Australian Government
Department of Defence
Department of Veterans' Affairs

DEPARTMENTS OF DEFENCE AND VETERANS' AFFAIRS HUMAN RESEARCH ETHICS COMMITTEE

DRAFT STANDARD OPERATING PROCEDURES

June 2026

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Xx xx 2026

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DEPARTMENTS OF DEFENCE AND VETERANS' AFFAIRS HUMAN RESEARCH ETHICS COMMITTEE STANDARD OPERATING PROCEDURES

Background: 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).

Issued by: These procedures have been issued by the Surgeon General Australian Defence Force (Defence) and the Deputy President, Repatriation Commission, DVA.

Purpose: The procedures ensure compliance with the *National Statement on Ethical Conduct in Human Research* (National Statement), the *Australian Code for the Responsible Conduct of Research*, and other relevant legislative instruments, departmental policies and national guidelines.

The terminology used within the procedures are consistent with the National Statement.

Scope and applicability: The procedures are applicable to all Defence and DVA personnel and external stakeholders wishing to conduct research that falls within the scope and responsibility outlined in the DDVA HREC Terms of Reference.

The procedures do not provide guidance on the processes supporting low risk projects that fall within the scope of any extant low risk panels or processes for the review of evaluation/quality assurance activities that sit within DVA's remit.

Management: The procedures are to be reviewed at least every three years from publication, or as required, to ensure ongoing compliance with national guidelines, legislative instruments and institutional policies.

In between major reviews, the issuing delegates or other departmental staff, the Committee, the Secretariat and other stakeholders, may suggest minor amendments for consideration on an ad hoc basis.

The DDVA HREC are to be consulted on proposed changes. Revisions are subject to departmental review processes and are to be approved by Defence and DVA.

Availability: The procedures are available for public release, in accordance with the National Statement.

Policy Domain: Human Research Ethics

Accountable officer:	Surgeon General Australian Defence Force (Defence) and the Deputy President, Repatriation Commission and MRCC, DVA
Policy owners:	Surgeon General Australian Defence Force and the First Assistant Secretary response for research, DVA
Policy contact:	Assistant Director Research Ethics, Defence Assistant Director Research Services, DVA
Cancellation:	The DDVA HREC Standard Operating Procedures replace the DDVA HREC Researcher and Administrative Guidelines.
Definitions:	Definitions that apply to these guidelines are at Annex A.

Table of Contents

FOREWORD

The Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC) is registered with the National Health and Medical Research Council (EC00460) and as an Institutional Review Board (IORG0007579) with the Office for Human Research Protections in the United States.

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 the Department of Veterans' Affairs (DVA)

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.

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 their primary institution. Mutual recognition of the primary ethical review should then be obtained by the DDVA HREC.

The DDVA HREC will 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.

Information on the purpose, relationship to other processes of ethical review, relationship to non-affiliated researchers, institutional accountability, mechanisms of reporting, remuneration of members and fees for ethical review, is outlined in the DDVA HREC Terms of Reference.

DEPARTMENTS OF DEFENCE AND VETERANS' AFFAIRS HUMAN RESEARCH ETHICS COMMITTEE

Terms of Reference

The DDVA HREC Terms of Reference are available on the DDVA HREC website.

Security Clearances

1. All members of the Committee and the Secretariat are to hold a minimum security clearance of Negative Vetting 1.

Confidentiality

2. All members are strictly bound by privacy and confidentiality laws and regulations.

3. Members are to:

a. ensure that any matters that they are privy to as part of the deliberations of the Committee remain confidential

b. sign a confidentiality agreement upon appointment and reappointment to the Committee.

Conflicts of Interest

4. Members are required to notify the Secretariat of any potential or perceived conflicts of interest which may arise during their tenure on the Committee including, but not limited to:

a. personal involvement or participation in the research

b. financial or other interest of affiliation

c. involvement in competing research.

5. Conflict of Interest Forms are to be completed upon appointment and reappointment to the Committee and on an adhoc basis where necessary.

Consideration of Research Applications

6. Members are responsible for deciding whether a proposal 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.

APPLICATIONS FOR ETHICAL REVIEW

7. The Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC) is responsible for reviewing research that is in scope under its Terms of Reference and:

a. higher risk projects and/or seeks a waiver of consent for research using personal information in medical research, or personal health information (National Statement, 2.3.9)

b. lower risk projects that do not fall within the scope of any extant low risk panels

8. Approval from the DDVA HREC must be sought for the use of new unregistered items in accordance with the *Therapeutic Goods Act 1989* (Therapeutic Goods Act), as detailed in the *Defence Health Manual* Volume 2 Part 15 Chapter 6.

Applications That Can Be Reviewed Under Other Pathways

9. Defence has established several mechanisms for the assessment of lower risk research and quality assurance activities. Further information is available in the DDVA HREC Terms of Reference.

10. DVA has established an internal ethics review process for DVA quality assurance/evaluation activities. If the activity also fits within the remit of Defence, it is not eligible for the DVA process. Contact the Ethics POC for further information via ethics.poc@dva.gov.au.

11. Where lower risk research or quality assurance/evaluation projects are outside of the remit of the processes listed above, applications will be considered out-of-session by the Chair and/or Deputy Chair with the assistance of the Secretariat. The application may be forwarded to other members or subject matter experts for review and/or advice as determined appropriate by the Chair or Deputy Chair.

12. Defence and DVA recognise that researchers will often need to approach multiple ethical review bodies to obtain ethical approval of their research, for example, when conducting research through a university or hospital that is also in scope for the DDVA HREC. 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 ethics approval by the DDVA HREC.

13. The DDVA HREC can consider accepting the outcome of an ethical review body under mutual recognition pathways in accordance with National Statement Chapter 5.5 where:

a. the research does not involve the active participation of Defence personnel

b. the study is funded by Defence however, research participants are external to the department

c. the study is not funded by DVA or recruiting participants through a DVA service or program, or if it is, the relevant program manager agrees in writing that ethics review from another institution is acceptable

d. if the study is using DVA data, the research organisation responsible is a Commonwealth Accredited Integrating Authority.

14. Applications that are submitted for mutual recognition by the DDVA HREC will be reviewed out of session by the Chair and/or Deputy Chair and should include all of the documentation that has been approved by the primary ethical review body, along with a copy of the letter/correspondence advising that ethical approval has been granted. The approving ethical review body is the primary body responsible for the ongoing monitoring of the research. Copies of any reports/amendments submitted to and approved by the approving ethical review body should be submitted

to the DDVA HREC. In some instances, additional information and/or governance approvals from Defence and/or DVA may be required.

New Applications

15. Applications are deemed to be 'new' when the:

a. research proposal has not previously been considered by the DDVA HREC

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

c. the original research proposal was not approved, and a significant revision was requested.

16. When drafting a new application for consideration by the DDVA HREC, researchers are encouraged to allow adequate time in their project timeline for ethical review.

17. The process for submitting new applications to the DDVA HREC, including the pro forma, supporting templates and additional guidance, is available on the DDVA HREC website.

18. For PhD or other student research, the DDVA HREC requires the Principal Investigator to be the primary supervisor, as they are responsible for guiding and supporting the research from conceptualisation to dissemination of findings.

Applications involving student researchers are to:

a. ensure that the mechanisms in place for supervision are clearly outlined

b. include evidence of confirmation of candidature in the supporting documentation provided for ethical review.

19. Research ethics proposals and any correspondence to research participants are to be clear, detailed and written in plain language. All technical terms and acronyms are to be explained in simple language, and technical jargon is to be avoided.

20. The Principal Investigator is to ensure that all relevant supporting documentation is attached to the application.

Defence Specific Requirements

21. For research conducted by or involving Defence personnel (or their data), evidence of Defence Organisational Support and Command Approval must be obtained prior to submission to the DDVA HREC. Further information is available in the DDVA HREC Facts Sheets on Organisational Support and Command Approval.

22. Defence, through Joint Health Command, 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 DDVA HREC secretariat via ddva.hrec@defence.gov.au.

Department of Veterans' Affairs Specific Requirements

23. For research or quality assurance/evaluation activities involving ex-serving personnel (or their data), the submission will be sent to the DVA Ethics POC to conduct an organisational review in addition to being reviewed by the DDVA HREC.

24. For research recruiting participants through DVA programs or services, or using DVA data, the researcher will need to obtain approval from the relevant DVA program manager and/or data custodian (Senior Executive Service (SES) Band 1 or above) prior to commencing the research. Researchers wishing to use DVA data or recruit participants through DVA should discuss their plan with DVA before submitting their ethics application. DVA will generally only assist with recruitment of study participants for research commissioned by the department.

Submission Closing Dates

25. For applications that require full HREC review (at a meeting), completed applications are to be submitted electronically by the meeting submission closing date, as indicated on the DDVA HREC website.

26. Applications for research that do not require ethical review by the full HREC are not subject to meeting dates or submission deadlines, and can be submitted for out-of-session review at any time. This includes lower risk research, quality assurance/evaluation activities, applications for mutual recognition and exemptions from ethical review.

Ethical Review of Applications

27. Higher risk applications will be included on the agenda for the next available HREC meeting. Applications that have been deemed to be lower risk or a quality assurance/evaluation activities will be sent for out-of-session review by the Chair and/or Deputy Chair and if required other members of the DDVA HREC.

28. Where an application involves ex-serving members, DVA clients or their data and the research is either funded through DVA or recruited via DVA means, 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 prior to the relevant meeting or out of session review for the Committee's consideration.

29. The Committee may seek advice from subject matter experts on study proposals that fall outside the Committee's knowledge base. Applications may also be discussed with other directorates within Defence and/or DVA if required.

30. Where advice is sought external to the Committee, the reviewers are to disclose any conflicts of interest and are to ensure confidentiality of applications is maintained.

31. The Committee are not able to grant retrospective ethical approval of a research project once it has commenced, as per the guidelines in the National Statement.

Unregistered Therapeutic Substances and Medical Devices

32. The DDVA HREC will review requests for the use of new unregistered items, as required under the Therapeutic Goods Act. Applications are to be tabled for review

by the minimum membership (as per the National Statement) and the Defence Health Graduate.

Resubmissions

33. The Chair and/or Deputy Chair, in consultation with the Committee if required, is to determine if resubmissions require review:

a. at a scheduled meeting by the full HREC

b. out-of-session by the full HREC

c. out-of-session by the Chair/Deputy and/or other Committee members

d. out-of-session by the Secretariat.

34. Resubmissions requiring full HREC review are to be submitted by the meeting submission closing date. Dates for resubmissions requiring full HREC review are available on the DDVA HREC website.

35. Resubmissions that do not require review by the full HREC will be circulated for out-of-session consideration by the Chair and/or Deputy Chair (and nominated Committee members if required) to determine the ethical acceptability of the response.

36. When submitting a resubmission, it is essential that the Principal Investigator ensures that dates and version control numbers are updated on all relevant documentation.

Withdrawal of Applications

37. An applicant can withdraw their application at any time prior to ethical approval being granted by informing the Secretariat via email.

38. An application is deemed to be withdrawn when a response to a request for further information or administrative review has not been received within three months and an extension has not been approved by the Chair and/or Deputy Chair or Secretariat. Any future submissions for the study will be considered as new applications.

Confidentiality

39. Researcher contact details are not provided to third parties. Whenever a third party requests details, the Secretariat will contact the researcher and provide details of the third party. The researcher can then, if agreeable, contact the third party directly.

Methods of Decision-Making

40. 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.

Outcomes of Ethical Review

41. Upon review of an application, any one of the three outcomes indicated below

is available to the DDVA HREC:

a. **The project is approved.** This means that the protocol conformed to all the necessary requirements, and the DDVA HREC is satisfied that the research meets the ethical requirements outlined in the National Statement.

b. **A resubmission/new application is requested.** A letter will be sent to the researcher requesting further information on issues that should be addressed in a resubmission or new application.

c. **The project 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.

Duration of Ethics Approval

42. Ethics approval will be granted for a minimum period of two years and up to five years from the date of the approval letter, with the exception of longitudinal studies. Ethics approval is to remain current whilst data analysis is being undertaken and until a final draft research paper has been submitted for review. If a project is to extend beyond the original ethical expiry date, the Principal Investigator is required to apply for an extension to the period of ethical approval prior to ethical approval lapsing. If an extension is not received, all research activities should cease.

Record Keeping

43. The Secretariat will maintain an electronic record of all applications that have been submitted for consideration on the Defence Protected Network, in accordance with the Defence Records Management Policy. Project files are held securely within the electronic filing system on the Defence server.

MEETINGS

Frequency of Meetings

44. 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.

45. The meeting schedule is developed at least 3 months in advance and is to be developed in consultation with members. Where necessary, meeting dates may need to be adjusted in order to ensure quorum is obtained for each meeting. The schedule should specify the meeting date, new application submission date and resubmission closing dates.

Attendance of Committee Members at Meetings

46. The Secretariat will maintain a list of Committee members, the category of membership they fit into and which meetings they attend. Names of individual members who attended or provided out-of-session comments will not be disclosed without the consent of members.

47. The Chair and/or Deputy Chair will attend meetings in person, where possible. Other members may attend via video or teleconference.

48. Where an alternate member is not available to attend, the absent member is to provide feedback on the tabled agenda items and return it to the Secretariat at least three business days prior to a scheduled meeting.

Attendance of People Other Than Members at Meetings

49. Staff from Defence and DVA may 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. Attendance of external observers will be considered by the Chair and/or Deputy Chair on a case-by-case basis.

50. Observers are to ensure that any matters that they are privy to as part of the deliberations of the Committee remain confidential.

Attendance of Investigators at Meetings

51. Investigators may be invited to present their applications at a meeting at the discretion of the Chair and/or Deputy Chair. This may be done either in person or remotely.

52. Where investigators attend meetings, they are able to present the application and answer questions that the Committee may have however; they are not to be present whilst Committee members discuss and provide specific feedback on the application.

Conduct and Structure of Meetings

53. The Chair and/or Deputy 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. 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. Meetings may be cancelled where there are no complete applications (including resubmissions) for consideration by the DDVA HREC by the relevant closing date.

54. 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. Where meetings are held out-of-session or remotely, those dialling into the meeting are to ensure that the location that they are dialling in from is appropriate for ensuring the confidentiality of the discussions.

55. The presence of members or 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. The Chair and/or Deputy Chair will determine the appropriate course of action when a perceived or actual conflict of interest is disclosed.

56. If all agenda items have not been considered within the allocated meeting time, the following options are available:

a. the meeting may 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. The additional meeting should occur within five business days.

Preparation of Meeting Agenda/Minutes

57. The Secretariat is responsible for drafting the meeting agenda and minutes as soon as practicable before and after a scheduled meeting.

58. The meeting agenda and papers are to be collated and distributed to members no later than ten business days prior to the scheduled meeting. A copy of the agenda is also to be provided to institutional delegates, as per the DDVA HREC Terms of Reference.

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

60. Meeting minutes are to include the following:

a. a summary of key discussion points

b. a record of decisions made

c. declarations of perceived or actual conflicts of interest

d. the receipt of written comments by absent members and/or subject matter experts

e. reference to relevant guidelines and/or legislative instruments where appropriate.

61. 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.

62. Once the minutes are drafted and cleared by the Assistant Director Research Ethics, they are to be provided to the Chair and/or Deputy 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.

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

MONITORING OF APPROVED PROJECTS

64. The Principal Investigator is responsible for ensuring ongoing compliance with the conditions of ethical approval as per the requirements of the National Statement. Templates for submission of the various activities outlined below are available on the DDVA HREC website.

Table 1: Monitoring activities and timeframes

Description	Timeframe
Amendments	Prior to implementation
Adverse events	30 calendar days
Serious adverse events	72 hours

Deviations	As soon as possible
Complaints	72 hours
Progress Reports	
Clinical trials	Every six months
Other research	Annually
Final Reports	Upon completion or abandonment

Amendments

65. Prior to implementation of any amendments to an approved project, the Principal Investigator must seek ethical approval from the DDVA HREC. An Amendment Form is to be submitted along with any supporting documentation. The request for amendment is to be signed by the Principal Investigator.

66. When submitting a request for amendment(s), it is essential that the Principal Investigator ensures dates and version control numbers are updated on all relevant documentation.

67. For projects approved under mutual recognition pathways, the request for amendment must be approved by the primary ethical review body first. A copy of the amendment and approval letter/correspondence are to be submitted to the DDVA HREC for review and filing.

68. Project amendments will initially be considered out-of-session by the Chair, Deputy Chair or Secretariat. Where it is deemed appropriate, other members may be asked to review amendments or the Chair/Deputy Chair may request that the amendment be submitted to the full HREC at the next scheduled meeting.

Adverse and Serious Adverse Event Reports

69. A report detailing a serious adverse event details and the implications for the research is to be submitted to the DDVA HREC within 72 hours. The DDVA HREC must be notified of any other adverse events within 30 calendar days.

70. For research that is approved under mutual recognition pathways, a copy of the documentation submitted to the primary ethical review body and the outcome of their review is to be submitted to the DDVA HREC as soon as possible.

71. For research involving Defence personnel and/or their data, researchers should familiarise themselves with the requirements to notify those who have provided research governance authorisation (organisational support and those who have granted command approval).

72. For research that has recruited participants through a DVA service or program, notification of any adverse event should likewise be provided by the

researcher to the relevant DVA program manager (taking care not to identify any individual participants). This should occur once the DDVA HREC written advice of the outcome of the review of the event/s has been received, or sooner if the researcher considers it appropriate.

73. 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.

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

Deviations

75. Any deviations from the approved project must be notified to the DDVA HREC as soon as possible.

76. For projects approved under mutual recognition pathways, a copy of the report and outcome of review by the primary ethical review body are to be submitted to the DDVA HREC as soon as possible.

Complaints or Concerns Regarding the Research

77. The Principal Investigator is to:

a. advise the DDVA HREC within 72 hours, in writing, of any complaints regarding the ethical conduct of the research. This is to include a summary of the complaint and any relevant outcomes.

b. the Secretariat 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 will be put to the Chair and/or Deputy Chair for consideration and resolution.

78. 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 be necessary to withdraw ethical approval from the project temporarily until the matter is resolved, or permanently if significant problems are identified.

Complaints about the Consideration of Research by the Committee or Committee Conduct

79. Where a researcher wishes to submit a complaint about the consideration of their research proposal by the Committee or the conduct of the Committee, they

should contact the DDVA HREC secretariat with details of the complaint. Where appropriate, the complaint will be directed to the SGADF and/or the Deputy President, DVA. A decision will be made based on all evidence received, including the response submitted by the researcher.

80. Complaints should be submitted in writing and must detail the grounds for the concern or complaint.

81. If the matter is not resolved to the satisfaction of the complainant, further steps may be taken including:

a. The DDVA HREC or the complainant can contact the Australian Health Ethics Committee for advice on interpreting guidelines that are issued by the National Health and Medical Research Council in order help the complainant understand the reasons for the ethical review body's decision.

b. Complainants can request a meeting with the Chair and the Assistant Director Research Ethics. The complainant(s) can be accompanied by one or more support persons/colleagues.

c. Subject to the agreement of the institution/s and the complainant, an independent third party may be engaged to facilitate further discussion. The mediator should consider all relevant materials prior to meeting with the parties to resolve any outstanding issues. A report of the results to the meeting should be provided to the institution.

Progress Reports

82. The Principal Investigator is required to submit Progress Reports for the duration of the project. The frequency of reports is outlined below:

a. every six months for clinical trials

b. annually for all other approved projects.

83. The DDVA HREC can increase the frequency of reporting for studies where it is considered necessary. Any changes to the scheduled reporting requirements, will be advised to the Principal Investigator.

84. Upon receipt of a Progress 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 approval of the report.

85. For projects approved under mutual recognition pathways, copies of Progress Reports that were submitted and approved by the primary ethical review body are to be provided to the DDVA HREC as soon as possible.

86. Failure to submit a Progress Report may result in the withdrawal of ethical approval.

Audits

87. The DDVA HREC or their delegate may conduct random inspections of research sites and review their study documentation. The Principal Investigator

and/or point of contact will be contacted by the Secretariat to schedule a mutually convenient time for the audit to be conducted. A summary of the outcome of the audit will be provided to the Principal Investigator and point of contact highlighting any areas requiring corrective action. The report will identify a timeframe in which any outstanding matters are to be addressed.

88. Desktop audits are conducted by the Secretariat either for cause (for example, submission of a serious adverse event or multiple adverse events or complaints) or at random to ensure protocols are complying with the conditions of ethical approval. The outcome of desktop audits are not shared with researchers unless matters for addressing have been identified.

Final Reports

89. Researchers are required to submit a Final Report at the completion (all data analysis has been completed and a final draft research paper has been submitted) or abandonment of their project.

90. Failure to submit a Final Report will result in a notation made on the file indicating non-compliance with monitoring obligations, ethical approval will be withdrawn and the protocol closed.

91. The Final Report that is submitted to the DDVA HREC is a separate requirement to the report that is submitted to research sponsor/s.

92. Where research has been abandoned researchers should, where possible, ensure that participants are advised that the research has been abandoned.

93. 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.

Withdrawal of Ethical Approval

94. Where the Chair and/or Deputy Chair has deemed that circumstances have arisen that prevent ongoing ethical approval of the research project being maintained, the principle investigator will be notified that ethical approval may be withdrawn.

Circumstances for this decision may include, but are not limited to:

a. significant deviation or multiple deviations from the approved protocol

b. failure to comply with the conditions of ethical approval

c. failure to submit a Progress Report or Final Report within the timeframe specified by the Secretariat

d. upon receipt of a complaint where significant concerns about the ongoing ethicality of a project have been raised upon notification of an adverse or serious adverse event.

95. When this occurs the Secretariat 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.

96. Where the project is approved under mutual recognition pathways, the primary ethical review body is to be contacted to discuss concerns.

97. Where ethics approval is withdrawn, no further analysis of data or publication of findings is to occur.

COMMUNICATION WITH RESEARCHERS

98. To facilitate a streamlined application process, informal communications with the Secretariat is encouraged.

99. All communication regarding the deliberations of the DDVA HREC will be in writing. The requirement does not mean that communication is limited to written communication, and follow up discussions may occur via other mechanisms.

Researcher Contact Details

100. To facilitate the management of research protocols and correspondence, researchers are to ensure that they provide contact details to the Secretariat. The Secretariat should be notified promptly of any change in contact details. Wherever possible, an email address should be supplied.

DISSEMINATION OF RESEARCH FINDINGS

Defence Specific Requirements

101. Researchers are required to obtain clearance of the research outputs/ outcomes from the relevant Defence sponsor. This includes dissertations that form part of an academic requirement. The sponsor/s must be a senior commander or manager of a rank/APS classification no lower than one Star /SES Band 1. Review of the findings may require review and advice from other relevant areas, where appropriate.

102. 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 itself. If there is a request for copies of slides or other visual aids used in a verbal presentation, the researcher is to provide them.

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

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

Department of Veterans' Affairs Specific Requirements

105. Publications arising from research funded by DVA, using DVA data or that recruited participants through DVA programs should be provided to DVA for review

prior to submission to the intended journal or conference. The DVA review is designed to ensure that the nature and findings of the DVA research in question are appropriately represented, terminology relating to DVA policies or services is accurate and the DVA contribution is acknowledged. Researchers should use the *DVA Review Prior to Publication* form, available by contacting research@dva.gov.au. The form includes further details of DVA review processes and required acknowledgement/disclaimer wording. Other conditions arising from the relevant contract or data agreement may apply.

106. Publications relating to research involving ex-serving members or their families, but not funded by DVA, not using DVA data and not recruiting participants through DVA services, do not need review by DVA prior to publication.

OTHER DEPARTMENT OF VETERANS' AFFAIRS SPECIFIC REQUIREMENTS

Department of Veterans' Affairs Sponsored Research – Letter of first contact

107. If participants are recruited 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 or accompanied by a letter (including email) 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 should explain why the individual is being contacted by DVA about the study.

108. A copy of the 'Letter of first contact' is to be provided to the DDVA HREC for consideration.

109. 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. For projects specific to a particular DVA program the letter may be signed by the program manager at SES Band 1 level or higher.

Assurance of Confidentiality and Entitlements – Mazengarb Clause

110. For research that is sponsored by DVA and involves direct contact with ex-serving personnel as research 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.

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.

111. Where the participant cohort consists of current serving and ex-serving Defence members and is sponsored by DVA and involves direct contact with research participants, 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.

ANNEX A

Definitions

Administrative Review	A review conducted by the Secretariat of an application to identify any deviations, inconsistencies and missing data.
Adverse Event	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.
Amendment	A proposed change or addition to the previously approved protocol.
Clinical Trial	A form of research designed to find out the effects of an intervention, including a treatment or diagnostic procedure.
Command Approval	Command approval facilitates the release of Defence personnel (Defence members, Australian Public Service employees and contractors) to participate in research and allows for commanders/managers to provide input into activities that may affect operation of their unit or organisation.
Conflict of Interest (COI)	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.
Consent	A person's or group's agreement, based on adequate knowledge and understanding of relevant material, to participate in research.
Data	Bits of information in their raw form. Data can refer to raw data, cleaned data, transformed data, summary data and metadata (data about data). It can also refer to research outputs and outcomes.
Defence Personnel	All Australian Public Service (APS) employees, Defence employees engaged locally overseas, Defence civilians, Defence members and the equivalents from other Defence organisations on exchange to Defence.
Deviation	Departure from the approved study protocol/standards.
Ethics Review	Review of research by a Human Research Ethics Committee (HREC) or other body.

Ex-serving personnel	All individuals who have previously served as a Defence member and are no longer serving.
Full HREC Review	Ethical review conducted by the full DDVA HREC at a scheduled meeting.
Harm	That which adversely affects the interests or welfare of an individual or a group. Harm includes physical harm, anxiety, pain, psychological disturbance, devaluation or personal worth and social disadvantage.
Higher Risk Research	Research in which there is a risk of harm and in which there may also be a foreseeable burden. The risk of harm in higher risk research may or may not be a risk of significant harm and may be harm to the individual, group, community, societal or global level.
Human Research	Research which is conducted with or about people, their data or tissue.
Lower Risk Research	Research in which there is no risk of harm, but in which there is a risk of discomfort and in which there may also be a foreseeable burden (low risk research) OR research in which there is no risk of harm or discomfort, but which includes a potential for minor burden or inconvenience (minimal risk research).
New Application	A research proposal that 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.
Organisational Support	Organisational support is part of Defence's research governance requirements and aims to ensure that: • the research proposal aligns with Defence's strategic priorities • the research proposal is consistent with Defence policy • there is a benefit to Defence • duplication of research is minimised.
Out-of-Session Review	When a protocol is reviewed by the members of the Committee between scheduled DDVA HREC meetings.
Participant	Anyone who takes part in an investigation, study, or experiment, such as by performing tasks set by the experimenter or by answering questions set by a researcher.
Principal Investigator (PI)	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.
Resubmission	A research proposal that was previously submitted to the Committee and the revised documentation is subsequently submitted for consideration.
Secretariat	Administration officers responsible for the organisation, management and facilitation of the DDVA HREC.
Serious Adverse Event	Any untoward medical occurrence that: results in death; is life- threatening; requires inpatient 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.