



**Australian Government**

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**Department of Defence**

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**Department of Veterans' Affairs**

**DEPARTMENTS OF DEFENCE AND VETERANS' AFFAIRS  
HUMAN RESEARCH ETHICS COMMITTEE**

**RESEARCHER AND ADMINISTRATIVE GUIDELINES**

A handwritten signature in black ink, appearing to read 'TL Smart'.

**TL Smart**  
Air Vice-Marshal  
Surgeon General Australian Defence Force

Department of Defence  
CANBERRA ACT 2600

12 March 2019

A handwritten signature in black ink, appearing to read 'CW Orme'.

**CW Orme DSC AM CSC**  
Deputy President

Department of Veterans' Affairs  
CANBERRA ACT 2600

12 March 2019

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<sup>1</sup> <http://www.comlaw.gov.au/Series/C1968A00063>

<sup>2</sup> <http://www.comlaw.gov.au/Series/C1914A00012>

## FOREWORD

The Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC) is a joint human research ethics committee (HREC) for the Department of Defence (Defence) and the Department of Veterans' Affairs (DVA). The DDVA HREC is registered with the National Health and Medical Research Council (EC00460).

The purpose, scope of responsibility and relationship to other processes ethical review are outlined in the DDVA HREC [Terms of Reference](#)<sup>3</sup>.

The DDVA HREC is also responsible for the ongoing monitoring of approved research.

Secretariat support is provided within Defence and supported by DVA.

These guidelines are to be reviewed at least every three years from publication, or as required, to ensure ongoing compliance with national guidelines and legislative instruments.

Amendments may be requested by the Chair/Deputy Chair, the Committee or recommended by the Secretariat. Changes will be considered on an ad hoc basis and are to be approved by DDVA HREC. Where proposed amendments are considered to constitute substantive changes to these guidelines, a complete review will be requested. Revisions are subject to internal review processes and are to be approved by both Defence and DVA.

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<sup>3</sup> [http://www.defence.gov.au/health/hrec/docs/171205\\_DDVA\\_HREC\\_Terms-of-Reference.pdf](http://www.defence.gov.au/health/hrec/docs/171205_DDVA_HREC_Terms-of-Reference.pdf)

## AMENDMENT CERTIFICATE

Proposals for amendment of the Departments of Defence and Veterans' Affairs Human Research Ethics Committee Researcher and Administrative Guidelines are to be forwarded to:

DDVA HREC Secretariat  
CP3-7-038  
Department of Defence  
CANBERRA ACT 2600

<b>Amendment number</b>	<b>Chapter(s)</b>	<b>Amendment</b>	<b>Effected date</b>
1.1	Front matter	Updates to delegate titles, clarification on scope of DDVA HREC, delete reference to ADHREC and DVA HREC approved studies, removal of duplicate information	12 March 2019
1.2	Definitions	Updates to reflect changes in national guidelines	12 March 2019
1.3	Chapter 1	Updates to delegate titles; advice on non-HREC review pathways; removal of duplicate information and reference back to HUMRESMAN; clarification on processes; references to national guidelines updated; changes to frequency of submission of progress reports	12 March 2019
1.4	Chapter 2	Updates to delegate titles; editorial amendment to information regarding attendance at meetings; changes to dates for draft agenda, submission closing dates, and frequency of submission of progress reports; deletion of conditional approval as an outcome of ethical review; clarification that minor amendments can be approved by the Secretariat; changes to frequency of submission of progress reports, minor amendment to guidance on consideration of items under the Therapeutic Goods Act 1989	12 March 2019

## CONTENTS

<b>Chapter 1</b>	<b>1-1</b>
<b>Researcher guidelines</b>	<b>1-1</b>
<b>Introduction</b>	<b>1-1</b>
<b>Researcher responsibilities</b>	<b>1-1</b>
Conflicts of interest	1-1
Researcher contact details	1-1
When should I seek approval from the Departments of Defence and Veterans' Affairs Human Research Ethics Committee?	1-2
Federal Wide Assurance	1-2
<b>Human research</b>	<b>1-2</b>
Minimising duplication of ethical review	1-2
New applications	1-3
Resubmissions	1-4
Amendments to existing protocols	1-4
Presentation of research protocols	1-4
Student research	1-5
<b>Consent</b>	<b>1-5</b>
Waivers of consent	1-5
<b>On duty</b>	<b>1-6</b>
<b>Payments to research participants, investigators, departments and institutions</b>	<b>1-6</b>
Research participants	1-6
Investigators, Departments and institutions	1-6
<b>Recruitment of participants</b>	<b>1-7</b>
Limited contact	1-7
Guidelines for volunteers	1-7
DVA sponsored research - Letter of first contact	1-7
Standing requirement – Mazengarb clause (ex-serving personnel research)	1-7
<b>Research data</b>	<b>1-8</b>
Data matching/data linkage	1-8
Retention of materials and research data	1-8
<b>Clinical trials</b>	<b>1-9</b>
<b>Principal investigators' assurance</b>	<b>1-10</b>
<b>Monitoring</b>	<b>1-10</b>
Complaints or concerns	1-10
Progress reports	1-10
Adverse and Serious Adverse Event Reports	1-10
Deviations from approved protocols	1-11
Final reports	1-11
<b>Dissemination of research outcomes</b>	<b>1-11</b>
<b>Chapter 2</b>	<b>2-1</b>
<b>Administrative guidelines</b>	<b>2-1</b>
<b>Introduction</b>	<b>2-1</b>
<b>Terms of reference</b>	<b>2-1</b>
<b>Fees for ethical review</b>	<b>2-1</b>
<b>Membership</b>	<b>2-1</b>

Composition	2-1
Recruitment and appointment of members	2-1
Indemnity of members	2-2
Termination of appointments	2-2
<b>Member responsibilities</b>	<b>2-3</b>
Details on membership	2-3
Confidentiality	2-3
Training	2-3
Conflicts of interest	2-3
Consideration of research applications	2-3
Preparation for and attendance at meetings	2-3
Out of session considerations	2-3
<b>Subject matter expert advice</b>	<b>2-4</b>
<b>Meetings</b>	<b>2-4</b>
Frequency of meetings	2-4
Attendance of Committee members at meetings	2-4
Attendance of observers at meetings	2-4
Conduct and structure of meetings and deliberations	2-5
<b>Preparation and distribution of meeting agendas and papers</b>	<b>2-5</b>
Meeting agendas and papers	2-5
Preparation of meeting minutes	2-6
<b>Consideration and review of applications</b>	<b>2-6</b>
New applications	2-6
Resubmissions	2-7
Protocol amendments	2-7
Expedited review	2-8
Unregistered therapeutic substances and medical devices	2-8
Confidentiality of applications and deliberations	2-8
Methods of decision making	2-9
Outcomes of ethical review	2-9
Period of ethical approval	2-9
Prompt notification of decisions	2-9
Managing conflicts of interest	2-10
Communication with researchers	2-10
Principal Investigators' Assurance	2-10
Record keeping	2-10
<b>Monitoring of approved research</b>	<b>2-11</b>
Progress Reports	2-11
Audits	2-11
Reporting and handling of adverse and serious adverse events	2-12
Final reports	2-12
<b>Withdrawal of ethical approval</b>	<b>2-12</b>
<b>Finalisation of files</b>	<b>2-13</b>
<b>Receiving and handling of complaints</b>	<b>2-13</b>
<b>Glossary</b>	<b>i</b>

# CHAPTER 1

## RESEARCHER GUIDELINES

### INTRODUCTION

1.1 This chapter provides information for researchers on when to seek approval from the Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC), the processes for submitting an application and researchers' ongoing monitoring and reporting obligations. These obligations also relate to research that has obtained ethical approval from the DDVA HREC and protocols that were transferred for ongoing monitoring by the Australian Defence Human Research Ethics Committee (ADHREC) and/or the Department of Veterans' Affairs Human Research Ethics Committee (DVA HREC).

### RESEARCHER RESPONSIBILITIES

1.2 Researchers are required to ensure compliance with the '[National Statement on Ethical Conduct in Human Research](#)<sup>4</sup>' (the National Statement) and other relevant Commonwealth, State and Territory legislation, guidelines and codes of practice governing the conduct of research in Australia. Where research involves collaboration with international stakeholders and/or recruitment or use of data of individuals from other countries, compliance with their relevant legislations, regulations and guidelines is also required.

#### Conflicts of interest

1.3 Researchers should establish transparent processes to identify and manage actual and potential conflicts of interest.

1.4 A researcher is to disclose any actual or potential conflicts of interest, including financial or other interest or affiliation, that bears on the research at the time of the application or as they arise during the active life cycle of the research project.

#### Researcher contact details

1.5 To facilitate the management of research protocols and correspondence, researchers are to ensure that they provide contact details to the DDVA HREC Secretariat (the Secretariat). The Secretariat should be notified promptly of any change in contact details. Wherever possible, an email address should be supplied as a lot of the correspondence from the Secretariat is sent via email.

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<sup>4</sup> <https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018>

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

1.6 Ethical approval should be sought from the DDVA HREC for research that requires full HREC review where one or more of the following apply:

- a. research is conducted on Defence members, other Defence personnel or ex-serving personnel, their data or tissue
- b. participants are recruited, either directly or indirectly, through a service provided by Defence or the Department of Veterans' Affairs (DVA)
- c. research is conducted by Defence or DVA personnel
- d. research is conducted on/in a Defence establishment
- e. research is sponsored, endorsed or funded in any part by Defence or DVA.

1.7 For information on the mechanisms for the review of low and negligible risk research please refer to the DDVA HREC Terms of Reference and the guidance on the DDVA HREC website.

1.8 DDVA HREC approval must also be sought for the use of new registered items in accordance with the [Therapeutic Goods Act 1989](#)<sup>5</sup>, as detailed in the Defence Health Manual Volume 2 Part 15 Chapter 8 Annex 5A.

### Federal Wide Assurance

1.9 Through Joint Health Command, Defence holds a Federal Wide Assurance in regard to human subject research protection for international collaboration with the United States. Any reliance on this Assurance requires reporting to [Assistant Director Research Ethics](#)<sup>6</sup>.

## HUMAN RESEARCH

### Minimising duplication of ethical review

1.10 Defence and DVA recognise that researchers will often need to approach multiple ethical review bodies to obtain ethical approval of their protocols, for example, when conducting research through a university or hospital. The DDVA HREC will take into consideration the deliberations of other ethical review bodies when considering research proposals. The research proposal should clearly state that the protocol has, or will be, considered by another ethical review body. If available, the outcome of such consideration should be provided in support of the

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<sup>5</sup> [http://www.austlii.edu.au/au/legis/cth/consol\\_act/tga1989191/](http://www.austlii.edu.au/au/legis/cth/consol_act/tga1989191/)

<sup>6</sup> [ddva.hrec@defence.gov.au](mailto:ddva.hrec@defence.gov.au)



application. If it is not available upon submission the DDVA HREC should be advised on the outcome of the review once it is available.

1.11 Researchers whose projects fall under the auspices of multiple institutions should engage with the administrators of the relevant ethical review bodies to determine if full ethical approval is required for research that has been granted ethical approval by the DDVA HREC.

### **New applications**

1.12 Applications are considered to be ‘new’ when:

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

1.13 The pro formas and other supporting documentation for submission of new applications are available on the [DDVA HREC website](#)<sup>7</sup>.

1.14 Research proposals are to be clear and comprehensive and written in lay (plain) language. All technical terms and acronyms are to be explained in simple language and technical jargon is to be avoided.

1.15 The Principal Investigator is to ensure that all relevant documents are attached to the application. Examples of supporting documentation are:

- a. Participant Information and Consent Forms (PICFs)
- b. Surveys/questionnaires
- c. Letters of invitation and recruitment materials (including website content, newspaper advertisements etc)
- d. previous PICFs for proposals that are requesting to use data obtained under a previously approved study.

1.16 PICFs are to be in lay language that is easy to understand and phrased in a manner appropriate for the study cohort.

1.17 Completed applications are to be submitted electronically by the submission closing date as indicated on the [DDVA HREC website](#). Late applications will not be accepted unless approved by the Chair or Deputy Chair.

1.18 For research conducted by or involving Defence personnel (or their data), evidence of organisational support and command approval must be obtained prior to

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<sup>7</sup> <http://www.defence.gov.au/Health/hrec/>

submission to the DDVA HREC. Further information is available in the [Human and Animal Research Manual](#)<sup>8</sup>.

1.19 Researchers are encouraged to submit protocol applications as early as possible. Completed applications are to be submitted electronically to [DDVA HREC](#)<sup>9</sup> by the submission closing date as indicated on the [DDVA HREC website](#). Late applications will not be accepted unless approved by the Chair or Deputy Chair.

### **Resubmissions**

1.20 A resubmission may consist of a revised protocol, supporting documentation or provision of further information. Resubmissions may require review by the full DDVA HREC or may be reviewed by the Chair, the Chair and other specified members or the Secretariat.

1.21 Dates for resubmissions requiring full HREC review are available on the [DDVA HREC website](#)<sup>10</sup>.

### **Amendments to existing protocols**

1.22 Prior to implementation of any amendments to an approved protocol, the Principal Investigator must seek ethical approval of the amendment from the DDVA HREC. A Research Protocol Amendment Form is to be submitted along with any relevant supporting documentation (eg copies of surveys, updated PICFs, curriculum vitae for any additional research personnel). The request for amendment is to be signed by the first listed Principal Investigator as they have overall responsibility for the conduct of the research.

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

### **Presentation of research protocols**

1.24 The DDVA HREC encourages researchers to make themselves available, if required, for contact during the DDVA HREC meeting where their project is being considered. This may include attendance in person or via telephone. It is advisable that researchers provide a mobile telephone number or after hours telephone details to facilitate contact where appropriate. The Chair or delegate is to approve attendance of researchers at meetings.

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<sup>8</sup> <http://www.defence.gov.au/health/shc/ddhrc/Docs/Human-Animal-Research-Manual.pdf>

<sup>9</sup> [ddva.hrec@defence.gov.au](mailto:ddva.hrec@defence.gov.au)

<sup>10</sup> <http://www.defence.gov.au/Health/hrec/>

## Student research

1.25 For PhD or other student research, the DDVA HREC requires that the first listed Principal Investigator is the primary supervisor of the student researcher as they have overall responsibility for the conduct of the research.

1.26 Applications involving student researchers are to ensure that the mechanisms in place for supervision of their research are clearly articulated.

## CONSENT

1.27 A person's decision to participate in research **must be voluntary** and based on sufficient information and an adequate understanding of the proposed research and the implications of participation.

1.28 The consent process should also ensure that it is **free from coercion**.

1.29 The [National Statement](#)<sup>11</sup> outlines the information that must be communicated to potential participants. Additionally, researchers who are conducting clinical research should make themselves familiar with the requirements under the [Integrated Addendum to ICH E6 \(R1\): Guideline for Good Clinical Practice E6\(R2\)](#)<sup>12</sup>.

1.30 Written information must be presented in ways suitable to each participant, although it will most often take the shape of a PICF. A PICF template is available on the [DDVA HREC website](#)<sup>13</sup>.

1.31 It is essential that when drafting both the ethics application and the consent documentation that researchers' give adequate consideration to the future use of data in research.

## Waivers of consent

1.32 Researchers who are requesting a waiver of consent under [National Statement](#) Chapter 2.3 are required to demonstrate the following:

- a. the involvement in the research carries no more than low risk to participants
- b. the benefits from the research justify any risks of harm associated with not seeking consent
- c. it is impracticable to obtain consent (for example due to the quantity, age or accessibility of the records)

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<sup>11</sup> <https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018>

<sup>12</sup> <https://www.tga.gov.au/publication/note-guidance-good-clinical-practice>

<sup>13</sup> <http://www.defence.gov.au/Health/hrec/>

- d. there is no known or likely reason that participants would not have consented if they had been asked
- e. there is sufficient protection of participants' privacy
- f. there is an adequate plan to protect the confidentiality of data
- g. in cases where the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them
- h. 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
- i. the waiver is not prohibited by State, federal, or international law.

### **ON DUTY**

1.33 Defence personnel should be considered 'on duty' when participating in research.

## **PAYMENTS TO RESEARCH PARTICIPANTS, INVESTIGATORS, DEPARTMENTS AND INSTITUTIONS**

### **Research participants**

1.34 As Defence personnel are deemed to be on duty whilst participating in research, any payments made to participants are to be for out-of-pocket expenses only. Consideration may be given to incentive payments for ex-serving personnel and civilian cohorts on a case-by-case basis. Payment of money or incentives of any kind should not result in pressure on individuals to consent to participate. The use of lottery-style incentive payments will not be supported.

### **Investigators, Departments and institutions**

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

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

1.37 Payments on a per capita basis pose a problem because they raise the possibility of a conflict between the clinical responsibilities of a researcher and their financial gain. A researcher is to disclose the amounts, sources or potential sources of funding in any research proposal and, following approval of the proposal, any subsequent funding sources.

## RECRUITMENT OF PARTICIPANTS

### Limited contact

1.38 Where no response is received to the initial invitation to participate, any follow up contact should be limited to one additional letter or email and/or one phone call (successful in obtaining a response), unless otherwise specifically indicated in the approved protocol.

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

### Guidelines for volunteers

1.40 The DDVA HREC has developed a set of Guidelines for Volunteers, informing them of their rights and of HREC's role and responsibilities. Each participant is to be given a copy of these guidelines to keep. The Guidelines are available on the [DDVA HREC website](#)<sup>14</sup>.

### DVA sponsored research - Letter of first contact

1.41 There is a standing requirement that, if a proposed project recruits participants using contact information supplied by DVA and involves face-to-face or telephone contact with ex-serving personnel or relevant Defence communities, such contact must be preceded by a letter from DVA informing the individual of the aims of the study and inviting them to participate. This letter is referred to as the "letter of first contact" and ideally should be in 14-point font.

1.42 Where members of the veteran or relevant Defence communities are contacted in the first instance by mail (eg a mail survey), a letter of first contact must accompany the mail-out.

1.43 The letter of first contact will be signed by the Principal Medical Adviser or the Repatriation Commissioner, or the relevant Deputy Commissioner if the study is confined to a particular State.

### Standing requirement – Mazengarb clause (ex-serving personnel research)

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

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<sup>14</sup> <http://www.defence.gov.au/Health/hrec/>

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

1.45 Where the participant cohort consists of current serving and ex-serving Defence members, the following clause should be used:

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

1.46 Where appropriate and approved by the DDVA HREC, the clause may be extended to include reference to other government agencies or other organisations.

## RESEARCH DATA

### Data matching/data linkage

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

### Retention of materials and research data

1.48 Research data and materials are to be retained by the Principal Investigator for not less than five years from the date of publication or 15 years for clinical trials. If the research results are challenged, the research data and materials are to be retained until the matter is resolved. Where records may be relevant to allegations of research misconduct, research data and materials must not be destroyed. Additionally, if the research has community or heritage value the data should be retained permanently.

1.49 Research documents created by Defence research institutions or other Commonwealth agencies are Commonwealth records and are to be managed in accordance with the [Archives Act 1983](http://www.austlii.edu.au/au/legis/cth/consol_act/aa198398/)<sup>15</sup> (the Archives Act) and (for Defence research institutions) the Records Management Policy Manual (RECMAN). For research that is conducted by agencies external to Defence and DVA, the records are to be stored in accordance with the [Privacy Act 1988](http://www.austlii.edu.au/au/legis/cth/consol_act/pa1988108/)<sup>16</sup> (the Privacy Act), the [Archives Act](#) and other appropriate legislation.

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<sup>15</sup> [http://www.austlii.edu.au/au/legis/cth/consol\\_act/aa198398/](http://www.austlii.edu.au/au/legis/cth/consol_act/aa198398/)

<sup>16</sup> [http://www.austlii.edu.au/au/legis/cth/consol\\_act/pa1988108/](http://www.austlii.edu.au/au/legis/cth/consol_act/pa1988108/)

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

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

1.52 At the completion of the approved research, data must be returned, stored or destroyed in accordance with approved protocols, the [Archives Act](#) and any contractual requirements.

1.53 All data supplied by DVA and/or collected on behalf of DVA remains the property of the Commonwealth.

1.54 No attempt should be made by researchers to identify any individual(s) from data that was provided by DVA in re-identifiable or non-identifiable format, unless specifically approved as part of the study protocol.

## **CLINICAL TRIALS**

1.55 Researchers are responsible for registering clinical trials in a publicly accessible register prior to the commencement of the clinical phase of the research. Evidence of the registration of the trial must be provided to the DDVA HREC for inclusion on the protocol file.

1.56 The DDVA HREC also requires that a nominal roll of participants is retained for all clinical trials. This is to enable the tracing of study participants some time in the future should any issues arise that may be related to the research that was conducted. Researchers are to ensure that potential participants are informed of this requirement in the PICF.

1.57 Sufficient detail is to be provided to enable tracing of each individual at a later date. For clinical trials conducted by individuals, the nominal roll is to be provided to the DDVA HREC once consent has been obtained and will be stored in the relevant protocol file. Researchers may need to consider appropriate amendments to the Mazengarb clause in this instance.

1.58 Where a clinical trial is conducted by a Defence research organisation (such as the Australian Defence Force Malaria and Infectious Diseases Institute, the Institute of Aviation Medicine or the Defence Science and Technology Group), that organisation is to certify that it will undertake the safe storage of the nominal roll for the requisite period in accordance with the [Archives Act](#)<sup>17</sup> and the RECMAN.

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<sup>17</sup> [http://www.austlii.edu.au/au/legis/cth/consol\\_act/aa198398/](http://www.austlii.edu.au/au/legis/cth/consol_act/aa198398/)

## PRINCIPAL INVESTIGATORS' ASSURANCE

1.59 All Principal Investigators are to sign and return a Principal Investigators' Assurance prior to commencing the research project.

### MONITORING

1.60 Researchers are responsible for providing scheduled and for cause reports to ethical review bodies in accordance with [National Statement](#)<sup>18</sup> Chapter 5.5. Paragraphs 60 – 67 outline the requirements for advising participants' points of contacts for complaints or concerns, notifying the DDVA HREC of complaints, submission of progress reports, adverse and serious adverse event reports, notification of deviations from approved protocols and submission of final reports to the DDVA HREC.

#### Complaints or concerns

1.61 Participants are to be advised of points of contact for complaints or concerns about a research project. This is to include a contact/s on the research team and indicate that they alternatively may wish to contact the DDVA HREC (refer to the PICF template for further details).

1.62 The Principal Investigator is to advise the DDVA HREC within 72 hours of any complaints that might affect the continued ethical acceptability of the project. In addition to this, a summary of any complaints received is to be provided to the DDVA HREC in the project's progress reports.

#### Progress reports

1.63 The Principal Investigator is required to submit a progress report at least annually for the lifespan of the project, with the exception of clinical trial research and research whose duration is less than 12 months. Progress Reports for research falling within this remit are required six monthly. The report is to be signed by the first listed Principal Investigator as they have overall responsibility for the conduct of the research. The progress report template is available on the [DDVA HREC website](#)<sup>19</sup>.

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

#### Adverse and Serious Adverse Event Reports

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

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<sup>18</sup> <https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018>

<sup>19</sup> <http://www.defence.gov.au/Health/hrec/>



with 72 hours for serious adverse events and 30 days for adverse events. The Adverse and Serious Adverse Event Report is available on the [DDVA HREC website](#).

1.66 Researchers should also be mindful of the requirements to notify those who have provided research governance authorisation (research sponsors and those who have granted command approval) for research involving recruitment of Defence personnel in accordance with the [Human and Animal Research Manual](#)<sup>20</sup>.

### Deviations from approved protocols

1.67 Any deviations from the approved protocol must be notified to the DDVA HREC as soon as possible and documented in the protocols progress and final reports.

### Final reports

1.68 Researchers are required to submit a final report at the completion or abandonment of their project. The Final Report template is available on the [DDVA HREC website](#).

1.69 Failure to submit a final report will result in a notation made on the file indicating non-compliance with monitoring obligations and advice of non-compliance being sent to the research sponsor/s and/or head of organisation/s.

## DISSEMINATION OF RESEARCH OUTCOMES

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

1.71 Researchers are required to obtain clearance of the research outcomes from the relevant Defence and/or DVA sponsor/s or their delegate/s. The sponsor/s must be a senior commander or manager of a rank/APS classification no lower than one Star /Senior Executive Service Band 1. In instances where a Defence or DVA sponsor was not required, advice should be sought from the Secretariat. Review of the findings may also require review and advice from other relevant areas, where appropriate.

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

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<sup>20</sup> <http://www.defence.gov.au/health/shc/ddhrc/Docs/Human-Animal-Research-Manual.pdf>

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

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

1.75 All publications should include the following in the body of the manuscript:

- a. a detailed statement on relevant ethical approvals
- b. an acknowledgment of the use of Defence and/or DVA resources and personnel where appropriate
- c. a disclaimer stating that the opinions expressed therein are those of the author/s and do not necessarily reflect those of Defence or DVA, or reflect requirements under extant policy.

1.76 A copy of the final document is to be provided to the DDVA HREC secretariat for inclusion on the protocol file. This should include advice on who cleared the document.

## CHAPTER 2

# ADMINISTRATIVE GUIDELINES

### INTRODUCTION

2.1 This chapter provides guidance on the administrative processes supporting the Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC).

### TERMS OF REFERENCE

2.2 The DDVA HREC Terms of Reference are available on the [DDVA HREC website](#)<sup>21</sup>.

### FEES FOR ETHICAL REVIEW

2.3 The DDVA HREC does not charge a fee for ethical review.

### MEMBERSHIP

#### Composition

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

#### Recruitment and appointment of members

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

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

2.7 A selection committee that consists of representatives from the Department of Defence (Defence) and the Department of Veterans' Affairs (DVA) shall review the candidate's curricula vitae and may conduct an interview. A recommendation will be made to the Vice Chief of the Defence Force (VCDF) and the Deputy President, DVA.

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<sup>21</sup> <http://www.defence.gov.au/Health/hrec/>

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

- a. the date of appointment
- b. length of tenure
- c. assurance that indemnity will be provided in respect of liabilities that may arise in the course of bona fide conduct of their duties as a DDVA HREC member
- d. conditions of their appointment
- e. circumstances where their membership may be terminated.

2.9 The letter of appointment will be jointly signed by VCDF and the Deputy President, DVA.

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

2.11 Members will be advised when their term of appointment is due to expire. Reappointment is on invitation from the VCDF and First Assistant Secretary External Stakeholder and Government Relations, DVA. The Chair, the Director General Health Business and Plans, Defence and the Chief Data Officer, DVA will recommend any reappointments to the Committee.

### **Indemnity of members**

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

### **Termination of appointments**

2.13 Surgeon General Australian Defence Force (SGADF) and the Deputy President, DVA may terminate the appointment of any member of the Committee if they are of the opinion that:

- a. it is necessary for the proper and effective functioning of the Committee
- b. the person is not a fit and proper person to serve on a Committee
- c. the person has failed to carry out their duties as a Committee member.

## **MEMBER RESPONSIBILITIES**

### **Details on membership**

2.14 Members must agree to their name and profession being made available to the public, including being published on the [DDVA HREC website](#)<sup>22</sup>.

### **Confidentiality**

2.15 Members are to ensure that any matters that they are privy to as part of the deliberations of the committee remain confidential. Members are to sign a confidentiality agreement upon appointment and reappointment to the Committee.

### **Training**

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

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

### **Conflicts of interest**

2.18 Members are required to notify the Secretariat of any potential or perceived conflicts of interest which may arise during their tenure on the committee. This is to be done upon appointment/reappointment and on an adhoc basis.

### **Consideration of research applications**

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

### **Preparation for and attendance at meetings**

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

### **Out of session considerations**

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

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<sup>22</sup> <http://www.defence.gov.au/Health/hrec/>

## **SUBJECT MATTER EXPERT ADVICE**

2.22 The committee may seek advice from subject matter experts about study proposals that are outside of the committee’s knowledge base.

2.23 Subject matter experts are required to disclose any conflicts of interest and are to ensure confidentiality of applications is maintained.

## **MEETINGS**

### **Frequency of meetings**

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

2.25 The meeting schedule is developed at least six months in advance and is available on the [DDVA HREC website](#)<sup>23</sup>. The schedule is to be developed in consultation with members.

2.26 A meeting roster will be developed based on member availability and the minimum membership requirements.

### **Attendance of Committee members at meetings**

2.27 The Chair will attend meetings in person. Other members may attend via video or teleconference.

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

2.29 Where an alternate member is not available to attend, the absent member is to complete an absentee comment forms and return them to the Secretariat at least three business days prior to a scheduled meeting. The Secretariat will provide members with templates of these forms for planned absences.

### **Attendance of observers at meetings**

2.30 Staff from Defence and DVA will be invited to attend meetings as observers. They may provide advice on Defence or DVA specific requirements as required; however, they do not form part of the decision making process of the committee.

2.31 The Chair will consider attendance of other observers at a meeting. Observers are to ensure that any matters that they are privy to as part of the deliberations of the committee remain confidential.

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<sup>23</sup> <http://www.defence.gov.au/Health/hrec/>

2.32 Where an observer identifies a potential or actual conflict of interest with an agenda item, the observer is required to declare the conflict. See paragraph 2.70 for further information regarding management of conflicts of interest.

### **Conduct and structure of meetings and deliberations**

2.33 The composition of the DDVA HREC is outlined in the Committee's Terms of Reference.

2.34 The Chair may decide to cancel a meeting if the minimum membership cannot be met and if, in their view, this would compromise the committee's ability to fulfil its duties under the [National Statement on Ethical Conduct in Human Research](#)<sup>24</sup>. Where there is less than full attendance, the Chair must be satisfied before a decision is reached that those who are absent have had the opportunity to have their views considered.

2.35 Meetings may also be cancelled where there are no complete applications for consideration by the DDVA HREC by the submission closing date.

2.36 Meetings are scheduled to last for three hours. If all agenda items have not been considered within the allocated time, the meeting may:

- a. continue until all items have been completed
- b. out-of-session review of specific items may be requested
- c. an additional meeting may be scheduled.

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

2.38 In order to ensure confidentiality and open discussion of agenda items, meetings will be scheduled in a secure meeting room. Meeting room details will be provided on the meeting agenda.

## **PREPARATION AND DISTRIBUTION OF MEETING AGENDAS AND PAPERS**

### **Meeting agendas and papers**

2.39 For scheduled meetings, the Secretariat is to prepare the draft agenda within five business days of the submission closing date. Meeting papers are to be collated and distributed to members no later than ten business days prior to the scheduled meeting.

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<sup>24</sup> <https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018>

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

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

### **Preparation of meeting minutes**

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

2.43 Meeting Minutes are to include the following:

- a. a summary of relevant discussions
- b. a record of decisions made
- c. reference to views expressed by absent members
- d. reference to relevant guidelines and/or legislative instruments where appropriate.

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

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

2.46 The Minutes of each meeting are to also be provided to departmental delegates in accordance with the [DDVA HREC Terms of Reference](#)<sup>25</sup>.

## **CONSIDERATION AND REVIEW OF APPLICATIONS**

### **New applications**

2.47 Applications for ethical approval are to be submitted in accordance with the procedures outlined on the [DDVA HREC website](#)<sup>26</sup>.

2.48 The submission closing date for new applications is available on the DDVA HREC website. Closing dates are to allow for sufficient time for an administrative review to be completed and sufficient time for members to review applications.

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<sup>25</sup> <http://www.defence.gov.au/health/hrec/#ToR>

<sup>26</sup> <http://www.defence.gov.au/Health/hrec/>



2.49 Applications will be checked for completeness by the Secretariat prior to inclusion on the agenda. Incomplete applications will be returned to the applicant. Where minor administrative amendments are identified, the applicant will be asked to provide an updated application and/or additional information within a specified timeframe for inclusion on the next meeting's agenda.

2.50 Where the application involves veterans and/or ex-serving members (or their data) the application will be provided to the point of contact at DVA to facilitate the necessary reviews. Advice on the outcome of these reviews will be provided to the committee at the relevant meeting for their consideration.

2.51 Each complete application will be assigned a unique identification number. The Secretariat will send an email acknowledging receipt of the application and confirm inclusion in the meeting agenda within seven working days of the submission closing date.

2.52 Complete applications will be included on the agenda at the next scheduled meeting, subject to receipt of the application by the submission closing date. In the event of a large number of applications are received for review at any one meeting, some applications may be held over to the following DDVA HREC meeting. If this occurs, prioritisation will occur at the discretion of the Chair.

2.53 Where there is an operational imperative to do so, an application may be circulated for out-of-session consideration at the discretion of the Chair. A summary of any out-of-session considerations is to be provided as part of the next scheduled meeting agenda.

### **Resubmissions**

2.54 The Chair/Deputy Chair is to determine if resubmissions require review by the full DDVA HREC, the Chair/Deputy Chair, other members or the Secretariat.

2.55 Resubmissions requiring full DDVA HREC review are to be submitted by the submission closing date. All resubmissions must be signed by all relevant personnel. Failure to obtain signatures on resubmitted applications may result in a delay in ethical approval being considered.

2.56 Resubmissions that do not require review by the full DDVA HREC will be circulated for out-of-session consideration by the Chair, the Deputy Chair and/or other nominated individuals to determine the ethical acceptability of the resubmission. A summary of any out-of-session resubmissions is to be provided as part of the next scheduled meeting agenda.

### **Protocol amendments**

2.57 Protocol amendments will initially be considered out-of-session by the Chair or the Deputy Chair. Where it is deemed appropriate, other members may be asked to review protocol amendments out-of-session or the Chair/Deputy Chair may request that the amendment be submitted to the full DDVA HREC at the next scheduled meeting. Minor amendments that do not affect the substance of the protocol (eg spelling mistakes, addition or removal of research personnel or amendments to recruitment materials) may be approved by the Secretariat.

## Expedited review

2.58 Defence have established other review level mechanisms for the review of low- and negligible-risk research, as outlined in the [DDVA HREC Terms of Reference](#)<sup>27</sup>.

2.59 Consideration of the applications under expedited review will be by the Chair and/or the Deputy Chair and the Secretariat. The application may be forwarded on to other committee members or subject matter experts for review and/or advice as appropriate.

2.60 Review of applications may occur out-of-session at the discretion of the Chair. An update on applications approved under expedited review is to be provided at the next scheduled committee meeting.

## Unregistered therapeutic substances and medical devices

2.61 The DDVA HREC will review requests for the use of new unregistered items, as required by the [Therapeutic Goods Act 1989](#)<sup>28</sup>. If supported, the Secretariat (on behalf of the DDVA HREC) will raise an approval letter, to be signed by the Chair, and provide this to the Director Health Materiel Logistics and Pharmacy, Defence. The Secretariat will also raise and forward an approval letter covering the original request to SGADF (with a copy to the Director General Health Capability (DGHC)). If the request is not supported, the Secretariat will raise a letter of notification to the originating Commander (with a copy to DGHC).

## Confidentiality of applications and deliberations

2.62 Protocol files are held securely within the electronic filing system on the Defence server. Access is limited to those who require access to the files because the information contained therein is intrinsic to the conduct of their role. Research protocols may be discussed with other directorates within Defence and/or DVA if there is an operational requirement to do so.

2.63 Researcher details are not provided to third parties. Whenever a third party requests details of a particular type of protocol or details of who conducted particular protocols, the Secretariat will contact the researcher and provide details of the third party. The researcher can then, if agreeable, contact the third party directly.

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

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<sup>27</sup> <http://www.defence.gov.au/health/hrec/#ToR>

<sup>28</sup> [http://www.austlii.edu.au/au/legis/cth/consol\\_act/tga1989191/](http://www.austlii.edu.au/au/legis/cth/consol_act/tga1989191/)

## Methods of decision making

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

2.66 The DDVA HREC will not grant retrospective approval of protocols.

## Outcomes of ethical review

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

- a. **The protocol is approved outright.** This means that the protocol conformed to all the necessary requirements, the DDVA HREC is satisfied that the research is ethical and can be conducted as detailed in the submission. A letter stating that the research has been approved will be sent to the researcher. A Principal Investigators Assurance form will be enclosed for the principal investigator(s) signature and return.
- b. **The protocol is not approved and a resubmission is requested.** A letter will be sent to the researcher explaining why the study was not approved and provide details on any amendments or issues that should be addressed in a resubmission. If the relevant documentation is not resubmitted within three months of the date of the outcome letter, a complete new application will need to be submitted. Where the amendments required are substantial, researchers must note that the committee may insist on reconsidering the protocol resubmission during a subsequent formal meeting. Resubmissions where the amendments are not substantial may be reviewed out-of-session by the Chair, Deputy Chair or other delegates. Minor amendments that do not affect the substance of the protocol may be approved by the Secretariat.
- c. **The protocol is not approved and a resubmission is not requested.** This will occur where a research proposal is judged to be fundamentally flawed on ethical grounds. A letter will be sent to the researcher explaining why the study was not approved. Any subsequent submission would be subject to the same process as the original submission.

## Period of ethical approval

2.68 Ethical approval for all protocols is valid for up to three years from the date of that approval being given. The dates will be indicated on the ethical approval letter. If a protocol will be used beyond this period, the Principal Investigator is required to apply for an extension before the expiration date of the current period of ethical approval.

## Prompt notification of decisions

2.69 The Principal Investigator and, where appropriate, the project's point of contact, will be notified in writing of the outcome of the ethical review within five

business days of the meeting. The Principal Investigator and, where appropriate, the point of contact, will be advised of any delay in the formal correspondence.

### **Managing conflicts of interest**

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

2.71 The Chair or Deputy Chair will determine if this results in a conflict of interest and the appropriate course of action. Where appropriate, this may include individuals removing themselves from the meeting for the discussion of the corresponding agenda item. All declarations of conflicts of interest, the action taken and any absences of those in attendance are to be minuted by the Secretariat.

### **Communication with researchers**

2.72 Good ethical review requires open communication between review bodies and researchers. In order to facilitate open communication, the committee and the Secretariat do not limit engagement with researchers to written communication and recognises the value of both telephone and face-to-face discussions with not only researchers but other key stakeholders.

2.73 Researchers may be asked to attend meetings to provide clarification on any concerns raised by the committee. Additionally, researchers are encouraged to engage early with the Secretariat when developing research proposals.

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

### **Principal Investigators' Assurance**

2.75 A Principal Investigators' Assurance Form will be sent by the Secretariat when the research has been granted ethical approval.

### **Record keeping**

2.76 The Secretariat shall maintain an electronic record of all research proposals that have been submitted for consideration. An electronic folder will also be raised and maintained for all research proposals. Each protocol will be assigned a unique protocol number. Access to the files is restricted.

## **MONITORING OF APPROVED RESEARCH**

2.77 The DDVA HREC will monitor approved protocols during the active lifespan of the project. This includes protocols transferred over for ongoing monitoring by the Australian Defence Human Research Ethics Committee and/or the Department Veterans' Affairs Human Research Ethics Committee.

### **Progress Reports**

2.78 For all active research protocols, the Secretariat will email a reminder to the Principal Investigator regarding the submission of progress reports approximately one month prior to the due date.

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

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

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

2.82 In the event that a progress report is not received by the due date, the Secretariat will email the Principal Investigator and, where relevant, the point of contact, to advise them that the progress report for their project is overdue, and that the matter of non-compliance will be reported to the DDVA HREC at their next meeting. The committee may agree to grant an extension for submission of the progress report or withdraw ethical approval.

### **Audits**

2.83 The DDVA HREC or their delegate may conduct random inspections of research sites and review their study documentation. A summary of the outcome of the audit will be provided to the committee at the next scheduled meeting following finalisation of the report.

2.84 Additionally, desktop audits of protocol files will be conducted periodically to ensure completeness of applications and compliance with the approved protocol and any conditions of ethical approval. Where the audit raises areas for concern that require consideration by the DDVA HREC, the committee will be asked to consider the findings either out-of-session or at the next scheduled meeting (depending on the urgency of the findings). Where appropriate, consideration of the findings may be delegated to the Chair, Deputy Chair or another member.

## **Reporting and handling of adverse and serious adverse events**

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

- a. notation of the occurrence
- b. increased monitoring of the project
- c. request for amendment to the protocol or supporting documentation
- d. a request for additional information
- e. suspension of ethical approval
- f. termination of ethical approval.

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

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

## **Final reports**

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

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

## **WITHDRAWAL OF ETHICAL APPROVAL**

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

- a. deviation from the approved protocol
- b. failure to comply with the conditions of ethical approval
- c. failure to submit a progress report
- d. upon receipt of a complaint where significant concerns about the ongoing ethicality of a project have been raised

e. upon notification of an adverse or serious adverse event.

2.91 When this occurs the committee will inform the Principal Investigator, the investigator's home institution and, where appropriate, the relevant Departmental sponsor/s and commander/s who are responsible for Defence personnel who are participating in the research in writing of the decision to withdraw ethical approval and any circumstances under which ethical approval may be reinstated.

### **FINALISATION OF FILES**

2.92 Protocol files will be finalised when a research project is completed, abandoned, withdrawn or when no correspondence has been received from the researchers within the preceding 12 months. Finalisation means that the protocol is removed from the active protocol list and no further action is taken by the Secretariat regarding that file. Researchers will be notified in writing when a file is finalised. If the researcher wishes to resume the project at a later date, the file may be reactivated upon agreement from the Chair. In the case of no correspondence having been received for 12 months, a finalisation letter will be sent to the researcher at the last known address and a letter will be sent to the Departmental sponsor/s and/or commander/s responsible for the study participants (where appropriate).

### **RECEIVING AND HANDLING OF COMPLAINTS**

2.93 Complaints regarding the conduct of research are to be submitted to the Secretariat. They will consult with relevant representatives from Defence and/or DVA, where appropriate, and will aim to resolve the complaint in the first instance. If this is not possible, the complaint may be put to the Chair or the Committee for consideration and resolution. Where the complaint relates to the ethical conduct of research, the committee is to be advised of the complaint at the next scheduled meeting, for consideration and a formal response.

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

2.95 Where a researcher wishes to submit a complaint about the consideration of their research protocol by the committee, they should contact the Secretariat in writing with details of the complaint. The Secretariat will aim to resolve any issues raised. A decision will be made based on all evidence received, including any response submitted by the researcher.

2.96 Where a complaint relates to the conduct of the committee, the Assistant Director Research Ethics is the initial point of contact for the complaint. Where appropriate, the complaint will be directed to the SGADF and/or the Deputy President, DVA.

2.97 The Secretariat will maintain a complaints register for audit purposes.

## GLOSSARY

## DEFINITIONS

Term	Definition	List
<b>Adverse event</b>	Is an untoward occurrence that has resulted in one or more of the following: participant distress; requirement for medical treatment or cessation in the research; or a breach of privacy or confidentiality.	AL1
<b>Amendment</b>	Is where the principal investigator proposes changes to a previously approved protocol.	
<b>Commander</b>	Is an Australian Defence Force officer who, by virtue of a delegation or instrument of appointment, exercises authority and holds responsibility for assigned Defence personnel and includes an Administrative Commanding Officer.	AL1
<b>Conflict of interest (in the research context)</b>	Where a person's individual interests or responsibilities have the potential to influence the carrying out of their institutional role or professional obligation in research; or where an institution's interest or responsibilities have the potential to influence the carrying out of its research obligations. A conflict of interest exists in a situation where an independent observer might reasonably conclude that the professional actions of a person are or may be unduly influenced by others interests. This refers to a financial or non-financial interest which may be a perceived, potential or actual conflict of interest.	AL1
<b>Consent (in research)</b>	Refer to the <a href="#">National Statement on Ethical Conduct in Human Research</a> .	AL1
<b>Data</b>	Refer to the <a href="#">National Statement on Ethical Conduct in Human Research</a> .	AL1
<b>Defence</b>	The Department of Defence and the Australian Defence Force.	
<b>Defence Australian Public Service employee (Defence APS employee)</b>	Is a person employed under the <i>Public Service Act 1999</i> in the Department of Defence.	
<b>Defence civilian</b>	Refer to section 3 of the <i>Force Discipline Act 1982</i> .	AL1
<b>Defence member</b>	Refer to the <i>Defence Force Discipline Act 1982</i> .	AL1
<b>Defence personnel</b>	All Australian Public Service employees, Defence employees engaged locally overseas, Defence civilians, Defence members and the equivalents from other Defence organisations on exchange to Defence.	AL1



<b>Term</b>	<b>Definition</b>	<b>List</b>
<b>Ethics review</b>	Refer to the <a href="#">National Statement on Ethical Conduct in Human Research</a> .	AL1
<b>Ex-serving personnel</b>	Includes all individuals who have previously served as a Defence member (and are no longer serving).	AL1
<b>Harm</b>	Refer to the National Statement on Ethical Conduct in Human Research.	AL1
<b>Human Research</b>	Is research which is conducted with or about people, their data or tissue.	
<b>Low risk (research)</b>	Refer to the <a href="#">National Statement on Ethical Conduct in Human Research</a> .	AL1
<b>Manager</b>	Means Defence personnel, a Department of Veterans' Affairs employee or a Defence or Department of Veterans' Affairs contractor who directs a range of human and physical resources and their associated financial responsibilities to achieve objectives. A manager may be a first-level supervisor or perform the role of a first-level supervisor where they have immediate subordinates, as well as the role of a second-level supervisor where they have Defence or Department of Veterans' Affairs personnel supervised by those subordinates.	AL1
<b>Monitoring (of research)</b>	Refer to the <a href="#">National Statement on Ethical Conduct in Human Research</a> .	AL1
<b>New application</b>	Is where a research proposal has not been considered by the committee previously or where significant time has elapsed since the research proposal was first considered and it requires the submission to be treated as a new application.	AL1
<b>Negligible risk (research)</b>	Refer to the <a href="#">National Statement on Ethical Conduct in Human Research</a> .	AL1
<b>Participant (in research)</b>	Refer to the <a href="#">National Statement on Ethical Conduct in Human Research</a> .	AL1
<b>Personal information</b>	Refer to the <a href="#">National Statement on Ethical Conduct in Human Research</a> .	AL1
<b>Principal Investigator</b>	Is the researcher(s) with primary responsibility for a research project including the preparation, conduct, and administration of the research, the associated funding, cooperative agreements, training, supervision, and delegation of any related tasks in compliance with applicable laws, regulations and institutional policy governing the conduct of human research.	

Term	Definition	List
<b>Privacy</b>	Refer to the <a href="#">National Statement on Ethical Conduct in Human Research</a> .	AL1
<b>Publication</b>	Is any book, journal, periodical, thesis or such publication, including any abstract or poster created for a conference, or any part thereof, which contains material, articles or text written by members of educational or research bodies on area of educational or scholastic learning, research or debate.	AL1
<b>Re-identifiable data</b>	Refers to data from which identifiers have been removed and replaced by a code, but it remains possible to re-identify a specific individual by, for example, using the code or linking different data sets.	
<b>Research</b>	Includes at least investigation undertaken to gain knowledge and understanding or to train researchers. It includes the creation of new knowledge and/or the use of existing knowledge in a new and creative way so as to generate new concepts, methodologies, inventions and understandings. This could include synthesis and analysis of previous research to the extent that it is new and creative.	AL1
<b>Research governance</b>	Are those matters concerning the authorisation, monitoring, quality, safety, privacy, risk management, legislative and regulatory guidance, financial management and ethical acceptability of research.	
<b>Resubmission</b>	Is where a research proposal was previously submitted to the committee and was not approved and revised documentation is subsequently submitted for consideration.	
<b>Risk</b>	Is the function of the magnitude of harm and the probability that it will occur. It includes the probability of damage, injury, negative occurrence or adverse/serious adverse events.	AL1
<b>Serious Adverse Event</b>	Is any untoward medical occurrence that: results in death; is life-threatening; requires in-patient hospitalisation or prolongation of existing hospitalisation; results in persistent or significant disability/incapacity; is a congenital anomaly/birth defect; or is a medically important event or reaction.	

<b>Term</b>	<b>Definition</b>	<b>List</b>
<b>Sponsor (in the research context)</b>	Is a senior commander or manager of no lower rank / APS classification than a one Star / Senior Executive Service Band 1 who takes responsibility for initiation, authorisation/approval/endorsement, management and/or financing of research.	
<b>Voluntary participation</b>	Refer to the <a href="#">National Statement on Ethical Conduct in Human Research</a> .	AL1

## **ACRONYMS AND ABBREVIATIONS**

<b>ADF</b>	Australian Defence Force
<b>ADHREC</b>	Australian Defence Human Research Ethics Committee
<b>APS</b>	Australian Public Service
<b>DDVA HREC</b>	Departments of Defence and Veterans' Affairs Human Research Ethics Committee
<b>Defence</b>	Department of Defence
<b>DVA</b>	Department of Veterans' Affairs
<b>DVA HREC</b>	Department of Veterans' Affairs Human Research Ethics Committee
<b>HREC</b>	Human Research Ethics Committee
<b>National Statement</b>	National Statement on Ethical Conduct in Human Research
<b>PICF</b>	Participant Information and Consent Form
<b>SGADF</b>	Surgeon General Australian Defence Force
<b>RECMAN</b>	Records Management Policy
<b>SES</b>	Senior Executive Service
<b>TGA</b>	Therapeutic Goods Administration
<b>The Code</b>	Australian Code for the Responsible Conduct of Research