Australian Government

Department of Veterans' Affairs

DVA Human Research Ethics Committee

ADMINISTRATIVE GUIDELINES

DVA HREC Administrative Guidelines
Version 9.0
Feb 2015

CONTENTS

1. DVA Human Research Ethics Committee (DVA HREC)

1.1 Role of Committee

1.2 Authority of Committee

1.3 Terms of Reference

1.4 Membership

1.5 Recruitment and Appointment

1.6 Terms of membership of DVA HREC

1.7 Filling casual vacancies on DVA HREC

1.8 Expert Advice

1.9 Authority of Chair

1.10 Members' Responsibilities

1.11 Conflict of Interest

1.12 The Harmonisation of Multi-centre Ethical Review (HoMER) initiative

1.13 Legal Protection of Members

2. Administrative Procedures

2.1 Frequency of Meeting

2.2 Attendance at Meetings

2.3 Transport Costs

2.4 Remuneration of DVA HREC members

2.5 Use of e-Technology

2.6 Agendas

2.7 Minutes

2.8 Timely Consideration

2.9 Methods of Decision Making

2.10 Notification of Decision

2.11 Decision Types

2.12 Expedited Review for Minimal Risk Research

2.13 Survey Fatigue

2.14 Fees

2.15 Access to Funding Not Automatic

2.16 Access to Data Not Automatic

2.17 Monitoring

2.18 Complaints Procedure

2.19 Record Keeping

2.20 Confidentiality of Protocols

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

2.22 Annual Report

2.23 Review of DVA HREC Administrative Guidelines

1. The Department of Veterans' Affairs Human Research Ethics Committee

1.1 Role of Committee

The primary roles of a Human Research Ethics Committee are:

(1) to protect the welfare and rights of participants in human research, being research conducted with or about people, their data or tissue, and

(2) to promote good research.

The primary responsibility of each member is to decide, independently, whether, in their opinion, the conduct of each research proposal submitted to the Department of Veterans' Affairs Human Research Ethics Committee (DVA HREC) will so protect the participants.

The DVA HREC considers ethical aspects of proposed research, irrespective of whether or not the Department is funding or is likely to be responsible for the research, and takes into account social and moral implications of the research for the veteran and defence communities. It ensures that research involving departmental data and/or members of the veteran and defence communities 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 Australian Privacy Principles detailed in the *Privacy Act 1988*.

The Committee also monitors 'survey fatigue' among members of the veteran and defence communities and how that may impact on the integrity of information required of and received from participants. It does not consider requests for special access to medical records under the *Archives Act 1983*.

Finally, the DVA HREC 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 DVA HREC 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 annual reporting to the NHMRC. The Department was required to agree to these arrangements in order to conduct or contract human research.

The functions and authorities of the DVA HREC are embedded in these *DVA HREC Administrative Guidelines.*

The DVA HREC is appointed by and reports directly to the Repatriation Commission and the Military Rehabilitation and Compensation Commission (the Commissions). The Commissions, in turn, provide general oversight of the Committee, and are responsible for approving proposed changes to the governance documents, such as these Administration Guidelines.

Proposed amendments to the Administrative Guidelines shall be sighted in writing by all members of DVA HREC for their information prior to submission to the Commissions for approval.

These *DVA HREC Administrative Guidelines* were sighted by the DVA HREC on Friday 15 March 2013 and agreed by the Commissions on 16 May 2013. Minor updates were endorsed by DVA HREC on 21 February 2015.

1.3 Terms of Reference

The terms of reference for the DVA HREC approved by the Commissions, are to:

- consider requests for approval of health and/or social research 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;
- consider access to Australian Government-owned client data for specific medical and social research;
- notify researchers in writing of DVA HREC 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 or defence communities; and
- for significant research projects, provide advice to researchers prior to considering requests for DVA HREC approval.

1.4 Membership

The National Statement is the basis for the 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 designated “the 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 directly involved in pastoral care; and
f. at least one member who is a lawyer.

The DVA HREC also includes one voting and one non-voting ‘ex-officio’ member, both of whom are representatives of the Department of Veterans’ Affairs. The DVA HREC Coordinator provides the DVA HREC with secretariat support and liaison is ‘ex-officio’ and non-voting. Committee membership records will indicate whether or not an ‘ex-officio’ member has voting rights.

In addition to the adherence to the National Statement on membership constituency, DVA encourages the representation of veterans within the membership of the DVA HREC, particularly contemporary veterans and female veterans.

A contemporary veteran perspective adds value to the DVA HREC in facilitating an appreciation of the issues, from an individual with direct involvement. It would be appropriate that a designated contemporary veteran representative be drawn from the cohort who has served in one or more of the conflicts involving Australian troops since 1999.

No more than one third of the membership of the DVA HREC should be DVA employees.

The DVA HREC reports directly to the Commissions on its constitution and the Commissions appoint members of the DVA HREC.

1.5 Recruitment and Appointment

The recruitment and appointment of DVA HREC members is open and transparent. Periodic advertising in specific media forums seek Expressions of Interest from subject matter experts. Individuals are shortlisted for interview and appointment recommendations are presented to the Commissions for endorsement. In some cases, consideration will be given to individuals recommended by DVA representatives. All shortlisted individuals will be interviewed and appointment recommendations are presented to the Commissions for endorsement. Please refer to Table 1.1 for details of the appointment process.

Table 1.1 Process for appointment of DVA HREC members (12 week process)

Stage	Process	Outcome
Stage 1 Recruitment Drive	Call for Expressions of Interest. Advertised in specific media and recommendations from DVA representatives.	Collation of all Expression of Interests. Letters sent to all applicants confirming their interest by Secretariat.
Stage 2 Assessment for interview	Expressions of Interests are assessed by Director, Research Section, for: • Subject matter expertise • Knowledge of veteran issues • Experience and knowledge of ethics and research.	Short list created for interview stage. Each shortlisted applicant will be invited to attend interview in person or via e-technology.
Stage 3 - Interview	All short listed applicants will be interviewed by: • Assistant Secretary, Policy Branch • Chair, DVA HREC	Reports written on each shortlisted applicant interviewed and recommended to First Assistant Secretary, H&C Services for clearance.
Stage 4 – Endorsement by MRCC	Commission Submission will be presented to the MRCC requesting endorsement of recommended applicants.	Formal endorsement by MRCC and official letter sent to applicants advising of their membership of DVA HREC and requesting completion of the DVA HREC Induction Program.

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

All appointees will take part in a DVA HREC induction program. The induction program will include the following:

- meeting with the Chair of the DVA HREC;
- meeting with the Repatriation Commissioner;
- meeting with DVA staff responsible for the administration of the DVA HREC;
- attending at least one of the specific Military Culture and History training workshops regularly held by DVA;
- an induction package to include:
    - DVA HREC Administrative Guidelines;
    - NHMRC National Statement;
    - DVA HREC Ethics Review application;

- Information for Researchers;
- DVA HREC Annual reports, and
- Other relevant documents relating to DVA administrative issues.

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.

1.6 Terms of membership of DVA HREC

From 1 January 2013 a system of rotating six-year terms with a one-term limit will commence. Effective from that date, the members of the Committee will be divided as evenly as practicable into two groups: the first with a three-year term, the second with a six-year term, and without the possibility of reappointment.

After the expiration of the first group's term, all subsequent appointments would be for a six-year term (one term limit) excepting appointments to casual vacancies.

As a matter of good practice, appointments to the DVA HREC are reviewed at least every three years and reported to the Commissions.

1.7 Filling casual vacancies on DVA HREC

With respect to casual vacancies – which is to say when a seat on the DVA HREC has been permanently vacated (usually this will be by resignation) – it is widespread practice in many representative bodies and committees that a person selected to fill a casual vacancy is appointed for the remainder of the term of the person who has vacated the seat.

The HREC Chair has the authority to appoint an individual to fill a casual vacancy (under six months) in consultation with DVA. From 1 January 2013 when a casual vacancy occurs over six (6) months, the Commissions will appoint a person to fill the vacancy for the remainder of the term of the person who vacated the seat. All persons appointed to the HREC are expected to complete the DVA HREC induction program.

The Chair of the DVA HREC may appoint a temporary stand-in for another member when considered necessary. The Chair may appoint a stand-in for the Chair from existing committee members. 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.

1.8 Expert Advice

The DVA HREC 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.

The consideration given to privacy matters is discussed at Section 3.6.

1.9 Authority of Chair

The Chair of the DVA HREC may:

- consider research proposals and advise researchers on whether or not a project requires DVA HREC approval;
- reconsider and, if appropriate, approve revised proposals after initial consideration by the DVA HREC, 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 DVA HREC'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 the Chair, when considered necessary;
- provide advice to DVA staff on DVA HREC functions and on ethical issues in research; and
- perform other tasks as delegated by the DVA HREC.

1.10 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 and a stand-in has not been appointed by the Chair, provide opinions on the ethical acceptability of research proposals before the meeting; and
- continually improve their knowledge and understanding of current and emergent ethical issues in human research including enrolling in education or training programs from time-to-time.

1.11 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 relevant interests to the DVA HREC and Secretariat, 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.

In August 2012, the NHMRC published *Guideline Development and Conflicts of Interest*. In brief, having particular regard to international events, failure to disclose interests and/or publish negative findings from industry-sponsored research, it establishes:

> *policies … to ensure the integrity of the publications issued by NHMRC committees and working groups developing guidelines and to strike an appropriate balance between the existence of 'interests' in the topic under review and the expertise required to make sound and meaningful recommendations.*

The HREC Administrative Guidelines align with the NHMRC's 2012 published *Guideline Development and Conflicts of Interest*.

1.12 The Harmonisation of Multi-centre Ethical Review (HoMER) initiative

The NHMRC introduced the Harmonisation of Multi-centre Ethical Review (HoMER) initiative as a means of developing a range of tools to support researchers and HRECs to collaborate within a single ethical review.

The DVA HREC will encourage cross sector collaboration within a single ethical review where appropriate and continue to work on ways to move closer to adopting the HoMER principles.

1.13 Legal Protection of Members

Legal protection is provided to DVA HREC members involved in ethical review of research for any liability 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.

While acting for the DVA HREC, 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 last updated on 19 August 2003.

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 will meet at least every three months, on the third Friday of February, May, August and November unless the Chair in consultation with the Secretariat otherwise determines. Meeting dates are to be advertised on the Department's Intranet and Internet webpage, and notified to participants and senior departmental staff by email.

2.2 Attendance at Meetings

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

2.3 Transport Costs

The Department will arrange transport and accommodation for interstate DVA HREC members to attend meetings or will reimburse reasonable costs in line with departmental Secretary's Instructions. Reasonable costs may include mileage, parking fees, bus fares, etc for local or interstate DVA HREC members to attend meetings.

The Department does not reimburse the cost to researchers of attending meetings.

2.4 Remuneration of DVA HREC members

The Repatriation Commission and the Military Rehabilitation and Compensation Commission agreed on 16 May 2013 to the introduction of daily fees (one reading day and one sitting day per scheduled meeting) for members of the DVA HREC.

The Minister for Veterans' Affairs, in whose portfolio the public offices comprising the DVA HREC are located, determined that pursuant to clause 2.3.1. of the *Remuneration Tribunal Determination 2012/13 - Remuneration and Allowances for Holders of Part-Time Public Office (Remuneration Tribunal Determination 2012/013),* that the category of daily fees to be paid to the Chairperson and a member of HREC is the amount set out in Category 2 of Table 2A of the Remuneration Tribunal Determination 2012/013.

Table 2A: Public Offices not specified in this Determination – Daily Fees with effect from 1 July 2012.

Office	Category 2
	$ per day
Chairperson	564
Member	418

The exception is Commonwealth and State/Territory employees, who are not entitled to remuneration. The basis for this decision is Section 7(11) of the *Remuneration Tribunal Act 1973.*

Remuneration rates are to be reviewed by the Repatriation Commission at the next scheduled review of the Administrative Guidelines in 2016.

2.5 Use of e-Technology

In line with government initiatives for a move to shared services and environmental work practices, DVA is encouraging a transition towards a "paperless" work environment. While a "paperless" environment

is in its conceptual stage within DVA presently, the HREC is being encouraged to embrace the concept of new technology devices such as tablets, laptops and secure portals for the distribution of material and for the work practice of HREC members.

2.6 Agendas

Agenda papers and research protocols are distributed to committee members no less than seven (7) days before the meeting (so as received by the first Friday of the month). Papers shall be distributed by post, courier or electronically, as 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.

Standing items for each meeting agenda:

- Opening and welcome, including any late business, apologies and conflicts of interest;
- Committee membership;
- Minutes of Previous Meeting;
- Out of Session Considerations;
- Re-Submissions
- Revised Proposals
- Protocol Changes;
- New Proposals;
- Progress/Final Reports on approved proposals;
- Other Business.

The views of DVA's Privacy Officer on each research proposal being considered are always made available at or before each meeting.

2.7 Minutes

Minutes of DVA HREC meetings are written up as soon as practicable after the meeting and cleared by the Chair. The minutes are sent to committee members with the agenda and papers for the subsequent meeting. The minutes are considered and approved, with or without amendment, at the subsequent meeting. The Chair shall certify the approved minutes as a true and accurate record of the meeting.

2.8 Timely Consideration

Proposals submitted to a DVA HREC meeting will generally be considered at that meeting. If additional information is required from the researcher, he/she will be requested to provide such information. Researchers, and DVA sponsors, may be asked to make themselves available for contact during the meeting as appropriate.

If a proposal cannot be dealt with at the scheduled meeting, the DVA HREC will decide when and how it should be considered and the Researcher notified.

Urgent research proposals received between normal 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 is subject to ratification at the next formal meeting of the DVA HREC.

2.9 Methods of Decision Making

The DVA HREC will endeavour to reach decisions by consensus. This need not involve unanimity but failure to achieve consensus may require an extension of time for reconsideration of the research protocol and/or amendments thereto.

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 DVA HREC 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 DVA HREC has seen all documents and material used to inform the potential participants including information sheets, consent forms, questionnaires, letters of invitation, internet content and promotional material;
- 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 Australian Privacy Principles of the *Privacy Act 1988* 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 in accordance with the principles of Section 95 of the *Privacy Act 1988*;
- the value of the initiative as a scientific exercise compared with the inconvenience visited on the proposed research participants who are members of the veteran or defence communities.

2.10 Notification of Decision

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

2.11 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 research;

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 research;

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

2.12 Expedited Review for Minimal/Low Risk Research

On receipt of a research 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 DVA HREC.

2.13 Survey Fatigue

DVA monitors 'survey fatigue' among members of the veteran or defence communities and the DVA HREC supports this as it may impact on the integrity of information required of and received from participants. DVA aims to avoid having the same groups surveyed more than once every two years.

It should be noted, the Department of Defence closely monitors research participant fatigue among their cohort. It is recommended researchers also discuss with the Department of Defence any research involving serving defence personnel.

2.14 Fees

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

2.15 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, if applicable.

2.16 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.

It is recommended researchers also discuss with the Department of Defence any data requirements for research involving serving defence personnel, as this may not be held by DVA.

2.17 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.

Failure to comply with the above reporting requirements may result in withdrawal of approval.

2.18 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.

Where a complaint arises regarding the conduct of the DVA HREC, the Chair of the DVA HREC should be the initial point of contact. Where appropriate, the complaint will be directed to the office of the Repatriation Commission and the Military Rehabilitation and Compensation Commission.

2.19 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.

2.20 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. DVA HREC files are to be kept in locked cabinets and accessed only by authorised individuals.

2.21 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;
- conflicts of interest; and
- record of complaints and the outcomes.

2.22 Annual Report

The activities of the DVA HREC are reported annually to the MRCC and the NHMRC on a calendar year basis. It may be of interest to veterans to gain access to the details of the HREC activities each year, accessible via the official DVA website after MRCC endorsement. According to the NHRMC National Statement, the annual report should include the following:

• membership and membership changes;
• number of meetings;
• confirmation of participation by required categories of members;

• number of protocols presented, approved and rejected, and
• complaints procedures and number of complaints.

2.23 Review of Administrative Guidelines

As a matter of good practice, and with a view to ensuring the DVA HREC *Administrative Guidelines* reflect periodic amendments to the National Statement and like documents, it is proposed that every three years from 1 January 2013 the Secretariat to the DVA HREC will commence a review of all governance and administrative documents and practices and report to the DVA HREC no later than 1 July of that year.

Results of triennial reviews will be presented to the MRCC for endorsement.

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2.2 Attendance at Meetings

2.3 Transport Costs

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2.5 Use of e-Technology

2.6 Agendas

2.7 Minutes

2.8 Timely Consideration

2.9 Methods of Decision Making

2.10 Notification of Decision

2.11 Decision Types

2.12 Expedited Review for Minimal Risk Research

2.13 Survey Fatigue

2.14 Fees

2.15 Access to Funding Not Automatic

2.16 Access to Data Not Automatic

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- notify researchers in writing of DVA HREC 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 or defence communities; and
- for significant research projects, provide advice to researchers prior to considering requests for DVA HREC approval.

1.4 Membership

The National Statement is the basis for the 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 designated “the 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 directly involved in pastoral care; and
f. at least one member who is a lawyer.

The DVA HREC also includes one voting and one non-voting ‘ex-officio’ member, both of whom are representatives of the Department of Veterans’ Affairs. The DVA HREC Coordinator provides the DVA HREC with secretariat support and liaison is ‘ex-officio’ and non-voting. Committee membership records will indicate whether or not an ‘ex-officio’ member has voting rights.

In addition to the adherence to the National Statement on membership constituency, DVA encourages the representation of veterans within the membership of the DVA HREC, particularly contemporary veterans and female veterans.

A contemporary veteran perspective adds value to the DVA HREC in facilitating an appreciation of the issues, from an individual with direct involvement. It would be appropriate that a designated contemporary veteran representative be drawn from the cohort who has served in one or more of the conflicts involving Australian troops since 1999.

No more than one third of the membership of the DVA HREC should be DVA employees.

The DVA HREC reports directly to the Commissions on its constitution and the Commissions appoint members of the DVA HREC.

1.5 Recruitment and Appointment

The recruitment and appointment of DVA HREC members is open and transparent. Periodic advertising in specific media forums seek Expressions of Interest from subject matter experts. Individuals are shortlisted for interview and appointment recommendations are presented to the Commissions for endorsement. In some cases, consideration will be given to individuals recommended by DVA representatives. All shortlisted individuals will be interviewed and appointment recommendations are presented to the Commissions for endorsement. Please refer to Table 1.1 for details of the appointment process.

Table 1.1 Process for appointment of DVA HREC members (12 week process)

Stage	Process	Outcome
Stage 1 Recruitment Drive	Call for Expressions of Interest. Advertised in specific media and recommendations from DVA representatives.	Collation of all Expression of Interests. Letters sent to all applicants confirming their interest.
Stage 2 Assessment for interview	Expressions of Interests are assessed by Director, Research Development and Coordination, for: • Subject matter expertise • Knowledge of veteran issues • Experience and knowledge of ethics and research.	Short list created for interview stage. Each shortlisted applicant will be invited to attend interview in person or via e-technology.
Stage 3 - Interview	All short listed applicants will be interviewed by: • Assistant Secretary, R&D Branch • Chair, DVA HREC	Reports written on each shortlisted applicant interviewed and recommended to First Assistant Secretary, H&C Services for clearance.
Stage 4 – Endorsement by MRCC	Commission Submission will be presented to the MRCC requesting endorsement of recommended applicants.	Formal endorsement by MRCC and official letter sent to applicants advising of their membership of DVA HREC and requesting completion of the DVA HREC Induction Program

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

All appointees will take part in a DVA HREC induction program. The induction program will include the following:

- meeting with the Chair of the DVA HREC;
- meeting with the Repatriation Commissioner;
- meeting with DVA staff responsible for the administration of the DVA HREC;
- attending at least one of the specific Military Culture and History training workshops regularly held by DVA;
- an induction package to include:
    - DVA HREC Administrative Guidelines;
    - NHMRC National Statement;

- DVA HREC Ethics Review application;
- Information for Researchers;
- DVA HREC Annual reports, and
- Other relevant documents relating to DVA administrative issues.

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.

1.6 Terms of membership of DVA HREC

From 1 January 2013 a system of rotating six-year terms with a one-term limit will commence. Effective from that date, the members of the Committee will be divided as evenly as practicable into two groups: the first with a three-year term, the second with a six-year term, and without the possibility of reappointment.

After the expiration of the first group's term, all subsequent appointments would be for a six-year term (one term limit) excepting appointments to casual vacancies.

As a matter of good practice, appointments to the DVA HREC are reviewed at least every three years and reported to the Commissions.

1.7 Filling casual vacancies on DVA HREC

With respect to casual vacancies – which is to say when a seat on the DVA HREC has been permanently vacated (usually this will be by resignation) – it is widespread practice in many representative bodies and committees that a person selected to fill a casual vacancy is appointed for the remainder of the term of the person who has vacated the seat.

The HREC Chair has the authority to appoint an individual to fill a casual vacancy (under six months) in consultation with DVA. From 1 January 2013 when a casual vacancy occurs over six (6) months, the Commissions will appoint a person to fill the vacancy for the remainder of the term of the person who vacated the seat. All persons appointed to the HREC are expected to complete the DVA HREC induction program.

The Chair of the DVA HREC may appoint a temporary stand-in for another member when considered necessary. The Chair may appoint a stand-in for the Chair from existing committee members. 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.

1.8 Expert Advice

The DVA HREC 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.

The consideration given to privacy matters is discussed at Section 3.6.

1.9 Authority of Chair

The Chair of the DVA HREC may:

- consider research proposals and advise researchers on whether or not a project requires DVA HREC approval;
- reconsider and, if appropriate, approve revised proposals after initial consideration by the DVA HREC, 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 DVA HREC'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 the Chair, when considered necessary;
- provide advice to DVA staff on DVA HREC functions and on ethical issues in research; and
- perform other tasks as delegated by the DVA HREC.

1.10 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 and a stand-in has not been appointed by the Chair, provide opinions on the ethical acceptability of research proposals before the meeting; and
- continually improve their knowledge and understanding of current and emergent ethical issues in human research including enrolling in education or training programs from time-to-time.

1.11 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 relevant interests 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.

In August 2012, the NHMRC published *Guideline Development and Conflicts of Interest*. In brief, having particular regard to international events, failure to disclose interests and/or publish negative findings from industry-sponsored research, it establishes:

> *policies … to ensure the integrity of the publications issued by NHMRC committees and working groups developing guidelines and to strike an appropriate balance between the existence of 'interests' in the topic under review and the expertise required to make sound and meaningful recommendations.*

The HREC Administrative Guidelines align with the NHMRC's 2012 published *Guideline Development and Conflicts of Interest*.

1.12 The Harmonisation of Multi-centre Ethical Review (HoMER) initiative

The NHMRC introduced the Harmonisation of Multi-centre Ethical Review (HoMER) initiative as a means of developing a range of tools to support researchers and HRECs to collaborate within a single ethical review.

The DVA HREC will encourage cross sector collaboration within a single ethical review where appropriate and continue to work on ways to move closer to adopting the HoMER principles.

1.13 Legal Protection of Members

Legal protection is provided to DVA HREC members involved in ethical review of research for any liability 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.

While acting for the DVA HREC, 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 last updated on 19 August 2003.

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 will meet at least every three months, on the third Friday of February, May, August and November unless the Chair in consultation with the Secretariat otherwise determines. Meeting dates are to be advertised on the Department's Intranet and Internet webpage, and notified to participants and senior departmental staff by email.

2.2 Attendance at Meetings

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

2.3 Transport Costs

The Department will arrange transport and accommodation for interstate DVA HREC members to attend meetings or will reimburse reasonable costs in line with departmental Chief Executive Instructions (CEI 5.10, 5.16, 5.21). Reasonable costs may include mileage, parking fees, bus fares, etc for local or interstate DVA HREC members to attend meetings.

The Department does not reimburse the cost to researchers of attending meetings.

2.4 Remuneration of DVA HREC members

The Repatriation Commission and the Military Rehabilitation and Compensation Commission agreed on 16 May 2013 to the introduction of daily fees (one reading day and one sitting day per scheduled meeting) for members of the DVA HREC.

The Minister for Veterans' Affairs, in whose portfolio the public offices comprising the DVA HREC are located, determined that pursuant to clause 2.3.1. of the *Remuneration Tribunal Determination 2012/13 – Remuneration and allowances for Holders of Part-Time Public Office* (Remuneration Tribunal Determination 2012/013), that the category of daily fees to be paid to the Chairperson and a member of HREC is the amount set out in Category 2 of Table 2A of the Remuneration Tribunal Determination 2012/013.

Table 2A: Public Offices not specified in this Determination – Daily Fees with effect from 1 July 2012.

Office	Category 2
	$ per day
Chairperson	564
Member	418

The exception is Commonwealth and State/Territory employees, who are not entitled to remuneration. The basis for this decision is Section 7(11) of the *Remuneration Tribunal Act 1973.*

2.5 Use of e-Technology

In line with government initiatives for a move to shared services and environmental work practices, DVA is encouraging a transition towards a "paperless" work environment. While a "paperless" environment is

in its conceptual stage within DVA presently, the HREC is being encouraged to embrace the concept of new technology devices such as tablets, laptops and secure portals for the distribution of material and for the work practice of HREC members.

2.6 Agendas

Agenda papers and research protocols are distributed to committee members no less than seven (7) days before the meeting (so as received by the first Friday of the month). Papers shall be distributed by post, courier or electronically, as 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.

Standing items for each meeting agenda:

- Opening and welcome, including any late business, apologies and conflicts of interest;
- Committee membership;
- Minutes of Previous Meeting;
- Out of Session Considerations;
- Re-Submissions
- Revised Proposals
- Protocol Changes;
- New Proposals;
- Progress/Final Reports on approved proposals;
- Other Business.

The views of DVA's Privacy Officer on each research proposal being considered are always made available at or before each meeting.

2.7 Minutes

Minutes of DVA HREC meetings are written up as soon as practicable after the meeting and cleared by the Chair. The minutes are sent to committee members with the agenda and papers for the subsequent meeting. The minutes are considered and approved, with or without amendment, at the subsequent meeting. The Chair shall certify the approved minutes as a true and accurate record of the meeting.

2.8 Timely Consideration

Proposals submitted to a DVA HREC meeting will generally be considered at that meeting. If additional information is required from the researcher, he/she will be requested to provide such information. Researchers, and DVA sponsors, may be asked to make themselves available for contact during the meeting as appropriate.

If a proposal cannot be dealt with at the scheduled meeting, the DVA HREC will decide when and how it should be considered and the Researcher notified.

Urgent research proposals received between normal 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 is subject to ratification at the next formal meeting of the DVA HREC.

2.9 Methods of Decision Making

The DVA HREC will endeavour to reach decisions by consensus. This need not involve unanimity but failure to achieve consensus may require an extension of time for reconsideration of the research protocol and/or amendments thereto.

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 DVA HREC 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 DVA HREC has seen all documents and material used to inform the potential participants including information sheets, consent forms, questionnaires, letters of invitation, internet content and promotional material;
- 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 1988* 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 in accordance with the principles of Section 95 of the *Privacy Act 1988*;
- the value of the initiative as a scientific exercise compared with the inconvenience visited on the proposed research participants who are members of the veteran or defence communities.

2.10 Notification of Decision

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

2.11 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 research;

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 research;

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

2.12 Expedited Review for Minimal/Low Risk Research

On receipt of a research 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 DVA HREC.

2.13 Survey Fatigue

DVA monitors 'survey fatigue' among members of the veteran or defence communities and the DVA HREC supports this as it may impact on the integrity of information required of and received from participants. DVA aims to avoid having the same groups surveyed more than once every two years.

It should be noted, the Department of Defence closely monitors research participant fatigue among their cohort. It is recommended researchers also discuss with the Department of Defence any research involving serving defence personnel.

2.14 Fees

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

2.15 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, if applicable.

2.16 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.

It is recommended researchers also discuss with the Department of Defence any data requirements for research involving serving defence personnel, as this may not be held by DVA.

2.17 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.

Failure to comply with the above reporting requirements may result in withdrawal of approval.

2.18 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.

Where a complaint arises regarding the conduct of the DVA HREC, the Chair of the DVA HREC should be the initial point of contact. Where appropriate, the complaint will be directed to the office of the Repatriation Commission and the Military Rehabilitation and Compensation Commission.

2.19 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.

2.20 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. DVA HREC files are to be kept in locked cabinets and accessed only by authorised individuals.

2.21 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
- conflicts of interest; and
- record of complaints and the outcomes.

2.22 Annual Report

The activities of the DVA HREC are reported annually to the MRCC and the NHMRC on a calendar year basis. It may be of interest to veterans to gain access to the details of the HREC activities each year, accessible via the official DVA website after MRCC endorsement. According to the NHRMC National Statement, the annual report should include the following:

• membership and membership changes;
• number of meetings;
• confirmation of participation by required categories of members;

• number of protocols presented, approved and rejected, and
• complaints procedures and number of complaints.

2.23 Review of Administrative Guidelines

As a matter of good practice, and with a view to ensuring the DVA HREC *Administrative Guidelines* reflect periodic amendments to the National Statement and like documents, it is proposed that every three years from 1 January 2013 the Secretariat to the DVA HREC will commence a review of all governance and administrative documents and practices and report to the DVA HREC no later than 1 July of that year.

Results of triennial reviews will be presented to the MRCC for endorsement.

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Australian Government

Department of Veterans' Affairs

DVA Human Research Ethics Committee

ADMINISTRATIVE GUIDELINES

DVA HREC Administrative Guidelines
Version 4.0
June 2012

CONTENTS

1. DVA Human Research Ethics Committee (DVA HREC)

1.1 Role of Committee

1.2 Authority of Committee

1.3 Terms of Reference

1.4 Membership

1.5 Appointment

1.6 Expert Advice

1.7 Authority of Chair

1.8 Members' Responsibilities

1.9 Conflict of Interest

1.10 Legal Protection of Members

2. Administrative Procedures

2.1 Frequency of Meeting

2.2 Attendance at Meetings

2.3 Transport Costs

2.4 Agendas

2.5 Minutes

2.6 Timely Consideration

2.7 Methods of Decision Making

2.8 Notification of Decision

2.9 Decision Types

2.10 Expedited Review for Minimal Risk Research

2.11 Survey Fatigue

2.12 Fees

2.13 Access to Funding Not Automatic

2.14 Access to Data Not Automatic

2.15 Monitoring

2.16 Complaints Procedure

2.17 Record Keeping

2.18 Confidentiality of Protocols

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

3. Researchers

3.1 Researchers' Responsibilities

3.2 Conflict of Interest

3.3 When Do you Need Ethics Approval

3.4 Data Identifiability

3.5 Data Matching/ Data Linkage

3.6 Submission Types

3.7 New Submissions

3.8 Privacy Considerations

3.9 Informed Consent (Participant Information and Consent)

3.10 Cognitive Impairment

3.11 Letter of First Contact

3.12 Standing Requirement—Contact with Members of the Veteran Community (Mazengarb Clause)

3.13 Limited Contact

3.14 Declaration of Funding Sources

3.15 Payments for Participants

3.16 Lotteries

3.17 Complaints/Adverse Occurrences

3.18 Minimising Duplication of Ethical Review

3.19 Student Research

3.20 Presentation of Research Protocols

3.21 Approved in Principle

3.22 Condition of Approval

3.23 Change to Protocol

3.24 Reporting Requirements

3.25 Abandoned Research

3.26 Data Management

3.27 Withdrawal of Approval

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 human research, being research conducted with or about people, their data or tissue. The primary responsibility of each member is to decide, independently, whether, in their opinion, the conduct of each research proposal submitted to the HREC will so protect the participants.

The DVA HREC considers ethical aspects of proposed research, irrespective of whether or not the Department is funding or is likely to be responsible for the research, and takes into account social and moral implications of the research for the veteran and relevant defence communities. It ensures that research involving departmental data and/or members of the veteran and defence communities 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' among members of the veteran and defence communities and how that may impact on the integrity of information required of and received from participants. It does not consider requests for special access to medical records under the *Archives Act 1983*.

Finally, the DVA HREC 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 DVA HREC 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 annual reporting to the NHMRC. The Department was required to agree to these arrangements in order to conduct or contract human research.

In fulfilling the Role of the Committee at Section 1.1, the DVA HREC operates as a semi-independent governance body. The functions and authorities of the DVA HREC are embedded in the *DVA HREC Administrative Guidelines.*

The DVA HREC is appointed by and reports directly to the Repatriation Commission (the Commission). The Commission, in turn, provides general oversight of the Committee, and is responsible for approving proposed changes to the governance documents – including these Administrative Guidelines – that constitute the DVA HREC.

Proposed amendments to the Administrative Guidelines shall be sighted in writing by all members of DVA HREC for their information prior to submission to the Repatriation Commission for approval.

These *DVA HREC Administrative Guidelines* were sighted by the DVA HREC on June 2012 and agreed by the Repatriation Commission on June 2012.

1.3 Terms of Reference

The terms of reference for the DVA HREC approved 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 DVA HREC 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 or relevant defence communities; and
- for significant research projects, provide advice to researchers prior to considering requests for DVA HREC approval.

1.4 Membership

The National Statement is the basis for the 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 designated “the 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 one voting and one non-voting ex-officio member, both of whom are representatives of the Department of Veterans’ Affairs, and the DVA HREC Coordinator who provide the DVA HREC with support and liaison. Committee membership records will indicate whether or not an ex-officio member has voting rights.

No more than one third of the membership of the DVA HREC should be DVA employees.

The DVA HREC reports directly to the Repatriation Commission on its constitution and the Repatriation Commission appoints members of the DVA HREC.

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.

From 1 January 2013 a system of staggered three-year terms with a maximum of four consecutive terms will commence. Effective from that date, the members of the Committee will be divided as evenly as practicable into four groups with limits of two, three and four terms respectively, and without the possibility of reappointment beyond those limits. At the expiration of the first three year term subsequent to the introduction of this arrangement, all new appointees will have the maximum four-term limit.

As the Repatriation Commission (the Commission) has the power to appoint members to the Committee, it would seem to follow that it should decide the division of the Committee for this purpose, by and with the advice and consent of the Committee.

In the Chair's absence the Deputy Chair will preside and perform all other duties related to the position of Chair, both in and out of session. In the absence of both the Chair and the Deputy Chair the Committee shall appoint a Chair *pro tem* for that meeting. Where a Committee member has advised that they will be absent for a meeting, the Chair shall appoint a suitably qualified *pro tem* replacement. No committee member may delegate their seat or vote to a proxy.

1.6 Expert Advice

The DVA HREC 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.

The consideration given to privacy matters is discussed at Section 3.6.

1.7 Authority of Chair

The Chair of the DVA HREC may:

- consider research proposals and advise researchers on whether or not a project requires DVA HREC approval;
- reconsider and, if appropriate, approve revised proposals after initial consideration by the DVA HREC, 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 DVA HREC'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 suitably qualified *pro tem* replacement for absent members as necessary;
- provide advice to DVA staff on DVA HREC functions and on ethical issues in research; and
- perform other tasks as delegated by the DVA HREC.

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 and a *pro tem* replacement has not been appointed by the Chair, provide opinions on the ethical acceptability of research proposals before the meeting; and
- continuously improve their knowledge and understanding of current and emergent ethical issues in human research including enrolling in education or training programs from time-to-time.

1.9 Conflict of Interest

DVA HREC Committee Members, and also any experts whose advice is sought, are bound by confidentially 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.

NB: The NHMRC's *Guideline Development and Conflicts of Interest*, came into effect on 1 August 2012. In brief, having particular regard to international events such as failure to disclose interests and/or publish negative findings from industry-sponsored research, it establishes:

> policies … to ensure the integrity of the publications issued by NHMRC committees and working groups developing guidelines and to strike an appropriate balance between the existence of 'interests' in the topic under review and the expertise required to make sound and meaningful recommendations.

This will impact on any future review of the DVA HREC AGs, because guidelines – such as the AGs – must be approved by the NHMRC under s.14A of the *National Health and Medical research Council Act 1992* (NHMRC Act). Guideline developers must:

> comply with the principles about disclosure of interests contained in this document in order to meet Standard A6 of the *NHMRC Procedures and requirements for meeting the 2011 NHMRC standard for clinical practice guidelines*.

1.10 Legal Protection of Members

Legal protection is provided to DVA HREC members involved in ethical review of research for any liability 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.

While acting for the DVA HREC, 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 last updated on 19 August 2003.

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 will meet at least every three months, on the second Friday of February, May, August and November unless the Chair in consultation with the Secretariat otherwise determines. Meeting dates are to be advertised on the Department's Intranet and Internet webpage, and notified to participants and senior departmental staff by email.

2.2 Attendance at Meetings

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

2.3 Transport Costs

The Department will arrange transport and accommodation for interstate DVA HREC members to attend meetings or will reimburse reasonable costs in line with departmental Chief Executive Instructions. Reasonable costs may include mileage, parking fees, bus fares, etc for local or interstate DVA HREC members to attend meetings.

The Department does not reimburse the cost to researchers of attending meetings (see Section 3.18 of these guidelines - *Presentation of Research Protocols*).

2.4 Agendas

Agenda papers and research protocols are distributed to committee members no less than seven (7) days before the meeting (so as received 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.

Standing items for each meeting agenda:

- Opening and welcome, including any late business, apologies and conflicts of interest;
- Committee membership;
- Minutes of Previous Meeting;
- Out of Session Considerations;
- Re-Submissions
- Revised Proposals
- Protocol Changes;
- New Proposals;
- Progress/Final Reports on approved proposals;
- Other Business.

The views of DVA's Privacy Officer on each research proposal being considered are always made available at or before each meeting.

2.5 Minutes

Minutes are written up as soon as practicable after the meeting and are sent to committee members with the agenda and papers for the subsequent meeting. The minutes are considered and approved, with or without amendment, at the subsequent meeting. The Chair shall certify the approved minutes as a trua and accurate record of the meeting.

2.6 Timely Consideration

Proposals submitted to a DVA HREC meeting will generally be considered at that meeting. If additional information is required from the Researcher, he/she will be requested to provide such information. Researchers, and DVA sponsors, may be asked to make themselves available for contact during the meeting as appropriate.

If a proposal cannot be dealt with at the scheduled meeting, the DVA HREC will decide when and how it should be considered and the Researcher notified.

Urgent research proposals received between normal 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 is subject to ratification at the next formal meeting of the DVA HREC.

2.7 Methods of Decision Making

The DVA HREC will endeavour to reach decisions by consenus. This need not involve unanimity but failure to achieve consenus may require an extension of time for reconsideration of the research protocol and/or amendments thereto.

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 DVA HREC 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 DVA HREC has seen all documents and material used to inform the potential participants including information sheets, consent forms, questionnaires, letters of invitation, internet content and promotional material;
- 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 1988* 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 in accordance with the principles of Section 95 of the *Privacy Act 1988*;
- the value of the initiative as a scientific exercise compared with the inconvenience visited on the proposed research participants who are members of the veteran or relevant defence communities.

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 DVA HREC requires further information on the proposal, the Principal Researcher will be advised of this 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 research;

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 research;

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

2.10 Expedited Review for Minimal Risk Research

On receipt of a research 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 DVA HREC.

2.11 Survey Fatigue

DVA monitors 'survey fatigue' among members of the veteran or relevant defence communities and the DVA HREC supports this as it may impact on the integrity of information required of and received from participants. DVA aims to avoid having the same groups surveyed more than once every two years.

It should be noted, the Department of Defence closely monitors research participant fatigue among their cohort. It is recommended researchers also discuss with the Department of Defence any research involving serving defence personnel.

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, if applicable.

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.

It is recommended researchers also discuss with the Department of Defence any data requirements for research involving serving defence personnel, as this may not be held by DVA.

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. DVA HREC 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 Conflicts 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 or relevant defence communities 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 research 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 or relevant defence communities being targeted because of their veteran affiliation, this includes family members and carers;
- research involving the use of collected veterans' data for a purpose, or by a person, other than for which/whom it was collected, including DVA owned data for mail-out lists, treatment usage, medical records of the former Repatriation General Hospitals;
- research involving the use of any data which contains means for identification of veterans, e.g. re-identification through a code, by data linkage or by nature of the sample size or other information collected – see Section 3.5 below;
- variation to a DVA HREC 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 DVA HREC;
- research involving the general public which coincidentally includes members of the veteran or relevant defence communities who are NOT being specifically included because of their veteran affiliation;
- research on collections of data already in the public domain;
- aggregated data which does NOT provide the means for re-identification of an individual veteran (care needs to be taken in assessing this – see Sections 3.4 and 3.5 below); and
- literature reviews or scoping studies for development and design of research protocols, which do not involve any of the activities detailed above for which approval should be sought.

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 3.17 of these guidelines). All submissions should be sent to the DVA HREC Secretariat at ethics.committee@dva.gov.au.

3.4 Data Identifiability

Data are pieces of information, which can be collected or derived from a variety of sources including from interviews, questionnaires, focus groups, personal histories, clinical, social and other observations, and from human tissue such as blood, bone, muscle and urine.

Data may be collected, stored or disclosed in three mutually exclusive forms:

- *individually identifiable data*: where the identity of a specific individual can reasonably be ascertained. Examples of identifiers include the individual's name, image, date of birth or address;
- *re-identifiable data*: from which identifiers have been removed but it remains possible to re-identify a specific individual by, for example, using the code or linking different data sets (data linkage); and
- *non-identifiable data*: which have never been labelled with individual identifiers or from which identifiers have been permanently removed and by means of which no specific individual can be identified. A subset of non-identifiable data are those that can be linked with other data so it can be known that they are about the same data subject although the person's identity remains unknown.

The National Statement avoids the term '*de-identified data*', as its meaning is unclear. While it is sometimes used to refer to a record that cannot be linked to an individual ('non-identifiable'), it may also be used to refer to a record in which identifying information has been removed but the means still exist to re-identify the individual. Where the term 'de-identified data' is used, the DVA HREC will endeavour to establish precisely which of these possible meanings is intended.

3.5 Data Matching/ Data Linkage

Researchers should inform the DVA HREC if they intend to link or match data from another source, what the other source is, and what data is going to be obtained from the other source.

The ability for individuals to be indentified from matched or linked data should be a consideration in all applications to DVA HREC.

3.6 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.

3.7 New Submissions

The DVA HREC has a pro forma - available for download from 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 3.4 to 3.18 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 DVA HREC.

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. Researchers should discuss this with the relevant Deputy Commissioner in their state or their DVA Sponsor.

3.8 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 meaning 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 IPPs, 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 IPP(s) in question.

All substantive submissions and protocol changes are referred to the DVA Privacy Officer for comment prior to each meeting. The DVA HREC gives due consideration to these comments at its meetings and in the course of out of session approval processes.

3.9 Informed Consent (Participant Information and Consent)

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

Information on the following matters should be communicated to participants prior to their involvement in research:

a) the purpose, methods, risks and possible benefits of the research;
b) what precisely will be required of or from the participant;
c) any alternatives to participation;
d) how the research will be monitored;
e) provision of services to participants adversely affected by the research;
f) contact details of the researcher and person to receive complaints (see Section 3.15 below);
g) how privacy and confidentiality will be protected;
h) the Mazengarb Clause (see Section 3.10 below);
i) any implications of withdrawal, and whether it will be possible to withdraw data (care should be taken to ensure this is communicated in an impartial, non-threatening manner);
j) the amounts and sources of funding for the research (see Section 3.11 below);
k) financial or other relevant declarations of interests of researchers, sponsors or institutions;
l) any payments to participants (see Section 3.13 and 3.14 below);
m) the likelihood and form of dissemination of the research results, including publication;
n) any expected benefits to the wider community;
o) any other relevant information, including research-specific information required under other chapters of the National Statement.

This information must be presented in ways suitable to each participant, although it will most often take the shape of a Participant Information and Consent Forms (PICF).

Whether or not participants will be identified, research should be designed so that each participant's voluntary and informed decision to participate will be clearly established. DVA HREC prefers that a signed Consent Form is obtained from each participant. An opting-out process, i.e. "No response from you will be considered consent", does not constitute "voluntary" nor "informed" consent from participants.

3.10 Cognitive Impairment

Researchers should inform DVA HREC how they propose to determine the capacity of a person with a cognitive impairment, an intellectual disability, or a mental illness to consent to the research. This information should include:

(a) how the decision about the person's capacity will be made;
(b) who will make that decision;
(c) the criteria that will be used in making the decision; and

(d) during the course of the research, the process for reviewing the participant's capacity to consent and to participate in the research.

Consideration should be given to a possible or perceived conflict of interest. Researchers may wish to consider the professional opinion of a qualified and independent person in validating the ability of the participant to give consent.

It is obligatory if a person is under guardianship or enduring power of attorney that the guardianship board knows and the power of attorney is informed. If there is a guardianship rule, that person may also need to be present during contact with the participant.

3.11 Letter of First Contact

The DVA HREC has a standing requirement that, if a proposed project is sponsored by the Department of Veterans' Affairs and involves face to face or telephone contact with members of the veteran or relevant defence communities, 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 or relevant defence communities are contacted in the first instance by mail (e.g. a mail survey), a letter of first contact must accompany the mail-out.

The letter of first contact will be signed by the Principal Medical Adviser, the Repatriation Commissioner or a Deputy Commissioner where the study is confined to their particular state.

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

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. The Mazengarb Clause should appear in **bold type** on the letter of first contact and/or participant information and consent forms. It may 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 appropriate and approved, the clause may be extended to include reference to other government agencies.

3.13 Limited Contact

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 authorised by DVA HREC or the participant themselves.

Where the invitation is refused, contact must cease immediately.

3.14 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.

3.15 Payments for Participants

It is generally unacceptable to DVA HREC for researchers 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. Where applicable, advice of endorsement by the DVA sponsor should also be included.

3.16 Lotteries

DVA HREC does not in principle approve any form of lottery as an incentive for research participants on the grounds that:

a) it is shown to be ineffective in recruiting participants;
b) it is shown to be in breach of the principles of ethical research, in particular the principles of equity and justice; and
c) lotteries with substantial prizes may distort the judgement of putative applicants regarding their decision to give Informed Consent.

3.17 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 Human Research Ethics Committee within the Principal Researcher's organisation, if applicable, or to the DVA HREC via:

DVA HREC Secretariat
Department of Veterans' Affairs
PO Box 9998
CANBERRA ACT 2601
ethics.committee@dva.gov.au

3.18 Minimising Duplication of Ethical Review

It should be noted that approval by another Human Research Ethics Committee in addition to the DVA HREC may be necessary for some research proposals. Approval by another Human Research 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;
- 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.

3.19 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.

In accordance with the data management requirements outlined in Section 3.24, students must not remove research data from the approved location and must not copy, email or download data to laptops or other electronic mobile devices. Unauthorised use of data by a person or for a purpose other than that approved by DVA HREC and permitted under the *Privacy Act 1988* is strictly prohibited.

3.20 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, if required.

3.21 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 DVA HREC 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.

3.22 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 an approval. The Principal Researcher will be formally notified of any conditions of approval by the DVA HREC at the time of approval.

3.23 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.

3.24 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. Shorter-term studies are required to submit a final report with research findings as soon as practicable after completion of the study.

Progress reports are designed to assure the DVA HREC that the research protocol as approved has not changed and that the project is progressing satisfactorily. Researchers should use the template available from the DVA HREC website to provide advice as to:

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

In addition, final reports on completed studies should include advice as to:

- any benefits resulting from completed research and any other avenues of research this may have opened up as a result;
- the arrangements for the study data (i.e. particulars of long or short term storage, destruction. See also Section 3.24 below);
- conclusion of other research requirements such as contractual arrangements with DVA; and
- an electronic and hard copy of research results and any published findings.

3.25 Abandoned Research

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

3.26 Data Management

All data supplied by DVA and collected on behalf of DVA, remains the property of the Commonwealth as represented by DVA.

Researchers must ensure data is collected, stored, accessed, amended, used and, where necessary, disclosed or destroyed in accordance with the Information Privacy Principles (IPPs) and the protocols approved by DVA HREC.

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.

Research files are to be kept in locked cabinets at the location approved by DVA HREC and accessed only by authorised individuals. 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 by DVA HREC.

Unauthorised access and/or use of data by a person or for a purpose other than that approved by DVA HREC and permitted under the *Privacy Act 1988* is strictly prohibited.

At the completion of the approved research, data must be either returned, stored or destroyed in accordance with approved protocols, the *Archives Act 1983* and in accordance with any contractual requirements.

3.27 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.

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Australian Government

Department of Veterans' Affairs

DVA Human Research Ethics Committee

ADMINISTRATIVE GUIDELINES

DVA HREC Administrative Guidelines
Version 4.0
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CONTENTS

1. DVA Human Research Ethics Committee (DVA HREC)

1.1 Role of Committee

1.2 Authority of Committee

1.3 Terms of Reference

1.4 Membership

1.5 Appointment

1.6 Expert Advice

1.7 Authority of Chair

1.8 Members' Responsibilities

1.9 Conflict of Interest

1.10 Legal Protection of Members

2. Administrative Procedures

2.1 Frequency of Meeting

2.2 Attendance at Meetings

2.3 Transport Costs

2.4 Agendas

2.5 Minutes

2.6 Timely Consideration

2.7 Methods of Decision Making

2.8 Notification of Decision

2.9 Decision Types

2.10 Expedited Review for Minimal Risk Research

2.11 Survey Fatigue

2.12 Fees

2.13 Access to Funding Not Automatic

2.14 Access to Data Not Automatic

2.15 Monitoring

2.16 Complaints Procedure

2.17 Record Keeping

2.18 Confidentiality of Protocols

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

3. Researchers

3.1 Researchers' Responsibilities

3.2 Conflict of Interest

3.3 When Do you Need Ethics Approval

3.4 Data Identifiability

3.5 Data Matching/ Data Linkage

3.6 Submission Types

3.7 New Submissions

3.8 Privacy Considerations

3.9 Informed Consent (Participant Information and Consent)

3.10 Cognitive Impairment

3.11 Letter of First Contact

3.12 Standing Requirement—Contact with Members of the Veteran Community (Mazengarb Clause)

3.13 Limited Contact

3.14 Declaration of Funding Sources

3.15 Payments for Participants

3.16 Lotteries

3.17 Complaints/Adverse Occurrences

3.18 Minimising Duplication of Ethical Review

3.19 Student Research

3.20 Presentation of Research Protocols

3.21 Approved in Principle

3.22 Condition of Approval

3.23 Change to Protocol

3.24 Reporting Requirements

3.25 Abandoned Research

3.26 Data Management

3.27 Withdrawal of Approval

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 human research, being research conducted with or about people, their data or tissue. The primary responsibility of each member is to decide, independently, whether, in their opinion, the conduct of each research proposal submitted to the HREC will so protect the participants.

The DVA HREC considers ethical aspects of proposed research, irrespective of whether or not the Department is funding or is likely to be responsible for the research, and takes into account social and moral implications of the research for the veteran and relevant defence communities. It ensures that research involving departmental data and/or members of the veteran and defence communities 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' among members of the veteran and defence communities and how that may impact on the integrity of information required of and received from participants. It does not consider requests for special access to medical records under the *Archives Act 1983*.

Finally, the DVA HREC 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 DVA HREC 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 annual reporting to the NHMRC. The Department was required to agree to these arrangements in order to conduct or contract human research.

In fulfilling the Role of the Committee at Section 1.1, the DVA HREC operates as a semi-independent governance body. The functions and authorities of the DVA HREC are embedded in the *DVA HREC Administrative Guidelines.*

The DVA HREC is appointed by and reports directly to the Repatriation Commission (the Commission). The Commission, in turn, provides general oversight of the Committee, and is responsible for approving proposed changes to the governance documents – including these Administrative Guidelines – that constitute the DVA HREC.

Proposed amendments to the Administrative Guidelines shall be sighted in writing by all members of DVA HREC for their information prior to submission to the Repatriation Commission for approval.

These *DVA HREC Administrative Guidelines* were sighted by the DVA HREC on June 2012 and agreed by the Repatriation Commission on June 2012.

1.3 Terms of Reference

The terms of reference for the DVA HREC approved 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 DVA HREC 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 or relevant defence communities; and
- for significant research projects, provide advice to researchers prior to considering requests for DVA HREC approval.

1.4 Membership

The National Statement is the basis for the 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 designated “the 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 one voting and one non-voting ex-officio member, both of whom are representatives of the Department of Veterans’ Affairs, and the DVA HREC Coordinator who provide the DVA HREC with support and liaison. Committee membership records will indicate whether or not an ex-officio member has voting rights.

No more than one third of the membership of the DVA HREC should be DVA employees.

The DVA HREC reports directly to the Repatriation Commission on its constitution and the Repatriation Commission appoints members of the DVA HREC.

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.

From 1 January 2013 a system of staggered three-year terms with a maximum of four consecutive terms will commence. Effective from that date, the members of the Committee will be divided as evenly as practicable into four groups with limits of two, three and four terms respectively, and without the possibility of reappointment beyond those limits. At the expiration of the first three year term subsequent to the introduction of this arrangement, all new appointees will have the maximum four-term limit.

As the Repatriation Commission (the Commission) has the power to appoint members to the Committee, it would seem to follow that it should decide the division of the Committee for this purpose, by and with the advice and consent of the Committee.

In the Chair's absence the Deputy Chair will preside and perform all other duties related to the position of Chair, both in and out of session. In the absence of both the Chair and the Deputy Chair the Committee shall appoint a Chair *pro tem* for that meeting. Where a Committee member has advised that they will be absent for a meeting, the Chair shall appoint a suitably qualified *pro tem* replacement. No committee member may delegate their seat or vote to a proxy.

1.6 Expert Advice

The DVA HREC 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.

The consideration given to privacy matters is discussed at Section 3.6.

1.7 Authority of Chair

The Chair of the DVA HREC may:

- consider research proposals and advise researchers on whether or not a project requires DVA HREC approval;
- reconsider and, if appropriate, approve revised proposals after initial consideration by the DVA HREC, 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 DVA HREC'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 suitably qualified *pro tem* replacement for absent members as necessary;
- provide advice to DVA staff on DVA HREC functions and on ethical issues in research; and
- perform other tasks as delegated by the DVA HREC.

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 and a *pro tem* replacement has not been appointed by the Chair, provide opinions on the ethical acceptability of research proposals before the meeting; and
- continuously improve their knowledge and understanding of current and emergent ethical issues in human research including enrolling in education or training programs from time-to-time.

1.9 Conflict of Interest

DVA HREC Committee Members, and also any experts whose advice is sought, are bound by confidentially 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.

NB: The NHMRC's *Guideline Development and Conflicts of Interest*, came into effect on 1 August 2012. In brief, having particular regard to international events such as failure to disclose interests and/or publish negative findings from industry-sponsored research, it establishes:

> policies … to ensure the integrity of the publications issued by NHMRC committees and working groups developing guidelines and to strike an appropriate balance between the existence of 'interests' in the topic under review and the expertise required to make sound and meaningful recommendations.

This will impact on any future review of the DVA HREC AGs, because guidelines – such as the AGs – must be approved by the NHMRC under s.14A of the *National Health and Medical research Council Act 1992* (NHMRC Act). Guideline developers must:

> comply with the principles about disclosure of interests contained in this document in order to meet Standard A6 of the *NHMRC Procedures and requirements for meeting the 2011 NHMRC standard for clinical practice guidelines*.

1.10 Legal Protection of Members

Legal protection is provided to DVA HREC members involved in ethical review of research for any liability 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.

While acting for the DVA HREC, 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 last updated on 19 August 2003.

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 will meet at least every three months, on the second Friday of February, May, August and November unless the Chair in consultation with the Secretariat otherwise determines. Meeting dates are to be advertised on the Department's Intranet and Internet webpage, and notified to participants and senior departmental staff by email.

2.2 Attendance at Meetings

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

2.3 Transport Costs

The Department will arrange transport and accommodation for interstate DVA HREC members to attend meetings or will reimburse reasonable costs in line with departmental Chief Executive Instructions. Reasonable costs may include mileage, parking fees, bus fares, etc for local or interstate DVA HREC members to attend meetings.

The Department does not reimburse the cost to researchers of attending meetings (see Section 3.18 of these guidelines - *Presentation of Research Protocols*).

2.4 Agendas

Agenda papers and research protocols are distributed to committee members no less than seven (7) days before the meeting (so as received 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.

Standing items for each meeting agenda:

- Opening and welcome, including any late business, apologies and conflicts of interest;
- Committee membership;
- Minutes of Previous Meeting;
- Out of Session Considerations;
- Re-Submissions
- Revised Proposals
- Protocol Changes;
- New Proposals;
- Progress/Final Reports on approved proposals;
- Other Business.

The views of DVA's Privacy Officer on each research proposal being considered are always made available at or before each meeting.

2.5 Minutes

Minutes are written up as soon as practicable after the meeting and are sent to committee members with the agenda and papers for the subsequent meeting. The minutes are considered and approved, with or without amendment, at the subsequent meeting. The Chair shall certify the approved minutes as a trua and accurate record of the meeting.

2.6 Timely Consideration

Proposals submitted to a DVA HREC meeting will generally be considered at that meeting. If additional information is required from the Researcher, he/she will be requested to provide such information. Researchers, and DVA sponsors, may be asked to make themselves available for contact during the meeting as appropriate.

If a proposal cannot be dealt with at the scheduled meeting, the DVA HREC will decide when and how it should be considered and the Researcher notified.

Urgent research proposals received between normal 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 is subject to ratification at the next formal meeting of the DVA HREC.

2.7 Methods of Decision Making

The DVA HREC will endeavour to reach decisions by consenus. This need not involve unanimity but failure to achieve consenus may require an extension of time for reconsideration of the research protocol and/or amendments thereto.

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 DVA HREC 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 DVA HREC has seen all documents and material used to inform the potential participants including information sheets, consent forms, questionnaires, letters of invitation, internet content and promotional material;
- 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 1988* 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 in accordance with the principles of Section 95 of the *Privacy Act 1988*;
- the value of the initiative as a scientific exercise compared with the inconvenience visited on the proposed research participants who are members of the veteran or relevant defence communities.

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 DVA HREC requires further information on the proposal, the Principal Researcher will be advised of this 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 research;

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 research;

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

2.10 Expedited Review for Minimal Risk Research

On receipt of a research 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 DVA HREC.

2.11 Survey Fatigue

DVA monitors 'survey fatigue' among members of the veteran or relevant defence communities and the DVA HREC supports this as it may impact on the integrity of information required of and received from participants. DVA aims to avoid having the same groups surveyed more than once every two years.

It should be noted, the Department of Defence closely monitors research participant fatigue among their cohort. It is recommended researchers also discuss with the Department of Defence any research involving serving defence personnel.

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, if applicable.

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.

It is recommended researchers also discuss with the Department of Defence any data requirements for research involving serving defence personnel, as this may not be held by DVA.

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. DVA HREC 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 Conflicts 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 or relevant defence communities 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 research 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 or relevant defence communities being targeted because of their veteran affiliation, this includes family members and carers;
- research involving the use of collected veterans' data for a purpose, or by a person, other than for which/whom it was collected, including DVA owned data for mail-out lists, treatment usage, medical records of the former Repatriation General Hospitals;
- research involving the use of any data which contains means for identification of veterans, e.g. re-identification through a code, by data linkage or by nature of the sample size or other information collected – see Section 3.5 below;
- variation to a DVA HREC 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 DVA HREC;
- research involving the general public which coincidentally includes members of the veteran or relevant defence communities who are NOT being specifically included because of their veteran affiliation;
- research on collections of data already in the public domain;
- aggregated data which does NOT provide the means for re-identification of an individual veteran (care needs to be taken in assessing this – see Sections 3.4 and 3.5 below); and
- literature reviews or scoping studies for development and design of research protocols, which do not involve any of the activities detailed above for which approval should be sought.

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 3.17 of these guidelines). All submissions should be sent to the DVA HREC Secretariat at ethics.committee@dva.gov.au.

3.4 Data Identifiability

Data are pieces of information, which can be collected or derived from a variety of sources including from interviews, questionnaires, focus groups, personal histories, clinical, social and other observations, and from human tissue such as blood, bone, muscle and urine.

Data may be collected, stored or disclosed in three mutually exclusive forms:

- *individually identifiable data*: where the identity of a specific individual can reasonably be ascertained. Examples of identifiers include the individual's name, image, date of birth or address;
- *re-identifiable data*: from which identifiers have been removed but it remains possible to re-identify a specific individual by, for example, using the code or linking different data sets (data linkage); and
- *non-identifiable data*: which have never been labelled with individual identifiers or from which identifiers have been permanently removed and by means of which no specific individual can be identified. A subset of non-identifiable data are those that can be linked with other data so it can be known that they are about the same data subject although the person's identity remains unknown.

The National Statement avoids the term '*de-identified data*', as its meaning is unclear. While it is sometimes used to refer to a record that cannot be linked to an individual ('non-identifiable'), it may also be used to refer to a record in which identifying information has been removed but the means still exist to re-identify the individual. Where the term 'de-identified data' is used, the DVA HREC will endeavour to establish precisely which of these possible meanings is intended.

3.5 Data Matching/ Data Linkage

Researchers should inform the DVA HREC if they intend to link or match data from another source, what the other source is, and what data is going to be obtained from the other source.

The ability for individuals to be indentified from matched or linked data should be a consideration in all applications to DVA HREC.

3.6 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.

3.7 New Submissions

The DVA HREC has a pro forma - available for download from 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 3.4 to 3.18 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 DVA HREC.

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. Researchers should discuss this with the relevant Deputy Commissioner in their state or their DVA Sponsor.

3.8 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 meaning 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 IPPs, 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 IPP(s) in question.

All substantive submissions and protocol changes are referred to the DVA Privacy Officer for comment prior to each meeting. The DVA HREC gives due consideration to these comments at its meetings and in the course of out of session approval processes.

3.9 Informed Consent (Participant Information and Consent)

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

Information on the following matters should be communicated to participants prior to their involvement in research:

a) the purpose, methods, risks and possible benefits of the research;
b) what precisely will be required of or from the participant;
c) any alternatives to participation;
d) how the research will be monitored;
e) provision of services to participants adversely affected by the research;
f) contact details of the researcher and person to receive complaints (see Section 3.15 below);
g) how privacy and confidentiality will be protected;
h) the Mazengarb Clause (see Section 3.10 below);
i) any implications of withdrawal, and whether it will be possible to withdraw data (care should be taken to ensure this is communicated in an impartial, non-threatening manner);
j) the amounts and sources of funding for the research (see Section 3.11 below);
k) financial or other relevant declarations of interests of researchers, sponsors or institutions;
l) any payments to participants (see Section 3.13 and 3.14 below);
m) the likelihood and form of dissemination of the research results, including publication;
n) any expected benefits to the wider community;
o) any other relevant information, including research-specific information required under other chapters of the National Statement.

This information must be presented in ways suitable to each participant, although it will most often take the shape of a Participant Information and Consent Forms (PICF).

Whether or not participants will be identified, research should be designed so that each participant's voluntary and informed decision to participate will be clearly established. DVA HREC prefers that a signed Consent Form is obtained from each participant. An opting-out process, i.e. "No response from you will be considered consent", does not constitute "voluntary" nor "informed" consent from participants.

3.10 Cognitive Impairment

Researchers should inform DVA HREC how they propose to determine the capacity of a person with a cognitive impairment, an intellectual disability, or a mental illness to consent to the research. This information should include:

(a) how the decision about the person's capacity will be made;
(b) who will make that decision;
(c) the criteria that will be used in making the decision; and

(d) during the course of the research, the process for reviewing the participant's capacity to consent and to participate in the research.

Consideration should be given to a possible or perceived conflict of interest. Researchers may wish to consider the professional opinion of a qualified and independent person in validating the ability of the participant to give consent.

It is obligatory if a person is under guardianship or enduring power of attorney that the guardianship board knows and the power of attorney is informed. If there is a guardianship rule, that person may also need to be present during contact with the participant.

3.11 Letter of First Contact

The DVA HREC has a standing requirement that, if a proposed project is sponsored by the Department of Veterans' Affairs and involves face to face or telephone contact with members of the veteran or relevant defence communities, 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 or relevant defence communities are contacted in the first instance by mail (e.g. a mail survey), a letter of first contact must accompany the mail-out.

The letter of first contact will be signed by the Principal Medical Adviser, the Repatriation Commissioner or a Deputy Commissioner where the study is confined to their particular state.

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

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. The Mazengarb Clause should appear in **bold type** on the letter of first contact and/or participant information and consent forms. It may 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 appropriate and approved, the clause may be extended to include reference to other government agencies.

3.13 Limited Contact

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 authorised by DVA HREC or the participant themselves.

Where the invitation is refused, contact must cease immediately.

3.14 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.

3.15 Payments for Participants

It is generally unacceptable to DVA HREC for researchers 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. Where applicable, advice of endorsement by the DVA sponsor should also be included.

3.16 Lotteries

DVA HREC does not in principle approve any form of lottery as an incentive for research participants on the grounds that:

a) it is shown to be ineffective in recruiting participants;
b) it is shown to be in breach of the principles of ethical research, in particular the principles of equity and justice; and
c) lotteries with substantial prizes may distort the judgement of putative applicants regarding their decision to give Informed Consent.

3.17 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 Human Research Ethics Committee within the Principal Researcher's organisation, if applicable, or to the DVA HREC via:

DVA HREC Secretariat
Department of Veterans' Affairs
PO Box 9998
CANBERRA ACT 2601
ethics.committee@dva.gov.au

3.18 Minimising Duplication of Ethical Review

It should be noted that approval by another Human Research Ethics Committee in addition to the DVA HREC may be necessary for some research proposals. Approval by another Human Research 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;
- 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.

3.19 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.

In accordance with the data management requirements outlined in Section 3.24, students must not remove research data from the approved location and must not copy, email or download data to laptops or other electronic mobile devices. Unauthorised use of data by a person or for a purpose other than that approved by DVA HREC and permitted under the *Privacy Act 1988* is strictly prohibited.

3.20 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, if required.

3.21 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 DVA HREC 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.

3.22 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 an approval. The Principal Researcher will be formally notified of any conditions of approval by the DVA HREC at the time of approval.

3.23 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.

3.24 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. Shorter-term studies are required to submit a final report with research findings as soon as practicable after completion of the study.

Progress reports are designed to assure the DVA HREC that the research protocol as approved has not changed and that the project is progressing satisfactorily. Researchers should use the template available from the DVA HREC website to provide advice as to:

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

In addition, final reports on completed studies should include advice as to:

- any benefits resulting from completed research and any other avenues of research this may have opened up as a result;
- the arrangements for the study data (i.e. particulars of long or short term storage, destruction. See also Section 3.24 below);
- conclusion of other research requirements such as contractual arrangements with DVA; and
- an electronic and hard copy of research results and any published findings.

3.25 Abandoned Research

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

3.26 Data Management

All data supplied by DVA and collected on behalf of DVA, remains the property of the Commonwealth as represented by DVA.

Researchers must ensure data is collected, stored, accessed, amended, used and, where necessary, disclosed or destroyed in accordance with the Information Privacy Principles (IPPs) and the protocols approved by DVA HREC.

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.

Research files are to be kept in locked cabinets at the location approved by DVA HREC and accessed only by authorised individuals. 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 by DVA HREC.

Unauthorised access and/or use of data by a person or for a purpose other than that approved by DVA HREC and permitted under the *Privacy Act 1988* is strictly prohibited.

At the completion of the approved research, data must be either returned, stored or destroyed in accordance with approved protocols, the *Archives Act 1983* and in accordance with any contractual requirements.

3.27 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.

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Australian Government

Department of Veterans' Affairs

DVA Human Research Ethics Committee

ADMINISTRATIVE GUIDELINES

DVA HREC Administrative Guidelines
Version 3.0
July 2008

CONTENTS

1. DVA Human Research Ethics Committee (DVA HREC)

1.1 Role of Committee

1.2 Authority of Committee

1.3 Terms of Reference

1.4 Membership

1.5 Appointment

1.6 Expert Advice

1.7 Authority of Chair

1.8 Members' Responsibilities

1.9 Conflict of Interest

1.10 Legal Protection of Members

2. Administrative Procedures

2.1 Frequency of Meeting

2.2 Attendance at Meetings

2.3 Transport Costs

2.4 Agendas

2.5 Minutes

2.6 Timely Consideration

2.7 Methods of Decision Making

2.8 Notification of Decision

2.9 Decision Types

2.10 Expedited Review for Minimal Risk Research

2.11 Survey Fatigue

2.12 Fees

2.13 Access to Funding Not Automatic

2.14 Access to Data Not Automatic

2.15 Monitoring

2.16 Complaints Procedure

2.17 Record Keeping

2.18 Confidentiality of Protocols

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

3. Researchers

3.1 Researchers' Responsibilities

3.2 Conflict of Interest

3.3 When Do you Need Ethics Approval

3.4 Submission Types

3.5 New Submissions

3.6 Privacy Considerations

3.7 Declaration of Funding Sources

3.8 Payments for Participants

3.9 Standing Requirement – Contact with Members of the Veteran Community (Mazengarb Clause)

3.10 Signature Block on Letter of First Contact

3.11 Complaints / Adverse Occurrences

3.12 Minimising Duplication of Ethical Review

3.13 Student Research

3.14 Presentation of Research Protocols

3.15 Approved in Principle

3.16 Condition of Approval

3.17 Change to Protocol

3.18 Reporting Requirements

3.19 Abandoned Research

3.20 Withdrawal of Approval

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 confidentially 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.

Australian Government

Department of Veterans' Affairs

DVA Human Research Ethics Committee

ADMINISTRATIVE GUIDELINES

DVA HREC Administrative Guidelines
Version 3.0
July 2008

CONTENTS

1. DVA Human Research Ethics Committee (DVA HREC)

1.1 Role of Committee

1.2 Authority of Committee

1.3 Terms of Reference

1.4 Membership

1.5 Appointment

1.6 Expert Advice

1.7 Authority of Chair

1.8 Members' Responsibilities

1.9 Conflict of Interest

1.10 Legal Protection of Members

2. Administrative Procedures

2.1 Frequency of Meeting

2.2 Attendance at Meetings

2.3 Transport Costs

2.4 Agendas

2.5 Minutes

2.6 Timely Consideration

2.7 Methods of Decision Making

2.8 Notification of Decision

2.9 Decision Types

2.10 Expedited Review for Minimal Risk Research

2.11 Survey Fatigue

2.12 Fees

2.13 Access to Funding Not Automatic

2.14 Access to Data Not Automatic

2.15 Monitoring

2.16 Complaints Procedure

2.17 Record Keeping

2.18 Confidentiality of Protocols

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

3. Researchers

3.1 Researchers' Responsibilities

3.2 Conflict of Interest

3.3 When Do you Need Ethics Approval

3.4 Submission Types

3.5 New Submissions

3.6 Privacy Considerations

3.7 Declaration of Funding Sources

3.8 Payments for Participants

3.9 Standing Requirement – Contact with Members of the Veteran Community (Mazengarb Clause)

3.10 Signature Block on Letter of First Contact

3.11 Complaints / Adverse Occurrences

3.12 Minimising Duplication of Ethical Review

3.13 Student Research

3.14 Presentation of Research Protocols

3.15 Approved in Principle

3.16 Condition of Approval

3.17 Change to Protocol

3.18 Reporting Requirements

3.19 Abandoned Research

3.20 Withdrawal of Approval

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 confidentially 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.

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- 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.

Australian Government

Department of Veterans' Affairs

DVA Human Research Ethics Committee

ADMINISTRATIVE GUIDELINES

DVA HREC Administrative Guidelines
Version 3.0
July 2008

CONTENTS

1. DVA Human Research Ethics Committee (DVA HREC)

1.1 Role of Committee

1.2 Authority of Committee

1.3 Terms of Reference

1.4 Membership

1.5 Appointment

1.6 Expert Advice

1.7 Authority of Chair

1.8 Members' Responsibilities

1.9 Conflict of Interest

1.10 Legal Protection of Members

2. Administrative Procedures

2.1 Frequency of Meeting

2.2 Attendance at Meetings

2.3 Transport Costs

2.4 Agendas

2.5 Minutes

2.6 Timely Consideration

2.7 Methods of Decision Making

2.8 Notification of Decision

2.9 Decision Types

2.10 Expedited Review for Minimal Risk Research

2.11 Survey Fatigue

2.12 Fees

2.13 Access to Funding Not Automatic

2.14 Access to Data Not Automatic

2.15 Monitoring

2.16 Complaints Procedure

2.17 Record Keeping

2.18 Confidentiality of Protocols

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

3. Researchers

3.1 Researchers' Responsibilities

3.2 Conflict of Interest

3.3 When Do you Need Ethics Approval

3.4 Submission Types

3.5 New Submissions

3.6 Privacy Considerations

3.7 Declaration of Funding Sources

3.8 Payments for Participants

3.9 Standing Requirement – Contact with Members of the Veteran Community (Mazengarb Clause)

3.10 Signature Block on Letter of First Contact

3.11 Complaints / Adverse Occurrences

3.12 Minimising Duplication of Ethical Review

3.13 Student Research

3.14 Presentation of Research Protocols

3.15 Approved in Principle

3.16 Condition of Approval

3.17 Change to Protocol

3.18 Reporting Requirements

3.19 Abandoned Research

3.20 Withdrawal of Approval

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 confidentially 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.

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DVA Human Research Ethics Committee

ADMINISTRATIVE GUIDELINES

Role of DVA Human Research Ethics Committee

Terms of Reference

Membership
Authority of chair
Appointment
Legal protection of members
Transport costs

Administrative Procedures
Frequency of meeting
Attendance at meetings
Preparation of agendas and minutes
Distribution of papers
Presentation of research protocols
Seeking expert advice
Timely consideration
Methods of decision making
Notification of decisions
Conditional approval
Change to protocol
Progress reports
Access to data not automatic
Monitoring
Complaints / Adverse occurrences
Discontinue research
Confidentiality of protocols
Fees
Compliance reports to the ONHMRC
Hard copy files
Expedited review for minimal risk research
Declaration of funding sources
Standing requirement – contact with members of the veteran community
Privacy considerations
APPENDIX 1 - DVA Human Research Ethics Committee Meeting dates 2000
APPENDIX 2 - Privacy Act 1988 - Information Privacy Principles
Further information
APPENDIX 3 - DVA Human Research Ethics Committee Membership
(As at 1 August 2000)
APPENDIX 4 - Study protocol
Researcher Responsibilities
Conditional approval
Change to protocol
Progress reports
Access to data not automatic
Complaints / Adverse occurrences
Discontinue research
Standing requirement – contact with members of the veteran community

DVA Human Research Ethics Committee
Administrative Guidelines

Role of DVA Human Research Ethics Committee

The primary role of an HREC is to protect the welfare and the rights of participants in research and 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 Human Research Ethics Committee 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 the veteran community has a valid scientific purpose. It considers whether, in relation to medical research, personal information that is normally protected by the Privacy Act may be dealt with in ways that may infringe the Information privacy principles detailed in the Act. The Committee also monitors 'survey fatigue' amongst veterans and how that may impact on the integrity of information required of and received from them.

The Committee takes note of all DVA surveys and requests for information relevant to it. 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 conformed to the protocol as approved.

Terms of Reference

The terms of reference, as agreed, are to:

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

  for access to Commonwealth-owned client data for specific medical research;
- notify the researcher in writing of Committee decisions and of any conditions applying;
- provide regular monitoring of research projects until completion to ensure that they continue to conform with the approval given;
- remain informed on NHMRC ethical guidelines and, where possible, developments and new requirements through publications, journals, and conferences; and
- provide the NHMRC data from its records as required.

More recently, responding to requests from Departmental officers, the role of the Committee has expanded to oversight all unsolicited surveys and requests brought to its attention for medical information directed at the veteran community.

Membership
The National Statement on Ethical Conduct of Research Involving Humans published June 1999 as signed by the Minister for Health and Aged Care, Minister for Education, Training and Youth Affairs and Minister for Industry, Science and Resources is the basis for the DVA HREC operation.

The minimum membership of an HREC is seven members, being men and women comprising:

(a) a chairperson;
(b) at least two lay people, one man and one woman;
(c) at least one member 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.

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 amended applications 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 project review forms;
- approve changes to Committee procedure in special circumstances, within the framework of the requirements of the national Statement;
- provide advice to staff on Committee functions and on ethical issues in research; and
- perform other tasks as delegated by the Committee

Appointment
The Repatriation Commission makes appointments to the DVA HREC, each appointment being advised in writing, including specification of the category of membership and include a copy of these guidelines and of the National Statement. There is no fixed term for an appointment. Members are appointed as individuals for their expertise, and not in any representative capacity.

The Chairperson may appoint a stand-in for a member when considered necessary.

Legal protection of members
Members who are Commonwealth employees or officials will be provided legal assistance in accordance with the provisions of Appendix E to the Legal Services Directions which took effect on 1 September 1999.

Members who are not Commonwealth employees or officials will be provided legal assistance for legal costs in accordance with the provisions of Finance Circular 1997/19 "Indemnification of persons acting in an official capacity on behalf of the Commonwealth or Commonwealth Bodies" while acting for the DVA HREC.

Depending on the circumstances such members may also be “employees” for the purposes of the Safety, Rehabilitation and Compensation Act 1988.

Transport costs
The Department will arrange transport and accommodation for interstate members to attend meetings or will reimburse reasonable costs in line with departmental procedures.

Administrative Procedures

Frequency of meeting
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 will be advertised on the DVA Intranet and Internet.

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.

Preparation of agendas and minutes
Two weeks before the regular meetings a Stateline email is sent out requesting details projects that need DVA HREC consideration.

Agenda papers always include:

- Research proposals subject to Guidelines on the Protection of Privacy in the Conduct of Medical Research; and
- Research proposals not subject to Guidelines on the Protection of Privacy in the Conduct of Medical Research

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

Distribution of papers
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 Express Post or by courier, if necessary, to ensure timely delivery.

Presentation of research protocols
The DVA HREC has a proforma (Appendix 4) that each researcher must complete in order to submit a research project. Additional supporting papers and especially proposed consent forms must also be submitted.

The DVA HREC encourages researchers to attend the meeting when their project is being considered in order to answer any questions that may arise. This mostly occurs with projects from within the Department and particularly from National Office.

Seeking expert advice
The Committee may appoint special advisers with expertise in their particular field as required, to address individual study protocols outside the Committee’s knowledge base.

Timely consideration
All proposals submitted to the bimonthly 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.

A researcher should advise DVA HREC when a research protocol has been changed, so that the Committee can consider this change at its earliest opportunity.

Urgent research proposals received between normal bi-monthly meetings may be considered out of session. (See distribution of papers). Committee members responses will be accepted by phone, facsimile or email. The approval of an out of session proposal will be reviewed at the next formal meeting.

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 less than full attendance is achieved, the Chairperson must be satisfied, before a decision is reached, that all members have received all the papers and have had an opportunity to contribute their views, have them recorded and 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 the 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, questionaries and letters of invitation.
- 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 Principle of the Privacy Act that might be breached in the course of the proposed research, survey etc as applied to in-house requests.
- The identification and consideration of matters referred to in the NHMRC guidelines to show whether the proposed research involving disclosure of personal information by a Commonwealth 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 the agency.
- The value of the initiative as a scientific exercise compared with the inconvenience visited on the veteran.

Notification of decisions
The principal researcher 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.

The letter will also include requirements placed on the researcher by way of reporting:
- any changes to the approved protocol;
- the contact for any complaints – normally the Committee coordinator as a first point of contact; and
- the requirements for regular progress reports.

Conditional approval
In cases where a proposal is approved subject to certain conditions or modifications, the specified matters must be resolved to the satisfaction of the Committee prior to the commencement of the study. All changes must be documented in writing and forwarded to the DVA HREC Coordinator as soon as practicable.

Change to protocol
Principal researchers are required to advise the DVA HREC in writing if their research protocol as approved 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.

Progress reports
Principal researchers are requested to provide the DVA HREC with progress reports 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. Apart from that requirement, there is no specific format for a progress or final report.

Access to data not automatic
It needs to be made clear to the researcher that the NHMRC guidelines do not override the decision making process of Commonwealth 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.

Monitoring
Frequency of monitoring should reflect the degree of risk to participants in the research project. As a minimum the DVA HREC shall review all proposals at least annually. Reports from principal researchers should include:
- progress to date or outcome if project completed;
- maintenance and security of records;
- compliance to agreed protocol; and
- compliance to the conditions of approval

The HREC shall as a condition of approval of each protocol require researchers to 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
- unforseen events that might effect continued ethical acceptability of the project.

The DVA HREC shall as a condition of approval of each protocol require researchers to advise the DVA HREC, giving reasons should the project be discontinued before the expected completion date.

Complaints / Adverse occurrences
Participants, researchers and institutions are to be advised that the first point of contact for complaints is the DVA HREC coordinator. The consent form signed by participants should include the name and contact number of this contact when first provided to participants.

Discontinue research
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 recommend that the research project be suspend or discontinued.

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 Committee coordinator at the next meeting from proper disposal in accordance with departmental procedures for the destruction of classified material. Committee files are to be kept in lockable cabinets.

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

Compliance reports to the Office of National Health and Medical Research Council (ONHMRC)

The 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;
- monitor procedures in place and any problems encountered; and
- complaints procedures and number of complaints.

Hard copy files
In addition to any electronic records and registers maintained, a registry file will be raised for each meeting and it will include all documentation relating to items considered at that meeting. Out-of-session activity will be filed on the file for the next meeting as out-of-session decisions are ratified at the next meeting. Policy matters are handled on different files. Policy and other general matters are filed on other files raised for that purpose.

Expedited review for minimal risk research
On receipt of a study protocol that initially appears to be of minimal risk, clarification is sought from the chairperson to decide whether the protocol requires full consideration

the whole Committee or sub-Committee. Any decisions made in this manner will be confirmed at the next full meeting of the Committee.

Declaration of funding sources
A researcher is required to disclose the amounts, sources or potential sources of funding for research and must declare affiliation or financial interest when proposing and when reporting the research.

Standing requirement – contact with members of the veteran community
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. Where members of the veteran community are contacted in the first instance by mail (eg a mail survey), such a consent letter must accompany the mail-out. In addition, such letters 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 paragraph should appear in **bold type** and the covering letter ideally should be in 14 point font.

The wording of the standard paragraph 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, <u>will not</u> be passed to the Department of Veterans' Affairs. Your answers will not in any way affect your pension, benefits or any health services you are entitled to from DVA. If you wish, you can discontinue your participation in this study at any time.**

Signature block
The letter to the veteran will be signed by either the principal medical Officer Dr Graeme Killer AO, or the appropriate Deputy Commissioner.

Privacy considerations
Part B 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 a Commonwealth agency whose research involves personal information obtained from a Commonwealth agency, the disclosure of which might involve a breach of one or more IPPs.

The NHMRC defines 'personal information' (as defined in the *Guidelines for the Protection of Privacy in Medical Research under Section 95 of the Privacy Act 1988*. NHMRC. March 2000) 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.

If necessary, the principal researcher should seek approval in principle for research from the relevant DVA state office before submitting an application to the DVA HREC. This should be referred to in a covering letter to the DVA HREC. The state office 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 in your State.

APPENDIX 1 - DVA Human Research Ethics Committee Meeting dates 2002

The DVA Human Research Ethics Committee meets every two months, usually on the second Friday of every second month starting in February.

Note that this schedule cannot always be followed and meeting dates may change from time to time. It is advisable to check with the DVA HREC Coordinator well in advance of scheduled dates.

The scheduled meeting dates for 2001 are:

- 8 FEBRUARY
- 12 APRIL
- 14 JUNE
- 9 AUGUST
- 11 OCTOBER
- 13 DECEMBER

APPENDIX 2 - Privacy Act 1988 - Information Privacy Principles

Principle 1 - Manner and purpose of collection of personal information

1. Personal information shall not be collected by a collector for inclusion in a record or in a generally available publication unless:
   (a) the information is collected for a purpose that is a lawful purpose directly related to a function or activity of the collector; and
   (b) the collection of the information is necessary for or directly related to that purpose.
2. Personal information shall not be collected by a collector by unlawful or unfair means.

Principle 2 - Solicitation of personal in formation from individual concerned

Where:

(a) a collector collects personal information for inclusion in a record or in a generally available publication; and
(b) the information is solicited by the collector from the individual concerned;

the collector shall take such steps (if any) as are, in the circumstances, reasonable to ensure that, before the information is collected or, if that is not practicable, as soon as practicable after the information is collected, the individual concerned is generally aware of:

(c) the purpose for which the information is being collected;
(d) if the collection of the information is authorised or required by or under law - the fact that the collection of the information is so authorised or required; and
(e) any person to whom, or any body or agency to which, it is the collector's usual practice to disclose personal information of the kind so collected, and (if known by the collector) any person to whom, or any body or agency to which, it is the usual practice of that first mentioned person, body or agency to pass on that information.

Principle 3 - Solicitation of personal information generally

Where:

(a) a collector collects personal information for inclusion in a record or in a generally available publication; and
(b) the information is solicited by the collector;

the collector shall take such steps (if any) as are, in the circumstances, reasonable to ensure that, having regard to the purpose for which the information is collected:

(c) the information collected is relevant to that purpose and is up to date and complete; and
(d) the collection of the information does not intrude to an unreasonable extent upon the personal affairs of the individual concerned.

Principle 4 - Storage and security of personal information

A record-keeper who has possession or control of a record that contains personal information shall ensure:

(a) that the record is protected, by such security safeguards as it is reasonable in the circumstances to take, against loss, against unauthorised access, use, modification or disclosure, and against other misuse, and
(b) that if it is necessary for the record to be given to a person in connection with the provision of a service to the record-keeper, everything reasonably within the power of the record-keeper is done to prevent unauthorised use or disclosure of information contained in the record

Principle 5 - Information relating to records kept by record-keeper

1. A record-keeper who has possession or control of records that contain personal information shall, subject to clause 2 of this Principle, take such steps as are, in the circumstances, reasonable to enable any person to ascertain:
   (a) whether the record-keeper has possession or control of any records that contain personal information; and
   (b) if the record-keeper has possession or control of a record that contains such information:
      (i) the nature of that information;
      (ii) the main purposes for which that information is used; and
      (iii) the steps that the person should take if the person wishes to obtain access to the record.
2. A record-keeper is not required under clause I of this Principle to give a person information if the record-keeper is required or authorised to refuse to give that information to the person under the applicable provisions of any law of the Commonwealth that provides for access by persons to documents.

3. A record-keeper shall maintain a record setting out:
   (a) the nature of the records of personal information kept by or on behalf of the record-keeper;
   (b) the purpose for which each type of record is kept;
   (c) the classes of individuals about whom records are kept;
   (d) the period for which each type of record is kept;
   (e) the persons who are entitled to have access to personal information contained in the records and the conditions under which they are entitled to have that access; and
   (f) the steps that should be taken by persons wishing to obtain access to that information.

4. A record-keeper shall:
   (a) make the record maintained under clause 3 of this Principle available for inspection by members of the public; and
   (b) give the Commissioner, in the month of June in each year, a copy of the record so maintained.

Principle 6 - Access to records containing personal information

Where a record-keeper has possession or control of a record that contains personal information, the individual concerned shall be entitled to have access to that record, except to the extent that the record-keeper is required or authorised to refuse to provide the individual with access to that record under the applicable provisions of any law of the Commonwealth that provides for access by persons to documents.

Principle 7 - Alteration of records containing personal information

1. A record-keeper who has possession or control of a record that contains personal information shall take such steps (if any), by way of making appropriate corrections, deletions and additions as are, in the circumstances, reasonable to ensure that the record:
   (a) is accurate; and
   (b) is having regard to the purpose for which the information was collected or is to be used and to any purpose that is directly related to that purpose, relevant, up to date, complete and not misleading.
2. The obligation imposed on a record-keeper by clause I is subject to any applicable limitation in a law of the commonwealth that provides a right to require the correction or amendment of documents.
3. Where:

(a) the record-keeper of a record containing personal information is not willing to amend that record, by making a correction deletion or addition, in accordance with a request by the individual concerned; and
(b) no decision or recommendation to the effect that the record should be amended wholly or partly in accordance with that request has been made under the applicable provisions of a law of the Commonwealth;

the record-keeper shall, if so requested by the individual concerned, take such steps (if any) as are reasonable in the circumstances to attach to the record any statement provided by that individual of the correction, deletion or addition sought.

Principle 8 - Record-keeper to check accuracy etc of personal information before use

A record-keeper who has possession or control of a record that contains personal information shall not use that information without taking such steps (if any) as are, in the circumstances, reasonable to ensure that, having regard to the purpose for which the information is proposed to be used, the information is accurate, up to date and complete

Principle 9 - Personal information to be used only for relevant purposes

A record-keeper who has possession or control of a record that contains personal information shall not use the information except for a purpose for which the information is relevant.

Principle 10 - Limits on use of personal information

1. A record-keeper who has possession or control of a record that contains personal information that was obtained for a particular purpose shall not use the information for any other purpose unless:
   (a) the individual concerned has consented to use of the information for that other purpose;
   (b) the record-keeper believes on reasonable grounds that use of the information for that other purpose is necessary to prevent or lessen a serious and imminent threat to the life or health of the individual concerned or another person;
   (c) use of the information for that other purpose is required or authorised by or under law;
   (d) use of the information for that other purpose is reasonably necessary for enforcement of the criminal law or of a law imposing a pecuniary penalty, or for the protection of the public revenue; or
   (e) the purpose for which the information is used is directly related to the purpose for which the information was obtained.

Where personal information is used for enforcement of the criminal law or of a law imposing a pecuniary penalty, or for the protection of the public revenue, the record-keeper shall include in the record containing that information a note of that use.

Principle 11 - Limits on disclosure of personal information

1. A record-keeper who has possession or control of a record that contains personal information shall not disclose the information to a person, body or agency (other than the individual concerned) unless:
   (a) the individual concerned is reasonably likely to have been aware, or made aware under Principle 2, that information of that find is usually passed to that person, body or agency;
   (b) the individual concerned has consented to the disclosure;
   (c) the record-keeper believes on reasonable grounds that the disclosure is necessary to prevent or lessen a serious and imminent threat to the life or health of the individual concerned or of another person;
   (d) the disclosure is required or authorised by or under law; or

(e) the disclosure is reasonably necessary for the enforcement of the criminal law or of a law imposing a pecuniary penalty, or for the protection of the public revenue.

2. Where personal information is disclosed for the purposes of enforcement of the criminal law or of a law imposing a pecuniary penalty, or for the purpose of the protection of the public revenue, the record-keeper shall include in the record containing that information a note of the disclosure.
3. A person, body or agency to whom personal information is disclosed under clause I of this Principle shall not use or disclose the information for a purpose other than the purpose for which the information was given to the person, body or agency.

PRIVACY COMMISSIONER, GPO Box 5218, SYDNEY, NSW, 2001
Privacy Hotline 1800 023 985 Telephone (02) 9284 9600 TTY 1800 620 241 Fax (02) 281 9666

Further information
http://www.privacy.gov.au/news/p6_4_1.html#Principles

APPENDIX 3 - DVA Human Research Ethics Committee Membership

(As at 1 August 2000)

Dr Tony s 47F	Chairman
Mrs Helen s 47F	Laywoman
Mr David s 47F	Layman
Monsignor John s 47F	Minister of religion
Mr Graeme s 47F	Lawyer
Professor Donald s 47F	Medical graduate with research experience
Dr G s 47F K s 47F	Practicing medical professional
Mr Ken s 47F	Relevant expert (statistical)
Mr Barry s 47F	Ex officio
Mr Wayne s 47F	Ex officio
Georgina s 47F	DVAEC Coordinator

APPENDIX 4 - Study protocol

DVA HUMAN RESEARCH ETHICS COMMITTEE
Application for consideration of proposed research involving contact with the veteran community or access to data held by DVA

Part A: STUDY PROTOCOL

1.	**Study title** *(short title preferred)*	
2.	**Principal researcher**'s surname	
3.	Given name(s)	
4.	Address	
		Postcode
5.	Telephone No.	Fax No.
	( )	( )
6.	Email address	

Other investigators (include details for all personnel with access to study data) **Investigator 1**		
7.	Surname	
8.	Given name(s)	
9.	Address	
		Postcode
10.	Telephone No.	Fax No.
	( )	( )
11.	Email address	

	Investigator 2	
12.	Surname	
13.	Given name(s)	
14.	Address	
		Postcode
15.	Telephone No.	Fax No.
	( )	( )
16.	Email address	
If more than 2 investigators, please copy above table rows here and include relevant details.		

17.	Study site where data will be managed.
18.	Study site where fieldwork will occur.

19.	Provide a brief description of the proposed study *(include a statement on the purpose of the study and its expected benefits, and a plain English description of its aims and objectives in a form that can be readily understood by those members of the DVA HREC who are not scientifically or medically trained).*
NB	**The information provided in Questions 20 to 24 should provide greater detail and reflect that provided at Question 19. Attach extra pages if necessary.**
20.	Please give details of study aims and objectives.
21.	Please give details of study methodology.
22.	What is the sample size and selection?
23.	What is the proposed method of data analysis?
24.	What is the projected timetable?
25.	What data will be required from DVA?
26.	What data will be required from other sources?
27.	If personal information is to be used rather than de-identified data, state why this is necessary.
28.	If it will be necessary to approach members of the veteran community directly, please state how you propose to go about it (Include details of how potential participants will be identified and recruited, how initial contact will be made and who will make contact, and how consent will be obtained. **Attach copies of letters, consent forms, survey instruments or other pertinent documentation as appropriate**).
29.	State whether you consider members of the veteran community are likely to experience any possible adverse effects or raise issues through their participation in the study. If so, outline the measures you have adopted to manage this (for example, referral to counselling or other appropriate service, provision of additional information and reviews by independent person).
30.	What are the particular benefits in the study for the veteran community?
31.	General supporting comments (include here any information that might assist the DVA HREC to better assess your application).

32. Details of funding sources for this research proposal (amount and source).

Part B: PRIVACY CONSIDERATIONS

The Commonwealth Privacy Commissioner under section 95 of the Privacy Act 1988 has approved guidelines for the protection of privacy in the conduct of medical research.

The guidelines apply to a researcher not employed by a Commonwealth agency where that research involves personal information obtained from a Commonwealth agency, the disclosure of which might involve a breach of one or more Information Privacy Principles (IPPs).

However, as the NHMRC recommends that the guidelines be applied to all research involving the use of personal information, DVA officers with responsibility for undertaking studies of the veteran community on behalf of the Department should also complete this part.

In order that your proposal can be assessed in accordance with the privacy guidelines, please address each of the following points P1-P11.

P1	State the specific uses to which the personal information acquired or developed during the study will be put (refer IPP 9 and IPP 10).
P2	State the estimated time of retention of the personal information so acquired (Good scientific practice entails the retention of original data for periods of at least 5 years).
P3	State the security procedures that will be applied to the personal information so acquired (data should be protected against loss, unauthorised access, use, modification and disclosure and against other misuse including unauthorised use or disclosure of information by a third party).
P4	State how the data so acquired will be stored and controlled (data should be retained in accordance with good scientific practice and in a form that is at least as secure as it was in the sources from which the data were obtained).
P5	List the personnel with access to the personal information.
P6	List the safeguards that will be applied to protect personal information that will be made available to third parties including other researchers (if applicable).
P7	State what will be done with the personal information on completion of the study (include the proposed method of disposal of the personal information having regard to the Archives Act 1983 for Commonwealth records and the legislative requirements of a state or territory).

P8	State whether the final results will be published (include details of intended publications if known).
P9	State whether the final results will be made available to other researchers and if so, in what form.
P 10	State the safeguards that will be applied to protect personal information disclosed by the Department of Veterans' Affairs. (This applies to personal information such as a mailing list or other means of identifying veterans or war widows for the purpose of contacting them, identifiable data on health service usage and so on. Please also make note, if applicable, of the terms of any disclosure agreement that has been entered into between DVA and the principal researcher that governs limits on use and disclosure of personal information obtained from DVA).
P 11	Does the proposed research involve a breach of any of the IPPs? If so, state the IPP(s) concerned and provide your reasons for believing that the public interest in the outcome of the proposed research outweighs to a substantial degree the public interest in maintaining the protection of personal privacy.

Part C: AGREEMENT

This agreement relates to a study titled ……..…(Insert short title)……..……

I, ... acknowledge that the information contained in this form is true and accurate, and I undertake to ensure the security and privacy of the personal information entrusted to me in accordance with the arrangements described in this form.

.....…/ /
Principal Researcher

Researcher Responsibilities

Conditional approval
In cases where a proposal is approved subject to certain conditions or modifications, the specified matters must be resolved to the satisfaction of the Committee prior to the commencement of the study. All changes must be documented in writing and forwarded to the DVA HREC Coordinator as soon as practicable.

Change to protocol
Principal researchers are required to advise the DVA HREC in writing if their research protocol as approved 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.

Progress reports
Principal researchers are requested to provide the DVA HREC with progress reports 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. Apart from that requirement, there is no specific format for a progress or final report.

Access to data not automatic
It needs to be made clear to the researcher that the NHMRC guidelines do not override the decision making process of Commonwealth 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.

Complaints / Adverse occurrences
Participants, researchers and institutions are to be advised that the first point of contact for complaints is the DVA HREC coordinator. The consent form signed by participants should include the name and contact number of this contact when first provided to participants. The current nominated DVA HREC contact is Georgina Dudzinski, (02) 6289 6280, DVA HREC Coordinator, PO Box 21, WODEN ACT 2606.

Discontinue research
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 recommend that the research project be suspend or discontinued.

Standing requirement – contact with members of the veteran community
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. Where members of the veteran community are contacted in the first instance by mail (eg a mail survey), such a consent letter must accompany the mail-out. In addition, such letters 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 paragraph should appear in **bold type** and the covering letter ideally should be in 14 point font.

The wording of the standard paragraph 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, <u>will not</u> be passed to the Department of Veterans' Affairs. Your answers will not in any way affect your pension, benefits or any health services you are entitled to from DVA. If you wish, you can discontinue your participation in this study at any time.**

DVA Human Research Ethics Committee

ADMINISTRATIVE GUIDELINES

Role of DVA Human Research Ethics Committee

Terms of Reference

Membership
Authority of chair
Appointment
Legal protection of members
Transport costs

Administrative Procedures
Frequency of meeting
Attendance at meetings
Preparation of agendas and minutes
Distribution of papers
Presentation of research protocols
Seeking expert advice
Timely consideration
Methods of decision making
Notification of decisions
Conditional approval
Change to protocol
Progress reports
Access to data not automatic
Monitoring
Complaints / Adverse occurrences
Discontinue research
Confidentiality of protocols
Fees
Compliance reports to the ONHMRC
Hard copy files
Expedited review for minimal risk research
Declaration of funding sources
Standing requirement – contact with members of the veteran community
Privacy considerations
APPENDIX 1 - DVA Human Research Ethics Committee Meeting dates 2000
APPENDIX 2 - Privacy Act 1988 - Information Privacy Principles
Further information
APPENDIX 3 - DVA Human Research Ethics Committee Membership
(As at 1 December 1999)
APPENDIX 4 - Study protocol
Researcher Responsibilities
Conditional approval
Change to protocol
Progress reports
Access to data not automatic
Complaints / Adverse occurrences
Discontinue research
Standing requirement – contact with members of the veteran community

DVA Human Research Ethics Committee
Administrative Guidelines

Role of DVA Human Research Ethics Committee

The primary role of an HREC is to protect the welfare and the rights of participants in research and 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 Human Research Ethics Committee 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 the veteran community has a valid scientific purpose. It considers whether, in relation to medical research, personal information that is normally protected by the Privacy Act may be dealt with in ways that may infringe the Information privacy principles detailed in the Act. The Committee also monitors 'survey fatigue' amongst veterans and how that may impact on the integrity of information required of and received from them.

The Committee takes note of all DVA surveys and requests for information relevant to it. 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 conformed to the protocol as approved.

Terms of Reference

The terms of reference, as agreed, are to:

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

  for access to Commonwealth-owned client data for specific medical research;
- notify the researcher in writing of Committee decisions and of any conditions applying;
- provide regular monitoring of research projects until completion to ensure that they continue to conform with the approval given;
- remain informed on NHMRC ethical guidelines and, where possible, developments and new requirements through publications, journals, and conferences; and
- provide the NHMRC data from its records as required.

More recently, responding to requests from Departmental officers, the role of the Committee has expanded to oversight all unsolicited surveys and requests brought to its attention for medical information directed at the veteran community.

Membership
The National Statement on Ethical Conduct of Research Involving Humans published June 1999 as signed by the Minister for Health and Aged Care, Minister for Education, Training and Youth Affairs and Minister for Industry, Science and Resources is the basis for the DVA HREC operation.

The minimum membership of an HREC is seven members, being men and women comprising:

(a) a chairperson;
(b) at least two lay people, one man and one woman;
(c) at least one member 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.

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 amended applications 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 project review forms;
- approve changes to Committee procedure in special circumstances, within the framework of the requirements of the national Statement;
- provide advice to staff on Committee functions and on ethical issues in research; and
- perform other tasks as delegated by the Committee

Appointment
The Repatriation Commission makes appointments to the DVA HREC, each appointment being advised in writing, including specification of the category of membership and include a copy of these guidelines and of the National Statement. There is no fixed term for an appointment. Members are appointed as individuals for their expertise, and not in any representative capacity.

The Chairperson may appoint a stand-in for a member when considered necessary.

Legal protection of members
Members who are Commonwealth employees or officials will be provided legal assistance in accordance with the provisions of Appendix E to the Legal Services Directions which took effect on 1 September 1999.

Members who are not Commonwealth employees or officials will be provided legal assistance for legal costs in accordance with the provisions of Finance Circular 1997/19 "Indemnification of persons acting in an official capacity on behalf of the Commonwealth or Commonwealth Bodies" while acting for the DVA HREC.

Depending on the circumstances such members may also be “employees” for the purposes of the Safety, Rehabilitation and Compensation Act 1988.

Transport costs
The Department will arrange transport and accommodation for interstate members to attend meetings or will reimburse reasonable costs in line with departmental procedures.

Administrative Procedures

Frequency of meeting
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 will be advertised on the DVA Intranet and Internet.

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.

Preparation of agendas and minutes
Two weeks before the regular meetings a Stateline email is sent out requesting details projects that need DVA HREC consideration.

Agenda papers always include:

- Research proposals subject to Guidelines on the Protection of Privacy in the Conduct of Medical Research; and
- Research proposals not subject to Guidelines on the Protection of Privacy in the Conduct of Medical Research

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

Distribution of papers
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 Express Post or by courier, if necessary, to ensure timely delivery.

Presentation of research protocols
The DVA HREC has a proforma (Appendix 4) that each researcher must complete in order to submit a research project. Additional supporting papers and especially proposed consent forms must also be submitted.

The DVA HREC encourages researchers to attend the meeting when their project is being considered in order to answer any questions that may arise. This mostly occurs with projects from within the Department and particularly from National Office.

Seeking expert advice
The Committee may appoint special advisers with expertise in their particular field as required, to address individual study protocols outside the Committee’s knowledge base.

Timely consideration
All proposals submitted to the bimonthly 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.

A researcher should advise DVA HREC when a research protocol has been changed, so that the Committee can consider this change at its earliest opportunity.

Urgent research proposals received between normal bi-monthly meetings may be considered out of session. (See distribution of papers). Committee members responses will be accepted by phone, facsimile or email. The approval of an out of session proposal will be reviewed at the next formal meeting.

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 less than full attendance is achieved, the Chairperson must be satisfied, before a decision is reached, that all members have received all the papers and have had an opportunity to contribute their views, have them recorded and 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 the 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, questionaries and letters of invitation.
- 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 Principle of the Privacy Act that might be breached in the course of the proposed research, survey etc as applied to in-house requests.
- The identification and consideration of matters referred to in the NHMRC guidelines to show whether the proposed research involving disclosure of personal information by a Commonwealth 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 the agency.
- The value of the initiative as a scientific exercise compared with the inconvenience visited on the veteran.

Notification of decisions
The principal researcher 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.

The letter will also include requirements placed on the researcher by way of reporting:
- any changes to the approved protocol;
- the contact for any complaints – normally the Committee coordinator as a first point of contact; and
- the requirements for regular progress reports.

Conditional approval
In cases where a proposal is approved subject to certain conditions or modifications, the specified matters must be resolved to the satisfaction of the Committee prior to the commencement of the study. All changes must be documented in writing and forwarded to the DVA HREC Coordinator as soon as practicable.

Change to protocol
Principal researchers are required to advise the DVA HREC in writing if their research protocol as approved 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.

Progress reports
Principal researchers are requested to provide the DVA HREC with progress reports 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. Apart from that requirement, there is no specific format for a progress or final report.

Access to data not automatic
It needs to be made clear to the researcher that the NHMRC guidelines do not override the decision making process of Commonwealth 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.

Monitoring
Frequency of monitoring should reflect the degree of risk to participants in the research project. As a minimum the DVA HREC shall review all proposals at least annually. Reports from principal researchers should include:
- progress to date or outcome if project completed;
- maintenance and security of records;
- compliance to agreed protocol; and
- compliance to the conditions of approval

The HREC shall as a condition of approval of each protocol require researchers to 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
- unforseen events that might effect continued ethical acceptability of the project.

The DVA HREC shall as a condition of approval of each protocol require researchers to advise the DVA HREC, giving reasons should the project be discontinued before the expected completion date.

Complaints / Adverse occurrences
Participants, researchers and institutions are to be advised that the first point of contact for complaints is the DVA HREC coordinator. The consent form signed by participants should include the name and contact number of this contact when first provided to participants.

Discontinue research
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 recommend that the research project be suspend or discontinued.

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 Committee coordinator at the next meeting from proper disposal in accordance with departmental procedures for the destruction of classified material. Committee files are to be kept in lockable cabinets.

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

Compliance reports to the Office of National Health and Medical Research Council (ONHMRC)

The 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;
- monitor procedures in place and any problems encountered; and
- complaints procedures and number of complaints.

Hard copy files
In addition to any electronic records and registers maintained, a registry file will be raised for each meeting and it will include all documentation relating to items considered at that meeting. Out-of-session activity will be filed on the file for the next meeting as out-of-session decisions are ratified at the next meeting. Policy matters are handled on different files. Policy and other general matters are filed on other files raised for that purpose.

Expedited review for minimal risk research
On receipt of a study protocol that initially appears to be of minimal risk, clarification is sought from the chairperson to decide whether the protocol requires full consideration

the whole Committee or sub-Committee. Any decisions made in this manner will be confirmed at the next full meeting of the Committee.

Declaration of funding sources
A researcher is required to disclose the amounts, sources or potential sources of funding for research and must declare affiliation or financial interest when proposing and when reporting the research.

Standing requirement – contact with members of the veteran community
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. Where members of the veteran community are contacted in the first instance by mail (eg a mail survey), such a consent letter must accompany the mail-out. In addition, such letters 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 paragraph should appear in **bold type** and the covering letter ideally should be in 14 point font.

The wording of the standard paragraph 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, <u>will not</u> be passed to the Department of Veterans' Affairs. Your answers will not in any way affect your pension, benefits or any health services you are entitled to from DVA. If you wish, you can discontinue your participation in this study at any time.**

Signature block
The letter to the veteran will be signed by either the principal medical Officer Dr Graeme Killer AO, or the appropriate Deputy Commissioner.

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 a Commonwealth agency whose research involves personal information obtained from a Commonwealth agency, the disclosure of which might involve a breach of one or more IPPs.

The NHMRC defines 'personal information' (as defined in the *Guidelines for the Protection of Privacy in Medical Research under Section 95 of the Privacy Act 1988*. NHMRC - March 2000) to mean information or an opinion (including information or an opinion forming part of a database), whether true of 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.

If necessary, the principal researcher should seek approval in principle for research from the relevant DVA state office before submitting an application to the DVA HREC. This should be referred to in a covering letter to the DVA HREC. The state office 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 in your State.

APPENDIX 1 - DVA Human Research Ethics Committee Meeting dates 2001

The DVA Human Research Ethics Committee meets every two months, usually on the second Friday of every second month starting in February.

Note that this schedule cannot always be followed and meeting dates may change from time to time. It is advisable to check with the DVA HREC Coordinator well in advance of scheduled dates.

The scheduled meeting dates for 2001 are:

- 9 FEBRUARY
- 20 APRIL
- 8 JUNE
- 10 AUGUST
- 12 OCTOBER
- 7 DECEMBER

APPENDIX 2 - Privacy Act 1988 - Information Privacy Principles

Principle 1 - Manner and purpose of collection of personal information

1. Personal information shall not be collected by a collector for inclusion in a record or in a generally available publication unless:
   (a) the information is collected for a purpose that is a lawful purpose directly related to a function or activity of the collector; and
   (b) the collection of the information is necessary for or directly related to that purpose.
2. Personal information shall not be collected by a collector by unlawful or unfair means.

Principle 2 - Solicitation of personal in formation from individual concerned

Where:

(a) a collector collects personal information for inclusion in a record or in a generally available publication; and
(b) the information is solicited by the collector from the individual concerned;

the collector shall take such steps (if any) as are, in the circumstances, reasonable to ensure that, before the information is collected or, if that is not practicable, as soon as practicable after the information is collected, the individual concerned is generally aware of:

(c) the purpose for which the information is being collected;
(d) if the collection of the information is authorised or required by or under law - the fact that the collection of the information is so authorised or required; and
(e) any person to whom, or any body or agency to which, it is the collector's usual practice to disclose personal information of the kind so collected, and (if known by the collector) any person to whom, or any body or agency to which, it is the usual practice of that first mentioned person, body or agency to pass on that information.

Principle 3 - Solicitation of personal information generally

Where:

(a) a collector collects personal information for inclusion in a record or in a generally available publication; and
(b) the information is solicited by the collector;

the collector shall take such steps (if any) as are, in the circumstances, reasonable to ensure that, having regard to the purpose for which the information is collected:

(c) the information collected is relevant to that purpose and is up to date and complete; and
(d) the collection of the information does not intrude to an unreasonable extent upon the personal affairs of the individual concerned.

Principle 4 - Storage and security of personal information

A record-keeper who has possession or control of a record that contains personal information shall ensure:

(a) that the record is protected, by such security safeguards as it is reasonable in the circumstances to take, against loss, against unauthorised access, use, modification or disclosure, and against other misuse, and
(b) that if it is necessary for the record to be given to a person in connection with the provision of a service to the record-keeper, everything reasonably within the power of the record-keeper is done to prevent unauthorised use or disclosure of information contained in the record

Principle 5 - Information relating to records kept by record-keeper

1. A record-keeper who has possession or control of records that contain personal information shall, subject to clause 2 of this Principle, take such steps as are, in the circumstances, reasonable to enable any person to ascertain:
   (a) whether the record-keeper has possession or control of any records that contain personal information; and
   (b) if the record-keeper has possession or control of a record that contains such information:
      (i) the nature of that information;
      (ii) the main purposes for which that information is used; and
      (iii) the steps that the person should take if the person wishes to obtain access to the record.
2. A record-keeper is not required under clause I of this Principle to give a person information if the record-keeper is required or authorised to refuse to give that information to the person under the applicable provisions of any law of the Commonwealth that provides for access by persons to documents.

3. A record-keeper shall maintain a record setting out:
   (a) the nature of the records of personal information kept by or on behalf of the record-keeper;
   (b) the purpose for which each type of record is kept;
   (c) the classes of individuals about whom records are kept;
   (d) the period for which each type of record is kept;
   (e) the persons who are entitled to have access to personal information contained in the records and the conditions under which they are entitled to have that access; and
   (f) the steps that should be taken by persons wishing to obtain access to that information.

4. A record-keeper shall:
   (a) make the record maintained under clause 3 of this Principle available for inspection by members of the public; and
   (b) give the Commissioner, in the month of June in each year, a copy of the record so maintained.

Principle 6 - Access to records containing personal information

Where a record-keeper has possession or control of a record that contains personal information, the individual concerned shall be entitled to have access to that record, except to the extent that the record-keeper is required or authorised to refuse to provide the individual with access to that record under the applicable provisions of any law of the Commonwealth that provides for access by persons to documents.

Principle 7 - Alteration of records containing personal information

1. A record-keeper who has possession or control of a record that contains personal information shall take such steps (if any), by way of making appropriate corrections, deletions and additions as are, in the circumstances, reasonable to ensure that the record:
   (a) is accurate; and
   (b) is having regard to the purpose for which the information was collected or is to be used and to any purpose that is directly related to that purpose, relevant, up to date, complete and not misleading.
2. The obligation imposed on a record-keeper by clause I is subject to any applicable limitation in a law of the commonwealth that provides a right to require the correction or amendment of documents.
3. Where:

(a) the record-keeper of a record containing personal information is not willing to amend that record, by making a correction deletion or addition, in accordance with a request by the individual concerned; and
(b) no decision or recommendation to the effect that the record should be amended wholly or partly in accordance with that request has been made under the applicable provisions of a law of the Commonwealth;

the record-keeper shall, if so requested by the individual concerned, take such steps (if any) as are reasonable in the circumstances to attach to the record any statement provided by that individual of the correction, deletion or addition sought.

Principle 8 - Record-keeper to check accuracy etc of personal information before use

A record-keeper who has possession or control of a record that contains personal information shall not use that information without taking such steps (if any) as are, in the circumstances, reasonable to ensure that, having regard to the purpose for which the information is proposed to be used, the information is accurate, up to date and complete

Principle 9 - Personal information to be used only for relevant purposes

A record-keeper who has possession or control of a record that contains personal information shall not use the information except for a purpose for which the information is relevant.

Principle 10 - Limits on use of personal information

1. A record-keeper who has possession or control of a record that contains personal information that was obtained for a particular purpose shall not use the information for any other purpose unless:
   (a) the individual concerned has consented to use of the information for that other purpose;
   (b) the record-keeper believes on reasonable grounds that use of the information for that other purpose is necessary to prevent or lessen a serious and imminent threat to the life or health of the individual concerned or another person;
   (c) use of the information for that other purpose is required or authorised by or under law;
   (d) use of the information for that other purpose is reasonably necessary for enforcement of the criminal law or of a law imposing a pecuniary penalty, or for the protection of the public revenue; or
   (e) the purpose for which the information is used is directly related to the purpose for which the information was obtained.

Where personal information is used for enforcement of the criminal law or of a law imposing a pecuniary penalty, or for the protection of the public revenue, the record-keeper shall include in the record containing that information a note of that use.

Principle 11 - Limits on disclosure of personal information

1. A record-keeper who has possession or control of a record that contains personal information shall not disclose the information to a person, body or agency (other than the individual concerned) unless:
   (a) the individual concerned is reasonably likely to have been aware, or made aware under Principle 2, that information of that find is usually passed to that person, body or agency;
   (b) the individual concerned has consented to the disclosure;
   (c) the record-keeper believes on reasonable grounds that the disclosure is necessary to prevent or lessen a serious and imminent threat to the life or health of the individual concerned or of another person;
   (d) the disclosure is required or authorised by or under law; or

(e) the disclosure is reasonably necessary for the enforcement of the criminal law or of a law imposing a pecuniary penalty, or for the protection of the public revenue.

2. Where personal information is disclosed for the purposes of enforcement of the criminal law or of a law imposing a pecuniary penalty, or for the purpose of the protection of the public revenue, the record-keeper shall include in the record containing that information a note of the disclosure.
3. A person, body or agency to whom personal information is disclosed under clause I of this Principle shall not use or disclose the information for a purpose other than the purpose for which the information was given to the person, body or agency.

PRIVACY COMMISSIONER, GPO Box 5218, SYDNEY, NSW, 2001
Privacy Hotline 1800 023 985 Telephone (02) 9284 9600 TTY 1800 620 241 Fax (02) 281 9666

Further information
http://www.privacy.gov.au/news/p6_4_1.html#Principles

APPENDIX 3 - DVA Human Research Ethics Committee Membership

(As at 1 January 2001)

Dr Tony s 47F
DVA State Office
PO Box 359
PYMBLE NSW 2073

Chairman
Phone: s 47F
Fax: (02) 9213 7349 (Janet s 47F
(02) 9488 2289 (Neringah Hospital)
Mobile: s 47F

Mrs Helen s 47F
War Widows' Guild of Australia
PO Box 3398
MANUKA ACT 2603

Laywoman
Phone: (s 47F)
Fax: (02) 6295 0178 (w)

s 47F

Mr David s 47F
PO Box 3819
WESTON CREEK ACT 2611

Layman
Phone: s 47F

Monsignor John s 47F
St Patricks Presbytery
1 Ford Street
WANGARATTA VIC 3677

Minister of religion
Phone: s 47F
Fax: (03) 5721 2305

Mr Graeme s 47F
DVA Contract Advisory Unit
Department of Veterans' Affairs

Lawyer
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Professor Donald MacLellan
Department of Surgery
The Canberra Hospital
PO Box 11
WODEN ACT 2606

Medical graduate with research experience
Phone: s 47F
Fax: (02) 6244 3042
Email: s 47F
Secretary: Stephanie s 47F

Dr Gs 47F**K**s 47F
Principal Medical Adviser
Department of Veterans' Affairs

Practicing medical professional
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Fax: (02) 6289 4721
Email: s 47F
Secretary: May s 47F

Mr Ken s 47F
Assistant Director
Research & Development
Department of Veterans' Affairs

Relevant expert (statistical)
Phone: s 47F
Fax: (02) 6289 4776
Email: s 47F

Mr Barry s 47F
Branch Head
Housing & Aged Care
Department of Veterans' Affairs

Ex officio
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Email: s 47F
Secretary: Lil s 47F

Mr Wayne s 47F
Director
Research & Development
Department of Veterans' Affairs

Ex officio
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Fax: (02) 6289 4776
Email: s 47F

Georgina s 47F
Research & Development
Department of Veterans' Affairs

DVAEC Coordinator
Phone: s 47F
Fax: (02) 6289 4776
Email: s 47F

APPENDIX 4 - Study protocol

DVA HUMAN RESEARCH ETHICS COMMITTEE
Application for consideration of proposed research involving contact with the veteran community or access to data held by DVA

Part 1: STUDY PROTOCOL

1.	Study title (Short title preferred):
Short title:	

2.	Principal researcher (Include address and contact phone number):
Name:	
Address:	
Phone:	
Mobile:	
email:	

3.	Other investigators (Include names and contact details for all personnel with access to study data):

4.	Study site (A: where data will be managed; B: where fieldwork will occur):
A:	
B:	

5.	Provide a brief description of the proposed study (Include a statement on the purpose of the study and its expected benefits, and a plain English description of its aims and objectives in a form that can be readily understood by those members of the DVA HREC who are not scientifically or medically trained):

6.	Provide details of the proposed study including aims and objectives, methodology, sample size and selection, proposed method of data analysis, and project timetable (Attach extra pages if necessary. The information provided here should provide greater detail reflect that provided at Q5 but in greater detail)

7.	What data will be required (A: from DVA; B: from other sources):
A:	
B:	

8.	If personal information is to be used rather than de-identified data, state why this is necessary:

9.	If it will be necessary to approach members of the veteran community directly, please state how you propose to go about it (Include details of how potential participants will be identified and recruited, how initial contact will be made and who will make contact, and how consent will be obtained. Attach copies of letters, consent forms, survey instruments or other pertinent documentation as appropriate):

10.	State whether you consider members of the veteran community are likely to experience any possible adverse effects or raise issues through their participation in the study. If so, outline the measures you have adopted to manage this (For example, referral to counselling or other appropriate service, provision of additional information, reviews by independent person etc):

11.	What are the particular benefits in the study for the veteran community?

12.	General supporting comments (Include here any information that might assist the DVA HREC to better assess your application):

13.	Details of funding sources for this research proposal (amount and source).

Part 2: PRIVACY CONSIDERATIONS

The Commonwealth Privacy Commissioner under section 95 of the Privacy Act 1988 has approved guidelines for the protection of privacy in the conduct of medical research.

The guidelines apply to a researcher not employed by a Commonwealth agency where that research involves personal information obtained from a Commonwealth agency, the disclosure of which might involve a breach of one or more Information Privacy Principles (IPPs).

However, as the NHMRC recommends that the guidelines be applied to all research involving the use of personal information, DVA officers with responsibility for undertaking studies of the veteran community on behalf of the Department should also complete this part.

In order that your proposal can be assessed in accordance with the privacy guidelines, please address each of the following points P1-P10:

P1	State the specific uses to which the personal information acquired or developed during the study will be put (Refer IPP 9 and IPP 10):

P2	State the estimated time of retention of the personal information so acquired (Good scientific practice entails the retention of original data for periods of at least 5 years):

P3	State the security procedures that will be applied to the personal information so acquired (Data should be protected against loss, unauthorised access, use, modification and disclosure and against other misuse including unauthorised use or disclosure of information by a third party):

P4	State how the data so acquired will be stored and controlled (Data should be retained in accordance with good scientific practice and in a form that is at least as secure as it was in the sources from which the data were obtained):

P5	List the personnel with access to the personal information:

P6	List the safeguards that will be applied to protect personal information that will be made available to third parties including other researchers (if applicable):

P7	State what will be done with the personal information on completion of the study (Include the proposed method of disposal of the personal information having regard to the Archives Act 1983 for Commonwealth records and the legislative requirements of a state or territory):

P8	State whether the final results will be: A. published (Include details of intended publications if known) B. made available to other researchers and if so, in what form:
A:	
B:	

P9	State the safeguards that will be applied to protect personal information disclosed by the Department of Veterans' Affairs (This applies to personal information such as a mailing list or other means of identifying veterans or war widows for the purpose of contacting them, identifiable data on health service usage and so on. Please also make note, if applicable, of the terms of any disclosure agreement that has been entered into between DVA and the principal researcher that governs limits on use and disclosure of personal information obtained from DVA):

P10	Does the proposed research involve a breach of any of the IPPs? If so, state the IPP(s) concerned and provide your reasons for believing that the public interest in the outcome of the proposed research outweighs to a substantial degree the public interest in maintaining the protection of personal privacy:

Part 3: AGREEMENT

This agreement relates to a study titled ……..…(Insert short title)……..……

I, ... acknowledge that the information contained in this form is true and accurate, and I undertake to ensure the security and privacy of the personal information entrusted to me in accordance with the arrangements described in this form.

.....
Principal Researcher

Researcher Responsibilities

Conditional approval
In cases where a proposal is approved subject to certain conditions or modifications, the specified matters must be resolved to the satisfaction of the Committee prior to the commencement of the study. All changes must be documented in writing and forwarded to the DVA HREC Coordinator as soon as practicable.

Change to protocol
Principal researchers are required to advise the DVA HREC in writing if their research protocol as approved 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.

Progress reports
Principal researchers are requested to provide the DVA HREC with progress reports 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. Apart from that requirement, there is no specific format for a progress or final report.

Access to data not automatic
It needs to be made clear to the researcher that the NHMRC guidelines do not override the decision making process of Commonwealth 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.

Complaints / Adverse occurrences
Participants, researchers and institutions are to be advised that the first point of contact for complaints is the DVA HREC coordinator. The consent form signed by participants should include the name and contact number of this contact when first provided to participants. The current nominated DVA HREC contact is Georgina Dudzinski, (02) 6289 6280, DVA HREC Coordinator, PO Box 21, WODEN ACT 2606.

Discontinue research
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 recommend that the research project be suspend or discontinued.

Standing requirement – contact with members of the veteran community
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. Where members of the veteran community are contacted in the first instance by mail (eg a mail survey), such a consent letter must accompany the mail-out. In addition, such letters 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 paragraph should appear in **bold type** and the covering letter ideally should be in 14 point font.

The wording of the standard paragraph 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, <u>will not</u> be passed to the Department of Veterans' Affairs. Your answers will not in any way affect your pension, benefits or any health services you are entitled to from DVA. If you wish, you can discontinue your participation in this study at any time.**

DVA Human Research Ethics Committee

ADMINISTRATIVE GUIDELINES

Role of DVA Human Research Ethics Committee

Terms of Reference

Membership
Authority of chair
Appointment
Legal protection of members
Transport costs

Administrative Procedures
Frequency of meeting
Attendance at meetings
Preparation of agendas and minutes
Distribution of papers
Presentation of research protocols
Seeking expert advice
Timely consideration
Methods of decision making
Notification of decisions
Conditional approval
Change to protocol
Progress reports
Access to data not automatic
Monitoring
Complaints / Adverse occurrences
Discontinue research
Confidentiality of protocols
Fees
Compliance reports to the ONHMRC
Hard copy files
Expedited review for minimal risk research
Declaration of funding sources
Standing requirement – contact with members of the veteran community
Privacy considerations
APPENDIX 1 - DVA Human Research Ethics Committee Meeting dates 2000
APPENDIX 2 - Privacy Act 1988 - Information Privacy Principles
Further information
APPENDIX 3 - DVA Human Research Ethics Committee Membership
(As at 1 August 2000)
APPENDIX 4 - Study protocol
Researcher Responsibilities
Conditional approval
Change to protocol
Progress reports
Access to data not automatic
Complaints / Adverse occurrences
Discontinue research
Standing requirement – contact with members of the veteran community

DVA Human Research Ethics Committee
Administrative Guidelines

Role of DVA Human Research Ethics Committee

The primary role of an HREC is to protect the welfare and the rights of participants in research and 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 Human Research Ethics Committee 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 the veteran community has a valid scientific purpose. It considers whether, in relation to medical research, personal information that is normally protected by the Privacy Act may be dealt with in ways that may infringe the Information privacy principles detailed in the Act. The Committee also monitors 'survey fatigue' amongst veterans and how that may impact on the integrity of information required of and received from them.

The Committee takes note of all DVA surveys and requests for information relevant to it. 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 conformed to the protocol as approved.

Terms of Reference

The terms of reference, as agreed, are to:

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

  for access to Commonwealth-owned client data for specific medical research;
- notify the researcher in writing of Committee decisions and of any conditions applying;
- provide regular monitoring of research projects until completion to ensure that they continue to conform with the approval given;
- remain informed on NHMRC ethical guidelines and, where possible, developments and new requirements through publications, journals, and conferences; and
- provide the NHMRC data from its records as required.

More recently, responding to requests from Departmental officers, the role of the Committee has expanded to oversight all unsolicited surveys and requests brought to its attention for medical information directed at the veteran community.

Membership
The National Statement on Ethical Conduct of Research Involving Humans published June 1999 as signed by the Minister for Health and Aged Care, Minister for Education, Training and Youth Affairs and Minister for Industry, Science and Resources is the basis for the DVA HREC operation.

The minimum membership of an HREC is seven members, being men and women comprising:

(a) a chairperson;
(b) at least two lay people, one man and one woman;
(c) at least one member 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.

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 amended applications 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 project review forms;
- approve changes to Committee procedure in special circumstances, within the framework of the requirements of the national Statement;
- provide advice to staff on Committee functions and on ethical issues in research; and
- perform other tasks as delegated by the Committee

Appointment
The Repatriation Commission makes appointments to the DVA HREC, each appointment being advised in writing, including specification of the category of membership and include a copy of these guidelines and of the National Statement. There is no fixed term for an appointment. Members are appointed as individuals for their expertise, and not in any representative capacity.

The Chairperson may appoint a stand-in for a member when considered necessary.

Legal protection of members
Members who are Commonwealth employees or officials will be provided legal assistance in accordance with the provisions of Appendix E to the Legal Services Directions which took effect on 1 September 1999.

Members who are not Commonwealth employees or officials will be provided legal assistance for legal costs in accordance with the provisions of Finance Circular 1997/19 "Indemnification of persons acting in an official capacity on behalf of the Commonwealth or Commonwealth Bodies" while acting for the DVA HREC.

Depending on the circumstances such members may also be “employees” for the purposes of the Safety, Rehabilitation and Compensation Act 1988.

Transport costs
The Department will arrange transport and accommodation for interstate members to attend meetings or will reimburse reasonable costs in line with departmental procedures.

Administrative Procedures

Frequency of meeting
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 will be advertised on the DVA Intranet and Internet.

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.

Preparation of agendas and minutes
Two weeks before the regular meetings a Stateline email is sent out requesting details projects that need DVA HREC consideration.

Agenda papers always include:

- Research proposals subject to Guidelines on the Protection of Privacy in the Conduct of Medical Research; and
- Research proposals not subject to Guidelines on the Protection of Privacy in the Conduct of Medical Research

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

Distribution of papers
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 Express Post or by courier, if necessary, to ensure timely delivery.

Presentation of research protocols
The DVA HREC has a proforma (Appendix 4) that each researcher must complete in order to submit a research project. Additional supporting papers and especially proposed consent forms must also be submitted.

The DVA HREC encourages researchers to attend the meeting when their project is being considered in order to answer any questions that may arise. This mostly occurs with projects from within the Department and particularly from National Office.

Seeking expert advice
The Committee may appoint special advisers with expertise in their particular field as required, to address individual study protocols outside the Committee’s knowledge base.

Timely consideration
All proposals submitted to the bimonthly 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.

A researcher should advise DVA HREC when a research protocol has been changed, so that the Committee can consider this change at its earliest opportunity.

Urgent research proposals received between normal bi-monthly meetings may be considered out of session. (See distribution of papers). Committee members responses will be accepted by phone, facsimile or email. The approval of an out of session proposal will be reviewed at the next formal meeting.

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 less than full attendance is achieved, the Chairperson must be satisfied, before a decision is reached, that all members have received all the papers and have had an opportunity to contribute their views, have them recorded and 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 the 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, questionaries and letters of invitation.
- 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 Principle of the Privacy Act that might be breached in the course of the proposed research, survey etc as applied to in-house requests.
- The identification and consideration of matters referred to in the NHMRC guidelines to show whether the proposed research involving disclosure of personal information by a Commonwealth 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 the agency.
- The value of the initiative as a scientific exercise compared with the inconvenience visited on the veteran.

Notification of decisions
The principal researcher 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.

The letter will also include requirements placed on the researcher by way of reporting:
- any changes to the approved protocol;
- the contact for any complaints – normally the Committee coordinator as a first point of contact; and
- the requirements for regular progress reports.

Conditional approval
In cases where a proposal is approved subject to certain conditions or modifications, the specified matters must be resolved to the satisfaction of the Committee prior to the commencement of the study. All changes must be documented in writing and forwarded to the DVA HREC Coordinator as soon as practicable.

Change to protocol
Principal researchers are required to advise the DVA HREC in writing if their research protocol as approved 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.

Progress reports
Principal researchers are requested to provide the DVA HREC with progress reports 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. Apart from that requirement, there is no specific format for a progress or final report.

Access to data not automatic
It needs to be made clear to the researcher that the NHMRC guidelines do not override the decision making process of Commonwealth 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.

Monitoring
Frequency of monitoring should reflect the degree of risk to participants in the research project. As a minimum the DVA HREC shall review all proposals at least annually. Reports from principal researchers should include:
- progress to date or outcome if project completed;
- maintenance and security of records;
- compliance to agreed protocol; and
- compliance to the conditions of approval

The HREC shall as a condition of approval of each protocol require researchers to 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
- unforseen events that might effect continued ethical acceptability of the project.

The DVA HREC shall as a condition of approval of each protocol require researchers to advise the DVA HREC, giving reasons should the project be discontinued before the expected completion date.

Complaints / Adverse occurrences
Participants, researchers and institutions are to be advised that the first point of contact for complaints is the DVA HREC coordinator. The consent form signed by participants should include the name and contact number of this contact when first provided to participants.

Discontinue research
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 recommend that the research project be suspend or discontinued.

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 Committee coordinator at the next meeting from proper disposal in accordance with departmental procedures for the destruction of classified material. Committee files are to be kept in lockable cabinets.

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

Compliance reports to the Office of National Health and Medical Research Council (ONHMRC)

The 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;
- monitor procedures in place and any problems encountered; and
- complaints procedures and number of complaints.

Hard copy files
In addition to any electronic records and registers maintained, a registry file will be raised for each meeting and it will include all documentation relating to items considered at that meeting. Out-of-session activity will be filed on the file for the next meeting as out-of-session decisions are ratified at the next meeting. Policy matters are handled on different files. Policy and other general matters are filed on other files raised for that purpose.

Expedited review for minimal risk research
On receipt of a study protocol that initially appears to be of minimal risk, clarification is sought from the chairperson to decide whether the protocol requires full consideration

the whole Committee or sub-Committee. Any decisions made in this manner will be confirmed at the next full meeting of the Committee.

Declaration of funding sources
A researcher is required to disclose the amounts, sources or potential sources of funding for research and must declare affiliation or financial interest when proposing and when reporting the research.

Standing requirement – contact with members of the veteran community
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. Where members of the veteran community are contacted in the first instance by mail (eg a mail survey), such a consent letter must accompany the mail-out. In addition, such letters 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 paragraph should appear in **bold type** and the covering letter ideally should be in 14 point font.

The wording of the standard paragraph 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, <u>will not</u> be passed to the Department of Veterans' Affairs. Your answers will not in any way affect your pension, benefits or any health services you are entitled to from DVA. If you wish, you can discontinue your participation in this study at any time.**

Signature block
The letter to the veteran will be signed by either the principal medical Officer Dr Graeme Killer AO, or the appropriate Deputy Commissioner.

Privacy considerations
Part B 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 a Commonwealth agency whose research involves personal information obtained from a Commonwealth agency, the disclosure of which might involve a breach of one or more IPPs.

The NHMRC defines 'personal information' (as defined in the *Guidelines for the Protection of Privacy in Medical Research under Section 95 of the Privacy Act 1988*. NHMRC. March 2000) 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.

If necessary, the principal researcher should seek approval in principle for research from the relevant DVA state office before submitting an application to the DVA HREC. This should be referred to in a covering letter to the DVA HREC. The state office 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 in your State.

APPENDIX 1 - DVA Human Research Ethics Committee Meeting dates 2002

The DVA Human Research Ethics Committee meets every two months, usually on the second Friday of every second month starting in February.

Note that this schedule cannot always be followed and meeting dates may change from time to time. It is advisable to check with the DVA HREC Coordinator well in advance of scheduled dates.

The scheduled meeting dates for 2002 are:

- 15 FEBRUARY
- 12 APRIL
- 14 JUNE
- 9 AUGUST
- 11 OCTOBER
- 13 DECEMBER

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Australian Government

Department of Veterans' Affairs

DVA Human Research Ethics Committee

GUIDELINES

FOR RESEARCHERS

DVA HREC Guidelines for Researchers
Version 1.2
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CONTENTS

Researchers

1.1 Researchers' Responsibilities

1.2 Conflict of Interest

1.1 When Do you Need Ethics Approval

1.4 Data Identifiability

1.5 Data Matching/ Data Linkage

1.6 Submission Types

1.7 New Submissions

1.8 Privacy Considerations

1.9 Informed Consent (Participant Information and Consent)

2.1 Cognitive Impairment

2.2 Letter of First Contact

2.3 Standing Requirement—Contact with Members of the Veteran Community (Mazengarb Clause)

2.4 Limited Contact

2.5 Declaration of Funding Sources

2.6 Payments for Participants

2.7 Lotteries

2.8 Complaints/Adverse Occurrences

2.9 Minimising Duplication of Ethical Review

3.1 Student Research

3.2 Presentation of Research Protocols

3.3 Approved in Principle

3.4 Condition of Approval

3.5 Change to Protocol

3.6 Reporting Requirements

3.7 Abandoned Research

3.8 Data Management

3.9 Withdrawal of Approval

1. Researchers

1.1 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.

1.2 Conflicts 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.

1.3 When Do You Need Ethics Approval

Approval should be sought from the DVA HREC for:

- research involving a member of the veteran or relevant defence communities 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 research 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 or relevant defence communities being targeted because of their veteran affiliation, this includes family members and carers;
- research involving the use of collected veterans' data for a purpose, or by a person, other than for which/whom it was collected, including DVA owned data for mail-out lists, treatment usage, medical records of the former Repatriation General Hospitals;
- research involving the use of any data which contains means for identification of veterans, e.g. re-identification through a code, by data linkage or by nature of the sample size or other information collected – see Section 1.5 below;

- any variation to a DVA HREC 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 DVA HREC;
- research involving the general public which coincidentally includes members of the veteran or relevant defence communities who are NOT being specifically included because of their veteran affiliation;
- research on collections of data already in the public domain;
- aggregated data which does NOT provide the means for re-identification of an individual (care needs to be taken in assessing this – see Sections 1.4 and 1.5 below); and
- literature reviews or scoping studies for development and design of research protocols, which do not involve any of the activities detailed above for which approval should be sought.

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. All submissions should be sent to the DVA HREC Secretariat at ethics.committee@dva.gov.au.

1.4 Data Identifiability

Data are pieces of information, which can be collected or derived from a variety of sources including from interviews, questionnaires, focus groups, personal histories, clinical, social and other observations, and from human tissue such as blood, bone, muscle and urine.

Data may be collected, stored or disclosed in three mutually exclusive forms:

- *individually identifiable data*: where the identity of a specific individual can reasonably be ascertained. Examples of identifiers include the individual's name, image, date of birth or address;
- *re-identifiable data*: from which identifiers have been removed but it remains possible to re-identify a specific individual by, for example, using the code or linking different data sets (data linkage); and
- *non-identifiable data*: which have never been labelled with individual identifiers or from which identifiers have been permanently removed and by means of which no specific individual can be identified. A subset of non-identifiable data are those that can be linked via a linkage key with other data (so it can be known that they are about the same data subject) although the person's identity remains unknown.

The National Statement avoids the term '*de-identified data***'**, as its meaning is unclear. While it is sometimes used to refer to a record that cannot be linked to an individual ('non-identifiable'), it may also be used to refer to a record in which identifying information has been removed but the means still exist to re-identify the individual. Where the term 'de-identified data' is used, the DVA HREC will endeavour to establish precisely which of these possible meanings is intended.

1.5 Data Matching/ Data Linkage

Researchers should inform the DVA HREC if they intend to link or match data from another source, what the other source is, and what data is going to be obtained from the other source.

The ability for individuals to be indentified from matched or linked data should be a consideration in all applications to DVA HREC.

1.6 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.

1.7 New Submissions

The DVA HREC has a pro forma - available for download from 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 the Principal Researcher's signature block.

All submissions must be received by the DVA HREC Secretariat by no later than the closing date for submissions, usually at least two weeks prior to each meeting. Late submissions will only be considered with the consent of the DVA HREC Chair.

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. Researchers should discuss this with the relevant Deputy Commissioner in their state or their DVA Sponsor.

1.8 Privacy Considerations

Part 2 of the pro forma is dedicated to addressing privacy considerations described by the Australian Privacy Principles (APPs) 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 APPs.

The NHMRC defines 'personal information' as meaning 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 APPs, 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 APP(s) in question (refer to Section 95 of the *Privacy Act 1988)*.

All substantive submissions and protocol changes (where relevant) are referred to the DVA Privacy Officer for comment prior to each meeting. The DVA HREC gives due consideration to these comments at its meetings and in the course of out-of-session approval processes.

1.9 Informed Consent (Participant Information and Consent)

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

Information on the following matters should be communicated to participants prior to their involvement in research:

a) the purpose, methods, risks and possible benefits of the research;
b) what precisely will be required of or from the participant;
c) any alternatives to participation;
d) how the research will be monitored;
e) provision of services to participants adversely affected by the research;
f) contact details of the researcher and person to receive complaints (see Section 2.8 below);
g) how privacy and confidentiality will be protected;
h) the Mazengarb Clause (see Section 2.3 below);
i) any implications of withdrawal, and whether it will be possible to withdraw data (care should be taken to ensure this is communicated in an impartial, non-threatening manner);
j) the amounts and sources of funding for the research (see Section 2.5 below);
k) financial or other relevant declarations of interests of researchers, sponsors or institutions;
l) any payments to participants (see Section 2.6 and 2.7 below);
m) the likelihood and form of dissemination of the research results, including publication;
n) any expected benefits to the wider community;
o) any other relevant information, including research-specific information required under other chapters of the National Statement.

This information must be presented in ways suitable to each participant, although it will most often take the shape of a Participant Information and Consent Forms (PICF).

Whether or not participants will be identified, research should be designed so that each participant's voluntary and informed decision to participate will be clearly established. DVA HREC prefers that a signed Consent Form is obtained from each participant. An opting-out process, i.e. "No response from you will be considered consent", does not constitute "voluntary" nor "informed" consent from participants.

2.1 Cognitive Impairment

Researchers should inform DVA HREC how they propose to determine the capacity of a person with a cognitive impairment, an intellectual disability, or a mental illness to consent to the research. This information should include:

(a) how the decision about the person's capacity will be made;
(b) who will make that decision;
(c) the criteria that will be used in making the decision; and
(d) during the course of the research, the process for reviewing the participant's capacity to consent and to participate in the research.

Consideration should be given to a possible or perceived conflict of interest. Researchers may wish to consider the professional opinion of a qualified and independent person in validating the ability of the participant to give consent.

It is obligatory if a person is under guardianship or enduring power of attorney that the guardianship board knows and the power of attorney is informed. If there is a guardianship rule, that person may also need to be present during contact with the participant.

2.2 Letter of First Contact

The DVA HREC has a standing requirement that, if a proposed project is sponsored by the Department of Veterans' Affairs and involves face to face or telephone contact with members of the veteran or relevant defence communities, 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 or relevant defence communities are contacted in the first instance by mail (e.g. a mail survey), a letter of first contact must accompany the mail-out.

The letter of first contact will be signed by the Principal Medical Adviser, the Repatriation Commissioner or a Deputy Commissioner where the study is confined to their particular state.

2.3 Standing Requirement - Contact with Members of the Veteran Community (known as the Mazengarb Clause)

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. The Mazengarb Clause should appear in **bold type** on the letter of first contact and/or participant information and consent forms. It may 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 appropriate and approved, the clause may be extended to include reference to other government agencies.

2.4 Limited Contact

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 authorised by DVA HREC or the participant themselves.

Where the invitation is refused, contact must cease immediately.

2.5 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.

2.6 Payments for Participants

It is generally unacceptable to DVA HREC for researchers 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. Where applicable, advice of endorsement by the DVA sponsor should also be included.

2.7 Lotteries

DVA HREC does not in principle approve any form of lottery as an incentive for research participants on the grounds that:

a) it is shown to be ineffective in recruiting participants;
b) it is shown to be in breach of the principles of ethical research, in particular the principles of equity and justice; and
c) lotteries with substantial prizes may distort the judgement of putative applicants regarding their decision to give Informed Consent.

2.8 Complaints/Adverse Occurrences

Participants are to be advised of the first point of contact for complaints regarding the conduct of research. 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 Human Research Ethics Committee within the Principal Researcher's organisation, if applicable, or to the Chair of the DVA HREC via:

DVA HREC Secretariat
Department of Veterans' Affairs
PO Box 9998
CANBERRA ACT 2601
ethics.committee@dva.gov.au

See also the DVA HREC *Administrative Guidelines* Section 2.18 'Complaints Procedure'.

Researchers are required to **immediately** report any complaints or adverse occurrences that might affect the continued ethical acceptability of the project (see Section 3.6 below).

Where a complaint arises regarding the conduct of the DVA HREC, the Chair of the DVA HREC (via the address above) should be the initial point of contact. Where appropriate the complaint will be directed to the office of the Repatriation Commission and the Military Rehabilitation and Compensation Commission.

2.9 Minimising Duplication of Ethical Review

It should be noted that approval by another Human Research Ethics Committee in addition to the DVA HREC may be necessary for some research proposals. Approval by another Human Research 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;
- 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.

3.1 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.

In accordance with the data management requirements outlined in Section 3.8, students must not remove research data from the approved location and must not copy, email or download data to laptops or other electronic mobile devices. Unauthorised use of data by a person or for a purpose other than that approved by DVA HREC and permitted under the *Privacy Act 1988* is strictly prohibited.

3.2 Presentation of Research Protocols

The DVA HREC encourages researchers to make themselves available for contact, possibly including attendance if considered necessary, 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, if required.

3.3 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 DVA HREC prior to the commencement/continuation of the study. Responses must be documented in writing and forwarded to the DVA HREC Secretariat as soon as possible.

3.4 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 an approval. The Principal Researcher will be formally notified of any conditions of approval by the DVA HREC at the time of approval.

3.5 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.

3.6 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. Shorter-term studies are required to submit a final report with research findings as soon as practicable after completion of the study.

Progress reports are designed to assure the DVA HREC that the research protocol as approved has not changed and that the project is progressing satisfactorily. Researchers should use the template available from the DVA HREC website to provide advice as to:

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

In addition, final reports on completed studies should include advice as to:

- any benefits resulting from completed research and any other avenues of research this may have opened up as a result;
- the arrangements for the study data (i.e. particulars of long or short term storage, destruction. See also Section 3.8 below);
- conclusion of other research requirements such as contractual arrangements with DVA; and
- an electronic and hard copy of research results and any published findings.

Failure to comply with the above reporting requirements may result in withdrawal of ethical approval (see Section 3.9 below).

3.7 Abandoned Research

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

3.8 Data Management

All data supplied by DVA and collected on behalf of DVA, remains the property of the Commonwealth as represented by DVA.

Researchers must ensure data is collected, stored, accessed, amended, used and, where necessary, disclosed or destroyed in accordance with the Australian Privacy Principles (APPs) and the protocols approved by DVA HREC.

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.

Research files are to be kept in locked cabinets at the location approved by DVA HREC and accessed only by authorised individuals. 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 by DVA HREC.

Unauthorised access and/or use of data by a person or for a purpose other than that approved by DVA HREC and permitted under the *Privacy Act 1988* is strictly prohibited.

At the completion of the approved research, data must either be returned, stored or destroyed in accordance with approved protocols, the *Archives Act 1981* and in accordance with any contractual requirements.

3.9 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.

Failure to comply with the reporting requirements specified in Section 3.6 above may result in withdrawal of ethical approval.