Australian Government
Department of Defence
Department of Veterans' Affairs

DEPARTMENTS OF DEFENCE AND VETERANS' AFFAIRS HUMAN RESEARCH ETHICS COMMITTEE

STANDARD OPERATING PROCEDURES

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22 May 24

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DEPARTMENTS OF DEFENCE AND VETERANS' AFFAIRS HUMAN RESEARCH ETHICS COMMITTEE STANDARD OPERATING PROCEDURES

Background: The Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC) is a joint Human Research Ethics Committee for the Department of Defence (Defence) and the Department of Veterans' Affairs (DVA).

Issued by: These procedures have been issued by the Surgeon General Australian Defence Force (Defence) and the Deputy President, Repatriation Commission, DVA.

Purpose: The procedures ensure compliance with the *National Statement on Ethical Conduct in Human Research*[1] (National Statement), the *Australian Code for the Responsible Conduct of Research*[2], the *Defence Interim Human and Animal Research Manual*[3] and other relevant legislative instruments, departmental policies and national guidelines.

The terminology used within the procedures are consistent with the National Statement.

Scope and applicability: The procedures are applicable to all Defence and DVA personnel and external stakeholders wishing to conduct research that falls within the scope and responsibility outlined in the DDVA HREC Terms of Reference.

The procedures do not provide guidance on the processes supporting the Defence People Research Low Risk Ethics Panel, the Defence Science and Technology Low Risk Panel or processes for the review of evaluation/quality assurance activities that sit within DVA's remit.

Management: The procedures are to be reviewed at least every three years from publication, or as required, to ensure ongoing compliance with national guidelines, legislative instruments and institutional policies.

In between major reviews, the issuing delegates or other departmental staff, the Committee, the Secretariat and other stakeholders, may suggest minor amendments for consideration on an ad hoc basis.

The DDVA HREC are to be consulted on proposed changes. Revisions are subject to departmental review processes and are to be approved by Defence and DVA.

Availability: The procedures are available for public release, in accordance with the National Statement.

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[1] https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023#block-views-block-file-attachments-content-block-1

[2] https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018

[3] https://www.defence.gov.au/adf-members-families/health-well-being/business-plans/ddva-hrec/resources

Policy Domain:	Human Research Ethics
Accountable officer:	Surgeon General Australian Defence Force (Defence) and the Deputy President, Repatriation Commission and MRCC, DVA
Policy owners:	Surgeon General Australian Defence Force and the First Assistant Secretary response for research, DVA
Policy contact:	Assistant Director Research Ethics[4], Defence Assistant Director Research Services[5], DVA
Cancellation:	The DDVA HREC Standard Operating Procedures replace the DDVA HREC Researcher and Administrative Guidelines.
Definitions:	Definitions that apply to these guidelines are at Annex A.

[4] ddva.hrec@defence.gov.au
[5] ethics.poc@dva.gov.au

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FOREWORD

The Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC) is registered with the National Health and Medical Research Council (EC00460) and as an Institutional Review Board (IORG0007579) with the Office for Human Research Protections in the United States.

Research proposals involving humans will be reviewed by the DDVA HREC where one or more of the following apply:

a. participants are or include Defence members, other Defence personnel (as a specific study group or sub-group), their information (data) and/or tissue

b. participants are recruited, either directly or indirectly, through a service provided by Defence or the Department of Veterans' Affairs (DVA)

c. the research is to be conducted by Defence or DVA personnel in the course of their employment

d. the research is to be conducted on/in a Defence establishment

e. the research is sponsored, endorsed or funded in any part by Defence or DVA.

Researchers undertaking research that involves ex-serving personnel as a target cohort or a study sub-group, but does not fall under the categories above, are encouraged to obtain ethical approval from the DDVA HREC in addition to any approvals required by their own institution.

The DDVA HREC will also review requests under the Special Access Scheme for the use of unapproved therapeutic goods in accordance with section 19(1)(a) of the *Therapeutic Goods Act 1989*[6].

Information on the purpose, relationship to other processes of ethical review, relationship to non-affiliated researchers, institutional accountability, mechanisms of reporting, remuneration of members and fees for ethical review, is outlined in the DDVA HREC Terms of Reference[7].

[6] http://www.austlii.edu.au/au/legis/cth/consol_act/tga1989191/
[7] https://www1.defence.gov.au/sites/default/files/2020-08/DDVA_HREC_Terms-of-Reference.pdf

APPLICATIONS FOR ETHICAL REVIEW

When should I seek ethical review from the Departments of Defence and Veterans' Affairs Human Research Ethics Committee?

1. The Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC) is responsible for reviewing research that is in scope under its Terms of Reference and:

a. higher risk

b. requires full Human Research Ethics Committee (HREC) review in accordance with *the National Statement on Ethical Conduct on Human* Research[8] as follows:

   i. Chapter 4.1: Women who are pregnant and the human fetus

   ii. Chapter 4.4: People highly dependent on medical care who may be unable to give consent

   iii. Chapter 4.5: People with a cognitive impairment, an intellectual disability, or a mental illness

   iv. Chapter 4.6: People who may be involved in illegal activities

   v. Chapter 4.7: Aboriginal and Torres Strait Islander Peoples

   vi. Chapter 4.8: People in other countries

   vii. Paragraph 2.3.4: involves the active concealment, planned deception or aims to expose illegal activity

   viii. Paragraph 2.3.9: seeks a waiver of consent for research using personal information in medical research, or personal health information.

c. lower risk research that does not fit within the remit of the Defence People Research Low Risk Ethics Panel or the Defence Science and Technology Low Risk Ethics Panel.

2. Approval from the DDVA HREC must also be sought for the use of new unregistered items in accordance with the *Therapeutic Goods Act 1989* (Therapeutic Goods Act)[9], as detailed in the *Defence Health Manual* Volume 2 Part 15 Chapter 6.

Applications that can be reviewed under other pathways

3. Defence and DVA have established mechanisms for expedited review of lower risk research and quality assurance/evaluation activities. Further information is provided in paragraphs 34 and 35 – and paragraph 42 respectively.

Risk profiles of research

4. Risk in research exists on a continuum with the risk profile of an individual research project falling somewhere falling along this continuum, as outlined in the National Statement. Figure 1 below, describes the risk profile of research.

[8] https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023
[9] http://www6.austlii.edu.au/cgi-bin/viewdb/au/legis/cth/consol_act/tga1989191/

Figure 1: Risk profiles of research

Lower risk		**Higher risk**	
Minimal	**Low**	**Greater than low**	**High**
No risk of harm or discomfort; potential for minor burden or inconvenience	No risk of harm; risk of discomfort (+/- foreseeable burden)	Risk of harm (+/- foreseeable burden)	Risk of significant harm (+/- foreseeable burden)

New applications

5. Applications are deemed to be 'new' when the:

a. research proposal has not previously been considered by the DDVA HREC

b. original research proposal submission was not approved by the DDVA HREC and resubmission has been delayed by three months or more

c. original research proposal was not approved and significant revision was requested.

6. When drafting a new application for consideration by the DDVA HREC, researchers are encouraged to allow adequate time in their project timeline for ethical review. The majority of new applications will require at least one resubmission and this should be factored into project timelines.

7. The process for submitting new applications to the DDVA HREC, including the pro forma, supporting templates and additional guidance is available on the DDVA HREC website[10].

8. For PhD or other student research, the DDVA HREC requires that the first listed Principal Investigator is the primary supervisor, as they are responsible for guiding and supporting the research from conceptualisation to dissemination of findings[11]. Applications involving student researchers are to:

a. ensure that the mechanisms in place for supervision are clearly outlined

b. include evidence of confirmation of candidature in the supporting documentation provided for ethical review.

9. Research proposals are to be clear, detailed and written in plain language. All technical terms and acronyms are to be explained in simple language and technical jargon is to be avoided. Further information regarding drafting an application is available in the 'Drafting an ethics application Fact Sheet' (see DDVA HREC website).

10. Participant Information Sheets and Consent Forms are to be written in plain language that is easy to understand and is phrased in a manner that is easily understood by the research participants. Participants are to be advised of points of contact for complaints or concerns about a research project. This is to include a contact/s on the research team and indicate that they alternatively may wish to contact the DDVA HREC (refer to the Participant Information Sheet and Consent Form template for further guidance).

[10] https://www.defence.gov.au/adf-members-families/health-well-being/business-plans/human-research-ethics-committee
[11] https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018

11. The Principal Investigator is to ensure that all relevant documents are attached to the application. Examples of supporting documentation are provided on the Project Description template.

Defence specific requirements

12. For research conducted by or involving Defence personnel (or their data), evidence of Defence organisational support and command approval must be obtained prior to submission to the DDVA HREC. Further information is available in the *Defence Interim Human and Animal Research Manual* and the DDVA HREC Facts Sheets on Organisational Support and Command Approval (see DDVA HREC website).

13. Defence, through Joint Health Command, holds a Federal Wide Assurance in regard to human subject research protection for international collaboration with the United States. Any reliance on this Assurance requires reporting to Assistant Director Research Ethics via ddva.hrec@defence.gov.au.

Department of Veterans' Affairs specific requirements

14. For research recruiting participants through DVA programs or services, or using DVA data, the researcher will need to obtain approval from the relevant DVA program manager and/or data custodian (Senior Executive Service (SES) Band 1 or above) prior to commencing the research. Ethics approval from the DDVA HREC can be sought first, but does not guarantee or replace relevant DVA program and/or data custodian approval. Researchers wishing to use DVA data or recruit participants through DVA should discuss their plan with DVA before submitting their ethics application. DVA will generally only assist with recruitment of study participants for research commissioned by the department.

Submission closing dates

15. For applications that require full HREC review, completed applications are to be submitted electronically by the submission closing date, as indicated in the DDVA HREC website. Late applications will not be accepted unless the investigator has negotiated a late submission with the Chair/Deputy Chair (via the Secretariat).

16. Researchers are encouraged to submit their applications in advance of the submission closing date, where possible. Submission of an application early will ensure that there is sufficient time for the Secretariat to conduct an administrative review of the application and allow applicants to address the feedback prior to the application being circulated for ethics review.

17. Applications for research that does not require ethical review by the full HREC (lower risk research, quality assurance/evaluation activities and applications for mutual recognition) are not subject to meeting dates or submission deadlines, so can be submitted at any time.

Receipt and administrative review of applications

18. Upon receipt of a new application (regardless of the review pathway), the application will be checked by the Secretariat for the following:

a. the application is submitted on the correct pro forma

b. identify incomplete responses, deviations from policy and inconsistencies between the application and supporting documentation

c. that the application is clear and comprehensive

d. all signatures are included in the application (electronic signatures are acceptable)

e. the relevant governance approvals (evidence of Defence organisational support and command approval, where appropriate) have been provided

f. all supporting documentation has been provided, including but not limited to curriculum vitae for all research personnel, recruitment materials, Participant Information Sheet and Consent Form, surveys, interview/focus group outlines, standardised measures

g. version details have been included on all relevant documents.

19. Administrative reviews should be conducted within three business days. Where there are anticipated delays, this should be communicated to the point of contact. Where minor administrative amendments are identified, the applicant will be asked to provide an updated application and/or additional information within a specified timeframe, in order for the application to be included on the upcoming meeting agenda or circulated for ethical review pathways.

20. Incomplete/invalid applications will be returned to the applicant and they are to be advised in writing:

a. the reasons why the application, as submitted, is invalid

b. that the application will require amendment and/or further documentation prior to being tabled for ethical review

c. for applications that require full HREC review, a date for the updated application to be submitted if it is to be tabled for consideration at the next scheduled meeting.

21. Upon receipt of a complete application the Secretariat will:

a. assign the application a unique identification (project) number

b. file all relevant correspondence in Objective in a project file

c. enter all relevant information into SharePoint

d. send an email to the point of contact acknowledging receipt of the application

e. advise on the review pathway.

Ethical review of applications

22. Complete applications (that require full HREC review) will be included on the agenda for the next scheduled meeting, subject to receipt of the application by the submission closing date.

23. If a large number of applications are received for review at any one meeting, some applications may be held over to the following DDVA HREC meeting. If this occurs, prioritisation will occur at the discretion of the Chair or Deputy Chair.

24. Once papers have been circulated to members, the applicant is unable to make any revisions to the documentation.

25. Where there is an operational imperative to do so, an application may be circulated for out-of-session consideration by the minimum membership (as per the National

Statement) or an extraordinary meeting may be convened at the discretion of the Chair or Deputy Chair. The Defence Health Graduate and/or contemporary veteran member(s) should also be provided with application where the study relates to their categories of membership (for example, if the study does not fall within Defence's remit, the application does not need to be provided to the Defence Health Graduate). Requests for out-of-session review are not justifiable solely on the grounds that the project will not meet deadlines. Applicants are responsible for ensuring the timely submission of their application for ethics review.

26. A summary of any new applications considered out-of-session by the full committee is to be included under Matters for Noting at the next scheduled meeting. The Secretariat should refer to the 'Matters for Noting' template for further guidance on what information is to be provided within the summary.

27. Where an application involves ex-serving members, DVA clients or their data, the application will be provided to the point of contact at DVA to facilitate the necessary reviews. Applications are to be provided to DVA no later than 10 business days prior to the meeting (except where the Chair has approved the late inclusion of an agenda item). Advice on the outcome of these reviews will be provided to the committee at the relevant meeting for their consideration.

28. The Committee may seek advice from subject matter experts about study proposals that are outside of the committee's knowledge base. Applications may also be discussed with other directorates within Defence and/or DVA if there is an operational requirement to do so.

29. Where advice is sought external to the Committee, the reviewers are to disclose any conflicts of interest and are to ensure confidentiality of applications is maintained.

30. The Committee are not able to grant retrospective approval of a research project once it has commenced, as per the National Statement.

Unregistered Therapeutic Substances and Medical Devices

31. The DDVA HREC will review requests for the use of new unregistered items, as required under the Therapeutic Goods Act. Applications are to be tabled for review by the minimum membership (as per the National Statement) and the Defence Health Graduate.

32. If supported, the Secretariat (on behalf of the DDVA HREC) will raise an approval letter, to be signed by the Chair, and provide this to the Director Health Materiel Logistics and Pharmacy, Defence. The Secretariat will also raise and forward an approval letter covering the original request to the Surgeon General Australian Defence Force (SGADF) (with a copy to the Director General Operational Health (DGOH)). If the request is not supported, the Secretariat will raise a letter of notification to the originating Commander (with a copy to DGOH).

Review of lower risk human research and quality assurance activities

33. Defence has established the Defence People Research Low Risk Ethics Panel and the Defence Science and Technology Low Risk Ethics Panel, for the review of lower risk research and quality assurance activities. Further information is available in the Defence Interim Human and Animal Research Manual and the DDVA HREC Terms of Reference (both are available on the DDVA HREC website).

34. DVA has established an internal ethics review process for DVA program quality assurance/evaluation activities. If the activity also fits within the remit of Defence, it is not eligible for the DVA process. Further information is available via ethics.poc@dva.gov.au.

35. Where lower risk research or quality assurance/evaluation projects are outside of the remit of the panels or processes listed above, applications will be considered out-of-session by the Chair and/or Deputy Chair and the Secretariat. The application may be forwarded to other members or subject matter experts for review and/or advice as determined appropriate by the Chair or Deputy Chair.

36. Where required, the Secretariat may need to schedule a teleconference with reviewers to discuss applications. Where this occurs, notes summarising the key points raised during the discussion are to be taken and filed in the corresponding project file.

37. Where the application involves ex-serving members or their data, the application will be provided to the point of contact at DVA to facilitate the necessary reviews, with a 10 business day turn around (unless negotiated otherwise).

38. Where reviewers deem the research requires review by the full HREC (as outlined in paragraph 1a and 1b, the application is to be tabled at the next available DDVA HREC meeting.

39. An update on all new applications that were considered out-of-session is to be included in the upcoming DDVA HREC meeting agenda.

Minimising duplication of ethical review/ mutual recognition

40. Defence and DVA recognise that researchers will often need to approach multiple ethical review bodies to obtain ethical approval of their research, for example, when conducting research through a university or hospital that is also in scope for the DDVA HREC. Researchers whose projects fall under the auspices of multiple institutions should engage with the administrators of the relevant ethical review bodies to determine if full ethical approval is required for research that has been granted ethics approval by the DDVA HREC.

41. The DDVA HREC is able to consider accepting the outcome of ethical review body under mutual recognition pathways in accordance with National Statement Chapter 5.5 where:

a. the research does not involve the active participation of Defence personnel

b. the study is funded by Defence however research participants are external to the department

c. the study is not funded by DVA or recruiting participants through a DVA service or program, or if it is, the relevant program manager agrees in writing that ethics review from another institution is acceptable

d. if the study is using DVA data, the research organisation responsible is a Commonwealth Accredited Integrating Authority.

42. Where an application is submitted for review under mutual recognition pathways, the Chair or Deputy Chair will review the application to ensure that any Defence or DVA specific considerations have been sufficiently addressed. This may include but is not limited

to ensuring the relevant governance approvals being obtained. They may determine the following:

a. acceptance of the outcome of the ethical review

b. in principle support of the approved study, subject to minor changes

c. submission for review by the DDVA HREC or another Defence ethical review body is required.

43. Applications that are submitted for mutual recognition are to include all of the documentation that was approved by the primary ethical review body and a copy of the letter/correspondence advising that ethical approval has been granted.

44. Where the application involves ex-serving members or their data, the application will be provided to the point of contact at DVA to facilitate the necessary reviews, with a 10 business day turn around (unless negotiated otherwise).

45. An update on any matters considered under mutual recognition pathways is to be included in the upcoming DDVA HREC meeting agenda.

46. The approving ethical review body is the primary body responsible for the ongoing monitoring of the research. Copies of any reports/amendments submitted to and approved by the approving ethical review body should be submitted to the DDVA HREC. In some instances, additional information and/or governance approvals from Defence and/or DVA may be required.

Resubmissions

47. The Chair/Deputy Chair, in consultation with the Committee/reviewers (for activities that do not require full review), is to determine if resubmissions require review:

a. at a scheduled meeting by the full HREC

b. out-of-session by the full HREC

c. out-of-session by the Chair/Deputy and/or other members

d. out-of-session by the Secretariat.

48. A resubmission may consist of a revised Project Description, supporting documentation or provision of further information. Changes are to be clearly highlighted in the updated documents using Microsoft Word™ track changes or similar function and version control details should be updated on all relevant documentation. Responses are to be accompanied by a covering letter. Where changes are minor in nature, a response via email may be appropriate. If there are revisions made in addition to those raised during the ethical review process, the Chair or delegate, may advise that the application is to be withdrawn and a new application is to be submitted.

49. Resubmissions requiring full HREC review are to be submitted by the submission closing date. All resubmissions must be signed by all relevant personnel. Failure to obtain signatures on resubmitted applications may result in a delay processing of the response. Dates for resubmissions requiring full HREC review are available on the DDVA HREC website.

50. Resubmissions that do not require review by the full HREC will be circulated for out-of-session consideration by the nominated individuals to determine the ethical acceptability

of the response. A summary of any out-of-session resubmissions is to be provided as part of the next scheduled meeting agenda.

51. When submitting a resubmission it is important that the Principal Investigator ensures that dates and version control numbers are updated on all relevant documentation. Failure to update these may delay consideration of the response.

Withdrawal of applications

52. An applicant can withdraw their application at any time prior to ethical approval being granted by informing the Secretariat via email.

53. An application is deemed to be withdrawn when a response to a request for further information has not been received within three months (or two meetings, whichever is greater) and an extension has not been approved by the Secretariat. Any future submissions for the study will be treated as a new application.

Confidentiality

54. Researcher contact details are not provided to third parties. Whenever a third party requests details, the Secretariat will contact the researcher and provide details of the third party. The researcher can then, if agreeable, contact the third party directly.

Methods of decision-making

55. The DDVA HREC will try to reach decisions by general agreement. This need not involve unanimity, but failure to achieve agreement may require an extension of time for further consideration of the application and/or a request for additional information.

Outcomes of ethical review

56. Upon review of an application, any one of the three outcomes indicated below is available to the DDVA HREC:

a. **The project is approved.** This means that the protocol conformed to all the necessary requirements, the DDVA HREC is satisfied that the research is ethical and can be conducted as detailed in the submission. A letter stating that the research has been approved will be sent to the researcher. A Principal Investigators Assurance form will be enclosed for the principal investigator(s) signature and return.

b. **The project is not approved and a resubmission is requested.** A letter will be sent to the researcher explaining why the study was not approved and provide details on any amendments or issues that should be addressed in a resubmission. If the relevant documentation is not resubmitted within three months of the date of the outcome letter, a complete new application will need to be submitted. Where the amendments required are substantial, researchers must note that the committee may insist on reconsidering the protocol resubmission during a subsequent formal meeting. Resubmissions where the amendments are not substantial may be reviewed out-of-session by the Chair, Deputy Chair or other delegates. Minor amendments that do not affect the substance of the protocol may be approved by the Secretariat.

c. **The project is not approved and a resubmission is not requested.** This will occur where a research proposal is judged to be fundamentally flawed on ethical

grounds. A letter will be sent to the researcher explaining why the study was not approved. Any subsequent submission would be subject to the same process as the original submission.

57. Outcome letters are to include reference to relevant guidelines and/or legislative instruments where appropriate.

Duration of ethics approval

58. Ethics approval can be granted for a period of up to five years from the date of the approval letter. Ethics approval is to remain current whilst data analysis and report writing and academic publications are being undertaken. Dates for the period of ethical approval are to be included in the ethical approval letter. If a project is to extend beyond this date, the Principal Investigator will need to apply for an extension to the period of ethical approval, prior to the expiration of the current period of ethical approval. If an extension is not received, all research activities should cease.

59. A desktop audit should be conducted prior to an extension being granted. Where an audit has previously been conducted and there are no further concerns that would require an audit to be conducted, an additional audit is not required. Each extension is not to exceed five years. A shorter extension may be granted where there has been a lack of progress with the study or where a desktop audit has identified other concerns.

Record keeping

60. The Secretariat will maintain an electronic record of all applications that have been submitted for consideration on the Defence Protected Network, in accordance with the Defence Records Management Policy[12]. Project files are held securely within the electronic filing system on the Defence server. Access is limited to those who require access to the files because the information contained therein is intrinsic to the conduct of their role.

61. An electronic folder is to be raised for all applications. Each complete application will be assigned a unique project number. Incomplete applications are to be filed in a prospective study folder in the corresponding year and allocated a project number upon receipt of missing documentation.

MEETINGS

Frequency of meetings

62. The DDVA HREC will meet up to ten times per year. Meetings commence in February of each year. Extra meetings may be scheduled as required.

63. The meeting schedule is developed at least six months in advance and is to be developed in consultation with members. Where necessary, meeting dates may need to be adjusted in order to ensure quorum is obtained for each meeting. The schedule should specify the meeting date, new application submission date and resubmission closing dates.

64. The closing dates for applications should be no earlier than 20 business days (new applications) and no later than 15 business days (resubmissions and other items requiring

[12] http://drnet.defence.gov.au/AssociateSecretary/Web-Records-Digital/Records-Management/Pages/Records-Management.aspx

full review) prior to the meeting. Due to stand down periods, this may need to be adjusted for meetings that are scheduled in February of each year.

65. Once the dates have been finalised, they are to be included on the DDVA HREC website.

Roster

66. The Secretariat will develop a roster based on member availability. The roster is to ensure that the requirements outlined under National Statement are met. The roster may need to change based on member availability, changes to membership and/or the types of application tabled for review at a specific meeting.

67. The Secretariat should:

a. ensure that members are asked to advise of their availability for the following calendar year by the end September in the preceding year

b. finalise and send the roster for the following calendar year to members by end October.

Meeting agendas and papers

68. For scheduled meetings, the Secretariat is to prepare the draft agenda within five business days of the submission closing date. Meeting papers are to be collated and distributed to members no later than ten business days prior to the scheduled meeting. A copy of the agenda is also to be provided to institutional delegates, as per the DDVA HREC Terms of Reference.

69. Meeting papers will be made available electronically to members. Hard copies will be provided only by exception.

70. The Chair will consider inclusion of late agenda items on a case-by-case basis.

Attendance of Committee members at meetings

71. The Chair will attend meetings in person, where possible. Other members may attend via video or teleconference.

72. The Chair, via the Secretariat, is to be notified of any planned absences a minimum of four weeks in advance of a scheduled meeting.

73. Where an alternate member is not available to attend, the absent member is to provide feedback on the tabled agenda items and return it to the Secretariat at least three business days prior to a scheduled meeting.

74. The Secretariat will maintain a list of how many members in each category of membership attended each meeting for public distribution. Names of individual members who attended or provided out-of-session comment will not be disclosed without the consent of members.

Attendance of people other than members at meetings

75. Staff from Defence and DVA will be invited to attend meetings as observers. They may provide advice on Defence or DVA specific requirements as required; however, they do not form part of the decision making process of the committee. Attendance of external observers will be considered by the Chair and/or Deputy Chair on a case by case basis.

76. The Chair is to approve the attendance of observers at a meeting. Observers are to ensure that any matters that they are privy to as part of the deliberations of the committee remain confidential.

77. Where an observer identifies a potential or actual conflict of interest with an agenda item, the observer is required to declare the conflict. See paragraphs 125 - 141 for further information regarding declaration and management of conflicts of interest.

Attendance of investigators at meetings

78. Investigators may be invited to present their applications at a meeting.at the discretion of the Chair. This may be done either in person or remotely.

79. Where investigators attend meetings, they are able to present the application and answer questions that the Committee may have however; they are not to be present whilst Committee members provide specific feedback on the application.

Conduct and structure of meetings

80. The Chair may decide to cancel a meeting if the minimum membership cannot be met and if, in their view, this would compromise the committee's ability to fulfil its duties under the National Statement. Where there is less than full attendance, the Chair must be satisfied before a decision is reached that those who are absent have had the opportunity to have their views considered.

81. Meetings may also be cancelled where there are no complete applications (including resubmissions) for consideration by the DDVA HREC by the relevant closing date.

82. In order to ensure confidentiality and open discussion of agenda items, meetings will be scheduled in a secure meeting room. Meeting room details will be provided on the meeting agenda. Where meetings are held out-of-session or remotely, those dialling into the meeting are to ensure that the location that they are dialling in from is appropriate for ensuring the confidentiality of the discussions.

83. Meetings are scheduled to last for three hours. If all agenda items have not been considered within the allocated time, the following options are available:

a. the meeting may continue until all items have been completed

b. out-of-session review of specific items may be requested

c. an additional meeting may be scheduled.

84. In the latter case, the additional meeting should occur within five business days.

Preparation of meeting Minutes

85. The Secretariat is responsible for drafting the meeting Minutes as soon as practicable after a scheduled meeting. The Minutes are to be filed electronically in the corresponding meetings folder.

86. Meeting Minutes are to include the following:

a. a summary of relevant discussions

b. a record of decisions made

c. the receipt of written comments by absent members, subject matter experts or DVA

d. reference to relevant guidelines and/or legislative instruments where appropriate.

87. In recording the Minutes, comments are not to be attributed to individual members, except for in circumstances where the individual has expressly asked that their comment be recorded.

88. Once the Minutes are drafted they are to be provided to the Chair for clearance. Cleared Minutes are to be emailed to members by the Secretariat. A copy of the Minutes will also be recirculated to members as part of the subsequent meetings agenda package for ratification.

89. The Minutes of each meeting are to also be provided to departmental delegates in accordance with the DDVA HREC Terms of Reference.

MONITORING OF APPROVED PROJECTS

90. The Principal Investigator is responsible for ensuring ongoing compliance with the conditions of ethical approval. Templates for submission of the various activities outlined below are available on the DDVA HREC website[13]. Table 1: Monitoring activities and timeframes identifies the various monitoring activities and timeframes for submission of the relevant reports:

[13] https://www.defence.gov.au/adf-members-families/health-well-being/business-plans/human-research-ethics-committee

Table 1: Monitoring activities and timeframes

Description	Timeframe
Amendments	Prior to implementation
Adverse events	30 calendar days
Serious adverse events	72 hours
Deviations	As soon as possible
Complaints	72 hours (where the complaint may affect the ongoing viability of the study) 30 calendar days for all other complaints
Progress Reports	
- short term projects (less than 18 months)	Half way
- clinical trials	every six months
- other research	at least annually
Final Reports	Upon completion or abandonment (see paragraph 116 for further guidance)

Amendments

91. Prior to implementation of any amendments to an approved project, the Principal Investigator must seek ethical approval of the amendments from the DDVA HREC. An Amendment Form is to be submitted along with any supporting documentation (eg copies of surveys, updated Participant Information Sheet and Consent Form, curriculum vitae for any additional research personnel). The request for amendment is to be signed by the first listed Principal Investigator, as they have the overall responsibility for the conduct of the research.

92. For projects that are approved under mutual recognition pathways, the request for amendment is to be approved by the primary ethical review body first. A copy of the amendment and approval letter/correspondence are to be submitted to the DDVA HREC.

93. When submitting a request for amendment/s it is important that the Principal Investigator ensures that dates and version control numbers are updated on all relevant documentation. Failure to update these may delay consideration of the amendment.

94. Project amendments will initially be considered out-of-session by the Chair, Deputy Chair or Secretariat. Where it is deemed appropriate, other members may be asked to review amendments out-of-session or the Chair/Deputy Chair may request that the amendment be submitted to the full HREC at the next scheduled meeting. Minor amendments that do not affect the substance of the protocol (eg spelling mistakes, addition or removal of research personnel, amendments to recruitment materials or extensions to the period of ethical approval) may be approved by the Secretariat (at the Australian Public Service (APS) 6 (or equivalent level) or above). If the Secretariat has concerns about approving requests for amendments that they have the delegation to approve, the Chair or Deputy Chair should be consulted. Refer to Annex B: Amendments for further guidance on delegations and actions for project amendments.

Adverse and Serious Adverse Event Reports

95. Researchers have a significant responsibility in monitoring research as they are in best position to observe any adverse events. A report detailing the event details and the implications for the research is to be submitted to the DDVA HREC within 72 hours for

serious adverse events and 30 days for adverse events. For research that is approved under mutual recognition pathways, a copy of the documentation submitted to primary ethical review body and the outcome of their review is to be submitted to the DDVA HREC as soon as possible.

96. For research involving Defence personnel and/or their data, researchers should also be mindful of the requirements to notify those who have provided research governance authorisation (research sponsors and those who have granted command approval) in accordance with the Human and Animal Research Manual.

97. For research that has recruited participants through a DVA service or program, notification of an adverse or serious adverse event should likewise be provided by the researcher to the relevant DVA program manager (taking care not to identify any individual participants). This should occur once the DDVA HREC written advice of the outcome of the review of the event/s has been received, or sooner if the researcher considers it appropriate.

98. Upon receipt of an adverse or serious adverse event report, the report will be forwarded to the Chair, or the Deputy Chair, who shall determine the appropriate course of action, which may include:

a. notation of the occurrence

b. increased monitoring of the project

c. request for amendment to the protocol or supporting documentation

d. a request for additional information

e. suspension of ethical approval

f. termination of ethical approval.

99. Where appropriate, additional advice may be sought from other committee members and/or subject matter experts.

100. The Principal Investigator will receive written advice of the outcome of the review of the event/s and the course of action. Additionally, the committee will receive a copy of the report and an update on the outcome of the review at the next scheduled meeting.

Deviations

101. Any deviations from the approved project must be notified to the DDVA HREC as soon as possible and documented in the protocols progress and final reports. For projects approved under mutual recognition pathways, a copy of the report and outcome of review by the primary ethical review body are to be submitted to the DDVA HREC.

Complaints or concerns regarding the research

102. The Principal Investigator is to:

a. advise the DDVA HREC (via the Secretariat) within 72 hours, in writing (there is not a template for this), of any complaints regarding the ethical conduct of the research

b. advise the DDVA HREC, in writing, of any other complaints within 30 calendar days

c. include a summary of the complaint and the outcome in the projects next progress/final report.

103. The Secretariat will consult with relevant representatives from Defence and/or DVA, where appropriate, and will aim to resolve the complaint in the first instance. If this is not possible, the complaint may be put to the Chair or Deputy Chair for consideration and resolution. The committee is to be advised of the complaint at the next scheduled meeting.

104. Where a complaint is made against a researcher, or against the way in which a study is being conducted it may be necessary to suspend the research pending resolution of the complaint. Depending on the nature of the complaint, it may also be necessary to withdraw ethical approval from the project temporarily until the matter is resolved, or permanently if significant problems are identified.

Progress Reports

105. The Principal Investigator is required to submit progress reports for the lifespan of the project. The frequency of reports is outlined below:

a. every six months for clinical trials

b. at the half way mark for studies whose duration is less than 12 months

c. at least annually for all other approved projects.

106. The DDVA HREC can increase the frequency of reporting for studies where it is considered necessary. Any changes to the scheduled reporting requirements, will be advised to the Principal Investigator.

107. For projects approved under mutual recognition pathways, copies of progress reports that were submitted and approved by the primary ethical review body are to be provided to the DDVA HREC. A copy of the notification of approval of the report should also be provided. The frequency of reporting for these studies should be aligned with the primary ethical review body's requirements however; the frequency should not exceed 12 month intervals.

108. For all active projects, the Secretariat will email a reminder to the Principal Investigator regarding the submission of the progress report approximately one month prior to the due date.

109. The Progress Report is to be signed by the first listed Principal Investigator as they have overall responsibility for the conduct of the research.

110. Upon receipt of a progress report, the Secretariat will review the report against the project file and either request further information or advise the Principal Investigator that no further action is required. Where significant concerns are raised the report will be forwarded to the Chair or Deputy Chair. At their direction, the matter will be included on the next meeting agenda or circulated to members for out-of-session consideration.

111. Random audits of progress reports may also be conducted by the Chair or Deputy Chair.

112. Progress reports are to be a standing agenda item and an update on received and outstanding reports is to be included at each DDVA HREC meeting. Members may request copies of individual reports.

113. Failure to submit a progress report may result in ethical approval being withdrawn.

Audits

114. The DDVA HREC or their delegate may conduct random inspections of research sites and review their study documentation. The Principal Investigator and/or point of contact will be contacted by the Secretariat to schedule a mutually convenient time within a four-week period for the audit to be conducted. A summary of the outcome of the audit will be provided to the Principal Investigator and point of contact in the first instance and should identify any areas that require provision of additional information/supporting documentation and/or matters for addressing. The report is to also identify a timeframe in which any outstanding matters are to be addressed. A copy of the report is to be tabled at the next scheduled meeting following finalisation of the report.

115. Additionally, desktop audits (either for cause or random) of project files will be conducted periodically to ensure completeness of applications and compliance with the approved protocol and any conditions of ethical approval. Where the audit raises areas for concern that require consideration by the DDVA HREC, the committee will be asked to consider the findings either out-of-session or at the next scheduled meeting (depending on the urgency of the findings). Where appropriate, consideration of the findings may be delegated to the Chair, Deputy Chair or another member. If minor administrative matters are identified, the Secretariat are to email the Principal Investigator and/or the point of contact and request clarification and/or missing documentation in order to finalise the audit.

Final Reports

116. Researchers are required to submit a final report at the completion (all data analysis, report writing and publications are finished) or abandonment of their project. Failure to submit a final report will result in a notation made on the file indicating non-compliance with monitoring obligations and advice of non-compliance being sent to the research sponsor/s and/or head of organisation/s. The Final Report that is submitted to the DDVA HREC is not the same as the report that is submitted to research sponsor/s.

117. Where research has been abandoned, researchers should where possible, ensure that participants are advised that the research has been abandoned.

118. Upon receipt of a final report, the report will be reviewed by the Secretariat on behalf of the Committee. Where significant concerns are raised, the report will be forwarded to the Chair or Deputy Chair for review. Where necessary additional information will be requested prior to closure of the file.

119. Notification of submission of final reports will be included as a standing item on the meeting agenda. Members will be provided with a copy of final reports at their request.

Finalisation of files

120. Project files will be finalised when a research project is completed, abandoned, withdrawn or when no correspondence has been received from the researchers within the preceding 12 months. Finalisation means that the project is removed from the active project list and no further action is taken by the Secretariat regarding that file.

121. Researchers will be notified in writing when a file is finalised. If the researcher wishes to resume the project at a later date, the file may be reactivated upon agreement from the Chair.

122. In the case of no correspondence having been received for 12 months, a finalisation letter will be sent to the researcher at the last known address and a letter will be sent to the Departmental sponsor/s and/or commander/s responsible for the study participants (where applicable). Where the project is approved under mutual recognition pathways, the primary ethical review body is to be included on the correspondence.

Withdrawal of ethical approval

123. Where the committee has deemed that circumstances have arisen that prevent ongoing ethical approval of the research project being maintained, it may recommend that ethical approval be withdrawn. Circumstances for this decision may include, but are not limited to:

a. significant deviation or multiple deviations from the approved protocol

b. failure to comply with the conditions of ethical approval

c. failure to submit a progress report

d. upon receipt of a complaint where significant concerns about the ongoing ethicality of a project have been raised upon notification of an adverse or serious adverse event.

124. When this occurs the committee will inform the Principal Investigator, the investigator's home institution and, where appropriate, the relevant Departmental sponsor/s and commander/s who are responsible for Defence personnel who are participating in the research in writing of the decision to withdraw ethical approval and any circumstances under which ethical approval may be reinstated. Where the project is approved under mutual recognition pathways, the primary ethical review body is to be included on the correspondence.

125. Where ethics approval is withdrawn, no further analysis of data or publication of findings is to occur.

CONFLICTS OF INTEREST

A conflict of interest exists in a situation where an independent observer might reasonably conclude that the professional actions of a person are or may be unduly influenced by other interests. The perception that a conflict of interest exists is a serious matter and can raise concerns about the integrity of individuals or the management practices of the institution, potentially undermining community trust in research – *Disclosure of interests and management of conflicts of interest: A guide supporting the Australian Code for the Responsible Conduct of Research.*

126. Conflicts of interest can include but are not limited to:

a. financial interests or any other relevant direct or pecuniary interest

b. working and personal relationships

c. affiliations or associations with any organisations or activities which could reasonably be perceived to be an influence

d. any other influences which might reasonably be considered likely to affect or lead to the perception by others that the judgement of the individual is/ may be compromised.

127. It is important that those involved in the conduct and review of research declare conflicts of interest in a timely manner.

Researchers

128. Researchers should establish transparent processes to identify and manage actual and potential conflicts of interest. A researcher is to disclose any actual or potential conflicts of interest, including financial or other interest or affiliation, that bears on the research at the time of the application or as they arise during the active life cycle of the research project.

129. Where an actual or perceived conflict of interest is identified, the researchers should include detail about how the conflict of interest will be managed.

130. Where there is a conflict of interest for one of the researchers, the Committee may require:

a. an appropriate individual be involved in overseeing all or some of the research

b. that the researcher undertake a different role in the research or remove themselves entirely

c. disclosure of the interest to research participants

d. disclosure of the interest when publishing or presenting the research.

131. Researchers should update any disclosures of interest as circumstances change, and at least annually while the research remains while the research remain active.

Committee members

132. Members are to declare their conflicts of interest:

a. on appointment or reappointment

b. annually (by 1 July of each year)

c. on an adhoc basis, as required (eg at meetings or where members are asked to consider items out-of-session).

133. Failure to disclose a conflict of interest may result in termination of appointment to the Committee.

Subject Matter Experts

134. Where subject matter experts are asked to provide advice on an item for consideration by the Committee, they should be asked to declare any actual or perceived conflicts of interest in writing. Any conflict of interest should be advised to the Chair or Deputy Chair is to determine the appropriate course of action.

At meetings

135. The presence of individuals who have a conflict of interest/s with tabled agenda items during the deliberation of that item, inhibits the ability of the Committee to objectively deliberate the corresponding agenda item. Committee members, the Secretariat and any observers are to advise of any actual or perceived conflicts of interest as soon as practicable during the DDVA HREC meeting. Their disclosure should indicate the nature of the conflict of interest and which agenda item it relates to.

Out-of-session review

136. Where applications are circulated for out-of-session review, the reviewers are to be asked to advise of any actual or perceived conflicts of interest. Where a conflict of interest is declared, the Chair or Deputy Chair is to determine the appropriate course of action.

Management of conflicts of interest

137. The Chair or Deputy Chair will determine the appropriate course of action when a perceived or actual conflict of interest is disclosed. Measures may include:

a. no action

b. individuals removing themselves from the meeting for the discussion for all or part of the corresponding agenda item

c. for out-of-session reviews, individuals removing themselves from the review process.

138. In considering the appropriate course of action, consideration should be taken to the closeness of the member's interest in the application and the potential for a conflict of interest. In some cases, the declaration of the interest may in itself be sufficient to ensure that the decision of the Committee is not unduly influenced.

139. Where the member concerned is the Principal Investigator or another key investigator / collaborator named on the application form, the Committee should not proceed with the review until the member has excused themselves from the meeting room. The member can be invited back into the room to answer questions raised by the Committee if necessary, but should again leave the room when the discussion and deliberations resume.

140. All declarations of conflicts of interest, the action taken and any absences of those in attendance are to be minuted by the Secretariat. The Minutes should include detail on the nature of the conflict of interest and the course of action, as determined by the Chair or Deputy Chair.

141. Where a Committee member states a conflict of interest that requires their absence for the consideration and decision making for an application, the quorum requirements must still be upheld.

142. Copies of annual conflict of interest forms are to be provided to the Defence Integrity Division via the Integrity Forms mailbox in accordance with the Defence Integrity Policy Manual[14].

COMMUNICATION WITH RESEARCHERS

Open communication

143. Good ethical review requires open communication between review bodies and researchers. In order to facilitate open communication, the Committee and the Secretariat do not limit engagement with researchers to written communication and recognises the value of telephone and face-to-face conversations with researchers and other key stakeholders.

[14] http://drnet/AssociateSecretary/integrity-assurance/Conflict-interest-post-separation-employment/Pages/Conflict-of-Interest.aspx

144. Researchers are encouraged to engage early with the Secretariat when developing their research proposals. Researchers may also be asked to attend meetings to provide clarification on any concerns raised by the Committee.

145. All communication regarding the deliberations of the DDVA HREC will be in writing. In order to promote awareness of research guidelines, legislation and institutional policy, written communication will reference source documentation as appropriate. The requirement does not mean that communication is limited to written communication, and follow up discussions may occur via other mechanisms as outlined above.

Researcher contact details

146. To facilitate the management of research protocols and correspondence, researchers are to ensure that they provide contact details to the Secretariat. The Secretariat should be notified promptly of any change in contact details. Wherever possible, an email address should be supplied.

Prompt notification of decisions

147. The Principal Investigator and, where applicable, the project's point of contact, will be advised of the outcome of the ethical review within five business days of the meeting or within five business days of the date that reviewers were asked to provide feedback by for out-of-session considerations. Where there are delays in the provision of formal correspondence, the Principal Investigator and point of contact (where applicable) will be advised in writing.

COMPLAINTS

148. Where a researcher wishes to submit a complaint about **the consideration of their research proposal** by the Committee or the conduct of the Committee, they should contact the Assistant Director Research Ethics (designated officer) with details of the complaint. The designated officer will aim to resolve any issues raised. Where appropriate, the complaint will be directed to the SGADF and/or the Deputy President, DVA. A decision will be made based on all evidence received, including and response submitted by the researcher.

149. Complaints should be submitted in writing and must detail the grounds for the concern or complaint.

150. If the matter is not resolved to the satisfaction of the complainant, further steps may be taken including:

a. The DDVA HREC or the complainant contacting the Australian Health Ethics Committee for advice on interpreting guidelines that are issued by the National Health and Medical Research Council in order help the complainant understand the reasons for the ethical review body's decision.

b. Complainants can request a meeting with the Chair and the Assistant Director Research Ethics. The complainant(s) can be accompanied by one or more support persons/colleagues. A record of these meetings are to be included on the project file.

c. Subject to the agreement of the institution/s and the complainant, an independent third party may be engaged to facilitate further discussion. The mediator should consider all relevant materials prior to meeting with the parties to resolve any

outstanding issues. A report of the results to the meeting should be provided to the institution.

RECRUITMENT OF RESEARCH PARTICIPANTS

151. For research that involves humans as participants, researchers are to ensure that their applications clearly outline:

a. who is being recruited

b. how they will be recruited

c. the timeframe for recruitment.

152. The application should also include copies of materials to be used to recruit participants.

153. Further information is available in the Advertising Materials Fact Sheet.

Limited contact

154. Where no response is received to the initial invitation to participate, any follow up contact should be limited to one additional letter, email, text message or one phone call, unless otherwise specifically indicated in the approved protocol.

155. Where the invitation is refused, contact must cease immediately.

Department of Veterans' Affairs Sponsored research – Letter of first contact

156. If participants are recruited using contact information supplied by DVA and involves face-to-face or telephone contact with ex-serving personnel or relevant Defence communities, such contact must be preceded or accompanied by a letter (including email) from DVA informing the individual of the aims of the study and inviting them to participate. This letter is referred to as the "letter of first contact" and should explain why the individual is being contacted by DVA about the study.

157. A copy of the 'Letter of first contact' is to be provided to the DDVA HREC for consideration.

158. The letter of first contact will be signed by the Principal Medical Adviser or the Repatriation Commissioner, or the relevant Deputy Commissioner if the study is confined to a particular State. For projects specific to a particular DVA program the letter may be signed by the program manager at SES Band 1 level or higher.

Assurance of confidentiality and entitlements – Mazengarb clause

159. For research that is sponsored by DVA and involves direct contact with ex-serving personnel as research participants, researchers must assure the member of the veteran or relevant Defence community that their existing or future entitlements with the Department will not be affected by their answers, or whether they participate or not, and that they are free to withdraw from the study at any time. This statement – the Mazengarb Clause – should appear in bold type on the letter of first contact and/or participant information and consent forms. It may be amended to suit a particular context but should encompass the following sentiment.

Your answers will be completely confidential and any personal details, which may identify you in any way, will not be passed to the Department of Veterans' Affairs. Your answers will not in any way affect any current or future pension, benefits or health services entitlements from DVA.

160. Where the participant cohort consists of current serving and ex-serving Defence members and is sponsored by DVA and involves direct contact with research participants, the following clause should be used:

Your answers will be completely confidential and any personal details, which may identify you in any way, will not be passed to the Department of Defence or the Department of Veterans' Affairs. Your answers will not in any way affect any pension, benefits or health services entitlements from Defence or DVA.

CONSENT

161. The process for obtaining consent from research participants should:

a. ensure that a person's decision to participate in research is **voluntary**

b. ensure the decision to participate is based on sufficient information and an adequate understanding of the proposed research and the implications of participation

c. ensure that written information is presented in ways that are suitable to each participant

d. be free from coercion.

162. The National Statement outlines the information that must be communicated to potential participants. Additionally, researchers who are conducting clinical research should ensure that they make themselves familiar with the Integrated Addendum to ICH E6 (R1): Guidelines for Good Clinical Practice E6 (R2)[15].

163. It is essential that researchers give adequate consideration to the future use of data in the planning stages of their project/s.

164. Where research involves active participation of individuals, researchers should ensure that future use of data is clearly defined in the Participant Information Sheet and Consent Form (or survey preambles for online surveys).

Waivers of consent

165. Researchers who are requesting a waiver of consent under the National Statement paragraph 2.3.10 are to ensure that this is adequately addressed in their ethics applications.

166. Applications (including amendments) that seek a waiver of consent for health and medical research are to be tabled for consideration by the full HREC.

[15] https://www.tga.gov.au/resources/publication/publications/ich-guideline-good-clinical-practice

167. If a waiver is granted, the decision to grant the waiver is to be included in the HREC approval letter.

Opt out consent

168. Requests for consent via an opt out approach are to be considered by the full HREC.

169. Where an opt out process is being requested, researchers are to ensure that potential participants are provided with sufficient information to understand what the project involves, who to contact if they do not wish to participate and the timeframe that this should occur within.

Limited disclosure

170. In accordance with the National Statement, only an HREC can review and approve research that involves active concealment or planned deception.

171. Following the collection of the data, researchers should provide participants with a full explanation of the study. During this process, participants should be allowed the opportunity to withdraw their data from the study.

PAYMENTS TO RESEARCH PARTICIPANTS, INVESTIGATORS, DEPARTMENTS AND INSTITUTIONS

Research participants

172. As Defence personnel are deemed to be on duty whilst participating in research, any payments made to participants are to be for out-of-pocket expenses only. Consideration may be given to incentive payments for ex-serving personnel and civilian cohorts on a case-by-case basis.

173. Payment of money or incentives of any kind should not result in pressure or unduly influence an individual's decision to participate in research. The use of lottery-style incentive payments will not be supported by the DDVA HREC.

174. Where payments are proposed, researchers are to ensure they provide information on the rationale for the payment, how the rate has been calculated, the method and timing of the payment.

175. Payments should not be reliant on the participant completing the study and pro rata payments should be considered where appropriate.

176. Further guidance is available in the National Statement, the *Payment of participants in research: Information for researchers, HRECs and other ethics review bodies*[16] and in the DDVA HREC Advertising Materials Fact Sheet.

Investigators, Departments and Institutions

177. A researcher is to disclose the amounts, sources or potential sources of funding in any research proposal and, following approval of the proposal, any subsequent funding sources.

[16] https://www.nhmrc.gov.au/about-us/publications/payment-participants-research-information-researchers-hrecs-and-other-ethics-review-bodies

178. An investigator should not derive direct personal or financial benefit from the conduct of a commercially-sponsored project. However, adequate compensation can be provided for personal expenses arising from the protocol.

179. All remuneration should be paid into a fund used to finance the execution of the study and should be administered under a formal contractual arrangement that is open to scrutiny.

180. Payments on a per capita basis pose a problem because they raise the possibility of a conflict between the clinical responsibilities of a researcher and their financial gain.

CLINICAL TRIALS

181. Researchers are responsible for registering clinical trials in a publicly accessible register prior to the commencement of the clinical phase of the research. Once the trial has been registered, the Principal Investigator is to advise the DDVA HREC of the registration details.

182. The DDVA HREC requires that a nominal roll that includes sufficient information to enable re-contact of participants if required, is retained for all clinical trials. Researchers are to ensure that potential participants are informed of this requirement in the Participant Information Sheet and Consent Form.

183. Where a clinical trial is conducted by a Defence research organisation, that organisation is to certify that it will undertake the safe storage of the nominal roll for the requisite period in accordance with the *Archives Act 1983* (Archives Act)[17] and the Defence Records Management Policy.

RESEARCH DATA

Data management plan

184. Researchers should ensure that:

a. they develop a data management plan in the design stages of their project, noting the guidance in National Statement paragraph 3.1.45

b. the data management plan is consistent with any contractual and/or data custodian requirements, where applicable.

Data matching/data linkage

185. Researchers should inform the DDVA HREC if they intend to link or match data from another source/s, what the other source/s is/are, and what data is going to be obtained from the other source/s. The ability for individuals to be identified from matched or linked data should be a consideration in all ethics applications.

186. Further information is available in the Use of Existing Data in Research Fact Sheet on the DDVA HREC website.

[17] http://www8.austlii.edu.au/cgi-bin/viewdb/au/legis/cth/consol_act/aa198398/

Retention of research data and materials

187. Research data and materials are to be retained by the Principal Investigator for not less than five years from the date of publication or 15 years for clinical trials.

188. Research documents created by Defence research institutions or other Commonwealth agencies are Commonwealth records and are to be managed in accordance with the Archives Act[18], General Records Authority 37: Research and Development[19] and (for Defence research institutions) the Defence Records Management Policy. For research that is conducted by agencies external to Defence and DVA, the records are to be stored in accordance with the *Privacy Act 1988*[20] (Privacy Act), the Archives Act and other appropriate legislation.

189. If research results are challenged, the research data and materials are to be retained until the matter is resolved. Where records may be relevant to allegations of research misconduct, research data and materials must not be destroyed. Additionally, if the research has community or heritage value the data should be retained permanently.

190. Researchers must ensure data is collected, stored, accessed, amended, used and, where necessary, disclosed or destroyed in accordance with the approved application. Research data must not be removed from the approved location and must not be copied, emailed or downloaded to laptops or other electronic mobile devices, unless otherwise approved.

191. Unauthorised access and/or use of data by a person or for a purpose other than that indicated in the approved protocol and permitted under the Privacy Act are strictly prohibited.

192. At the completion of the approved research, data must be returned, stored or destroyed in accordance with the approved application, the Archives Act and any contractual requirements.

DISSEMINATION OF RESEARCH FINDINGS

193. Researchers may wish to publicly present research findings or publish articles in journals or other publishing forms. This may include submissions as a thesis or treatise, based on information acquired through DDVA HREC approved human research. This also includes research that was previously approved by the Australian Defence Human Research Ethics Committee or the Department of Veterans' Affairs Human Research Ethics Committee.

194. All publications should include the following in the body of the manuscript:

a. a detailed statement on relevant ethical approvals

b. an acknowledgment of the use of Defence and/or DVA resources and personnel where appropriate

[18] http://www8.austlii.edu.au/cgi-bin/viewdb/au/legis/cth/consol_act/aa198398/
[19] https://www.naa.gov.au/information-management/records-authorities/types-records-authorities/general-records-authority-37
[20] http://www5.austlii.edu.au/au/legis/cth/consol_act/pa1988108/

c. a disclaimer stating that the opinions expressed therein are those of the author/s and do not necessarily reflect those of Defence or DVA (as applicable).

195. A copy of the final document is to be provided to the DDVA HREC secretariat for inclusion on the protocol file. This should include advice on who cleared the document if Defence or DVA clearance was required (as outlined below).

196. Where research was co-funded or supported by Defence and DVA, both departments' requirements (as outlined below) will apply to publications unless otherwise agreed. Researchers should discuss the situation with their Defence or DVA contract manager or research sponsor.

Defence specific requirements

197. Researchers are required to obtain clearance of the research outputs/ outcomes from the relevant Defence sponsor. This includes dissertations that form part of an academic requirement. The sponsor/s must be a senior commander or manager of a rank/APS classification no lower than one Star /SES Band 1. Review of the findings may also require review and advice from other relevant areas, where appropriate.

198. Researchers should submit articles and/or abstracts of verbal presentations that are to be published and/or presented to the relevant sponsor/s or delegate/s (as directed), noting that this does not include the verbal presentation per se. If there is a request for copies of slides or other visual aids used in a verbal presentation, the researcher is to provide them.

199. Where Defence has approved a draft manuscript and that manuscript is subsequently amended prior to publication, the amended manuscript is to be re-submitted for approval.

200. No classified material is to be included in any manuscript which is to be published as open source material. Defence retain the right to prohibit or otherwise place conditions on the publication of a submitted manuscript.

Department of Veterans' Affairs specific requirements

201. Publications arising from research funded by DVA, using DVA data or that recruited participants through DVA programs should be provided to DVA for review prior to submission to the intended journal or conference. The DVA review is designed to ensure that the nature and findings of the DVA research in question are appropriately represented, terminology relating to DVA policies or services is accurate and the DVA contribution is acknowledged. Researchers should use the *DVA Review Prior to Publication* form, available by contacting research@dva.gov.au. The form also includes further details of DVA review processes and required acknowledgement/disclaimer wording. Other conditions arising from the relevant contract or data agreement may also apply.

202. Publications relating to research involving ex-serving members or their families but not funded by DVA, not using DVA data and not recruiting participants through DVA services do not need review by DVA prior to publication.

DEPARTMENTS OF DEFENCE AND VETERANS' AFFAIRS HUMAN RESEARCH ETHICS COMMITTEE

Terms of Reference

203. The DDVA HREC Terms of Reference are available on the DDVA HREC website[21].

Composition

204. The composition of the committee is detailed in the DDVA HREC Terms of Reference. A list of the current membership is available on the DDVA HREC website.

Recruitment and appointment of members

205. Members are appointed as individuals rather than in a representative capacity. A pool of members will be maintained to ensure the membership equips the committee with the skills necessary to consider the categories of research that are likely to be submitted. Where possible one or more of the members are to be experienced in analysing and reflecting on ethical decision-making.

206. Members may be recruited by direct approach, nomination or by advertisement. Applicants will be asked to provide a copy of their curriculum vitae for review by the selection committee. Prospective members may be invited to attend a DDVA HREC meeting as an observer prior to considering an appointment.

207. A selection committee that consists of representatives from the Defence and DVA shall review the candidate's curricula vitae and may conduct an interview. A recommendation will be made to the Chief of Personnel and the Deputy President of the Repatriation Commission and MRCC and where supported, the delegates will jointly sign the letter of appointment.

208. A formal letter of appointment will be provided to all members and will include:

a. the date of appointment

b. length of tenure

c. category/ies of appointment

d. assurance that indemnity will be provided in respect of liabilities that may arise in the course of bona fide conduct of their duties as a DDVA HREC member

e. conditions of their appointment

f. circumstances where their membership may be terminated.

209. Members are appointed for a period of up to three years. Appointments are subject to annual review to ensure that the ongoing requirements of the committee are being met.

210. Members will be advised when their term of appointment is due to expire. The Chair, the Deputy Surgeon General Australian Defence Force, Defence and the Assistant Secretary responsible for research, DVA will recommend any reappointments to the Chief of Personnel and the Deputy President of the Repatriation Commission and MRCC. Where supported, the delegates will jointly sign the letter of appointment.

[21] https://www.defence.gov.au/adf-members-families/health-well-being/business-plans/human-research-ethics-committee

Indemnity of members

211. Defence and DVA will provide indemnity in respect to liabilities that may arise in the course of bona fide conduct of duties as a member of the DDVA HREC.

Security clearances

212. All members of the Committee and the Secretariat are to hold a minimum security clearance of Negative Vetting 1. All members are strictly bound by privacy and confidentiality laws and regulations.

Termination of appointments

213. The accountable officers (as identified on page 3) may terminate the appointment of any member of the Committee if they are of the opinion that:

a. it is necessary for the proper and effective functioning of the Committee

b. the person is not a fit and proper person to serve on a Committee

c. the person has failed to carry out their duties as a Committee member.

Details on membership

214. Members must agree to their name and profession being made available to the public, including being published on the DDVA HREC website.

Confidentiality

215. Members are to:

a. ensure that any matters that they are privy to as part of the deliberations of the committee remain confidential

b. sign a confidentiality agreement upon appointment and reappointment to the Committee.

Training

216. Members will be provided with an induction upon appointment to the Committee. This includes provision of resources, meeting with the Chair and Secretariat, an opportunity to observe meetings, allocation of a mentor (where appropriate) and site induction.

217. Members are required to attend continuing education or training programs in research ethics at least every three years. The Secretariat is to be advised of completion of training. This will be included on the Member Training Register.

218. Failure to attend ongoing training may result in termination of appointment.

Conflicts of interest

219. Members are required to notify the Secretariat of any potential or perceived conflicts of interest which may arise during their tenure on the committee including, but not limited to:

a. personal involvement or participation in the research

b. financial or other interest of affiliation

c. involvement in competing research.

220. Conflict of Interest Forms are to be completed upon appointment/reappointment, on an annual basis and on an adhoc basis where necessary.

Consideration of research applications

221. Members are responsible for deciding whether a proposal meets the requirements of the relevant research guidelines, legislative instruments and other relevant policy. In order to do this, members are to make themselves familiar with the relevant guidelines, policy and legislative instruments.

Preparation for and attendance at meetings

222. Members are to ensure that they prepare for and attend scheduled meetings.

Out-of-session considerations

223. Members will review out-of-session items as requested. Members are to advise the Secretariat if they are unable to review such items in the required time frame.

ANNEX A

DEFINITIONS

Table 1A: Definitions

Term	Definition
Administrative review	Review of the application by the Secretariat to identify incomplete responses, identify deviations from policy, identify inconsistencies in information provided or request additional information.
Adverse event	Is an untoward occurrence that has resulted in one or more of the following: participant distress; requirement for medical treatment or cessation in the research; or a breach of privacy or confidentiality
Amendment	Is where the principal investigator proposes changes to a previously approved protocol.
Clinical trial	Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes[22].
Commander	Is an Australian Defence Force officer who, by virtue of a delegation or instrument of appointment, exercises authority and holds responsibility for assigned Defence personnel and includes an Administrative Commanding Officer.
Conflict of interest (in the research context)	Where a person's individual interests or responsibilities have the potential to influence the carrying out of their institutional role or professional obligation in research; or where an institution's interest or responsibilities have the potential to influence the carrying out of its research obligations. A conflict of interest exists in a situation where an independent observer might reasonably conclude that the professional actions of a person are or may be unduly influenced by others interests. This refers to a financial or non-financial interest which may be a perceived, potential or actual conflict of interest.
Consent (in research)	A person or groups agreement, based on adequate knowledge and understanding of relevant material, to participate in research.
Data	Refer to the 'National Statement on Ethical Conduct in Human Research' (National Statement)[23].
Defence	The Department of Defence and the Australian Defence Force.
Defence Australian Public Service employee (Defence APS employee)	Is a person employed under the *Public Service Act 1999*[24] in the Department of Defence.
Defence civilian	Refer to section 3 of the *Defence Force Discipline Act 1982*[25].
Defence member	Refer to the *Defence Force Discipline Act 1982*.

[22] https://www.australianclinicaltrials.gov.au/what-clinical-trial
[23] https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023
[24] http://www8.austlii.edu.au/cgi-bin/viewdb/au/legis/cth/consol_act/psa1999152/
[25] http://classic.austlii.edu.au/au/legis/cth/consol_act/dfda1982188/

Term	Definition
Defence personnel	All Australian Public Service employees, Defence employees engaged locally overseas, Defence civilians, Defence members and the equivalents from other Defence organisations on exchange to Defence.
Deviation	Departure from the approved study protocol/standards.
Ethics review	Refer to the National Statement.
Expedited review	A mechanism for the review of research that does not require full HREC review.
Evaluation activity	Refer to 'Ethical Considerations in Quality Assurance and Evaluation Activities'[26].
Ex-serving personnel	Includes all individuals who have previously served as a Defence member (and are no longer serving).
Full-HREC review	Ethical review conducted by the minimum membership, as per the National Statement.
Harm	That which adversely affects the interests or welfare of an individual or a group. Harm includes physical harm, anxiety, pain, psychological disturbance, devaluation or personal worth and social disadvantage.
Higher risk research	Refer to the National Statement.
Human research	Is research which is conducted with or about people, their data or tissue.
Lower risk (research)	Refer to the National Statement.
Manager	Means Defence personnel, a Department of Veterans' Affairs employee or a Defence or Department of Veterans' Affairs contractor who directs a range of human and physical resources and their associated financial responsibilities to achieve objectives. A manager may be a first-level supervisor or perform the role of a first-level supervisor where they have immediate subordinates, as well as the role of a second-level supervisor where they have Defence or Department of Veterans' Affairs personnel supervised by those subordinates.
Monitoring (of research)	The process of verifying that the conduct of the research conforms to the approved proposal.
New application	Is where a research proposal has not been considered by the committee previously or where significant time has elapsed since the research proposal was first considered and it requires the submission to be treated as a new application.
Participant (in research)	Anyone who is the subject of research in any of the ways outlined in the National Statement.
Personal information	Refer to the National Statement.
Principal Investigator	Is the researcher(s) with primary responsibility for a research project including the preparation, conduct, and administration of the research, the associated funding, cooperative agreements, training, supervision,

[26] https://www.nhmrc.gov.au/about-us/resources/ethical-considerations-quality-assurance-and-evaluation-activities

Term	Definition
	and delegation of any related tasks in compliance with applicable laws, regulations and institutional policy governing the conduct of human research.
Privacy	A domain within which individuals and groups are entitled to be free from the scrutiny of others.
Publication	Is any book, journal, periodical, thesis or such publication, including any abstract or poster created for a conference, or any part thereof, which contains material, articles or text written by members of educational or research bodies on area of educational or scholastic learning, research or debate.
Quality assurance	Refer to 'Ethical Considerations in Quality Assurance and Evaluation Activities'.
Re-identifiable data	Refers to data from which identifiers have been removed and replaced by a code, but it remains possible to re-identify a specific individual by, for example, using the code or linking different data sets.
Research	Includes at least investigation undertaken to gain knowledge and understanding or to train researchers. It includes the creation of new knowledge and/or the use of existing knowledge in a new and creative way so as to generate new concepts, methodologies, inventions and understandings. This could include synthesis and analysis of previous research to the extent that it is new and creative.
Research governance	Are those matters concerning the authorisation, monitoring, quality, safety, privacy, risk management, legislative and regulatory guidance, financial management and ethical acceptability of research.
Resubmission	Is where a research proposal was previously submitted to the committee and was not approved and revised documentation is subsequently submitted for consideration.
Risk	The function of the magnitude of harm and the probability that it will occur. It includes the probability of damage, injury, negative occurrence or adverse/serious adverse events.
Serious adverse event	Is any untoward medical occurrence that: results in death; is life-threatening; requires inpatient hospitalisation or prolongation of existing hospitalisation; results in persistent or significant disability/incapacity; is a congenital anomaly/birth defect; or is a medically important event or reaction.
Sponsor (in the research context)	Is a senior commander or manager of no lower rank / Australian Public Service classification than a one Star / Senior Executive Service Band 1 who takes responsibility for a research project. This may include initiation, authorisation/approval/endorsement, management and/or financing of research.
Voluntary participation	Participation that is free of coercion and pressure.

ANNEX B

AMENDMENTS

Table 2A: Amendments

Nature of amendment	Delegation	Action
Waiver of consent for health or medical research	Full HREC	To be tabled for consideration at a meeting.
Decreases to the size of the cohort	Chair or Deputy Chair	To be forwarded to the Chair or Deputy Chair for review as it may affect the validity of the study.
Additional research cohorts	Chair or Deputy Chair	This generally requires updated consent documentation and possibly recruitment materials. If this documentation is missing, the Secretariat should request it prior to forwarding to the delegate for review. The title of the protocol should be reviewed to ensure that it is reflective of the additional cohort (eg adding in current serving personnel).
Administration of additional surveys or psychological tests	Chair or Deputy Chair	Where amendments request the administration of additional surveys or psychological tests, the researchers should provide a copy of these documents in support of the protocol amendment. The Participant Information Sheet and Consent Form and any recruitment materials should be reviewed to ensure that they do not need to be updated. Where the Secretariat identifies that the documents should be updated, they should request missing documentation from the researcher prior to forwarding the amendment to the delegate for review.
Addition or removal of diagnostic or test methods	Chair or Deputy Chair	This type of amendment is very broad. All amendments of this nature should be reviewed by the Chair/Deputy Chair in the first instance.
Administration of a survey via an online tool	Chair or Deputy Chair	Administration of online surveys are to be via an online tool that has an Australian based server. The Secretariat should confirm with the researchers that an Australian based server will be used prior to forwarding the

Nature of amendment	Delegation	Action
		amendment to the delegate for review.
Changes to diagnostic or test methods	Chair or Deputy Chair	This type of amendment is very broad. All amendments of this nature should be reviewed by the Chair/Deputy Chair in the first instance.
Interviews and/or focus groups	Chair or Deputy Chair	Scripts are to be provided in support of the amendment and the number of anticipated participants are to be indicated. The Secretariat should ensure that this information is provided prior to forwarding onto the delegate for review.
Amendments made as a result of an adverse or serious adverse event	Chair or Deputy Chair	Upon submission of any such amendment, the Secretariat should ensure that an adverse/serious adverse event report has been submitted. The report is to be provided to the delegate for their information when reviewing the protocol amendment.
Additional phase for studies	Chair or Deputy Chair	This type of amendment is very broad. All amendments of this nature should be reviewed by the Chair/Deputy Chair in the first instance.
Research personnel (addition and removal)	Secretariat	Check that a brief curriculum vitae (CV) has been provided for all additional personnel (if not provided check the DDVA HREC researchers CV folder in Objective for a current (less than three years) CV). Check the role of any additional personnel (eg Principal Investigator, Associate Investigator, Research Assistant) has been specified). Check to see if the study is open to current enrolment and check that the consent documentation does not need to be updated to reflect the change. If they state that they are a registered health practitioner, their registration status is to be checked on the Australian Health Practitioner Regulation Agency[27].

[27] Australian Health Practitioner Regulation Agency https://www.ahpra.gov.au/

Nature of amendment	Delegation	Action
Advertising materials – including additional sites, mechanisms	Secretariat	The messages within the document should be consistent with the research protocol. Guidance on the types of information that should be included in advertising materials is included in the Advertising Materials Fact Sheet[28].
Additional sites	Secretariat	Where additional sites are requested for research that fits within Defence's remit, the research protocol is to be reviewed. This should include information relating to organisational support and command approval. Where these sites are not within the scope of the existing governance approvals, the researcher will need to seek updated approvals prior to ethical approval being granted.
Increases to the size of the research cohort	Secretariat	When considering a request to increase the size of a research cohort, the Secretariat should check the research proposal to ensure that in the case of research that fits with the Defence remit, that the command approval does not specify a number of participants to the recruited. Where this is the case, the researcher will need to obtain evidence of approval to increase the size of the cohort prior to ethical approval being granted. The Secretariat will also need to consider if the increase in the size of the cohort also includes recruitment of participants from other areas of Defence or other research cohorts.
Extensions to the period of ethical approval	Secretariat	Ensure that all relevant documentation is on file, either via conduct of a desktop audit (where there is not a recent audit) or via review of the file. If no progress has been made on the study for some time, it may be appropriate to grant an extension for 12 months, with subsequent

[28] http://www.defence.gov.au/health/hrec/docs/20180716-FACTSHEET-Advertising-materials.pdf

Nature of amendment	Delegation	Action
		extensions needing to demonstrate progress of the study. This should be discussed with the Chair or Deputy Chair. If there have been any complaints, deviations, adverse or serious adverse events; the Chair or Deputy Chair are to be consulted.