



UNIVERSITY
OF WOLLONGONG
AUSTRALIA

University of Wollongong & Illawarra Shoalhaven Local Health District
Human Research Ethics Committee
TERMS OF REFERENCE
April 2019

1. OBJECTIVES

The objectives of the UOW & ISLHD HREC are to:

- 1.1. Protect the mental and physical welfare, rights, dignity and safety of participants of research;
- 1.2. Promote ethical principles in human research;
- 1.3. Review research in accordance with the National Statement on Ethical Conduct in Human Research (2007) incorporating all updates [National Statement]; and
- 1.4. Facilitate ethical research through efficient and effective review processes.

2. FUNCTIONS

The HREC functions on behalf of the University of Wollongong and Illawarra Shoalhaven Local Health District are to:

- 2.1. Provide independent oversight of human research projects;
- 2.2. Provide competent, timely review and monitoring of human research projects in respect of their ethical and scientific acceptability for as long as projects are active;
- 2.3. Determine the compliance of a human research project with the National Statement and grant, withhold or withdraw ethical approval; and
- 2.4. Provide advice to the ISLHD and the UOW on strategies to promote awareness of the ethical conduct of human research.

3. ACCOUNTABILITY OF THE HREC

- 3.1. The HREC is accountable to the ISLHD Chief Executive through the Chief Executive's nominee, the Area Director of Research Management, in the conduct of its business. The minutes of the H&M HREC meeting shall be



forwarded to the Area Director, following confirmation. A copy of all correspondence from the Ethics Unit to researchers on applications involving the ISLHD will be send to the ISLHD Research Directorate Office.

- 3.2. The HREC is accountable to the Deputy Vice Chancellor (Research & Innovation) and the University Research Committee (through the Research Integrity Committee) of the University of Wollongong in the conduct of its business.
- 3.3. The HREC shall provide regular reports, at least on an annual basis, to the Chief Executive, the Deputy Vice Chancellor (Research & Innovation) and the Research Integrity Committee, which will include information on membership, the number of proposals reviewed, status of proposals, a description of any complaints received and their outcome, and general issues raised.
- 3.4. The HREC may from time to time bring to the attention of the Chief Executive/RIC/DVC(R&I) or delegate issues of significant concern.
- 3.5. The HREC will provide reports to the:
 - Australian Health Ethics Committee (AHEC) in accordance with the requirements of the National Health and Medical Research Council (NHMRC); and
 - NSW Privacy Commissioner in accordance with the requirements of the Health Records and Information Privacy Act 2002 (NSW).
- 3.6. The HREC will undertake its review in a timely and efficient manner and have mechanisms to monitor and evaluate its performance.
- 3.7. The HREC Terms of Reference, Standard Operating Procedures and membership will be available upon request to the general public and will be posted on the University of Wollongong website.

4. SCOPE OF RESPONSIBILITY

The responsibilities of the UOW & ISLHD HREC are to:

- 4.1. Review human research applications where the research involves patients, staff or students of the ISLHD or the UOW.
- 4.2. Review human research applications where the research takes place at:
 - any institutions governed by ISLHD; and/or



- any institutions governed by UOW; and/or
- any institutions governed by NSW Public Health organisations for multi-centre studies; and/or
- external institutions/organisations and researchers in accordance with NSW Health policy (PD2008_046 or subsequent updates); and/or
- interstate institutions/organisations within the scope of a scheme of mutual acceptance of ethical and scientific review entered into by NSW Ministry of Health on behalf of the HREC.

This term of reference does not prohibit the institution from accepting an ethical approval undertaken by another HREC as a sufficient ethical approval to allow the institution to approve the commencement of the project, provided that such other HREC is registered with the Australian Health Ethics Committee. For research involving the ISLHD, the HREC must be on the approved NSW Health HREC list available at

<http://www.health.nsw.gov.au/ethics/research/contactshrec.asp>

4.3. HREC Executive Committee

- 4.3.1. The HREC has an Executive Committee comprising at least the HREC Chairperson or their delegate and a member of the research office.
- 4.3.2. The HREC Executive Committee is delegated to undertake expedited review and approval of business that does not require full HREC review, including some or all of the following:
 - low and negligible risk research applications;
 - amendments to current HREC approved research projects;
 - responses to HREC queries, as approved by the full HREC for HREC Executive Committee review and approval;
 - annual progress reports and final reports; and
 - serious adverse events and suspected unexpected serious adverse reactions reports.
- 4.3.3. The minutes and decisions of the HREC Executive Committee are noted at the next HREC meeting.

- 4.4. The HREC may appoint such sub-committees as it sees fit to carry out a scientific or technical review of a research proposal or ethical review of minimal risk research submitted to the HREC. The Chair of any such sub-



committee will be appointed by the Chief Executive or DVC(R&I). Members of the sub-committee need not be members of the HREC.

5. STATUS OF THE HREC WITHIN THE ISLHD AND THE UOW

- 5.1. The HREC is an advisory committee of the ISLHD and the UOW with responsibility for:
- granting ethical approval;
 - withholding ethical approval; and
 - withdrawing ethical approval
- for research to be carried out within the institutions noted in paragraph 3.
- 5.2. The ISLHD Chief Executive or delegate is responsible for granting the ISLHD's institutional approval for research to be conducted within its institution(s) giving due consideration to the advice of the HREC. (Note: The Chief Executive may not give approval for research to be conducted within the ISLHD's institutions unless ethical approval has been granted by the HREC)
- 5.3. The UOW DVC(R&I) or delegate is responsible for granting the UOW's institutional approval for research to be conducted within its institution(s) giving due consideration to the advice of the HREC.

6. MEMBERSHIP

6.1 Composition

- 6.1.1 The composition of each HREC shall be in accordance with the *National Statement* and shall include at least:
- a chairperson;
 - two members who are lay people, one man and one woman, who have no affiliation with the ISLHD or UOW, and are not currently involved in medical, scientific, or legal work;
 - two members with knowledge of, and current experience in, the areas of research that are regularly considered by the HREC;
 - a member with knowledge of, and current experience in, the professional care, counselling or treatment of people;
 - one member who is a minister of religion, or a person who performs a similar role in the community; and
 - one member who is a lawyer.



- 6.1.2 To ensure the membership will equip the HREC to address all the relevant considerations arising from the categories of research likely to be submitted, some or all of the above categories may be represented by more than one person.
- 6.1.3 The HREC shall be free to consult any person(s) considered by the HREC to be qualified to provide expert advice and assistance in the review of any research proposal submitted to it, subject to that person(s) having no conflict of interest and providing an undertaking of confidentiality. Such person(s) shall not be entitled to vote on any matter.

6.2 Appointment

- 6.2.1 The Chief Executive and DVC(R&I) or delegate shall appoint members of the HREC, in consultation with the HREC and other senior ISLHD and UOW officials, as deemed appropriate.
- 6.2.2 Prospective members of the HREC may be recruited by direct approach, nomination or by advertisement.
- 6.2.3 A selection committee, consisting of the Chairperson, the Executive Officer and, where possible, one other HREC member shall meet with prospective members, consult with the HREC members and make a recommendation to the Chief Executive and DVC(R&I) or delegate.
- 6.2.4 Appointments will allow for continuity, the development of expertise within the HREC, and the regular input of fresh ideas and approaches.

6.3 Terms of appointment

- 6.3.1 Members are appointed for a period of two years. The Chairperson, Deputy Chair and Chair of any subcommittee may serve longer terms with the approval of the Chief Executive and DVC(R&I).
- 6.3.2 Reappointment is on invitation from Chief Executive and/or DVC(R&I) based on a recommendation from the Chairperson of the HREC.
- 6.3.3 Membership will lapse if a member fails without reasonable excuse or without notifying the Chairperson to attend three consecutive meetings of the HREC, unless exceptional circumstances exist. The Chairperson in writing will notify the member of such lapse of membership. Steps shall be taken to fill the vacancy of the lapsed member.



- 6.3.4 A member may resign from the HREC at any time upon giving notice in writing to the Chairperson. Steps shall be taken to fill the vacancy of the former member.
- 6.3.5 The Chief Executive and DVC(R&I) may terminate the appointment of any member of the HREC if they are of the opinion that:
- it is necessary for the proper and effective functioning of the HREC;
 - the person is not a fit and proper person to serve on an HREC; and/or
 - the person has failed to carry out their duties as an HREC member.
- 6.3.6 The ISLHD and the UOW provide indemnity for members of the HREC for any liabilities that arise as a result of the member exercising his or her duties as a member in good faith. Such indemnity is provided through the NSW Treasury Managed Fund and the UOW liability protections.

6.4 Conditions of appointment

- 6.4.1 Members must agree to their name and profession being made available to the public, including being published on the University of Wollongong website.
- 6.4.2 Payments made to HREC members may only be made in relation to the following items and at the following rates and on the following basis:
- The Chair of each HREC will receive a payment sufficient to pay for the release of academic staff from teaching or research activities for one day per week;
 - Provision of specialist knowledge to the Executive Committee of the HREC on a regular basis, where the person is not employed by the UOW or the ISLHD; and
 - Reimbursement of legitimate expenses incurred in attending HREC meetings or in otherwise carrying out the business of the HREC.
- 6.4.3 Members will be required to sign a statement undertaking that:
- all matters of which he/she becomes aware during the course of his/her work on the HREC will be kept confidential;
 - any conflicts of interest which exist or may arise during his/her tenure on the HREC will be declared; and



- he/she has not been subject to any criminal conviction or disciplinary action which may prejudice his/her standing as a HREC member.

6.5 Education for HREC members

- 6.5.1 Newly appointed members shall be provided with adequate orientation and documentation.
- 6.5.2 Each member is expected to become familiar with the National Statement and consult other guidelines relevant to the review of specific research applications.
- 6.5.3 Throughout their tenure, members shall be given the opportunity to attend conferences and workshops relevant to the work and responsibilities of the HREC, at the expense of the ISLHD and the UOW.

7. CONDUCT OF BUSINESS

7.1 Procedures

The HREC will perform its functions according to written standard operating procedures. These procedures shall be reviewed at least every three years and amended and updated as necessary. All HREC members shall have access to and/or be provided with copies of the procedures and shall be consulted with regard to changes thereto.

7.2 Meetings

- 7.2.1 The HREC shall meet on a regular basis, which will normally be at monthly intervals.
- 7.2.2 Meeting dates and agenda closing dates will be published.
- 7.2.3 For the purposes of holding a meeting of the HREC, a quorum shall exist when a representative of each of the categories designated in the *National Statement* (and specified in paragraph 1.21) is present. In circumstances where such core members cannot be present, they may provide written comments in lieu of attendance. However, in those circumstances, there must be at least 5 members physically present to achieve quorum, including one of each of the following categories: Chair/Deputy Chair, lay person, researcher familiar with the types of proposals that are normally reviewed by the HREC.



7.3 Declaration of interest

Any member of the HREC who has any interest, financial or otherwise, in a proposal or other related matter(s) considered by the HREC, should as soon as practicable declare such interest. If the member is present at a meeting at which the project is the subject of consideration, the member will withdraw from the meeting until the HREC's consideration of the relevant matter has been completed. The member will not participate in the discussions and will not be entitled to vote in the decision with respect to the matter. All declarations of interest and absence of the member concerned will be minuted.

7.4 Confidentiality

HREC meetings are held in private. The agenda and minutes of meetings, applications, supporting documentation and correspondences are all treated confidentially.

7.5 Decision making

The HREC will endeavour to reach a decision concerning the ethical acceptability of a proposal by unanimous agreement. Where a unanimous decision is not reached, the decision will be considered to be carried by a majority of two-thirds of members who examined the proposal, provided that the majority includes at least one layperson. Any significant minority view (i.e. 2 or more members) shall be noted in the minutes.

7.6 Records

7.6.1 The Executive Officer will prepare and maintain written records of the HREC's activities, including agendas and minutes of all meetings of the HREC.

7.6.2 Files shall be kept securely and confidentially in accordance with the requirements of the State Records Act 1998.

7.6.3 Records shall be held for sufficient time to allow for future reference. The minimum period for retention is at least 5 years from the date of completion of a project but for specific types of research, such as clinical research, 15 years shall apply.

7.6.4 The HREC will maintain a register of all the applications received and reviewed in accordance with the NHMRC National Statement.



7.7 Monitoring research projects

7.7.1 The HREC will monitor approved projects to ensure compliance with the conditions of approval and to protect the rights, safety and welfare of participants. This includes review of annual progress reports and final reports, safety reports and reports of protocol violations.

7.7.2 The HREC will, as a condition of approval of each project, require that investigators immediately report anything which might warrant review of ethical approval of the project, including:

- proposed changes in the research protocol or conduct;
- unforeseen events that might affect continued ethical acceptability of the project;
- serious or unexpected adverse events; and
- if the project is abandoned for any reason.

7.7.3 The HREC has the discretion to adopt other appropriate mechanisms for monitoring depending on the complexity, design and risk perceived, including:

- discussion of relevant aspects of the project with investigators, at any time;
- random inspection of research sites, data, or consent documentation;
- interview with research participants or other forms of feedback from them; and
- request and review reports from independent agencies such as a Data and Safety Monitoring Board.

7.8 The HREC also has the discretion to recommend in the letter of approval that the site co-ordinates onsite monitoring at recommended intervals or randomly throughout the project.

8. APPEALS AND COMPLAINTS

8.1 Appeals regarding HREC rejection

8.1.1 Where the HREC has rejected an application, the investigator has the discretion to:

- submit a new application to the same HREC, taking due account of the HREC's concerns; or



- lodge an appeal with the HREC Chairperson specifying the grounds of the appeal in writing. Complaints may also be made to the Chief Executive or DVC(R&I).

8.2 Appeals regarding HREC approval

8.2.1 Where the HREC has given a favourable decision on an application and:

- an ethical or scientific issue is subsequently identified by any party;
or
 - it has become apparent that the decision was based on inconsistent application of policy and guidelines
- a written appeal is lodged with the Chairperson in the first instance.

8.3 Appeals to the Chief Executive

8.3.1 If the appellant considers that the HREC has failed to follow due process after making an appeal in line with 8.1 and 8.2 and remains unsatisfied with the outcome, they have the discretion to lodge an appeal with the Chief Executive, DVC(R&I), or nominee, or request the Chairperson to do so.

8.4 Complaints about the conduct of HREC members

Complaints about the conduct of an HREC member are managed by the Ethics & Integrity Manager who informs the Chairperson of the complaint. Complaints may also be made to the Chief Executive or DVC(R&I), or delegate, who will inform the Chairperson.

8.5 Complaints concerning the conduct of an approved project

Any concern or complaint about the conduct of a project should be directed to the Ethics & Integrity Manager. The Ethics & Integrity Manager shall notify the Chairperson as soon as possible after a complaint is received. The Ethics & Integrity Manager and Chairperson of the HREC will investigate the complaint and make a recommendation on the appropriate course of action. If the complainant is not satisfied with the outcome of the investigation, then he/she can refer the complaint to the Chief Executive or DVC(R&I), or request the Chairperson or Ethics & Integrity Manager to do so.



9. AMENDMENT TO THE TERMS OF REFERENCE

These Terms of Reference may be amended by following the procedure below:

9.1 For those proposals made by a HREC member:

- The proposal must be in writing and circulated to all HREC members for their consideration.
- The views of the members should be discussed at the next scheduled meeting of the HREC, and a vote taken at that meeting. Any member unable to attend such a meeting may register his or her views in writing.
- The proposal shall be ratified if two thirds of the members agree to the amendment.
- The Chairperson shall send the amendment to the Chief Executive, RIC and DVC(R&I) for review and approval if appropriate.

9.2 For those proposals made by the Chief Executive, RIC or DVC(R&I):

- the Chief Executive/RIC/DVC(R&I) will send the proposal to the HREC and seek the views of any relevant person.

10. TERMINATION OF HREC RESPONSIBILITY

10.1 Where the HREC is to be merged, closed or has ceased to function, the ISLHD and the UOW will notify the NHMRC and determine the appropriate course of action, such as the status of its registration and/or status as a certified institution with the NHMRC and the monitoring of previously approved research. The ISLHD and the UOW will also notify the NSW Ministry of Health.