

PROJECT DESCRIPTION

Full title:

[Full titles should not include acronyms]

Short title:

Name of contact person:

Telephone number: [Include area code for land lines]

Email:

Version:

Date:

Prior to submitting your application for ethical review:

1. 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.
2. Obtain Defence organisational support and command approval, where required.
3. 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[[1]](#footnote-1) 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.] |
| --- | --- |
|  |  |

DEFINITIONS

| Term  | Meaning [All technical terms in the Project Description are to be listed and defined.] |
| --- | --- |
|  |  |

1. STUDY SYNOPSIS

|  |  |
| --- | --- |
| Aim | [The research aim should be short and succinct and state the intention/aspiration of the study. The aims should be specific, measurable, achievable, realistic and time constrained.] |
| Hypothesis (where relevant)  | [The hypothesis should be a predictive statement about the possible outcomes of the research. If not relevant, indicate N/A.] |
| Inclusion criteria [National Statement paragraphs 1.4(a) ~~and 3.1.15~~] |

|  |  |
| --- | --- |
| [[Select all that apply][ ]  Current serving Defence members (or their data) [where this is selected please identify each service that is included][ ]  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:**  |
| Exclusion criteria [National Statement paragraphs 1.4(a) ~~and 3.1.15~~] |  |
| Number of participants/records |  |
| ~~Amount and~~ Sources or potential sources of research funding [National Statement paragraph 5.3.7]  |  [Select all that apply][ ]  Defence [ ]  DVA [ ]  Other – please specify |
| Site/s  |  |
| What organisation has overall responsibility for the project? | [For research conducted by Defence personnel, please specify the branch and directorate details as well.] |
| Anticipated start date  | [Should not be prior to obtaining ethics approval.] |
| Anticipated completion date [National Statement paragraph 5.2.19(i)] | [Should include time to review and write up findings.] |
| Five keywords/phrases to describe or define the field of research |  |
| Does the project include collection of:  | Health information [ ]  Yes [ ]  No Personal information [ ]  Yes [ ]  NoSensitive information [ ]  Yes [ ]  No[Refer to the Privacy Act 1988[[2]](#footnote-2) for definitions.]  |

The research will involve the following:

|  |  |
| --- | --- |
| Active participation of human participants | [ ]  Yes [ ]  No  |
| Human biospecimens  | [ ]  Yes [ ]  No |
| Human gametes or assisted reproductive technology embryos | [ ]  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 |

1. 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.

For student research, the primary supervisor is to be listed as the 1st Principal Investigator.

|  |  |
| --- | --- |
| **Name** |  |
| **Institution** |  |
| **Position** |  |
| **Role**  | [ ]  Principal Investigator  |
| **Responsibilities**  | [Describe the activities they are responsible for in the study] |
| **Professional registration**  | [Provide Australian Health Practitioner (AHPRA) or equivalent bodies registration number. If not applicable, indicate N/A] |
| **Contact details** | Phone: Email:  |
|  |
| **Name** |  |
| **Institution** |  |
| **Position** |  |
| **Role**  | [Select one only] [ ]  Principal Investigator [ ]  Co-investigator [ ]  Research Assistant [ ]  Student researcher [ ]  Other, please specify |
| **Responsibilities**  | [Describe the activities they are responsible for in the study] |
| **Professional registration**  | [Provide AHPRA or equivalent bodies registration number. If not applicable, indicate N/A] |
| **Contact details** | Phone: Email:  |
| **For student research, the educational program undertaken for this project** | [If not relevant, delete this row.] |
| **For student research, supervisory arrangements, support and training to be provided** | [If not relevant, delete this row.] |

1. 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 5.6, The Australian Code for the Responsible Conduct of Research[[3]](#footnote-3) – responsibility 24]

[ ]  Yes [ ]  No

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

1. RESOURCES

**4.1 Resources necessary for the study to be conducted** [National Statement paragraph 1.1 (f)] [Describe the resources that are necessary to conduct the research]

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

|  |  |  |
| --- | --- | --- |
| **Source/potential source** | **Amount** | **Type** [financial/ in-kind/ per capita payment/ other – specify] |
|  |  |  |

**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.** [If not applicable, state N/A.]

1. BACKGROUND

**5.1 Has the scientific or academic merit of the project been evaluated**? [For student research, the evaluation should have been conducted at a minimum by the student’s supervisor/s.]
[ ]  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)] [Evidence of confirmation of candidature should be provided, where applicable.]

**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 purpose of the literature review is to demonstrate that the proposed research is based on a thorough understanding of what is known about this topic and therefore how this study proposes to add to the knowledge. The literature review that needs to demonstrate that the researcher(s) have an adequate understanding of both the theoretical background to the research and also its practical implications. The literature review should be concise (eg maximum of 1,000-1,500 words or approximately three to five pages of double spaced text) and written in plain English. A simple "cut and paste” from the literature review section of a university thesis at any level is not appropriate. *It should be targeted at providing the ethics committee members who may have no specific knowledge of the topic with a clear and precise summary of the state of the research area.* The literature review must include references from the academic literature which must be provided in Section 20 of this document. The literature review may also reference extant Departmental policies and other documents as well as elements of the grey literature.]

**5.5 Rationale/Justification** [National Statement paragraphs 1.1(a)] [How will this research fill any identified gaps, contribute to the field of research or contribute to existing or improved practice?

**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)]

* 1. **Expected outcomes**
1. PROJECT DESIGN
	1. **Research setting** [physical sites, online forums and alternatives]
	2. **Research design and methodological approach/es** [National Statement paragraph 1.1(b) and Chapter 3.1 Element 1] [For Aboriginal and Torres Strait Islander research, describe the methodology for engagement with social/cultural practices]
	3. **Rationale for choices of method/s (tied to project aims/objectives)** [National Statement paragraph 1.1(b) and Chapter 3.1 Element 1]
	4. **Sample size, statistical power issues (where applicable) and justification**

Research activities

* 1. **What are you going to do?**
1. BENEFITS AND RISKS

[National Statement paragraphs 1.6 – 1.9 and Chapter 2.1]

**7.1 What are the benefits to participants?** [If there is no direct benefit to participants, this should be stated.]

**7.2 What are the benefits to the wider community?**

**7.3 What are the benefits to the researchers?** [For student research, include the academic benefit to the student researcher.]

**7.4 What are the risks to participants and the researchers, what is the likelihood of the risk and how will they be mitigated?**

**7.5 How do the benefits of the research outweigh the risks associated with the research?**

1. PARTICIPANTS

[Check responses in this section against section 1 to ensure consistency]

**8.1 Does the research involve active participation by individuals?** [ ]  Yes [ ]  No

If no, go to section 10.

**8.1.1 How will you engage with your participants?**

|  |  |
| --- | --- |
| [ ]  Survey(s) /questionnaire(s)  | [ ]  Focus groups  |
| [ ]  Structured interviews  | [ ]  Semi-structured interviews  |
| [ ]  Other – please specify here |

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

|  |  |
| --- | --- |
| [ ]  Face-to-face  | [ ]  Telephone/Teams etc  |
| [ ]  Online – please specify platform here  |
| [ ]  Other – please specify here |

**8.1.3 What are participants requested to do (participant commitment)?**
[Describe the sequence and duration of all components of the study that involves direct interaction with participants, including provision of transcripts for review or follow-up, if any. If not relevant, indicate N/A.]

**8.1.4 Will participants be offered monetary or other compensation to participate in the research?**
[ ]  Yes [ ]  No

**8.1.4.1 If yes, please describe.** [The response should include information on how the reimbursement/rate of payment has been determined, the method and timing of disbursements and how prospective participants will be advised of the provision of payment, noting the guidance in the ‘Payment of participants in research: information for researchers, HRECs and other ethics review bodies[[4]](#footnote-4)’ paragraph 1.6. Payments should neither present problems of coercion nor undue influence. Payments should be prorated and not wholly contingent upon completion of participation, noting the guidance in Integrated Addendum to ICH E6(R1): guideline for Good Clinical Practice[[5]](#footnote-5) paragraph 3.1.8.]

**8.1.5 Will there be any follow up of participants?** [Follow-up does not include the provision of transcripts for review and verification.]
[ ]  Yes [ ]  No

**8.1.5.1 If yes, please describe** [Describe what follow up is intended, and if this is clear in the information provided to participants.]

**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 If no, go to section 8.3.

* + 1. **What age/s or age group/s are you intending to recruit as participants?**

**8.2.3 How will you determine a child’s vulnerability and capacity to consent to participate in the study?**

**8.2.4 Describe the form of any proposed discussions with children and young people about the research, its effects and likely outcomes, taking into consideration their capacity and level of comprehension and their capacity to consent.**

**8.2.5 What measures will be put into place to ensure the child or young person’s safety, emotional and psychological security, and wellbeing?**

**8.3 PEOPLE IN DEPENDENT OR UNEQUAL RELATIONSHIPS**[National Statement Chapter 4.3 – Examples include:

* carers and people with chronic conditions or disabilities, including long-term hospital patients, involuntary patients, or people in residential care or supported accommodation
* health care professionals and their patients or clients
* teachers and their students
* prison authorities and prisoners
* governmental authorities and refugees
* employers or supervisors and their employees (including members of the Police and Defence Forces)
* service-providers (government or private) and especially vulnerable communities to whom the service is provided.]

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 Why is it necessary to conduct the research in this population?** [People in this population are vulnerable to being over-researched because of the relative ease of access to them as a research population – this is of particular relevance to the Defence and veteran (ex-serving Defence members) population] [National Statement paragraph 4.3.4]

**8.3.3 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.**

**8.3.4 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?** [National Statement paragraph 4.3.1 and 4.3.2]

**8.3.5 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?**

**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 If no, go to section 8.5.

**8.4.2 What mechanisms will be put into place to determine the person’s capacity to consent?** [The response should include how the decision will be made about the person’s capacity to consent, who will make that decision and the criteria that will be used in making that decision.]

**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)[[6]](#footnote-6)
* Keeping research on track II (2018)[[7]](#footnote-7)
* Australian Institute of Aboriginal and Torres Strait Islander Studies Code of Ethics for Aboriginal and Torres Strait Islander Research (2020)[[8]](#footnote-8)
* United Nations Declaration on the Rights of Indigenous People (2007)[[9]](#footnote-9)

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

If you have answered no to all three questions above, go to section 8.6.

**8.5.4 Describe how you will take into account the cultural sensitivities of discrete Aboriginal and Torres Strait Islander communities.**

**8.5.5 Describe how the principle of Indigenous Data Sovereignty will be addressed** [including creation, development, stewardship, analysis, dissemination and infrastructure]

 **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 If no, go to section 9.

**8.6.2 Does the research rely on Defence’s Federal Wide Assurance[[10]](#footnote-10) in regard to human subject research protection for international collaboration with the United States?**

[ ]  Yes [ ]  No

**If yes, please describe.**

**8.6.3 Describe the ethical review processes (including how they function) for research to be conducted in other countries and whether the processes are mandatory or voluntary.**

**8.6.4 What are the values and principles on which the ethical review processes rely?**

**8.6.5 Do the processes for ethical review in the other countries require reporting of the Australian review bodies approval?**

[ ]  Yes [ ]  No

**8.6.5.1 If yes, please describe**

**8.6.6 Is there a local, readily accessible contact for participants to receive responses, ask questions or lodge complaints about the research?**

[ ]  Yes [ ]  No

**8.6.6.1 Please describe**

**8.6.7 Describe how the recruitment processes ensure respectful engagement within the cultural context.**

1. RECRUITMENT

[National Statement Chapter 3.1 (element 2)]

* 1. **How will participants be identified and recruited?** [Where required, describe how the recruitment technique/s will ensure that they are appropriate for specific populations]
	2. **How does the recruitment methodology ensure that recruitment is free from coercion?** [National Statement paragraph 2.2.9]
	3. **What are the potential effects on the study’s recruitment of any current or future relationship between researchers and potential participants?**
	4. **How will the recruitment strategy ensure that participants can make an informed decision about their participation?**
	5. **Are there any risks associated with the recruitment strategy for potential participants or for the viability of the project?**
	[ ]  Yes [ ]  No
		1. **If yes, please describe.**
	6. **What is the timeframe for recruitment?** [This is not the period for the entire study. Recruitment is not to occur prior to ethics approval being granted.]
	7. **Will the potential participants be screened?**
	[ ]  Yes [ ]  No
		1. **If yes, by whom and how will this occur?**
1. 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?**

**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.**

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

 [ ]  Yes [ ]  No If no, go to question 10.3

**10.2.1 Are there are suitable alternatives involving fuller disclosure by which the aims of the research can be achieved?**

[ ]  Yes [ ]  No

**Please describe:**

**10.2.2 Please describe the extent of the limited disclosure:**

**10.2.3 Will participants be provided with information regarding the aims of the research and an explanation of why the omission/alteration was necessary?** [National Statement paragraph 2.3.2b)]

[ ]  Yes [ ]  No

**Please describe:**

**10.2.4 Will participants be offered the opportunity to withdraw any data or tissue provide by them after their participation has ended?** [National Statement paragraph 2.3.1e)(ii)]

[ ]  Yes [ ]  No

**Please describe:**

**10.2.5 Is there any known or likely reason that participants would not have consented if they had been fully aware of what the research involved?** [National Statement paragraph 2.3.2c)]

[ ]  Yes [ ]  No

**Please describe:**

**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?** [If not relevant, indicate N/A]

**10.5 Are there any limitations or consequences for participants who withdraw consent?** [Consider the identifiability of data at any given time when considering your response]

[ ]  Yes [ ]  No
**10.5.1 If yes, please describe.**

1. WAIVER OF CONSENT

**11.1 Are you requesting a waiver of the requirement for consent for some or all participants?**
[ ]  Yes [ ]  No If no, go to section 12

**11.2 Does the request seek a waiver under Section 95 of the Privacy Act 1988?**[[11]](#footnote-11)

[ ]  Yes [ ]  No

**11.3 Does the request seek a waiver under Section 95a of the Privacy Act 1988?**[[12]](#footnote-12)

[ ]  Yes [ ]  No

**11.4 From which agency/ies will the information be sought?** [Include the potential number of records and name of the data source in your response]

**11.5 Does the data include sensitive information?** [Check response against section 1 and refer to section 1 for further guidance][ ]  Yes [ ]  No

* + 1. **If yes, why is it necessary to use sensitive information?**

**11.6 Why is de-identified information unable to be used?**

**11.7 In each of the following, describe in detail the nature of involvement:** [National Statement paragraph 2.3.10]

1. **Involvement in the research carries no more than low risk to participants**
2. **The benefits of the research justify any risks of harm associated with not seeking consent**
3. **It is impracticable to obtain consent (for example due to the quantity, age or accessibility of the records)**
4. **There is no known or likely reason that participants would not have consented if they had been asked**
5. **There is sufficient protection of their privacy**
6. **There is an adequate plan to protect the confidentiality of data**
7. **In case the results have significance for participants’ welfare, there is, where practicable, a plan for making information arising from the research available to them (for example via a disease specific website or regional news media)**
8. **The possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled.**
9. **The waiver is not prohibited by state/territory, federal or international law.**

**11.8 For medical research involving a waiver of consent for the disclosure of personal information held by agencies, complete the following table:**

|  |
| --- |
| **Which Australian Privacy Principles[[13]](#footnote-13) (APPs) would be or are likely to be breached if a waiver of consent is not granted?**  |
| APP 1 – Open and transparent management of personal information |  |
| APP 2 – Anonymity and pseudonymity |  |
| APP 3 – Collection of solicited personal information |  |
| APP 4 – Dealing with unsolicited personal information |  |
| APP 5 – Notification of the collection of personal information  |  |
| APP 6 – Use or disclosure of personal information |  |
| APP 7 – Direct marketing  |  |
| APP 8 – Cross-border disclosure of personal information |  |
| APP 9 – Adoption, use or disclosure of government related identifiers  |  |
| APP 10 – Quality of personal information |  |
| APP 11 – Security of personal information |  |
| APP 12 – Access to personal information |  |
| APP 13 – Correction of personal information |  |
| **To what degree is the research likely to contribute to:** |
| 1. Identification, prevention or treatment of illness or disease
 |  |
| 1. Scientific understanding relating to health
 |  |
| 1. The protection of health of individuals and/or communities
 |  |
| 1. The improved delivery of health services
 |  |
| 1. Scientific understanding or knowledge
 |  |
| Are there any likely benefits of the study to individuals, to the category of persons to which they belong, or to the wider community that will arise from the medical research being undertaken in the manner proposed?  | [ ]  Yes [ ]  No Refer to Section 7Please describe: |
| Can the requirements of the medical research design be satisfied without risking infringement of an APP?  | [ ]  Yes [ ]  No Please describe: |
| Are there scientific defects in the research design that might arise if the research is not conducted in the manner proposed?  | [ ]  Yes [ ]  No Please describe: |
| What are the potential financial costs of not undertaking the medical research (to government, the public, the health care system, etc.)?  |  |
| Describe the importance of the research to the public interest?  |  |
| **The extent to which the data being sought are ordinarily available to the public from that agency?** |
| 1. Does the medical research involve use of data in a way which is inconsistent with the purpose for which the data was made public?
 | [ ]  Yes [ ]  No Please describe: |
| 1. Does the medical research require an alteration of the format of the data of a kind that would, if used by an agency, involve a breach of an APP?
 | [ ]  Yes [ ]  No Please describe: |
| Is the risk of harm to a person whose personal information is to be used in proposed research minimal, having regard to the elements of that research provided in response to paragraph 2.3 of the Guidelines under Section 95 of the *Privacy ACT 1988?* | [ ]  Yes [ ]  No Please describe: |
| **The standards of conduct that are to be observed in the medical research, including:** |
| The study design and the scientific credentials of the researchers. | [ ]  Yes [ ]  No Refer to Section 6 – regarding Study Design. Refer to Section 2 and attached CVs regarding scientific credentials of researchers. Please describe: |
| Does the research involve contact with participants?  | [ ]  Yes [ ]  No  |
| Is access to personal information restricted to appropriate researchers? | [ ]  Yes [ ]  No Refer to Section 13 Please describe: |
| Is there a risk that a person or group could be identified in the published results? | [ ]  Yes [ ]  No Refer to question 15.2Please describe: |
| Are procedures in place that will be followed at the completion of the research to ensure that all data containing personal information are at least as secure as they were in the sources from which the data was obtained, including the date when the data will be destroyed or returned? | [ ]  Yes [ ]  No Refer to question 13.4.1 and Section 16. Please describe: |

1. CLINICAL TRIALS
* Integrate Addendum to ICH E6(R1): Guideline for good clinical practice[[14]](#footnote-14)
* Principles, regulations and governance of clinical trials[[15]](#footnote-15)
* The National Clinical Trials Governance Framework and user guide for health service organisations conducting clinical trials[[16]](#footnote-16)
* CTN scheme[[17]](#footnote-17)
* CTA scheme[[18]](#footnote-18)

**12.1 Is this project a clinical trial**[[19]](#footnote-19)**?** [ ]  Yes [ ]  No If no, go to section 13.

|  |
| --- |
| **CLINICAL TRIAL RESEARCH**  |
| Sponsor Details  |
| Name:  |  |
| Address:  |  |
| **Monitor Details (if different to the Sponsor)**  |
| Name:  |  |
| Address:  |  |
| **Sponsor’s Medical Expert/Dentist (where appropriate)**  |
| Name:  |  | Title: |  |
| Address:  |  |
| Telephone Numbers: | (w):  | (m):  |
| **Qualified Physician responsible for all trial-site related medical (or dental) decisions (other than the Investigator)** |
| Name:  |  | Title: |  |
| Address:  |  |
| Telephone Numbers: | (w):  | (m):  |

**12.2 For research involving administration of a drug or device, what is/are the drug(s) and/or device(s)?** [A separate table should be completed for each drug/device]

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|

|  |  |
| --- | --- |
| Approved name |  |
| Trade name |  |
| Manufacturer |  |
| Supplier of drug/device (e.g. manufacturer/pharmacy) |  |
| Believed mode of action |  |
| Dosage regimen |  |
| Mode of excretion |  |
| Known adverse events |  |
| Known contra-indications or warnings |  |
| Is the drug/device registered in Australia for the intended purposes of the research? | [ ]  Yes [ ]  No If no, the sponsor is to ensure that registration with the Therapeutic Goods Administration occurs prior to use of the goods.  |

 |

**12.3 If arrangements have been made for the Pharmacy Department to receive or dispense the drugs involved in this project, explain how the drugs will be received and dispensed for the purposes of the research project.**

**12.4 What are the participant responsibilities?**

**12.5 What compensation and/or treatment is available to the participant in the event of trial-related harm or injury?**

**12.6 Are there any trial-related expenses to be borne by the participant?**
[ ]  Yes [ ]  No

**12.6.1 If yes, please specify.**

**12.7 Will a Data Safety Monitoring Board be established?**
[ ]  Yes [ ]  No

**12.7.1 Please provide further detail/s.**

**12.8 What are the primary and secondary endpoints, if any, to be measured during the trial?**

**12.9 What type of trial will be conducted?** [Select all that apply]

|  |  |  |
| --- | --- | --- |
| [ ]  Double blind | [ ]  Placebo-controlled | [ ]  Parrallel design |
| [ ]  Phase 0 | [ ]  Phase I | [ ]  Phase II |
| [ ]  Phase III | [ ]  Phase IV | [ ]  Other – please specify |

**12.10 Provide a design diagram (schematic diagram) detailing the trial design, procedures and stages.**

**12.11 What measures will be taken to minimise or avoid bias, including randomisation and blinding?**

**12.12 Describe the trial treatment(s) and the dosage and the dosage regimen of the investigational product(s). Include a description of the dosage form, packaging, and labelling of the investigational product(s).**

**12.13 What are the ‘stopping rule’ or criteria for discontinuation of the study or for individual participants or aspects of the study?**

**12.14 What are the accountability procedures for the investigational product(s), including the placebo(s) and comparator(s), if any?**

**12.15 Describe the maintenance of trial treatment randomisation codes and procedures for breaking codes.**

**12.16 Describe the identification process for any data that is to be recorded directly on the Case Report Forms (i.e. if there is no prior written or electronic record of data), and this is to be considered source data.**

1. COLLECTION, USE AND MANAGEMENT OF DATA AND INFORMATION

[‘National Statement’ Chapter 3.1 (element 4)]

**Data Collection/Gathering:**

* 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.]
	2. **How will you collect/gather the information?**
	3. **What is the likely effect on the data in the event that the participant/s withdraw from the study?**

**Data Analysis:**

* 1. **How will you measure, manipulate and/or analyse the information that you collect/gather?**
	2. **What matching and sampling strategies will you be using?** [Include theoretical justification]
	3. **How will you account for potential bias, confounding factors and missing information?**
	4. **Statistical power calculation** [If not relevant, indicate 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]

[Responses should ensure relevant policies and procedures; contractual and licensing agreements; any confidentiality agreements; what information, if any, needs to be communicated to participants]

|  |  |
| --- | --- |
| **Provision of access** | [Who will have access to the data?] |
| **Sharing** | [What are your plans for sharing data once this project is complete? Indicate if there any plans to add the data/information to be banked or added to an open or mediated access repository for future access.] |
| **Disclosure**  | [Are there any mandatory reporting obligations that would require the research team to report certain information if it were disclosed by an individual whilst participating in the research?] |
| **Storage**  | [Include details on physical network, system security, other technological measures and in what form the data/information will be stored. This includes storage of consent documentation.]  |
| **Intellectual Property (IP) rights and Copyright arrangements** | [Describe the IP and Copyright arrangements] |
| **Transfer** | [Include details on how data is to be transferred throughout the project eg for projects using existing data, indicate if the data is to be transferred via email, USB, Cloud based servers etc] |
| **Archival**  |  |
| **Destruction** | [How will the data/records be destroyed following the data retention period – ensure that there is reference to relevant policy and/or policies?] |
| **Training for members of the project team and others, as appropriate** |  |

1. 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**

**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**

**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**

1. 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)]

* 1. **How will the privacy of participants be assured in any research outputs/outcomes?**

**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?**

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

**15.6 Are there any restrictions on the dissemination of project outputs and outcomes?** [National Statement paragraph 3.1.68] [Note: The Defence Human and Animal Research Manual require one Star or equivalent approval of research outcomes prior to dissemination. Academic publications arising from research funded by DVA or using DVA data require review by DVA prior to submission for publication. Other restrictions may apply depending on conditions specified in contracts, Memorandums of Understanding or other agreements.]
[ ]  Yes [ ]  No

**15.5.1 If yes, please provide detail**.

1. PRINCIPAL INVESTIGATOR DECLARATION

The research team has certified that:

1. All information in this application and supporting documentation is correct and as complete as possible.
2. 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.
3. We/I have considered and addressed in this application any relevant legislation, regulations, research guidelines and organisational policies.
4. All relevant financial and non-financial interests of the project team have been disclosed.
5. 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:

1. Not commence this study prior to obtaining all relevant ethics and governance approvals
2. To notify the approving ethical review body/ies of:
	1. any changes to the study prior to their implementation
	2. serious adverse or adverse events
	3. deviations
	4. discontinuation of the study
	5. changes to research personnel (or their contact details) and/or
	6. any complaints received about the conduct of the study.
3. Ensure that all conditions of ethical approval are adhered to.
4. 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.
5. Participate in on-site audits, if requested.

The person/s named below are authorised to sign this application on behalf of the research team.

[ ]  Yes [ ]  No

|  |  |  |  |
| --- | --- | --- | --- |
| Name:  |  | Signature: |  |
| Date: | Select date. |  |

1. 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. |

 |
|  |

|  |
| --- |
| Command approval is required when volunteers are sought from an ADF unit or 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.]  |

1. COMMAND APPROVAL

**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:

1. REFERENCES
2. ATTACHMENTS

Naming conventions for attachments are to be clear and consistent with the referenced document in the Project Description. It may be necessary to insert a title on the document so that it is clear which attachment it is.

Mandatory (for all research proposals) –

* Curriculum vitae for all research personnel [Not exceeding five pages each. Please include them in the order that they are listed on the application.]

Other [This is a guide and not intended to be an exhaustive list. Where applicable, provision of the additional documents is mandatory.]

* 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 as per the attachment.

* Draft emails to potential participants [ ]  Yes [ ]  No [ ]  N/A

List each item.

* Participant Information Sheet and Consent Form [ ]  Yes [ ]  No [ ]  N/A

List each item where there are multiple forms.

* Survey/questionnaire [ ]  Yes [ ]  No [ ]  N/A

List each item.

* Interview questions [ ]  Yes [ ]  No [ ]  N/A

List each item.

* Standardised measures [ ]  Yes [ ]  No [ ]  N/A

List each item.

* Other, please specify ­­–

For research involving use of existing data from previous studies –

* Copies of the Participant Information Sheet and Consent Forms from those studies should be provided.

For Clinical Trials

* Investigators Brochure [ ]  Yes [ ]  No [ ]  N/A
* Safety Information [ ]  Yes [ ]  No [ ]  N/A

**Working With Vulnerable People (or State/Territory equivalent)** [checks are to be paid and not volunteer capacity] [ ]  Yes [ ]  No [ ]  N/A

**Aboriginal and Torres Strait Islander Research**

Evidence of support for the research project from relevant Aboriginal and Torres Strait Islander communities or groups [ ]  Yes [ ]  No [ ]  N/A

1. https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023 [↑](#footnote-ref-1)
2. https://www8.austlii.edu.au/cgi-bin/viewdb/au/legis/cth/consol\_act/pa1988108/ [↑](#footnote-ref-2)
3. https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018 [↑](#footnote-ref-3)
4. https://www.nhmrc.gov.au/about-us/publications/payment-participants-research-information-researchers-hrecs-and-other-ethics-review-bodies [↑](#footnote-ref-4)
5. https://www.tga.gov.au/resources/publication/publications/ich-guideline-good-clinical-practice [↑](#footnote-ref-5)
6. https://www.nhmrc.gov.au/about-us/resources/ethical-conduct-research-aboriginal-and-torres-strait-islander-peoples-and-communities [↑](#footnote-ref-6)
7. https://www.nhmrc.gov.au/about-us/resources/keeping-research-track-ii [↑](#footnote-ref-7)
8. https://aiatsis.gov.au/research/ethical-research/code-ethics [↑](#footnote-ref-8)
9. https://www.ohchr.org/en/indigenous-peoples/un-declaration-rights-indigenous-peoples [↑](#footnote-ref-9)
10. https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subjecct/index.html [↑](#footnote-ref-10)
11. https://www.nhmrc.gov.au/sites/default/files/documents/attachments/guidelines-s95a-privacy-act-pr2-2024.pdf [↑](#footnote-ref-11)
12. https://www.nhmrc.gov.au/about-us/publications/guidelines-approved-under-section-95a-privacy-act-1988 [↑](#footnote-ref-12)
13. https://www.oaic.gov.au/privacy/australian-privacy-principles/read-the-australian-privacy-principles [↑](#footnote-ref-13)
14. https://database.ich.org/sites/default/files/E6\_R2\_Addendum.pdf [↑](#footnote-ref-14)
15. https://www.australianclinicaltrials.gov.au/researchers/principles-and-governance [↑](#footnote-ref-15)
16. https://www.safetyandquality.gov.au/sites/default/files/2022-05/final\_design\_-\_national\_clinical\_trials\_governance\_framework\_and\_user\_guide\_-\_30\_may\_2022.pdf [↑](#footnote-ref-16)
17. https://www.tga.gov.au/clinical-trials#ctn-scheme [↑](#footnote-ref-17)
18. https://www.tga.gov.au/clinical-trials#cta-scheme [↑](#footnote-ref-18)
19. https://www.australianclinicaltrials.gov.au/about/what-is-a-clinical-trial [↑](#footnote-ref-19)