or killed?	O	O	O	O	O
2.58 Do you believe your action or inaction resulted in someone being seriously injured? e.g. in combat or as a result of rules of engagement or UN restrictions not allowing you to act	O	O	O	O	O
2.59 Do you believe your actions or inaction resulted in someone being killed? e.g. in combat or as a result of rules of engagement or UN restrictions not allowing you to act	O	O	O	O	O

Section Two: Chemical and Environmental Exposures

2.60 During your last deployment to the MEAO, for how long were you outside your base in a hostile area?

- O Not at all
- O Up to one week
- O Up to one month
- O More than a month

2.61 Are there any additional experiences you would like to tell us about? Please comment.

Section Three: Your Work on Deployment

3.1 Did you feel that the work asked of you in theatre generally matched your trade experiences and ability?

- O Yes
- O No, work was generally above my trade experience and ability
- O No, work was generally beneath my trade experience and ability

3.2 Thinking of one very difficult experience on this deployment, do you feel that:

a) Your colleagues did what was expected of them?	O Yes	O No
b) You did what was expected of you?	O Yes	O No

The following statements relate to the equipment you were provided with while on your last deployment to the MEAO. Please indicate the degree to which you either agree or disagree with each statement.

	STRONGLY DISAGREE	SOMEWHAT DISAGREE	NEITHER AGREE NOR DISAGREE	SOMEWHAT AGREE	STRONGLY AGREE
3.3 I experienced pain or injury from using the equipment provided to me	O	O	O	O	O
3.4 I felt that I had adequate practical experience using my equipment	O	O	O	O	O
3.5 I had all the supplies and equipment needed to get my job done	O	O	O	O	O

3.6 Please give examples:

Section Three: Your Work on Deployment

3.7 The following questions ask about your work during your last deployment to the MEAO. Please answer how often you performed these duties during your deployment, and if you did perform the duty, whether you think this benefited the local community.

	NEVER	OCCAS-IONALLLY	FREQ-UENTLY	IF OCCASIONALLY OR FREQUENTLY, DO YOU THINK THIS BENEFITED THE LOCAL COMMUNITY?	
				YES	NO
a) Work with the National Police / Army (e.g. patrols)?	O	O	O	O	O
b) Assist in the building of infrastructure e.g. wells / roads?	O	O	O	O	O
c) Train local Police / Army?	O	O	O	O	O
d) Take part in Hearts and Minds campaigns, e.g. interacted with the community?	O	O	O	O	O
e) Work with DFAT* / NGO** or Aid organisations*** to assist the locals?	O	O	O	O	O

* DFAT = Department of Foreign Affairs and Trade
** NGO = Non-Government Organisation
*** Aid Organisation = e.g. Red Cross

3.8 How much do you agree or disagree with the following statements?

Please shade ONE circle for each statement under the answer that best describes how you felt during your deployment to the MEAO.

	STRONGLY AGREE	AGREE	NEITHER AGREE NOR DISAGREE	DISAGREE	STRONGLY DISAGREE
a) I felt a sense of comradeship (or closeness) between myself and other people in my Unit	O	O	O	O	O
b) There was someone I could go to in my Unit if I had a personal problem	O	O	O	O	O
c) My superiors were interested in what I did or thought	O	O	O	O	O
d) I felt well informed about what was going on in my Unit	O	O	O	O	O
e) I had good communication with other Australian forces / Australian H.Q. from my Unit	O	O	O	O	O

Section Four: Your Health on Deployment

4.1 How many times did you attend sick parade during your LAST deployment to the MEAO?			
If you did attend sick parade: What was the reason? (please shade all that apply)			
	YES	**NO**	**IF YES NUMBER OF DAYS OUT OF ROLE**
a) Injury from a motor vehicle accident	O	O	
b) Injury sustained in combat	O	O	
c) Musculoskeletal injury sustained in your job / role (not combat related)	O	O	
d) Musculoskeletal injury sustained during training	O	O	
e) Musculoskeletal injury sustained during recreation or sport	O	O	
f) Head injury / concussion	O	O	
If YES, how long were you unconscious?	days	hours	minutes
g) Heat stress / exhaustion / dehydration	O	O	
h) Effects of cold or exposure	O	O	
i) Respiratory illness (e.g. cold / flu)	O	O	
If YES, did you have a fever?	O	O	
j) Dental problems	O	O	
k) Skin rashes / irritations	O	O	
l) Diarrhoea and/or vomiting	O	O	
m) Other, please specify:	O	O	

Section Four: Your Health on Deployment

If you had diarrhoea or vomiting during your last deployment to the MEAO:

4.2 Did the symptoms of diarrhoea and/or vomiting prevent you from carrying out your duties? O Yes O No O Not Applicable, I did not have diarrhoea or vomiting

4.3 Did you need intravenous fluids (a drip) as a result of diarrhoea and/or vomiting? O Yes O No O Not Applicable, I did not have diarrhoea or vomiting

4.4 Did the symptoms of diarrhoea or vomiting resolve when you exited the MEAO? O Yes O No O Not Applicable, I did not have diarrhoea or vomiting

In regard to your sleep and rest while on your last deployment to the MEAO:

4.5 How well did you sleep? O Very poorly O Poorly O Neither good nor poorly O Good O Very good

4.6 How satisfied were you with your sleep?
O Very dissatisfied O Dissatisfied O Neither satisfied nor dissatisfied O Satisfied O Very satisfied

4.7 Did you have difficulties with sleeping?
O Not at all O A little O A moderate amount O Very much O An extreme amount

4.8 How much did any sleep problems worry you?
O Not at all O A little O A moderate amount O Very much O An extreme amount

4.9 Did you take any medication to help you sleep? O No O Yes, once or twice O Yes, regularly

4.10 During your last deployment to the MEAO, on an average day, how many 250 - 375ml beverages containing caffeine did you drink (such as caffeine containing energy drinks, coffee, tea, coca-cola)?
O None O 1-2 per day O 3-5 per day O 6-10 per day O 11 or more per day

Section Four: Your Health on Deployment

4.11 During your last deployment to the MEAO, did you take any of the following supplements?

a) Body building supplements (such as amino acids, weight gain products, creatine, etc.)

O Never O Less than once a month O Monthly O Weekly O Daily or almost daily

If YES, what was the name (generic or brand name) of the supplement that you used?

b) Energy supplements (such as energy drinks, pills, or energy enhancing herbs)

O Never O Less than once a month O Monthly O Weekly O Daily or almost daily

If YES, what was the name (generic or brand name) of the supplement that you used?

c) Weight loss supplements

O Never O Less than once a month O Monthly O Weekly O Daily or almost daily

If YES, what was the name (generic or brand name) of the supplement that you used?

4.12 Have you had a previous or current military injury compensation pension arising from your last deployment to the MEAO? O Yes O No

If YES: Was this for?

O Musculoskeletal injury, please specify:

O Hearing loss, please specify:

O Injury sustained in combat, please specify:

O Mental health, please specify:

O Other reason, please specify:

Section Four: Your Health on Deployment

4.13 Do you plan on claiming a military injury compensation pension arising from your last deployment to the MEAO in the future? O Yes O No O Don't know / Undecided

If YES: What is this for?

O Musculoskeletal injury, please specify:

O Hearing loss, please specify:

O Injury sustained in combat, please specify:

O Mental health, please specify:

O Other reason, please specify:

4.14 Compared to your health BEFORE your last deployment to the MEAO, how would you rate your health in general NOW?

O Much better now O Somewhat better now O About the same O Somewhat worse now O Much worse now

4.15 To what extent do you agree with the following statement?

The change in my health is because of my last deployment to the MEAO.

O Strongly Agree O Agree O Neither Agree nor Disagree O Not applicable O Disagree O Strongly Disagree

Section Five: Other Deployment Experiences

5.1 During your last deployment to the MEAO, did you have any major personal problems at home? (e.g. financial problems, family problems, etc). Please shade ONE circle for each statement.

	AGREE	DISAGREE	NOT APPLICABLE
a) I received enough personal support from my family	O	O	O
b) I had serious financial problems	O	O	O
c) My partner / spouse left me	O	O	O
d) There were problems with my children	O	O	O
e) I was concerned I might lose my civilian job	O	O	O
f) I faced other major problems at home whilst deployed	O	O	O

5.2 Did the military provide any reassurance / support to your spouse / partner whilst you were deployed? (e.g. phone calls or visits, arranging 'get togethers' with other service families, newsletters, etc.)

- O Yes, it was sufficient
- O Yes, but it was not sufficient
- O No
- O Not applicable

Section Six: Post Deployment Experiences

6.1 Why did you exit from theatre? (Please shade ONE circle only)

- O End of Deployment
- O CASEVACed through combat related injury
- O CASEVACed through non-combat related injury
- O Compassionate leave
- O Problems at home
- O Routine change of role / appointment / posting
- O To attend professional courses
- O Other, please specify:

6.2 Did you receive a Return to Australia Psychological Screen brief? O Yes O No

If YES:

6.3 Do you believe this process was useful? (please shade ONE circle only)

O Not at all useful O Not particularly useful O Neither useful nor un-useful O Somewhat useful O Extremely useful

6.4 After leaving the theatre of operation, did you have a short period of time somewhere away from the operation area for you to relax before returning to your home base?

O Yes O No - **please skip to question 6.6**

6.5 **If YES:**

a) For how many days?

b) Was the majority of this time…? O Structured (a daily programme of activities, e.g. fitness) O Unstructured (no planned activities)

c) Did you find this period of time useful? O Yes O No

d) What were the good points?

e) What were the bad points?

Section Six: Post Deployment Experiences

6.6 After returning to your usual home base, were you required to spend some time in or around your home Unit before being allowed to go on Post Operational Leave?

- O Yes
- O No - **please skip to question 6.8**
- O Not applicable, did not go on Post Operational Leave - **please skip to question 6.8**

6.7 **If YES:**

a) For how many days were you required at your home Unit? ☐☐☐

b) Was the majority of this time...?
- O Structured (a daily programme of activities e.g. fitness / administration)
- O Unstructured (no planned activities)

c) Did you find this period of time useful? O Yes O No

d) What were the good points?

e) What were the bad points?

6.8 How long was it before you could relax properly on return to Australia?

O Immediately O 1 Week O 2 Weeks O 3-4 Weeks O 4-8 Weeks O 9 or more weeks O Have not

6.9 How long before you stopped scanning the environment for risk?

O Immediately O 1 Week O 2 Weeks O 3-4 Weeks O 4-8 Weeks O 9 or more weeks O Have not

6.10 Overall, do you think the Australian public were supportive of the mission to the MEAO during your MOST RECENT deployment? O Yes O No

6.11 Since returning home from your last deployment, has anyone had a go at you, or given you a hard time because you went to the MEAO? O Yes O No

Section Six: Post Deployment Experiences

6.12 To what extent do you agree or disagree with the following statements?

In the weeks after I came home...

	AGREE	DISAGREE	NOT APPLICABLE
a) I was well supported by the military	O	O	
b) I found it difficult to adjust to being back home	O	O	
c) People didn't understand what I had been through	O	O	
d) I did not want to talk about my experiences with my family / friends	O	O	
e) I found it difficult to resume my normal social activities	O	O	
f) I had serious financial problems	O	O	
g) I argued more with my spouse / partner	O	O	O
h) I have been let down by people who I thought would stand by me	O	O	
i) I had other major problems on return from deployment	O	O	

6.13 Were any of the following a problem?

a) Loss of seniority, promotion opportunity, or responsibility	O Yes	O No
b) Medical classification (MEC) downgraded	O Yes	O No

6.14 Overall, have your experiences on YOUR LAST DEPLOYMENT TO THE MEAO made you more or less likely to continue your military career?

O Very Likely O No difference O Less likely O Already Discharged

Section Six: Post Deployment Experiences

6.15 Were you married or in a significant relationship when you last deployed to the MEAO? ○ Yes ○ No - go to question 6.17

If YES: 6.16 In the weeks after you returned from your deployment:

a) How well did your partner meet your needs?	Poorly	○ 1	○ 2	○ 3	○ 4	○ 5	Extremely well
b) How good was your relationship compared to most?	Poor	○ 1	○ 2	○ 3	○ 4	○ 5	Excellent
c) How often did you wish you hadn't married or lived together?	Never	○ 1	○ 2	○ 3	○ 4	○ 5	Very Often
d) To what extent did your marriage or relationship meet your original expectations?	Hardly at all	○ 1	○ 2	○ 3	○ 4	○ 5	Completely

e) Which best described the degree of happiness, all things considered, in your relationship at the time?

○ Extremely unhappy ○ Fairly unhappy ○ A little unhappy ○ Happy ○ Very happy ○ Extremely happy ○ Perfectly happy

Please answer the following questions if you DEPLOYED AS A RESERVIST.

Otherwise, please go to Section Seven.

6.17 Were you in civilian employment at the time of your call-up for deployment?

○ Yes ○ No ○ Already in full time regular service or equivalent

6.18 Post-deployment, did you return to the same job you held before your deployment?

- ○ Yes
- ○ No, resigned at time of call-up / mobilisation
- ○ No, contract of employment ended just before / during deployment
- ○ No, employer kept job open for me but I chose not to return
- ○ No, employer did not keep job open for me, but I wanted to return
- ○ No, employer did not keep job open for me, and I didn't want to return
- ○ No, other reason, please specify:

6.19 Were any of the following a problem?

	YES	NO	NOT APPLICABLE
a) Loss of seniority, promotion opportunity, or responsibility in civilian job	○	○	○
b) Loss of income during call-up	○	○	○
c) Resentment from co-workers	○	○	○

Section Seven: Final Questions

As a check of our coverage in this questionnaire, please answer these final questions.

7.1 Are there other important military experiences or exposures we have not asked you about? ○ Yes ○ No

If YES: please give details in the space provided

Thank you for your time and effort in completing this questionnaire.

APPENDIX 6: PARTICIPANT LIAISON PROTOCOL

Appendix 6A: Protocol for Answering Participants‟ Telephone Enquiries

Answering telephone enquiries:

- Answer telephone “Good <<morning/afternoon>> Military Health Outcomes Program. <<Name>> speaking, how can I help you?”
- Identify the caller byfull name
- Identify which study they are involved in (they should be able to identify this from the title on each webpage or the front page of hardcopy questionnaire).
    - If they don‟t know which study they are involved in, look up their name and/or their PMKeyS number on DMAC Management Information System (MIS)
- Address enquiry as required (see Section 3 below)
- If the enquiry cannot be addressed immediately refer the call to the Study Manager concerned.
- Ask them if this has addressed their needs.
- Thank them for their enquiry
- Record details on the Message Form
- File hardcopy of the Message Form in appropriate participant files

Replying to emails:

- Identify who the email is from
- Identify which study they are involved in. If they haven‟t identified this, look up their name and/or their PMKeys number on the MIS.
- Address enquiry as required (see Section 3 below) on an email Reply
- If the enquiry cannot be addressed immediately forward the email to the Study Manager concerned.
- Record details of the enquiry on the Message Form
- Print out the original email and the reply email.
- Staple printout to the back of the Message Form
- File hardcopy of the Message Form with attachments in appropriate participant files

Types of enquiries:

- Technical problems with the web-based questionnaire
- Lost username / password
- Questions about how to answer the specific items on the survey
- Want to know more about the study
- Want to register a complaint
- Want to register their participation
- Want to register their refusal to participate
- Want to request another hardcopy questionnaire
- Want to update their own contact details
- Want to reschedule their physical testing test
- Want to reschedule their neurocognitive test

- Want to know where and/or when their physical test is
- Want to know where and/or when their neurocognitive test is
- Want access to own personal data
- Third party wants access to participants data

Technical problem with web based questionnaire:

1. Ask for participant"s contact details – best phone contact and also an email address just in case can"t contact
2. Ask for a short summary of the technical problem i.e. can"t open web page etc.
3. Make note of technical problem on Message Form
4. If possible, provide participant with an answer
5. If unable to solve problem:
    a) For Health Wellbeing Survey forward an email immediately providing details of enquiry to Belinda Mitchell (bel.mitchell@defence.gov.au) or call Belinda Mitchell (ph: 02 6127 2158), provide details of enquiry, obtain solution to problem, and contact participant with the solution
    b) For Prospective Study email immediately, providing details of enquiry, to dmac.support@adelaide.edu.au or if very urgent, transfer participant"s phone call to Andrew Holton (08 8303 4890)
6. If an email is sent notify caller that they will receive a response to their query within <<48 hours>>

Lost username or password:

1. Ask participant for details of lost username or password
2. Make note of the technical problem on the Message Form
3. For security purposes, ask participant for 3 pieces of identifying information:
    a) Full name
    b) Date of birth
    c) PMKeyS number
4. Look up the participant on the DMAC MIS by inputting their name and/or PMKeyS number
5. Cross check that the details they have provided are correct
6. If the participant"s details are correct, look up their username and/or password on the DMAC MIS
7. Provide participant with their username and/or password

Questions about how to answer the specific items on the survey:

1. Identify Item number/s where there is a query.
2. Look up the question on the questionnaire
3. Answer query if possible
4. If can not answer the query:
5. Ask for contact details – best phone contact and also an email address just in case cant contact
6. Make note of item query on the Message Form
7. Provide details to the appropriate party:

    a. If Health Wellbeing Survey forward call to Miranda Van Hooff or if not available forward an email immediately to miranda.vanhooff@adelaide.edu.au
    b. If Prospective Study forward call to Christopher Barton or Carol Davy or if not available forward an email immediately to either carol.davy@adelaide.edu.au or christopher.barton@adelaide.edu.au
8. If the query is forwarded by email, notify the caller that it will be answered within 48 hours

Want to know more about the study:

1. Identify specific information that is required.
2. Provide information if possible by referring to FAQ"s
3. If can not provide the information:
4. Ask for contact details (best phone number to contact and an email address just in case they can"t be contacted by phone)
5. Record details of query on the Message Form
6. Provide details to the appropriate party:
    a. If Health Wellbeing Survey forward call to Miranda Van Hooff or if not available forward an email immediately to miranda.vanhooff@adelaide.edu.au
    b. If Prospective Study forward call to Christopher Barton or Carol Davy or if not available forward an email immediately to either carol.davy@adelaide.edu.au or christopher.barton@adelaide.edu.au
7. If request is forwarded by email, notify the caller that will be answered within 48 hours

Want to register a complaint:

1. Obtain a short summary of the complaint and record on the Message Form
2. If not able to deal with it to the satisfaction of the caller or the participant liaison officer then provide details to the appropriate party:
    a. If Health Wellbeing Survey forward call to Miranda Van Hooff or if not available forward an email immediately to miranda.vanhooff@adelaide.edu.au
    b. If Prospective Study forward call to Christopher Barton or Carol Davy or if not available forward an email immediately to either carol.davy@adelaide.edu.au or christopher.barton@adelaide.edu.au
3. If request is forwarded by email, notify the caller that will be answered within 48 hours
4. Note action taken to follow-up complaint on Message Form, photocopy and put copy in the Complaints Log

Want to register their participation:

1. Explain to them that they are registered.
2. Establish where they are in the recruitment process (ie which letter they have received)
3. Explain the rest of the process to them
4. Establish whether they are happy to do the questionnaire hardcopy or web based:
    a. If the participant wishes to do it via the web, then confirm their email address
    b. If the participant wishes to fill out the hardcopy questionnaire, then confirm their postal address

Want to register their refusal to participate:

1. Establish reason for refusal
2. Attempt to overcome any barriers they have to participation by referring to the Barriers to Participation document.
3. If barriers cannot be overcome, suggest that they may want to leave out areas which they don‟t feel comfortable with.
4. If they still wish to withdraw, verify identity by either PMKeys or Study ID number.
5. If in the prospective study explain that they are able to withdraw from the pre deployment but still participate in the post deployment component.
6. If they do not want to participate in any MilHOP Study, record this on the Do Not Contact List located on the CMVH Share Drive S:\HealthSciences\SPHCP\CMVH\Projects\MILHOP PROGRAM\Do Not Contact List .
7. Register refusal on MIS
8. If a consent form has already been completed and they wish to change the consent provided then complete a Revocation of Consent Form
9. Place one copy in hardcopy participant file
10. Send one copy to the participant

Want to request another hardcopy questionnaire:

1. Ask for Study ID or PMKeys
2. Verify address
3. Inform them that hardcopy questionnaire will be sent to them within the week
4. Inform data manager to develop questionnaire with study ID on it and post out

Want to update contact details:

1. Ask for Study ID or PMKeys
2. Ask for new contact details
3. Update DMAC system

Want to reschedule their physical testing test:

1. Ask for Study ID or PMKeyS
2. Ask for reason for requested change
3. Check availability of other times/dates
4. If another time slot is available book in
5. Change sms reminder for saliva to new date if appropriate

Want to reschedule their physical testing test during Special Forces test period (after July 2010):

1. Ask for Study ID or PMKeyS
2. Forward call SOC Administration Officer

Want to reschedule their neurocognitive test:

1. Ask for Study ID or PMKeyS
2. Ask for reason for requested change
3. Check availability of other times/dates
4. If another time slot is available book in
5. Change sms reminder for saliva to new date if appropriate

Want to reschedule their neurocognitive testing during Special Forces test period (after July 2010):

1. Ask for Study ID or PMKeyS
2. Forward call SOC Administration Officer

Want to know where and/or when their physical test is:

1. Ask for study ID or PMKeyS
2. Check PT schedule
3. Advise participant
4. Check participant is available on day

Want to know where and/or when their neurocognitive test is:

1. Ask for study ID or PMKeyS
2. Check neurocognitive schedule
3. Advise participant
4. Check participant is available on day

Want access to own personal data:

1. Ask for study ID or PMKeys
2. Verify identity
    a. Date of Birth
    b. Check PMKeyS matches with name
3. Identify what information they want
4. Explain that it will need to be passed on to a senior member of staff and will take up to 1 week
5. Provide details of request in an email immediately to Alexander McFarlane alexander.mcfarlane@adelaide.edu.au to decide what action should be taken.
6. CC: details to the appropriate party:
    a. If Health Wellbeing Survey forward call to Miranda Van Hooff or if not available forward an email immediately to miranda.vanhooff@adelaide.edu.au
    b. If Prospective Study forward call to Christopher Barton or Carol Davy or if not available forward an email immediately to either carol.davy@adelaide.edu.au or christopher.barton@adelaide.edu.au

Want access to third party personal data:

1. Advise that not able to provide that information to any third party
2. If they require further information than immediately Provide details to the appropriate party:
    a. If Health Wellbeing Survey forward call to Miranda Van Hooff or if not available forward an email immediately to miranda.vanhooff@adelaide.edu.au
    b. If Prospective Study forward call to Christopher Barton or Carol Davy or if not available forward an email immediately to either carol.davy@adelaide.edu.au or christopher.barton@adelaide.edu.au

Appendices

- FAQs
- Message Form
- Process for transferring 1800 number calls Frequently Asked Questions
- Barriers to Participation
- Revocation of Consent Form
- List of study IDs
- Copy of all questionnaires

Appendix 6B: Frequently Asked Questions

Prospective Study

1.0 ABOUT MilHOP

1.1 WHAT IS MilHOP?

The Military Health Outcomes Program (MilHOP) is a comprehensive large-scale program aimed at assessing the physical and mental health status of currently serving and ex-serving ADF personnel. This program has been set up in response to a Government decision in 1999 to conduct health reviews on future overseas deployments, and builds on recent CMVH health studies that explored deployments to the Near North Area of Influence.

There are three different studies being rolled out in 2010/11 under the MilHOP banner:

(i.) The Middle East Area of Operations (MEAO) Prospective Health Study

The aim of this study is to understand the changes that occur to health and wellbeing during your deployment to the MEAO. As such, we will complete an assessment before you deploy and then again when you return from the deployment.

(ii.) The Middle East Area of Operations (MEAO) Health Study

The aim of this study is to better understand the long term health of ADF personnel who have already deployed to the Middle East Area of Operations between 2002 and 2009.

(iii.) The Health and Wellbeing Survey

The aim of this survey is to better understand the health and wellbeing of Australian Defense Force Members. It‟s part of the Federal Government‟s commitment to conduct health reviews of military personnel.

1.2 WHO IS CONDUCTING THESE STUDIES?

These studies are being conducted by the Centre for Military and Veterans‟ Health at the University of Adelaide and the University of Queensland. We‟ve been contracted by the Australian Defence Force (ADF) Joint Health Command to conduct the MilHOP studies, with the support of the Chief of the Defence Force and the Repatriation Commissioner.

1.3 WHO IS RESPONSIBLE FOR THIS STUDY WITHIN DEFENCE?

The ultimate responsibility for this study lies with the Head of Joint Health Command, Major-General Paul Alexander. Within Defence Health Services we report the study outcomes to our Program Management Board, which is chaired by Brigadier Steve Rudzki, the Director General Strategic Health Coordination, Joint Health Command. The Service Chiefs and Ministers for Defence and Veterans‟ Affairs will also be briefed on the study outcomes.

2.0 PRIVACY/CONSENT

2.1 WHAT WILL HAPPEN TO THE INFORMATION I GIVE?

The information from all participants combined will be summarised in a report to Defence and in articles in the scientific literature. These will include summary information only and neither you nor anyone else will be individually identifiable.

2.2 HOW WILL MY PRIVACY BE ASSURED?

Everything you tell us is completely confidential and won‟t be passed to any other person or organisation, including the Departments of Defence or Veterans‟ Affairs. Answers from your questionnaire and data from your Defence health records (or any other health assessments) will be identified by a unique study number and treated anonymously, so that your name will never be associated with any of the information collected by us. Any reports or published articles resulting from the study will also preserve your anonymity.

Any personal data collected will be used only for the deployment health studies conducted by the Centre for Military and Veterans‟ Health, unless you give your express permission for it to be used in other research. Data are accessed only by authorised personnel and are be stored on password-protected computers and in secure storage facilities at the Universities of Queensland and Adelaide

2.3 HOW DID THE STUDY INVESTIGATORS GET MY NAME?

Your contact details, including PMKeyS, and Unit contact information have been provided to CMVH by the Department of Defence for the purposes of conducting the Prospective Study.

Defence has contracted CMVH to conduct this study because they specifically want to improve the health services in the ADF. CMVH was chosen because we have extensive experience in identifying and seeking solutions to military and veterans‟ health issues.

In addition, as CMVH is not part of Defence you will be able to provide your personal opinions freely and anonymously. All of information collected as part of this study will be treated confidentially. No identified data will be passed to the Department of Defence. Any reports or published articles resulting from the study will not include any personally identifying information and will preserve your anonymity. Data are able to be accessed only by authorised personnel and will be stored on password-protected computers and in secure storage facilities. All personnel working on the study will have restricted security clearances.

You also need to remember your participation is completely voluntary and the Department of Defence will not be told about whether or not you agree to take part in this study. Your details will not be forwarded to any other individual or agency and will not be used for any purpose without your specific agreement, as indicated by signing the Consent Form that is supplied with your questionnaire.

2.4 WHY DO YOU WANT MY CONTACT DETAILS?

We need your contact details so we can send you the questionnaire and contact you for further follow-up. Because Defence personnel move around a lot we also ask for the names of up to two relatives or friends who may be able to tell us where you are. These individuals will only be contacted if we cannot contact you at the address you have given us. To ensure confidentiality of your information, contact information will be stored separately from the rest of your information. Your questionnaire will be identified not by name but by a unique study number only, which will be linked by a code stored securely and separately from your study information.

2.5 WHY DO YOU WANT PERMISSION TO CONTACT MY SPOUSE/PARTNER?

The Centre for Military and Veteran‟s Health is concerned with all aspects of health and wellbeing that could be affected by ADF personnel deployments. This would include how deployments may also affect loved ones involved, so future research could look at these areas. However, your consent to this action would provide us only with permission to contact your spouse to invite him or her to take part in any such research. It does not mean that she or he has to participate.

3.0 STUDY PARTICIPATION

3.1 WHY HAVE I BEEN INCLUDED IN THIS STUDY?

Questionnaire

You have been invited to complete the self administered questionnaire component of the Middle East Area Of Operations (MEAO) Prospective Study as you have been identified by Defence as deploying to the MEAO after the 1st June 2010, and will return from deployment before the end of November 2011.

Physical Testing

You may also have been invited to complete a physical test comprising of measurement of height, weight and waist to hip ratio; lung function test; step test; a photograph of hands, feet, back and non identifiable sections of the face; and provide a blood and saliva sample to assess a range of biochemical, cellular and immunological factors that may contribute to health states. The physical tests will take approximately one hour to complete.

Neurocognitive Assessment

Some ADF members are also invited to undertake a test of neurocognitive assessment. This test will measure resting electrical activity, emotion recognition, response inhibition, target detection and your reaction to a loud sound.The neurocognitive testing component will also take approximately one hour to complete.

3.2 DO I HAVE TO TAKE PART IN THE STUDY?

Your participation in the Study is entirely **voluntary**. There is no obligation to take part in the study and you can withdraw from the study at any time by contacting the Study Team on 1800 886 567 or emailing milhop@cmvh.org.au.

Information about whether you have participated or not will not be passed on to the Departments of Defence or Veterans‟ Affairs. Nor will your decision to take part impact in any way on your career, pension, future health care or any current or future claim for compensation.

3.3 WHY SHOULD I PARTICIPATE IN THE STUDY?

The results of this study may assist you and other current or former Service personnel in gaining recognition for Service-related ill-health. It may also assist the ADF in developing the most appropriate supportive and protective measures against future health threats.

3.4 IS THE STUDY ONLY FOR CURRENT SERVING MEMBERS OF DEFENCE?

The MEAO Prospective Study involves only currently serving ADF members.

3.5 WILL I BE DISADVANTAGED IF I DON'T PARTICIPATE?

Your decision to take part will not impact in any way on your career, pension, future health care or any current or future claim for compensation. If you are interested in the results of the study, you will be welcome to review summaries of findings which will be published on the MilHOP website in due course.

3.6 WHO IS RESPONSIBLE FOR THIS STUDY WITHIN DEFENCE?

The ultimate responsibility for this study lies with the Head of Joint Health Command, Major-General Paul Alexander. Within Defence Health Services we report the study outcomes to our Program Management Board, which is chaired by Brigadier Steve Rudzki, the Director General Strategic Health Coordination, Joint Health Command. The Service Chiefs and Ministers for Defence and Veterans‟ Affairs will also be briefed on the study outcomes.

3.7 WHAT COMMAND APPROVALS HAVE BEEN OBTAINED?

The MEAO Prospective Study has been endorsed by Chief of the Defence Force, Air Chief Marshal Angus Houston, AC, AFC, and the Vice Chief of the Defence Lieutenant General David Jurley, AO, DSC.

3.8 I COMPLETED A CMVH DEPLOYMENT SURVEY ON SOLOMON ISLANDS, BOUGAINVILLE / EAST TIMOR – DO I HAVE TO DO IT AGAIN?

We really appreciate the participation of those who have already taken part in the Near North Area of Influence studies. However, the MEAO Prospective and Health Studies will be gathering information specific to the MEAO deployments. We would also like to take the opportunity to gather current information from you as your health and other circumstances may have changed over time.

3.9 CAN I VOLUNTEER FOR THE STUDY?

All participation in the study is voluntary. If you haven‟t received an invitation and would like to participate please ring 1800 886 567 or email or milhop@cmvh.org.au.

3.10 WHY HAVEN'T I RECEIVED AN INVITATION?

If you are **currently** a **Regular** member of the ADF and you are about to deploy to the MEAO you should receive an invitation for the MEAO Prospective Study approximately three months prior to your deployment. If you are deploying within the next three months and haven‟t received an invitation, please contact 1800 232 904 or email cmvh@adelaide.edu.au.

3.11 WHAT WILL THE STUDY INVOLVE?

You will be asked to complete a questionnaire three months before you deploy and four months after you return regarding:

- Your previous deployments
- Your health now
- Your deployment experiences

You will be provided with the option of completing the questionnaire in an online format or on paper. If you have difficulty with either of these methods we can collect the data by a telephone interview. Filling out the questionnaire should take between 30 and 60 minutes, however, the time will depend on individual responses.

A number of people (~750) will also be asked to undergo the following physical health assessments:

- Measurement of height, weight and waist to hip ratio;
- Lung function test;
- Step test to assess aerobic capacity;
- A dermatological assessment which involves photographing hands, feet, back and non identifiable sections of the face; and
- Blood and saliva sample to assess a range of biochemical, cellular and immunological factors that may contribute to health states.

The physical tests will take approximately one hour to complete.

A number of people (~n = 400) will also be asked to undertake a neurocognitive assessment. This test will measure:

- resting electrical activity;
- emotion recognition;
- response inhibition;
- target detection; and
- reaction to a loud sound.

The neurocognitive testing component will also take approximately one hour to complete.

With your consent, data from routine Defence health assessments including RtAPS and POPS may also be linked to the data we have directly collected from you during the study.

All aspects of the study are **voluntary** and you can choose which aspects of the study you **do** or **do not** wish to participate in when completing the Study Consent Form. The ADF Chief of Defence has given permission for you to complete any component of this study during work time.

3.12 DOES MY COMMANDING OFFICER KNOW ABOUT THIS STUDY?

Your CO should have been informed that the study is taking place. If you are currently serving in the Defence Force you can complete the questionnaire in work time. This study has the support of the Chief of the Defence Force and the Repatriation Commissioner.

3.13 CAN I DEFER MY PARTICIPATION?

If you are unable to take part at present, but would like the opportunity to consider participating at a later date, please contact the MilHOP team on 1800 886 567 or by email milhop@cmvh.org.au and tell us your Study ID number and the date when you‟ll be available, and we will arrange to contact you again then. We will suppress any study reminders which you would have received in the meantime.

3.14 WILL MY ANSWERS AFFECT MY DEPLOYMENT ELIGIBILITY?

No. Individual information collected as part of this study will not be passed on to the Department of Defence.

3.15 WHAT WILL HAPPEN TO THE INFORMATION THAT I GIVE?

Your responses to the questionnaire, information from your Defence health records and data from any physical health assessments conducted by CMVH (if applicable) will be collated and analysed to determine whether the health of Service personnel differs in relation to their deployments and the nature of those deployments.

3.16 WILL I BE ABLE TO GET A COPY OF THE RESULTS OF THE STUDY?

The MEAO Prospective Study involves collection of your answers to a questionnaire. You may find it helpful to make a copy of your questionnaire before you return it, if you would like to keep your answers for future reference. Otherwise, you can request a copy of your answers from the Study Team.

Both summary and final reports of aggregated data will be available on the Defence, DVA and Centre for Military and Veterans‟ Health (www.cmvh.org.au) websites.

If you would like to receive individual feedback on the information you have provided as part of this study, please phone 1800 232 904 or email cmvh@adelaide.edu.au.

4.0 COMPLETING THE QUESTIONNAIRE

4.1 DO I HAVE TO ANSWER EVERY QUESTION?

It‟s fine to omit any question that you would prefer not to answer; just leave it blank and move on to the next one. Also, note that not every question will be applicable to you. Therefore, the questionnaire may appear longer or bigger than what you will end up completing.

4.2 WHY ARE THE QUESTIONS REPETITIVE?

The questions we are using come from standardised questionnaires which have been used in other similar studies. They have therefore been tested to ensure that they capture the information we need. Using them also allows us to compare our results with previous studies.

4.3 WHY DOES THE QUESTIONNAIRE SEEM SO LONG?

The questionnaire is divided into different parts, or booklets to help simplify the types of questions that you are asked to complete. Keep in mind that not every question will be applicable to you and there will be questions or even entire sections that you will therefore be asked to skip.

Also, you are able to save your progress in the web based questionnaire at any point so that you may continue the rest of the questionnaire at a later time. There is no limit on how many times you save your progress, so you can complete the questionnaire at your leisure.

4.4 WHAT HAPPENS IF I CAN'T PARTICIPATE IN THE PRE-DEPLOYMENT COMPONENT?

If you are unable to take part before you deploy, but would like the opportunity to consider participating post deployment, please contact the MilHOP team on 1800 232 904 or by email cmvh@adelaide.edu.au and tell us your Study ID number, and we will arrange to contact you once you return from deployment. We will also suppress any study reminders which you would have received in the meantime.

4.5 THE QUESTIONS ARE DISTRESSING.

If you find any of the questions distressing and would like to seek help, there is a list of support organisations included in the information sheet. If you prefer, you can also complete the questionnaire by a telephone interview. It is also fine to omit any particular question which you would prefer not to answer

4.6 I HAVE HAD / MY PARTNER HAS HAD MORE THAN FOUR PREGNANCIES – HOW DO I COMPLETE SECTION SEVEN 'YOUR REPRODUCTIVE HISTORY' IN THE HARD COPY VERSION OF THE QUESTIONNAIRE?

Please call the MilHOP team on 1800 232 904 and a team member will take down the details of these pregnancies over the phone.

4.7 WHY DOESN'T THE ONLINE QUESTIONNAIRE DISPLAY / OPERATE PROPERLY?

Our online survey has been tested using most common browser programs. However, depending on your particular settings in your own browser software, it may not always display or operate as intended. If you experience this problem, please contact the Study Team on 1800 232 904 or cmvh@adelaide.edu.au and we can send you a hard copy of the questionnaire or arrange to collect your data by a telephone interview. Alternatively, if you change your browser settings or have access to another computer, you could try again.

4.8 WHY AM I NOT RECEIVING EMAILS THAT I SHOULD BE GETTING?

Emails (e.g., invitation emails, reminder emails, and emails to resume online questionnaire completion) are sent out using online survey software. Depending on the settings you have for your own email program, study emails may be diverted to the junk email folder. Make sure to check your junk mail in case this has happened. Sometimes these emails may be undeliverable if your mail server was down at the time the email was sent or if your mailbox is full.

Alternatively we may have an outdated or incorrect email address for you. Please contact us on 1800 232 904 or by email at cmvh@adelaide.edu.au if you think this may be the case and provide a team member with your current email address.

4.9 I HAVE LOST MY PASSWORD OR WEBLINK.

If you have lost your password or web-link, please ring the MILHOP free-call number on 1800 232 904 and you will be referred to a database specialist who will be able to assist you with your problem. Alternatively, send an email with your query to cmvh@adelaide.edu.au and you will be contacted via email/telephone with a solution to your problem.

4.10 WHERE CAN I GET MORE INFORMATION ABOUT THE STUDY?

To obtain more information about the Study you can contact the MilHOP Team on the toll free number: 1800 232 904 or by email at cmvh@adelaide.edu.au.

The contact details of the study investigators are provided on the back panel of the information sheet and in a separate link on the landing page of the website.If you have any concerns and wish to speak to someone not directly involved in running the study you can also contact any of the ethics committees who have given approval for this study, whose contact details are also listed in the information brochure.

Appendix 6C: Telephone Message Form

Message Form

Date: _____/_____/_____	Time: _____:_____am/pm
Taken by: _____	❑ Live call ❑ Phone Message ❑ Email Message

Caller Identification:

Study ID: ..... **PMKeys No:**.....

Name: ..... **DOB:**.....

Study: Health & Wellbeing / Prospective / Census

Reply via: Phone: (……..).....

Email:.....

Reason for enquiry:	
❑ General study enquiry (inc. confidentiality)	❑ Withdraw from study once started (not data)
❑ Specific survey item query	❑ Withdrawal from study and of data
❑ Technical problems with online survey	❑ Distressed
❑ Username / password or link lost	❑ Returning .....'s call / email
❑ Update contact details	❑ Reschedule interview
❑ Request hardcopy questionnaire	❑ Reschedule physical testing test
❑ Register a complaint	❑ Reschedule neurocognitive test
❑ Register participation	❑ Want to know where/when their physical test is
❑ Deferral of participation	❑ Want to know where/when their neurocognitive test is
❑ Do not contact at home	❑ Want access to own personal data
❑ Refusal to participate	❑ Third party wants access to participants data
	❑ Other.....

Query status: ❑ Query dealt with

Additional details of enquiry:
(continue overleaf if required)

Response to enquiry:
(continue overleaf if required)

Appendix 6D: Barriers to Participation

- Don‟t have time/too busy to do questionnaire
- Don‟t have time/too busy to do physical/neurocognitive testing
- Too many surveys
- Not a good time for them due to too many problems or issues in life
- Want to spend time with family/friends before deployment- not fill in surveys
- Been on other deployments before and have not had negative effects

Don't have time/too busy to do questionnaire

It is not essential that the questionnaire be filled in all in one sitting. If you are doing the questionnaire online, make sure that you click the save the button and you will be emailed a new login in order to return to the questionnaire at a later time.

Don't have time/too busy to do physical testing/neurocognitive testing

The Chief of Defence has endorsed and your Commanding Officer has allocated a specific time slot for you to complete these components. Would you like us to ring and verify that this time is acceptable to your particular work circumstances?

Too many Surveys

Health and Wellbeing Study
This is the first time that the entire ADF is being surveyed (HWB + Census).

This is happening as an outcome of the Dunt review of mental health problems in the ADF which means that from a government perspective this study is intended to bring about positive change for ADF personnel.

If you don‟t participate results may not be entirely representative of everyone

Prospective Study
This is the first time that ADF members are being surveyed before and after deployment which will let us see specific changes that occur during deployment.

The overall results of the study will inform Defence about the effects to the health and wellbeing of Defence members while on deployment, which will highlight the specific issues to health and wellbeing that occur as a result of deployment to the Middle East.

Not a good time for them due to too many problems or issues in life?

If you feel it‟s too difficult to take part at present, but would like the opportunity to consider participating at a later date, we can arrange to contact you again when things have settled down. Would it be alright if I called you in a few months time? We will suppress any study reminders which you would have received in the meantime.

Want to spend time with family/friends before deployment- not fill in surveys

I completely understand and know that this is a busy time for you, but a study such as this can have important long term benefits for you and your family.

Specific health issues and well being issues will be looked at, including the impact of the deployment on your family.

You should be able to arrange time during work hours to do the questionnaire.

I've been on other deployments before and have not had any negative effects

We want to get a representative sample; if only people with problems filled out the survey then would we would get a very negative view of deployment and its outcomes.

Your individual point of view won't be represented if you don't participate.

Each deployment is different, and the effect of multiple deployments can also be important.

Appendix 6E: Revocation of Consent Form

MILITARY HEALTH OUTCOMES PROGRAM

WITHDRAWAL OF CONSENT FORM

SID:

It has been recorded that .....wishes to withdraw consent for the:

- Health and Wellbeing Survey ☐
- MEAO Prospective Study ☐

The participant wishes to withdraw consent for (please tick all that apply):

- Questionnaire data ☐
- CIDI Interview data ☐
- Physical Testing Data ☐
- Neurocognitive Testing Data ☐
- Linkage to Defence health records ☐
- Linkage to Defence psychological records ☐
- Being contacted about future studies ☐

_____
Signature of Research Officer

____/_____/_____
Date Consent Change or Revoked Recorded

Revocation of Consent Form-MilHOP-CD-20100407-v2.doc

APPENDIX 7: TELEFORM SCANNING INSTRUCTIONS

PRINTING QUESTIONNAIRES FOR MAIL OUT

1. Open Teleform Auto Merge Publisher using the shortcut on the desktop or the following link: Start Menu>Programs>Cardiff Teleform>Teleform Auto Merge Publisher

2. Once it opens, go to File>Schedule Print.

3. You are in the form tab. Click in the box next to the word Form. It will bring up a box to open the questionnaire. Pick the questionnaire you want and press ok.

4. Change the number of copies you want.

5. **IMPORTANT** Click the Auto Increment Fill tab. Tick the box that says “Enable automatic fill”. Fill the ID field from the prepared database.

PRINTING A SINGLE QUESTIONNAIRE

1. Open Teleform Auto Merge Publisher using the shortcut on the desktop or the following link: Start Menu>Programs>Cardiff Teleform>Teleform Auto Merge Publisher

2. Once it opens, go to File>Schedule Print.

3. You are in the form tab. Click in the box next to the word Form. It will bring up a box to open the questionnaire. Pick the questionnaire you want and press ok.

4. **IMPORTANT** Click the Auto Increment Fill tab. Tick the box that says “Enable automatic fill”. Fill the ID field.

SCANNING A COMPLETED QUESTIONNAIRE

1. Open Teleform Scan Station, Teleform Reader and Teleform Scan Station in Start Menu>Programs>Cardiff Teleform

2. Put booklet/interview in the photocopier feeder (face up). On the photocopier, go to the “scan” tab, and press online.

3. On the computer, go to Scan Station. Press the “new batch” button at the top left. If you want to scan double sided make sure that the process tab>feeder says “front & back”. Press start. This will scan the document.

4. A window followed by another window will pop up. Press OK at the first window then Cancel at the second window. Press Accept.

5. Remove booklet and press offline on the photocopier.

6. Go to teleform reader. The text moving at the bottom of the screen is reading the data. That is all this window does. When the text stays still and says “Idle”, it has finished reading.

7. Go to teleform verifier. Press the refresh button on the right. The batch that you just scanned will be added to the bottom of the list. If there are things you need to verify it will tell you. Click on your batch and press the “process button”. TAB through the fields that need to be verified, changing them as necessary. Save the changes when prompted.

8. Press refresh again. Your batch should now say ready to be committed. If not, go through process again. When ready to commit the data, make sure your destination file is NOT open. Right click on your batch and press commit. Your data will be committed to a CSV file.

APPENDIX 8: SUICIDAL IDEATION RESPONSE PROTOCOL

MEAO Prospective Study
Suicidal Ideation Response Protocol

The purpose of this Suicidal Ideation Response Protocol is to set out the process for responding to and offering further support for participants in the MEAO Prospective Study who respond positively to a suicide ideation question on either the pre deployment or post deployment questionnaire.

1. *Identifying Participant Who May Require Additional Support*

- All questionnaire data including the answers to the questions pertaining to suicidal ideation will be reviewed by the research team on a weekly basis.
- The file of any participant suggesting suicidal ideation will be further reviewed by the Principal Investigator (a psychiatrist).
- Any participant answering yes to any of the questions pertaining to suicidal ideation would be provided with additional support as described below.

2. *Identifying the Correct Support Process*

The MEAO Prospective Study is inviting all ADF members deploying to the Middle East Area of Operations (MEAO) after June 2010 and returning from deployment by December 2011 to participate in a MEAO Prospective Study. Pre deployment data (including a questionnaire) may be collected sometime within the four months prior to deployment, with post deployment data collected up to four months after returning from the MEAO.

During the pre deployment phase of data collection, a small number of ADF members may complete the questionnaire just prior to deploying and therefore may have already left Australia by the time that the questionnaire is posted back to the research team and reviewed. Therefore, two separate processes have been identified (see Section 3 for those not deployed and Section 4 below for those already deployed).

3. *Supporting Participants Who Have Not as yet Deployed*

A research staff member who has completed an Applied Suicide Intervention Skills Training (ASIST) Course will contact all identified participants who have not as yet deployed (refer Section 2 above). This staff member will

- make sure they are speaking with the right person,
- introduce themselves and where they are from,
- remind them about the MEAO Prospective Questionnaire and emphasise once again that no information provided by them has been passed onto Defence,
- note the reason for the phone call relates to some of the answers given in the MEAO Prospective Study questionnaire; and
- ask if they have time to talk and are in a private environment (if not, the staff member will arrange for the most suitable time to ring back).

The ASIST protocol suicide intervention program will then be administered. This protocol is designed to identify someone who may be at risk of suicide; respond in ways that help increase their immediate safety; understand why suicide thoughts are present and link the identified participant to further help.

In addition, to offering to follow up the initial phone conversation at a later date, information pertaining to and encouragement to contact the following support services will be provided:

- ADF ALL HOURS SUPPORT LINE
- LIFELINE
- VETERANS AND VETERANS' FAMILY COUNSELLING SERVICE
  VETERANS' AFFAIRS NETWORK (VAN)
- DEPARTMENT OF VETERANS' AFFAIRS
- NATIONAL OFFICE FOR THE MILITARY COMPENSATION AND REHABILITATION SERVICE

Identified participants will also be invited to participate in a Composite International Diagnostic Interview (CIDI) (refer to 5 below for information pertaining to the CIDI). Another time suitable for the participant, will be organised for undertaking the CIDI if required.

4. Supporting Participants Who Have Already Deployed

As discussed in section 2 above, a very small number of identified participants may have already deployed. Where an identified participant is found to have already deployed, a letter addressed to the identified participant and marked confidential will be placed within a sealed envelope and sent to the units psychologist with instructions deliver the letter unopened. This letter is designed to:

- reassure the participant that their information has not been passed on to Defence and that the person delivering the letter is unaware of its contents,
- raise the issue/s of concern,
- encourage them to seek support; and
- provide information pertaining to the support services available to them including contacting the person who delivered the letter.

The letter will also include a return slip as well as a reply paid envelope which they will be asked to return to ensure that the letter has been received. If this reply is not received within three weeks, a follow up letter will be sent (refer Appendix B).

5. CIDI Interviews

The CIDI, which has already been adopted by both the MEAO Census Study and Health and Well-being Survey, is recognised internationally as the gold standard for assessing mental health as well as psychiatric disorders in epidemiological settings. Administered by telephone, the CIDI will be able to assess disorders including depression, mania, panic disorder, specific phobia, social phobia, agoraphobia, generalised anxiety disorder, PTSD (in relation to their worst lifetime event and a random event), obsessive compulsive disorder and separation anxiety disorder. Clinical calibration studies have demonstrated the validity of measures collected through CIDIs (Haro, Arbabzadeh-Bouchez et al. 2006).

If an identified participant accepts an invitation to participate in a CIDI, the research staff member will:

Prior to Conducting the CIDI

- Provide verbal information to the participant about the CIDI interview including the length of the interview and the type of questions which may be asked.
- Arrange a suitable time for the participant (including after hours if requested) to undertake the CIDI. At least 24 hours will lapse between acceptance of the invitation to participate and the CIDI taking place.
- Send the participant an email containing information pertaining to the the agreed date and time of the interview (refer Appendix C).

Conducting the CIDI

Interviewers who have completed the ASIST course will administer all CIDIs. A strict protocol for administering the CIDI can be found in Appendix F. In particular, this protocol ensures that the identified participant is provided with detailed information about the process prior to commencing and that they are made aware of their right to not answer any of the questions and to cease the interview at any time. At two separate time points during the information stage of the CIDI, identified participants are specifically asked about their wish to continue with the CIDI.

Most importantly for the identified participant, CIDIs provide an opportunity for research team member trained in applied suicide intervention skills to assess the participant and if necessary provide suicide first aid and encourage them to seek further support.

APPENDIX 9: SOC LIAISON OFFICER SOP

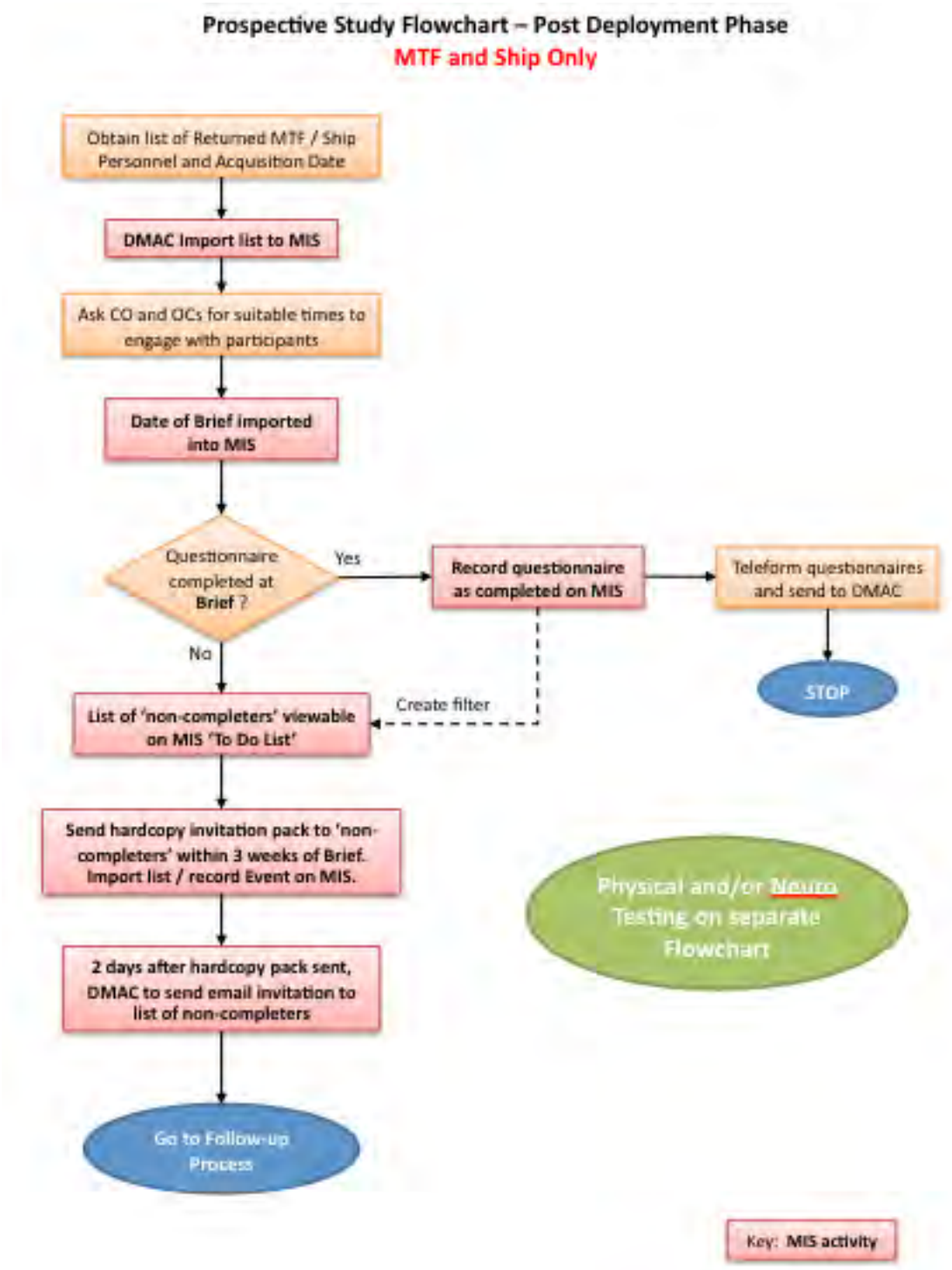
SOP: **POST DEPLOYMENT ADMIN OF NON-SPECIAL FORCE PERSONNEL**

PROCESS BREAKDOWN:

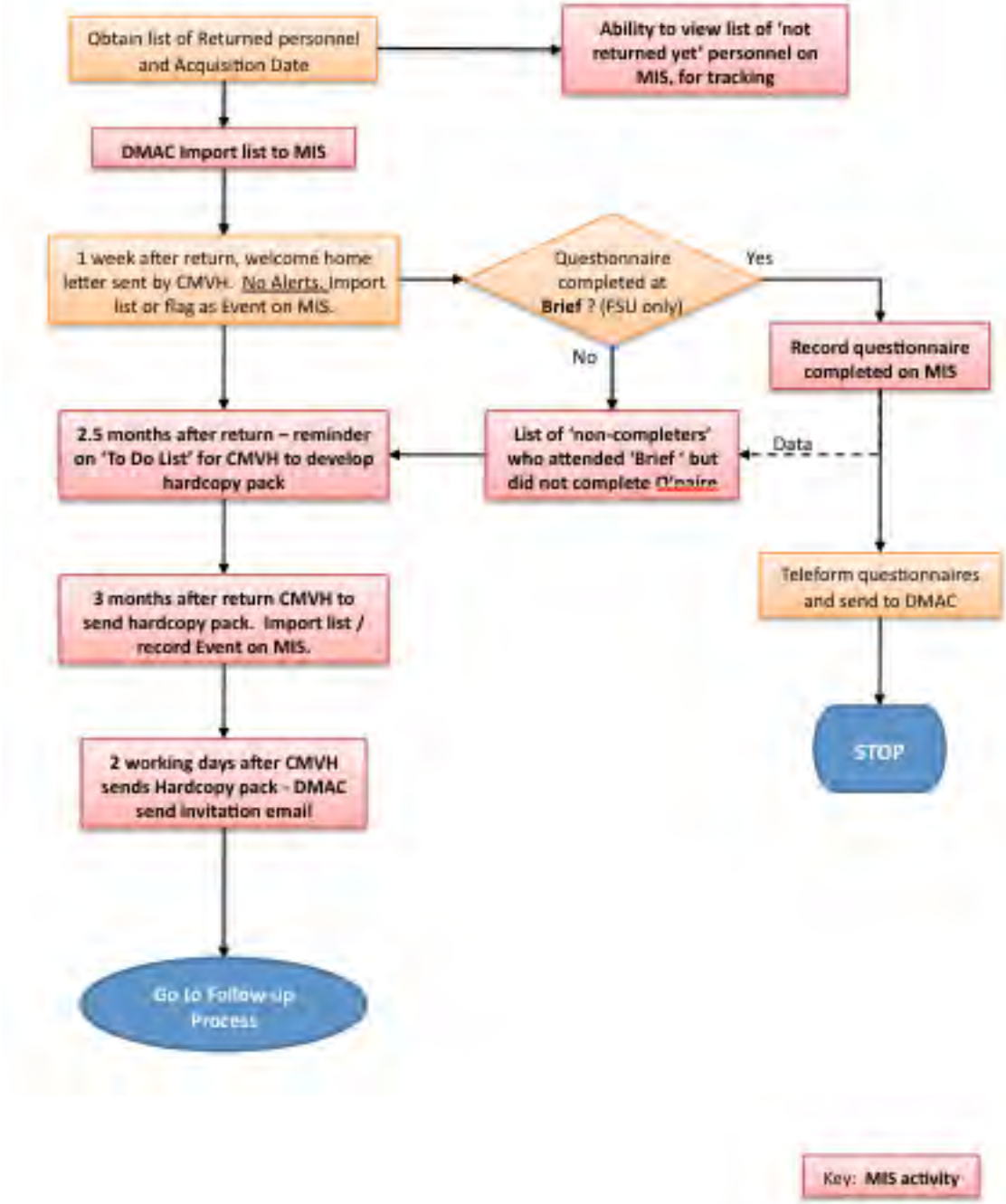
STEP	DESCRIPTION	RESPONSIBILITY	When
1.	Retrieve RTA Dates from OP LOGS within PMKeyS for formed body returns or within HOJOC PERS PLAN cell.	SOC Administration Officer	As early as possible
2.	Liaise with HQ JOC to retrieve RTA dates for the following groups: 1. Early return for no reason 2. NOTICAS – medical reason 3. COMCAS – compassionate reason	SOC Administration Officer	On a weekly basis
3.	Annotate the RTA dates on the deployed units database	SOC Administration Officer	Weekly
4.	Identify all eligible post deployment participants: 1. members who did not participate in any pre deployment activities 2. participants who completed just the pre deployment questionnaire 3. participants that completed the questionnaire and physical and/or Neurocognitive assessments	SOC Administration Officer	Weekly
5.	Provide the following to the Study Manager and PLO as soon as unit and individual deployment RTA dates are identified for each of the three lists noted in item 4 above. For each participant indicate: • Participant ID • Participant Rank, first and last name • RTA date • Whether associated with a formed unit • Reason for return as per item 2 above or alternatively "return as per deployment"	SOC Administration Officer	Weekly
7	Liaise with unit CO/OC for the return of Team for the post deployment follow up activities, ie questionnaires, physical and/or neuro testing approximately 2 – 4 months post deployment. These units include: Army:	Study Manager in collaboration with DLO	Within 1 month of RTA

	• MTF – members should be returning to their place of embarkation – members complete Questionnaire, Physical and Neuro • FSU – members should return to their place of embarkation Navy: • Ships – members should be returning to their place of embarkation Air Force: • C130 – members will be returning to their place of embarkation • P3 – members will be returning to their place of embarkation • C17s – members will be returning to their place of embarkation		
8	Send participant welcome home letters to those members who completed the pre deployment questionnaire, and new eligible participant welcome home letters to those who did not complete the pre deployment questionnaire	PLO	One month after RTA
10	Send questionnaire to those participants not included in a unit with face to face post deployment follow up (see item 7). This will include: Army • FCU – members will be returning to their nominated units located around Australia – mail out of questionnaire. • 39PSB member will be returning to their nominated unit located around Australia – mail out of questionnaires Airforce • CSU – members will be returning to their nominated units located around Australia – mail out of questionnaire. • TK - member will be returning to their nominated units located around Australia – mail out of questionnaire.	PLO	1.5 to 2 months after RTA
11	Undertake post deployment questionnaire, physical testing and Neurocognitive assessment base visits as appropriate (see item 7)	Study Teams	As agreed schedule in item 7

APPENDIX 10: PROSPECTIVE STUDY FLOWCHARTS

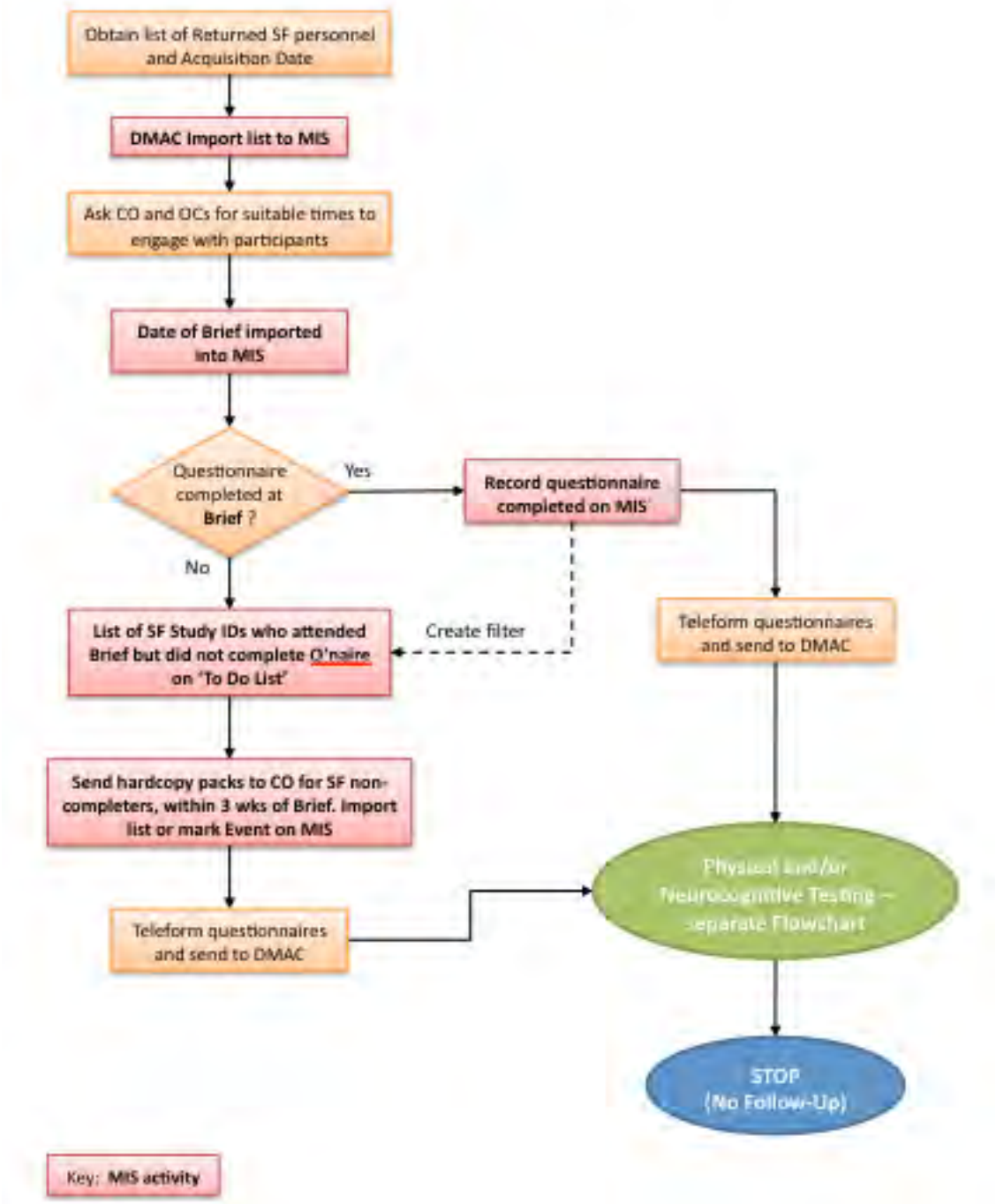


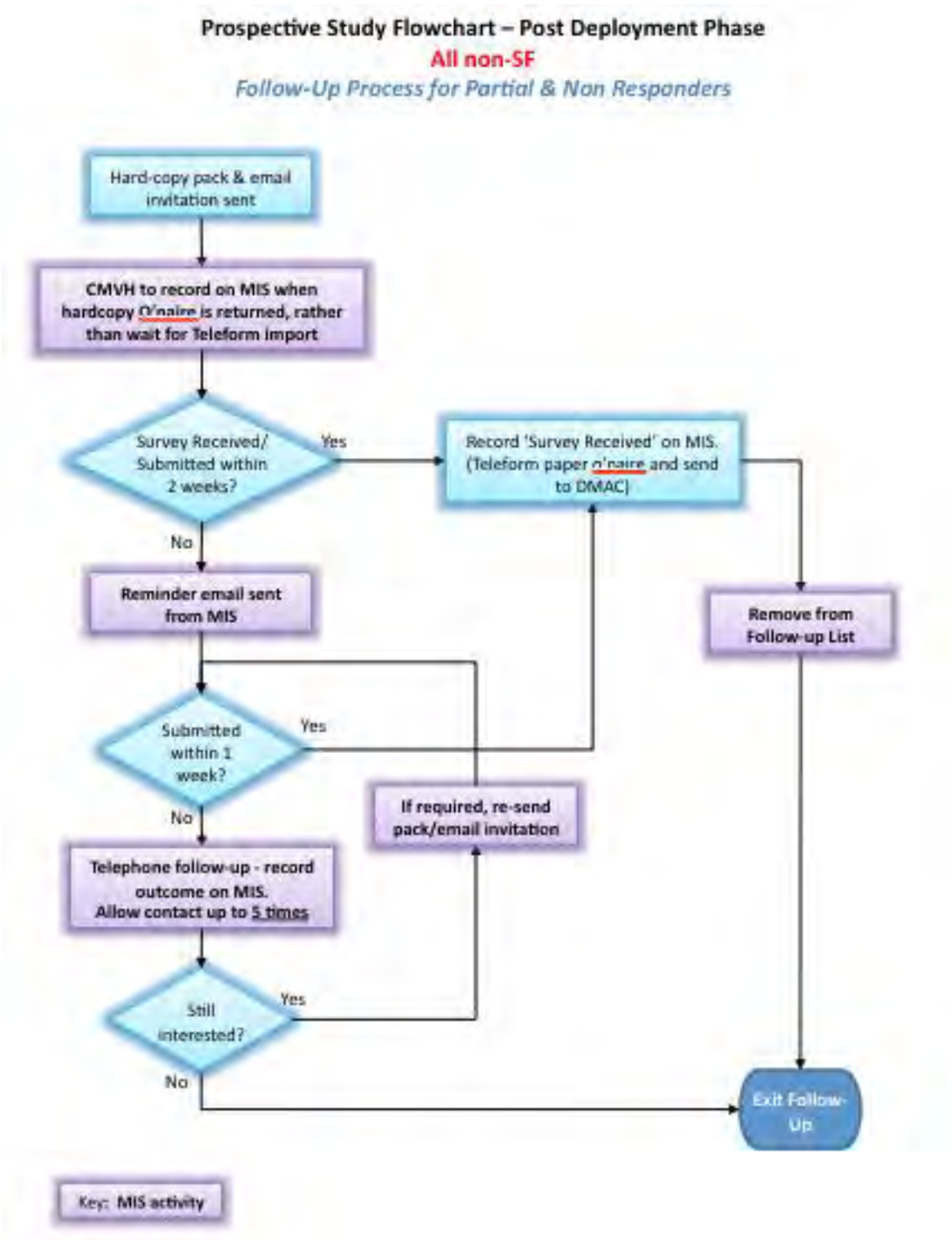
Prospective Study Flowchart – Post Deployment Phase
Non MTF / SF / Ship – No Physical/Neuro Testing



Prospective Study Flowchart – Post Deployment Phase

SF Only




Prospective Study Flowchart – Post Deployment Phase
All non-SF
Follow-Up Process for Partial & Non Responders
Hard-copy pack & email invitation sent
CMVH to record on MIS when hardcopy Q'naire is returned, rather than wait for Teleform import
Survey Received/ Submitted within 2 weeks?
Yes
Record 'Survey Received' on MIS. (Teleform paper q'naire and send to DMAC)
No
Reminder email sent from MIS
Remove from Follow-up List
Submitted within 1 week?
Yes
If required, re-send pack/email invitation
No
Telephone follow-up - record outcome on MIS. Allow contact up to 5 times
Still interested?
Yes
No
Exit Follow-Up
Key: MIS activity

APPENDIX 11: POST DEPLOYMENT NON RESPONDER FOLLOW UP PROTOCOL

Prospective Study Non-Responders/Partial Responders Follow-up Protocol

All non-responders and partial responders will receive a follow up phone call approximately one week after a reminder email has been sent to their nominated email address. While DMAC will be responsible for identifying and keeping track of who needs following up, the Participant Liaison Officer will be responsible for ensuring that follow up occurs in accordance with the following procedure. This includes:

- Training all Prospective Study staff in the follow up procedure
- Allocating non responders and partial responders to staff for follow up
- Auditing the system to ensure that all follow ups are undertaken
- Working with statisticians to report weekly uptake rates

Participant Allocation

DMAC will regularly upload a list of all non responders and partial responders onto the MIS – all participants who have not returned a post deployment questionnaire within 3 weeks of receiving it will appear on this list, so that they can be actioned for a follow up phone call. Participants will be allocated by the Participant Liaison Officer to all other Prospective study research officers to be contacted for follow up. This list of non-responders and partial responders on the MIS will be regularly and automatically updated by DMAC to reflect where participants in the follow up process (this will include updating the status of participants who were successfully contacted regarding the survey, removing participants who have since completed the survey, removing participants who have withdrawn from the study, adding new non-responders and partial responders who have not completed the survey in the allocated time frame, and leaving those non-responders and partial responders who could not be contacted in the previous weeks phone calls, or who agreed to complete the survey after receiving a phone reminder but didn't complete it.)

The headings on the follow up screen are as follows:

- Action/Due Date – date of when this action is due, i.e. due to be telephoned on this date.
- Last call outcome – if the participant has been previously contacted, the outcome of the last contact will be listed here.
- Survey Status – states whether the participant is a Partial or Non-Responder.

The system will allow research officers to view the entire list of non responders – 'ALL NON RESPONDERS' or alternatively, will allow research officers to restrict their view to

either non responders only –'NON RESPONDERS' (have not started an online or hard copy survey) or partial responders only – 'PARTIAL RESPONDERS' (completed part of the online survey).

- Research Officer – (to be used by the Participant Liaison Officer only) – click 'Not Yet Assigned' to assign a Research Officer to an individual participant. Or, open the 'Batch Actions' menu by using the 'click & drag' technique to assign a group of participants to a research officer.
- Action – click here to open the 'Follow-up screen' pop-up window (see separate section below).

Each participant will be on a 7-day refresh cycle. At the beginning of each person's follow up week, their default status will automatically set as 'follow up' however after follow up reminder phone calls have been made, their status will be automatically updated to reflect what stage they are at in the follow up process, and they will be moved to the bottom of the follow up list to reflect their urgency.

- If unsuccessful phone calls (unable to reach participant or did not leave a message on their voicemail) were made, the participant's status will remain as 'follow up'.
- If the participant was successfully reached (answered phone and successfully reminded or message left on voice mail) the participant's status will be changed to 'reminded' and they will be moved to the bottom of the follow up list.
- If after speaking to a participant they decide that they want to withdraw from the study, their status will be changed to 'withdrawn'- these participants will then be automatically be removed from the follow up list.

Research officers should work their way down the list of non-responders/partial responders allocated to them by the Participant Liaison Officer, ensuring that the participant's status is changed to reflect where they are at in the follow up process.

Calling Participants

The telephone script in Annex A should be used as a guide for all non-responder follow up phone calls. The script in Annex B should be used as a guide for all partial responders.

Participants can be successfully contacted up to five times (this includes either speaking to a participant, or leaving a message on their personal voicemail). After five contacts, participants will be automatically dropped off of the follow up list. That is, if a participant on the follow up list has been spoken to (or voicemail left) and reminded to complete the survey, he or she can be reminded a further 4 times (one contact a week until we receive their survey). You may attempt to contact the person as many times as it takes, on all available numbers, to reach the 5 contact limit. This list will be constantly updated (automatically), to reflect the addition of any new non-responders/ partial responders, the removal of participants who have since completed the survey, and the removal participants who have withdrawn from the study. Participants from the previous weeks who have still not been contacted or have not completed the survey will be left on the list to be followed up.

The appropriate number of reminders will be assessed at the end of each month. The number of contacts which can be made will be increased if conversion rates are not considered satisfactory.

Follow-up Outcome screen

This pop-up screen will be opened with you click 'Action' or 'Perform Milestone Action' on the 'Telephone Follow-up' section, and allows you to record the outcome of a Follow-Up telephone call.

Before you ring a participant, you should:

a) **ALWAYS Check the call log-** A 'call log' of previous calls will appear on the left-hand side of the follow up outcome screen- Check this to see whether the participant has been contacted before and reminded to complete the prospective study survey, if so how many phone calls they have received, what was said, if any voice messages were left (max 2 voice messages to be left) etc.. Once a participant has been contacted (only includes successful phone calls or voice messages) 5 times, they will be automatically dropped off the follow up list.

b) **ALWAYS Check whether the participant has any ALERTS**- If a participant has any Alerts, these will be listed in Red on the right hand side of the follow up outcome screen. Always check this prior to calling a participant to see if there are any relevant alerts. If there are, you will need to act accordingly. For example, if the participant has requested not to be contacted at home only ring work numbers, If the participant has registered a complaint make sure you take this into account if you feel it is still appropriate to call them. (Alerts specific to the Prospective Study will appear at the top). NB. You can view comments made on previous Calls & Alerts by hovering the mouse over a record.

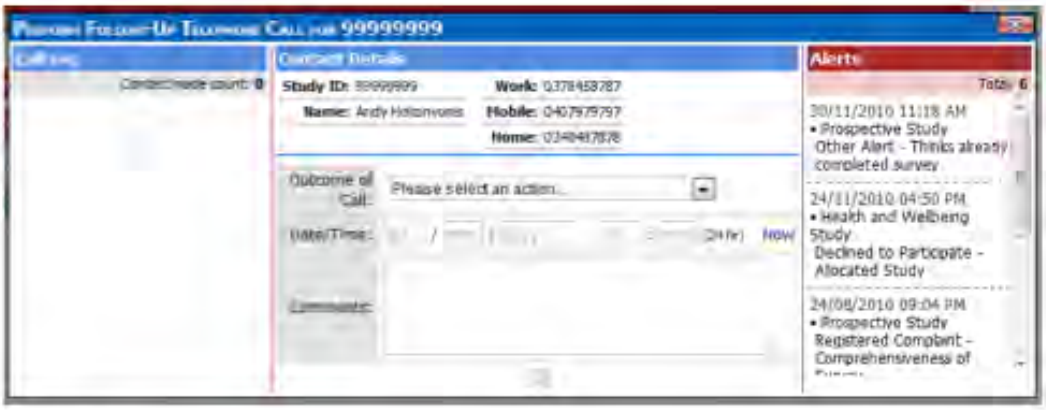
To record a non-responder follow-up call:

- Select the first person you have been allocated to on the participant follow up list
- Select the 'Action Taken' button → this will take you to the follow up outcome screen
- For "Outcome" select what the final outcome of the call (or series of calls) was (* denotes a count towards the 5 successful contacts made)

Outcome of Call:

1. *Agreed to finish- no further action required: you have spoken with the participant, and they have agreed to complete the survey (online or hardcopy) and you don't need to resend any material.
2. Did not speak to participant: You have called the participant on all their numbers, and were not able to speak to them or leave a voice message.
3. *Left voice message: you called the participant and left a voice message on their mobile or office voice mail (max 2)
4. *Participant thinks already completed: You have spoken to the participant and they believe that they have already completed the survey
5. *Send hardcopy survey: You have spoken to the participant and they have agreed to complete a survey but need a new survey sent out to them
6. *Send online link: You have spoken to the participant they have agreed to complete the survey, but need the online link sent to them. NB. this will automatically send a copy of the Invitation Email to the participant, following confirmation
7. *Withdrawn: You have spoken with the participant and they wish to withdraw themselves from the study (you will also need to record this as an 'alert' on the alert screen so that DMAC know to remove them from the follow up list).
8. Other

- **Date/Time:** Click "Now" to enter the time and date the call was made
- **Comments:** You should always enter details of the call in the comments box, this should include details such as:
  - All Phone numbers called – and outcomes of those calls
  - Reason for non-contact (e.g. engaged, talked to family member, rang out, phone number disconnected)
  - Any other relevant details (e.g. away on leave until jan)
- Press "Save"



Please Note:

- If the participant has not responded within a week, they will remain on the Follow-Up list, to be contacted again, and the Action Due date will be updated to 7 days after the last call.
- A participant can be successfully contacted up to 5 times (voice message or directly spoken to), after which they will be removed from the follow-up list.
- A participant will be removed from this list, if a questionnaire is marked as completed, or if they have had 5 successful contacts made.

Every time you attempt to call a participant you must work through the list of **all phone numbers listed** until the participant is spoken to, in the following order:

1. Start with work numbers,
2. then mobile,
3. then home.

If the participant cannot be contacted you can then leave a message on either their work or mobile phone. Messages must never be left on the home phone number.

You should record the outcome of each call on one record e.g: *"w- colleague said out of office for next two hours, m- voice mail-no message left"*

Many participants live interstate and are in different time zones, therefore if you have to call someone at a specific time (e.g. if they have asked you to call back when they are free) you can check what state they are in by looking at their work address on the "Contact info" tab.

Leaving voice messages:

No more than two voice messages should be left for each participant across the entire follow up period (you will need to check participants call records). Make sure you document when you leave a message in the "comments" box of the call record on the MIS. The message you leave should say something like:

"Hi, this is....., I'm calling from the Centre for Military and Veteran's Health about the MEAO Prospective Study and I am trying to get in touch with..... You can call us back on our toll free number: 1800 232 904, otherwise I will try calling you back at another time. Thank you.

Once you have made a call (or a series of calls in the one block of time) you need to log the final outcome of that call (or series of calls) on one record only. To do so, follow the process outlined below:

To send the email follow this process:

If the 'Send online link' option is chosen from the list of call outcomes, the MIS will automatically re-send the original invitation email to the participant's work email address. Research officers will not need to log this in the Materials sent screen as this has all been automated.

If someone requests to be sent a hardcopy survey:

- In the participant follow up pop up, log the call outcome as "send hardcopy survey" – this will automatically alert the data managers that a hardcopy pack needs to be sent to the participant.
- Double check with the participant which address they would like the pack to be sent to whilst they are still on the phone. Note this address in the comments section of the follow up pop up screen so the data managers know where to send the pack.
- The data managers will then send a new hardcopy pack to the participant and log this in the 'materials sent' screen.

If a someone decides that they no longer wish to participate in the study:

If someone decides that they no longer wish to participate in the study, you will need to log this on the Participant Follow-up screen as per usual AND you will need record the withdrawal as an 'Alert' – this will notify DMAC of participants who need to be taken off the follow up list. To record this as an alert, you will need to:

a. Select the 'Alerts' tab for that participant
b. Select 'declined to participate', or another reason if more appropriate
c. For 'Type/Reason', select 'Allocated Study', unless they revoke all consent for any study in the MilHOP program, in which case select 'All MilHOP studies'.

d. Record the time and date of the call by clicking on 'now'. This will automatically enter the time and date of the call, and must be done at the time of calling.
e. Add comments with any pertinent information, such as reason for refusal, complaints, participant comments, or any other relevant information.
f. Save the record.

An 'alert' should also be added if a participant wants to register a complaint or decides that they do not wish to be contacted at home.

ANNEX A:

Prospective Study Non Responder Follow-up: Telephone Script

1. "Helio, my name is _____ and I am a research officer from the Centre for Military and Veterans Health. May I please speak with _____?

   If correct person: *go to Q2*

   If correct person not available: *Find out when would be the best time to call them and make a note of this for yourself to follow-up*

2. I am calling today to thank you for your recent participation in the pre deployment phase of the Middle East Area of Operations Prospective Study. In order to better understand the impact of your deployment on your physical and mental wellbeing, we would now like to invite you to complete the post deployment questionnaire. You should have received an invitation in the post or via email recently – do you recall receiving this invitation and survey?

   If YES: *"Fantastic" (go to Q3)*

   If NO: *"Not a problem. The invitation is for the second part of a research study being conducted to better understand the health of members deployed to the Middle East." (go to Q3)*

3. "The survey will take between 30 and 60 minutes to fill out.
   The results from this research will help in the future to better prepare individuals for deployment. It will also provide Defence and the Department of Veteran Affairs with the best possible advice on how to support the mental and physical health needs of Defence Force members who deploy in the future.

   We know that Defence members are particularly concerned about the confidentiality of their personal information. As CMVH is independent from Defence we can assure you that any individually identifiable information you choose to provide us with, will not be accessible by Defence. Neither will any party outside of the immediate research team have access to your

identifiable information. Even if you do not believe that your deployment has had any adverse consequences on your health, your contribution to the post deployment phase is vital.

Do you think that filling out this survey is something that you might be able to do?"
****ENCOURAGE a "YES" to this question!**

***If YES**: "That's great" (go to Q4)*

***If NO**: Thank you and goodbye* (enter refusal in "alerts" on MIS)

4. "We can send you a new link to the survey right now or if you prefer I would be happy to send a you a hardcopy survey in the mail.
If email: Can I just confirm your email address? (confirm email- send email-if possible get them to check they have received it on the spot).

If hardcopy: Can I just confirm you mailing address? (enter the mailing address in the pop up box for the data manager's reference)

We really appreciate your contribution to this research. Please read through the information about the survey if you have any questions you can call the toll free number on the email, and then you will be able to complete it online. Thank you very much for your participation."

If the participant has questions about the study refer to the FAQs

ANNEX B

Prospective Study Partial Responder Follow-up: Telephone Script

1. "Hello, my name is..... and I am a research officer from the Centre for Military and Veterans' Health. I am calling to speak with..... ?

If correct person: *go to Q2*

If correct person not available: *Find out when would be the best time to call them and make a note of this for yourself to follow-up*

2. I am calling today to thank you for your recent participation in the pre deployment phase of the Middle East Area of Operations Prospective Study. However, in order to better understand the impact of your deployment on your physical and mental wellbeing, your participation in the post deployment phase of the study is vital. Our system is showing us that you recently began filling out the online version of the survey as part of the MilHOP program. Is this correct?

- If person answers **NO**, say:

"Ok, Would you be interested in filling out the survey? You can complete it online or we can mail you a hard copy"

- **NO** -> "OK, that's not a problem. Is there a reason why you feel you cannot participate at this time?"

  Then -> "I understand. The results from this research will help in the future to better prepare individuals for deployment. It will also provide Defence and the Department of Veteran Affairs with the best possible advice on how to support the mental and physical health needs of Australian Defence Force service personnel. Your contribution to this research is vital because we would like results that are representative of everyone who deployed. Do you think that filling out this survey is something that you might be able to do?"

  - **NO** -> "Ok, thank you for your time."

    Record 'refusal to participate' as the outcome of the call, and enter the refusal in the 'alert' tab

- **YES** -> "Excellent!" Confirm email/address details & record in MIS to either 'send online link', or 'send hardcopy survey', then thank you and goodbye.

- If person answers **YES**, say:

"This is just a courtesy call to check how you are progressing with the survey, and to help you resolve any difficulties you may be experiencing that have prevented you from completing it?"

- If person states that they **HAVE** been experiencing difficulties:

  Help to resolve their problem and encourage them to complete the survey as soon as possible – "Would you be willing to complete they survey in the next week or so?"

  - If person answers **YES**, say:

    "Great! Do you still have the link we sent you via email, or do you need me to email it to you again? Alternatively we can post you a hard copy version of the survey. What would you prefer?"

    "Excellent, we'll organise to send that to you very soon. Can I just confirm your email address/mailing address for our records?" (If necessary)

    Record in MIS to either 'send online link', or 'send hardcopy survey', or 'Agreed to finish- no further action required', then thank you and goodbye.

  - If person answers **NO**, say:

    NO -> "OK, that's not a problem. Is there a reason why you feel you cannot participate at this time?"

    Then -> "I understand. However, the results from this research will help in the future to better prepare individuals for deployment. It will also provide Defence and the Department of Veteran Affairs with the best possible advice on how to support the mental and physical health needs

of Australian Defence Force service personnel while on and directly after deployment. Your contribution to this research is vital because we would like to gain an understanding from as many deploying members as possible. Do you think that filling out this survey is something that you might be able to do?"

NO -> "Ok, thank you for your time."

Record 'refusal to participate' as the outcome of the call, and enter the refusal in the 'alert' tab

- If person answers **NO**, say:

"Great. I'm glad to hear that you didn't experience any difficulties. Would you still be willing to participate in the survey?

- If person says **NO**, say:

NO -> "OK, that's not a problem. Is there a reason why you feel you cannot participate at this time?"

Try to address any of the concerns they voice

"I understand. The results from this research will help in the future to better prepare individuals for deployment. It will also provide Defence and the Department of Veteran Affairs with the best possible advice on how to support the mental and physical health needs of Australian Defence Force service personnel while on and directly after deployment. Your contribution to this research is vital because we would like to gain an understanding from as many deploying members as possible . Do you think that filling out this survey is something that you might be able to do?"

NO -> "Ok, thank you for your time."

Record 'refusal to participate' as the outcome of the call, and enter the refusal in the 'alert' tab

- If person says **YES**, say:

"Great! Do you still have the link we sent you via email, or do you need me to email it to you again? Alternatively we can post you a hard copy version of the survey. What would you prefer?"

"Excellent, we'll organise to send that to you very soon. Can I just confirm your email address/mailing address for our records?"

Record in MIS to either 'send online link', or 'send hardcopy survey', or 'Agreed to finish- no further action required', then thank you and goodbye.

Appendix D

Physical Testing Protocol

CMVH
CENTRE FOR MILITARY & VETERANS' HEALTH

MIDDLE EAST AREA OF OPERATIONS (MEAO) PROSPECTIVE STUDY:

PHYSICAL TESTING PROTOCOL

Author: Maria Abraham and Carol Davy

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Australian Government
Department of Defence
Department of Veterans' Affairs

THE UNIVERSITY OF QUEENSLAND
AUSTRALIA

Charles Darwin
UNIVERSITY
Innovation in Education

THE UNIVERSITY OF ADELAIDE
AUSTRALIA

CONTENTS

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Revision History

Date	Version	Description	Track Changes
09/03/2011	1.0 to 19.00	Internal Development of Plan	No
16/6/2011		Alter post deployment section to reflect agreed procedures and clarify consent section to address the needs of potential participants who do not wish to participate in the physical testing	No

Approvals

This document requires the following approvals:

Name	Position	Signature	Date	Version
Prof Annette Dobson	Principal Investigator			
Prof Michael Moore	Scientific Advisory Committee			
BRIG Stephen Rudzki	Program Management Board			

1. BACKGROUND

The Middle East Area of Operations (MEAO) Health Study is part of the Centre for Military and Veterans‟ Health‟s (CMVH) Deployment Health Surveillance Program (DHSP) and consists of three major components: a Prospective Study, a Census Study, and a Mortality and Cancer Incidence Study.

Data for the MEAO Prospective Study will be collected at two time points, both pre- and post-deployment. At each of the time points, participants will be asked to complete a self-administered questionnaire. One subset of deploying Australian Defence Force (ADF) personnel will also be invited to complete a physical assessment, which includes the provision of both saliva and blood samples.

Clear scientific benefits and the potential to define future risk that can be modified for individuals could be achieved through a rigorous and thorough physical assessment program. In addition, physical assessment programs can communicate a concern and conviction by the ADF about the wish to protect ADF members. Defining health characteristics and their impact on performance also has a major capacity to sustain and develop the capability of the ADF.

2. PHYSICAL TESTING OBJECTIVES

The primary objective of the physical testing and blood/saliva collection component of the MEAO Prospective Study is to utilise a series of validated physical and laboratory tests on a subset of ADF personnel both pre and post deployment in order to identify the impact of MEAO specific defence force deployment on their health. This information will then be linked to the broader aims of the MEAO Prospective Study investigation.

3. PHYSICAL TESTS TO BE CARRIED OUT

The physical and laboratory tests being carried out are as follows:

- Measurement of height
- Measurement of weight
- Measurement of waist circumference
- Measurement of hip circumference
- Blood pressure
- Spirometry
- Step test
- Collection of a saliva sample
- Collection of a blood sample
- Photography of skin on hands, feet, back and portion of the face.

These measures are described in greater detail in section 6.3 of this protocol.

4. PHYSCIAL TESTING TEAM

The Physical Testing Team consists of up to two CMVH research staff members and eleven professional health staff from Healthscope. The Healthscope members comprise of one project coordinator to assist University of Adelaide CMVH staff to manage the movement of participants on the day, and ten allied health workers who are also qualified to collect blood. Staff from Healthscope will be responsible for conducting the physical assessments, collecting the blood samples, and preparing and transporting the biological samples for testing.

At least one Healthscope staff member at each testing session will be appropriately trained and certified to handle, pack and freight blood and saliva samples including those that require the use of dry ice. This Healthscope staff member will be responsible for preparing, packing and freighting each of the samples.

At least one CMVH research staff member will also be onsite as part of the Physical Testing Team to oversee the session and provide project coordination support. The CMVH staff member assigned to the Physical Testing Team will be responsible for meeting Healthscope staff at the Defence establishment, facilitating gaining access to the building and acting as a liaison with the Defence Point of Contact on base. Due to the strict security requirements on base, gaining access to the testing facility may take a significant amount of time and hence Healthscope staff will be required to present at the base a minimum of one hour before the Physical Testing session is due to commence with some form of photo identification.

The primary responsibilities of the CMVH staff member also include:

- ensuring that the Healthscope staff undertaking the tests have been adequately trained,*
- ensuring that facilities are suitable and appropriate for data collection,
- ensuring that all portable equipment and IT systems are on-site and set up and that the appropriate calibration procedures have been undertaken,
- being the onsite contact for participants,
- providing briefings, together with Healthscope staff, to study participants,
- providing a real time assessment of data quality,
- troubleshooting on-site,
- overseeing the transport of equipment to the appointment site and then back to CMVH Adelaide; and
- ensuring that all data collected during the physical testing session/s are returned to CMVH Adelaide.

*CMVH will provide training in the equipment and the standardised procedural manual that will be utilised at each Physical Testing session from March 2010 onwards. If necessary, additional training will be provided to Healthscope staff the day prior to each physical testing trip.

5. PHYSICAL TESTING STUDY PARTICIPANTS

A sample of ADF personnel deploying to the MEAO after June 2010 and returning to Australia by December 2011 will be invited to participate in the physical assessment component of the MEAO Prospective Study. Throughout this document these ADF personnel will be referred to as Physical Testing Participants. In comparison to other deploying ADF personnel not selected for the physical testing component, the Physical Testing Participants will be sent an invitation package (refer Questionnaire Protocol) containing an information sheet that will describe in detail the physical assessments, blood tests and laboratory investigations to be performed pre- and post-deployment. Eligible Physical Testing Participants will be able to consent to completing just the questionnaire component or both the physical testing and questionnaire components.

5.1 Selection of Physical Testing Participants

Eligible Physical Testing Participants will be selected from MEAO Prospective Study participants deploying as part of a frontline element at high risk of combat related exposures or who work within a stressful environment, and who have indicated on the consent form (returned at the time the questionnaire is completed) that they are willing to take part in this component of the study.

5.1.1 Inclusion Criteria

In order to be eligible to participate in the MEAO Prospective Study Physical Testing, individuals must:

- be eligible to participate in the Prospective Study questionnaire (refer sections 78 and 79 MEAO Prospective Study Detailed Research Plan);
- have completed a pre deployment questionnaire (refer to section 3 of the Questionnaire Protocol) ; and
- be assigned to either:
    - Special Operations Task Group (SOTG)
    - Mentoring Task Force (MTF)
    - Ships to be selected by Defence.

5.1.2 Exclusion Criteria

There are no specific exclusion criteria applicable to the MEAO Prospective Study Physical Testing.

6. PHYSICAL TESTING

Each Physical Testing Participant will be asked to complete the tests described in section 6.3 of this protocol on two separate occasions:

1. **Before Deployment** - Participants will receive their first physical assessment approximately three months prior to their deployment to the MEAO
2. **After Deployment** – Participants will receive their final physical assessment approximately four months post deployment to the MEAO.

6.1 Scheduling of Pre Deployment Appointments for Physical Tests

Special Forces: Once a Special Forces deploying unit has been identified, a Defence Liaison Officer and the Study Manager will make contact with the Officers in Command /Commanding Officers of the deploying Front Line Unit to provide further detailed briefs about the MEAO Prospective Study, and subsequently arrange suitable facilities and appropriate times for the Physical Testing Team to visit the base and test personnel. If possible, dates should be finalised with Defence at least one month prior to each testing trip. The Officers in Command/Commanding Officers of the deploying unit will then use the scheduling template provided to them by CMVH to allocate members to suitable testing timeslots. Complete testing schedules will then be forwarded to the SOC Administration Officer approximately one week prior to testing. The SOC Administration Officer will remove any identifying information and provide this list to the Physical Testing Team, who will inform Healthscope of the timetable.

One week prior to testing, the SOC Administration Officer will provide information to the Commanding Officers/ Officers in Command (or their point of contact) about the tests being conducted as well as what participants will need to bring with them and wear (i.e. light clothing). This information, as well as the testing dates and tines will then be relayed to participants.

All Other Personnel: Once a deploying unit eligible to participate in the physical testing component of the study has been identified, a Defence Liaison Officer and the Study Manager will contact the Officers in Command/Commanding Officers of the unit to provide a detailed brief about the MEAO Prospective Study, and arrange suitable facilities and appropriate times for the Physical Testing Team to visit the base and test personnel. If possible, dates should be finalised with Defence at least one month prior to each physical testing trip. The Officers in Command/Commanding Officers of the deploying unit will then use the scheduling template provided to them by CMVH to allocate members to suitable testing timeslots. Testing schedules will then be forwarded onto the SOC Administration Officer approximately one week prior to testing. This list will then be given to the Physical Testing Team who will enter the confirmed schedule into the Management Information System (MIS) and inform Healthscope of the timetable.

One week prior to testing, the SOC Administration Officer will provide information to the Commanding Officers/ Officers in Command abut the tests being conducted as well as what

participants will need to bring with them and wear (i.e. light clothing). This information, as well as the date and time of testing, will then be relayed on to participants.

All Physical Testing Participants: Participants will be allocated by their Commanding Officer/Officer in Command to one of four Physical Testing sessions (2 morning groups and 2 afternoon groups) on each designated testing day (see Appendix A). This will allow for up to 24 Physical Testing Participants (six groups of four) to be tested in the two morning sessions and up to 24 Physical Testing Participants (six groups of four) to be tested in the two afternoon sessions (up to 48 Physical Testing Personnel completed on each designated Physical Testing day).

6.2 Scheduling of Post Deployment Appointments for Physical Tests

As soon as a unit returns from deployment a CMVH Defence Liaison Officer or their delegate will contact the Commanding Officer or nominated POC to arrange a suitable physical testing time schedule and facilities for research staff to visit the base and conduct the investigations, taking into consideration the post-deployment assessments and other required activities.

The CMVH Defence Liaison Officer or their delegate will notify the Physical Testing Team of the Physical Testing time schedule and make arrangements for access to the various Defence Force establishments for the Physical Testing Team.

SF Personnel: The SOC Administration Officer will provide a list of SF Personnel who completed the pre deployment physical tests, together with a blank testing schedule to the CO of the SF unit or POC, who will be responsible for allocating these participants an appointment time on the testing schedule. In addition, the SOC Administration Officer will liaise with the CO and provide further information about the physical tests being conducted, including preparation instructions and confirm the date, time and location of the physical tests. The SOC Administration Officer will also enter the participants‟ scheduled appointment times into a stand alone SF Management Information System (SF MIS) and the DMAC Management Information System (MIS) by study ID only.

The SOC Administration Officer will advise the other members of the Physical Testing Team of all schedule appointments made for conducting the Physical Tests.

All Other Personnel: A SOC Administration Officer or their delegate who has been cleared to the appropriate security level will contact the POC and provide list of participants from that unit who have completed the pre deployment physical tests, together with a blank physical testing schedule. The POC will then identify a time which is most convenient to these participants and is within the agreed schedule for physical tests. In addition, the Participant Liaison Officer will liaise with the POC to provide further information over the phone about the physical tests being conducted, including preparation instructions and confirm the date, time and location of the physical tests.

The SOC Administration Officer or their delegate will advise the other members of the Physical Testing Team of all schedule appointments made for conducting the Physical Tests.

6.3 Calibration of Equipment Prior to Testing

6.3.1 Calibration of the Lufikin TM W606PM 2 Steel Measuring Tapes

Steel tapes will be checked against a 1 metre engineer's rule every 12 months.

6.3.2 Calibration of the A & D Personal Precision Scale (UC-321)

Scales will be calibrated by the supplier, AUC Health, before arriving at CMVH. The accuracy of the scales will be checked prior to each deployment via the use of precise calibration weights. Table 1 below shows maximum permissible error for the scales.

Table 1. Maximum permissible error for scales

MPE	For loads, mass, expressed in units of scale resolution
+/- 50g	Reading less than 25kg
+/- 100g	Reading between 25kg and 100kg
+/- 150g	Readings above 100kg

6.3.3 Calibration of the Omron HEM-907 Digital Sphygmomanometer

The Omron HEM-907 digital sphygmomanometer will be sent to Omoron Healthcare once every 12 months to be calibrated.

6.6.4 Printing Case Report Forms

Prior to leaving for each Physical Testing trip, the CMVH Data Manager will input the study ID‟s of participating personnel onto individual Case Report Forms (see Appendix B). These will then be shipped, along with all of the other physical testing equipment, to the various locations.

7 Testing Day Procedures

7.1 Setting Up Physical Testing and Blood Sampling Testing Points

The CMVH staff members assigned to the Physical Testing Team will travel to each of the designated barracks the day before the first designated testing day to set up five of the six testing points (blood pressure point, body measurement point, spirometry point, step test point, skin photography point). This includes setting up all of the portable equipment and IT systems required to undertake the physical tests, and performing all of the calibration procedures outlined in section 6.2.2 below. The blood collection testing point will be set up by Healthscope staff on the day of testing.

7.2 Calibration of the EasyOne Spirometer

Prior to each physical testing day, the EasyOne Spirometer will be calibrated via the use of a 3 litre calibration syringe and by following instructions outlined below. Once calibration has been performed, the EasyOne Spirometer will then produce and save a full calibration report. Calibration of the EasyOne Spirometer will initially be performed by spirometry expert, A/Prof Alan Crockett, who will also train the Physical Testing Team in how to use and calibrate the machines.

Calibration of EasyONE Spirometer:

1) Turn on spirometer, use arrow buttons to navigate, and press ENTER to select "check calibration"
2) Select "calibration check" and press ENTER
3) Remove red cap from calibration syringe
4) Insert rubber adapter to calibration syringe by twisting in
5) Insert spirette into rubber adapter, ensuring that the arrows are facing upwards
6) Attach spirometer to spirette, arrow to arrow
7) Select "ENTER" to accept that set up is DONE
8) Set baseline- place hand over spirette
9) Pump syringe 3 times slowly and evenly
10) Spirometer will display Expiration and Inspiration → Both need to be WITHIN 3.5%

*Repeat calibration process up to 3 times until Expiration and Inspiration are both within 3.5%. If, after 3 repeats, the reading is still not within 3.5%, the spirometer is not fit for usage.

7.3 Calibration of the Panasonic DMC-G10

The manual exposure of the camera will be set at the beginning of each session:

Make sure the main floor lamp is switched on and any lights on the ceiling, which will be on during the photography session, are on during the setting of the exposure. Hold the 18% Digital Grey Card against a staff members chest while they stand over the x and facing towards the tripod. This staff member should take care not to have their fingers obscure the surface of the "Digital Grey Card. Another staff member will zoom the camera towards the Digital Grey Card so that the centre of the LCD screen is filled with this Grey shade. With the camera set to M, use the scroll button to set the light meter to a zero value. With the Card in view, press the scroll button once and the aperture and shutter speed will appear on the LSD screen. You can alternate between aperture and shutter speed by depressing the scroll button on the rear of the camera. Firstly, set the aperture to 5.6. With the aperture selected, scroll backwards or forwards so that the value 5.6 is displayed above the centre line of the display. Secondly, adjust the shutter speed. Depress the shutter button once so that shutter speed is now highlighted in the display. Use the light meter at the very bottom of the LCD screen to calibrate your adjustment. Scroll the button backwards or forwards so that: With the Grey card at the centre of the cameras field of view the light meter will show a zero value. That is; no bars on the light meter will display towards a positive or negative value. After gaining a zero value, the camera has now had it"s exposure set. Do not

press the scroll button again during the session of photography as this will change the setting of the camera‟s exposure. The grey card can now be put away.

Take one photograph of the MacBeth Colour Checker Card at the beginning of each session. A staff member will pick up the MacBeth Colour Checker Card and hold it against their chest. This staff member then stands at the position of x and faces towards the tripod. This staff member should take care not to have their fingers obscure the surface of the MacBeth Colour Checker. Another staff member operates the controls of the tripod so the Cameras LCD screen shows the “MacBeth Colour Checker” at its centre. The MacBeth Colour Checker should be square with the borders of the LSD screen. That is; the colour checker should be perpendicular with the camera, and not at a diagonal angle. The camera is then zoomed to the point where an edge of approximately 10 cms is still visible around the borders of the “Macbeth Colour Checker”. Depress the shutter button once to take a photo.

7.4 Commencement of the Testing Session

On arrival at the physical testing session:

Special Forces personnel: A member of the SOC Liaison Team will be present to link SF Physical Testing Participants with their study ID‟s, record their attendance on the Participant Attendance Checklist and complete the front page of the Case Report Form.

The participant will then be given:

- A Case Report Form, pre-printed with the participant‟s correct study ID identified at the top right hand of each page (Appendix B)
- A flow chart for order of stations they are to attend
- Pre-printed identification labels for sticking on vacuette tubes for blood samples
- Pre-printed laboratory referral form

All Other Personnel: A CMVH research officer will identify each of the Physical Testing Participants by their study ID, record their attendance on the Participant Attendance Checklist, and complete the front page of the Case Report Form. The participant will then be given:

- A Case Report Form with the participant‟s correct study ID identified at the top right hand of each page (Appendix B)
- A flow chart for order of stations they are to attend
- Pre-printed identification labels for sticking on vacuettes of blood samples
- Pre-printed laboratory referral forms

Briefing: All Physical Testing Participants will then be briefed by a CMVH coordinator. This will involve explaining the rationale for the physical assessments/laboratory tests being conducted and briefly describing the procedure that each test will require.

8 Data Collection

All Physical Testing Participants will then undertake the tests in the specified order that is outlined on the flow chart they are provided on arrival. Testing points will include:

- **Blood Pressure Point** - Four stations to measure blood pressure (10 minutes)
- **Body Measurement Point** - Two stations to measure height, weight, hip circumference and waist circumference (5 minutes)
- **Spirometry Point** - Three stations to measure spirometry (10 minutes)
- **Step Test Point** - Three stations to administer the step test (10 minutes)
- **Blood Collection Point**- Five stations to collect blood (10 minutes)
- **Skin Photography point**- Two stations to take skin photographs (10 minutes)

A detailed time schedule is contained in Appendix A.

General Rules Regarding Completion of Case Report Forms:

- Testing outcomes for each Physical Testing Participant should be recorded on their Case Report Form (see Appendix B)
- All Case Report Forms should be completed using a blue or black pen
- If a Physical Testing Participant chooses not to or is unable to complete a test for a particular reason, this reason must be recorded in full on the Case Report Form by the Healthscope staff member undertaking the test
- Each protocol deviation should be recorded on a Test Station Protocol Deviation Summary sheet (see Appendix C)
- If boxes are intentionally left missing, Healthscope staff should cross out the missing item numbers
- Changes and additions must be legible
- In order to indicate a deletion, two single horizontal lines must be placed through the content to be deleted
- Changes, additions and deletions must be signed by the person making the change and dated
- Liquid paper must never be used

8.1 Measurement of Height

Equipment Provided

- Seca 214 Stadiometer

Procedure

- Height will be measured in centimeters (cm) to one decimal place using a Seca 214 stadiometer as the maximum distance from the floor to the vertex of the head with shoes removed

Recording of Height

- Height should be recorded on the Case Report Forms in centimeters, to one decimal place

8.2 Measurement of Weight

Equipment Provided

- A & D UC-321 Personal Precision Scale

Procedure

- Weight will be measured in kilograms (kg), to two decimal places, in light clothing and without shoes using the A & D UC-321 Personal Precision Scale.

Recording of Weight

- Weight should be recorded on Case Report Forms in kilograms, to two decimal places.

8.3 Measurement of Waist Circumference

Equipment Provided

- LufikinTM W606PM 2 metre metal tape graduated in millimeters

Procedure

- Waist circumference will be measured according to the protocol recommended by the World Health Organization (WHO Expert Committee, 1995).
- Instruct participants to remove any belts or heavy outer clothing as the measurement of waist circumference should be taken over, at most, one layer of light clothing.
- Instruct participants to stand comfortably with their weight evenly distributed on both feet, and their feet separated about 25-30 cm. Participants‟ arms should hang loosely at their sides.

Measurement of Waist Circumference

- Taken **midway between the inferior margin of the last rib and the crest of the ilium**, in the mid-axillary plane (refer to Figure 1 below) → Ensure that you **feel** for the inferior margin of the participant‟s last rib and the crest of their ilium with the side of your finger, not the tip (to ensure the participant‟s comfort) so as to determine the exact position of the tape.
- **To position the tape**, hold the case in the left hand and the stub in the right. Stand facing the side of the participant, pass the stub end around the participant, from their back to the front. Then take hold of the stub with the left hand which then holds both the stub and casing. At this point the right hand is free to manipulate the tape to the correct level. Apply sufficient tension to the tape to hold it at the position while the right hand reaches underneath the casing to take hold of the stub again. The tape is now around the waist. The middle fingers of both hands are free to exactly locate the tape at the landmark for measurement and to orientate the tape so that the zero is easily read (cross-handed technique of measurement: Norton, Whittingham, Carter, Kerr, Gore & Marfell-Jones, 1996).

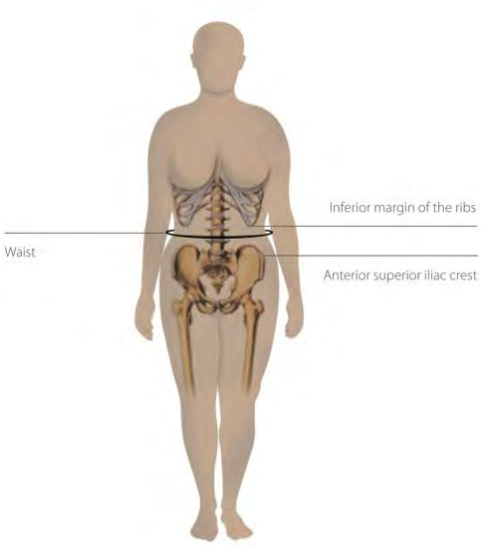

Figure 1. Measurement of waist circumference

- Waist circumference will be measured with the inelastic tape maintained in a horizontal plane, **at the end of normal expiration.** The tape should be snug, but should not compress the underlying soft tissue.
- When reading the tape, the measurer"s eyes must be at the same level as the tape to avoid any error of parallax.

Recording of Waist Circumference

- All raw measurements should be recorded on the Case Report Form.
- The measurement should be recorded at the end of a normal expiration **to the nearest 0.1 cm**.
- A repeat measurement should be taken and recorded **to the nearest 0.1 cm**.
- If the two measurements disagree by more than 1 cm, a third measurement should be taken.
- The subject's measured waist circumference should subsequently be calculated as the mean of the two observations, or the mean of the two closest measurements if a third is taken.
- It may be necessary to round the mean value to the nearest 0.1 cm. If so, rounding should be to the nearest even digit to reduce systematic over-reporting. For example, a mean value of 72.25 cm would be rounded to 72.2 cm, while a mean value of 72.35 cm would be rounded to 72.4 cm.

Extreme values at the lower and upper end of the distribution of measured waist circumference should be checked both during data collection and after data entry. Individuals should not be excluded on the basis of true biological difference.

Last-digit preference, and preference or avoidance of certain values, should be analysed in the total sample and (if relevant) by observer, survey site and over time if the survey period is long.

8.4 Measurement of Hip Circumference

Equipment Provided

- LufikinTM W606PM 2 metre metal tape graduated in millimeters

Procedure

- Hip circumference will be measured according to the protocol recommended by the World Health Organization (WHO Expert Committee, 1995).
- Participants should wear only non-restrictive briefs or underwear (most preferred), or light clothing. Instruct participants to remove any belts or heavy outer clothing as the measurement of hip circumference should be taken over, at most, one layer of light clothing.
- Instruct participants to stand erect with their arms at their side, feet together and their gluteal muscles relaxed.

Measurement of Hip Circumference

- Will be taken with the tape passed horizontally around the body at the position of the maximum circumference around the buttocks, when viewed from the side.

Figure 2. Measurement of hip circumference

- **To position the tape**, hold the case in the left hand and the stub in the right. The measurer should sit at the side of the subject so that the level of maximum posterior extension of the buttocks can be seen. Pass the stub end around the participant, from their back to their front, and then take hold of the stub with the left hand which then holds both the stub and casing. At this point the right hand is free to manipulate the tape to the correct level. Apply sufficient tension to the tape with the left hand to hold it at the position while the right hand reaches underneath the casing to take hold of the stub again. The tape is now around the hip. The middle fingers of both hands are free to exactly locate the tape at the landmark for measurement and to orientate the tape so that the zero is easily read (cross-handed technique of measurement: Norton et. al., 1996).

- The inelastic tape should be placed around the buttocks in a horizontal plane. The tape should make contact with participant‟s skin but not compress the underlying soft tissue.
- When reading the tape the measurer‟s eyes must be at the same level as the tape to avoid any error of parallax.
- Fatty aprons should be excluded from the hip circumference measurement.

Recording of Hip Circumference Measurement

- All raw measurements should be recorded on the Case Report Form.
- The measurement should be recorded to the **nearest 0.1 cm**.
- Repeat measurements should be taken and recorded to the **nearest 0.1 cm**. If the two measurements disagree by more than 1 cm, then a third measurement should be taken.
- The subject's measured hip circumference should subsequently then be calculated as the mean of the two observations, or the mean of the two closest measurements if a third is taken.
- It may be necessary to round the mean value to the nearest 0.1 cm. If so, rounding should be to the nearest even digit to reduce systematic over reporting. For example, a mean value of 102.25 cm would be rounded to 102.2 cm, while a mean value of 102.35 cm would be rounded to 102.4 cm.
- Any reasons for the non-collection of hip circumference data should be stated on the participant‟s case record form.

Extreme values at the lower and upper end of the distribution of measured hip circumference should be checked both during data collection and after data entry. Individuals should not be excluded on the basis of true biological difference.

Last digit preference, and preference or avoidance of certain values, should be analysed in the total sample and (if relevant) by observer, surve y site and over time if the survey period is long.

8.5 Measurement of Blood Pressure

Blood pressure will be taken by trained Healthscope nurses or allied health professionals using a digital calibrated sphygmomanometer with appropriate sized cuffs (Omron HEM-907).

Equipment Provided

- Omron HEM-907 digital sphygmomanometer
- Large/medium sphygmomanometer cuffs

Procedure

- Ask participants if they have been at rest for at least 5 minutes – mark on Case Report Form.
- Ask participants if they have abstained from food and caffeine for a minimum of 30 minutes – mark on Case Report Form.
- Instruct participants to resume a seated position.
- The participant‟s left arm should be supported at heart level via the use of a cushion resting on a table.
- Blood pressure is to be measured on the participant‟s **left arm only.**

- Remove any tight or restrictive clothing covering the participant‟s left arm.
- Secure an appropriate sized cuff onto the participant‟s left arm: Align the artery position mark (ART.) with the brachial artery so the lower edge of the cuff is 1.2cm-2.5cm above the elbow. The monitor has been pre-set to take 3 serial measurements at intervals of 1 minute.
- Measure blood pressure using the HEM-907 digital sphygmomanometer.
    - Mode set on AVG
    - P-SET on AUTO
    - Press START

Recording of Blood Pressure

- BP should be recorded onto the Case Report Form as **three serial measurements** at **intervals of at least one minute** (the blood pressure machine is to be pre-set).
- An additional three serial measures should be taken if the difference between any two measurements of SBP is more than 8 mm Hg and DBP is more than 5 mm Hg.

8.6 Spirometry

Lung function testing will be conducted by a trained Healthscope nurse or allied health professional using an EasyOne™ spirometer according to the guidelines for conducting spirometry specified by Miller et. al,. 2005b, in the series of papers titled „ATS/ERS Task Force: Standardisation of lung function testing‟.

The EasyOne™ spirometer will be utilised due to its ease of use, portability and superior reliability. The EasyOne™ spirometer utilises digital ultrasonic flow measurement technology. Ultrasonic flow measurement eliminates problems associated with traditional methods of flow measurement and has no moving parts, thus does not require repeated calibration or maintenance. However, for research purposes the EasyOne™ spirometer will be calibrated prior to testing via the use of a 3 litre calibration syringe and by following the spirometer‟s inbuilt protocol. Once calibration has been performed, the EasyOne™ spirometer will then produce and save a full calibration report.

At the end of the first day of testing, the spirometry .mdb file will be emailed to A/Prof Alan Crockett who will review the quality of the spirometry conducted and provide feedback directly to the Healthscope staff if adjustment to technique is required.

Equipment Provided

- EasyOne™ spirometer
- Spirettes
- Ventolin and spacer
- 3 litre calibration syringe

Procedure

There are three distinct phases to the forced vital capacity (FVC) manoeuvre, as follows: 1) maximal inspiration; 2) a „blast" of exhalation; and 3) continued complete exhalation to the end of test (EOT). The technician should demonstrate the appropriate technique and follow the procedure for recording FVC described below:

EASYONE Spirometer instructions

- Need 3 acceptable and 2 reproducible tests
- Most common errors: (a) Inspiration not deep enough, (b) Hesitant start of test, (c) Less than maximum effort, (d) Exhalation not long enough.

EASYONE Ratings

- A = Best 2 FEV1 & FVC within 100ml
- B= Best 2 within 150 ml
- C, D & F are not acceptable – trials should be repeated (only up to 8)

Button Functions

- ON/OFF- press and hold for 2 seconds
- ESC- press and hold for 1 second
- <- delete last character or scroll back
- >-scroll right or down
- ENTER- confirm or go to next field
- Number Buttons- press once for number, repeatedly for letters

Spirometry Steps

1. Insert Spirette
2. Turn on and press ENTER to select „Perform Test"
3. Press ENTER again to select „NEW"
4. Enter study ID, press ENTER
5. Leave name blank, press ENTER
6. Enter age, press ENTER
7. Refer to participant data sheet and enter height, DO NOT press ENTER. (press and hold ESC to return to previous menu item if needed)
8. Refer to participant data sheet and enter weight in kilograms, press ENTER
9. Press ENTER to select CAUCASIAN (note: select Caucasian regardless of participants ancestry)
10. Use < or > buttons to select gender, press ENTER
11. Use < or > buttons to select „YES", „NO" or „FORMER" for Smoker, press ENTER
12. USE < or > buttons to select „YES" „NO" or „POSSIBLE" for Asthma, press ENTER

13. Enter Tech ID (your payroll number), press ENTER
14. Explain the test to participant
15. Prepare the Physical Testing Participant:
    - There are certain activities that should preferably be avoided prior to lung function testing. Ask participants if they have: (if participants say yes to any of the below activities, mark on Case Report Form)
        - Smoked within at least 1 hour of testing
        - Consumed alcohol within 4 hours of testing
        - Performed vigorous exercise within 30 minutes of testing
        - Worn clothing that substantially restricts full chest and abdominal expansion
        - Eaten a large meal within 2 hours of testing.
    - There are conditions where suboptimal lung function results are likely to occur. Ask participants if they are experiencing any: (if participants say yes to any of the below conditions, mark on Case Report Form)
        - Chest or abdominal pain of any cause
        - Oral or facial pain exacerbated by a mouthpiece
        - Stress incontinence
        - Dementia or a confusional state
        - Respiratory infections
16. Instruct and demonstrate the test to the subject, including:
        - Correct posture with head slightly elevated
        - Inhale rapidly and completely
        - Position of the mouthpiece (open circuit)
        - Exhale with maximal force
17. Have subject assume the correct posture- testing should preferably be done in the sitting position, using a chair with arms and without wheels

Perform Maneuver: refer to steps below

18. Press ENTER to select FVC (Expiratory)
19. Instruct participants to inhale completely and rapidly with a pause of <1 second at total lung capacity (TLC)- The test assumes a full inhalation before beginning the forced exhalation, and it is imperative that the subject takes a complete inhalation before beginning the maneuver.
20. Block Spirette, press ENTER until prompted to „BLAST OUT"
21. Give Spirometer to participant and commence test.
22. Instruct participant to place mouthpiece in mouth and close lips around the mouthpiece making sure the lips are sealed around the mouthpiece and that the tongue does not occlude it.
23. Instruct participants to exhale maximally until no more air can be expelled while

maintaining an upright posture- The subject should be prompted to „blast“ not just „blow“ the air from their lungs, and then he/ she should be encouraged to fully exhale.

24. Repeat instructions as necessary, coaching vigorously- throughout the manoeuvre, enthusiastic coaching of the subject using appropriate body language and phrases, such as „keep going“, is required.
25. After the participant has completed their blow, the display will show „BEST TRIAL“. Press enter to see session quality and any instructions. For example: „deeper breath“, „blow out harder“ etc. Coach participant accordingly.

Message	**Explanation**	**Action required**
Don't hesitate	Back-extrapolated volume greater than 150 ml or 5% whichever is greater	The patient must exhale all air at once and not exhale in short bursts.
Blast out faster	Time until peak flow greater than 120 ms	The patient must exhale more explosively and as firmly and quickly as possible.
Blow out longer	Expiration time less than 2 seconds or volume accumulation has not dropped below 100 ml per 0.5 seconds	The patient stopped exhaling too early. The patient must exhale still further and force as much air as possible out of his or her lungs
Good effort, do next	Test meets above criteria Good test. Only one to two more good tests and the test is complete.	
Blast out harder	Peak flow not reproducible. Difference with respect to best test greater than 1.0 l/s	The test differs greatly from previous best test. The patient can blow even more firmly and achieve a higher peak flow.
Deeper breath	FEV1 or FVC* not reproducible. Difference with respect to best test greater than 150 ml	The test differs greatly from previous tests. The patient can inhale even more deeply and exhale even more air.
Test complete	Three acceptable tests, FEV1 and FVC* within 200 ml / 250 ml (after 5 trials)	The test is complete. An adequate number of good tests is available.**

** Not necessarily. The easyone will read 'test complete' after a 'C' result. For our protocol we require 'A' or 'B' so additional blows may be required.

26. In addition to following the quality messages displayed by the spirometer after each effort, staff should also view the graph for each blow to ensure that there are no coughs etc.
27. Press ENTER to select „NEXT“ and have participant blow again.
28. An adequate test requires a minimum of three acceptable FVC manoeuvres. Acceptable repeatability is achieved when the difference between the largest and the

next largest FVC is ≤ 0.200 L and the difference between the largest and next largest FEV_1 is ≤ 0.200 L (Ferris et. al., 1978 cited in Miller et. al., 2005). If these criteria are not met in three maneuvers, additional trials should be attempted, up to, but usually no more than, eight maneuvers. **When the participant has completed 3 acceptable AND 2 reproducible blows** „SESSION QUALITY" will read „A" or „B" and the screen will display „SESSION COMPLETE". If a participant obtains a session quality C in less than 8 trials, but the spirometer indicates that the session is complete, staff should add further blows to ensure that at a minimum, a session quality „B" is obtained. To add further blows, scroll across using the > key to ADD and select field by pressing ENTER

29. Press and hold „ESC" to return to start screen in preparation for next participant.

To ensure the early identification of a bronchospasm (an excessive and prolonged contraction of the smooth muscle of the bronchi and bronchioles, resulting in an acute narrowing and obstruction of the respiratory airway- a cough with generalized wheezing and/or volume of FEV1 decreases by more than 500mls across trails usually indicates this condition) please adhere to the following:
If a participant records a „D" on the 3rd blow and the message on the spirometer reads „deeper breath" OR „blast out faster" you need to start recording the FEV1 for each subsequent blow on the Case Report Form to see if there is a continual decrease. To access the FEV1, use > key to select „DATA" and press enter. The most recent results will be displayed, record FEV1 on case report form. Press „ENTER" three more times to display the „BEST TRIAL", record the highest FEV1 on the case report form then press „ESC" to continue the test. Repeat this process for each subsequent blow.
If the FEV1 decreases from the best trial by 500ml or more discontinue test, administer ventolin and notify supervisor. After 15 minutes rest, Healthscope staff should administer the test one more time (single blow) so as to ensure that the participant's lung function is back to normal (their start point).
If the FEV1 increases from the previous blow you can stop recording each result and continue testing as normal.

It is particularly helpful to observe the subject with occasional glances to check for distress, and to observe the tracing or computer display during the test to help ensure maximal effort. If the patient feels „dizzy", the maneuver should be stopped, since syncope could follow due to prolonged interruption of venous return to the thorax. This is more likely to occur in older subjects and those with airflow limitation.

8.7 The Step Test

The Queens College Step Test (McArdle et. al., 1972) as applied in the Australian Gulf War Veterans' Health Study will be utilised.

Equipment Provided

- 41.3cm step

- Digital stopwatch
- Digital metronome
- Heart rate monitor
- Resuscitation equipment - * tests should be supervised by operators trained in CPR.

Procedure Part A: Assessing Suitability for Test

Prior to conducting the test, each person‟s suitability to undertake the Queens College Step Test should be assessed by referring to the following criteria:

- Ask the participant if they have any of the **absolute contraindications (**a situation that makes a particular procedure absolutely inadvisable) listed on page 5 of the Case Report Form (ask participant to read and mark Case Report Form). These include:
  - Ischaemic Heart Disease
  - Unstable angina
  - Aortic Stenosis
  - Uncontrolled hypertension
  - Uncontrolled asthma
  - Epilepsy
  - Respiratory failure
- If a participant indicates „YES‟ on the Case Report Form to any of the above conditions, they should be advised that they are <u>not</u> to complete the step test.
- Ask the participant if they have any of the **relative contraindications** (a condition which makes a particular procedure **somewhat inadvisable** but does not rule it out) listed on page 8 of the Case Report Form (ask participant to read and mark Case Report Form). These include:
  - Participant older than 50
  - Currently pregnant, or childbirth in previous three months
  - Surgery in previous three months
  - Systolic blood pressure greater than 150
  - Diastolic blood pressure greater than 95
  - History of heart disease
  - Treating physician's advice not to exercise
  - Musculoskeletal problem likely to be aggravated by the exercise
  - Any other reason given by the participant for not doing the test
- If a participant indicates „YES‟ on the Case Report Form to any of the above conditions, they should be advised that they are not to complete the step test. This should then be marked on the Case Report Form.

Procedure Part B

- Instruct the participants to remove their shoes and socks – the participant should have bare feet.

- Fit chest strap firmly around chest ensuring that the transmitter is positioned at the front, over soft tissue below the sternum. AFTER positioning, moisten the underside of the transmitter with a wet sponge.
- Secure the heart rate monitor „watch" to the participants wrist.
- Press the button on the wrist monitor repeatedly until „EXE" appears on the screen. A timer will start and within 15 seconds the pulse rate should display. If the pulse does not display check that chest monitor is snug and in the correct position.
- Start the metronome ticking at 88 BPM, for females, and 96 BPM for males.
- Have the participant start with both feet on the floor and facing the 41.3 cm step. Ask participants to practice the stepping cycle as follows:
  - Up - right foot up (on first tick of metronome)
  - Up - left foot up (on second tick of metronome)
  - Down - right foot down (on third tick of metronome)
  - Down - left foot down (on fourth tick of metronome)
- Ensure that, at the top of the box, the participant"s legs are straight. Only allow practice to continue as long as it is necessary to determine that the participant can correctly complete the test.
- Once the participant has started stepping, ensure that he or she keeps in time with the ticking of the metronome.
- The participant must maintain the stepping cycle for three minutes. After 1½ minutes instruct the participant to change his/her lead leg.
- Immediately following 3 minutes of stepping, ask the participant to stop stepping and to immediately sit on the stepping box.

Recording of Step Test Performance

- Record the heart rate from the monitor **within five seconds of completing stepping**, and again **15 seconds later** (at 20 second time point), directly on the Case Report Form.
- Throughout the test the instructor should regularly monitor how the participant is feeling. If the participant feels any discomfort, or if the person cannot keep up with the metronome (after encouragement), the test should be stopped. Record the duration of the test, the reason for stopping, the heart rate within five seconds of completing stepping and again 15 seconds later, directly on the Case Report Form.
- If a participant asks for feedback on his or her performance, multiply the 15 second heart rate by 4 to give a heart rate per minute. Compare this with the ratings in Table 2 below.

Table 2: Step Test scores

Exercise Pulse		
Rating	**Men**	**Women**
Very Good	<110	<116

Good	100-124	116-130
Average	125-140	131-146
Poor	141-155	147-160
Very Poor	>155	>160

8.8 Blood Test

Equipment Provided by HEALTHSCOPE

- Sharps containers
- Vacuette tubes
- Vacuette holders
- Tourniquets
- Alcohol swabs
- Small pressure pads (Purzellin pads)
- Tape
- Protective gloves
- Hand sanitising gel
- Syringes
- Needle
- Butterfly collection systems
- Protecta pads
- Biohazard specimen bags
- Request forms
- Eskies
- Ice-bricks
- 2 Centrifuges
- Tube racks
- 7 pillows
- 7 pillow cases
- 2 sheets
- Biohazard bin bags
- Alcohol wipes
- Pens
- Scissors
- Box of tissues
- Transport chain of custody form
- Sample checklists
- Transport consignment notes
- Site Operating Procedure

Equipment Provided by CMVH

- 5 desk lamps
- Soft drink
- Paper cups
- Blanket
- First aid kit
- Pens

Equipment Provided by Defence

- 10 tables (approx 700cm x 700cm)
- 30 chairs
- 1 bench/long table (approx 2m)
- 1 fold-up bed / stretcher / reclining chair
- 14 small screens

Procedure

40.5 ml of blood will be collected from consenting participants in vacuette tubes (2 x 4.0 ml EDTA tubes, 1 x 2ml EDTA tube, 3 x 8.5 ml serum tubes, 1 x 5 ml serum tubes) following the procedure outlined below.

1. Seat the patient comfortably in the chair. Assess both arms for the most suitable vein. Remove any tight clothing from the upper arm. Ask the patient to extend his/her arm along the arm of the chair. Add a pad or cushion for extra support if necessary.

2. Check if the patient has a tendency to faint. Lie the patient down if this is the case, or if he/she is feeling unwell.

3. Ensure that there is good lighting immediately above the selected venepuncture sight.

4. Prepare all of the equipment ensuring it is in easy reach.

5. Wash hands or use alcohol hand rubs as recommended.

6. Select an appropriate vein. Apply tourniquet to the upper part of the extended arm for as short a time as possible, and **no longer than 1 minute**.

7. Swab the selected site with an alcohol wipe in a circular motion concentrically from the centre outward with sufficient pressure to remove superficial dirt.

8. Do not touch the vein site after swabbing as far as possible, but if necessary to palpate vein immediately prior to venepuncture, first wipe finger with alcohol wipe. If the phlebotomist is not confident at this stage of performing a clean venepuncture, loosen the tourniquet and repeat the procedure from point 6 above.

9. Perform **venepuncture evacuation method** below.

a) Select the appropriate tubes for the tests required – 2 x 4.0 ml EDTA tubes, 1 x 2ml EDTA tube, 3 x 8.5 ml serum tubes, 1 x 5 ml serum tubes
b) Select an appropriate size gauge vacutainer needle. While firmly grasping the cover of the needle in one hand, twist and remove the grey cover with the other hand. Do not touch the exposed rubber sleeved needle. Carefully but firmly screw the needle into the plastic barrel.
c) Remove the cover from the needle. With the patient‟s arm in a downward position and tube cap uppermost (to prevent backflow), insert the needle into the vein. The needle should pierce the skin quickly, bevel side up, at approximately a 45 degree angle to minimise the amount of skin tissue it must pass through before it enters the vein.
d) Recommended order of collection for blood containers:
    1. Plain tubes with no additives
    2. Tubes with additives
e) Firmly grasp the barrel with one hand to restrict movement and introduce the tube into the barrel with the other.
f) Place forefinger and middle finger on the flanges of the barrel and thumb on the base of the tube.
g) Centre the tubes in the barrel when penetrating the cap to prevent sidewall penetration and subsequent premature vacuum loss.
h) Advance the tube into the barrel and onto the needle valve, puncturing the diaphragm on the stopper.
i) Hold in place by pressing the tube with the thumb to ensure complete vacuum draw. Blood will follow immediately if the needle is in the vein.
j) When vacuum in tube has been exhausted and blood ceases to flow, apply soft pressure with the thumb against the flange to remove the tube from the barrel. Repeat step 4 with further tubes if necessary. Gently invert each tube with anticoagulant 8-10 times, as soon as it is filled. DO NOT SHAKE.
k) Dispose of needle immediately with needle notcher, directly into sharps container.
l) Place the barrel into the used barrel bucket for sterilisation.

10. Release the tourniquet once blood flow is established or before the last 2 mls have been collected – should the blood flow slow or stop you may want to re-apply the tourniquet pressure. Never leave a tourniquet on for more than 1 minute total time – to do so is uncomfortable and may result in haemo-concentration or a variation in blood test values. If a tourniquet must be applied for a preliminary vein selection, it should be released and re-applied after a wait of 2 minutes.

11. When collection is completed, remove the tourniquet, apply a small piece of purzellin lightly over the site, withdraw the needle then apply firm pressure over the puncture site, keeping the patient‟s arm straight. Bending the elbow does not always apply pressure at the correct point and can result in bruising. The patient can be asked to apply this pressure. Time for pressure will vary from patient to patient but extended time (5 minutes) will be required for anticoagulated patients.

12. When the bleeding has stopped, apply micropore tape over a small piece of purzellin to the puncture site. Do not rub puncture site before applying, as this will disturb the clot. If patient is allergic to micropore, apply a bandaid.

In the event of a participant fainting, please refer to Appendix E for a full fainting protocol.

6.3.8.1 Centrifugation, Packing and Freighting of Blood Samples

The bloods will then be prepared on-site for transport and storage by the nurse. This will involve centrifugation where appropriate, using a portable centrifuge, of the whole blood to separate serum. Aliquots of the serum will be taken and placed on ice for transport by courier to specified laboratories with appropriate expertise and capacity to conduct each pathology test for the study.

Preparation

- Prepare a sample Checklist (Register) for each esky at the beginning of each test day – up to four will be required. Fill each checklist in as you place samples in each esky (refer to Appendix H for Sample Packing Checklist).
- Have 4 eskies prepared at the beginning of each testing day; two eskies with ice- bricks in the esky pockets; two eskies without ice-bricks.
- Using the pre-prepared labels provided, each esky should be labelled with the test type in the clear sleeve on the side of the esky. This makes sorting the samples easier on-site and in the laboratory.
- The eskies without the ice-bricks are for all the main samples and the saliva samples and should have a label: “MAIN SAMPLES FOR ADELAIDE”.
- The eskies with ice-bricks are for the TNF Alpha/Interleukin samples ONLY. Use one chilled esky for the morning TNF Alpha/IL samples and one for the afternoon TNF/IL samples. These eskies should be labelled “TNF/IL SAMPLES – TO BE ALIQUOTTED AND FROZEN ASAP”.

Centrifugation

- Seven blood sample tubes would have been collected from each Physical Testing Participant;
  - 2 x 4 ml EDTA (mauve top),
  - 1 x 2 ml EDTA (mauve top),
  - 3 x 8.5 ml serum (gold top),
  - 1 x 5 ml serum (gold top).

- When the serum samples (gold tubes) have clotted, centrifuge every gold top tube for 10 minutes at 3000 rpm. Do not spin the mauve (EDTA) tubes.
- After centrifugation, place the spun gold top samples, their mauve top tubes and the saliva samples if present with their correct request forms.

Saliva Samples:

Three saliva tube samples will have been collected by study participant prior to the test day (2 x evening samples, 1 x morning sample).

Keep each patient episode samples together with their correct saliva request forms:

Salivary Adrenaline/Nor-Adrenaline – 1 x 2000h (approx) sample

Salivary Cortisol - 1 x 2000h (approx) sample and

- 1 x early morning sample
- 2 samples in total

Procedure for Loading the Centrifuge:

- Collect blood into a gel separator tube. Ensure that both the specimen and request form are labelled correctly with the participant‟s study ID and the lab reference number.
- Allow specimen to 'stand' for a minimum of 20-30 minutes allowing blood to clot.
- Place specimens into tube holders, then put aerosol prevention caps on the loaded holders, ensuring correct balancing of the rotor.
- Close the lid and lock the latch. Do not operate this instrument with the lid catch disengaged.
- Start the centrifuge. When centrifugation has ceased ensure the rotor has completely stopped turning before opening the lid.
- Remove the blood tubes.

Sorting the samples

Sort the samples for each patient episode in the following way:

- Place 1x5 ml gold top with the TNF Alpha, Interleukin (IL) request form in a biohazard bag – check the sample ID against the form to ensure the form & sample matches
- Place the remainder of the blood samples in a biohazard bag (3x mauve, 3x large gold,) with the main request form (the one with the large number of test requests) – check the sample ID against the form to ensure the form & samples match.

Place one evening saliva sample and the morning sample with the salivary Cortisol form in a biohazard bag

- check the sample ID against the form to ensure the form & samples match

Place the other evening saliva sample with the Adrenaline and Noradrenaline request form.

- check the sample ID against the form to ensure the form and sample match.

Packaging

- Place the TNF/IL samples & form for each patient episode in the biohazard bags in the esky with ice-bricks as soon as the samples have been spun and sorted. It is important to keep these samples chilled as soon as possible after centrifugation. Fill in the sample checklist for that particular esky every time you place a sample in it.
- Place the other sorted samples for all the main tests and the saliva samples, all with their request forms in a biohazard bag in the esky without the ice-bricks. Fill in the sample checklist for that particular esky every time you place a sample in it.

Sending the Samples

- The TNF/IL samples are sent to the designated laboratory twice per test day because they need to be aliquotted and frozen ASAP. Send the morning samples once they have all been processed and packed. All of the other samples are sent at the end of the test day, along with the afternoon TNF/IL samples.

  Morning: one esky sent after the morning tests (TNF/IL samples in a chilled esky)
  Afternoon: all the remaining eskies sent after the afternoon testing (TNF/IL samples in one chilled esky; the other samples in one or more other eskies)

- After the morning samples have been centrifuged, checked, sorted and packed, place the sample checklist for that esky in a plastic sleeve inside the esky on top of the samples and seal the esky. Send the TNF/Interleukin esky only to the designated Healthscope Laboratory in that state via the Gribbles Pathology courier. This is because these samples must be aliquotted and frozen ASAP.

- After the afternoon samples have been centrifuged, checked, sorted and packed in the eskies, place the sample checklist for each esky inside the esky on top of the samples. These are to be sent by Gribbles courier to the designated laboratory in that state.

Courier and Laboratory

Phone the courier number in that state to arrange a courier. Preferably the courier should be arranged the evening before or first thing in the morning for both the morning and afternoon pick-ups. The Healthscope Project coordinator should ring the courier and notify the laboratory prior to the test days.

NSW:

Courier: Tel: 02 9736 7000
Laboratory Address: Davies Campbell De Lambert
2 Leeds St

Rhodes NSW 2138

Tel: 02 9736 7000

Cut-off time for last samples to arrive in laboratory that evening: 1900 hrs

Courier Contact: Sam Michail; Tel: 02 9736 7000 (M: 0407 780 185)

Laboratory Specimen Reception Manager: Mukerrem Ildes; Tel: 02 9736 7000 Laboratory Operations Manager: Shelley Fox; Tel: 02 9736 7000 (M: 0457 766 348)

WA:

Courier: Tel: 08 9430 4850

Laboratory Address: General Pathology Laboratories

223 High St,

Freemantle WA 6160

Tel: 08 9430 4850

Cut-off time for last samples to arrive in laboratory that evening: 1800 hrs

Courier Contact: Pierre Rozells Tel: 08 9430 4850

Laboratory Specimen Reception Manager: Alison Fraser Tel: 08 9430 4850

Laboratory Operations Manager: Sam Moorthy; Tel: 08 9430 4850

SA:

Courier: Tel: 08 8205 5678

Laboratory Address: Gribbles Pathology

1 Goodwood Rd,

Wayville SA 5034

Tel: 08 8205 5655

Cut-off time for last samples to arrive in laboratory that evening: 1730 hrs

Courier Contact: Julie Hester Tel: 08 8205 5681

Laboratory Specimen Reception Manager Spiro Pazios Tel: 08 8205 5637

Laboratory Operations Manager: Richard Pierce; Tel: 08 8205 5677

General Reception Number: Tel; 08 8205 5655

NT:

Courier: 08 8945 2506

Laboratory Address: Healthscope Pathology

C/- Darwin Private Hospital,

Rocklands Drive

Tiwi NT 0810

Tel: 08 8945 2506

Cut-off time for last samples to arrive in laboratory that evening: 1600 hrs

Courier Contact: Tim Lane Tel: 08 8945 2506 (Mob: 0418 623 945)

Laboratory Specimen Reception Manager: 08 8945 2506

Laboratory Operations Manager: Michael Colyer 08 8945 2506

Commercial Manager: Kate Koleff Mob: 0419 146 543 – for any problems or issues all states

8.9 Skin Photography

Equipment Provided

- Panasonic DMC-G10
- Two 150W Quartz Halogen floor lamps.
- Swivel stool
- High backed chair
- White screen
- Screens/patitions for privacy
- 18% Grey colour chart
- Macbeth Colour Checker chart
- Mask to partially cover participants face
- Masking Tape

Setting up the picture station

1. The area where the pictures are to be taken should be away from strong sources of natural light such as a window.
2. The screens/partitions should be set up in a rectangle to provide privacy for the study participant while the photographs are taken.
3. Once the position has been found, the picture station should be set 1.2 meters from the wall and an x should be marked on the floor with white tape.
4. Place the stool over the x on the floor and the second chair should be behind the stool.
5. Tape the white sheet to the wall so that the bottom of the sheet is 22cm from the bottom of the floor
6. Set the tripod to the height of 940cms, and attach the camera to the tripod. The camera and tripod should be placed 80 cm from the marked X on the floor. Adjust the zoom on the camera and the angle of the camera so that the markings on sheet labelled „back" match the upper boundaries of the cameras LCD screen
7. The lamps are placed on the floor at a 30 degree angle to the marked X as per figure 3 below. The distance of the main lights to the x is 1.2 metres. The height of the lamps is set to 120 cm.
8. Turn the camera on.
9. The Camera should be set to manual (shown on the central dial on top of the camera as M). The manual settings for this camera are: variable shutter speed, with an aperture size of F5.0. The manual settings can be seen on the rear LCD screen as ¼ F5.0. This has been pre-set by CMVH and the shutter speed will need to be set for the lighting conditions of the

environment. With the manual setting selected, highlight the shutter speed and use the dial at the rear of the camera to scroll upwards and downwards until the light bar is in the middle. This setting must be done with all the lights on.

10. Set the white balance of the camera at the beginning of each session as per the calibration instructions (Section 6.2.3).

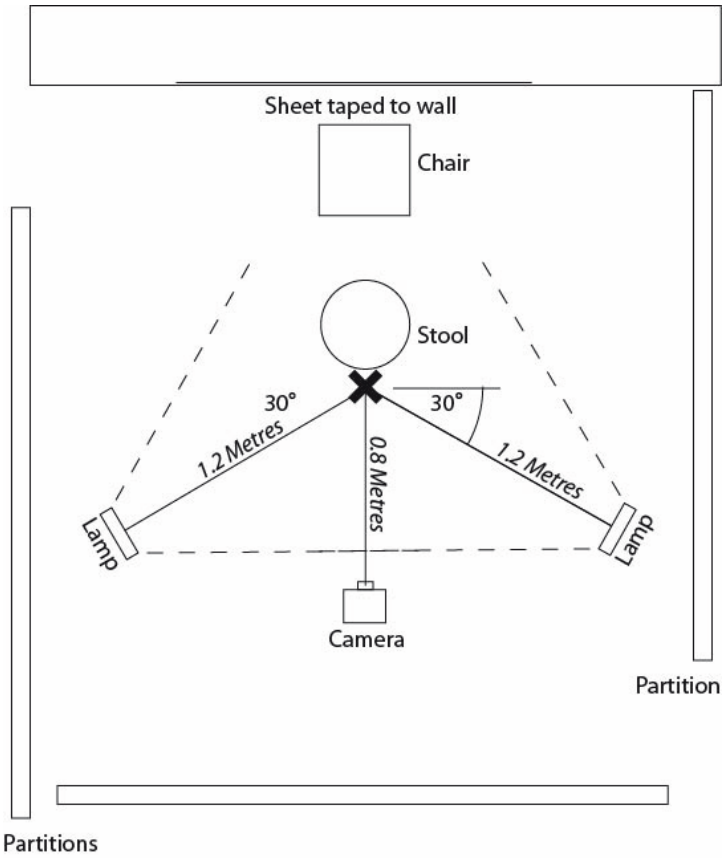

Figure 3. Picture Station

Procedure: Taking the photographs for assessment of dermatological conditions

1. Describe the photography session to participants and ask for them to provide verbal consent to continue. If they agree, mark this on the appropriate place on the Case Report Form.
2. Instruct the participant to stay as still a possible during each shot.

Photograph 1:

3. Photograph the front page of the participants Case Report Form. Ask the participant to stand in front of the x position with their CRF at stomach height. Make sure that their participant number is visible on the LCD screen and that their face or any other identifying feature is not visible on the LCD screen. Depress the shutter button once to take a photo.

Photograph 2:

4. The second photo will be of the participants back. Ask the participant to remove their shirt. For female participants, undergarments such as bra‟s do not need to be removed.

5. Check for any identifying markings such as tattoos on the participants back. If the participant has a tattoo care is taken not to photograph the section of torso covered with the tattoo. If this is not possible, do not take a photograph of the participants back.
6. Ask the participant to sit on the swivel stool facing the screen with their back to the camera – ensure that participants are sitting up straight, with their shoulders back and square.
7. The borders of the camera LCD screen at the rear of the camera should be zoomed so that the black rectangle on the screen behind the participant is just visible at the edges of the camera LCD screen. Depress the shutter button once to take a photo.

Photograph 3:

8. The third photo will be of the right hand. Swivel the camera so that the rectangle marked "right hand" on the screen behind the participant is in the centre of the camera LCD screen. Use the zoom function to zoom the camera so that the boarders of this rectangle are at the edges of the LCD screen.
9. Ask the participant to raise their right hand so that it is in the centre of the rectangle labelled "right hand" when viewed from the LCD screen on the camera. Depress the shutter button once to take a photo.

Photograph 4:

10. The fourth photo will be of the left hand. Swivel the camera so that the rectangle marked "left hand" is in the centre of the LCD screen. Use the zoom function to zoom the camera so that the borders of this rectangle are at the edges of the camera LCD screen.
11. Ask the participant to raise their left hand so that it is in the centre of the rectangle on the screen when viewed from the LCD screen on the camera. Depress the shutter button once to take a photo.

Photograph 5:

12. The fifth photo will be of the right side of the face. Ask the participant to turn so that the right side of their face is toward the camera.
13. Have the participant align their head with the markings on the mask. The mask should be oriented so that the words "right side" are facing the camera.
14. The mask should be positioned between the camera and the participant so that it obscures the area of the face not being photographed. Arrange the mask so that the participant"s full ear and nose is visible, but their eye is covered.
15. Swivel the camera so that the rectangle on the outer edge of the mask are at the centre of the camera LCD screen. Use the zoom function to zoom the camera so that the borders of this rectangle are at the edges of the camera LCD screen. Depress the shutter button once to take a photo.

Photograph 6:

16. The sixth photo will be of the left side of the face. Repeat the procedure above for the left side of the face, but with the mask oriented so that the words “left side” are facing the camera.
17. Swivel the camera so that the rectangle on the outer edge of the mask are at the centre of the LCD screen. Use the zoom function to zoom the camera so that the borders of this rectangle are at the edges of the LCD screen. Depress the shutter button once to take a photo.

Photograph 7:

18. The seventh photo will be of the soles of the feet. Ask the participant to remove their shoes and socks. Have the participant spread their toes.
19. Ask the participant to sit on the second chair with their legs resting on the stool in front of them.
20. Swivel the camera so that both feet are visible on the LCD screen. If the face is visible from the LCD screen, have the participant pick up the mask labelled “mask,” and hold it so that their face is not visible from the LCD screen. Depress the shutter button once to take a photo.

8.10 Saliva Collection

Once participants have completed all 6 testing stations and have handed in their case report form, they will be provided with a saliva collection pack, containing 3 salivette tubes (labelled with the participant‟s study ID, the date the sample is to be collected, and the time the sample is to be collected - AM or PM), and a set of instructions, Participants will be asked to collect three saliva samples using the enclosed tubes, and return them to the study team the following day.

The collection instructions will read as follows:

Dear Participant,

As part of the Physical Testing component of the Middle East Area of Operations Prospective Study, we will require you to provide three saliva samples using the salivette tubes enclosed, and following the instructions outlined below. Two samples are to be collected at 2000hrs the evening of your testing appointment and one sample is to be collected 30 minutes after waking the morning after your physical testing appointment.

IN PREPARATION FOR THE EVENING SALIVA COLLECTION AT 2000hrs:

- *Avoid alcohol on the day of the 2000hrs saliva collection.*
- *Avoid all foods and drink (except water) 60 minutes prior to collection of each specimen*
- *Avoid exercise for 60 minutes prior to collection*
- *Do not brush your teeth or apply make-up/lipstick prior to saliva collection*
- *If you use hormone creams, wait 12 hours after the last dose before collecting saliva*

IN PREPARATION FOR THE MONRING SALIVA COLLECTION 30 MINUTES AFTER WAKING

- *Avoid alcohol the evening before the morning saliva collection*
- *Fast overnight from 2200hrs the night before the morning saliva collection (water may be consumed during this time).*

- *Avoid the use of hormone creams (unless specifically prescribed by a medical practitioner), from 6pm the night before saliva collection until after the morning saliva sample has been collected.*
- *Avoid exercise for 60 minutes prior to collection*
- *Do not brush your teeth or apply make-up/lipstick prior to saliva collection*

SALIVA COLLECTION:

Remember you need to:

- *Collect 2 saliva samples at 2000hrs, the evening prior of your physical testing appointment.*
- *Collect the final saliva sample 30 minutes after waking, the morning following your physical testing appointment.*

AT THE DESIGNATED TIME FOR SALIVA COLLECTION:

- *Wash your hands thoroughly before handling the saliva specimen tubes as creams or other substances may contaminate the saliva.*
- *Rinse your mouth out with water.*
- *Fill the saliva collection tube with saliva from the front of your mouth up to the red line on the label.*
- *Important – do not express mucous or sputum from the back of the throat into the saliva tube.*
- *Replace the cap evenly and securely and wipe off any saliva on the outside of the tube.*
- *Place each saliva specimen tube in the sealed section of the clear plastic specimen bag provided.*
- *Seal the bag closed and place in the fridge (to maintain the integrity of the saliva specimens).*
- *Bring the sealed bag with saliva tubes with you of the day following the physical testing for collection by CMVH staff. Please keep stored in a cool, dark environment until collection.*

If you have any questions about your saliva collection please call the MEAO Prospective Health Study information line: 1800 232 904.

The following day, when participants return with their saliva samples, they will be directed to a Healthscope or CMVH staff member, who will complete the relevant section of their Case Report Form, ensure that all three saliva tubes have been labelled appropriately, and pack the saliva tubes for transport. The Healthscope co-ordinator will then organise for a courier to come to the base, collect the samples, and transport to the appropriate laboratory for testing.

9. DATA COLLECTION AND QUALITY CONTROL

Data for each of the physical assessments will be collected on a separate Case Report Form (see Appendix B) for each Physical Testing Participant. Physical Testing Participants will carry their Case Report Form with them from station to station. Once Physical Testing Participants have completed all six stations, they will report to the Healthscope Project Coordinator who will check over their Case Report Form looking for missing data, outlier scores, and discrepancies (refer to Quality Management Plan in Appendix F for full details). Only after the Healthscope Project Coordinator is satisfied that the Case Report Form has been appropriately completed will they sign-off the Case Report Form and thank

the Physical Testing Participant for their time and effort. Case Report Forms will then be forwarded to the CMVH research staff member or SOC Administration Officer who will then double-check them for completeness.

If the protocol is deviated from in any way for any reason (refer to Appendix F for what constitutes a protocol deviation), Healthscope staff will need to note this on the Case Report Form and the Test Station Protocol Deviation Summary (see Appendix C). At the end of the testing session, the Healthscope co-ordinator will need to provide this log to the CMVH coordinator who will transfer this information onto the Protocol Deviation Log (Appendix D), which will be forwarded to the Study Manager at the end of the physical testing day.

If any Serious Adverse Event (refer to Appendix F for definition) takes place, Defence health staff will be notified. The Healthscope coordinator will firstly take all action required to assist the Physical Testing Participant and notify the CMVH coordinator who is on site. The CMVH coordinator will be required to notify the Chief Investigator and the Study Manager of the event in writing within two hours.

At the end of each testing session, a check will be undertaken by the Healthscope coordinator and CMVH Coordinator to ensure that for each Physical Testing Participant listed on the Participant Attendance List, the following items have been collected and correctly labelled with the participant‟s study ID:

- A completed and checked Case Report Form
- six vacuette tubes

If any of the above items are missing, the SOC Administration Officer or the CMVH coordinator must investigate the circumstances leading to the missing item, ensure it is recorded in the Protocol Deviation Log (Appendix D) and send this log at the end of each testing day to the Study Manager.

10. END OF DAY TASKS

10.1 Download spirometry data

At the end of each physical testing day data from each spirometer will be downloaded to the physical testing laptop. To do this:

- Turn on the laptop and log in
- Open the EasyWare program
- Connect the spirometer base station cradle to the laptop using the supplied USB cable
- Place the spirometer in the cradle
- Turn the spiromteter on.
- Data will transfer automatically

At the end of each physical testing day, study ID numbers entered by Healthscope nursing staff (viewable via EasyWare) should be cross checked with a list of correct study ID numbers, to ensure that numbers are being entered accurately. If an ID is recorded incorrectly: EasyWare→ Edit→ Patient Data→ *edit incorrect numbers*

At the end of the first day of physical testing, the spirometry data base should be emailed to A/Prof Alan Crockett for review and continuous quality feedback to the Healthscope staff. To send the data base to A/Prof Crockett:

- Open Microsoft Outlook.
- Open a new email message. In the subject line write "MEAO Spirometry for review (date)"
- Attach the EasyOne .mdb file. This is located in the following path:
  C:\ProgramData\ndd\EasyWare.mdb
- Compress the file (zipped folder): right click→ send to → compressed zip folder
- In the Message please indicate the mobile phone number that A/Prof Crockett should use to contact you to advise of the spirometry quality and requirement for further instruction
- Send the zipped file to A/Prof Crockett.

10.2 Download photography

1. At the end of each session the pictures will be downloaded to the physical testing laptop.
2. Attach the interface cable K1HA08AD0003 (black cord) from the computer to the camera.
3. Turn the camera on.
4. A new hard drive will appear in the computer. It will probably be labled: Removable Disk (E:)
5. Open this hard drive and navigate to the DCIM folder, where another folder called "102_PANA" will be located
6. Copy this file to the computers hard drive via the path way Computer>Public>OffsitePictures>Camera A (or Camera B)
7. **If the camera is camera A; copy the pictures to the folder Camera A. If the camera is cameraB; copy the pictures to the folder Camera B.**
8. When this process has been completed rename the folder which you have just created in the hard drive. Start with the date, followed by the Camera identifier. i.e: 15022011CameraA.
9. After the pictures have been copied exit the camera"s hard drive by ejecting it in the task bar located on the lower right. Left click the flash drive icon, select "Safely remove USB Storage Device _ Drive (E). The computer will confirm the operation with "This device can now be removed from your computer." Disconnect all cables and turn off the camera.
10. Each photograph file should be labelled as follows studyID-photograph tag-body part-date photo taken (For example 1045657-A1-Left face-20100511.jpeg)
11. A hue adjustment will be made to all photos in a session based on the second photograph (of the MacBeth Colour Card) with the Adobe DNG Profile editor.
12. On completion of adjustment and relabling of files they are transferred to a CD which is taken to DMAC to transfer the photograph files to the Defence Health Database.

13. Once it is confirmed that the photos are transferred, the files on the CMVH computer and any remaining photo‟s on the camera memory card/storage device are deleted.

10.3 Charge camera batteries

At the end of each testing day, CMVH research officers will need to charge the camera batteries for the following day‟s use.

10.4 Store Case Report Forms

At the end of each testing day, completed Case Report Forms will need to be transported to, and stored at the CMVH Coordinator‟s accommodation.

10.5 Fax Logs to Study Manager

At the end of each testing day, CMVH Research Officer will fax Protocol Deviation and Adverse Event Logs to the Study Manager, if applicable.

10.6 Back up external hard drive

At the end of each testing day, the CMVH Research Officer will ensure that the physical testing lap top is backed up using an external hard drive- each day should have its own separate folder on the hard drive.

11. DATA MANAGEMENT

11.1 Participant Attendance

Once back in Adelaide, the CMVH Research Officer who attended the physical testing will use the hardcopy participant attendance list to log which participants attended each testing session on the MIS.

11.2 Case Report Forms

Once back in Adelaide, the CMVH Research Officer who attended the physical testing will log receipt of the Case Report form on the MIS, and check the Case Report Form for completeness.

If any part of the Case Report Form is found to be unintentionally incomplete or discrepant, the CMVH Research Officer will establish why the discrepancy has occurred and whether any follow-up action is required.

The CMVH Research Officer will then pass on the Case Report Form to the Data Manager who will:

- Scan complete Teleform Case Report Form (refer to Appendix G for Teleform scanning instructions) which will automatically populate a CSV file
- Transfer data to DMAC via a secure FileTransfer Protocol (FTP)
- File the hard-copy Teleformed Case Report Form in the participants files

11.3 Laboratory Test Results

Healthscope are responsible for ensuring that all post deployment tests are completed at the laboratory at which the pre deployment tests were conducted (see Appendix H).

Upon completion of each test laboratories will forward two copies of each hardcopy result to CMVH and one electronic copy to DMAC.

The Project Officer will log receipt of all hardcopy and electronic pathology test results that come back from the laboratories, and follow up any which are missing with Healthscope. In addition, the Project Officer will forward one hardcopy of each laboratory report to Dr Keith Horsley. Dr Keith Horsley will check for abnormalities and sign each hardcopy result (see Appendix I). If a result is identified as abnormal, Dr Keith Horsley will draft a letter identifying their abnormal results and provide them with information about actions to be taken (see Appendix J). Dr Keith Horsley will forward all signed hardcopy results and an electronic letter for those identified as abnormal to the Project Officer. The Project Officer will send to the identified participants an abnormal results letter, together with a copy of their blood results which they can then forward on to their personal GP (for more detail refer to section 12.3). The Project Officer will also send other participants‟ whose bloods come back as normal a letter (see Appendix K) thanking them for their participation in the physical testing component of the study. The Project Officer will record both letters on the MIS.

Upon completion, Dr Keith Horsley will also be responsible for directing the analysis of all data collected as part of the physical testing except for spirometry and skin photography (refer Statistical Analysis Plan).

11.4 Spirometry

After each physical testing trip all spirometers will be forwarded onto Associate Professor Alan Crockett (spirometry specialist), who will download a copy of participants‟ results, in order to assess the quality of individual blows so as to advise CMVH what may be improved upon in the future, and to identify participants who exhibited abnormal results (e.g. bronchial spasm). All spirometry results will then be forwarded on to DMAC via FTP or via the use of a CD.

To copy spirometry data onto CD:

- Open the EasyWare program.
- Click File, and a drop down menu will appear. Select „Export Data‟ and then Text Export (CSV) New Records.
- The files will be exported to the following folder: Desktop\Users\Public\PublicDocuments\ndd
- Copy the files to a CD.
  The CD will then be walked to DMAC who will upload the data to the Defence Health Research Database.

Upon completion of each post deployment spirometry data collection, Professor Alan Crockett will also analyse the results (refer Statistical Analysis Plan)

11.5 Photography

After each physical testing trip, all of the photographs that were taken will be downloaded, labelled (in the form [Participant ID]-[Folder/Camera ID]-[Part of anatomy]-[Date of photo] e.g. 1000000-A1-Back-20101012) and appropriately adjusted to ensure both consistency and accuracy. Once this process has been completed, each participant‟s set of photographs will be forwarded onto DMAC via FTP.

Upon completion of each post deployment skin photograph, the pre and matching post deployment skin photos will be analysed by a dermatologist (see Appendix L and Statistical Analysis Plan).

12. QUALITY MANAGEMENT

All members of the Physical Testing Team will adhere to the Quality Management Plan (Appendix F), in accordance with the Quality Control Measures specified above (refer to Section 7).

13. REPORTING

Healthscope will provide to CMVH within one month of undertaking each Physical Test a report for each individual participant, which will include at a minimum:

- Study ID
- Date of physical testing
- Number of blood tubes collected
- Number of saliva tubes collected
- Date samples sent to each laboratory
- Laboratory unique sample identified

Healthscope will notify the CMVH coordinator who is on site for physical testing of any of the following incidences:

- Any adverse or serious adverse event which affects or potentially may impact upon the health of any Physical Testing Participant (on occurrence of the event)
- Any incident which may lead to an occupational health and safety claim as a result of the activities within this contract (notify within 24 hours)
- Any other risk or potential risk which could impact upon the CMVH and/or Defence (notify within 24 hours)

The on-site CMVH Coordinator will provide the CMVH Study Manager with the following reports:

- Adverse or serious adverse event log (within 2 hours of an event)
- List of non-attenders (at end of each physical test day)
- Protocol deviation log (at end of each physical test day)

* Refer to Quality Management Plan (Appendix F) for full details.

14. ETHICAL CONSIDERATIONS

12.1 Ensuring Voluntary Participation

The initial information pack will emphasize the voluntary nature of the study and reassure participants that Defence will not be informed of their participation or lack of participation, and that their future health care, status within Defence, entitlements with DVA or compensation will not be affected by whether or not they choose to participate. However, the Physical Testing Team will ensure that Physical Testing Participants are aware that they will be free to withdraw from the study at any point. In addition, a cooling off period of at least 24 hours between study information sessions (briefings) and recruitment will ensure that Physical Testing Participants have time to carefully consider their involvement.

If at any time, during the physical testing a potential participant indicates that they have not consented to participate in the study, the physical testing team member must ask them if they wish to now consent to undertaking physical testing. If the participant has any concerns about participating the physical testing team member will attempt to address these concerns and if the participant is then willing to continue with the physical testing, the Physical Testing Team Member must then ask them to complete a new consent form. This consent form should be sealed in an envelope and given to the Participant Liaison Officer.

If after attempting to address any concerns, a participant still does not want to participate, the physical test must cease immediately and the participant must be free to leave at any time.

12.2 Data Security and Confidentiality

Data on Physical Testing Participants will be de-identified by the use of specifically generated study numbers. De-identified paper copies of Case Report Form will be kept in a locked, restricted facility. Blood and saliva samples will be de-identified at the time of collection, labelled with a study ID number and stored in a recognised laboratory facility. The keys linking study numbers to individuals‟ identifying information, self-report data and Defence-owned data will be kept and maintained by a facility that meets Defence physical and information security requirements applying to the particular participating personnel.

12.3 Testing of Biological Samples

Both the saliva and blood samples will be tested by the same recognised testing laboratory (see Appendix H for list of Laboratories) for pre and post samples. These laboratories are bound by the laws, regulations and obligations for testing human biological samples. The results of each of the pathology tests will be reviewed by Dr Keith Horsely. In the case of any abnormal results which may

indicate the need for a medical consultation, a plain language summary of the outcomes of the abnormal test s will be prepared and provided as part of feedback only to the participant involved (see Appendix J). In this case, the participant will also be provided with a copy of the original pathology results, which may be taken to their own doctor should they choose to take this course of action.

Table 2: Final list of pathology testing for the MEAO Prospective Health Study

Assessment Purpose	What is Assessed	How Collected	Freezer Storage
Exposure to Toxins	• *Blood chemistry and liver function* specifically: Sodium, Potassium, Chloride, Bicarbonate, Anion Gap, Glucose, Urea, Creatinine, total Cholesterol, Osmolarity, Urate, Phosphate, calcium, Ionised calcium, Albumin, Globulins, Total Protein, Bilirubin, GGT, ALP, ALT, AST, LD, CK, Magnesium, Amylase, Lipase, and C-Reactive Protein.	Clotted blood white top tube	Yes
	• *Heavy metal exposure* specifically: Lead	Whole blood K-EDTA tube	No
	• *Organophosphate exposure* specifically: paroxinase and red blood cell cholinesterase	Whole blood Li-Hep or K-EDTA tube	No
Exposure to Infections	• *Total Cell Count (CBE)* specifically: haemoglobin, red cell count, packed cell volume, mean corpuscular volume, mean corpuscular haemoglobin, mean corpuscular haemoglobin concentration, red cell distribution width, total white cell count and white cell differentiation counts and percentages (neutrophils, lymphocytes, monocytes, eosinophils, basophils and platelets). • *Erythrocyte Sedimentation Rate (ESR) as part of CBE* • *Viral infections* specifically:	Whole blood K-EDTA	No

	○ Epstein-Barr, ○ Cytomegalovirus, ○ Herpes Simplex, ○ Hepatitis C, *Bacterial infections* specifically ○ Mycoplasma, ○ Chlamydia (serology) ○ Helicobacter pylori (serology) • *Parasitic infections* specifically: Leishmaniasis	Clotted blood White Top Clotted blood White Top Serum White Top	
Physiological and Immunological Changes Arising from Stress	• *Inflammatory mediators* specifically: Interleukin 6, C-Reactive Protein, TNF Alpha, IL-1, IL-4 • *Stress hormones* specifically: cortisol, nor-adrenaline, adrenaline	Clotted blood White Top Morning/evening Saliva	Yes (6 months only) Yes (est. 6 months only)
Effects of the Deployed Environment	• *Cardiovascular Risk Factors* specifically: Total cholesterol and High Density Lipoproteins. • Glycated Haemoglobin • *Dietary Components* specifically: B12 and Folate	Clotted blood White Top (fasting not required) Clotted blood White Top (fasting preferred)	Yes Yes (30 days only)

Refer to Appendix J for review of MEAO Prospective Study pathology results

12.4 Storage of Biological Samples

Unused serum will be stored at -70° centigrade for a period of up to 10 years in order to conduct investigations in the future as new diagnostic technologies become available and/or as unexpected health concerns emerge among veterans.

12.5 Further Advice

For all general study enquiries, please contact: Dr. Carol Davy
For advice pertaining to this protocol please contact: Dr. Carol Davy/ Ms. Maria Abraham
For advice pertaining to equipment please contact: Dr. Carol Davy/ Ms. Maria Abraham
For advice pertaining to appointment schedules and participants please contact: Dr. Carol Davy

For advice pertaining to CMVH in general please contact: Dr. Carol Davy

For all after hours enquiries, please contact: Dr. Carol Davy

Dr. Carol Davy

MEAO Prospective Study Manager and Research Fellow

Centre for Military and Veterans' Health

The University of Adelaide, AUSTRALIA 5001

Ph: +61 8 8313 0676

Mobile: 0424 751 192

email: carol.davy@adelaide.edu.au

Should you have difficulty contacting any of the above please direct your enquiry to:

Centre for Military and Veterans‟ Health

The University of Adelaide, AUSTRALIA 5001

Ph: +61 8 8313 5200

13. REFERENCES

Armitage P. & Berry G. (1994) *Statistical Methods in Medical Research* (3rd edition). Blackwell.

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APPENDIX A: PLAN FOR PHYSICAL TESTING

Draft Plan for Physical Testing - 17 June 2010

	Blood Pressure (A) 10 minutes 4 stations	Height/Weight/Waist (B) 5 minutes 2 stations	Photograph (C) 10 minutes 2 stations	Blood (D) 10 minutes 5 stations	Spriometry (E) 10 minutes 2 stations	Step (F) 10 minutes 2 stations	Biol. samples preparat 10 minutes 2 Station
AM SESSION 1							
8:00			Welcome, OHS brief, and explanation of process				Saliva
8:10	Group 1	Group 2	Group 3				Saliva
8:15	Group 1	Group 1	Group 3				Saliva
8:20	Group 2	Group 3	Group 1				
8:25	Group 2		Group 1				
8:30	Group 3		Group 2	Group 1			
8:35	Group 3		Group 2	Group 1			
8:40				Group 2	Group 1		Group 1
8:45				Group 2	Group 1		Group 1
8:50				Group 3	Group 2	Group 1	Group 2
8:55				Group 3	Group 2	Group 1	Group 2
9:00					Group 3	Group 2	Group 3
9:05					Group 3	Group 2	Group 3
9:10						Group 3	Blood
9:15						Group 3	Blood
Morning Tea/set up am session 2							
AM SESSION 2							
10:00			Welcome, OHS brief, and explanation of process				Saliva
10:10	Group 4	Group 5	Group 6				Saliva
10:15	Group 4	Group 4	Group 6				Saliva
10:20	Group 5	Group 6	Group 4				
10:25	Group 5		Group 4				
10:30	Group 6		Group 5	Group 4			
10:35	Group 6		Group 5	Group 4			
10:40				Group 5	Group 4		Group 4
10:45				Group 5	Group 4		Group 4
10:50				Group 6	Group 5	Group 4	Group 5
10:55				Group 6	Group 5	Group 4	Group 5
11:00					Group 6	Group 5	Group 6
11:05					Group 6	Group 5	Group 6
11:10						Group 6	Blood
11:15						Group 6	Blood
Lunch set up pm session 1							
PM SESSION 1							
12:00			Welcome, OHS brief, and explanation of process				Saliva
12:10	Group 7	Group 8	Group 9				Saliva
12:15	Group 7	Group 7	Group 9				Saliva
12:20	Group 8	Group 9	Group 7				
12:25	Group 8		Group 7				
12:30	Group 9		Group 8	Group 7			
12:35	Group 9		Group 8	Group 7			
12:40				Group 8	Group 7		Group 7
12:45				Group 8	Group 7		Group 7
12:50				Group 9	Group 8	Group 7	Group 8
12:55				Group 9	Group 8	Group 7	Group 8
1:00					Group 9	Group 8	Group 9
1:05					Group 9	Group 8	Group 9
1:10						Group 9	Blood
1:15						Group 9	Blood
Afternoon tea/set up pm session 2							
PM SESSION 2							
2:00			Welcome, OHS brief, and explanation of process				Saliva
2:10	Group 10	Group 11	Group 12				Saliva
2:15	Group 10	Group 10	Group 12				Saliva
2:20	Group 11	Group 12	Group 10				
2:25	Group 11		Group 10				
2:30	Group 12		Group 11	Group 10			
2:35	Group 12		Group 11	Group 10			
2:40				Group 11	Group 10		Group 10
2:45				Group 11	Group 10		Group 10
2:50				Group 12	Group 11	Group 10	Group 11
2:55				Group 12	Group 11	Group 10	Group 11
3:00					Group 12	Group 11	Group 12
3:05					Group 12	Group 11	Group 12
3:10						Group 12	Blood
3:15						Group 12	Blood

Draft

ID:

Pre-deployment Physical Testing

Date: / /

Session Start Time: : HRS

Draft

Tester ID: | | | | | | | | ID: | | | | | | | | |

Saliva Collection

1.1 Did you have a drink containing alcohol in the 12 hours prior to collecting your saliva sample? ○ Yes ○ No

1.2 Time AM saliva sample was collected:	: HRS
Lab reference number:	-
○ AM salivette tube collected	
○ AM salivette tube labelled with study ID	

1.3 Time PM saliva sample (1) was collected:	: HRS
Lab reference number:	-
○ PM salivette tube collected	
○ PM salivette tube labelled with study ID	

1.4 Time PM saliva sample (2) was collected:	: HRS
Lab reference number:	-
○ PM salivette tube collected	
○ PM salivette tube labelled with study ID	

1.5 If saliva samples were not collected, please specify reason(s) for non-collection:

Tester ID: | | | | | | | | ID: | | | | | | | | |

Blood Pressure

2.1 Has the participant abstained from food for a minimum of 30 minutes?	○ Yes	○ No
2.2 Has the participant abstained from caffeine for a minimum of 30 minutes?	○ Yes	○ No
2.3 Has the participant been at rest for at least 5 minutes?	○ Yes	○ No

2.4 Blood Pressure measurements:

1			2		
Systolic 1	Diastolic 1	Pulse	Systolic 2	Diastolic 2	Pulse

3			Average 1-3		
Systolic 3	Diastolic 3	Pulse	Systolic Ave	Diastolic Ave	Pulse Ave

2.5 If the difference between any 2 measurements of SBP is more than 8 mm Hg and DBP is more than 5 mm Hg:

4			5		
Systolic 4	Diastolic 4	Pulse	Systolic 5	Diastolic 5	Pulse

6			Average 4-6		
Systolic 6	Diastolic 6	Pulse	Systolic Ave	Diastolic Ave	Pulse Ave

2.6 If blood pressure data was not collected, please specify reason:

Tester ID: ID:

Height and Weight

3.1 Height	. cm
3.2 Weight	. kg

If height or weight data was not collected, please specify reason:

Waist and Hip Measurements

	Measurement 1	Measurement 2	Measurement 3 (If Measurement 1 and Measurement 2 differ by more than 1cm)
4.1 Waist circumference	. cm	. cm	. cm
4.2 Hip circumference	. cm	. cm	. cm

4.3 If waist or hip circumference data was not collected, please specify reason:

Tester ID: | | | | | | | | ID: | | | | | | | | |

Photographs to Assess Changes in Skin Condition

5.1 **Please ask participant:**

"In order to assess dermatological conditions that develop on deployment, we would like to take photos of your back, palms of your hand, soles of your feet and a side view of your cheek, lower nose and lips. No identifying facial or body features will be photographed. Do you consent to these photos being taken?"

Record the participants reponse: ○ No, does not consent ○ Yes, consent given

5.2 **Record of photos taken:**

SKIN AREA PHOTOGRAPHED			IF PHOTOGRAPH NOT COLLECTED, SPECIFY REASON:
BACK	○ No	○ Yes	
PALMS OF RIGHT HAND	○ No	○ Yes	
PALMS OF LEFT HAND	○ No	○ Yes	
LEFT SIDE VIEW OF CHEEK, LOWER NOSE	○ No	○ Yes	
RIGHT SIDE VIEW OF CHEEK, LOWER NOSE	○ No	○ Yes	
SOLES OF FEET	○ No	○ Yes	

Please ensure that ALL circles have been shaded.

Draft

Tester ID: | | | | | | | | ID: | | | | | | | | |

Bloods

6.1 **3 x 8.5ml gold top (serum tube):** (please shade as completed)

	LAB REF. NO.	SAMPLE COLLECTED	IF SAMPLE NOT COLLECTED, SPECIFY REASON:
SAMPLE 1		-	○	
SAMPLE 2	☐ AS ABOVE	-	○	
SAMPLE 3	☐ AS ABOVE	-	○	

6.2 **1 x 5.0ml gold top (serum tube):** (please shade as completed)

	LAB REF. NO.	SAMPLE COLLECTED	IF SAMPLE NOT COLLECTED, SPECIFY REASON:
SAMPLE 1		-	○	

6.3 **2 x 4.0ml mauve top (EDTA):** (please shade as completed, samples NOT to be spun)

	LAB REF. NO.	SAMPLE COLLECTED	IF SAMPLE NOT COLLECTED, SPECIFY REASON:
SAMPLE 1		-	○	
SAMPLE 2	☐ AS ABOVE	-	○	

6.4 **1 x 2.0ml mauve top (EDTA):** (please shade as completed, samples NOT to be spun)

	LAB REF. NO.	SAMPLE COLLECTED	IF SAMPLE NOT COLLECTED, SPECIFY REASON:
SAMPLE 1		-	○	

6.5 [Ask participant] When did you last do any vigorous physical activity which made you breathe harder or puff and pant? (e.g. Strenuous Gym workout, a march with a full pack, other field exercise) | | times

Please ensure that ALL circles have been shaded.

11148

Tester ID: ID:

Spirometry

7.1 **Activities that should preferably be avoided prior to lung function testing**

Has the participant: (please tick all that apply)

- O Smoked within at least 1 hour of testing
- O Consumed alcohol within 4 hours of testing
- O Performed vigorous exercise within 30 minutes of testing
- O Worn clothing that substantially restricts full chest and abdominal expansion
- O Eaten a large meal within 2 hours of testing
- O None of these

7.2 **Conditions where suboptimal lung function results are likely to occur**

Is the participant exhibiting: (please tick all that apply)

- O Chest or abdominal pain of any cause
- O Oral or facial pain exacerbated by a mouthpiece
- O Stress incontinence
- O Dementia or a confusional state
- O Respiratory infections
- O None of these

7.3 **Spirometry recording**

		TEST PERFORMED			TEST PERFORMED
Test 1		O	Test 5	FEV$_1$ _____	O
Test 2		O	Test 6	FEV$_1$ _____	O
Test 3	FEV$_1$ _____	O	Test 7	FEV$_1$ _____	O
Test 4	FEV$_1$ _____	O	Test 8	FEV$_1$ _____	O

7.4 **Overall session quality** OA OB OC OD OF

7.5 **If spirometry data was not collected, please specify reason:**

Tester ID: | | | | | | | | ID: | | | | | | | | |

Queen's College Step Test

Fitness criteria for the Step Test

Prior to conducting the test, each person's suitability to undertake the Queens College Step Test should be assessed by referring to the following criteria (please shade any which apply):

8.1 Absolute Contraindications

- O Ischaemic Heart Disease
- O Unstable Angina
- O Aortic Stenosis
- O Uncontrolled Hypertension
- O Uncontrolled Asthma
- O Epilepsy
- O Respiratory Failure
- O No Contraindications

8.2 Relative Contraindications

- O Patient older than 50
- O Currently pregnant, or childbirth in the previous three months
- O Surgery in previous three months
- O Systolic blood pressure greater than 150
- O Diastolic blood pressure greater than 95
- O History of heart disease
- O Treating physician's advice not to exercise
- O Musculoskeletal problem likely to be aggravated by the exercise
- O Any other reason given by the participant for not doing the test
- O No Relative Contraindications

Precautions: Testing facilities must have appropriate resuscitation equipment and tests must be supervised by operators trained in CPR.

8.3 Is the participant fit to perform the brief fitness test? (candidates should be carefully screened for any contraindications)

- O Yes
- O No, please specify reason:

8.4 After participants have been stepping for 3 minutes, read the pulse monitor within 5 seconds of stopping and again 15 seconds later. Please record both readings.

			Pulse rate per minute within 5 seconds of stopping test
			Pulse rate per minute 15 seconds after the first reading

8.5 Did the participant stop before three minutes?

- O No
- O Yes

8.6 If YES:

a) Duration of test: | | minutes | | | seconds

b) Reason for stopping

- O Fatigue
- O Short of breath
- O Pain, specify site: | | | | | | | | | | | | | | | | | | | | | | | | |
- O Other, specify: | | | | | | | | | | | | | | | | | | | | | | | | |

Draft

ID:

Completeness Check

9.1 **This Physical Testing Form has been checked for completeness.**

PRINT NAME: _____

SIGN: _____

DATE: _____

APPENDIX C: TESTING STATION PROTOCOL DEVIATION LOG

Protocol Deviation Log

[DATE]

This log is to be completed by the CMVH on site project coordinator at the end of each day and emailed to the Physical Testing Research Fellow.

	Station	Session that protocol deviation occurred in	ID number of Person Reporting	Brief Description of Deviation	Steps Taken to Rectify
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					
11.					
12.					

APPENDIX D: TESTING STATION PROTOCOL DEVIATION SUMMARY

Testing Station Protocol Deviation Summary Sheet (please use a new sheet for each testing session)

This sheet is to be completed by Healthscope or CMVH staff if they identify a protocol deviation during testing. The protocol deviation should also be recorded in the Case Report Form.

Testing session time:_____ Testing date:_____

This testing station is _____

	ID of Testing Staff Member	Study ID of Participant Tested	If not, provide a short explanation describing the protocol deviation. (The protocol deviation must also be written in the Case Report Form)
1			
2			
3			
4			
5			
6			
7			
8			

HAND THIS SHEET TO THE HEALTHSCOPE PROJECT COORDINATOR AT THE END OF EACH TESTING SESSION

APPENDIX E: FAINTING PROTOCOL

sACC - FAINTING (SYNCOPE)

1. PURPOSE

This procedure is designed to instruct all collection centre staff in the steps to follow in the event of a patient fainting.

2. SCOPE

This procedure applies to all collection centre staff working in Accredited Collection Centres operated by Clinical Laboratories and/or its subsidiaries in South Australia, Broken Hill and the Northern Territory.

3. DEFINITIONS

Not Applicable

4. OH & S

Ensure the safe management of a patient, protected from injury.

5. ACTIONS

5.1 PROTOCOL

Fainting is due to a temporary disturbance of the nervous control of the blood vessels, allowing the arterioles to dilate so that blood is pooled in the tissues. Not enough blood returns to the heart and an inadequate supply of blood to the brain results.

Fainting in lay terms is used to describe a condition of sudden, brief loss of consciousness with the potential for full recovery. Fainting should not be confused with loss of consciousness from shock or any other cause.

Some conditions, which may cause fainting, include:

- The sight of needles, particularly prior to or after an injection.
- The sight of blood.
- Strong emotions like fear.
- Pain.
- Standing for prolonged periods in hot weather or a hot shower / bath.
- Lack of food / sleep.

5.2 RECOGNITION

Prior to loss of consciousness the victim usually feels light-headed, may feel nauseated, anxious and appears pale.

Other symptoms may include:

- Giddiness, unsteadiness and blurred vision.
- Cold and clammy skin.
- Yawning occurs.
- Shallow breathing.
- The pulse is weak and slow.
- Weakness and lethargy are followed by collapse with loss of consciousness

The diagnosis is confirmed by a rapid return of consciousness while lying flat.

Occasionally, fainting may be associated with local or generalised fitting.

Brain damage or death may occur if the victim is left supported in an upright position such as in a chair.

5.3 PREVENTION

Be aware that fainting may occur as a result of venepuncture or other specimen collection. Check if the patient has had any previous reactions or fainting episodes, or appears anxious. Always consider lying the person down in this instance.

It may be worth giving the patient a drink prior to the procedure, unless contraindicated for the test. This is particularly relevant to patients undergoing venesection

5.4 MANAGEMENT

1. Should patient begin to feel faint DO **NOT** try to finish collecting a sample. Ensure patient safety and protect from injury. (Samples may be collected once their condition is stabilised.)
2. Do not leave the patient and where possible call for assistance.
3. Lay the patient flat with legs raised and head lowered. **NOTE:** Never sit the victim on a chair with the head placed between the knees.
4. Ensure the airway is maintained.
5. Encourage deep breathing if conscious. Ensure a liberal supply of fresh air (the use of an electric or hand held fan might help).
6. Loosen clothing around the neck, chest and waist. Offer a cool wet face washer.
7. Reassure the patient.
8. Place all unconscious patients on their side- see below "Positioning an Unconscious Victim".
9. Monitor heart rate, blood pressure (if BP machine available) and level of consciousness every few minutes.
10. If Oxygen is available administer via a mask at 6-8 l per minute.
11. A Pregnant woman should be turned on to the left side if conscious or unconscious.
12. Assess the patient for any injuries resulting from the episode.
13. As the patient recovers, move them to a bed and encourage them to remain resting for 15 - 20 minutes. Offer them a cool drink.
14. Ensure the patient is fully recovered before allowing them to leave. If necessary arrange for a relative/friend to drive.
15. Discuss lying down for future tests.
16. Prolonged loss of consciousness indicates a condition more serious than simple fainting and should be treated by a physician. If the patient does not recover in a few minutes, re-check their pulse, respirations and blood pressure.

    AT WAYVILLE - Contact one of our doctors for assistance. Phone for an ambulance if required.

    AT OUTER CENTRES - Phone for an ambulance. (The requesting doctor should be notified of any complications)
17. Fainting constitutes a patient incident, and a "Report of Patient Clinical Problem" form must be completed and forwarded to the Patient Centre Manager. These are located in the Patient Centre Forms Register and are ordered via stores.

5.5 POSITIONING AN UNCONSCIOUS VICTIM

With an unconscious patient the care of the airway takes precedence over any injury including the possibility of spinal injury. All unconscious patients must be handled gently with no twisting or forward movement of the head or spine.

The unconscious person is turned on their side to:

- Obtain and maintain a clear airway.
- Provide ready access to the airway.
- Facilitate drainage and lessen the risk of inhaling foreign material.
- Avoid unnecessary bending and twisting of the neck.
- Permit continuing observation of the person.

Principles to be followed when positioning a person on their side:

- They should be as near a true lateral position as possible with the head in a low position to allow free drainage of fluid.
- The position should be stable.
- Any pressure in the chest that impairs breathing should be avoided.
- It should be possible to turn the victim onto their side and return to the back easily and safely, having particular regard to the possibility of cervical spine injury.
- Good observation of and access to the airway should be possible.
- The position itself should minimise further injury to the person.

5.6 FIT/SEIZURE ASSOCIATED WITH FAINTING

Occasionally some patients once they have fainted will have a fit/seizure. This often starts with the patient's eyes rolling back and can be accompanied by a groaning sound. The fit usually consists of a few body and/or limb jerks over 5-10 seconds. Patients who experience this will often take longer to recover and may fell unwell for the rest of the day.

5.6.1 Management

- Protect the patient from injury.
- Maintain the airway.
- Lie patient on their side.
- If available administer oxygen via a mask at 6-8 litres per minute.

6. FORMS

- Report of Patient Clinical Problem

7. REFERENCES

- First Aid Principles

APPENDIX F: QUALITY MANAGEMENT PLAN

Quality Management Plan for Physical Testing

Ensure Safety of Study Participants

Action	Responsible Party	Timeline
Adhere to the Healthscope Staff Agreement and Code of Conduct	All Healthscope Staff involved with the Study	At all times
Notify Defence Point of Contact if any participant experiences any Adverse Event (see definition below) while attending a physical testing appointment.	All Healthscope staff and CMVH coordinator	As soon as possible
Ensure immediate attendance by a medical doctor if any participant experiences any Serious Adverse Event (see definition below) while attending a physical testing appointment.	All Healthscope and CMVH Staff	As soon as possible
Notify the Chief Investigator and Study Manager of any Adverse or Serious Adverse Event	CMVH coordinator	Within two hours of the event occurring

Ensure that security and confidentiality requirements are adhered to

Action	Responsible Party	Timeline
Sign Confidentiality Agreement and Code of Conduct	All Healthscope Staff involved with the Study	Prior to commencing any study activity
Adhere to Healthscope Staff Agreement and Code of Conduct	All Healthscope Staff involved with the Study	At all times
Instruct Healthscope staff about the necessity for confidentiality and protocols pertaining to non identification of staff	CMVH Research Staff	At both initial and follow up training
Conduct themselves in a professional, discreet and ethical manner	All Healthscope Staff involved with the Study	At all times

Ensure safety of Healthscope Staff

Action	Responsible Party	Timeline
Adhere to OHS guidelines and principles and safe work practices as per the Gribbles Pathology Occupational Health and Safety Manual	All Healthscope Staff involved with the Study	At all times
Notify the CMVH on site research coordinator of any OH&S event	Healthscope Project Coordinator	Within 24 hours of the event occurring

Ensure All Required Data is Appropriately Collected for Each Participant

Action	Responsible Party	Timeline
Record each participant on the Participant Attendance Checklist	CMVH Coordinator/SOC Administration Officer	At start of each Physical Testing Session
Notify the Study Manager of any participant who does not attend the scheduled physical testing appointment	CMVH Coordinator/SOC Administration Officer	At end of each day of testing
Ensure that the required number of suitably trained and qualified staff are available at each testing station	Healthscope Project Coordinator	Prior to each scheduled testing session
Check the case report form for each participant to ensure all stations have been completed and recorded	Healthscope Project Coordinator	Prior to the participant leaving the physical testing facility
Check each item on the Case Report Form to ensure results are within allowable ranges	Healthscope Project Coordinator	Prior to the participant leaving the physical testing facility
Check that there is one fully completed Case Report Form for each participant recorded on the Participant Attendance Checklist and give to the CMVH Coordinator	Healthscope Project Coordinator	At the end of each physical testing session
Provide a written report by individual participant which includes: • Study ID • Date of physical testing • Number of blood tubes collected • Number of saliva tubes collected • Date samples sent to each laboratory • Laboratory unique sample identified	Healthscope SA BDM	Within one month of undertaking the physical test
Check the written report with DMAC records to ensure that all data has been received	Study Manager	Within one week of receiving report
Provide Healthscope BDM with a copy of protocol deviation log	Study Manager	At completion of physical testing series
Conduct an audit of 10 randomly selected Case Report Forms to ensure appropriate data is collected and has been entered into DMAC	Study Manager	Quarterly

Ensure that Samples are Stored and Shipped Appropriately

Action	Responsible Party	Timeline
Enter details of each sample to be shipped on the Sample Shipping Log	Healthscope Staff	At point of packing the sample
Ensure a Sample Checklist accompanies all the samples when packed in the eskies to enable the laboratory staff to check that all	Healthscope Staff	At point of packing the sample

samples sent have been received		
Send a copy of the Sample Shipping Log and Sample Checklist to the Study Manager	Healthscope SA BDM	Upon receipt of samples for referral
Check the samples against the Sample Checklist and report any missing samples to the Healthscope South Australian BDM	Receiving laboratory	Within 24 hours of receiving the samples
Check the samples to ensure suitable for testing and report any unsuitable samples to the Healthscope SA BDM	Receiving laboratory	Within 24 hours of receiving the samples
Report any missing samples in writing to the Study Manager	Healthscope South Australian BDM	Within 24 hours of receiving the laboratory notification
Conduct an audit of 10 randomly selected Case Report Forms to ensure associated samples have been labeled and stored correctly	Study Manager	Half yearly

Ensure consistency of all data collection

Action	Responsible Party	Timeline
Develop a detailed protocol for all aspects of the physical testing	Study Manager	Prior to commencing physical testing training
Provide initial and follow up training to all Healthscope staff on the protocol	Study Manager	Prior to commencing any physical testing
Ensure only Healthscope staff who have undertaken the Physical Testing Protocol training are permitted to undertake any physical testing procedure	Healthscope SA BDM	Prior to commencing any physical testing
Follow the Physical Testing Protocol for all physical testing	All Healthscope Staff	At all times
Ensure that laboratories selected to conduct pathology tests are appropriately staffed and resourced	Healthscope SA BDM	Prior to sending samples to the laboratories
Ensure that an individual's pre and post pathology tests are carried out by the same laboratory	Healthscope SA BDM	At all times

Ensure that all Protocol Deviations (see definition below) are recorded and followed up appropriately

Action	Responsible Party	Timeline
Record any errors or omissions to the protocol on the Case Report Forms	Any Healthscope or CMVH Staff member who identifies a protocol deviation	As soon as the deviation is identified
Record any errors or omissions to the protocol on the Testing Station Protocol Deviation Summary at each testing station	Any Healthscope or CMVH Staff member who identifies a protocol deviation	As soon as the deviation is identified
Collect the Testing Station Protocol Deviation list from each testing station and check to ensure that each protocol deviation is recorded	Healthscope Project Coordinator	At the end of each physical testing session

on a Case Report Form. Give Testing Station Protocol Deviation Summary to CMVH Coordinator		
Notify the Study Manager of any protocol deviations	CMVH Coordinator	At end of each physical testing day
Provide the Testing Station Protocol Deviation Summary Sheets to the Study Manager	CMVH coordinator	At completion of Physical Testing series
Take any action required to reduce the likelihood of any further Protocol Deviations	Study Manager	At all times

Appendix A - Definitions

Definition of Adverse and Serious Adverse Events

Grade 1 – Mild, self limited lasting less than 48 hours, no intervention required

Grade 2 – Moderate, some limitation in activity, some assistance possibly required no or minimal medical intervention required

Grade 3 – Severe, marked limitation in activity, some assistance usually required, medical intervention required, hospitalisation possible

Grade 4 – Life threatening, extreme limitation in activity, significant assistance required, hospitalisation probable

Grade 5 – Event results in death

1. ***Adverse Events***
   Adverse which can be categorised between Grades 1 to 3

2. ***Serious Adverse Events***
   Adverse which can be categorised between Grades 4 to 5 and/or involves any:
   - untoward medical occurrence that results in death
   - is life threatening
   - requires in patient hospitalisation or prolongation of existing hospitalisation
   - results in persistent or significant disability or incapacity
   - requires intervention to prevent permanent impairment or damage

Definition of a Protocol Deviation

A protocol deviation is defined as any action or inaction which digresses from the Physical Testing Protocol and which compromises the integrity of any physical testing data. This includes but is not limited to:

- One or more of the physical tests not being completed by the participant
- One or more physical tests not being completed in accordance with the method prescribed by the Physical Testing Protocol
- Data not being recorded on the Case Report Form
- Incorrect data being recorded on the Case Report Form
- Any information missing from the Case Report Form
- Any missing Case Report Forms

APPENDIX G: TELEFORM SCANNING INSTRUCTIONS

PRINTING QUESTIONNAIRES FOR MAIL OUT

1. Open Teleform Auto Merge Publisher using the shortcut on the desktop or the following link: Start Menu>Programs>Cardiff Teleform>Teleform Auto Merge Publisher

2. Once it opens, go to File>Schedule Print.

3. You are in the form tab. Click in the box next to the word Form. It will bring up a box to open the questionnaire. Pick the questionnaire you want and press ok.

4. Change the number of copies you want.

5. **IMPORTANT** Click the Auto Increment Fill tab. Tick the box that says “Enable automatic fill”. Fill the ID field from the prepared database.

PRINTING A SINGLE QUESTIONNAIRE

1. Open Teleform Auto Merge Publisher using the shortcut on the desktop or the following link: Start Menu>Programs>Cardiff Teleform>Teleform Auto Merge Publisher

2. Once it opens, go to File>Schedule Print.

3. You are in the form tab. Click in the box next to the word Form. It will bring up a box to open the questionnaire. Pick the questionnaire you want and press ok.

4. **IMPORTANT** Click the Auto Increment Fill tab. Tick the box that says “Enable automatic fill”. Fill the ID field.

SCANNING A COMPLETED QUESTIONNAIRE

1. Open Teleform Scan Station, Teleform Reader and Teleform Scan Station in Start Menu>Programs>Cardiff Teleform

2. Put booklet/interview in the photocopier feeder (face up). On the photocopier, go to the “scan” tab, and press online.

3. On the computer, go to Scan Station. Press the “new batch” button at the top left. If you want to scan double sided make sure that the process tab>feeder says “front & back”. Press start. This will scan the document.

4. A window followed by another window will pop up. Press OK at the first window then Cancel at the second window. Press Accept.

5. Remove booklet and press offline on the photocopier.

6. Go to teleform reader. The text moving at the bottom of the screen is reading the data. That is all this window does. When the text stays still and says “Idle”, it has finished reading.

7. Go to teleform verifier. Press the refresh button on the right. The batch that you just scanned will be added to the bottom of the list. If there are things you need to verify it will tell you. Click on your batch and press the “process button”. TAB through the fields that need to be verified, changing them as necessary. Save the changes when prompted.

8. Press refresh again. Your batch should now say ready to be committed. If not, go through process again. When ready to commit the data, make sure your destination file is NOT open. Right click on your batch and press commit. Your data will be committed to a CSV file.

APPENDIX H: HEALTHSCOPE TESTING LABORAGORIES

Test	Laboratory Name
MBA20	Healthscope - Wayville SA
CBE +ESR	Healthscope - Wayville SA
Epstein Barr Virus	Healthscope - Wayville SA
Cytomegalovirus	Healthscope - Wayville SA
Hep C	Healthscope - Wayville SA
Chlamydia	Healthscope - Wayville SA
Helicobacter	Healthscope - Wayville SA
B12	Healthscope - Wayville SA
Red Cell Folate	Healthscope - Wayville SA
Glycated Haemoglobin	Healthscope - Wayville SA
Leishmaniasis	Healthscope - Wayville SA
Lead	Healthscope - Clayton VIC
Herpes	Healthscope - Clayton VIC
Mycoplasma	Healthscope - Clayton VIC
Cortisol	Healthscope - Functional Pathology - Clayton VIC
Outsourced Tests	
Red Cell Cholinesterase	IMVS
Interleukin 1	WCH
Interleukin 4	WCH
Interleukin 6	WCH
TNF-alpha	WCH
Adrenaline/Nor Adrenaline	CPR

APPENDIX I: REVIEW OF MEAO PROSPECTIVE STUDY PATHOLOGY RESULTS

Standard Operating Procedure:
Review of MEAO Prospective Study pathology results

	What	Who	When
	Notifying of Potential Pathologies		
1.	Advise Dr Horsley by email of the dates that physical testing session are scheduled, the anticipated number of participants and the expected date of availability of pathology test.	Project Officer	As soon as advised by Defence
2.	Send two copies of the hardcopy pathology results to Project Officer.	All laboratories	As soon as available
3.	Collate one copy of each hardcopy pathology result by Study ID	Project Officer	As soon as received
4.	Send a collated hardcopy pathology results to Dr Horsley.	Project Officer	Within 2 working days of receiving
5.	Temporarily file one hardcopy laboratory results on participant files.	Project Officer	As soon as received
6.	Review hardcopy pathology results for each individual and if the result is indicative of a clinically relevant health risk or health disorder write a letter to the unidentified participant advising them of the results and further follow up.	Dr Horsley	Within 1 week of receiving
7.	Sign and date each copy of the pathology form indicating it has been reviewed. Note at the bottom of the page whether a result has been followed up either by telephone or letter.	Dr Horsley	Within 1 week of receiving
8.	Send all marked hardcopies plus letters to any participants to the Project Officer	Dr Horsley	Within 1 week of receiving
9.	Identify whether the participant is still in Australia or alternatively is on deployment	Project Officer	Within 2 working days of receiving
10.	Send letters from Dr Horsley to participants either at their Australian base address or deployment address	Project Officer	Within 1 working day of receiving
11.	Follow up any outstanding results not received from Dr Horsley.	Project Officer	Within 1 working day of receiving
12.	Shred the temporary hardcopy results that correspond with those returned from Dr Horsley	Project Officer	Within 1 working day of receiving
13.	File Dr Horsley's copy of results in participant's file	Project Officer	Within 1 working day of receiving
14.	Enter date and type of letter sent onto the MIS	Project Officer	Within 1 working day of receiving
	Positive Hepatitis C or active Epstien Barr Virus		
1.	Alert the Healthscope Business Manager if a positive result for Hepatitis C or active Epstein Barr Virus is detected	Laboratory staff	As soon as results are acquired
2.	Alert the Study Manager and Principal Investigator by email if there is a positive result for Hepatitis C or active Epstein Barr Virus (indicated by presence of IgM	Healthscope Business Manager	As soon as possible

	antibodies)		
3.	Alert Dr Horsley by telephone, providing contact information for participant with a positive result for Hepatitis C or active Epstein Barr Virus	Study Manager	As soon as possible
4.	Contact the individual by telephone to provide advice to the participant on the finding.	Dr Horsley	As soon as possible
5.	Send Project Officer details pertaining to positive results and action taken in writing	Study Manager	As soon as possible
6.	File the written information in the participant's file	Project Officer	Within 5 working days
	High Laboratory Alerts		
1.	Alert the Study Manager and the Principal Investigator by phone if a result for other laboratory tests is within the Healthscope high alert range.	Healthscope laboratory	As soon as results are acquired
2.	Identify whether the participant is on deployment	Study Manager	As soon as results are acqui
3.	Advise Dr Horsley by telephone and identify if the participant needs to be contacted immediately	Study Manager	As soon as possible
4.	If immediate contact is required, identify if on deployment	Study Manager	As soon as possible
5.	Provide either the Australian phone number or a contact number for the deploying unit to Dr Horsley	Study Manager	As soon as possible
6.	If in Australia, contact the individual by telephone if required	Dr Horsley	Immediately if required
7.	If on deployment, telephone the deploying unit contact and ask them to request the participant to return the phone call, if required. No information about the nature of the call should be provided to anyone other the participant	Dr Horsley	Immediately if required
8.	If no immediate action is required revert to item 6 of Notifying of Pathology Results (as above)	Dr Horsley	Within 2 working days

Agreed contact information:

Dr Keith Horsley
3 Valder Place
Fairer 2607
ACT 2607
Telephone: 0411264666
Email: keith.horsley@hotmail.com
CC Email: keith.horsley@meagroup.com.au

Dr Carol Davy
Study Manager
Level 2, 122 Frome Street
Adelaide SA, 5000
Telephone: 08 83130676 and 0424751592 (please leave message on both if not available)
Email: carol.davy@adelaide.edu.au

Professor Alexander McFarlane
First Chief Investigator
Level 2, 122 Frome Street
Adelaide SA 5000
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Ms Kate Kolet
Healthscope Business Manager
1 Goodwood Rd, Wayville SA 5034
Telephone: 0419146543
Email: Kate.Kolet@healthscope.com.au

Ms Emma Laurence
Project Officer
CMVH
2/122 Frome Street
Adelaide SA 5000
Telephone: 08 83036973
Email: emma.laurence@adelaide.edu.au

APPENDIX J: ABNORMAL BLOOD RESULTS LETTER TEMPLATE

Dear

Re: Participant ID Number

This letter is about your pathology tests that you had performed as part of the MILHOP research into the health of Defence Force members who are being deployed to the Middle East Area of Operations.

The pathology tests have shown the following result:

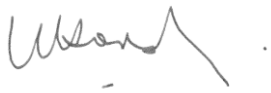
-

While the condition is not life-threatening at the moment, it does need to be fully investigated and treated. *(Further information is inserted depending on test).* We suggest that you consult your doctor at your convenience.

For your information, I have enclosed a copy of your results.

I would like to thank you for your participation in the study.

Yours sincerely



Dr Keith Horsley
Chief Investigator (Medical)
Centre for Military and Veteran Health
University of Adelaide

Specific to Helicobacter Pylori

Dear

Re: Participant ID Number

This letter is about your pathology tests that you had performed as part of the MILHOP research into the health of Defence Force members who are being deployed to the Middle East Area of Operations.

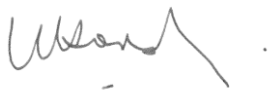
The pathology results have shown that you are serologically positive for an infection with a bacterium called *Helicobacter pylori*.

This means that you may currently be infected with *Helicobacter pylori*, or you may have been infected in the past. While the condition is not life-threatening, it does need to be fully investigated and treated. Studies have shown that, in the long-term, infection with *Helicobacter pylori* is associated with a number of diseases, such as peptic ulcer, and more rarely, gastric cancer. Infection with *Helicobacter pylori* can usually be treated by oral medication. For this reason we suggest that you should consult your doctor.

For your convenience, I have enclosed a copy of your results.

I would like to thank you for your participation in the study.

Yours sincerely



Dr Keith Horsley
Chief Investigator (Medical)
Centre for Military and Veteran Health
University of Adelaide

APPENDIX K: NORMAL BLOOD RESULTS LETTER TEMPLATE

<< Date>>

<< Name>>
<<Address line 1>>
<<Address line 2>>
<<Address line 3>>
<<Address line 4>>

Dear <<Rank>> <<Name>>

We are writing in regard to your recent participation in the physical testing component of the Middle East Area of Operations (MEAO) Prospective Study. As part of the this component a blood sample was taken in order to run a series of tests as described in the information sheet provided to you prior to participation (see attached).

These blood tests have now been completed and we are pleased to inform you that no significant abnormal results were reported. Should you require any further information regarding these tests or any other component of the MEAO Prospective Study, please do not hesitate to contact us on free call 1800 232 904 or email cmvh@adelaide.edu.au

We would like to take this opportunity to once again thank you for your valuable contribution to developing the future health services of the Australian Defence Forces. In addition, we look forward to meeting with you once again approximately three months after you return from your deployment in order to complete the study.

Yours sincerely

Professor Annette Dobson
Chief Investigator
MEAO Prospective Study
Centre for Military and Veterans' Health
University of Queensland

APPENDIX L: SOP REVIEW OF SKIN PHOTOGRAPHY

Standard Operating Procedure: Review of Skin Photography

	What	Who	When
	Reviewing Skin Photography and Providing Result Data		
1.	Notify Dr Jennifer Menz of anticipated post deployment physical testing schedules	Research Officer	As soon as Post deployment dates are identified
2.	Copy all pre and post deployment skin photographs for each participant to a separate file on a password protected CD	Research Officer	Within 5 working days uploading of post deployment photos
3.	Courier the password protected CD containing one file per participant of pre and post skin photography to Dr Menz	Research Officer	Within 5 working days of uploading post deployment photos
4.	Email the password to Dr Menz with date of despatch.	Research Officer	As soon as CD couriered
5.	Review pre and post skin photography and complete a Skin Photography Case Report Form for each participant (see attached)	Dr Menz	Within 10 working days of receiving CD
6.	Shred the CD.	Dr Menz	Once review completed
7.	Send completed Case Report Forms to Dr Davy at CMVH.	Dr Menz	Once review completed
8.	Review Skin Photography Case Report Forms for completeness and request any required additional information from Dr Menz	Research Officer	Within 2 working days of receiving
9.	Teleform Skin Photography Case Report Forms and send file to DMAC.	Data Manager	Within 2 working days of receiving
10.	File hardcopy of Skin Photography Case Report Form in the participant's restricted hardcopy file.	Research Officer	Within 5 working days of receiving
	Notification of Abnormal Skin Conditions which require Urgent Medical Attention		
1.	Identify any skin condition which requires urgent medical attention from photos*.	Dr Menz	Within 10 working days of receiving CD
2.	Complete the standard skin condition letter (see attached) with study ID, relevant clinical information and	Dr Menz	Within 10 working days of

	electronic signature		receiving CD
3.	Email the letter to the Research Officer.	Dr Menz	Within 10 working days of receiving CD
4.	Send letters from Dr Menz to participants either at their Australian base address	Research Officer	Within 2 working days of receiving notification
5.	File copy of letter in the participant's restricted file	Research Officer	Within 2 working days of receiving notification
6.	Enter date and type of letter sent onto the MIS	Research Officer	Within 2 working days of receiving notification

*The participant is notified of any abnormal skin conditions which are deemed to require urgent medical attention, as it is assumed that the participant will not have previously consulted a medical partitioner.

Agreed contact information:

Dr Jennifer Menz
Head of Dermatology,
Repatriation General Hospital,
Daw Park, South Australia 5041
Telephone: 08 8402017131
Email: jennifer.menz@gmail.com

Professor Annette Dobson
First Chief Investigator
University of Queensland
Telephone: 0417 214501
Email: a.dobson@uq.edu.au

Dr Carol Davy
Study Manager
Level 2, 122 Frome Street
Adelaide SA 5000
Telephone: 08 83130676 and 0424751192 (please leave message on both if not available)
Email: carol.davy@adelaide.edu.au

Ms Maria Abraham
Research Officer
CMVH
2/122 Frome Street
Adelaide SA 5000
Telephone: 08 83036965
Email: maria.abraham@adelaide.edu.au

Appendix E

Neurocognitive Assessment Protocol

CMVH
CENTRE FOR MILITARY & VETERANS' HEALTH

MIDDLE EAST AREA OF OPERATIONS (MEAO) PROSPECTIVE STUDY:

NEUROCOGNITIVE ASSESSMENT PROTOCOL

Author: Derek Browne and Carol Davy

Document Version: Version 10

Date Saved: 15/06/2011

Australian Government
Department of Defence
Department of Veterans' Affairs

THE UNIVERSITY OF QUEENSLAND
AUSTRALIA

Charles Darwin
UNIVERSITY
Innovation in Education

THE UNIVERSITY OF ADELAIDE
AUSTRALIA

CONTENTS

Document Administration

Document Location

The Master copy of this document is held at the following location:
S:\HealthSciences\SPHCP\CMVH\Projects\MILHOP PROGRAM\MEAO PROSPECTIVE STUDY\OPERATIONAL\PROCEDURE MANUAL\Neurocognitive Protocol

Revision History

Date	Version	Description	Track Changes
15/02/2011	1.0 to 9.00	Internal Development of Protocol	No
16/6/2011	10	Alter post deployment section to reflect agreed procedures and clarify consent section to address the needs of potential participants who do not wish to participate in the neurocognitive assessment	No

Approvals

This document requires the following approvals:

Name	Position	Signature	Date	Version
Prof Annette Dobson	Principal Investigator			
Prof Michael Moore	Scientific Advisory Committee			
BRIG Stephen Rudzki	Program Management Board			

1. BACKGROUND

Psychiatric disorders are increasingly being understood in relationship to the associated abnormalities of information processing and psychophysiological arousal. To date the impact of these impairments in Defence personnel has not been investigated. It is important to understand this dimension to ensure the safety and performance of those deployed in combat zones. Of particular interest are major depressive disorder and post-traumatic stress disorder (PTSD) being the most common post-war psychological disorders in Australian Gulf War veterans [1, 2]. Studies have also suggested that PTSD and major depression are more prevalent in veterans who had been deployed to Iraq and Afghanistan, in comparison to those who were not deployed [3-7].

The level of combat exposure of Australian Defence Force (ADF) personnel deployed to the Middle East Area of Operations (MEAO) means that there is a significant risk of these disorders. A further risk factor complicating the current combat environment is mild traumatic brain injury (MTBI) which is often associated with and can exacerbate psychiatric disorders [8]. Investigating the impact of MTBI in ADF members is important because of the attention and debate this has provoked, particularly in US veterans. Furthermore, in both MTBI and PTSD similar information processing disorders are acquired [9] and it is important to characterise their inter-relationship. It should not be forgotten that this relationship is not a new question; with PTSD being labelled as “shell shock” in World War I. Therefore, the ADF needs to monitor and investigate the relationships between these factors, which can impact on memory and concentration in deployed personnel and are critical to capability and performance.

2. OBJECTIVES

The MEAO Health Study is part of the Deployment Health Surveillance Program (DHSP). The DHSP aims to establish and maintain an integrated data system for monitoring the physical and mental health of deployed ADF personnel.

The MEAO Prospective Study is part of the MEAO Health Study. The MEAO Prospective Study has the following specific objectives:

- to investigate changes in health outcomes between pre- and post-deployment in ADF personnel scheduled to deploy to the MEAO in 2010/11,
- to investigate links between specific chemical, physical, biological and psychological exposures potentially encountered during the MEAO deployment and physical and psychological health outcomes,
- to understand the interrelationships between short-term and long-term physical and psychological health effects associated with deployment,
- to increase the utility of electronic ADF health records for monitoring of the physical and psychological health of serving members,
- to identify protective (resilience) factors for psychological health outcomes,
- to determine the trajectory and pattern of psychological morbidity and its somatic manifestations and antecedents,
- to understand the impact of deployment on information processing and decision making,
- to investigate the potential emergence of any post-deployment syndrome(s),
- to identify patterns of health care utilisation by personnel deployed to the MEAO,
- to investigate relationships between deployment, exposures and non-specific symptoms and specific health problems; and
- to identify health indicators that are predictive of disability and where early intervention or program change may minimise disability in ADF members and veterans.

Neurocognitive Assessments, one component of the MEAO Prospective Study, aim to utilise a psychophysiology assessment battery to investigate the relationships between factors which can impact on memory and concentration in deployed personnel and are critical to capability and performance.

Assessments will be conducted approximately three months pre-deployment and then again no longer than four months post-deployment. These two assessments will be compared to objectively measure clinically relevant change. This information will then be linked to the broader aims of the MEAO Prospective Study.

Assessments will involve the direct measurement of brain function in response to particular tasks. Five domains are being measured using these assessments to optimally cover as broad a range of activity as possible in a one-hour measurement period.

1. Quantitative EEG allows the measurement of cortical arousal in the resting state, which reflects the priming of the individual to deal with environmental challenge.
2. The Continuous Performance Task taps into a domain of function that is known to be abnormal in MTBI and psychiatric disorders and allows the measurement of reaction times.
3. The startle response task involves a measure of arousal modulation and orientation to the environment that is known to change in PTSD. It is also a symptomatic marker whose objective measurement may have the capacity to be used as a screen of psychological symptoms independent of self report.
4. The emotion processing task; important significant differences have been found in the processing of facial emotion in individuals with posttraumatic stress disorder. As well, the processing of unconscious facial expression provides particular information about the fear networks in the brain.
5. The Go/No Go Task is a measure of the capacity of the individual to suppress a natural tendency to respond. This captures frontal inhibition of response by using both speed and accuracy of responses as well as the ability to inhibit inappropriate automotive responses.

3. NEUROCOGNITIVE ASSESSMENT TEAM

The Neurocognitive Assessment Team consists of three CMVH UA staff members who have received in depth training to set up the equipment for and undertake Neurocognitive Assessments. The Neurocognitive Assessment Team will also consist of one assistant cleared to an appropriate security level who will be responsible for checking names against study IDs of participating ADF members, as well as assisting with the assessment procedures. For the purposes of Special Forces (SF) this assistant will be the SOC Administration Officer.

The CMVH Defence Liaison Officers, in conjunction with the Study Manager will be responsible for establishing points of contact, ensuring that the Neurocognitive Assessment Team has access to participating personnel and ensuring that appropriate facilities are available for both pre and post neurocognitive assessments.

The SOC Administration Officer will liaise with the Commanding Officer or nominated Point of Contact (POC) to organize scheduling of all SF personnel appointments.

4. NEUROCOGNITIVE ASSESSMENT PARTICIPANTS

4.1 Eligible Participants

Participants will be purposefully sampled.

4.1.1 Inclusion Criteria

In order to be eligible to participate in the Prospective Study Neurocognitive Assessment, individuals must:

- be eligible to participate in the Prospective Study questionnaire
- have completed a pre deployment questionnaire and
- be assigned to either:
  - Special Operations Task Group (SOTG)
  - Mentoring Task Force (MTF)
  - A ship which is to be selected by Defence.

4.1.2 Exclusion Criteria

There are no specific exclusion criteria applicable to the Prospective Study Neurocognitive Assessment.

5. NEUROCOGNITIVE ASSESSMENT PARTICIPANTS

Pre -deployment

5.1 Arranging Assessment Dates and Suitable Facilities

As soon as a deploying unit has been identified (minimum 4 months prior to deployment) a CMVH Defence Liaison Officer, in conjunction with the Study Manager will contact the Commanding Officer or nominated Point of Contact (POC) to arrange a suitable Neurocognitive Assessment time schedule, taking into consideration the training and exercises that are required in the pre-deployment phase. In addition, they will assist in organising appropriate facilities required for the Neurocognitive Assessment (see Appendix A for facility specification).

The CMVH Defence Liaison Officer will notify the Neurocognitive Assessment Team of the agreed schedule and make arrangements for access to the various Defence Force establishments for the Neurocognitive Assessment Team.

5.2 Information Provided to Eligible Participants

Approximately three months prior to deployment an information pack will be sent to all ADF members who are eligible to participate in the Neurocognitive Assessment (see section 4 above). The invitation package (refer MEAO Prospective Study Questionnaire Protocol for further information) will include the following documents:

- Letter of invitation from the CI
- Letter of support from the CDF and Repatriation Commissioner
- Information sheet
- Supplementary information sheet
- Consent form
- Contact details form

The Commanding Officer of the deploying Special Forces Unit will distribute information to SF personnel.

5.3 Contacting Eiegible Participants for Neurocognitive Assessment

SF Personnel: The SOC administration Officer will provide a testing schedule containing prefilled BRC ID‟s to the CO of the SF unit or POC, who will be responsible for recruiting participants from that unit and allocating them an appointment time on the testing schedule with an accompanying BRC ID number. In addition, the SOC Administration Officer will liaise with the CO and provide further information about the assessments being conducted, including preparation instructions and confirm the date, time and location of assessment. The SOC Administration Officer will also enter the participants‟

scheduled appointment times into a stand alone SF Management Information System (SF MIS) and the DMAC Management Information System (MIS) by study ID only.

The SOC Administration Officer will advise the other members of the Neurocognitive Assessment Team of all schedule appointments made for conducting the Neurocognitive Assessments.

All Other Personnel: A Participant Liaison Officer based at CMVH UA who has been cleared to the appropriate security level will contact the POC and provide a time schedule containing prefilled BRC ID"s. The POC will then identify a time which is most convenient to the eligible participants and is within the agreed schedule for Neurocognitive Assessments (see section 5.1). In addition, the Participant Liaison Officer will liaise with the POC to provide further information over the phone about the assessments being conducted, including preparation instructions and confirm the date, time and location of assessment. The Participant Liaison Officer will also enter the participants" scheduled appointment times into the DMAC Management Information System (MIS).

The Participant Liaison Officer will advise the other members of the Neurocognitive Assessment Team of all schedule appointments made for conducting the Neurocognitive Assessments.

5.4 Setup Procedure

Prior to the assessments, the CMVH Defence Liaison Officer will:

- Confirm that facilities are suitable and appropriate for data collection. (See Appendix A)
- Ensure that all equipment will be on-site by the required time. (See Appendix B for equipment list)

SF Personnel: The CO will provide the SOC Administration Officer with the testing schedule containing the participant"s PMKeys & BRC ID.

All Other Personnel: The POC will provide the Participant Liaison Officer with the testing schedule, including Name, PMKeys and BRC ID.

For each assessment, the Neurocognitive Assessment Team will travel to the Defence facility and organise transport of the portable equipment and IT systems required to undertake the assessments.

The Neurocognitive Assessment Team will be met by a CMVH Defence Liaison Officer at the Defence establishment who will facilitate gaining access to the building.

The two assessment stations will be set up by the Neurocognitive Assessment Team at the pre-identified facilities (see section 5.1). Both of the assessment stations will be operated simultaneously by three accredited research staff. (See Appendix C for Operating Procedure)

5.5 Assessment Procedure

SF Personnel: The SOC Administration Officer will greet each participant and check them against the Neurocognitive Participant List. This SOC Administration Officer will have sole responsibility and access to the key linking both ID numbers with participant names.

All Other Personnel: The assistant will greet each participant and check them against the Neurocognitive Participant List. This assistant will have sole responsibility and access to the key linking both ID numbers with participant names.

5.5.1 Neurocognitive Assessment Stations

The detailed assessment procedure is attached in Appendix B.

6. NEUROCOGNITIVE ASSESSMENT PARTICIPANTS

Post-deployment

6.1 Arranging Assessment Dates and Suitable Facilities

As soon as practicable after a unit returns from deployment a CMVH Defence Liaison Officer or designated person will contact the Commanding Officer or nominated POC to arrange a suitable Neurocognitive Assessment time schedule and facilities for research staff to visit the base and conduct the investigations, taking into consideration the post-deployment assessments and other required activities.

The CMVH Defence Liaison Officer or designated person will notify the Neurocognitive Assessment Team of the Neurocognitive Assessment time schedule and make arrangements for access to the various Defence Force establishments for the Neurocognitive Assessment Team.

6.3 Contacting Consenting Participants

SF Personnel: The SOC Administration Officer will provide a testing schedule containing prefilled BRC ID‟s and a list of SF Personnel who completed the pre deployment neurocognitive assessments to the CO of the SF unit or designated POC, who will be responsible for allocating these participants an appointment time on the testing schedule with an accompanying BRC ID number. In addition, the SOC Administration Officer will liaise with the CO and provide further information about the assessments being conducted, including preparation instructions and confirm the date, time and location of assessment. The SOC Administration Officer will also enter the participants‟ scheduled appointment times into a stand alone SF Management Information System (SF MIS) and the DMAC Management Information System (MIS) by study ID only.

The SOC Administration Officer will advise the other members of the Neurocognitive Assessment Team of all schedule appointments made for conducting the Neurocognitive Assessments.

All Other Personnel: A SOC Administration Officer or their delegate who has been cleared to the appropriate security level will contact the POC and provide a time schedule containing prefilled BRC ID‟s and a list of participants from that unit who have completed the pre deployment neurocognitive assessment. The POC will then identify a time which is most convenient to these participants and is within the agreed schedule for Neurocognitive Assessments (see section 5.1). In addition, the Participant Liaison Officer will liaise with the POC to provide further information over the phone about the assessments being conducted, including preparation instructions and confirm the date, time and location of assessment.

The SOC Administration Officer or their delegate will advise the other members of the Neurocognitive Assessment Team of all schedule appointments made for conducting the Neurocognitive Assessments.

6.4 Setup Procedure

Prior to the assessments the CMVH Defence Liaison Officer will:

- Confirm that facilities are suitable and appropriate for data collection;
- Ensure that all equipment will be on-site by the required time; and
- Confirm individual participant booking schedules.

For each assessment, the Neurocognitive Assessment Team will travel to the Defence facility and organise transport of the portable equipment and IT systems required to undertake the assessments.

The Neurocognitive Assessment Team will be met by a CMVH Defence Liaison Officer at the Defence establishment who will facilitate gaining access to the building.

The two assessment stations will be set up at the pre-identified facilities (see section 5.1). Both of the assessment stations will be operated simultaneously by two accredited research staff and an Administration Officer.

6.5 Assessment Procedure

SF Personnel: The SOC Administration Officer will greet each participant and re allocate the same BRC ID used in the pre deployment assessment with a „2‟ added at the end to indicate the second assessment. This SOC Administration Officer will have sole responsibility and access to the key linking ID numbers with participant names.

All Other Personnel: The assistant will greet each participant and re allocate the same BRC ID used in the pre deployment assessment. This assistant will have sole responsibility and access to the key linking ID numbers with participant names.

7. DATA MANAGEMENT

Data for each of the Neurocognitive Assessments will be saved on the operator computer. By the end of each day, this data will be backed-up to an external hard drive and uploaded to the BRC. A confirmation email from BRC will be automatically sent to the Neurocognitive Team Leader (TL) following each upload. Following the final upload, the Neurocognitive Team Leader will email the BRC support team (support@brainresource.com) with a summary detailing the number of completed assessments and notify them to commence analysis.

At the end of the assessment period, the BRC Lab will be packed up and transported back to the CMVH office at the University of Adelaide. The external hard drive containing the full set of Neurocognitive Assessments will be carried by the Neurocognitive Team back to the CMVH office at the University of Adelaide. The Neurocognitive Team Leader will be responsible for monitoring the safe return of all equipment.

Neurocognitive results are cleaned and scored by BRC (see Data Cleaning Plan). The results are made available 5-6 weeks after testing has taken place. When data is ready, it is placed on the BRC server for a period of two weeks in either CSV or SPSS format. BRC will notify DMAC that a zipped data file is ready to be collected and will provide details of how to access the data file via a web link.
BRC will provide DMAC with a password to download and open the file. DMAC is required to notify BRC once the data file has been downloaded successfully. The data file will be imported into the MilHOP database using the standard import tool.

8. ETHICAL CONSIDERATIONS

8.1 Voluntary Participation Free from Coercion

Potential participants will be sent a study pack containing an information sheet, consent form, and a letter of support signed by the Chief of the Defence Force, a senior Minister and the Principal Investigator, amongst other things. The study pack will emphasize the voluntary nature of the study, will reassure participants that Defence will not be informed of their participation or lack of participation, and that their future health care, status within Defence, entitlements with DVA or compensation will not be affected by whether or not they choose to participate. Individuals will be free to withdraw from the study at any point, however a cooling off period of at least 24 hours between study information sessions (briefings) and recruitment will also be available to participants.

Individuals wishing to participate in the study will be required to return a signed consent form to the CMVH. Information will be handled and logged in the MIS database by a member of the research team with appropriate security clearance.

If at any time, during the neurocgnitive assessment a potential participant indicates that they have not consented to participate in the study, the neurocognitive team member must ask them if they wish to now consent to undertaking neurocognitive assessment. If the participant has any concerns about participating, the Neurocognitive Tteam Member will attempt to address these concerns and if the participant is then willing to continue with the Neurocognitive Assessment, the Neurocognitive Assessment Team Member must then ask them to complete a new consent form. This consent form should be sealed in an envelope and given to the Participant Liaison Officer.

If after attempting to address any concerns, a participant still does not want to participate, the Neurocognitive Assessment must cease immediately and the participant must be free to leave at any time.

8.2 Data Security and Confidentiality

Data on study participants will be de-identified. All neurocognitive data will be identified by way of a BRC ID. The keys linking these BRCIDs to the Prospective Study IDs and individuals‟ identifying information will be kept by the appropriately secured Administration Officer.

The Neurocognitive Assessment data will not contain any identifiable information.

9. QUALITY MANAGEMENT

9.1 Data Quality

BRC technicians will review a randomly selected assessment from each acquirer each day to ensure that it is received in the appropriate format and that it is viable for the scoring process. If any problems are found the BRC technician will contact the Neurocognitive Team Leader within 24 hours of receiving the upload.

9.2 Quality of Processes

Assessment processes will only be undertaken by appropriately trained BRC accredited Neurocognitive Assessment personnel. This training includes a series of workshops and in addition, requires the individual to provide collected data for assessment by BRC.

See Appendix D for detailed Quality Management Plan.

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APPENDIX A: ONSITE BRC LABORATORY REQUIREMENTS

The Neurocognitive Assessment area must consist of two adjacent rooms, one for the operator workstation and one for the participant undergoing assessment.

Workstation

The room housing the workstation must be sufficiently large enough to hold a desk (1800cm x 600cm), 3 office chairs and enough storage space to hold the equipment cases and spare equipment. There should be access to a sink equipped with hot and cold water.

Assessment Room

- **Size –** Minimum size room for the assessment room is 2m x 3m.
- **Temperature –** The room must be temperature controlled to maintain a temperature between 18 and 26 degrees.
- **Lighting –** Any fluorescent lighting must be switched off and a lamp with a dimmer switched must be used for lighting.
- **Noise –** The room must be in a suitably quiet location or sufficiently insulated against outside noise.
- **Distractions –** The participant must be positioned with their back to the door and the walls should be of a neutral colour without any patterns. Any other distracters should be covered or removed.
- **Furniture –** Two medium sized desks with a height adjustable, padded chair and a screen or room divider.

APPENDIX B: LAB EQUIPMENT

Operators Workstation:

-Operators PC
-Operators Monitor
-Keyboard & Mouse
-Speakers
-Intercom

Participant Desk Hardware.

-Stimulus PC
-Recording PC
-CRT Monitor
-Recording Monitor
-Boxes A & B, Media Box & Battery Box
-NuAmps
-VNC
-Network Switch
-Button Box
-Camera
-Cables (6 ethernet cables, 2 audio cables, 3 USB cables, 2 VGA cables, 15 pin connector, cable, 25 pin connector cable, VNC connector cable, button box cable + 7 various power cables)
-4 NuAmps cables

-Respiration strap
-EDA electrodes
-ECG electrode

APPENDIX C: ASSESSMENT PROCEDURE

Connections

BOX B

- EDA cables connected
- Cables connecting X5 to „Event", X6 to EDA & GND to GND on NuAmps
- NuAmps cable from AUX to drape around power board
- Connected to Battery box with 15 pin connector cable

BOX A

- Must be aligned with BOX B and communicating (test button)
- Connect to Stimulus PC by USB cable
- Connect to Media Box with 25 pin flat „ribbon" cable

Media Box

- Connect to Stimulus PC by 25 pin connector cable **AND** USB cable
- Connect to Stimulus PC with audio cable („PC send" to green audio jack)
- Connect to Operator speakers with audio cable
- Connect to headphones with audio extension cable
- Connect to Button Box with „phone" cable
- Check at least one light on

NuAmps

- Connect to recording PC with USB cable

Stimulus PC

- Power cord
- Connect to CRT monitor with VGA cable(Port labelled „S")
- Connect to VNC (lower VGA port & mouse & keyboard plugs)
- Connect to Network switch with Ethernet cable.
- Connect to mouse with USB extension cord

Recording PC

- Power cord
- Connect to recording (LCD) monitor with VGA cable
- Connect to Network switch with Ethernet cable

VNC

- Power cord
- Connect to Network switch with Ethernet cable

Camera

- Power cord
- Connect to Network switch with Ethernet cable

Ethernet Switch

- Power cord

Consumables Preparation

1. Fill 2X 10ml syringes with „Quik-Gel“ and affix an applicator (blunt needle) to one syringe. Place in dish.
2. Place small amount of „NuPrep“ into a dish with 2 cotton buds
3. Have Pencil, tissues, surgical tape, tape-measure, etoh swabs, skin conductance paste, cotton bud on tray.
4. Ensure Quik-Cap has double adhesive stickers on all recording disks (small stickers around eyes, others large)
5. Ensure ECG & EDA recording disks have double adhesive stickers.

Computer Setup

Log in (brc. Acquire).
Open „scan“, log in with username & password.
Select „edit“ > „nuamps setup“ > preferences (A1-A2)
Open Impedance boards in acquisition menu.

Participant Setup

Liaison Officer to greet participant and allocate ID number.
Fill out Participant Data Acquisition checklist.

1. Fit respiration strap
2. Sit participant in chair
3. Measure head (1) circumference & (2) nasion to inion
4. Mark a horizontal line across the forehead 10% of distance (2) above the nasion.
5. While participant is looking straight ahead, mark two vertical lines on forehead intersecting the horizontal line directly above the pupils.
6. Mark the following positions with a cross
    a. Masseter muscle- locate masseter by asking participant to clench and release their jaw while palpating the area.
    b. C7 vertebrae- Ask participant to lean their head forward, C7 is the vertebrae with the most pronounced transverse process

c. ERB‟s point- Located approximately 2/3 of the way between the sternoclavicular joint and the shoulder. You should be able to palpate a pulse at this point.
d. VA, VB, HL, HR, ORB
e. L & R Mastoid bones
f. Radial Pulse- On most convenient (non-dominant) hand.

7. Clean and abrade these sites using NuPrep, wipe with gauze.
8. Fit cap to head
9. Fill electrodes to A1, A2, eyes, C7, clavicle and masseter with Quik-Gel and Attach
10. Attach double sided tape to forehead & cap
11. Secure chin strap
12. Fill ground electrode with gel.
13. Proceed to fill each electrode in cap with gel. Insert applicator needle until it is in contact with scalp, gently „rock‟ back and forth several times and then push syringe plunger to squeeze gel out while withdrawing needle.
14. Attach EEG electrode to Radial pulse, secure with tape.
15. Clean between 1st and 2nd knuckle of 3rd & 4th digits with alcohol swab. Fill electrodes with paste and attach. Secure with tape.
16. Check impedance on monitor is below 10khOms. „Re-rock‟ each electrode as needed.

Set-up display of EEG

1. Close the Impedance view, select „edit‟ >„Nuamps setup‟ and select „ground‟
2. Click on the green triangle at the top of the Scan toolbar to display EEG.
3. Save the data file with the participant ID number.
4. To record the data the sensitivity should be 125uV
5. When the warning banner on the stimulus machine prompts you to start recording, click the record icon (red circle)TWICE
6. When the acquisition is complete, ensure you click the record icon to stop recording.

Begin testing.

1. Type “begin”
2. Follow the prompts in the warning banner at all times **turn volume UP for startle response**

Uploading the data file

1. This process must occur after every acquisition
2. Double click on the „BRCUpload“ icon on the operator computer
3. Enter subject ID
4. Click „pack“
5. Enter the diagnosis. For all clinical patients this will be other/unsure. For PTSD patients this will be PTSD
6. Enter the head circumference
7. Select whether a report is required. For all full BRC acquisitions the report to select is Neurofeedback. For all QEEGs the report to select is Neurofeedback (EO/EC)
8. Press next
9. Select the files from the drop down menus.
10. Click Go
11. Once packing is completed select upload.

Cap Washing Procedure

Rinse cap with hose, squirt water at pressure into all electrodes to wash away gel.
Remove adhesive rings as you go.
Wash cap in warm water & detergent, rinse.
Soak in 150ml viraclean/ 800 ml warm water for 10 minutes.
Rinse.
Dry on rack in front of fan.

APPENDIX D: NEUROCOGNITIVE TESTING QUALITY MANAGEMENT PLAN

Quality Management Plan for the Neurocognitive Assessments

Ensure that security and confidentiality requirements are adhered to

Action	Responsible Party	Timeline
All CMVH UA staff associated with the study are cleared to restricted status	CMVH Security Officer	At all times
All identifiable information for SF Personnel is handled solely by the SOC Administration Officer who has a "secret" clearance	Study Manager	At all times
All neurocognitive data is only identified by the Study IDs	Study Manager	At all times

Ensure consistency of all data collection

Action	Responsible Party	Timeline
Neurocogntive Protocol is developed	Neurocogntivie Team Leader/Study Manager	Prior to commencing study
Neurocogntive Protocol is adhered to	All CMVH UA staff	At all times
Neurocognitive raw data is sent to BRC labs for scoring	Neurocognitive Team Leader	As soon as practicable after the assessments
A SOP for cleaning data is developed	Statisticians	Prior to analysis

Ensure that all Protocol Deviations (see definition below) are recorded and followed up appropriately

Action	Responsible Party	Timeline
Record any errors or omissions to the protocol on the Protocol Deviation Log	Any CMVH UA staff member	As soon as the deviation is identified
Collect and collate the Protocol Deviation Reports	Study Manager	Once per week
Take any action required to reduce the likelihood of any further Protocol Deviations	Study Manager	At all times

Appendix A - Definitions

Definition of a Protocol Deviation

A protocol deviation is defined as any action or inaction which digresses from the Questionnaire Protocol and which compromises the integrity of any questionnaire data.

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Appendix F

Questionnaire Components

Self Report Questionnaire Measure

Measures	Reference	In Pre-Deployment	In Post-Deployment
Brief Deployment History:			
For all previous deployments: • Year deployment started • Number of times deployed in that year • Total time deployed in months	Not Applicable	1.1 – 1.7	No
Health Questionnaire – Background Details:			
• Date survey completed • Sex and date of birth • Relationship characteristics • Impact of military career • Career characteristics • Questions for reserve members	Not Applicable	1.1 – 1.18	1.1 – 1.18
Health Questionnaire – Recent Health Symptoms:			
• Symptoms checklist	Based on the Hopkins Symptom Checklist [1]	2.1 – 2.67	2.1 – 2.67

• Mild Traumatic Brain Injury	Based on the Mild Traumatic Brain Injury Screening Instrument [2]	2.68 – 2.71	2.68 – 2.71
Health Questionnaire – Your Health Now:			
• General, physical and mental health as well as quality of life	Short Form 12 [3]	3.1 – 3.7	3.1 3.7
• Self-rated over-all health, quality of life, eyesight (with glasses or contact lenses), hearing, memory, teeth and gums	Drawn or adapted from the 45 and Up Study http://www.45andup.org.au/	3.8 – 3.13	3.8 – 3.13
• Non specific psychological distress	Kessler 10 Plus [4]	3.14 – 3.27	3.14 – 3.27
• Resilience	Two questions from Connor-Davidson Resilience Scale [5, 6] Also used in the Department of Defence LASER Study (unpublished)	3.28	3.28
• Doctor diagnosed conditions	Adapted from the Kings College Gulf War Research Unit [7], US Gulf War Study [8]	3.29 – 3.51	3.29 – 3.51
Health Questionnaire – Lifestyle Behaviours:			
• Use of tobacco products	Millennium Cohort Study – Smoking [9]	4.1 – 4.8	4.1 – 4.8
• Alcohol usage	Alcohol Use Disorder Identification Test [10, 11]	4.9 – 4.20	4.9 – 4.20
• Caffeine usage	Millennium Cohort Study – Caffeine [12]	4.21	4.21

• Gambling	Adapted from the Problem Gambling Severity Index [13, 14]	4.23 – 4.31 from March 2011	4.23 – 4.31
Health Questionnaire – Life Experiences:			
• Posttraumatic stress symptoms	PTSD Checklist – Civilian [15]	5.1 – 5.21	5.1 – 5.21
• Anger	Drawn from the Dimensions of Anger Reactions [16, 17]	5.22	5.22
• Aggression	Unknown origin	5.23 – 5.24	5.23 – 5.24
• Depressive symptoms	PHQ-9 Module [18]	5.25 – 5.34	5.25 – 5.34
• Anxiety including panic disorder, panic attack and other anxiety syndrome	PHQ-15 Anxiety Module [19]	5.35 – 5.56	5.35 – 5.56
• Suicide ideation	Adapted from PATH Through Life Project (1999-2000) [20]	5.57 – 5.60	5.57 – 5.60
• Barriers to care	Adapted from Hoge [21] and Decompression Survey [22]	No	5.62 – 5.74 from November 2011
Health Questionnaire - Your Respiratory Health:			
• Respiratory health	European Community Respiratory Health Survey 2 – Screening Questionnaire [23]	6.1 – 6.7	6.1 – 6.7

Health Questionnaire - Reproductive History:			
• Reproductive history	Developed by Capt (RAN) Sonya Bennett and Associate Professor Susan Treloar	7.1 – 7.4	No
Health Questionnaire – Recreation and Social Activities:			
• Recreation and social activities	Drawn from NNAI study questionnaire adapted from DVA instrument	8.1 – 8.11	7.1 – 7.10
• Open ended questions	Developed in house	9.1 – 9.2	8.1 – 8.2

Personality and Resilience			
• Personality	10 Item Personality Inventory [24]	1.1 – 1.10	No
• Social support	Schuster Social Support Scale [25]	2.1 – 2.8	No
• Childhood	Drawn from the Longitudinal ADF Study Evaluating Retention and Resilience (LASERR study)	3	No
• Care for emotional problems	Developed by Professor McFarlane	4	No
• Symptom Interpretation	Symptom Interpretation Questionnaire [26]	5.1 – 5.13	No
• Pre Existing Trauma	Adapted from Composite International Diagnostic Interview 2.1 with additions by Professor McFarlane	6.1 – 6.18	No

• Alexithymia	Toronto Alexithymia Scale [27]	7.1 – 7.20	No

Deployment Details and Experience			
• Deployment details	Developed in house	No	1.1 – 1.9
• Chemical and environmental exposures	Developed from MEAO Preliminary Study Focus Groups and Kings College London Phase 2 questionnaire	No	2.1 – 2.61
• Your work on deployment	Drawn from the Kings College London Phase 2 questionnaire, the Deployment Risk and Resilience Inventory [28] and questions developed in house	No	3.1 – 3.8
Deployment Details – Your Health on Deployment			
• Sick Parade	Developed in house	No	4.1
• Diarrhoea or vomiting	Developed in house	No	4.2 – 4.4
• Sleep	Adapted from the Intergenerational Health Effects of Military Service Study questionnaire	No	4.5 – 4.9
• Caffeine	Adapted from the Millennium Cohort Study questionnaire	No	4.10

• Supplements	Adapted from the Millennium Cohort Study questionnaire	No	4.11
• General health	Adapted from Kings College London Phase 1 questionnaire	No	4.12 – 4.13
Deployment Details – Other Deployment Experiences			
• Support from family	Adapted from the Kings College London Phase 2 questionnaire	No	5.1 – 5.2
Deployment Details – Post Deployment Experiences			
• Exiting from theatre	Adapted from the Kings College London Phase 2 questionnaire	No	6.1
• Post operative screening	Developed in house	No	6.2 – 6.3
• Post operative leave	Adapted from the Kings College London Phase 2 questionnaire and developed by Professor McFarlane	No	6.4 – 6.8
• Post operative misc.	Adapted from Kings College London Phase 2 questionnaire	No	6.9 – 6.11
• Military and social support	Adapted from Kings College London Phase 2 questionnaire and developed in house	No	6.12

• Promotion and seniority	Drawn from Return to Australia Psychological Screen (RtAPS)	No	6.13
• Continuation of military career	Drawn from Intergenerational Health Effects study questionnaire	No	6.14
• Significant relationships	Brief Dyadic Adjustment Scale [29]	No	6.15 – 6.16
• Reservists specific	Drawn from Kings College London Phase 2 questionnaire	No	6.17 – 6.19
• Open ended questions	Developed in house	No	7.1

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Appendix G

Pathology Details

Pathology Assays

Assay Name	Assay Reference Range	Assay Procedure	Control Measures	Analysis Laboratory
Total Cholesterol	<5.6 mmmol/L We do not usually provide a reference interval for total cholesterol, in line with the Australian Heart Foundation recommendations.	Analysis is performed on the Siemens Advia 2400. The cholesterol esters are hydrolysed by cholesterol esterase to cholesterol and free fatty acids. Cholesterol is then converted to cholesterol –3 by cholesterol oxidise in the presence of oxygen to form hydrogen peroxide. In a peroxidise reaction, a coloured complex is formed and absorbance measured as an endpoint reaction at 505nm.	Internal QC - MAS ChemTrak levels 1&3, three times per day and post unscheduled maintenance External QA - RCPA QAP	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034
High-Density Lipoprotein (HDL)	>1.0 mmol/L	Analysis is performed on the Siemens Advia 2400. Cholesterol esterase and oxidise eliminate VLDL, LDL and Chylomicrons from the reaction allowing the measurement of HDL Cholesterol after its release by a surfactant. The colour development produced by the Trinder reaction is measured at 596 nm and is proportional to HDL Cholesterol in the sample.	Internal QC - MAS ChemTrak levels 1&3, three times per day and post unscheduled maintenance External QA - RCPA QAP	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034
Low-Density Lipoprotein (LDL)	<2.5 mmol/L If a patient is classified as a high risk patient, then the cut off is < 2.0 mmol/L	Calculated Using Friedewald Equation. LDLC (mmol/L) = Total Cholesterol – HDL Cholesterol - (Triglycerides / 2.2)		Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034

Triglyceride	<1.5 mmol/L	Analysis is performed on the Siemens Advia 2400. Triglycerides are converted to glycerol and free fatty acids by lipoprotein lipase. Glycerol is then converted to glycerol-3-phosphate by glycerol kinase to form H2O2. The H2O2 is then converted to a colour complex in a peroxidise reaction, which is measured as an endpoint reaction at 505 nm. The change in absorbance is proportional to the amount of triglyceride in the sample.	Internal QC - MAS ChemTrak levels 1&3, three times per day and post unscheduled maintenance External QA - RCPA QAP	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034
Creatine Kinase	Female: <161 U/L, Male: 18-20y <251 U/L, Male >20y <201 U/L	Analysis is performed on the Siemens Advia 2400. Creatine Kinase reacts with creatine phosphate and ADP to form ATP which is coupled to the hexokinase reaction, generating NADPH. The concentration of NADPH is measured by the increase in absorbance at 340 nm.	Internal QC - MAS ChemTrak levels 1&3, three times per day and post unscheduled maintenance External QA - RCPA QAP	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034
Chlamydia IgG	<16RU/mL=N, ≥16-<22=B, ≥22=P	Automated EIA (Enzyme immunoassay)	Internal and external QC run daily	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034
Chlamydia IgA	<0.8 (index)=N, ≥0.8-<1.1=B, ≥1.1=P	Automated EIA (Enzyme immunoassay)	Internal and external QC run daily	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034
Chlamydia IgM	<0.8 (index)=N, ≥0.8-<1.1=B, ≥1.1=P	Automated EIA (Enzyme immunoassay)	Internal and external QC run daily	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034
Vitamin B12	180-10000 pmol/L Normal >180 pmol/L Equivocal 150 – 180 pmol/L Deficient <150 pmol/L	B12 from the patient sample competes with B12 labelled with acridinium ester for a limited amount of purified intrinsic factor, covalently coupled to paramagnetic particles. The assay uses releasing agent and DTT to release the B12 from the endogenous binding proteins in the sample and cobinamide to prevent rebinding after the paramagnetic particles are added. An inverse relationship exists between the amount of AFP present in the patient sample and the amount of relative light units (RLUs) detected by the system.	QC Material - BioRad Lyphochek Whole Blood Control, Levels 2 & 3; Frequency-Once per batch and post unscheduled maintenance. External QA RCPA QAP	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034

Red Cell Foliate	451-10000 nmol/L Normal >450 nmol/L Equivocal 350 – 450 nmol/L Deficient <350 nmol/L	The Siemens Centaur utilises a competitive immunoassay using chemiluminometric technology. Folate in the patient sample competes with acridinium ester-labelled folate for a limited amount of biotin-labelled folate binding protein. The biotin-labelled folate binding protein binds to avidin that is covalently coupled to paramagnetic particles. An inverse relationship exists between the amount of folate present in the patient sample and the amount of relative light units (RLUs) detected by the system.	Quality Control (QC) Material - MAS Liquimmune Levels 1, 2 & 3 and BioRad Lyphanaemia Control; Frequency-Once per day and post unscheduled maintenance. External QA - RCPA QAP	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034
Haemoglobin	Dacie / Lewis Practical Haematology, 9th edition. Haematology Pathologist consensus and reference range review group; ranges are reviewed in relation to previously used reference ranges, relevant data on the specific method and instrument used and any Expert Group guidelines available.	SLS-Haemoglobin method, absorbance at 555 nm.	QC material of known values, Drift control, External QA	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034
Red Cell Count	Dacie / Lewis Practical Haematology, 9th edition. Haematology Pathologist consensus and reference range review group; ranges are reviewed in relation to previously used reference ranges, relevant data on the specific method and instrument used and any Expert Group guidelines available.	Radio-Frequency/Direct Current (RF/DC) detection method with Hydrodynamic focusing	QC material of known values, Drift control, External QA	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5035

Packed Cell Volume	Dacie / Lewis Practical Haematology, 9th edition. Haematology Pathologist consensus and reference range review group; ranges are reviewed in relation to previously used reference ranges, relevant data on the specific method and instrument used and any Expert Group guidelines available.	Red Blood Cell pulse height detection method (Associated with the RF / DC detection of the Red Cell Count)	QC material of known values, Drift control, External QA	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5036
Mean Cell Volume	Dacie / Lewis Practical Haematology, 9th edition. Haematology Pathologist consensus and reference range review group; ranges are reviewed in relation to previously used reference ranges, relevant data on the specific method and instrument used and any Expert Group guidelines available.	Red Blood Cell pulse height detection method (Associated with the RF / DC detection of the Red Cell Count)	QC material of known values, Drift control, External QA	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5037
Mean Cell Haemoglobin	Dacie / Lewis Practical Haematology, 9th edition. Haematology Pathologist consensus and reference range review group; ranges are reviewed in relation to previously used reference ranges, relevant data on the specific method and instrument used and any Expert Group guidelines available.	Calculated value	QC material of known values, Drift control, External QA	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5038

Red Cell Distribution Width	Dacie / Lewis Practical Haematology, 9th edition. Haematology Pathologist consensus and reference range review group; ranges are reviewed in relation to previously used reference ranges, relevant data on the specific method and instrument used and any Expert Group guidelines available.	RF / DC detection method with Hydrodynamic focusing	QC material of known values, Drift control, External QA	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5039
White Cell Count	Dacie / Lewis Practical Haematology, 9th edition. Haematology Pathologist consensus and reference range review group; ranges are reviewed in relation to previously used reference ranges, relevant data on the specific method and instrument used and any Expert Group guidelines available.	Flow Cytometry method with a semi-conductor laser	QC material of known values, Drift control, External QA	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5040
Neutrophils Percentage	Dacie / Lewis Practical Haematology, 9th edition. Haematology Pathologist consensus and reference range review group; ranges are reviewed in relation to previously used reference ranges, relevant data on the specific method and instrument used and any Expert Group guidelines available.	Flow Cytometry method with a semi-conductor laser and fluorescent staining.	QC material of known values, Drift control, External QA	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5041

Neutrophils Absolute	Dacie / Lewis Practical Haematology, 9th edition. Haematology Pathologist consensus and reference range review group; ranges are reviewed in relation to previously used reference ranges, relevant data on the specific method and instrument used and any Expert Group guidelines available.	Flow Cytometry method with a semi-conductor laser and fluorescent staining.	QC material of known values, Drift control, External QA	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5042
Lymphocytes Percentage	Dacie / Lewis Practical Haematology, 9th edition. Haematology Pathologist consensus and reference range review group; ranges are reviewed in relation to previously used reference ranges, relevant data on the specific method and instrument used and any Expert Group guidelines available.	Flow Cytometry method with a semi-conductor laser and fluorescent staining.	QC material of known values, Drift control, External QA	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5043
Lymphocytes Absolute	Dacie / Lewis Practical Haematology, 9th edition. Haematology Pathologist consensus and reference range review group; ranges are reviewed in relation to previously used reference ranges, relevant data on the specific method and instrument used and any Expert Group guidelines available.	Flow Cytometry method with a semi-conductor laser and fluorescent staining.	QC material of known values, Drift control, External QA	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5044

Monocots Percentage	Dacie / Lewis Practical Haematology, 9th edition. Haematology Pathologist consensus and reference range review group; ranges are reviewed in relation to previously used reference ranges, relevant data on the specific method and instrument used and any Expert Group guidelines available.	Flow Cytometry method with a semi-conductor laser and fluorescent staining.	QC material of known values, Drift control, External QA	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5045
Monocots Absolute	Dacie / Lewis Practical Haematology, 9th edition. Haematology Pathologist consensus and reference range review group; ranges are reviewed in relation to previously used reference ranges, relevant data on the specific method and instrument used and any Expert Group guidelines available.	Flow Cytometry method with a semi-conductor laser and fluorescent staining.	QC material of known values, Drift control, External QA	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5046
Eosinophils Percentage	Dacie / Lewis Practical Haematology, 9th edition. Haematology Pathologist consensus and reference range review group; ranges are reviewed in relation to previously used reference ranges, relevant data on the specific method and instrument used and any Expert Group guidelines available.	Flow Cytometry method with a semi-conductor laser and fluorescent staining.	QC material of known values, Drift control, External QA	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5047

Eosinophils Absolute	Dacie / Lewis Practical Haematology, 9th edition. Haematology Pathologist consensus and reference range review group; ranges are reviewed in relation to previously used reference ranges, relevant data on the specific method and instrument used and any Expert Group guidelines available.	Flow Cytometry method with a semi-conductor laser and fluorescent staining.	QC material of known values, Drift control, External QA	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5048
Basophils Percentage	Dacie / Lewis Practical Haematology, 9th edition. Haematology Pathologist consensus and reference range review group; ranges are reviewed in relation to previously used reference ranges, relevant data on the specific method and instrument used and any Expert Group guidelines available.	Flow Cytometry method with a semi-conductor laser	QC material of known values, Drift control, External QA	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5049
Basophils Absolute	Dacie / Lewis Practical Haematology, 9th edition. Haematology Pathologist consensus and reference range review group; ranges are reviewed in relation to previously used reference ranges, relevant data on the specific method and instrument used and any Expert Group guidelines available.	Flow Cytometry method with a semi-conductor laser	QC material of known values, Drift control, External QA	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5050

Platelets	Dacie / Lewis Practical Haematology, 9th edition. Haematology Pathologist consensus and reference range review group; ranges are reviewed in relation to previously used reference ranges, relevant data on the specific method and instrument used and any Expert Group guidelines available.	RF / DC Detection method with Hydro Dynamic focusing	QC material of known values, Drift control, External QA	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5051
Erythrocyte Sedimentation Rate	Dacie / Lewis Practical Haematology, 9th edition. Haematology Pathologist consensus and reference range review group; ranges are reviewed in relation to previously used reference ranges, relevant data on the specific method and instrument used and any Expert Group guidelines available.	Westegren pipette method	External QA enrolment	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5052
Hepatitis C Antibody	<0.8=N, 0.8-1.0=E, ≥1.0=P	Automated Chemiluminescent assay		Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034
Sodium	136-146 mmol/L	Analysis is performed on the Siemens Advia 2400. Indirect ISE (Ion Selective Electrode)method. The sample is mixed with ISE buffer to provide a solution of constant pH and ionic strength. The sample is then passed through the ion selective electrode where the change in electrical potential is measured against the reference electrode and calibration data to quantitate a sodium result.	Internal QC - MAS ChemTrak levels 1&3, three times per day and post unscheduled maintenance External QA - RCPA QAP	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034

Potassium	3.5-5.2 mmol/L	Analysis is performed on the Siemens Advia 2400. The sample is mixed with ISE buffer. The sample is then passed through the ion selective electrode. The change in electrical potential is measured against the reference electrode and calibration data to quantitate potassium result. The measurement technique is referred to be indirect ISE.	Internal QC - MAS ChemTrak levels 1&3, three times per day and post unscheduled maintenance External QA - RCPA QAP	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034
Chloride	98-109 mmol/L	Analysis is performed on the Siemens Advia 2400. The sample is mixed with ISE buffer. The sample is then passed through the ion selective electrode block. The change in electrical potential, measured against the reference electrode, is used to calculate a chloride result. Determination is classed as an indirect ISE method.	Internal QC - MAS ChemTrak levels 1&3, three times per day and post unscheduled maintenance External QA - RCPA QAP	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034
Bicarbonate	20-32 mmol/L	Analysis is performed on the Siemens Advia 2400. Phosphoenolpyruvate carboxylase is used to catalyse the reaction of Bicarbonate with phosphoenol- pyruvate to produce oxaloacetate. Malate dehydrogenase is used to catalyse the indicator reaction in which the amount of NADH oxidised with the decreased absorbance at 410 nm is proportional to the amount of Bicarbonate present.	Internal QC - MAS ChemTrak levels 1&3, three times per day and post unscheduled maintenance External QA - RCPA QAP	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034
Urea	2.5-7.5 mmol/L (5-15 years), 2.5-8.0 mmol/L (15-50 years), 2.5-8.5 mmol/L (50-60 years)	Analysis is performed on the Siemens Advia 2400. Urea is hydrolysed by urease to produce ammonia and CO2. Glutamate Dehydrogenase then catalyses the reaction of ammonia, 2-oxoglutarate and NADH to form L-glutarate and NAD. This oxidation of NADH to NAD is measured as an inverse rate reaction at 340 nm and is proportional to the concentration of urea in the sample.	Internal QC - MAS ChemTrak levels 1&3, three times per day and post unscheduled maintenance External QA - RCPA QAP	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034

Creatinine	40-85 µmol/L (Females), 55-110 µmol/L (Males)	Analysis is performed on the Siemens Advia 2400. The creatinine reacts with the alkaline picric acid and forms a coloured complex measured at 505 nm. The rate of colour formation is proportional to the creatinine concentration. This method is a modification of the Jaffe method utilizing rate blanking and intercepts correction. Rate blanking is used to minimize interference by bilirubin.	Internal QC - MAS ChemTrak levels 1&3, three times per day and post unscheduled maintenance External QA - RCPA QAP	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034
Estimated Glomerular Filtration Rate		Calculated using modified diet renal disease (MDRD) formula. eGFR (mL/min/1.73m2)= 175 x [SerumCreatinine(umol/L) x 0.0113]-1.154 x Age(years)-0.203 (x 0.742 if female)		Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034
Urate	0.15-0.45 mmol/L (Females), 0.18-0.47 mmol/L (Males)	Analysis is performed on the Siemens Advia 2400. Uric acid is converted by uricase to allantoin and H2O2. In a peroxidise reaction, the H2O2 forms a coloured complex, the absorbance of which is measured as an endpoint reaction at 545 nm.	Internal QC - MAS ChemTrak levels 1&3, three times per day and post unscheduled maintenance External QA - RCPA QAP	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034
Glucose	3.0-5.4 mmol/L (Fasting), 3.0-6.9 mmol/L (Random)	Analysis is performed on the Siemens Advia 2400. Glucose is phosphorylated by ATP in the presence of Hexokinase. The resulting Glucose-6-phosphate (G6P) in the presence of Glucose-6-phosphat dehydrogenase (G-6-PDH) reduces NAD to NADH. The absorbance of NADH is measured as an endpoint reaction at 340 nm and is proportional to the glucose concentration.	Internal QC - MAS ChemTrak levels 1&3, three times per day and post unscheduled maintenance External QA - RCPA QAP	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034
Ionized Calcium		Calculated parameter utilising ELY, Ca, Alb & TP results to calculate iCa. Ca^{2+} = Total Ca (mmol/L) - 0.00613 x TCa x albumin (g/L) - 0.00244 x TCa x globulin (g/L) - 0.0043 x TCa x anion gap (mmol/L) - 0.00375 x TCa x bicarbonate (mmol/L)		Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034

Magnesium	0.7-1.0 mmol/L	Analysis is performed on the Siemens Advia 2400. Magnesium ions react with xylidyl blue dye in an alkaline medium to produce a water soluble purple-red chelate. The increase in absorbance is measured at 505 nm and is proportional to the concentration of magnesium in the sample.	Internal QC - MAS ChemTrak levels 1&3, three times per day and post unscheduled maintenance External QA - RCPA QAP	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034
Phosphate	0.75-1.45 mmol/L (>15 years)	Analysis is performed on the Siemens Advia 2400. Inorganic phosphate reacts with ammonium molybdate in the presence of sulphuric acid to form an unreduced phosphomolybdate complex, which is measured as an endpoint reaction at 340 nm. The amount of complex formed is directly proportional to the amount of phosphate in the sample.	Internal QC - MAS ChemTrak levels 1&3, three times per day and post unscheduled maintenance External QA - RCPA QAP	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034
Total Protein	57-80 g/L (16-60 years)	Analysis is performed on the Siemens Advia 2400. Protein peptide bonds interact with the cupric ions in the Biuret reagent (cupric sulphate in an alkaline solution) to form a purple complex that is measured as an endpoint reaction at 545 nm. The colour intensity is directly proportional to the amount of peptide bonds present in the sample and hence the amount of total protein present.	Internal QC - MAS ChemTrak levels 1&3, three times per day and post unscheduled maintenance External QA - RCPA QAP	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034
Albumin	35-50 (>16 years)	Analysis is performed on the Siemens Advia 2400. Serum Albumin is measured by a timed endpoint reaction at 596nm. Albumin in serum binds with Bromocresol purple BCP forming a complex. The concentration of albumin is proportional to the amount of albumin-BCP complex formed.	Internal QC - MAS ChemTrak levels 1&3, three times per day and post unscheduled maintenance External QA - RCPA QAP	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034

Alkaline Phosphatase	30-120 U/L (20-60 years)	Analysis is performed on the Siemens Advia 2400. ALP hydolyses pNPP substrate to form p-nitrophenol. The reaction is followed by the colorimetric measurement of the rate formation of p-nitrophenol at 410/478 nm, which si proportional to the ALP activity. A 2-amino-2-mehtyl-1-propanol (AMP) buffer is used to maintain the reaction pH at 10.3-10.4. Magnesium and zinc ions are added to the AMP buffer to activate and stabilise the enzyme.	Internal QC - MAS ChemTrak levels 1&3, three times per day and post unscheduled maintenance External QA - RCPA QAP	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034
Bilirubin	<25 µmol/L (> 1 month)	Analysis is performed on the Siemens Advia 2400. Serum Total Bilirubin is measured by a timed endpoint reaction at 451 nm. The total Bilirubin reaction is based on a chemical oxidation method using vanadate as an oxidising agent. This oxidation reaction causes the decrease in the optical density of the yellow colour which is specific to bilirubin. The decrease is proportional to the Total Bilirubin concentration in the sample.	Internal QC - MAS ChemTrak levels 1&3, three times per day and post unscheduled maintenance External QA - RCPA QAP	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034
Gamma Glutamyl Transferase	<50 U/L	Analysis is performed on the Siemens Advia 2400. GGT catalyses the reaction in which glycylglycine acts as an acceptor for the glutamyl residue from the synthetic substrate (L--glutamyl-3-carboxy-4-nitroanilide) and 5-amino-2-nitro-benzoate (ANB) is liberated. The liberated product has an absorption maximum near 400 nm; the rate of formation is measured at 410 nm as a zero-order kinetic assay.	Internal QC - MAS ChemTrak levels 1&3, three times per day and post unscheduled maintenance External QA - RCPA QAP	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034
Aspartate Aminotransferase	<41 U/L (>3 years)	Analysis is performed on the Siemens Advia 2400. AST activity is measured by the rate of decrease in absorbance of NADH after the addition of alpha ketoglutarate at a wavelength of 340 nm and is directly proportional to the amount of AST present.	Internal QC - MAS ChemTrak levels 1&3, three times per day and post unscheduled maintenance External QA - RCPA QAP	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034

Alanine Aminotransferase	<41 U/L (Female), <51 U/L (Male)	Analysis is performed on the Siemens Advia 2400. ALT reaction is initiated by the addition of alpha ketoglutarate as the second reagent. The concentration of NADH measured at 340 nm is measured with the rate of decline proportional to the amount of ALT present.	Internal QC - MAS ChemTrak levels 1&3, three times per day and post unscheduled maintenance External QA - RCPA QAP	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034
Lactate Dehydrogenase	50-280 U/L	Analysis is performed on the Siemens Advia 2400. LD catalyses the conversion of L-Lactate to pyruvate in the presence of NAD. The enzymatic activity of LD is proportional to the rate of production of NADH, measured by increased absorbance at 340nm.	Internal QC - MAS ChemTrak levels 1&3, three times per day and post unscheduled maintenance External QA - RCPA QAP	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034
Amylase	<111 U/L	Analysis is performed on the Siemens Advia 2400. Ethylidene blocked p-nitrophenyl-maltoheptaoside substrate is mixed with the indicator enzyme alpha-glucosidase to produce p-nitrophenol, the absorbance of which can be measured at 410 nm. The rate of change in absorbance is proportional to the activity of amylase present.	Internal QC - MAS ChemTrak levels 1&3, three times per day and post unscheduled maintenance External QA - RCPA QAP	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034
Lipase	110-290 U/L	Analysis is performed on the Siemens Dimension. Lipase catalyses the hydrolysis of the lipase substrate, 1,2-O-dilauryl-rac-glycero-3-glutaric acid-(6'-methylresorufin) ester in the presence of colipase, bile salt and CaCl2. The unstable intermediate glutaric acid-6'-methylresorufin ester is produced by this hydrolysis. This intermediate is then hydrolysed by H2O to yield free methylsorufin which absorbs at 577nm. Lipase activity is measured by a bichromatic rate reaction at 577and 700nm. The rate of the reaction is proportional to the amount of lipase in the sample.	Internal QC - MAS ChemTrak levels 1&3, three times per day and post unscheduled maintenance External QA - RCPA QAP	Healthscope Pathology, Ashford Laboratory, Ashford SA 5035

C-Reactive Protein	<3.0 mg/L	Analysis is performed on the Siemens Advia 2400. C-reactive protein is brought into contact with anti-CRP antibodies coupled to latex microparticles forming an antigen/antibody complex. The resulting turbidity is measured at 571 nm and compared to a six point standard curve in order to calculate the CRP concentration.	QC Material - MAS Cardiology, MAS Immunology; Frequency-3 x per day and post unscheduled maintenance. External QA RCPA QAP	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034
Haemoglobin A1C	<53 mmol/mol	Analysis is performed on the Roche Cobas Integra 800. Whole blood samples are haemolysed, releasing haemoglobin that is degraded by pepsin to make the β-N-terminal structures more accessible. The heme portions are oxidized for the Hb assay performed by a colorimetric method. The colour intensity is proportional to the Hb concentration. HbA1c is measured using a monoclonal antibody attached to a latex particle. The antibody binds to the β-N–Terminal fragments of HbA1c. Remaining free antibodies are agglutinated with a synthetic polymer. The change in turbidity is inversely related to the amount of bound glycopeptides and is measured turbidimetrically at 520nm.	QC Material - ASE HbA1c Control, Level 1 & 2; Frequency-3 x per day and post unscheduled maintenance. External QA RCPA QAP	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034
Cytomegalo Virus IgG	Reactive (ratio of ≥ 1.1); Non reactive (ratio of ,0.9); Indeterminate (ratio between 0.9 and <1.1)	Analysis is performed on the Siemens Immulite 2000 Xpi. CMV IgG is a solid-phase, sequential chemiluminescent enzyme immunoassay	QC Material - Siemens CVG Negative & Positive Control; Frequency-Once per day and post unscheduled maintenance.	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034
Cytomegalo Virus IgM	Reactive (ratio of ≥ 1.1); Non reactive (ratio of ,0.9); Indeterminate (ratio between 0.9 and <1.1)	Analysis is performed on the Siemens Immulite 2000 Xpi. CMV IgM is a solid-phase, enzyme-labelled chemiluminexcent three-step immunoassay.	QC Material - Siemens CMM Negative & Positive Control; Frequency-Once per day and post unscheduled maintenance.	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034

Helicobacter Pylori IgG	The majority of individuals exposed to H. pylori possess IgG antibodies to the organism. Prevalence of H. Pylori infection isabout 20% in Australia	Analysis is performed on the Siemens Immulite 2000 Xpi. *H. pylori* IgG is a solid-phase, chemiluminescent immunometric assay.	QC Material - Siemens HPG Negative, Low Positive & Positive Control; Frequency-Once per day and post unscheduled maintenance.	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034
Herpes Simplex Type 1 IgG	Novagnost Herpes Simplex Types 1 & 2 IgG test method - commercially available diagnostic Kit	ELISA	Quality control is reviewed for every Herpes Simplex Virus Test. Data is reviewed against established internal ranges.	Healthscope Pathology, 1868 Dandenong Road, Clayton VIC 3168
Herpes Simplex Type 2 IgG	Novagnost Herpes Simplex Types 1 & 2 IgG test method - commercially available diagnostic Kit	ELISA	Quality control is reviewed for every Herpes Simplex Virus Test. Data is reviewed against established internal ranges.	Healthscope Pathology, 1868 Dandenong Road, Clayton VIC 3168
Herpes Simplex Type 1 & 2 IgM	Enzygnost Herpes Simplex Virus IgM test method - commercially available diagnostic kit	ELISA	Quality control is reviewed for every Herpes Simplex Virus Test. Data is reviewed against established internal ranges.	Healthscope Pathology, 1868 Dandenong Road, Clayton VIC 3168
Leishmania IgG Antibody	≥1.1= positive	ELISA	%CV=21.8, MOU=1.4	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034
Mycoplasma Antibody IgG	Novagnost Mycoplasma pneumonia IgG commercially available diagnostic kit.	ELISA	Quality control is reviewed for every Mycoplasma Test. Data is reviewed against established internal ranges.	Healthscope Pathology, 1868 Dandenong Road, Clayton VIC 3168
Mycoplasma Antibody IgM	Novagnost Mycoplasma pneumoniae IgM commercially available diagnostic kit.	ELISA	Quality control is reviewed for every Mycoplasma Test. Data is reviewed against established internal ranges.	Healthscope Pathology, 1868 Dandenong Road, Clayton VIC 3168

Red Cell Cholinesterase	Expected Values: Serum/Plasma 2.4-5.1 mg/dL	Sample prep differs from that stated in the insert in that washed packed red cells are used instead of whole blood. The cells are lysed by adding 100 mcL packed red cells to 400 mcL Igepal CA 630 0.25% solution, which is then gently mixed for a minimum of 15 mins. The final cholinesterase result is calculated by the following: U/g Hb = [RBC cholinesterase activity (kU/L) / Hb (g/L)] x 8 x 1000; where 1000 = conversion from kU/L to U/L and 8 = dilution factor of Hb assay.	3 QCs used - Roche PreciControl ClinChem Multi 2, a 1/5 dilutsion of the PreciControl 2 and an in-house red cell control made from ARCBS donor units. Enrolled in RCPA General Chemistry EQAP - fortnightly multi-lab comparison of cholinesterase assay.	SA Pathology at Institute of Medical and Veterinary Science
Tumor Necrosis Factor-Alpha (TNF Alpha)	The effect of the JNK Inhibitor JIP peptide, on human T lymphocytes, Proliferation and Cytokine Production (2008) The Journal of Immunology 12/2008 181(10):7300-6	BD CBA Flex Set Capture Beads are a single bead population with distinct, fluorescent intensity. These beads are coated with capture antibody specific for a soluble protein (cytokine). The bead is resolvable in the NIR and red channels on the BD Canto 1. Each bead is designated as alpha-numeric position relative to the other beads in the Flex Set system. Multiplex assays can then be created by combining more than one flex set. Capture beads, PE-conjugated detection reagent, standards and test samples are incubated together to form sandwich complexes. Data is acquired using the Canto 1 and the sample results are generated using the FXAP Array Software.	QCs from NIBSC were used to validate the assay: TNF Alpha code 88/786. IL-1b code 86/680. IL-6 code 88/514. IL-10 code 92/516.	Department of Immunopathology, SA Pathology, Women's and Children's Hospital Campus, North Adelaide, South Australia 5006.
Interleukin 1	As for TNF Alpha	As for TNF Alpha	As for TNF Alpha	As for TNF Alpha
Interleukin 4	As for TNF Alpha	As for TNF Alpha	As for TNF Alpha	As for TNF Alpha
Interleukin 6	As for TNF Alpha	As for TNF Alpha	As for TNF Alpha	As for TNF Alpha
Epstein Barr Virus IgM	≥1.1= positive	ELISA	%CV=11.8, MOU=0.4	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034
Epstein Barr Virus IgG	≥1.1= positive	ELISA	%CV=11.25, MOU=0.78	Healthscope Pathology, 1 Goodwood Road, Wayville SA 5034

Appendix H

Duty of Care
Suicide Ideation

MEAO Prospective Study Suicidal Ideation Response Protocol

The purpose of this Suicidal Ideation Response Protocol is to set out the process for responding to and offering further support for participants in the MEAO Prospective Study who respond positively to a suicide ideation question on either the pre deployment or post deployment questionnaire.

1. *Identifying Participant Who May Require Additional Support*

- All questionnaire data including the answers to the questions pertaining to suicidal ideation will be reviewed by the research team on a weekly basis.
- The file of any participant suggesting suicidal ideation will be further reviewed by the Principal Investigator (a psychiatrist).
- Any participant answering yes to any of the questions pertaining to suicidal ideation would be provided with additional support as described below.

2. *Identifying the Correct Support Process*

The MEAO Prospective Study is inviting all ADF members deploying to the Middle East Area of Operations (MEAO) after June 2010 and returning from deployment by December 2011 to participate in a MEAO Prospective Study. Pre deployment data (including a questionnaire) may be collected sometime within the four months prior to deployment, with post deployment data collected up to four months after returning from the MEAO.

During the pre deployment phase of data collection, a small number of ADF members may complete the questionnaire just prior to deploying and therefore may have already left Australia by the time that the questionnaire is posted back to the research team and reviewed. Therefore, two separate processes have been identified (see Section 3 for those not deployed and Section 4 below for those already deployed).

3. *Supporting Participants Who Have Not as yet Deployed*

A research staff member who has completed an Applied Suicide Intervention Skills Training (ASIST) Course will contact all identified participants who have not as yet deployed (refer Section 2 above). This staff member will

- make sure they are speaking with the right person,
- introduce themselves and where they are from,
- remind them about the MEAO Prospective Questionnaire and emphasise once again that no information provided by them has been passed onto Defence,
- note the reason for the phone call relates to some of the answers given in the MEAO Prospective Study questionnaire; and
- ask if they have time to talk and are in a private environment (if not, the staff member will arrange for the most suitable time to ring back).

The ASIST protocol suicide intervention program will then be administered. This protocol is designed to identify someone who may be at risk of suicide; respond in ways that help increase their immediate safety; understand why suicide thoughts are present and link the identified participant to further help.

In addition, to offering to follow up the initial phone conversation at a later date, information pertaining to and encouragement to contact the following support services will be provided:

- ADF ALL HOURS SUPPORT LINE
- LIFELINE
- VETERANS AND VETERANS' FAMILY COUNSELLING SERVICE
  VETERANS' AFFAIRS NETWORK (VAN)
- DEPARTMENT OF VETERANS' AFFAIRS
- NATIONAL OFFICE FOR THE MILITARY COMPENSATION AND REHABILITATION SERVICE

Identified participants will also be invited to participate in a Composite International Diagnostic Interview (CIDI) (refer to 5 below for information pertaining to the CIDI). Another time suitable for the participant, will be organised for undertaking the CIDI if required.

4. Supporting Participants Who Have Already Deployed

As discussed in section 2 above, a very small number of identified participants may have already deployed. Where an identified participant is found to have already deployed, a letter (refer Appendix A) addressed to the identified participant and marked confidential will be placed within a sealed envelope and sent to the units psychologist with instructions deliver the letter unopened. This letter is designed to:

- reassure the participant that their information has not been passed on to Defence and that the person delivering the letter is unaware of its contents,
- raise the issue/s of concern,
- encourage them to seek support; and
- provide information pertaining to the support services available to them including contacting the person who delivered the letter.

The letter will also include a return slip as well as a reply paid envelope which they will be asked to return to ensure that the letter has been received. If this reply is not received within eight weeks, a follow up letter will be sent (refer Appendix B).

5. CIDI Interviews

The CIDI, which has already been adopted by both the MEAO Census Study and Health and Well-being Survey, is recognised internationally as the gold standard for assessing mental health as well as psychiatric disorders in epidemiological settings. Administered by telephone, the CIDI will be able to assess disorders including depression, mania, panic disorder, specific phobia, social phobia, agoraphobia, generalised anxiety disorder, PTSD (in relation to their worst lifetime event and a random event), obsessive compulsive disorder and separation anxiety disorder. Clinical calibration studies have demonstrated the validity of measures collected through CIDIs (Haro, Arbabzadeh-Bouchez et al. 2006).

If an identified participant accepts an invitation to participate in a CIDI, the research staff member will:

Prior to Conducting the CIDI

- Provide verbal information to the participant about the CIDI interview including the length of the interview and the type of questions which may be asked.
- Arrange a suitable time for the participant (including after hours if requested) to undertake the CIDI. At least 24 hours will lapse between acceptance of the invitation to participate and the CIDI taking place.
- Send the participant an email containing information pertaining to the the agreed date and time of the interview.

Conducting the CIDI

Interviewers who have completed the ASIST course will administer all CIDIs. A strict protocol for administering the CIDI can be found in Appendix F. In particular, this protocol ensures that the identified participant is provided with detailed information about the process prior to commencing and that they are made aware of their right to not answer any of the questions and to cease the interview at any time. At two separate time points during the information stage of the CIDI, identified participants are specifically asked about their wish to continue with the CIDI.

Most importantly for the identified participant, CIDIs provide an opportunity for research team member trained in applied suicide intervention skills to assess the participant and if necessary provide suicide first aid and encourage them to seek further support.

Appendix A – Deployed Letter

Dear <<participant name>>

We are writing to you with regards to the MEAO Prospective Study pre deployment questionnaire which you recently completed. In particular, we noted that you had indicated that during the last 12 months you had << type in the wording of the suicide question/s marked positively on the questionnaire>>.

Having these types of feelings and concerns may indicate a need to seek additional support to ensure you are able to manage the types of stressful situations which deploying personnel are often faced with. Support can be obtained from a number of sources including:

- << insert>>
- << insert>>
- << insert>>
- << insert>>

If you would prefer to also speak with someone outside of the ADF, we can offer a confidential telephone service through the University of Adelaide. A trained health research team member can be contacted by emailing cmvh@adelaide.edu.au or alternatively phoning our free call number 1800 232 904.

We would like to emphasise that none of the information collected by the MEAO Prospective Study has been or will be passed on to any member of the ADF. However, we do need to ensure that you receive this letter. Please detach and post back the confirmation slip attached to this letter, in the reply paid envelope provided. If we do not receive a return slip we will forward to you another copy of this letter.

Thank you once again for participating in this study and we look forward to meeting up with you again in the post deployment phase.

Yours sincerely

Professor Annette Dobson
Chief Investigator
MEAO Prospective Study
Centre for Military and Veterans' Health

Appendix B – Follow up Letter

Dear <<participant name>>

Several weeks ago we wrote to you regarding the MEAO Prospective Study pre deployment questionnaire which you recently completed. In particular, we noted in that letter that you had indicated that during the last 12 months you had << type in the wording of the suicide question/s marked positively on the questionnaire>>.

We do need to ensure that you have information which can be of assistance should you require. Having these types of feelings and concerns may indicate a need to seek additional support to ensure you are able to manage the types of stressful situations which deploying personnel are often faced with. Support can be obtained from a number of sources including:

- << insert>>
- << insert>>
- << insert>>
- << insert>>

If you would prefer to also speak with someone outside of the ADF, we can offer a confidential telephone service through the University of Adelaide. A trained health research team member can be contacted by emailing cmvh@adelaide.edu.au or alternatively phoning our free call number 1800 232 904.

We would again like to emphasise that none of the information collected by the MEAO Prospective Study has been or will be passed on to any member of the ADF. However, we do need to ensure that you receive this letter. Please detach and post back the confirmation slip attached to this letter, in the reply paid envelope provided. If we do not receive a return slip we will forward to you another copy of this letter.

Thank you once again for participating in this study and we look forward to meeting up with you again in the post deployment phase.

Yours sincerely

Professor Annette Dobson
Chief Investigator
MEAO Prospective Study
Centre for Military and Veterans' Health

Appendix I

Duty of Care Abnormal Pathology Results

Protocol: Review of Pathology Results

	What	Who	When
	Notifying of Potential Pathologies		
1.	Advise Dr Horsley by email of the dates that physical testing session has been scheduled, the anticipated number of participants and the expected date of availability of pathology test.	Project Officer	As soon as advised by Defence
2.	Send two copies of the hardcopy pathology results to Project Officer.	All laboratories	As soon as available
3.	Collate one copy of each hardcopy pathology result by Study ID	Project Officer	As soon as received
4.	Send a collated hardcopy pathology results to Dr Horsley	Project Officer	Within 2 working days of receiving final path results
5.	Temporarily file one hardcopy laboratory results on participant files	Project Officer	As soon as received
6.	Review hardcopy pathology results for each individual and if the result is indicative of a clinically relevant health risk or health disorder (refer Appendix A) write a letter to the unidentified participant advising them of the result/s and further follow up.	Dr Horsley	Within 1 week of receiving
7.	Sign and date each copy of the pathology form indicating it has been reviewed. Note at the bottom of the page whether a result has been followed up either by telephone or letter.	Dr Horsley	Within 1 week of receiving
8.	Send all marked hardcopies plus letters to any participants to the Project Officer	Dr Horsley	Within 1 week of receiving
9.	Identify whether the participant is still in Australia or alternatively is on deployment	Project Officer	Within 5 working days of receiving letters
10.	Send letters from Dr Horsley to participants either at their Australian base address or deployment address	Project Officer	Within 2 working day of receiving
11.	Follow up any outstanding results not received from Dr Horsley.	Project Officer	Within 10 working days of receiving
12.	Shred the temporary hardcopy results that correspond with those returned from Dr Horsley.	Project Officer	Within 2 working days of receiving
13.	File Dr Horsley's copy of results in participant's file	Project Officer	Within 2 working day of receiving
14.	Enter date and type of letter sent onto the MIS	Project Officer	Within 2 working days of letters being sent
15.	Send a "normal results" thank you letter to physical testing participants who did not have an abnormal results	Project Officer	Within 1 week of receiving
16.	Enter date and type of letter sent to participants who did not have an abnormal result onto the MIS	Project Officer	Within 1 week of sending letter

Notifiable Results			
1.	Alert the Study Manager by phone if there is a positive result for any of the items in Appendix B.	Healthscope Business Manager	Within 12 hours of result being known
2.	Identify whether the participant is on deployment	Study Manager	As soon as results are acquired
3.	Alert Dr Horsley by telephone, providing contact information for participant	Study Manager	As soon as possible
4.	If still in Australia contact the individual by telephone to provide advice to the participant on the finding.	Dr Horsley	As soon as possible
5.	If the participant has already left Australia, provide Dr Horsley with information	Study Manager	As soon as possible
6.	Identify whether direct contact by telephone is required and if so, request contact number. Alternatively write letter to participant regarding abnormal result and recommended follow up.	Dr Horsley	As soon as possible
7.	Request either deployment contact phone number of deployment address from the SOC Administration Officer	Study Manager	As soon as possible
8.	Arrange for Dr Horsley to obtain contact phone number or send letter to the deployment address	SOC Administration Officer	As soon as possible
9.	Provide information regarding details of follow up and any recommended/actual action taken	Dr Horsley	As soon as possible
10.	Add information to the file note and organise for the file note to be put in participants file	Study Manager	As soon as possible

Agreed contact information:

Dr Keith Horsley
3 Valder Place
Farrer 2607
ACT 2607
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CC Email: keith.horsley@hsagroup.com.au

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Ms Katrina Coppock
Regional Laboratories Manager
Commerical Pathology Operations Supervisor
Healthscope Pathology SA

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Appendix A : Guidelines for Clinical Reporting of Abnormal Results Under MilHop

Sodium	< 134, > 148
Potassium	<3.3, >5.2
Chlorine	<96, >111
Bicarbonate	<20, >33
Anion Gap	<6, >18
Urea	>8.3
Creatinine	>115
eGRF	<60
Urate	>.55
Glucose	<2.9, >7.0
Calcium	<2.05, >2.60
Calcium (ionised)	<1.07, >1.27
Magesium	<0.68, >1.02
Phosphate	<0.75, >1.47
Total Phosphate	<60, >82
Albumen	<35, >50
Globulin	<20, >39
Alk Phospatate	<30, >120
Bilirubin	>50
GGTP	>75
AST	>41
ALT	>51
LD	>280
Hb	<130
RBC	<4.50, >6.50
PCV	<0.40, >0.55
MCV	<80, >99
MCH	<27, >32
RDW	<11, >15
WCC	<4.0, >11.0
Neutrophils	<2.0, >8.0
Lmyphocytes	<1.0, >4.0
Monocytes	>1.1
Eosinophils	>0.6
ESR	>15
Vit B 12	<180
RBC Folate	<575
Total Cholersterol	>6.0
HDL Chol	<1.0
LDL Chol	>3.0
Triglyceride	>1.7
LDG/HDL Ratio	NFAIR
Chol/HDL Ratio	NFAIR
Creatinine Kinase	NFAIR
Amylase	>115
Lipase	>390
Cyto IgG	NFAIR
Cyto IgM	Positive
EB IgG	NFAIR
EB IgM	Positive
Chlamydia IgG	NFAIR
Chlamydia IgA	Positive
Chlamydia IgM	Positive

H. Pylor IgG	Positive
Herpes 1 IgG	NFAIR
Herpes 2 IgG	NFAIR
Herpes 1&2 IgM	Positive
Myco IgG	NFAIR
Myco IgM	Positive
Hep C screen	Positive
Leishmania IgG	Positive
HB A1c	<6%
CRP	NFAIR
Red Cell Cholin.	NFAIR
Blood Pb	> 1.9
PCV Pb	NFAIR
Corrected Pb	>1.9
Cortisol	NFAIR
Inter 1	NFAIR
Inter 41	NFAIR
Inter 61	NFAIR
TFN	NFAIR

Note: NFAIR means Not for Action Irrespective of Result

Appendix B – Notifiable Abnormal Results

- Potassium > 6;
- Hb < 120;
- Triglyceride > 10;
- Amylase > 140;
- Lipase > 440;
- Epstein Barr IgM positive or borderline;
- Hep C screen positive or borderline;
- Leishmania IgG positive or borderline;
- Any abnormality of full blood count that might indicate a proliferative lesion; **and**
- Any other grossly abnormal result that might indicate things such as haemolysis.

Appendix J

Duty of Care Abnormal Dermatology Results

Protocol: Review of Skin Photography

	What	Who	When
	Reviewing Skin Photography and Providing Result Data		
1.	Notify Dr Jennifer Menz of anticipated post deployment physical testing schedules	Research Officer	As soon as Post deployment dates are identified
2.	Copy all pre and post deployment skin photographs for each participant to a separate file on a password protected CD/DVD (see Appendix A)	Research Officer	Within 5 working days uploading of post deployment photos
3.	Courier the password protected CD/DVD containing one file per participant of pre and post skin photography to Dr Menz	Research Officer	Within 5 working days of uploading post deployment photos
4.	Email the password to Dr Menz with date of despatch.	Research Officer	As soon as CD couriered
5.	Review pre and post skin photography and complete a Skin Photography Case Report Form for each participant (see attached)	Dr Menz	Within 10 working days of receiving CD
6.	Shred the CD/DVD.	Dr Menz	Once review completed
7.	Send completed Case Report Forms to Dr Davy at CMVH.	Dr Menz	Once review completed
8.	Review Skin Photography Case Report Forms for completeness and request any required additional information from Dr Menz	Research Officer	Within 2 working days of receiving
9.	Teleform Skin Photography Case Report Forms and send file to DMAC.	Data Manager	Within 2 working days of receiving
10.	File hardcopy of Skin Photography Case Report Form in the participant's restricted hardcopy file.	Research Officer	Within 5 working days of receiving
	Notification of Abnormal Skin Conditions which require Urgent Medical Attention		
1.	Identify any skin condition which requires urgent medical attention from photos*.	Dr Menz	Within 10 working days of receiving CD
2.	Complete the standard skin condition letter (see Appendix B) with study ID, relevant clinical information and electronic signature	Dr Menz	Within 10 working days of receiving CD
3.	Email the letter to the Research Officer.	Dr Menz	Within 10 working days of receiving CD
4.	Send letters from Dr Menz to participants either at their Australian base address	Research Officer	Within 2 working days of receiving notification

5.	File copy of letter in the participant's restricted file	Research Officer	Within 2 working days of receiving notification
6.	Enter date and type of letter sent onto the MIS	Research Officer	Within 2 working days of receiving notification

*The participant is notified of any abnormal skin conditions which are deemed to require urgent medical attention, as it is assumed that the participant will not have previously consulted a medical partitioner.

Agreed contact information:

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Appendix A – Structure of CD/DVD

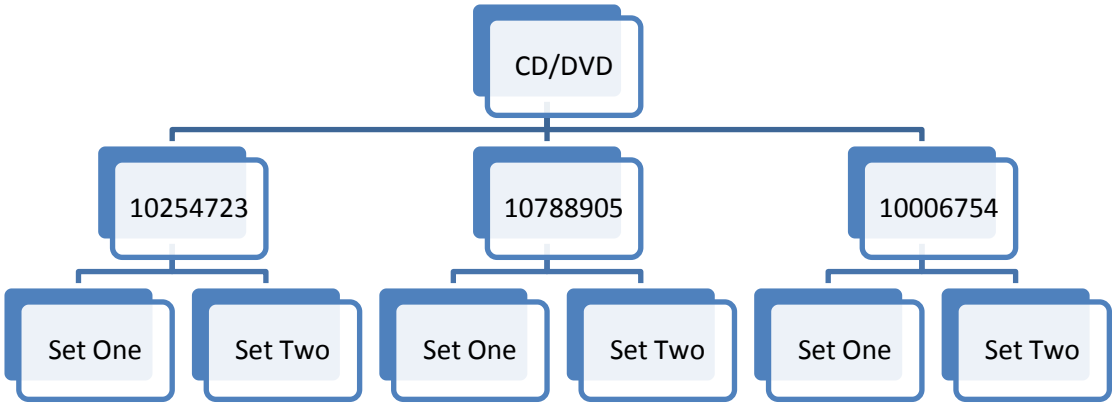
1. Photography **should only be copied to the CD/DVD once both pre and post** deployment photography has been completed.

2. A “Main Folder” for each participant should be created and labelled with their study ID.

3. Each “Main Folder” will contain two additional Sub Folders:
    - First Sub Folder should be labelled “Set One” and contain only photos for Set One as directed by the statistician (see 4. Below)
    - Second Sub Folder should be labelled “Set Two” and contain only photos for Set Two as directed by the statistician (see 4. Below)

4. **The statistician will provide a randomised list** of which photos will be applied to each Sub Folder (i.e. in some cases Set One folder will contain post deployment photos while for another participant Set One folder will contain pre deployment photos).

5. Password protect the disc prior to sending to Dr Menz.



Appendix B – Abnormal Results

<<date>>

<< address>>
<< address>>
<< address>>
<< address>>

Dear

Re: Participant ID Number << number>>

This letter pertains to the photos taken as part of the physical testing you have completed as part of the MILHOP research into the health of Defence Force members who are being deployed to the Middle East Area of Operations.

In reviewing the photograph of your <<area of photograph>> This photo indicates that << description of potential skin abnormality>>. While this may be of no concern, I strongly advise you to <<action to be taken ie consult your doctor>>.

Once again we would like to thank you for your participation in the study.

Yours sincerely

Dr Jennifer Menz
Head of Dermatology
Repatriation General Hospital
Daw Pk 5041 South Australia

Appendix K

Duty of Care Abnormal Spirometry Results

Protocol: Review of Spirometry

	What	Who	When
	Reviewing Skin Photography and Providing Result Data		
1.	Notify Assoc Professor Alan Crocket of anticipated pre- and post-deployment physical testing schedules	Research Officer	As soon as data collection dates are identified
2.	Provide Assoc Professor Alan Crocket with copy of electronic spirometry data identified only by study ID	Research Officer	Within 5 working days uploading of physical testing
3.	Review spirometry data	Assoc Prof Crockett	Within 10 working days of receiving
4.	Provide Research Officer with a list of spirometry results that can be included in the analysis	Assoc Prof Crockett	Within 10 working days of receiving
5.	Provide statistician with copy of the analysed results	Research Officer	Within 5 working days of receiving
	Notification of Abnormal Spirometry		
1.	Identify any spirometry results which need to be followed up	Assoc Prof Crockett	Within 10 working days of receiving
2.	Provide list of abnormal spirometry to the Study Manager	Assoc Prof Crockett	Within 10 working days of receiving
3.	Send letter to participant (see Appendix A)	Study Manager	Within 10 working days of receiving list
4.	File copy of letter in the participant's restricted file	Research Officer	Within 2 working days of receiving notification

Agreed contact information:

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Dr Carol Davy
Study Manager
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Appendix A – Letter to Participant

Dear <<participant>>>

This letter is about the lung function assessment, sometimes referred to as spirometry that was conducted as part of the MilHOP research into the health of Defence Force members who were being deployed to the Middle East Area of Operations.

A recent review of all lung function assessments suggests that you may have some airflow obstruction. While the assessment is not conclusive, we do recommend that you seek referral to a Respiratory Laboratory in your area for further investigation.

We would like to take this opportunity to thank you for your participation in the study. If you require any further information about your lung function assessment or any of the other tests you undertook, please do not hesitate to contact me on ph: 08 83130676 or alternatively email: carol.davy@adelaide.edu.au .

Yours sincerely

Dr Carol Davy
Research Fellow
Centre for Military and Veterans' Health
University of Adelaide