

RESEARCH PROTOCOL SUBMISSION FOR SCIENTIFIC AND ETHICAL APPROVAL

Part 1 - PROJECT TITLE

1. Title.

(If appropriate, please also provide an abbreviated title)

(Please also indicate the version number of this application).

<p>Title:</p> <p>Abbreviated title (<i>optional</i>):</p>
<p>Version number:</p> <p>Date of version:</p>

2. Reference number.

<p>Protocol reference number (<i>provided by ADHREC</i>):</p> <p>File number (<i>for ADHREC use only</i>):</p>

Part 2 - ENDORSEMENT BY DEFENCE ORGANISATION

Notes (*please remove this page from the submitted application*)

Before human research is conducted it must have appropriate support and have undergone review within Defence. This part seeks to establish the degree of support the intended research has obtained and extent of review the protocol application has undergone (see also section 14e.).

Organisational endorsement

The Chief Investigator/s should indicate details of organisational endorsement and support which has been provided for this protocol. Organisational endorsement should be sought from the Defence organisation that has responsibility for the subject area in which this research protocol would be best categorised.

Approval or endorsement could be provided in various forms:

- The intended research may be in response to approved Defence research and development/science and technology requirements documents or identified as part an approved Defence research plan (eg Task Plan or the approved business plans of a Defence research organisation). Please provide details—where appropriate, reference to the endorsement of the responsible organisational appointment (for example, a Research Leader) as meeting approved plans should be provided.
- The intended research may be sponsored, endorsed or otherwise approved by an appropriate authority within a Defence Service or Group. Please provide details.
- The intended research may be in support of an established Defence project. Please provide details (for example, reference to endorsed research plan of the project or endorsement of the appropriate appointment within the project management office).

Note: This list is neither exhaustive nor does it necessarily indicate the appropriate level of organisational support which may be required.

Organisational review

The protocol may have been subject to internal review within the Defence organisation, as appropriate, where this mechanism has been established. Where available this should include a methodological and scientific review in accord with the requirements of that organisation. Such review could consist of:

- Internal review by a higher authority within the organisation—for example a Research Leader (who should be independent of the actual conduct of the research).
- Review by an organisation's Scientific Committee which is independent of the conduct of the research.
- Review by an established Scientific Advisory Committee (SAC) which has been established for the purpose (for example, as part of a Defence project).
- Independent review by a Subject Matter Expert in Defence.

Note: This list is neither exhaustive nor does it necessarily indicate the appropriate level of review which may be required to satisfy the Australian Defence Human Research Ethics Committee's (ADHREC) requirements.

Organisational endorsement

The Chief Investigator/s should indicate details of organisational endorsement and support which has been provided for this protocol. References and details should be provided here:

Any relevant documentation should be forwarded or attached to this protocol application.

Organisational review

The protocol may have been subject to internal review of the methodology within the Defence organisation. References and details should be provided here:

Any relevant documentation should be forwarded or attached to this protocol application.

Part 3 - APPLICATION FOR ETHICAL APPROVAL

3. Aim of the project.

List the aims and potential significance of the project. Hypotheses to be tested should be clearly stated.

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4. Chief Investigators.

Rank/Title	Given names (indicate preferred name)	Initials	Surname

5. Associate Investigators.

Rank/Title	Given names (indicate preferred name)	Initials	Surname

6. Other requests for funding for this project (eg NHMRC):

Funding body	Amount requested (\$— do not show cents)

7. Actual units/institutions where project will be conducted.

Unit/Institution	Department	% allocation

8. Research support from other sources (current).

Funding source	Title	Time (%)	Chief Investigators	Funds (year and amount)

9. Chief Investigator details.

(Chief Investigator 1 will be considered to be the contact point for the application and will be understood to be acting for and in concurrence with all chief investigators.)

Chief Investigator 1					
Unit/Department					
Institution					
Postal address					
Courier address					
City/Suburb		State		Postcode	
Country		Previous ADHREC researcher (Yes/No):			
Telephone	Work		Other		
	Fax		Mobile		
Email address	Email 1		Email 2		
Appointment/Position					
Academic qualifications (degree, year, institution)					
Chief Investigator 2					
Unit/Department					
Institution					
Postal address					
Courier address					
City/Suburb		State		Postcode	

Country		Previous ADHREC researcher (Yes/No):		
Telephone	Work		Other	
	Fax		Mobile	
Email address	Email 1		Email 2	
Appointment/Position				
Academic qualifications (degree, year, institution)				

Chief Investigator 3				
Unit/Department				
Institution				
Postal address				
Courier address				
City/Suburb		State		Postcode
Country		Previous ADHREC researcher (Yes/No):		
Telephone	Work		Other	
	Fax		Mobile	
Email address	Email 1		Email 2	
Appointment/Position				
Academic qualifications (degree, year, institution)				
Chief Investigator 4				
Unit/Department				
Institution				
Postal address				

Courier address					
City/Suburb		State		Postcode	
Country		Previous ADHREC researcher (Yes/No):			
Telephone	Work		Other		
	Fax		Mobile		
Email address	Email 1		Email 2		
Appointment/ Position					
Academic qualifications (degree, year, institution)					

Chief Investigator 5					
Unit/Department					
Institution					
Postal address					
Courier address					
City/Suburb		State		Postcode	
Country		Previous ADHREC researcher (Yes/No):			
Telephone	Work		Other		
	Fax		Mobile		
Email address	Email 1		Email 2		
Appointment/Position					
Academic qualifications (degree, year, institution)					

10. Contributions of Associate Investigators

Associate Investigator 1:
Contribution to project:
Associate Investigator 2:
Contribution to project:
Associate Investigator 3:
Contribution to project:
Associate Investigator 4:
Contribution to project:
Associate Investigator 5:
Contribution to project:

11. Lay description of project.

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12. Five keywords/phrases to describe/define the field of research.

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13. Five keywords/phrases relevant to this research (for example: health issues/human performance/clinical/psychological/organisational/disease conditions).

14. Calculation of sample size.

Provide a rationale for the sample sizes chosen for all study groups.

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15. Ethical considerations regarding this research.

a. General considerations:

	Yes/No
Does this project include research involving humans?	
If the research is using humans, are there equal numbers of males and females? (If 'No' provide a brief explanation of the sample size and the ratio of males to females in the study, in question 16 below - 'Ethical Implications'.)	
Does this application involve the administration to humans of drugs, chemical agents or vaccines?	
Does this application involve the use of unregistered pharmaceuticals or devices? (for example; trial vaccine, unregistered radio pill, chemical mask etc.)	

Does this application involve experimentation on animals?	
Does this project involve organisms being genetically manipulated such that it falls within current guidelines of the Genetic Manipulation Advisory Committee?	
Does this project involve use of teratogenic, carcinogenic or highly toxic chemicals?	
Does this project involve the use of personal information obtained from a Commonwealth Department or agency (including former Repatriation Hospitals)?	
If this is a study of an intervention designed to inform clinical practice (including drugs, devices, surgical or other procedures), has it been registered with the Australian Clinical Trials Registry?	
Will this research result in the accreditation or credentialing of researchers involved in the conduct of the project: (for example academic degree)	
Are the researchers appropriately qualified and experienced to conduct the research?	
Do the researchers or others involved in any aspect of this research project require any additional training in order to undertake this research?	
Have appropriate approvals/guarantees been received that research participants will be deemed to be 'on duty' for all phases of the project?	
Will the project be undertaken on behalf of (or at the request of) a pharmaceutical company, other commercial entity, or any other sponsor?	

- b. **List any drugs/devices to be used, and their approval status both overseas and in Australia:**

- c. **Given the hierarchical nature of the ADF population (dependant / unequal relationships, possibility of being exploited), why is this research being conducted within Defence and not in the wider community?**

- d. **What safeguards have been included to ensure:**

- (1) **Recruitment is free from coercion (Note: A minimum 'cooling-off' period of 24 hours between study briefings and recruitment must be allowed for).**

- (2) **Wherever appropriate, there will be some benefit to individual participants (other than material benefit).**

and/or:

- (3) **There will be benefit to Defence.**

- (4) **Members may decline to participate without detriment to their future health care or career. Participants may withdraw at any time with no detriment to their future health care or career.**

- e. **Where tests are performed and unexpected results occur that may impact on a participant's career, management options are explained.**

For example: If an unexpected, abnormal screening test / examination occurs, this may impact on a member's career. In this event the following avenues are available for the member: functional trade tests, reallocation, transfer (give specific details).

- f. **Where the protocol itself may result in an adverse event occurring, the following avenues are available for compensation:**

- g. **What command approvals have been obtained?**

- h. **If the protocol involves use of personal information obtained from Defence by any procedure or by personnel who would not normally have access to this information, how have the ethical and privacy implications been addressed? (Note: where cohorts of five or less are present, these are not to be reported. This is to ensure participants cannot be identified).**

- i. **Specify the nature of any relationship (existing or possible) between the research team, or an organisation involved in the research, and the potential participants.**

- j. **If information is obtained during this research where it would be in the best interests of the participant to receive counselling or treatment, what systems/procedures are in place to address this contingency?**

- 16. Ethical implications of this research** (*including quantification of all risks—see chapter 4, subparagraph 4.12.g. for quantification of risks*).

- 17. Is approval required from other Human Research Ethics Committees (HREC) for this project?**

Yes / No

Detail of approval required from other HREC:

HREC	Protocol submitted (Yes/No)	Protocol approved (Yes/No/pending)

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Note: Copy of HREC approvals must be submitted to ADHREC.

18. Background, research plan and resource arrangements.

Insert up to five additional pages.

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19. Graphics associated with background, research plan and resource arrangements.

(When submitted electronically, individual graphic files must be sent).

20. References to work of other researchers relevant to this project.

Cite relevant publications with titles, or other works, which will help with this assessment. Do not provide copies of publications.

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21. Publications of Chief Investigators.

*List and number consecutively the most recent papers accepted for publication in refereed journals, by any of the Chief Investigators. Indicate (against the number) by * those that refer to this project, and indicate by ** a maximum of six publications which you consider best reflect your research contributions to date. Maximum one page per Chief Investigator.*

Chief Investigator:
Chief Investigator:

22. Detailed budget items.

(show \$ amounts—do not show cents)

Serial	Budget items	Funding source	Year 1 amount	Year 2 amount	Year 3 amount

1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
Year totals					
Project total					

23. Other resources not listed as budget items which are required.

This could include items such as administrative, personnel and transport resources or resources of other units.

24. Justification of budget items.

25. Certification by Administering Institution.

CERTIFICATION BY ADMINISTERING INSTITUTION

(The 'administering institution' is usually the institution which has primary responsibility for the conduct of the research.)

I certify that this request satisfies all the requirements of this Institution, and that this Institution has established administrative procedures for assuring sound scientific practice in accordance with the NHMRC Statement on Scientific Practice. I certify that the endorsements referred to in Part 2 of this application have been properly obtained. I certify that all information provided in support of this application is to the best of my knowledge correct.

Rank/Title	Initials	Surname	Formation/Institution
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Signature	Date
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Note: This certification should be completed by a responsible officer of the institution and the original certification is to be attached to this application and forwarded with the protocol submission as described in chapter 4 of Health Manual, volume 23.

26. Military command approval.

Military command approval will be required when volunteers are sought directly from an ADF unit or specific Defence organisation. As general guidance, this approval will be required when potential volunteers are recruited directly from their workplace and their participation would subsequently remove them from their usual place of work for a period. Volunteers are 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.

MILITARY COMMAND APPROVAL*

Pending approval of this protocol by ADHREC, I hereby grant access by the Investigators to the military personnel under my control (command or administration) for the purposes of seeking volunteers to participate in this proposed study. I acknowledge that those volunteers will be deemed to be 'on duty' when participating in the proposed study.

Rank/Title	Initials	Surname	Formation/Institution
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Signature	Date
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27. Certification by first listed Chief Investigator.

CERTIFICATION BY FIRST LISTED CHIEF INVESTIGATOR

I certify that all details given in this application are correct and that written agreement has been provided by all named Chief Investigators. I also certify that it is my intent to publish project results.

Rank/Title	Initials	Surname	Formation/Institution
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Signature		Date	
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Note

This certification should be completed by the first listed Chief Investigator who is assumed for this application to be the point of contact. The original certification is to be attached to this application and forwarded with the protocol submission as described in chapter 4 of Health Manual, volume 23.

28. Attachments:

All required documents should be attached to this submission. The protocol will not be considered for ethics approval if essential supporting documentation, certifications and approvals are missing.

Are the following documents attached:

1. Information sheet, consent form and Guidelines for Volunteers. **(A copy of these are to be given to every participant)** Yes / No
2. Clinical trials protocol Yes / No
3. Endorsements by Defence organisation(s) Yes / No
4. Certification by Administering Institution Yes / No

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|---|----------|
| 5. Military Command approval/s | Yes / No |
| 6. Certification by first listed Chief Investigator | Yes / No |
| 7. Scales, Questionnaires or Surveys | Yes / No |
| 8. Other (describe briefly) | |