

EXPLANATORY NOTES FOR COMPLETION OF RESEARCH PROTOCOL SUBMISSION

Instructions.

1. Applications must be submitted **at least** 25 working days prior to any scheduled ADHREC meeting to be considered at that meeting. This is to allow organisational approval to be obtained or confirmed prior to ADHREC meeting papers being prepared. While every attempt will be made to obtain the required organisational approval (in respect of meeting Defence research priorities and assessment of appropriate scientific methodology), **no assurances can be provided**. If organisational approval is not achieved prior to the ADHREC meeting (or has not already been provided prior to submission) then ADHREC consideration may be delayed to a subsequent ADHREC meeting. Consequently, researchers are encouraged to submit applications as early as possible and should not commit resources contingent on receiving approvals.

2. The electronic template for the form is available from the ADHREC website <http://www.defence.gov.au/health/research/adhrec/i-adhrec.htm>. Completed forms should be submitted electronically to ADHREC@defence.gov.au followed by an original signed copy. ADHREC will interact with the nominated chief investigator directly. The project must not proceed before ethical clearance has been obtained.

Information required in form.

3. The following sections are included in the submission form:

Part 1

1. Project title.

The project title should accurately reflect the nature of the research. It will be used in correspondence to assist in identification of the project. A separate protocol reference number will be issued and both should be quoted in correspondence.

2. Reference number.

The reference number is provided by ADHREC on arrival of your submission

Part 2

Endorsement by Defence Organisations.

Before *human research* is conducted in Defence, it is to be assessed by a properly constituted responsible Defence organisation to ensure that Defence research priorities are met, Defence resources are properly applied and the research is to be carried out using sound scientific methodology. If the protocol involves the use of survey instruments to collect data from participants, whether such instruments are paper or computer-based, registration of the survey is required.

Copies of all documentation relevant to organisational clearance should be attached to the protocol submission.

Part 3

3. Aim of the project (*List the aims and potential significance of the project. Hypotheses to be tested should be clearly stated*).

Specific aims including any hypotheses that will be tested should be stated. The potential significance of this research is to be stated.

Note: There should be a single aim for a project. If there are more than one, the number must be minimised to provide focus for the research. If there are multiple aims, splitting the protocol into separate projects should be considered for separate protocol submissions.

4. Chief Investigators.

Enter details of all Chief investigators. All correspondence related to this protocol will be addressed to the first listed investigator (Principal Investigator).

5. Associate Investigators.

Enter details for all other (Associate) Investigator/s who will be associated with this project.

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

Enter the names and corresponding application numbers of any other agency to which this protocol has been or will be submitted. Protocols which are very similar to this one or where the work overlaps with the proposed work described in this study should be included. Information may be sought from these bodies when this proposal is considered.

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

The names of those units and/or institutions (including the department or equivalent) where this project will be conducted are to be entered. The Chief Investigator(s) must have approval from all units, organisations or institutions where any part of the project will be conducted. These are in addition to endorsement by the Administering Unit or Institution in the certification section of this proposal.

8. Research support from other sources (current).

Enter details for all projects for which support is currently being provided.

9. Chief Investigator details.

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

10. Contributions of Associate Investigators.

List sequentially all individuals who will act as Associate Investigators for a component of this study. The contribution of each Associate Investigator should be entered as a short summary. For example, an individual may be responsible for statistics related to this project.

11. Lay description of project.

A brief description of the project is to be provided using wording that would be easily understood by an individual with no technical knowledge in the subject area. The overall aims of the research, reasons for performing the project and expected outcomes should be clearly stated. Use of technical terms and jargon should be avoided. This information may be used for reporting related to research projects within Defence.

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

Enter descriptive keywords or phrases that describe the broad field or discipline for this research proposal. A minimum of one entry and a maximum of five should be provided. This information will aid selection of peer reviewers for this project proposal if required and for future analysis of overall research profiles within Defence. For example, *Health Information Systems*, *Preventive Medicine* and *Occupational Health and Safety* are three phrases that would describe broad subject areas within public health.

13. Five keywords/phrases to describe specific health issues/human performance/clinical/disease conditions relevant to this research.

Enter descriptive keywords or phrases to provide specific disciplines/sub-disciplines which best describe the area of research for this project. A minimum of one entry and a maximum of five should be provided. For example, *Water Quality* or *Water Purification* would indicate specific areas within *Preventive Medicine*. This information may aid identification and allocation of resources to support this project, for reporting on research projects and for future reference to outcomes.

14. Calculation of sample size.

Where appropriate (e.g. number of participants in a trial) details of power calculations or other criteria for selection of sample sizes selected for studies must be provided. A statistical rationale should be provided for these selections.

15. Ethical considerations regarding this research (Note: Nominal roll/list of names of all participants is to be submitted to ADHREC for all clinical trials).

If any entry in this Table is Yes, the protocol must be submitted to ADHREC for approval. All questions within the ethics section must be completed. Further information is available from ADHREC (contact details listed in Chapter 3 of this manual) for guidance on any ethics related issue.

Where drugs, chemical agents or vaccines are administered or use of a device is proposed, the project may be subject to Clinical Trials Notification or Exemption schemes administered by the Therapeutic Goods Association (TGA). If animal experimentation is proposed, separate approval must be obtained from a properly constituted Animal Experimental Ethics Committee. Projects proposing genetic manipulation of organisms must conform with current guidelines available from the TGA.

Projects which plan to use teratogenic, carcinogenic or highly toxic chemicals or agents should consult NHMRC guidelines available from the Publications Officer of NHMRC. These projects must also conform with Occupational Health and Safety legislation and with policy and procedures from the institutions/units in which the project will be conducted. This includes storage and disposal of hazardous waste material. All details related to collection/storage/use of personal information obtained during conduct of a study must be provided to ADHREC, in particular, treatment of personal information must be in accord with the requirements of the Privacy Act 1988. If this project has been submitted to any other HREC then the decision/outcome of that application must be provided including copies of any related documentation.

16. Ethical implications of this research (*including quantification of all risks*).

Details must be provided for any question above where a 'Yes' answer is recorded. For all identified risks, for example, those associated with a procedure, participation in an activity or administration of a drug, each risk must be quantitated in terms of participant and researcher exposure.

17. Approval from other Human Research Ethics Committees (HREC) for this project (*Note: Copy of HREC approvals must be submitted to ADHREC*)?

Enter the names of all Human Research Ethics Committees (HREC's) to whom this protocol has been submitted. A copy of outcomes from all these HREC's must be submitted to ADHREC when the results are provided by each HREC.

18. Background, research plan and resource arrangements.

This section should contain sufficient information for a reviewer to evaluate the proposed conduct of a project. All experimental and related procedures should be summarised such that the research plan is complete. Any initial and/or pilot data should be included. Images (e.g. diagrams, plots and charts) can be entered into an electronic form of the research proposal and/or printed as attachments with suitable labels. Quality and resolution of all images must be sufficient that these can be printed or photocopied without loss of resolution by ADHREC.

This section must be divided into logical sections which include the following as applicable:

- Background
- Research plan including timelines
- Research methodology
- Resources
- Data analysis and statistics
- Potential outcomes

References should be cited by number with each complete reference entered in the section allocated for references related to the research plan below.

The research plan should be presented in detail and include, but not be limited to, relevant details of methodologies, clinical and scientific procedures, experimental design, techniques, data collection tools and methods of statistical analysis used in this project. The validity and/or reliability of quoted statistics must be indicated. References for instruments used must be provided. Where large subject groups are to be studied, the study design must be justified with evidence that the study can proceed in a timely fashion. A timeline with intermediate goals must be presented for this type of project.

Details of all Defence resources required for this project to proceed must be included. This should include transport, personnel, equipment and any other items.

Where study groups are to be used for statistical, sampling or other purposes, a power calculation to justify the number chosen for each group must be conducted. All statistical analyses are to be described where data will be analysed.

19. Graphics associated with Background, Research Plan and Resource Arrangements.

All common image formats are supported in the electronic form. Images should be inserted into the appropriate section of the form.

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).*

List references which were cited in the 'Background, research plan and resource arrangements' section in standard journal format.

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).*

22. Detailed budget items.

All sources of funding, sponsorship or provision of resources related to conduct of this project must be disclosed. For all sources of funds enter the budget expenditure for each line item. Chief Investigator(s) should ensure that the unit or institution is prepared to fully fund repair and service costs related to conduct of this project if this situation could arise (e.g. repairs to infrastructure).

23. Other resources not listed as budget items which are required *(This could include items such as transport or resources of other units).*

24. Justification of budget items.

The costs of the project should be justified e.g. travel and personnel costs.

25. Certifications *(Administering Institution, Military Command, first listed Chief Investigator).*

All relevant certifications must be provided. The project must not start if any of these certifications are not provided.

26. Attachments *(This includes Information sheet/s and consent forms, clinical trials protocol/s, other HREC approvals and other documents as required).*

For attachments, indicate the section to which each applies.