



**Australian Government**

**Department of Defence**

**Department of Veterans' Affairs**

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

### **BACKGROUND**

1. The Departments of Defence and Veterans' Affairs have jointly established the Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC) as the institutional human research ethics committee (HREC) in accordance with the [\*National Statement on Ethical Conduct in Human Research\*](#)<sup>1</sup> (the National Statement). The DDVA HREC is registered with the National Health and Medical Research Council (EC00460).

### **PURPOSE**

2. The purpose of the DDVA HREC is to provide expert review of research proposals submitted for ethical approval. In doing this, the committee aims to:
  - a. provide independent, competent and timely review of human research proposals in respect of their ethical acceptability
  - b. protect the mental and physical welfare, rights, dignity and safety of research participants
  - c. facilitate ethical research through efficient and effective review processes
  - d. promote an awareness and understanding of human research ethics within the Department of Defence (Defence), the Department of Veterans' Affairs (DVA) and the broader community
  - e. review human research in accordance with the National Statement, other national guidelines and legislative instruments
  - f. provide oversight, monitoring and advice on ethical aspects of human research.

### **SCOPE OF RESPONSIBILITY FOR ETHICS REVIEW**

3. Research proposals involving humans will be reviewed by the DDVA HREC where one or more of the following apply:
  - a. participants are or include Defence members, other Defence personnel (as a specific study group or sub-group), their information (data) and/or tissue
  - b. participants are recruited, either directly or indirectly, through a service provided by Defence or DVA

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<sup>1</sup> National Statement on Ethical Conduct in Human Research <https://www.nhmrc.gov.au/guidelines-publications/e72>

- c. the research is to be conducted by Defence or DVA personnel in the course of their employment
  - d. the research is to be conducted on/in a Defence establishment
  - e. the research is sponsored, endorsed or funded in any part by Defence or DVA.
4. Researchers undertaking research that involves ex-serving personnel as a target cohort or a study sub-group, but does not fall under the categories above, are encouraged to obtain ethical approval from the DDVA HREC in addition to any approvals required by their own institution.
  5. 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\*](#)<sup>2</sup>.

## **RELATIONSHIP TO OTHER PROCESSES OF RESEARCH REVIEW**

### **Lower risk research**

6. In accordance with the National Statement, Defence has established non- HREC levels of ethical review for lower risk human research and quality assurance/evaluation activities as follows:
  - a. Defence People Research Low Risk Ethics Panel – for the ethical review of lower risk research and quality assurance/evaluation activities that include obtaining opinions, thoughts feelings, views or experiences of Defence personnel across the organisation. It also includes the use of associated data.
  - b. Defence Science and Technology Group (DSTG) Low Risk Ethics Panel – for the ethical review of lower risk research and quality assurance/evaluation activities involving DSTG staff as named investigators and/or use of DSTG infrastructure or funding.
7. Where one of the low risk ethics panels listed at paragraph 6 determines that a research proposal requires HREC review, the research proposal is to be referred to the DDVA HREC. The low risk ethics panels may also seek advice on specific matters from the DDVA HREC, via the Secretariat, as required.
8. The ethics panels listed at paragraph 6 will provide six monthly reports to the DDVA HREC on approved research.
9. Lower risk research proposals and quality assurance/evaluation activities that do not fit within the remit of the panels listed at paragraph 6 are eligible for expedited review by the DDVA HREC Chair/Deputy Chair and other members as required.

### **Multi-centre research**

10. To facilitate multi-centre research the DDVA HREC may:
  - a. communicate with any other HREC

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<sup>2</sup> *Therapeutic Goods Act 1989* [http://www.austlii.edu.au/au/legis/cth/consol\\_act/tga1989191/](http://www.austlii.edu.au/au/legis/cth/consol_act/tga1989191/)

- b. provide its scientific/technical and/or ethical assessment of the research to another HREC.

## **RELATIONSHIP TO NON-AFFILIATED RESEARCHERS**

- 11. The DDVA HREC will conduct and monitor the ethical and scientific merit of research proposals for researchers external to Defence and DVA where the research involves any, or all of the instances outlined in paragraph 3.

## **INSTITUTIONAL ACCOUNTABILITY**

- 12. The committee is accountable to the:
  - a. Surgeon General Australian Defence Force (SGADF), Defence, in the conduct of its regular business
  - b. Deputy President, DVA.

## **MECHANISMS FOR ACCOUNTABILITY AND REPORTING**

- 13. In terms of reporting, the DDVA HREC will provide:
  - a. an annual report to the National Health and Medical Research Council in accordance with the National Statement paragraph 5.8.4
  - b. an annual report (based on a calendar year) to the Chief of Personnel and the Deputy President, DVA
  - c. regular updates on approved research proposals to the Defence Human Research Governance Board and the DVA Research Board
- 14. Agendas and Minutes of meetings shall be provided to Defence and DVA institutional representatives:
  - a. Deputy Surgeon General Australian Defence Force (Defence)
  - b. Assistant Secretary responsible for research (DVA)
  - c. Director Strategic Clinical Assurance and Ethics (Defence)
  - d. The Director responsible for ethics (DVA).
- 15. Additionally, SGADF and/or the First Assistant Secretary responsible for research and/or Deputy President, DVA will be provided the Agendas and Minutes upon request.

## **MEMBERSHIP**

### **Committee Composition**

- 16. The composition of the committee shall be in accordance with National Statement paragraph 5.1.30 and shall include:
  - a. a Chairperson with suitable experience, including previous membership of an HREC, whose other responsibilities will not impact on the HREC's capacity to carry out its obligations under the National Statement
  - b. at least two people who bring a broader community or consumer perspective and who have no paid affiliation with Defence or DVA

- c. at least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people; for example a nurse, counsellor or allied health professional
  - d. at least one person who performs a pastoral care role in a community, including but not limited to, an Aboriginal and/or Torres Strait Islander elder or community leader, a chaplain or a minister of religion or other religious leader.
  - e. at least one qualified lawyer, who may or may not be currently practicing and, where possible, is not engaged to advise Defence or DVA on research-related or any other matters
  - f. at least two people with current research experience that is relevant to research proposals to be considered at meetings they attend.
17. Additionally, the committee is to include:
- a. a Deputy Chair
  - b. at least one Defence health graduate (a current or ex-serving Defence member who has professional qualifications in medicine, nursing, dentistry, psychology or other health profession)
  - c. at least one contemporary veteran (an individual who has served in one or more of the conflicts involving Australian troops since 1999).
18. Members may be appointed to more than one of the categories identified above however, they cannot represent more than one of the categories at any individual meeting that they attend in accordance with National Statement paragraph 5.1.31.
19. In accordance with the National Statement paragraph 5.1.36, each meeting should ensure that membership is diverse and at least one third of the members are to be external to Defence and DVA. The Australian Government has an additional requirement that a gender balance of 60/40 (male/female) or better be maintained for all Government boards.

#### **REMUNERATION OF MEMBERS**

- 20. External members are offered a sitting fee for each meeting that they attend. The value of sitting fees will be determined by the Director Strategic Clinical Assurance & Ethics, Defence, and the Director responsible for ethics, DVA, and will be reviewed periodically.
- 21. All members will be reimbursed for legitimate expenses incurred in attending Committee meetings or in otherwise carrying out the business of the Committee.

#### **FEES FOR ETHICS REVIEW**

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