Australian Government
Department of Defence
Department of Veterans' Affairs

DEPARTMENTS OF DEFENCE AND VETERANS' AFFAIRS HUMAN RESEARCH ETHICS COMMITTEE

RESEARCHER AND ADMINISTRATIVE GUIDELINES

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[1] https://www.legislation.gov.au/Series/C1968A00063

[2] https://www.legislation.gov.au/Series/C1914A00012

[3] http://intranet.defence.gov.au/dsa/dsm/

FOREWORD

The Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC) is a joint human research ethics committee 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.

The DDVA HREC is responsible for reviewing and, where appropriate, granting ethical approval of research involving humans where one or more of the following applies:

a. is conducted on Defence members, other Defence personnel or ex-serving personnel, their information or tissue

b. participants are recruited, either directly or indirectly, through a service provided by Defence or DVA

c. is conducted by Defence or DVA personnel

d. is conducted on/in a Defence establishment

e. is sponsored, endorsed or funded in any part by Defence or DVA.

The DDVA HREC will also review requests under the Special Access Scheme for the use of unapproved therapeutic goods in accordance with section 19(1)(a) of the *Therapeutic Goods Act 1989*[4].

The DDVA HREC is also responsible for the ongoing monitoring of approved research. The monitoring responsibilities (for ethical review bodies) of active research approved by the Australian Defence Human Research Ethics Committee and/or the Department of Veterans' Affairs Human Research Ethics Committee prior to 01 July 2017 have been transferred to the DDVA HREC or to a non-HREC review arrangement as appropriate.

Secretariat support is provided within Defence by the Directorate of Health Research Coordination and supported by DVA.

These guidelines should be read in conjunction with the Defence Human and Animal Research Manual (pending). The guidelines are effective 01 July 2017. 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.

[4] http://www.austlii.edu.au/au/legis/cth/consol_act/tga1989191/

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

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
CP3-6-037
Department of Defence
CANBERRA ACT 2600

Amendment number	Chapter(s)	Amendment	Effected date

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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 relate to research that has obtained ethical approval from the DDVA HREC and active protocols (as of 01 July 2017) that were previously granted ethical approval 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*[1] (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 of 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 promptly provide contact to the DDVA HREC Secretariat[2] (the Secretariat).

[1] https://www.nhmrc.gov.au/guidelines-publications/e72

[2] ddva.hrec@defence.gov.au

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 where one or more of the following apply:

a. research is conducted on Defence members, other Defence personnel or ex-serving personnel, their information 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 DDVA HREC approval must also be sought for the use of new registered items in accordance with the *Therapeutic Goods Act 1989*[3], as detailed in the *Defence Health Manual Volume 2 Part 15* – "Provision of medicines to Australian Defence Force members"[4].

Federal Wide Assurance

1.8 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 the Directorate Health Research Coordination.

HUMAN RESEARCH

Minimising duplication of ethical review

1.9 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 though 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 been, or will be, considered by another ethical review body and, if available, the outcome of such consideration should be provided. If it is not available upon submission the DDVA HREC should be advised on the outcome of the review once it is available.

[3] http://www.austlii.edu.au/au/legis/cth/consol_act/tga1989191/

[4] http://intranet.defence.gov.au/home/documents/data/ADFPUBS/DHM/volume2/part15/01.pdf

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

New applications

1.11 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.

1.12 The pro forma and other supporting documentation for submission of new applications is available on the DDVA HREC website[5].

1.13 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.

1.14 The Principal Investigator is to ensure that all relevant documents are attached including, but not limited to, Participant Information and Consent Forms (PICFs), surveys/questionnaires, letters of invitation and recruitment materials (including website content, newspaper advertisements etc) and previous PICFs for proposals that are requesting to use data obtained under a previously approved study. PICFs are to be in lay language that is easy to understand and phrased in a manner appropriate for the study cohort (no greater than year 8 level is recommended).

1.15 Researchers are encouraged to submit protocol applications as early as possible, particularly if prior internal organisational clearance has not already been provided. Completed applications are to be emailed to the DDVA HREC 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.

1.16 For research conducted by or involving Defence personnel (or their data), evidence of organisational support and command approval must be obtained prior to submission to the DDVA HREC. Approval should be obtained from a commander or manager of a rank/Australian Public Service (APS) classification no lower than a one-Star/Senior Executive Service (SES) Band 1. In principle approval must be sought and achieved prior to submitting an ethics application. Final organisational authorisation is to be sought once ethical approval has been obtained from DDVA HREC and other relevant institutions.

1.17 Organisational endorsement of research does not imply access to Defence personnel for studies. Researchers who are seeking access to Defence personnel as

[5] http://www.defence.gov.au/Health/hrec/

research participants must obtain in-principle approval from the relevant unit/areas commander/manager prior to submission of their ethics application to DDVA HREC. Final command approval is to be sought once ethical approval has been obtained from DDVA HREC and any other relevant institutions.

Resubmissions

1.18 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.

1.19 Dates for resubmissions requiring full HREC review are available on the DDVA HREC website.

Amendments to existing protocols

1.20 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). For all research approved by the DDVA HREC, an updated ethics application is also required. For amendments to protocols that were approved by ADHREC and/or the DVA HREC, advice should be sought from the Secretariat on the specific requirements for updating. 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.

1.21 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

1.22 The DDVA HREC encourages researchers to make themselves available, if required, for contact – including attendance in person or via telephone – during the DDVA HREC meeting where their project is being considered. It is therefore advisable that researchers provide a mobile telephone number or after hours telephone details to facilitate contact where appropriate.

Student research

1.23 In considering approval of 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.

1.24 Applications involving student researchers are to ensure that the mechanisms in place for supervision of their research are clearly articulated to meet the requirements under section 3 of the *Australian Code for the Responsible Conduct of Research*[6] (the Code).

CONSENT

1.25 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.

1.26 Consideration also needs to be given to the consent process to ensure that it is **free from coercion**.

1.27 The National Statement section 2.2.6 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 *Therapeutic Goods Administrations Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)*[7] section 4.8.10.

1.28 This 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.

1.29 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 (see National Statement sections 2.2.14 – 2.2.18).

Waivers of consent

1.30 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 (eg due to the quantity, age or accessibility of the records)

d. there is no known or likely reason that participants would not have been consented if they were asked

e. there is sufficient protection of participants' privacy

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[6] https://www.nhmrc.gov.au/guidelines-publications/r39

[7] https://www.tga.gov.au/sites/default/files/ich13595an.pdf

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

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

PAYMENTS TO RESEARCH PARTICIPANTS, INVESTIGATORS, DEPARTMENTS AND INSTITUTIONS

Research participants

1.32 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

1.33 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.

1.34 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.

1.35 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

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

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

Guidelines for volunteers

1.38 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.

Department of Veterans' Affairs sponsored research – Letter of first contact

1.39 There is a standing requirement that, if a proposed project is sponsored 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.

1.40 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.

1.41 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)

1.42 In making first contact, 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, 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.

> **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 pension, benefits or health services which you are entitled to from DVA, or to which you may become entitled in the future. If you wish, you can discontinue your participation in this study at any time.**

1.43 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 which you are entitled to from Defence or DVA, or to which you may become entitled in the future. If you wish, you can discontinue your participation in this study at any time.**

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

RESEARCH DATA

Data matching/data linkage

1.45 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 indentified from matched or linked data should be a consideration in all ethics applications to the DDVA HREC.

Retention of materials and research data

1.46 Research data and materials are to be retained by the Principal Investigator for not less than five years from the date of publication or fifteen 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.

1.47 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*[8] (the Archives Act) and (for Defence research institutions) the *Records Management Policy Manual*[9] (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*[10] (the Privacy Act), the Archives Act and other appropriate legislation.

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[8] http://www.austlii.edu.au/au/legis/cth/consol_act/aa198398/

[9] http://intranet.defence.gov.au/home/documents/data/DEFPUBS/DEPTMAN/RECMAN/RECMAN.pdf

[10] http://www.austlii.edu.au/au/legis/cth/consol_act/pa1988108/

1.48 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.

1.49 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.

1.50 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.

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

1.52 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

1.53 Researchers are to ensure that they are familiar with the requirements under National Statement Chapter 3.3 when developing and conducting clinical trial research.

1.54 Researchers are responsible for registering clinical trials in a publicly accessible register prior to the commencement of the clinical phase of the research in accordance with National Statement section 3.3.12 and the Code paragraph 4.10. Evidence of the registration of the trial must be provided to the DDVA HREC for inclusion on the protocol file.

1.55 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.

1.56 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 (see paragraphs 1.42 to 1.44 above).

1.57 Where a clinical trial is conducted by a Defence research organisation (such as the Army Malaria 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 and the RECMAN.

PRINCIPAL INVESTIGATORS' ASSURANCE

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

MONITORING

1.59 Researchers are responsible for providing scheduled and for cause reports to ethical review bodies in accordance with National Statement Chapter 5.5. Paragraphs 60 – 66 outline the requirements for submission of progress reports, adverse and serious adverse event reports, and notification of deviations from approved protocols and submission of final reports to the DDVA HREC.

Progress reports

1.60 The Principal Investigator is required to submit a progress report to the DDVA HREC twice per year by 01 June and 01 December for the lifespan of the project. 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.

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

Adverse and Serious Adverse Event Reports

1.62 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 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.

1.63 Researchers should also be cognisant 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 *Defence Human and Animal Research Manual* (pending).

Deviations from approved protocols

1.64 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

1.65 In accordance with the National Statement section 5.5.5 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.

1.66 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

1.67 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.

1.68 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/SES Band 1. In instances where a Defence or DVA sponsor was not required, advice should be sought from the Directorate of Health Research Coordination. Review of the findings may also require review and advice from other relevant areas, where appropriate.

1.69 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.

1.70 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.

1.71 In accordance with the *Defence Security Manual*[11], 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.

1.72 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.

[11] http://intranet.defence.gov.au/dsa/dsm/

1.73 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.

COMPLAINTS OR CONCERNS

1.74 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).

1.75 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 (refer to paragraph 1.60).

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[1] are available on the DDVA HREC website[2].

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. To ensure the membership will equip the committee with the skills necessary to address all of the relevant considerations arising from the categories of research likely to be submitted, a pool of inducted members shall be maintained. Wherever possible one or more of the members are to be experienced in analysing and reflecting on ethical decision-making.

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

2.7 A selection committee consisting of representatives from the Department of Defence (Defence) and the Department of Veterans' Affairs (DVA) shall consider curricula vitae supplied by candidates, may interview candidates and will make a recommendation to the Vice Chief of the Defence Force (VCDF) and the Deputy Secretary/Chief Operating Officer (COO), DVA.

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[1] http://www.defence.gov.au/health/hrec/#ToR

[2] http://www.defence.gov.au/Health/hrec/

2.8 A formal letter of appointment will be provided to all members and shall include the date of appointment, length of tenure, 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, conditions of their appointment and circumstances whereby their membership may be terminated. The letter of appointment will be jointly signed by VCDF and the COO, DVA.

2.9 Members are appointed for a period of up to three years. During their tenure appointments are subject to annual review to ensure that the ongoing requirements of the committee are being met.

2.10 Members will be advised when their term of appointment is due to expire. Reappointment is on invitation from the VCDF and COO, DVA based on a recommendation from the Chair, the Director General Strategic Health Coordination, Defence and the relevant Star/Senior Executive Service (SES) Band 1 officer, DVA.

Indemnity of members

2.11 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

2.12 Surgeon General Australian Defence Force and the relevant SES Band 2 officer, 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

2.13 Members must agree to their name and profession being made available to the public, including being published on the DDVA HREC website.

Confidentiality

2.14 Members are to sign a statement undertaking that all matters of which they become aware of during the course of their work on the committee will be kept confidential.

Training

2.15 Members are required to attend continuing education or training programs in research ethics at least every three years. Advice of attendance at training is to be provided to the Secretariat for inclusion on the Member Training Register. Failure to attend ongoing training may result in termination of appointment.

Conflicts of interest

2.16 Members are required to notify the Secretariat of any conflicts of interest (via the conflicts of interest declaration form), pecuniary or otherwise, including potential or perceived conflicts of interest, which may arise during their tenure on the committee. This is to be done upon appointment/reappointment, annually and on an ad hoc basis.

Consideration of research applications

2.17 Members are responsible for deciding whether in their judgement a proposal submitted to the committee meets the requirements of relevant national and international research guidelines, legislative instruments and the specific organisational requirements as outlined in these guidelines, the Defence Human and Animal Research Manual (pending), and other relevant policy. In order to do this, members are to make themselves familiar with the relevant guidelines, policy and legislative instruments where appropriate.

Preparation for and attendance at meetings

2.18 Members are to ensure that they prepare for and attend scheduled meetings. If a rostered member is unable to attend a scheduled meeting, and an alternate member is unable to be scheduled to attend the meeting, the rostered member is required to provide written feedback on the ethical acceptability of the scheduled agenda items at least three business days prior to the meeting. See paragraph 2.24 for further information on meeting rosters.

Out of session considerations

2.19 Members will review out-of-session items as requested. Inability to review such items should be communicated to the Secretariat at the earliest possible opportunity.

SUBJECT MATTER EXPERT ADVICE

2.20 The committee may seek advice from subject matter experts as required to address individual study protocols outside of the committee's knowledge base.

2.21 Subject matter experts are required to disclose any conflicts of interest, as per paragraph 2.18, and are to ensure confidentiality of applications is maintained in accordance with paragraph 2.16.

MEETINGS

Frequency of meetings

2.22 The DDVA HREC will meet approximately ten times per year, commencing in February of each year. Additional meetings may be scheduled as required.

2.23 A meeting schedule, developed in consultation with members, is available on the DDVA HREC website, and is available at least six months in advance.

2.24 A meeting roster will be developed based on member availability and the minimum membership requirements (as per the *National Statement on Ethical Conduct in Human Research*[3] (the National Statement) sections 5.1.29 – 5.1.30).

Attendance at meetings

2.25 The Chair is required to attend meetings in person. All other members should make efforts to attend in person. Attendance via video or teleconference may be arranged if required.

2.26 The Chair, via the Secretariat is to be notified of any planned absences a minimum of four weeks in advance of a scheduled meeting, including a reason for the absence.

2.27 Where an alternate member in the pool is not available to attend, absent members are required to complete 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 any foreshadowed absence.

Attendance of observers at meetings

2.28 Representatives from Defence and the DVA will be invited to attend meetings as observers. They may provide advice on Defence- and DVA-specific requirements as required; however, they do not form part of the decision-making process of the committee when determining whether to grant ethical approval of a project.

2.29 Consideration will be given to attendance of other observers at a meeting at the discretion of the Chair. Observers are to ensure that any matters that they are privy to as part of the deliberations of the committee remain confidential.

2.30 Where an observer identifies a potential or actual conflict of interest in relation to an agenda item to be considered, the observer is required to declare their conflict.

Conduct and structure of meetings and deliberations

2.31 The National Statement section 5.1.30 outlines the minimum membership requirements as follows:

a. a Chairperson

b. at least two lay people (one man and one woman)

c. a person with knowledge of, and current experience in the professional care, counselling or treatment of people

d. a person who performs a pastoral care role

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[3] https://www.nhmrc.gov.au/guidelines-publications/e72

e. a lawyer

f. at least two people with current research experience relevant to research proposals to be considered at the meetings they attend.

2.32 The HREC should have equal numbers of men and women and at least one third of member should be from outside the institution for which the HREC is reviewing research.

2.33 The DDVA HREC Terms of Reference provides further detail on the composition of the DDVA HREC.

2.34 The Chair may decide to cancel a meeting if not all members are able to attend and if, in the Chair's view, this would compromise the DDVA HREC's ability to fulfil its duties under the National Statement. 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 not all agenda items have not been considered within the allocated time, the meeting may continue until all items have been completed, out-of-session review of specific items may be requested, or an additional meeting may be scheduled. In the latter case, the additional meeting should occur within five business days.

2.37 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

2.38 The Secretariat is to prepare the draft agenda within two business days of the submission closing date for a scheduled meeting. Meeting papers are to be collated and distributed to members no later than two weeks prior to the scheduled meeting.

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

2.40 At the discretion of the Chair, consideration will be given to inclusion of late agenda items on a case by case basis.

Preparation of meeting minutes

2.41 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.

2.42 The minutes are to include a summary of relevant discussions, a record of decisions made, reference to views expressed by absent members and reference to relevant guidelines and/or legislative instruments where appropriate. 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.

2.43 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 for their information. A copy of the minutes will also be recirculated to members as part of the subsequent meetings agenda package for ratification.

2.44 The minutes of each meeting are to also be provided to departmental delegates in accordance with the DDVA HREC Terms of Reference.

COSIDERATION AND REVIEW OF APPLICATIONS

New applications

2.45 Applications for ethical approval are to be submitted in accordance with the procedures outlined on the DDVA HREC website. Applications are to be emailed to the DDVA HREC[4].

2.46 New applications are to be submitted at least twenty working days prior to the scheduled meeting date to allow for sufficient time for members to review applications.

2.47 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.

2.48 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.

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

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[4] ddva.hrec@defence.gov.au

2.50 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 an excessive number of applications being received for review at any one meeting, some applications may be deferred to the following DDVA HREC meeting. If this occurs, prioritisation will occur at the discretion of the Chair.

2.51 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

2.52 Resubmissions may require review by the full DDVA HREC, the Chair/Deputy Chair, other members or the Secretariat, as determined by the Chair/Deputy Chair.

2.53 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.

2.54 Resubmissions that do not require review by the full DDVA HREC will be circulated for out of session consideration by either 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

2.55 Protocol amendments will be considered out-of-session in the first instance 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 or updated contact details in consent documentation) may be approved by the Secretariat.

Expedited review

2.56 Defence have established non-HREC review level mechanisms for the review of low- and negligible-risk research, as outlined in the DDVA HREC Terms of Reference. Research that does not sit within the remit of these review mechanisms is to be submitted to the DDVA HREC for consideration.

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

2.58 Expedited review of the 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

2.59 The DDVA HREC will review requests for the use of new unregistered items, as required by the *Therapeutic Goods Act 1989*[5]. If supported, the Secretariat (on behalf of the DDVA HREC) will raise and forward a letter of endorsement covering the original request to Surgeon General Australian Defence Force (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

2.60 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.

2.61 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.

2.62 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.

Methods of decision making

2.63 The DDVA HREC will endeavour 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.

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

[5] http://www.austlii.edu.au/au/legis/cth/consol_act/tga1989191/

Outcomes of ethical review

2.65 Upon review of an application, any one of the four 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 and the DDVA HREC is satisfied that the research is ethical and can be conducted as detailed in the submission. When this occurs, the researcher will be sent a letter stating that the research has been approved, noting the protocol number that has been assigned to it and enclosing a Principal Investigators Assurance for signature and return.

b. **The protocol is approved conditionally.** Some minor amendments may need to be made to the information sheets or consent forms, or clarification of some aspect of the methodology may be required. In this case, the researcher will be sent a letter stating that the DDVA HREC has approved the project subject to some changes or clarification, the nature of which will be detailed in the letter. This enables protocol alterations to be made before commencing the research. The research is not to commence until these amendments have been forwarded to the committee and the researcher has received a responding letter stating that the protocol has been formally approved and enclosing a Principal Investigators Assurance. 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 requested.** A letter will be sent to the researcher explaining why the study was not approved and detailing any amendments or issues that should be addressed in a resubmission. If the relevant documentation is not resubmitted 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.

d. **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

2.66 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 letter advising of ethical approval. 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

2.67 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 or as soon as practicable. The Principal Investigator and, where appropriate, the point of contact, will be advised of any delay in the formal correspondence.

Managing conflicts of interest

2.68 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.

2.69 The Chair will determine if this results in a conflict of interest and the appropriate course of action. All declarations of conflicts of interest, the action taken and any absences of members are to be minuted by the Secretariat.

Communication with researchers

2.70 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.

2.71 As outlined in paragraph 2.22, researchers may be asked to attend a scheduled meeting to provide clarification on any concerns raised by the committee. Additionally, researchers are encouraged to engage early with the Secretariat when developing research proposals so that they can advise on any specific institutional requirements.

2.72 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

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

Record keeping

2.74 The Secretariat shall maintain an electronic record of all research proposals that have been submitted for consideration in accordance with the National Statement section 5.2.24. 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

2.75 The DDVA HREC will monitor approved protocols during the active lifespan of the project.

2.76 Additionally, active research projects for research that requires full HREC review or is outside of the established non-HREC review level mechanisms within Defence, that obtained ethical approval by the Australian Defence Human Research Ethics Committee and/or the Department Veterans' Affairs Human Research Ethics Committee prior to 01 July 2017 will be monitored by the DDVA HREC as outlined in paragraphs 2.73–2.82.

Progress reports

2.77 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, noting that reports are due by 01 June and 01 December each calendar year for the life span of the project.

2.78 Upon receipt of a progress report, the Secretariat will send the report to the Chair for review. The Chair will review the protocol file against the information contained in the report and will either request further information or advise that no further action is required. Where significant concerns are raised the matter will be included on the next meeting agenda or circulated to members for out-of-session consideration. Progress reports are to be a standing agenda item and updates on received and outstanding reports are to be included at each DDVA HREC meeting. Members may request copies of any individual reports.

2.79 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 choose to grant an extension for submission of the progress report or withdraw ethical approval.

Audits

2.80 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.

2.81 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

2.82 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.

2.83 Where appropriate, additional advice may be sought from other committee members and/or subject matter experts in order to facilitate a considered review of the notification.

2.84 The Principal Investigator will receive written advice of the outcome of the review of the event/s and the appropriate 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

2.85 Upon receipt of a final report, the report will be reviewed by the Chair or Deputy Chair on behalf of the committee. Where necessary additional information will be requested prior to closure of the file.

2.86 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

2.87 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.

2.88 In such circumstances 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

2.89 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

2.90 Complaints regarding the conduct of research are to be submitted to the Secretariat who, in consultation with relevant representatives from Defence and/or DVA, where appropriate, will endeavour 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.

2.91 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.

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

2.93 Where a complaint arises regarding the conduct of the committee, the Executive Officer is the initial point of contact for the complaint. Where appropriate, the complaint will be directed to the Surgeon General Australian Defence Force and/or the relevant SES Band 2 officer, DVA.

2.94 The Directorate of Health Research Coordination will maintain a complaints register for audit purposes.

DEFINITIONS

Adverse event is an untoward occurrence.

Amendment is where the principal investigator proposes changes to a previously approved protocol.

Commander 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 (includes an Administrative Commanding Officer).

Conflict of interest (in the research context) 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.

Consent is a person's or group's agreement, based on adequate knowledge and understanding of relevant material, to participate in research.

Data refers to pieces of information.

Defence is the Department of Defence and the Australian Defence Force (ADF).

Defence Australian Public Service employee (Defence APS employee) is a person employed under the *Public Service Act 1999*[1] in the Department of Defence.

Defence civilian, as defined in section 3 of the *Defence Force Discipline Act 1982*[2] (DFDA), is a person (other than a Defence member) who:

(a) with the authority of an authorised officer as defined in the DFDA, accompanies a part of the ADF that is outside Australia, or on operations against the enemy; and

(b) has consented, in writing, to subject themselves to ADF discipline while so accompanying that part of the ADF.

Defence communities are groups of people in the general population that have a relationship to the ADF, whether through their own service or that of a spouse, partner or other family member.

Defence locally engaged employee is any person engaged overseas by contract or under section 74 of the *Public Service Act 1999*[3].

Defence member is a member of the Australian Defence Force, including Reserves regardless of their duty status.

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[1] https://www.legislation.gov.au/Series/C2004A00538

[2] https://www.legislation.gov.au/Details/C2013C00637/Html/Text#_Toc369186639

[3] https://www.legislation.gov.au/Details/C2013C00310/Html/Text#_Toc360194349

Defence personnel includes all Australian Public Service employees in the Department of Defence (Defence APS employees), Defence members, Defence locally engaged employees, Defence civilians, and foreign personnel on exchange to Defence.

Ethical review is the review of research by an Human Research Ethics Committee or other body.

Ethics refers to the concepts of right and wrong, justice and injustice, virtue and vice, good and bad, and activities to which these concepts apply.

Ex-serving personnel includes all individuals who have previously served as a Defence member.

Human Research is research which is conducted with or about people, their data or tissue.

Manager means Defence personnel, a DVA employee or a contractor who directs a range of human and physical resources and their associated financial responsibilities to achieve Defence or DVA objectives. A manager may be a first-level supervisor or performs 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 personnel supervised by those subordinates.

Monitoring is the process of verifying that the conduct of the research conforms to the approved proposal.

Participant is anyone who is the subject of research.

Personal information is information by which individuals can be identified.

Principal Investigator 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.

Re-identifiable data 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.

Research includes at least investigation undertaken to gain knowledge and understanding or to train researchers.

Research governance are those matters concerning the authorisation, monitoring, quality, safety, privacy, risk management, legislative and regulatory guidance, financial management and ethical acceptability of research.

Respect is recognition that each human being has value in themselves.

Resubmission is where a research proposal was previously submitted to the committee and was not approved and revised documentation is subsequently submitted for consideration.

Risk is the function of the magnitude of harm and the probability that it will occur.

Serious Adverse Event 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.

Sponsor (in the research context) 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.

ACRONYMS AND ABBREVIATIONS

ADF	Australian Defence Force
ADHREC	Australian Defence Human Research Ethics Committee
APS	Australian Public Service
COO	Chief Operating Officer
DDVA HREC	Departments of Defence and Veterans' Affairs Human Research Ethics Committee
Defence	Department of Defence
DGHC	Director-General Health Capability
DVA	Department of Veterans' Affairs
DVA HREC	Department of Veterans' Affairs Human Research Ethics Committee
HREC	Human Research Ethics Committee
National Statement	*National Statement on Ethical Conduct in Human Research*[1]
PICF	Participant Information and Consent Form
RECMAN	*Records Management Policy Manual*[2]
SES	Senior Executive Service
TGA	Therapeutic Goods Administration
The Code	*Australian Code for the Responsible Conduct of Research*[3]
VCDF	Vice Chief of the Defence Force

[1] https://www.nhmrc.gov.au/guidelines-publications/e72

[2] http://intranet.defence.gov.au/home/documents/data/DEFPUBS/DEPTMAN/RECMAN/RECMAN.pdf

[3] https://www.nhmrc.gov.au/guidelines-publications/r39