Australian Government
Department of Defence
Department of Veterans' Affairs

PROJECT DESCRIPTION

Full title:

Monitoring of low level blast exposure in Special Operations Command training

Short title:

Monitoring LLB in SOCOMD

Name of contact person s47E(d)

Telephone number s47E(d)

Email: s47E(d)

Version: 1

Date: 09/05/2024

Prior to submitting your application for ethical review:

a. Ensure that if you are requesting access to Defence or the Department of Veterans' Affairs (DVA) data that you have engaged with the relevant areas within the respective organisations and obtained in principle support for the release of the data.
b. Obtain Defence organisational support and command approval, where required.
c. If you are seeking volunteers through DVA, approval has been obtained from the relevant DVA program manager at the Senior Executive level. DVA does not generally assist with the recruitment of volunteers for studies that it has not commissioned.

These process are separate processes to ethical review by the Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC). Failure to obtain the relevant approvals will result in delays of the ethical review of the project.

Please refer to the resources page on the DDVA HREC website for further guidance.

Does your proposal involve any of the following (select all that apply):

- ☐ Waiver of consent for research using personal information in health/medical research, or personal health information [National Statement paragraph 2.3.9]
- ☐ Active concealment or planned deception [National Statement paragraph 2.3.4a)]
- ☐ Women who are pregnant and the human fetus [National Statement Chapter 4.1]
- ☐ People highly dependent on medical care who may be unable to give consent [National Statement Chapter 4.4]
- ☐ People with cognitive impairment, an intellectual disability or a mental illness [National Statement Chapter 4.5]
- ☐ People who may be involved in illegal activities [National Statement Chapter 4.6] or aims to expose illegal activities [National Statement paragraph 2.3.4b)]
- ☐ Aboriginal and Torres Strait Islander Peoples [National Statement Chapter 4.7]

If you have answered **'Yes'** to any of the above categories of research, ethical review by the **Full HREC** is required.

If the study involves **secondary use of non-identifiable data**, please discuss the ethical review pathway with the Secretariat.

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)

I wish to submit this application for consideration under the following pathway (select only one):

☒	Lower risk
☐	Higher risk
☐	Requires review by the Human Research Ethics Committee (HREC) due to the inclusion of one or more of the categories outlined above

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ACRONYMS

Abbreviation	**Description** [All acronyms in the Project Description are to be listed and defined.]
2CDO	Second Commando Regiment
ADFSSO	Australian Defence Force School of Special Operations
DAH	Director Army Health
DHR	Directorate of Health Research
DHRSG	Defence Health Research Steering Group
DSTG	Defence Science and Technology Group
DVA	Department of Veterans' Affairs
HLB	High-level blast
LLB	Low level blast
mTBI	Mild traumatic brain injury
NCAT	Neuro Cognitive Assessment Tool
N	Newton
OIC	Officer in Charge
psi	Pounds per square inch
RBE	Repeated blast exposure
RTC	Reinforcement Training Cycle
RTC	Reinforcement Training Cycle
SOCOMD	Special Operations Command
SOER	Special Operations Engineering Regiment
TBI	Traumatic brain injury

DEFINITIONS

Term	Meaning [All technical terms in the Project Description are to be listed and defined.]
Low-level blast (LLB) exposure	Overpressure exposure generally occurring within operational and training environments from outgoing (user directed) munitions
High-level blast (HLB) exposure	Overpressure exposure generally experienced in combat settings as a result of incoming or enemy-inflicted munitions, such as IEDs, rocket-propelled munitions, etc

1. STUDY SYNOPSIS

Aim	To establish a protocol to monitor for any impact of low level blast exposure during SOCOMD training to allow a greater understanding of the impact of the environment that SOCOMD members are training and operating in.
Hypothesis (where relevant)	N/A
Inclusion criteria [National Statement paragraphs 1.4(a) and 3.1.15]	☒ Current serving Defence members (or their data) ☐ Navy personnel ☒ Army personnel ☐ Air Force personnel ☐ Ex-serving Defence members (or their data) ☐ Australian Public Servants/ contractors (or their data) ☐ Families of current and/or ex-serving Defence members ☐ Civilians (not included in any of the above categories) ☐ Other – please specify **Please describe:** Current trainees and qualified operators serving in Special Operations Command.
Exclusion criteria [National Statement paragraphs 1.4(a) and 3.1.15]	None
Number of participants/records	100

Amount and sources or potential sources of research funding [National Statement paragraph 5.3.7]	☒ Defence - s47E(d) ☐ DVA ☐ Other – please specify
Site/s	Holsworthy Barracks
What organisation has overall responsibility for the project?	A collaborative project between Defence Science and Technology Group, Directorate of Health Research and SOCOMD
Anticipated start date	June 2024
Anticipated completion date [National Statement paragraph 5.2.19(i)]	December 2025
Five keywords/phrases to describe or define the field of research	Mild Traumatic Brain Injury (mTBI) Repeated blast exposure Blast overpressure Cognitive function Environmental testing

The research will involve the following:

Active participation of human participants	☒ Yes ☐ No
Human biospecimens	☐ Yes ☒ No
Data associated with human participants [use of data that has already been collected]	☐ Yes ☒ No

The research involves targeted (or high incidental) recruitment of the following: [check response against section 8]

Participants	**Status**
Women who are pregnant and the human fetus [National Statement Chapter 4.1]	☐ Yes ☒ No
Children and young people [National Statement Chapter 4.2]	☐ Yes ☒ No
People in dependent or unequal relationships [National Statement Chapter 4.3]	☒ Yes ☐ No
People highly dependent on medical care who may be unable to give consent [National Statement Chapter 4.4]	☐ Yes ☒ No
People with cognitive impairment, intellectual disability or mental illness [National Statement Chapter 4.5]	☐ Yes ☒ No
People who may be involved in illegal activities [National Statement Chapter 4.6]	☐ Yes ☒ No
Aboriginal and Torres Strait Islander peoples [National Statement Chapter 4.7]	☐ Yes ☒ No
People in other countries [National Statement Chapter 4.8]	☐ Yes ☒ No

2. PROJECT TEAM ROLES & RESPONSIBILITIES

Insert/delete rows as required. Contact details **must** be provided for all Principal Investigators, contact persons and supervisors (for student research). Please ensure that email addresses are consistent with the individual's institutional affiliation for the study.

Curriculum vitae (not exceeding five pages) are to be submitted for **all** research personnel.

Name	s47E(d)
Institution	Defence Science and Technology Group
Position	Science and Technology Advisor Human Performance
Role	☒ Principal Investigator ☐ Co-investigator ☐ Other, please specify
Responsibilities	Liaise with military, DSTG and JHC stakeholders, assist with data collection, data analysis, report writing and manuscripts.
Professional registration	N/A
Contact details	Phone s47E(d) Email:

Name	s47E(d)
Institution	Directorate of Health Research
Position	Assistant Director, Mental Health Research
Role	☒ Principal Investigator ☐ Co-investigator ☐ Other, please specify
Responsibilities	Liaise with military, DSTG and JHC stakeholders, assist with data collection, data analysis, report writing and manuscripts
Professional registration	N/A
Contact details	Phone s47E(d) Email:

Name	s47E(d)
Institution	Department of Defence
Position	SOJ07
Role	☐ Principal Investigator ☒ Co-investigator ☐ Other, please specify
Responsibilities	Liaise with military and JHC stakeholders, provide guidance on project to ensure alignment with SOCOMD requirements, review reports and manuscripts
Professional registration	N/A
Contact details	Phone s47E(d) Email:

Name	s47E(d)
Institution	Department of Defence
Position	Human Performance Manager
Role	☐ Principal Investigator ☒ Co-investigator ☐ Other, please specify
Responsibilities	Liaise with military stakeholders, facilitate engagement with SOCOMD, provide guidance on project to ensure alignment with SOCOMD requirements, review reports and manuscripts
Professional registration	N/A
Contact details	Phon s47E(d) Email:

Name	s47E(d)
Institution	Department of Defence

Position	Senior Medical Officer
Role	☐ Principal Investigator ☒ Co-investigator ☐ Other, please specify
Responsibilities	Liaise with military and JHC stakeholders, provide guidance on project to ensure alignment with SOCOMD requirements, review reports and manuscripts, upload members data to their health record (where they have consented).
Professional registration	AHPRA registration number: s47E(d)
Contact details	Phone s47E(d) Email:

3. CONFLICTS OF INTEREST

3.1 Does any member of the research team have an actual, potential or perceived conflict of interest with the research? ['National Statement' Chapter 5.4, The Australian Code for the Responsible Conduct of Research – responsibility 24]

☐ Yes ☒ No

3.1.1 If yes, please describe the nature of the conflict of interest and how it will be managed.

4. RESOURCES

4.1 Resources necessary for the study to be conducted [National Statement paragraph 1.1 (f)]

- 100 B3 Blast Gauges
- 2 Samsung Tablets
- 100 licences for Sway Medical Cognitive Testing application

4.2 Amount and sources of potential funding? [National Statement paragraph 5.3.7]

Source	Amount	Type
Headquarters Special Operations Command	s47E(d)	**Financial**

4.3. Will the research proceed without funding?

☐ Yes ☐ No ☒ Not applicable

4.3.1 Please describe the implications for the study if funding is not obtained.

N/A

5. BACKGROUND

5.1 Has the scientific or academic merit of the project been evaluated?

☒ Yes ☐ No

5.1.1 Please describe the process of evaluation or why this has not been assessed. [National Statement paragraph 3.1.1(g)].

Consultation has occurred with key stakeholders through the Defence Health Research Steering Group (DHRSG), including the Director Army Health (DAH), and chaired by the Deputy Surgeon General Australian Defence Force. It was noted that work is underway to develop the Blast Overpressure Monitoring and Research Program (the 'Program'), conducted with SFG units, in collaboration with DHR, DSTG and SOCOMD (Attachment I).

Similar testing protocols have been established in the New Zealand Defence Force (Tate et al., 2013) and United States Special Operations Force (Edlow et al., 2022).

5.2 Has this research project undergone prior ethics review?

☐ Yes ☒ No

5.2.1 If yes, please provide details on the outcome of the ethical review and include a copy of the correspondence from the approving ethical review body in support of your submission.

5.3 Will any further ethical review of this study be sought?

☐ Yes ☒ No

5.3.1 If yes, please provide details.

5.4 Literature review [National Statement paragraph 1.1(c)]

The current study outlines a monitoring protocol to assess outcomes associated with blast overpressure in Special Operations Command (SOCOMD). A recent review (Belding et al., 2021a) identified that a variety of terms have been used to describe the nature of blast exposures and associated outcomes. The review proposed a list of terminology for use when discussing blast-related exposures and outcomes, which will be adopted here. Low-level blast (LLB) exposure is defined as "overpressure exposure generally occurring within operational and training environments from outgoing (user directed) munitions". High-level blast (HLB) exposure is defined as "overpressure exposure generally experienced in combat settings as a result of incoming or enemy-inflicted munitions, such as IEDs, rocket-propelled munitions, etc". While HLB exposure has been identified as a significant source of morbidity and mortality within military populations, understanding of the impact of LLB on health outcomes is less understood (Belding et al., 2021b).

SOCOMD personnel experience higher rates of LLB during training than other ADF personnel through activities such as breaching. Breaching involves exposure to series of controlled blasts under supervised conditions to gain entry to a variety of structures. Blast exposure is controlled during breaching, therefore the effects from a single exposure to LLB do not prompt immediate concussion screening. Safety measures in place include use of safe standoff distances and hearing protection. Emerging evidence suggests that repeated exposure to LLB can lead to subtle yet significant neurological alterations. Chronic exposure to blasts has been associated with changes in brain structure, including alterations in white matter integrity, cortical thinning, and hippocampal volume reduction (MacDonald et al., 2011; Tate et al., 2014). Functional imaging studies have revealed disruptions in neural networks involved in attention, memory, and executive functions (Elder et al., 2009). These neurological changes may contribute to long-term cognitive deficits observed in individuals with blast exposure.

Cognitive impairment is a prevalent consequence of repeated LLB exposure in military training. Studies have documented deficits in attention, working memory, processing speed, and executive functions following blast exposures during training exercises (Lange et al., 2012; Levin et al., 2010). Research with New Zealand Defence Force breacher training courses observed neurocognitive deficits associated with LLB exposure

and detailed participant concerns about their long-term health and well-being following such exposures (Tate et al., 2013). A study with United States Marine Corps suggested that blast-induced impairment was present in selected domains of cognition among individuals subjected to sustained repetitive LLB (Carr et al., 2016). These cognitive impairments can impact operational readiness and decision-making, emphasising the importance of understanding blast-related cognitive deficits in training.

Furthermore, repeated LLB exposure in military training can lead to psychological and behavioural changes. Research indicates increased rates of post-traumatic stress disorder (PTSD), depression, anxiety, and aggression among military personnel exposed to blasts (Hoge et al., 2008; Vasterling et al., 2012). These psychological symptoms not only affect individual well-being but also have implications for unit cohesion and morale.

In addition to neurological, cognitive and psychological impacts, exposure to LLB can affect balance. Maintaining optimal balance is critical for military performance, as it directly influences agility, coordination, and overall operational readiness. Blast waves can induce vestibular system dysfunction, resulting in disruptions to postural control and equilibrium (Courtney et al., 2016; Xydakis et al., 2020). This can manifest as increased sway, decreased stability, and impaired proprioception, all of which are crucial components of balance (O'Connell et al., 2017). Several factors may contribute to the variability in balance impairments observed among individuals exposed to repeated LLBs during military training. These include blast intensity, proximity to the explosion, frequency of exposure, individual susceptibility, and pre-existing vestibular or neurological conditions (Phillips et al., 2018; Salinsky et al., 2017).

Given the potential adverse effects of repeated LLB exposure on neurological, cognitive, psychological and balance function, the current study outlines a protocol to monitor the impact of exposure to LLB in SOCOMD training. It is anticipated that the results will enable a greater understanding of the effects of LLB during training and inform policies to minimise the impact of LLB exposure during SOCOMD training.

5.5 Rationale/Justification [National Statement paragraph 1.1(a)]

The effects of LLB exposure are not fully understood, highlighting the importance of establishing a protocol to monitor the cognitive, behavioural and psychological function of personnel exposed to LLB during training. It is anticipated that the results will enable a greater understanding of the effects of LLB during training and inform policies to minimise the impact of LLB exposure during SOCOMD training.

5.6 Noting the description in section 1, how do the research questions relate to the aims and hypotheses of the research? [National Statement paragraph 1.1(b)]

The aim of the study is to further understand any health impacts of repeated exposure to LLB during training. Therefore, the research will assess balance, cognition and symptoms of mental ill health prior to exposure to LLB during training and again after exposure to determine if there are any differences in these outcomes, and whether the amount of exposure is related to any changes.

5.7 Expected outcomes

Outcomes for SOCOMD and wider ADF will include:

a. An established testing protocol to monitor blast exposure.

b. Blast exposure history uploaded to each member's medical records (if they consent).

c. Recommendations on safety distances for minimising blast overpressure exposure

6. PROJECT DESIGN

6.1 Research setting

The research project will be conducted on base at Holsworthy Barracks.

6.2 Research design and methodological approach/es [National Statement paragraph 1.1(b) and Chapter 3.1 Element 1]

Research Design: Descriptive Epidemiological Study

Methodology

Potential participants will be recruited from 4 SOCOMD groups providing a representative sample of trainees and qualified operators in SOCOMD from June 2024 to December 2025. A baseline assessment measuring balance, cognition and mental health will be conducted at the start of the project. Blast Gauges will then be issued to all participants to wear on their kit for the duration of the trial, to measure exposure to blast overpressure (measured in psi) during training. When an individual is exposed during training to a single blast peak overpressure > 4 psi or a cumulative blast overpressure impulse > 100psi•ms in a single calendar day we will ask them to repeat their balance, cognition and mental health assessment. Finally, at the end of the 18-month period we will conduct the balance, cognition and mental health assessments for all participants.

6.3 Rationale for choices of method/s (tied to project aims/objectives) [National Statement paragraph 1.1(b) and Chapter 3.1 Element 1]

Blast overpressure surveillance is a key step to the development, implementation and evaluation of any blast prevention program, as it provides key data in order to determine, quantify and/or prioritise potential problem areas in training. This information will then inform working groups to develop and implement specifically targeted blast overpressure prevention programs. Prior to intervention, a monitoring framework must be established and implemented to assist in any evaluation of any intervention. Similar testing protocols have been established in the New Zealand Defence Force (Tate et al., 2013) and United States Special Operations Force (Edlow et al., 2022).

A descriptive epidemiological study will allow us to understand the magnitude and frequency of exposure to blast overpressure during training in SOCOMD. Further, the assessment of balance, cognition and symptoms of mental ill health prior to

exposure to LLB during training and again after exposure determine if there are any differences in physical and mental health and performance due to the magnitude and frequency of LLB during training. Overall this information will help to inform safe training protocols and provide greater understanding of health monitoring tools.

6.4 Sample size, statistical power issues (where applicable) and justification

A representative sample of approx 100 SOCOMD members made up of:

s47E(d)

Research activities

6.5 What you are going to do?

The research activities are as follows:

- In-person research briefing and provision of PIS and PCFs across 4 groups of trainees and qualified operators in SOCOMD.
- A baseline assessment of balance, cognition and mental health for each participant.
- Blast Gauges issued to all participants to wear on their kit for the duration of the trial.
- Repeat individual balance, cognition and mental health assessments for any individual exposed to a single blast peak overpressure > 4 psi or a cumulative blast overpressure impulse > 100psi•ms in a single calendar day during training
- A final assessment of balance, cognition and mental health for each participant at the end of the 18-month trial.
- Data analysis using DPN SPSS and excel formulas
- Report write up

7. BENEFITS AND RISKS

[National Statement paragraphs 1.6 – 1.9 and Chapter 2.1]

7.1 What are the benefits to participants?

Blast exposure history will be uploaded to each participant's medical records (if they consent). This will be beneficial for participants should they require a record for

future claims with the Department of Veterans' Affairs. This may allow participants to access future preventive or rehabilitative treatments should they require.

7.2 What are the benefits to the wider community?

An established testing protocol to monitor regular blast exposure and potential impacts on physical and cognitive function to allow a greater understanding of the impact of the environment that SOCOMD members are training and operating in. This would enable individuals and commanders to track career long blast exposure and physical and cognitive changes to support future DVA claims. The findings of the project will have implications across the ADF to any member who may be exposed to the mechanisms of mTBI and low level blast exposure.

Recommendations on potential "optimal" location for safety staff and firer for specific weapon systems and training areas provided in the form of regular verbal briefs, 1 page infographics and a summary table of measured blast overpressure.

7.3 What are the benefits to the researchers?

This study will contribute to the larger base of scientific knowledge in the area, with the possibility of conducting further work with this population and other groups across the ADF. The results of this research are likely to also be presented at international conferences and published in peer-reviewed journals (subject to one Star or equivalent approval of research outcomes prior to dissemination).

7.4 What are the risks to participants?

Since the participants will be already performing the training under the direction of their commanders the injury risks involved with training (and blast exposure) will be the responsibility of the unit. The only risks involved in this research protocol is the collection and use of potentially sensitive information.

7.5 What are the risks to the researchers?

Exposure to blast when attending unit training activities to conduct data collection.

7.6 How will the risks be mitigated?

Privacy and use of sensitive data

~~To minimise the risk of inadvertent disclosure of potentially sensitive genetic information about participants, a~~All data will be de-identified (labelled with unique study ID) and a~~. A~~ register held by the listed project team stored securely on Objective will link participant's personal details (including name and contact information) to their study ID. This will be collected during the consent process and only accessible for the purpose of members who wish to have their data sent to them or uploaded to their medical records, which will be managed by the Senior Medical Officer (MAJ Antony Sutherland) listed in the project team. All data will be securely stored on industry standard purpose built (password protected) computers. Data that is collected through blast gauges, force plates, online surveys and cognitive testing will be linked only to the participant's study ID, not to their name or other personal details. Additionally, during the cognitive tasks, the participants will not receive an immediate result of their performance (or how these rank amongst the group/compared to normative values). This is due to the purposeful de-identification of data which reflects the measures in place to keep participant's privacy intact. All

findings will be reported as group aggregate data in reports and external publications.

Project Team

The project team will wear all required PPE when attending unit training activities on the range and will be briefed in and supervised by the range Officer in Charge (OIC) and safety staff to ensure they are a safe distance away from any mutations or breaching charges (i.e. in bunkers).

7.7 How do the benefits of the research outweigh the risks associated with the research?

All data will be captured during and around already planned breaching and heavy weapon training serials. SOCOMD members will not be exposed to any additional blast outside of their usual training and therefore the risks are assessed as minimal. The anticipated outcomes of an established testing protocol to monitor blast exposure, recommendations on safety distances for minimising blast overpressure exposure, and blast exposure history uploaded to each member's medical records (if they consent) provides immediate short term benefits to improve training techniques and procedures (TTPs) and potentially information to support members future health claims once injury thresholds are established.

8. PARTICIPANTS

8.1 Does the research involve active participation? ☒ Yes ☐ No

8.1.1 How will you engage with your participants?

☒ Survey(s) /questionnaire(s) ☐ Focus groups

☐ Structured interviews ☐ Semi-structured interviews

☒ Other – balance test

8.1.2 What is the method of delivery for engagement with participants?

☒ Face-to-face ☐ Telephone/Teams etc

☒ Online – Sway application

☐ Other – please specify here

8.1.3 What are participants requested to do (participant commitment)?

Potential participants will be recruited from 4 SOCOMD groups representing trainees and qualified operators from June 2024 to December 2025. An overview of study procedures is provided below in Table 1.

A single testing session is expected to last no longer than 30 minutes, and to occur at the start and end of the project, as well as post training activities with a single blast peak overpressure > 4 psi or a cumulative blast overpressure impulse > 100psi•ms in a single calendar day.

Table 1. Study procedures

Assessment	Activity (time to complete)	Start of Project	Post training activity blast exposure above threshold	End of Project
Demographics and blast exposure	Age, military history, rank, time in service (years), Blast Exposure Threshold Survey (10 mins)	✓		
Blast exposure (ongoing)	Blast gauges will be issued to participants to wear on their kit for the duration of their training to measure exposure to blast over pressure.	Consistently worn		
Self-report measures and cognitive assessment (15 mins)	A Neuro-cognitive assessment tool (SWAY) includes a suite of self-report questionnaires, and cognitive tests that assess reaction time, impulse control, timed visual processing, and working memory	✓	✓	✓
Balance assessment (3 minutes)	The test utilised is the modified Balance Error Scoring System (mBESS) which is recommended for use in populations with concussion or mTBI.	✓	✓	✓

8.1.4 Will participants be offered monetary or other compensation to participate in the research?

☐ Yes ☒ No

8.1.5 Will there be any follow up of participants?

☐ Yes ☒ No

8.1.5.1 If yes, please describe

8.2 CHILDREN AND YOUNG PEOPLE [National Statement Chapter 4.2]

8.2.1 Does the study cohort include children and young people?

☐ Yes ☒ No

8.3 PEOPLE IN DEPENDENT OR UNEQUAL RELATIONSHIPS

[National Statement Chapter 4.3 – refer to the introduction in this chapter for further guidance on the types of relationships that are included within this participant cohort.]

8.3.1 Does the study cohort include people in dependent or unequal relationships?

☒ Yes ☐ No If no, go to section 8.4.

8.3.2 Specify the nature of any existing relationship or one that is likely to arise during the research, between the potential participants and any member of the research team or an organisation involved in the research.

Rank is a key feature of military service. Participants may be of non-equal ranks.

8.3.3 What steps, if any, will be taken to ensure that the relationship does not impair participants' free and voluntary consent and participation in the project?

All prospective participants will be briefed b s47E(d) that participation in this research is free and voluntary. If a prospective participant elects to not participate, they will not be adversely impacted. Furthermore, participants will be informed of their freedom to withdraw from the study at any time without any detriment to their career. This can be done by informing the listed project members (either verbally or in writing), who will follow up in writing (via email) to confirm their request to withdraw. Any data collected will be removed accordingly and not be used in analysis.

8.3.4 What steps, if any, will be taken to ensure that decisions about participation in the research do not impair any existing or foreseeable future relationship between participants and researcher/investigator or organisations?

Potential participants will be informed that there is no obligation to participate, nor will they be penalised, or their career be negatively impacted, if they decide either to not participate, or to withdraw once started. It will be made clear to participants that all data will be de-identified and presented/reported as aggregate results only.

8.4 PEOPLE WITH COGNITIVE IMPAIRMENT, INTELLECTUAL DISABILITY OR MENTAL ILLNESS [National Statement Chapter 4.5]

8.4.1 Does the study cohort include the targeted recruitment of people with a cognitive impairment, intellectual disability or mental illness?

☐ Yes ☒ No

8.5 ABORIGINAL AND TORRES STRAIT ISLANDER PEOPLE

- National Statement Chapter 4.7
- Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholder (2018)
- Keeping research on track II (2018)
- Australian Institute of Aboriginal and Torres Strait Islander Studies Code of Ethics for Aboriginal and Torres Strait Islander Research (2020)
- United Nations Declaration on the Rights of Indigenous People (2007)

8.5.1 Does the study cohort include the targeted recruitment of Aboriginal and Torres Strait Islander People?

☐ Yes ☒ No

8.5.2 Does the geographic location of the research mean that a significant number of the population are likely to be Aboriginal or Torres Strait Islander?

☐ Yes ☒ No

8.5.3 Is the research focused on a topic or disease/health burden identified as being of specific concern to Aboriginal and Torres Strait Islander peoples?

☐ Yes ☒ No

8.6 PEOPLE IN OTHER COUNTRIES [National Statement Chapter 4.8]

8.6.1 Does the study cohort include the targeted recruitment of people in other countries?

☐ Yes ☒ No

9. RECRUITMENT

[National Statement Chapter 3.1 (element 2)]

9.1 Does the study involve active participation by individuals?

☒ Yes ☐ No

9.2 How will participants be identified and recruited?

Potential participants will be recruited from 4 SOCOMD groups representing trainees and qualified operators in SOCOMD. These groups represent new trainees beginning their career in a high exposure area, and qualified operators within multiple high exposure elements of SOCOMD. s47E(d) will verbally brief the study protocol to potential participants at a time suitable to them where they will have the opportunity to have any questions answered by the project team and will be provided with a 'Participant Information Sheet' outlining the purpose, methods, risks and potential benefits of the study.

9.3 What is the timeframe for recruitment?

June – August 2024

9.4 Will the potential participants be screened?

☐ Yes ☒ No

9.5 What are the potential effects on the study's recruitment of any current or future relationship between researchers and potential participants?

All potential participants will be informed that participation is entirely voluntary, and the decision to participate/not participate will have no impact on their training, or possible future career within SOCOMD.

DSTG staff s47E(d) ill conduct the recruitment of participants in the absence of any other uniformed military members who may hold rank over the participants.

9.6 **How will the recruitment strategy ensure that participants can make an informed decision about their participation?**

A Participant Information and Consent Form and verbal overview of the study will be provided to potential participants by s47E(d) at Holsworthy Barracks prior to commencement of their training. Participants will be given time to read the Participant Information and Consent Form prior to indicating that they understand the aims of the research project, how it will be conducted, and their role as a participant.

Participants will be reminded that participation is voluntary and that they can refuse with no detriment to their career.

9.7 Are there any risks associated with the recruitment strategy for potential participants or for the viability of the project?

☐ Yes ☒ No

9.7.1 If yes, please describe.

10. CONSENT

[National Statement Chapter 2.2 and Chapter 3.1 (element 3)]

For research involving current serving Defence members, researchers are to consider the command structure when presenting information to participants ['National Statement' Chapter 4.3]

10.1 Will you obtain consent from all participants?

☒ Yes ☐ No ☐ Not applicable

10.1.1 If yes, how will you obtain consent?

A Participant Information and Consent Form and verbal overview of the study will be provided to potential participants by s47E(d) at Holsworthy Barracks prior to commencement of their training. Participants will be given time to read the Participant Information and Consent Form prior to indicating that they understand the aims of the research project, how it will be conducted, and their role as a participant. Members that choose to participate in the study will sign the hard copy Consent form.

Participants will be reminded that participation is voluntary and that they can refuse.

10.1.2 If no, specify why consent will not be obtained from all participants.

10.2 What type of consent is being requested? [National Statement paragraph 2.2.14]

☐ Specific [Limited to the specific project under consideration]

☒ Extended [For use of data or tissue in future projects that are: (i) an extension of, or closely related to, the original project; or (ii) in the same general area/s of research]

☐ Unspecified [Given for the use of data or tissue in any future research] [See also 'National Statement' paragraphs 2.2.15 and 2.2.16]

10.2.1 Please describe why this type of consent is being requested.

The initial findings of this study may warrant further exploration of certain characteristics or aspects of blast exposure during training and potential impacts on physical and cognitive function. This data will be beneficial to the broader Australian Defence Force and Five Eyes partner nations (including United States, Canada, United Kingdom and New Zealand) working in the mTBI research space aiming to establish injury thresholds to support members future health claims.

Further, typical blast exposure during training and potential impacts on physical and cognitive function will support interventions to increase cognitive health and support the knowledge for JHC to deliver preventative interventions to areas identified as high exposure roles.

10.2 Does the study involve consent via limited disclosure? [National Statement paragraph 2.3.1 – 2.3.4]

☐ Yes ☒ No

10.3 Will potential participants be invited to discuss their participation with someone who is able to support them in the decision-making process? [National Statement paragraph 4.3.2]

Yes ☒ No ☐

10.4 Where necessary, who will be confirming or re-negotiating consent with participants and how will this be done?

N/A

10.5 Are there any limitations or consequences for participants who withdraw consent?

Yes ☒ No ☐

If participants opt to have results and data collected on them removed from the study, this will be done as soon as possible upon receiving the request from the participant. There will be minimal impact on the study if the participant requests to withdraw their data prior to the analysis of data at the end of the study period. If a participant withdraws consent after the analysis of data sets containing that participants' data, it will likely not be possible to remove that participants' data from the analysis. Equally, any documents drafted for the publication of results cannot be altered upon a participant's withdrawal from the study. If a participant withdraws from the study after the completion of data collection, the register

linking their personal details to their study ID will have been destroyed and it will not be possible to remove their de-identified samples and data from the study. Importantly though, all analyses and reporting of results will be done as group data and no individual results will be reported upon.

11. WAIVER OF CONSENT

11.1 Are you requesting a waiver of the requirement for consent for some or all participants?

☐ Yes ☒ No

11.2 From which agency/ies will the information be sought?

N/A

12. CLINICAL TRIALS

12.1 Is this project a clinical trial?

☐ Yes ☒ No If no, go to section 13.

13. COLLECTION, USE AND MANAGEMENT OF DATA AND INFORMATION

['National Statement' Chapter 3.1 (element 4)]

Data Collection/Gathering:

13.1 What information are you going to collect/gather? [For projects that include or are limited to use of existing data, your response should be clear on what the source of data is and what variables are being requested.]

- Demographics [Attachment B]
    - Gender, Age, Current Unit, Years of Service
- Previous blast exposure [Attachment C]
    - The Blast Exposure Threshold Survey (BETS) is a 5–8 min survey designed by Naval Medical Research Center and Walter Reed Army Institute of Research to describe the likelihood of developing symptoms associated with lifetime exposure to blast from weapons systems (Modica et al., 2021; Turner et al., 2022).

Blast exposure:

- Blast Gauges will be issued to participants to wear on their kit for the duration of the trial, to measure exposure to blast overpressure (measured in psi) during training. Blast gauges are in sets of 3, to be worn on the rear of the helmet, top of the shoulder strap of the body armour and front of the body armour.

Self-report measures and Cognitive assessment:

- The Sway neuro-cognitive assessment tool will be used at the start and end of the project, as well as post training activities with blast exposures > 4psi to collected data on self-report measures and cognitive performance:
    - Pittsburgh Sleep Quality Index (PSQI; Backhaus et al., 2002; Buysse et al., 1989) [Attachment D]. This has been used to assess sleep quality and disturbances related to repeated blast exposure in United Sates Special Operations Forces Personnel (Edlow et al., 2022).
        - A modified version of the PSQI will be used at baseline where participants have completed selection in the previous month. Participants will be asked to complete the questionnaire based on the prior two weeks, excluding the selection course.
    - Patient Health Questionnaire-9 (PHQ-9; Kroenke et al., 2001) [Attachment E]. This has been used to assess symptoms of depression related to repeated blast exposure in United Sates Special Operations Forces Personnel (Edlow et al., 2022).
    - Pain intensity and pain interference measured by the EuroQol Group 5 dimension 5 level version quality-of-life (EQ-5D-5L) (Herdman et al., 2011) [Attachment F]. This has been used to assess pain related to chronic mild traumatic brain injury in United States military personnel (Hoot et al., 2018).
        - EQ-5D-5L for pain is a 5-point ordinal scale on which respondents rate their current pain as none, slight, moderate, severe or extreme.
    - Neurobehavioural Symptom Inventory (NSI; Cicerone et al., 1995) [Attachment G]. This inventory has been used to monitor symptoms related to repeated blast exposure in in United States Special Operations Command training (McEvoy et al., 2024).
    - A suite of four cognitive tests assessing reaction time, impulse control, timed visual processing, and working memory.
        - Reaction time: the participant will hold the tablet horizontally (landscape) and move the device as rapidly as possible in any direction when the screen colour changes from white to orange. The participant will complete five trials. The most rapid and the slowest trial reaction times will be excluded in order to remove outliers and the values from the three remaining trials will be averaged to calculate the score for the test.

- Impulse control: the participant will hold the tablet horizontally and then move it as rapidly as possible in any direction when a green circle with a white check mark is displayed on a blank screen. They do not move the device if a red circle with a white "*X*" is presented on a blank screen. Eight total trials will be administered (five "go" trials and three "no-go" trials). The five "go" trials will be retained for scoring. Of these five trials, the most rapid and the slowest reaction times will be excluded and the values from the three remaining trials will be averaged to calculate the score for the test.
- Timed visual processing: the participant will hold the tablet horizontally and see two T-shaped lines, one on each side of the screen. One of the two lines is long and one is short. The long end of two "Ts" is quickly hidden and the participant will tap the device screen on the side where the longer line was presented. They will not tap the device screen if they are unsure about which of the two lines is longer. If the participant makes two incorrect responses at any refresh interval, they must repeat and get two in a row correct at that interval with one more screen refresh to complete the test. The maximum number of trials is 20. An examinee's score is the screen refresh rate at the conclusion of the test.
- Working Memory: the participant will hold the tablet vertically. They will first see three letters (all consonants) on the screen for 3 s and then are asked to remember the letters. Next, the letters disappear and a 2 (columns) × 4 (rows) grid of squares appears. One of the squares briefly flashes orange and then the examinee touches the square that flashed orange. Two squares then turn orange, one at a time, and then the examinee reproduces the sequence on the grid. The sequence continues to lengthen until the examinee makes one mistake; at that point, the grid disappears, they type in the three letters shown at the beginning of the test, and the test concludes. The score for this test is created with a formula that accounts for both accurate recall of the three letters and progress through the grid sequence.

Balance [Attachment H]:

- Balance testing will be conducted on VALD force-plates will be used to conduct Balance assessments at the start and end of the project, as well as post training activities with a single blast peak overpressure > 4 psi or a cumulative blast overpressure impulse > 100psi•ms in a single calendar day. The test utilised is the modified Balance Error Scoring System (mBESS) which is recommended for use in populations with concussion or mTBI. The balance test requires participants to close their eyes and stand as still as possible for 20seconds in 3 conditions, double stance, single stance (non-dominant leg) and tandem stance.

13.2 How will you collect/gather the information?

Demographics

- This will be a short paper based questionnaire asking participants to report their: age, height, weight, ethnicity, job role, years of military service, concussion history and blast exposure history

Blast exposure:

- BlackBox Biometrics Blast Gauges will be issued to participants to wear on their kit for the duration of the trial, to measure exposure to blast overpressure (measured in psi) during training. Blast gauges are in sets of 3, to be worn on the rear of the helmet, top of the shoulder strap of the body armour and front of the body armour.
- Blast overpressure (psi), impulse (psi•ms) and acceleration ($m \bullet s^{-2}$) data will be recorded from the blast gauges coded to each participants de-identified study ID. De-identified data is viewable on an UNCLASS tablet via Bluetooth and transferred to an UNCLASS computer via USB. Both UNCLASS tablet and computer store data locally and do not connect to the internet. De-identified data in the form of excel spreadsheets will be transferred from the UNCLASS device to the DPN IAW Section 13.9.
- Where possible, details including the activity being undertaken, training area, weapon system used, type and size of charge and position relative to blast will also be recorded by the investigators on pen and paper to provide further context about the exposure. This information will be used to provide recommendations on potential "optimal" location for safety staff and firer for specific weapon systems and training areas, 1 page infographics for training, and a summary table of measured blast overpressure.

Self-report measures and Cognitive assessment:

- Participants will complete the listed self-report questionnaires and cognitive assessments on the SWAY Neuro Cognitive Assessment Tool (SWAY Medical Inc., Tulsa, OK, USA) phone application. The SWAY application includes a suite of self-report questionnaires and cognitive tests recommended for use in populations with concussion or mTBI
- The SWAY phone application is a cloud based application, approved for de-identifiable use from the Chief Information Officer Group (CIOG) and Australian School of Special Operations. All data is saved on a secure server which members access the platform by a phone application using an issued test cod s47E(d) nd their de-identified study ID. No personally identifiable details are entered into the application.
- s47E(d) will be present to offer further clarification to participants if needed on the application.

Balance:

- The modified Balance Error Scoring System (mBESS) will be conducted on VALD Force-Plates. The mBESS is recommended for use in populations with concussion or mTBI and requires participants to close their eyes and stand as still as possible

for 20seconds in 3 conditions, doubles stance, single stance (non-dominant leg) and tandem stance.

- 3D Force (N) data will be recorded from the VALD force-plates during the 3 balance assessments and coded to each participants de-identified study ID. Data will be stored on VALD's secure cloud server which has been approved for de-identifiable use from the Chief Information Officer Group (CIOG) and Australian School of Special Operations. No personally identifiable details are entered into the VALD software, and all data will be transferred to the DPN IAW Section 13.9.

13.3 What is the likely effect on the data in the event that the participant/s withdraw from the study?

In the event that a participant withdraws from the study they will have the option to choose whether or not the data collected from their participation remains a part of the study. If participants choose to retain their data and results in the study, the inclusion of this information will depend on the completeness of the data collected from them. The researchers will decide on a case-by-case basis if it is appropriate for the data set to be retained as a part of the research data set. If participants opt to have results and data collected on them removed from the study, this will be done as soon as possible upon receiving the request from the participant. There will be minimal impact on the study if the participant requests to withdraw their data prior to the analysis of data at the end of the study period. If a participant withdraws consent after the analysis of data sets containing that participants' data, it will likely not be possible to remove that participants' data from the analysis. Equally, any documents drafted for the publication of results cannot be altered upon a participant's withdrawal from the study. If a participant withdraws from the study after the completion of data collection, the register linking their personal details to their study ID will have been destroyed and it will not be possible to remove their de-identified samples and data from the study. Importantly though, all analyses and reporting of results will be done as group data and no individual results will be reported upon. This is made clear to participants in the "Participant Information Sheet".

Data Analysis:

13.4 How will you measure, manipulate and/or analyse the information that you collect/gather?

The primary aim of this study is to establish a protocol to monitor the impact of LLB on members during SOCOMD training.

The primary statistical aim is to assess any difference between measures of cognitive, psychological and balance function post blast exposure during training. Blast exposure will be quantified as peak blast over pressure and impulse for each recorded exposure.

All de-identified data will be analysed using SPSS (version 25, IBM, USA). A one-way repeated measures ANOVA or Wilcoxon signed rank tests will be performed to determine if there are any differences between the mean or median, respectively, assessments of cognitive function, psychological symptoms or balance pre-training and post-blast exposure.

13.5 What matching and sampling strategies will you be using?

N/A

13.6 How will you account for potential bias, confounding factors and missing information?

N/A

13.7 Statistical power calculation

N/A

Data Linkage:

13.8 Do you plan on conducting any data linkage?

Yes ☐ No ☒

13.8.1 If yes, describe what linkages are planned or anticipated? [If not relevant, indicate N/A.]

Data Management:

13.9 Please describe the following: [National Statement paragraph 3.1.44]

Provision of access	The duration of data collection, participants' names will be linked to their unique identifier numbers. An Excel file containing this information will be stored on a password-protected laptop that will only be accessible to members of the research team on a need-to-know basis. Immediately after data collection has concluded the Excel file of this information will be destroyed.
Sharing	De-identified data collected from this study may be shared with other DSTG and JHC researchers, and Five Eyes partner researchers if it is deemed beneficial for any future investigations for similar studies and research purpose. De-identified data collected in this study may also be combined with datasets from similar studies or used for future, related projects. This is stated in the "Participant Information Sheet"
Disclosure	Participants personal information will not be disclosed at any time, except as required by law in the case that they may pose a threat to themselves or others
Storage	All paper-based data will be stored in a locked place that will only be accessible to members of the project team with a need-to-know. All electronic copies of data will be stored on the following as required: password-protected laptops, hard drives on the Defence Protected Network, and Defence's official recording keeping system (i.e. Objective). All electronic data will be locked in password-protected accounts/folders and will only be accessible to members of the research team with a need-to-know.
Intellectual Property (IP) rights and Copyright arrangements	Defence owns the IP rights and Copyright arrangements.
Transfer	De-identified data in the form of excel spreadsheets collected on UNCLASS devices will be transferred from the UNCLASS device to the DPN via a KANGURU Defender 3000 USB drive approved by COIG for transferring files between UNCLASS and PROTECED Defence networks.

Archival	Data will be archived in accordance with the Records Management Policy Manual (RECMAN 2014). Both physical and digital records will be stored in an approved recordkeeping system (e.g. Objective, lockable filing cabinet) and accessible upon request to those outside of the research team as detailed in the Archives Act 1983 and Freedom of Information Act 1982.
Destruction	The data obtained from this project will be retained for a minimum of seven years following the publication of research findings. Approval must be sought by the National Archives of Australia for the disposal of Defence related research data in accordance with Archives Act 1983. Data will be destroyed in accordance with the Defence Security Principles Framework, Annex H Classification and Protection of Official Information – Disposal and destruction of protectively marked information and assets. Disposal of data is to be recorded in the Classified Document Register. Electronic data is to be sanitised/destroyed in accordance to the Information Security Manual (ISM). Paper based classified research materials may be destroyed by compliant shredders (ASIO Security Equipment Guide (SEG)-01 *Class A and B Paper Shredders*) or destructors (ASIO SEG-18 *Destructors*). Once processed these materials can be disposed of via garbage or recycling via the local refuse disposal process.
Training for members of the project team and others, as appropriate	N/A

14. COMMUNICATION OF RESEARCH FINDINGS OR RESULTS TO PARTICIPANTS

14.1 Could the research generate findings or results of interest to the participants?

Yes ☒ No ☐

14.1.1 If yes, please describe

The participants may be interested in the findings which describe any impact of LLB exposure during training on cognitive function, psychological symptoms or balance.

Data from the blast gauges will allow members to determine optimal locations for the conduct of firing, breaching, shooting, and supervising in SF training within the current requirements of standing safety doctrine. Since the injury thresholds are unknown, personnel positioning in the lowest overpressure areas is easy to implement and action.

14.2 Will participants be provided with their individual results? [National Statement paragraphs 3.1.62 and 3.1.64]

Yes ☒ No ☐

14.2.1 If yes, please describe

Participants will be provided a copy of their individual results if requested.

14.3 Could the findings or results be of significance to the current or future welfare or wellbeing of participants or others? [National Statement paragraphs 3.1.63 – 3.1.67]

Yes ☒ No ☐

14.3.1 Are the participants in the research informed of this possibility?

Yes ☒ No ☐

14.3.1.1 Please describe

Participants are informed of the benefits of taking part in the research in the Participant information and consent form. They will benefit from a greater understanding of the impact of LLB exposure during training to SOCOMD members.

15. DISSEMINATION OF PROJECT OUTPUTS AND OUTCOMES

15.1 What is the plan for reporting, publishing or otherwise disseminating outputs/outcomes of the research? [National Statement paragraph 3.1.68(a)]

The researchers will use the results to support and inform both the current and future wellbeing and welfare of SOCOMD members. Specifically:

- Recommendations on potential "optimal" location for safety staff and firer for specific weapon systems and training areas will be provided to SOCOMD members in the form of regular verbal briefs, 1 page infographics and a summary table of measured blast overpressure
- The researchers will also write the aggregated findings up for peer-reviewed publication. The results will be presented at national and international conferences.

15.2 How will the privacy of participants be assured in any research outputs/outcomes?

The data collected will only be disclosed as collective, aggregated results. The intent of this will be contained in the PICF. Steps will be taken to protect against deductive disclosure such as collapsing cells in the reporting of results so there are no cells with personal information that are less than n=5 individuals.

15.3 Will the findings or results be disclosed to third parties and/or the public?

Yes ☒ No ☐

15.4 Who will communicate the findings or results and how?

The investigators will be responsible for acquiring approval and disseminating project outcomes. The Principal Investigator will write a summary of the aggregated results. This will be reviewed by DSTG, JHC and SOCOMD and when approved, will be uploaded to Defence internal websites, including a link to any peer-reviewed publication. The researchers will also write the aggregated findings up for peer-reviewed publication and will be presented at national and international conferences.

15.5 How will the planned dissemination of the outputs/outcomes contribute to knowledge or practice or serve the public?

This project will support and inform both the current and future wellbeing and welfare of Defence members.

15.6 Are there any restrictions on the dissemination of project outputs and outcomes? [National Statement paragraph 3.1.68]

Yes ☒ No ☐

15.5.1 If yes, please provide detail.

Any report or peer-reviewed publication will seek DSTG, JHC and SOCOMD organisational endorsement prior to dissemination.

16. PRINCIPAL INVESTIGATOR DECLARATION

The research team has certified that:

a. All information in this application and supporting documentation is correct and as complete as possible.

b. We/I have read and addressed in this application the requirements of the National Statement on Ethical Conduct in Human Research (National Statement) and any other relevant guidelines.

c. We/I have considered and addressed in this application any relevant legislation, regulations, research guidelines and organisational policies.

d. All relevant financial and non-financial interests of the project team have been disclosed.

e. In the capacity of a supervisor, as applicable, we/I have reviewed this application and will provide appropriate supervision to the student(s) in accordance with the arrangements specified in this application and those associated with the student's educational program.

In submitting this application, the research team agrees to:

a. Not commence this study prior to obtaining all relevant ethics and governance approvals

b. To notify the approving ethical review body/ies of:

   i. any changes to the study prior to their implementation

   ii. serious adverse or adverse events

   iii. deviations

   iv. discontinuation of the study

   v. changes to research personnel (or their contact details) and/or

   vi. any complaints received about the conduct of the study.

c. Ensure that all conditions of ethical approval are adhered to.

d. Uphold the principles of the National Statement and the Australian Code for the Responsible Conduct of Research and where relevant, the Good Clinical Practice Guidelines and the applicable regulatory requirements.

e. Participate in on-site audits, if requested.

Name: s47E(d)

Signature: s47E(d)

Date: 29 May 2024

17. DEFENCE ORGANISATIONAL SUPPORT

For Defence research (including studies that are funded by or involve recruitment of Defence personnel that are conducted by external organisations), support should also be obtained from at least a one Star or equivalent, in accordance with the Human and Animal Research Manual. To avoid any actual or perceived conflicts of interest, the responsible officer should not be directly involved in the research.

Evidence of Defence organisational support is to be submitted with this application. Failure to submit the certification will result in the study being deemed to be invalid and will delay the consideration of the proposal.

Defence organisational support is not required for studies that are limited to ex-serving Defence members or use of data from the Department of Veterans' Affairs.

I certify that:

☒ this request satisfies all the requirements of this Institution

☒ the relevant endorsements of this application have been obtained

☒ all information provided in support of this application, is to the best of my knowledge, correct.

Name (including rank/title):

Position:

Formation/Institution:

Signature: Date: Select date.

18. COMMAND APPROVAL

Command approval is required when volunteers are sought from an ADF unit or specific Defence organisation. As general guidance, this approval will be required when potential volunteers are recruited from their workplace and their participation would subsequently remove them from their usual place of work for a period. Approval is to be obtained from an individual who is senior to participants within the chain of command. **Participants will be deemed to be on duty.**

The intent of this section is to provide Commanding Officers (or heads or directors of organisations) with an opportunity for input where conduct of this research protocol could affect the operation of their unit or organisation. This page should be copied as required and original copies attached to the research protocol.

This section is not applicable to research that does not involve Defence personnel. [**Note** that the term 'Defence Personnel' includes APS and contracted staff, and is not limited to uniformed Defence members.]

Pending ethical approval of this protocol by the Departments of Defence and Veterans' Affairs Human Research Ethics Committee, I hereby grant authority for the Investigators to engage with personnel under my control (command and/or line management) for the purposes of seeking volunteers to participate in this proposed study. I acknowledge that participants will be deemed to be 'on duty' when participating in the proposed study in accordance with the Interim Human and Animal Research Manual. This approval does not constitute endorsement of the project (organisational support) or a direct order to participate in research.

Approved number of participants:

Approved dates:

Name (including rank/title):

Position:

Formation/Institution:

Signature:

Date: Select date.

Comments:

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20. ATTACHMENTS

Mandatory (for all research proposals) –

- Curriculum vitae for all research personnel [Not exceeding five pages each]

Other

- Confirmation of candidature [for student research] Yes ☐ No ☐ N/A ☒

- Advertisements (flyers, posters, online media content, newspaper advertisements) Yes ☐ No ☐ N/A ☒

  List each item.

- Draft emails to potential participants Yes ☐ No ☐ N/A ☒

  List each item.

- Participant Information Sheet and Consent Form Yes ☒ No ☐ N/A ☐
  Attachment A

  List each item where there are multiple forms.

- Survey/questionnaire Yes ☒ No ☐ N/A ☐

  Attachment B – Demographics

- Interview questions Yes ☐ No ☐ N/A ☒

  List each item.

- Standardised measures Yes ☒ No ☐ N/A ☐

Attachment C - The Blast Exposure Threshold Survey (BETS)

Attachment D – Pittsburgh Sleep Quality Index

Attachment E – Patient Health Questionnaire-9

Attachment F - EuroQol Group 5 dimension 5 level version quality-of-life (EQ-5D-5L)

Attachment G – The Neurobehavioural Symptom Inventory (NSI)

Attachement H - mBESS