



Australian Government

Department of Veterans' Affairs

DVA Human Research Ethics Committee

ADMINISTRATIVE GUIDELINES

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1. Human Research Ethics Committee (DVA HREC)

1.1 Role of Committee

The primary role of an HREC is to protect the welfare and rights of participants in research. The primary responsibility of each member is to decide, independently, whether, in his/her opinion, the conduct of each research proposal submitted to the HREC will so protect participants.

The DVA HREC considers ethical aspects of proposed research and takes into account social and moral implications of the research for the veteran community. It ensures that research involving DVA held data and/or members of the veteran community has a valid scientific purpose. It considers whether, in relation to medical research, personal information is likely to be dealt with in ways that infringe the Information Privacy Principles detailed in the *Privacy Act 1988*. The Committee also monitors 'survey fatigue' amongst veterans and how that may impact on the integrity of information required of and received from them. It does not consider requests for special access to medical records under the *Archives Act 1983*.

Finally, the Committee also has a role in monitoring research projects to their completion to verify that researchers have complied with the protocol as approved.

1.2 Authority of Committee

In 1999 the National Health and Medical Research Council (NHMRC) in accordance with the *NHMRC Act 1992*, released the *National Statement on Ethical Conduct in Research Involving Humans* (National Statement).

The Committee complies with the National Statement (revised 2007) which requires that all human research ethics committees be constituted and act in accordance with that statement, including reporting annually to the NHMRC. If DVA had not agreed to these arrangements it would not be able to conduct or contract human research.

The Repatriation Committee appoints members of the Ethics Committee and the Committee reports back to the Commission on its activities.

The guidelines detailed here were considered and agreed by the Repatriation Commission on 14 July 2008.

1.3 Terms of Reference

The terms of reference, for the DVA HREC endorsed by the Repatriation Commission, are to:

- consider for approval requests from:
 - researchers in hospitals and institutions, research establishments and universities;
 - independent researchers; and
 - manufacturers of medical drugs and equipment, prosthetics and aids to daily living;

for access to Australian Government-owned client data for specific medical research;

- notify researchers in writing of Committee decisions and of any condition/s that may apply;
- provide regular monitoring of research projects until completion to ensure that they continue to conform with the approved research protocol;
- remain informed on any amendments to NHMRC ethical guidelines and, where possible, other developments and new requirements communicated via publications, journals, and conferences;

- provide the NHMRC data from DVA HREC records as required;
- oversee all unsolicited surveys and requests for medical information directed at the veteran community; and
- for significant research projects, provide advice to researchers prior to approval.

1.4 Membership

The National Statement is the basis for the operation and constitution of the DVA HREC. In accordance with the Statement, the minimum membership of an HREC is eight members, both male and female, comprising:

- a. a chairperson (also referred to as Chair);
- b. at least two lay people, one man and one woman;
- c. at least two members with knowledge and current experience in areas of research that are regularly considered by the HREC;
- d. at least one member with knowledge and current experience in professional care, counselling or treatment of people;
- e. at least one person who is a minister of religion; and
- f. at least one member who is a lawyer.

The DVA HREC also includes voting and non-voting ex-officio members and the DVA HREC Coordinator who provide the committee with support and liaison. Committee membership records and minutes of meetings will indicate whether or not an ex-officio has voting rights.

1.5 Appointment

The Repatriation Commission makes appointments to the DVA HREC, each appointee being advised in writing and provided with a copy of these guidelines and of the National Statement.

In accordance with the National Statement, members are appointed as individuals for their knowledge, qualities and experience, and not as representatives of any organisation, group or opinion. Appointments to the HREC are reviewed at least every three years.

The Chair of the DVA HREC may appoint a stand-in for any member, including himself, when considered necessary. The stand-in for the Chair will be referred to as Acting Chair. There is no authority for other committee members to delegate their own positions or responsibilities to proxies.

1.6 Expert Advice

The Committee may seek assistance from special advisers with expertise in a particular field when required, to address individual study protocols outside the Committee's knowledge base.

1.7 Authority of Chair

The Chair of the Committee may:

- consider research proposals and advise researchers on whether or not a project requires committee approval;
- reconsider and, if appropriate, approve revised proposals after initial consideration by the Committee, when authorised to do so by the Committee;
- consider and authorise minor amendments to approved projects, including amendments and extensions to periods of approval;
- at the request of the applicant or supervisor, provide clarification and/or further information on the Committee's evaluation of an application;
- consider and endorse progress reports;
- approve changes to committee procedures in special circumstances, within the framework of the requirements of the National Statement;
- appoint a stand-in for any member, including himself, when considered necessary;

- provide advice to staff on committee functions and on ethical issues in research; and
- perform other tasks as delegated by the Committee.

1.8 Members' Responsibilities

Each member of the DVA HREC is responsible for deciding whether, in his or her judgement, a proposal submitted before the committee meets the requirements of the National Statement and is ethically acceptable. To fulfil that responsibility, each member of the Committee should:

- be familiar with the National Statement and any other guidelines relevant to the review of the specific proposal;
- attend meetings of the DVA HREC or, if unavailable, provide opinions on the ethical acceptability of research proposals before the meeting; and
- consider the need for education or training programs in research ethics at least every three years.

1.9 Conflict of Interest

DVA HREC Committee Members, and also any experts whose advice is sought, are bound by confidentiality and conflict of interest requirements. Their other responsibilities, interests or affiliations should not impair the DVA HREC's capacity to carry out its obligations under the *National Statement on Ethical Conduct in Human Research 2007*.

Members/experts should disclose any actual or potential conflict to the DVA HREC and Coordinator, including any:

- a) personal involvement or participation in the research;
- b) financial or other interest or affiliation; or
- c) involvement in competing research.

The DVA HREC has measures to manage such conflicts. In the case of members these measures may include exclusion from the Committee's deliberations on the conflicted matter, or in the case of expert advisors, requesting only written advice from them.

1.10 Legal Protection of Members

Legal protection is provided to DVA HREC members involved in ethical review of research for liabilities that may arise in the course of *bona fide* conduct of their duties in this capacity.

Members who are Australian Government employees or officials will be provided legal assistance in accordance with the provisions of the *Legal Services Directions 2005* which commenced on 1 March 2006.

Members who are not Australian Government employees or officials will be provided legal assistance for legal costs in accordance with the provisions of *Indemnification of Persons Acting in an Official Capacity on Behalf of the Commonwealth or Commonwealth Bodies Finance Circular 1997/19* as updated on 19 August 2003 while acting for the DVA HREC.

Depending on the circumstances such members may also be regarded as "employees" for the purposes of the *Safety, Rehabilitation and Compensation Act 1988*.

2. Administrative Procedures

2.1 Frequency of Meetings

The DVA HREC meets every two months, currently on the second Friday of that month. Generally meetings are held in February, April, June, August, October and December each year. These dates are advertised on the DVA Intranet and Internet.

2.2 Attendance at Meetings

Meetings are arranged so as to allow as many of the DVA HREC committee members to attend as possible. Where a member cannot attend he/she should advise the Committee Coordinator before the Committee meeting of their views / concerns on the items tabled for consideration.

2.3 Transport Costs

The Department will arrange transport and accommodation for interstate DVA HREC committee members to attend meetings or will reimburse reasonable costs in line with departmental procedures. The Department does not reimburse the cost to researchers of attending meetings (see Section 3.14 of these guidelines - *Presentation of Research Protocols*).

2.4 Agendas

Agenda papers and research protocols are distributed to committee members no later than a week before the meeting (by the first Friday of the month). The papers are distributed by post or by courier, if necessary, to ensure timely delivery. Receipt of agenda papers is confirmed with members prior to the meeting. Where the member is expecting to be absent from the meeting, their views and opinions on agenda items are sought.

Agenda papers always include:

- Minutes of Previous Meeting;
- Out of Session Considerations;
- Re-Submissions/Revised Proposals/Protocol Changes;
- New Proposals;
- Progress/Final Reports on approved proposals;
- Other Business.

2.5 Minutes

Minutes are written up shortly after the meeting and are sent to committee members as part of the next meeting agenda. The minutes are considered and approved at the subsequent meeting. The Chair signs the approved minutes.

2.6 Timely Consideration

All proposals submitted to the bi-monthly DVA HREC meeting are considered at that meeting. If additional information is required from the researcher, he/she will be contacted to provide more information. Researchers, and occasionally DVA sponsors, may be asked to make themselves available for contact during the meeting if answers to relatively simple questions are sought.

Urgent research proposals received between normal bi-monthly meetings may be considered out of session. Committee members' responses will be accepted by phone, facsimile or email. The out of session approval of a proposal will be ratified at the next formal meeting of the DVA HREC.

In certain circumstances (e.g. re-submission of material on a previously considered proposal or minor protocol change) the Chair may assess, grant or deny approval out of session. The Chair's decision will be ratified at the next formal meeting of the DVA HREC.

2.7 Methods of Decision Making

The DVA HREC will endeavour to reach decisions by general agreement. This need not involve unanimity, but failure to agree may require an extension of time to reconsider the research protocol and its possible amendment.

Meetings of the DVA HREC are so arranged as to allow all members to be fully informed by receipt of all relevant papers and the opportunity to attend. Where there is less than full attendance, the Chair must be satisfied, before a decision is reached, that those absent have had the opportunity to have their views considered.

The Committee may seek advice and assistance from experts to consider a particular research protocol, as long as the experts have no conflict of interest, including any personal involvement or participation in the research, any financial interest in the outcome, or involvement with competing research.

The decisions of the DVA HREC will be made after consideration of all of the following:

- that the research protocol gives adequate consideration to participants' welfare, rights, beliefs, perceptions, customs and cultural heritage both individual and collective;
- that the Committee has seen all documents and material used to inform the potential participants including information sheets, consent forms, questionnaires, letters of invitation and internet content;
- the identification of the purpose of the research and the manner in which personal data will be used in achieving that purpose;
- the identification and consideration of the relevant Information Privacy Principles of the Privacy Act that might be breached in the course of the proposed research;
- the identification and consideration of matters referred to in the National Statement to show whether the proposed research involving disclosure of personal information by an Australian Government agency is in the public interest;
- the determination that the public interest in the proposed research outweighs, or does not outweigh, to a substantial degree the public interest in the protection of privacy;
- the value of the initiative as a scientific exercise compared with the inconvenience visited on the veteran.

2.8 Notification of Decision

The Principal Researcher and, where applicable, the DVA Project Sponsor or other relevant contact will be notified in writing of the Committee's decision as soon as possible following the respective meeting dates. If the proposal is not approved or the Committee requires further information on the proposal, the Principal Researcher will be advised as soon as possible after the meeting.

2.9 Decision Types

Approval Not Required – the submission does not impinge on privacy and/or other ethical considerations relevant to DVA HREC;

Not Approved – the submission has failed to meet privacy and/or other ethical considerations relevant to DVA HREC;

Approved – the submission satisfies all privacy and other ethical considerations relevant to DVA HREC;

Approved in Principle (Chair can approve) – previously “Conditionally Endorsed” -does not equate to approval. Specified matters must be resolved to the satisfaction of the Chair prior to commencement/continuation of the study;

Approved in Principle (Committee to approve)– previously “Conditionally Endorsed” - does not equate to approval. Specified matters must be resolved to the satisfaction of the Committee prior to commencement/continuation of the study;

More Information Required – the submission lacks sufficient information to properly assess if it meets all privacy and/or other ethical considerations relevant to DVA HREC.

2.10 Expedited Review for Minimal Risk Research

On receipt of a study protocol that initially appears to be of minimal risk, clarification may be sought from the Chair to decide whether the protocol requires consideration by the whole Committee or a sub-committee of two or more DVA HREC members. Any decisions made in this manner will be confirmed at the next full meeting of the Committee.

2.11 Survey Fatigue

DVA monitors 'survey fatigue' amongst veterans and the Committee supports this as it may impact on the integrity of information required of and received from them. DVA aims to avoid having the same group of veterans surveyed more than once every two years.

2.12 Fees

The DVA HREC does not charge fees for the consideration of research proposals.

2.13 Access to Funding Not Automatic

It needs to be made clear to the Researcher that, even when the research proposal has been approved by the DVA HREC, DVA funding for projects is not guaranteed. It remains the responsibility of a researcher to negotiate directly with the appropriate section of the Department of Veterans' Affairs regarding funding.

2.14 Access to Data Not Automatic

It needs to be made clear to the Researcher that the National Statement does not override the decision making process of Australian Government agencies that could preclude the release of personal information even when the research proposal has been approved by the DVA HREC. It remains the responsibility of a researcher to negotiate directly with the appropriate section of the Department of Veterans' Affairs about its requirements for data release.

2.15 Monitoring

The DVA HREC shall, as a condition of approval of each protocol, require researchers to report on a six-monthly basis from the date of approval, and immediately report anything that may warrant a review of the protocol including:

- serious and unexpected adverse effects on participants;
- proposed changes to the protocol; and
- unforeseen events that might affect continued ethical acceptability of the project.

2.16 Complaints Procedure

Where a complaint about a researcher raises the possibility of 'research misconduct' as described in the *Australian Code for the Responsible Conduct of Research*, the matter will be handled in accordance with the 'research misconduct' processes specified in that document.

Where a complaint about a researcher alleges serious misconduct that falls outside the range of 'research misconduct' as described in the *Australian Code for the Responsible Conduct of Research*, the matter will be dealt with under governmental processes for dealing with other forms of misconduct, for example harassment or bullying.

2.17 Record Keeping

In addition to any manual or electronic records maintained, a DVA registry file (TRIM) will be raised for each DVA HREC meeting and it will include all documentation relating to items considered at that meeting. Out-of-session activity will be included on the agenda for ratification at the next meeting and included in the registry file for that meeting. DVA HREC administrative matters are recorded on a separate registry file.

2.18 Confidentiality of Protocols

DVA HREC papers and protocols are to be maintained in a secure environment. All papers distributed to Committee members are to be returned to the DVA HREC Coordinator for disposal in accordance with departmental procedures for the destruction of classified material. Where retention of paperwork is necessary, committee members must ensure secure storage and destruction of the material. Committee files are to be kept in locked cabinets and accessed only by authorised individuals.

2.19 Compliance Reports to the National Health and Medical Research Council (NHMRC)

The DVA HREC is to maintain the following records of its activities:

- membership and membership changes;
- number of meetings;
- confirmation of participation by required categories of members;
- number of protocols presented, approved and rejected;
- monitoring procedures in place and any problems encountered;
- complaints procedures and number of complaints; and
- record of complaints and the outcomes.

3. Researchers

3.1 Researchers' Responsibilities

It is expected researchers will be aware of the values and principles of ethical and responsible conduct of human research, including appropriate consideration of:

- research merit and integrity;
- justice;
- beneficence; and
- respect.

This should be reflected in any proposal put to the DVA HREC for consideration.

Researchers should also be familiar with the *National Statement on Ethical Conduct in Human Research* and *The Australian Code for Responsible Conduct of Research*. These documents can be obtained from the National Health and Medical Research Council website at www.nhmrc.gov.au.

3.2 Conflict of Interest

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

A conflict of interest in the context of research exists where:

- a person's individual interests or responsibilities have the potential to influence the carrying out of his or her institutional role or professional obligations in research; or
- an institution's interests or responsibilities have the potential to influence the carrying out of its research obligations.

While a conflict may relate to financial interests, it can also relate to other private, professional or institutional benefits or advantages that depend significantly on the research outcomes.

A researcher with a conflict of interest bearing on research should immediately inform the DVA HREC about the conflict.

3.3 When Do You Need Ethics Approval

Approval should be sought from the DVA HREC for:

- research involving a member of the veteran community being submitted to an intervention, being included in a control group, being interviewed, participating in a focus group or survey, undergoing psychological, physiological or medical testing or treatment, completing a questionnaire, or any activity that constitutes intrusion on the individual;
- research involving the collection and/or use of a veteran's body organs, tissues or fluids, access to a veteran's personal documents or other material;
- members of the veteran community being targeted because of their veteran affiliation, this includes family members and carers;
- the use of collected veterans' data for a purpose, or by a person, other than for which/whom it was collected, including DVA held data for mail-out lists, treatment usage, medical records of the former Repatriation General Hospitals;
- use of aggregated data which contains means for identification of veterans;
- variation to an Ethics Committee approved research protocol.

What does NOT require review by the DVA HREC:

- correlation of statistics or research on data already collected by the person and for the purpose approved by the Ethics Committee;
- research involving the general public which coincidentally includes members of the veteran community who are NOT being specifically included because of their veteran affiliation;
- research on collections of data already in the public domain, i.e. aggregated non-identifiable data, which do NOT provide means for re-identification of veterans (care needs to be taken in assessing this).

Matters requiring consideration by DVA HREC should be put to the Committee in writing. Care should be taken to ensure the accuracy and completeness of submissions (see Sections 3.4 to 3.14 of these guidelines). All submissions should be sent to the DVA Ethics Committee Coordinator at ethics.committee@dva.gov.au.

3.4 Submission Types

New Submission – a research proposal NOT considered by DVA HREC previously;

Re-Submission – a submission on an **unapproved** research proposal that has been considered by DVA HREC previously. The submission could be a revised proposal, provision of further information or a response to specified matters of in-principle approval;

Protocol Change – only on previously **approved** research proposals where there is a change in protocol relating to methodology. A change in rationale need not require DVA HREC approval but should be assessed before reaching that decision.

3.5 New Submissions

The DVA HREC has a pro forma - see either the DVA internet site or intranet - that each researcher must complete in order to submit a research proposal. In answering each point of the pro forma, there should not be any "see attached" references - all information must be included in the pro forma. Applications must be typed not hand-written, dated, signed and submitted electronically to ethics.committee@dva.gov.au.

New submissions must also include all documents and material used to inform the potential participants including information sheets, consent forms, questionnaires, letters of invitation and internet content.

All participant information sheets should include a signature block. Researchers should also note the requirements of Sections 3.6 to 3.14 of these guidelines.

All submissions must be received by the DVA HREC by no later than the close off for submissions, usually 2 weeks prior to each meeting. Late submissions will only be considered with the consent of the Committee.

If necessary, the Principal Researcher should seek support for research from the appropriate DVA business area before submitting an application to the DVA HREC. Any such support should be referred to in the covering letter to the DVA HREC. The DVA Sponsor would then receive a copy of the Committee's response to the Principal Researcher.

It may also be necessary to consider consultation with appropriate ex-service organisations. You should discuss this with the Department's Deputy Commissioner or your DVA Sponsor.

3.6 Privacy Considerations

Part 2 of the pro forma is dedicated to addressing privacy considerations described by the Information Privacy Principles (IPPs) set out under Section 95 of the *Privacy Act 1988*.

The guidelines apply to a researcher not employed or contracted by an Australian Government agency whose research involves personal information obtained from an Australian Government agency, the disclosure of which might involve a breach of one or more IPPs.

The NHMRC defines 'personal information' (as defined in *Aspects of Privacy in Medical Research: An Information Paper and Guidelines for the Protection of Privacy in the Conduct of Medical Research*. NHMRC. June 1995) to mean information or an opinion (including information or an opinion forming part of a database), whether true or not, and whether recorded in a material form or not, about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion.

When a proposed research project is likely to breach one or more of the Information Privacy Principles, the possible breach should be referred to in the application for DVA HREC approval. The reference

should include reasons for believing that the public interest in the research outweighs to a substantial degree the public interest in adhering to the Information Privacy Principle in question.

All substantive submissions and protocol changes are referred to the DVA Privacy Officer for comment prior to each meeting.

3.7 Declaration of Funding Sources

A researcher is required to disclose the amounts, sources or potential sources of funding in any research proposal and, following approval of the proposal, any subsequent funding sources.

3.8 Payments for Participants

It is generally unacceptable to DVA HREC to pay participants for their involvement in research. A payment, gift, reward or any other inducement that is likely to encourage participants to take risks is ethically unacceptable.

Reimbursement of direct costs to participants of taking part in research, including costs such as travel, accommodation and parking may be permitted. The case for this should be put to the DVA HREC.

3.9 Standing Requirement—Contact with Members of the Veteran Community (known as the Mazengarb Clause)

The DVA HREC has a standing requirement that, if a proposed project involves face to face or telephone contact with members of the veteran community, such contact must be preceded by a letter from the Department informing them of the aims of the study and asking them to participate. This letter is referred to as the “letter of first contact” and ideally should be in **14 point font**. Where members of the veteran community are contacted in the first instance by mail (e.g. a mail survey), a letter of first contact must accompany the mail-out.

In addition, letters of first contact must include a paragraph assuring the member of the veteran community that their entitlements will not be affected whether they participate or not, and that they are free to withdraw from the study at any time. The wording of the standard paragraph should appear in **bold type** and should of course be amended to suit a particular context but should at the very least 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.

Where no response is received from the veteran to the initial invitation to participate, any follow up contact should be limited to one additional letter or one phone call.

3.10 Signature Block on Letter of First Contact

The letter to the veteran will be signed by either the Principal Medical Adviser or the Repatriation Commissioner or a Deputy Commissioner.

3.11 Complaints/Adverse Occurrences

Participants are to be advised of the first point of contact for complaints. The consent form signed by participants should include the name and telephone number of this contact when first provided to participants.

The first instance of a complaint should be directed to the Principal Researcher of the project. If the situation remains unresolved, the complaint should be directed to the ethics committee within the Principal Researcher's organisation, if applicable, or to the DVA HREC via:

DVA HREC Coordinator
Department of Veterans' Affairs
PO Box 21
WODEN ACT 2606
ethics.committee@dva.gov.au

3.12 Minimising Duplication of Ethical Review

It should be noted that approval by other ethics committees may be necessary for some research proposals. Clearance by another ethics committee does not remove the requirement for a proposal to be put to the DVA HREC.

Researchers should inform the DVA HREC of all other locations at which the research will be conducted, and of the name and location of any other body that will conduct, or has conducted, an ethical review of the research and any decisions made about the research by those bodies (in Australia or elsewhere).

The Researcher should also advise the DVA HREC if they wish to nominate a particular ethical review body as the primary consenting/approving and monitoring body for any given research. The DVA HREC will endeavour to eliminate unnecessary duplication of review, where possible.

3.13 Student Research

In considering approval of PhD or other student research, the DVA HREC will consider the merit and integrity of the proposed study, including whether:

- the potential benefit of the research will outweigh any possible harm to participants;
- the results of the research will create new knowledge or be a slight revision of other research;
- the design and methodology of the research is appropriate to achieving desired aims;
- the research will be closely supervised by a person or team with experience, qualifications and competence appropriate to the research;
- the research will be conducted using facilities and resources appropriate to the research;
- the research will be carried out using the recognised principles of research conduct.

All correspondence from the (student) researcher - especially to participants - should be on university stationery, clearly identifying the status of the Researcher within the University. *Information to Participants* should also identify the Supervisor in such a way that indicates their professional oversight of, and responsibility for, the research activity.

Students must ensure secure storage and, where necessary, destruction of data. Research files are to be kept in locked cabinets at the university responsible for the research, and accessed only by authorised individuals.

3.14 Presentation of Research Protocols

The DVA HREC encourages researchers to make themselves available for contact, including attendance, at the meeting when their project is being considered in order to answer any questions that may arise. It may be reasonable in some instances for the DVA Sponsor to attend on behalf of the Researcher. Facilities are available during DVA HREC meetings for conference call connection with researchers and this is normally sufficient. The DVA Secretariat will contact researchers prior to the meeting to make appropriate arrangements.

3.15 Approved in Principle

In principle approval does not equate to approval. Where a submission is approved in principle subject to certain conditions or modifications, the specified matters must be resolved to the satisfaction of the Committee prior to the commencement/continuation of the study. Responses must be documented in writing and forwarded to the DVA HREC Coordinator as soon as possible.

3.16 Condition of Approval

It is a condition of approval that researchers comply with conduct requirements automatically implied in the granting of approval by the DVA HREC. Although rare, other conditions may apply to approval. The Principal Researcher will be formally notified of any conditions of approval by the DVA HREC at the time of approval.

3.17 Change to Protocol

Principal researchers are required to advise the DVA HREC in writing if their research protocol, as approved by DVA HREC, changes before the study commences or at any time during the study. The DVA HREC will then reassess the proposal and reach a decision based on the revised protocol. It is preferable that significant protocol changes on studies which have not yet commenced be shown as 'track changes' on the original approved proposal.

3.18 Reporting Requirements

Principal researchers are requested to provide the DVA HREC with progress reports every six months, for studies covering a period of one year or longer. The Committee is also interested in receiving a copy of the final report. Shorter-term studies are required to submit a final report as soon as practicable after completion of the study.

Progress reports should be designed to assure the Committee that the research protocol as approved has not changed, and that the project is progressing satisfactorily. While there is no specific format for a progress or final report, researchers must in the very least ensure they provide advice as to:

- progress to date, or outcome in the case of completed or abandoned research;
- any events of significance that have occurred during the study, particularly in relation to adverse outcomes;
- maintenance and security of records;
- compliance with the approved proposal and protocol; and
- compliance with any conditions of approval.

3.19 Abandoned Research

Researchers are required to advise the DVA HREC if and why an approved project is discontinued before the expected completion date.

3.20 Withdrawal of Approval

If the DVA HREC becomes aware that a research project is not being conducted in accordance with the agreed protocol and the welfare and rights of participants are not or will not be protected, the DVA HREC may withdraw its approval by advising the researcher/ organisation or institution of such withdrawal, and recommending that the research project be suspended or discontinued.

end.