Ethical Human Research

Overview

The dignity, rights, safety and wellbeing of participants must be the main consideration in any research study.

This DHSV policy relating to ethical human research should be read in conjunction with the Australian Code for the Responsible Conduct of Research¹, with the National Statement on Ethical Conduct in Human Research², with the DHSV Research Governance Framework and the other policies and agreements listed herein. This policy summarises the terms of reference under which the DHSV Human Research Ethics Committee (HREC) operates and all human research must abide by the HREC requirements.

DHSV formally recognises the Australian Code for the Responsible Conduct of Research (hereafter called ‘the Code’) and the National Statement on Ethical Conduct in Human Research (hereafter called ‘the National Statement’) and is committed to ensuring that any and all research undertaken by DHSV complies with the Code and National Statement.

Human research is research conducted with or about people, or their data or tissue. Research involving humans should be undertaken with commitment to merit and integrity, justice, beneficence and respect with the likely outcome of the research justifying the means by which the research was performed and any risks involved. This is described in more detail below, based on wording and information from the National Statement.

Merit and integrity

Research should be justifiable by its potential benefit. It should use methods appropriate for achieving the aims of the research proposal and should be designed and undertaken in a manner that ensures that respect for the participants is not compromised by the aims of the research, by the methodology, or by the results. It should be conducted or supervised by responsible persons with appropriate experience, qualifications and competence; and should be conducted using appropriate facilities and resources.

Research involving humans must have a commitment to searching for knowledge and understanding; following recognised code of conduct in undertaking research; honesty; and appropriate dissemination of results, regardless of the outcomes.

Justice

Justice reflects the scope and objectives of the research plan; equity in the selection, exclusion and inclusion of categories of research participants and in their recruitment; ensuring there is no unfair burden of participation placed on particular groups and no exploitation of participants; ensuring there is fair distribution of the benefits of participation in the research and fair access to the benefits of research.

¹ NHMRC Australian Code for the Responsible Conduct of Research
² NHMRC National Statement on Ethical Conduct in Human Research
Beneficence

The research must be of benefit and the likely benefit must justify any risks of harm or discomfort to participants. The likely benefit may be to the research participants, to the wider community, or to both.

Researchers are responsible for:

- taking care in the design of the research to minimise the risks of harm or discomfort to participants; clearly describing the potential benefits and risks of the research;
- ensuring the welfare of the study participants at all times.

If the research participants are unlikely to personally benefit from their involvement in the study, the risk to these participants should be lower than would be ethically acceptable where there are such likely benefits.

Respect

In human research, recognition of and respect for the intrinsic value of the person is paramount. It includes abiding by the values of research merit and integrity, justice and beneficence. Due regard must be given to the welfare, beliefs, perceptions, customs and cultural heritage, both individual and collective, of those involved in research.

Policy

This policy is intended as a guide to promote the ethical conduct of research involving humans and to ensure safety of research participants, researchers and any other people involved in the research or on whom the research impacts.

The policy applies to: all research and other relevant personnel associated with or employed by DHSV, currently or in the past, including staff, volunteers, dental students, research students, other students, and affiliates.

Procedure

The ethics application and review process (for more detail see DHSV Research Governance Framework and the flow chart at the end of this policy)

Application for ethics approval

Informed consent is central to research involving patients, service users, volunteers, or their data. The DHSV Human Research Ethics Committee (HREC) has oversight over all research projects involving humans.

Projects requiring ethics approval include surveys, interviews, certain types of observational studies, administration of tests or stimuli, collection or use of human tissue and clinical trials. Proposed studies that are deemed to be low risk, that is those which pose such little risk to participants, do not need to be reviewed by the full HREC and may be approved under delegated authority by the HREC sub-committee.

The HREC application form is found at:

Researchers must not commence their research until they have written advice that their project has ethics approval or notification that ethics approval is not required for the particular project. The Chief Investigator will receive a formal letter from the HREC advising that the project, identified by a unique HREC number, has been approved.

The HREC membership and roles (as at 5 December 2013) are:

<table>
<thead>
<tr>
<th>NAME</th>
<th>Role</th>
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<tbody>
<tr>
<td>Cameron Clark (Chair)</td>
<td>DHSV Board Member</td>
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<tr>
<td>Helene Bender</td>
<td>DHSV Board Member</td>
</tr>
<tr>
<td>Dr Paula Bacchia (Executive sponsor)</td>
<td>Senior DHSV Staff</td>
</tr>
<tr>
<td>Associate Professor Menaka Abuzar (Current researcher)</td>
<td>Senior DHSV Staff</td>
</tr>
<tr>
<td>Minister of Religion - Rev. Lynda McMinn</td>
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<tr>
<td>Dr Jacqueline Martin (Current researcher)</td>
<td>Senior DHSV Staff</td>
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<tr>
<td>Associate Professor Andrea de Silva (Current researcher)</td>
<td>Senior DHSV Staff</td>
</tr>
<tr>
<td>Associate Professor Mark Gussy (Current researcher)</td>
<td>LaTrobe University Bendigo</td>
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<tr>
<td>Ms Kavitha Chandra-Shekeran</td>
<td>Layperson</td>
</tr>
<tr>
<td>Associate Professor Rodrigo Marino (Current researcher)</td>
<td>University of Melbourne</td>
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<tr>
<td>Wendy Bacalja (Nurse)</td>
<td>Senior DHSV Staff</td>
</tr>
<tr>
<td>Mr Peter Martin</td>
<td>Layperson</td>
</tr>
<tr>
<td>Ms Christine Willshire</td>
<td>Lawyer</td>
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Review of research applications

The HREC application form is to be completed and submitted to the HREC according to the required timelines. For each research proposal that is reviewed by the HREC, a project summary report will be completed which summarises the main details and any concerns about the project. Additionally the HREC is required to report to the Applied Research Governance Committee annually for the previous calendar year's activities. Once a project has been approved, the HREC will require annual HREC project reports on the progress of the project.
**Full review**

The HREC will meet quarterly to consider full applications. The submission and meeting dates for the first half of 2014 are listed below and are subject to change.

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Venue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submission closing date</td>
<td>6 February 2014</td>
<td>Close of business</td>
</tr>
<tr>
<td>Meeting Date</td>
<td>6 March 2014</td>
<td>4 pm – 6 pm</td>
</tr>
<tr>
<td>Submission closing date</td>
<td>8 May 2014</td>
<td>Close of business</td>
</tr>
<tr>
<td>Meeting Date</td>
<td>5 June 2014</td>
<td>4 pm – 6 pm</td>
</tr>
<tr>
<td>Submission closing date</td>
<td>7 August 2014</td>
<td>Close of business</td>
</tr>
<tr>
<td>Meeting Date</td>
<td>4 September 2014</td>
<td>4 pm – 6 pm</td>
</tr>
<tr>
<td>Submission closing date</td>
<td>6 November 2014</td>
<td>Close of business</td>
</tr>
<tr>
<td>Meeting Date</td>
<td>4 December 2014</td>
<td>4 pm – 6 pm</td>
</tr>
</tbody>
</table>


The original single-sided signed application and an electronic copy must reach the HREC Secretariat by **5 pm on the deadline date** (3 weeks prior to the HREC meeting). The delivery address is:

Dental Health Services Victoria  
Executive Officer  
Human Research Ethics Committee  
Dental Health Services Victoria  
720 Swanston Street  
Carlton Vic 3053  
Fax: (03) 9341 1234

The outcome of the application will normally be advised within two to three weeks after the HREC meeting.

**Low risk review (see below)**

Low risk applications may be reviewed by delegated authority through a sub-committee of three members of the HREC, or Department Head or a DHSV Executive Member at any time. One original signed application is required and an electronic copy. It should be delivered to:
HREC Responsibility:

Committee

The HREC committee should maintain an accurate and up-to-date record of all research proposals received and reviewed, including at least the following (listed as per the National Statement):

- name/s of the institution/s to which the research approval is provided;
- project identification number/s;
- name/s of principal researcher/s;
- title of the project;
- correspondence between the review body and the researcher about the review;
- acceptance or rejection of any changes to the proposal;
- proposed date of completion of the proposal;
- formal advice of final ethical approval or non-approval, with date;
- terms and conditions, if any, of approval of any proposal;
- duration of the approval;
- name of any other review body whose opinion was considered;
- mechanisms to be used to monitor the conduct of the research; and
- relevance, if any, of the Commonwealth, State or Territory legislation or guidelines relating to privacy of personal or health information.

Individuals

Individual HREC members must be responsible for deciding whether, in his or her judgment, a proposal submitted to the review body meets the requirements of this National Statement and is ethically acceptable. Chapter five of the National Statement provides detailed information relating to the responsibilities of individual HREC members and all members should be aware of their responsibilities. As listed in the National Statement, each HREC member should:

- become familiar with the National Statement, and consult other guidelines relevant to the review of specific research proposals;
- prepare for and attend scheduled HREC meetings or provide opinions on the ethical acceptability of research proposals in the event of an approved absence from a meeting;
- attend continuing education or training programs in research ethics at least every three years.
- disclose any actual or potential conflict of interest, including any financial or other interest or affiliation, that bears on any research being assessed by the HREC.

As per NHMRC National Statement on Ethical Conduct in Human Research, each research proposal and application, the HREC should retain a copy of the application, proposal, any

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4 National Statement on Ethical Conduct in Human Research 2007 (Updated May 2013). The National Health and Medical Research Council, the Australian Research Council and the Australian Vice-Chancellors’ Committee. Commonwealth of Australia, Canberra.
amendments, participant information sheets, consent forms, correspondence and any other documentation. For each research proposal and application, the HREC should record any decisions about approval, amendment or rejection of proposals and list reasons for approval or rejection based on the National Statement.

Proposals that do not require ethics approval:
The DHSV HREC complies with the Australian Health Ethics Committee (AHEC) advice, which indicates that an appropriately planned activity can proceed without review by an HREC if:

Both:
(a) the activity is undertaken with the consent of the patients, carers, health care providers or institutions involved;

or

is consistent with National Privacy Principle 2.1(a), which states: 'An organisation must not use or disclose personal information about an individual for a purpose (the secondary purpose) other than the primary purpose of collection unless’ ... ‘both of the following apply:
(i) the secondary purpose is related to the primary purpose of collection and, if the personal information is sensitive information, directly related to the primary purpose of collection;
(ii) the individual would reasonably expect the organisation to use or disclose the information for the secondary purpose’;

And:
(b) it is an activity where participants, including patients, carers, health care providers or institutions are unlikely to suffer burden or harm (physical, mental, psychological, spiritual or social).

Researchers may be requested to provide additional information or may be requested to complete a full application if the delegated authority deems the research does not comply with the requirements for 'low risk'.

Reporting Requirements:
The DHSV HREC approval is conditional upon the research being undertaken according to the methodology provided in the application and approved. Any changes to the project which may affect the ethical undertaking of the project will invalidate the approval. Researchers must comply with the DHSV Research Reporting Policy and undertake timely reporting as required by DHSV HREC and any funding body.

All reports required by the DHSV HREC are to be submitted to:
Mrs Pamela Beeston
Tel: 9341 1328
Email: Pamela.beeston@dhsv.org.au

All reports required by the NHMRC are to be sent to

Ms Alexandra Geale  
Tel: 9341 1707  
Email: Alexandra.geale@dhsv.org.au  

These reports include annual and final scientific reports as well as annual financial reports.  

**Adverse events reporting**  
Researchers must immediately report to the HREC secretariat anything which might warrant review of ethical approval including any serious or unexpected adverse effects on participants or others involved in the project, and any unforeseen events that might impact on the ethical nature of the research study.

**Annual progress report and final report**  
Human research ethics approval is granted for a maximum period of three years providing a satisfactory annual report is submitted according to DHSV and funding guidelines. Upon completion of the research project, a brief final report is required to be submitted to the HREC by the chief or principal investigator of the project. Any issues of an ethical nature which arose during the research study should be indicated.

**Discontinuation and completion of project**  
It is a condition of approval that researchers inform the HREC if the research project is discontinued prematurely. Reasons must be given.

**Conflict of interest reporting**  
A researcher should disclose to the DHSV Human Research Ethics Committee any actual or potential conflicts of interest, including any financial or other interest or affiliation, that may have the potential or perceived potential to impact on the research.

In an report submitted as required as listed in the paragraphs above, the researcher should ensure he/she discloses any actual, potential or perceived conflicts of interest that may have or have had the potential or perceived potential to impact on the research.

**Responding to an allegation that research has not been conducted responsibly:**  
see DHSV Policy on responsible conduct of research and DHSV Governance Framework
DHSV Processing Human Research Ethics Applications

**How to Apply**

1. An HREC application approved by any HREC within Australia (attach approval letter to this document).
2. Attach completed RDHM Head of Department Form.

**OR**

If you do not have a HREC application/approval from any HREC within Australia:

   - You will need to create a login with a username and password to access the application form.
3. Attach completed RDHM Head of Department Form.

Forward completed application to:
- Pamela Beeston email: pamela.beeston@dhsv.org.au
- Phone: 9341 1328

**Is the research deemed as low risk?**

- Only foreseeable risk is no more than inconvenience
- No foreseeable risk of harm or discomfort
- Does the research involve the use of existing collections of data or records that contain only non-identifiable data about human beings?
- Evidence of other Australian Universities & Victorian Hospitals Health Services Ethics approval
- Executive Sponsor completes HREC low check list
- Confirmation by Chair & Executive Sponsor that application can be reviewed by circular resolution

**DHSV HREC Review**

- Application to be presented at HREC
- If a 'waiver of consent' is required, the project must be presented to the DHSV HREC
- If any issues need to be addressed by the Investigator, the Executive Sponsor writes to the Investigator and requests a response to issues raised by the reviewers
- Final approval for research, when it has resource implications for DHSV cannot be given until it has received DHSV budget approval.
- Statement form signed by RDHM Head of Dept. & DHSV Executive Member approving budget allocation to undertake research project and accessing of Department to be completed. Budget implications must be approved by DHSV Board.
- On receipt of final approval, the HREC Secretary notifies the Investigator of outcome of application and the relevant RDHM Head of Department.

**Circular Review**

- The HREC Secretary emails application to 2 DHSV HREC members (including 1 researcher)
- Comments are emailed back to HREC Secretary within 4 wks.
- If no issues are identified, and after final approval from the HREC Executive Sponsor, the HREC Secretary advises the Investigator that ethics approval has been granted.
- Investigator’s response is circulated to the initial reviewers. If reviewers are satisfied with response, a letter is sent advising the Investigator that ethics approval has been granted.
- If reviewers still require clarification on minor issues, provisional approval may be granted until Investigator responds to issues raised.
- If reviewers cannot reach agreement on response from Investigator or there are issues of concern, the application will proceed for full HREC review (meetings held quarterly)
Procedure 170 - Version 1
Valid to: December 2016

Revision date

December 2016

Policy owner

Director, OHPracRU and Director, APHIRST – OH

Approved by

Executive Director, Oral Health Leadership

Date approved

December 2013

Related documents

This procedure needs to be read in conjunction with relevant award and / or Certified Agreement provisions.

1. National Statement on Ethical Conduct in Human Research
2. The Australian Code for the Responsible Conduct of Research
3. DHSV Research Governance Framework
4. Department of Health Victoria : Developing best practice in human research ethics review
6. Values and Ethics – Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research
7. Guidelines for Ethical Research in Indigenous Studies
8. Statement on Consumer and Community Participation in Health and Medical Research (the Statement on Participation)
12. DHSV Responsible Conduct of Research Policy
13. DHSV Research Reporting Policy
14. DHSV Conflict of Interest in Research Policy
15. DHSV Research Misconduct Policy
16. DHSV Disciplinary and Suspension of Employees Guidelines
17. DHSV Policy on Authorship and Intellectual Property
18. Managing Conflicts of Interest in the Public Sector Toolkit
19. Guidelines Approved under Section 95A of the Privacy Act 1988 (2001);
20. Guidelines Issued under Section 95 of the Privacy Act 1988 (2000);
21. Whole of Victorian Government Common Funding Agreement (service agreement)