**Terms of Reference - Human Research Ethics Committee 2016**

Western Sydney University is a confirmed research leader in Australia. Researchers at Western Sydney conduct research involving human participants and the University has an obligation to ensure the research design and conduct is in accordance with the [Australian code for the responsible conduct of research](https://www.nhmrc.gov.au/guidelines-publications/r39) and has undergone ethical review in accordance with the [National Statement on Ethical Conduct in Human Research (2007)](https://www.nhmrc.gov.au/guidelines-publications/e72) (National Statement) which is a series of guidelines issued by the National Health and Medical Research Council (NHMRC) in accordance with the [National Health and Medical Research Council Act 1992](https://www.legislation.gov.au/Series/C2004A04516) (Cth). Accordingly, the University maintains a Human Research Ethics Committee (HREC).

The Western Sydney University HREC is an accredited committee of the NHMRC. It is not accredited to review and approve a limited number of types of research, including that conducted with public health patients or in public health facilities.

The Western Sydney University HREC deals with all of the ethical aspects of procedures where humans participate in research and in teaching projects; these include confidentiality and privacy issues in addition to the physical and psychological welfare of participants.

These Terms of Reference should be read in conjunction with Section 5 of the National Statement which provides further Terms with which the Human Research Ethics Committee is compliant.

**Summary of Committee responsibilities**

It is the responsibility of the Western Sydney University Human Research Ethics Committee to:

* Review proposals for research to be undertaken by staff and students or on the premises of the University or its affiliates, to determine whether they are ethically acceptable and in accordance with relevant standards and guidelines.
* Grant approval for research proposals, including amendments to proposals, where review has determined that they are ethically acceptable and in accordance with relevant standards and guidelines.
* Withhold ethical approval for research proposals where review has determined that they are not ethically acceptable and/or are not in accordance with relevant standards and guidelines.
* Withdraw ethical approval for research proposals where review has determined that they are not ethically acceptable and/or are not in accordance with relevant standards and guidelines.
* Monitor the conduct of approved research through the receipt of annual and completion reports.

The Human Research Ethics Committee has jurisdiction over the research of all Western Sydney University staff (paid and honorary) and research students, and all visiting staff, including those using Western Sydney facilities.

The Human Research Ethics Committee will recognise the ethical approval of a research proposal granted by another NHMRC registered Human Research Ethics Committee where that HREC accepts responsibility for ongoing monitoring of all sites and all researchers.

**Definitions**

Staff includes honorary academic appointments comprising visiting appointments, adjunct appointments and TAFE-Western Sydney University Associate.

Principal Researcher/Chief Investigator means the researcher or higher degree research student (doctoral or masters by research only) who is principally responsible for conducting a research project.

Researcher includes Principal Researchers/Chief Investigators, co-investigators, higher degree research students, undergraduate honours students, honorary staff and visiting staff.

Funded research is limited to externally funded projects where the funding is HERDC reportable and these projects will be registered on the University’s research management database.

Confirmation of Candidature and Masters of Research Proposal of Project confirmation are the formal review and acceptance of, among other things, the research merit and integrity of a higher degree research student project.

**Objectives**

The objectives of the Human Research Ethics Committee are to:

a) Protect the mental and physical welfare, rights, dignity and safety of participants of research;

b) Promote ethical principles in human research;

c) Review research in accordance with the *National Statement on Ethical Conduct in Human Research (2007)* incorporating all updates [National Statement]; and

d) Facilitate ethical research through efficient and effective review processes including review of low or negligible risk research proposals through its Low and Negligible Risk Committee (LNR Committee) in accordance with the National Statement.

The Committee is concerned in particular to ensure that a participant’s inclusion in a research study complies with the Principles of Ethical Conduct set down in *the National Statement on Ethical Conduct in Human Research (2007)*. The Principles of Ethical Conduct examined by the Committee cover the principles of:

• Research Merit and Integrity

• Justice

• Beneficence, and

• Respect

and the themes:

• risk and benefit, and

• participant’s consent.

Reference: *National Statement on Ethical Conduct in Human Research*, Section 1, pp. 11 – 13; Section 2, pp. 15-24.

**The Committee will:**

* normally only review research proposals deemed to be greater than low risk (high and low 2 categories)
* abide by the *Values and Principles of Ethical Conduct outlined in the National Statement on Ethical Conduct in Human Research (2007)* issued by the National Health and Medical Research Council (NHMRC) in accordance with the NHMRC Act, 1992 (Cth.) and all other relevant Acts and legislative requirements including the [Guidelines Under Section 95 of the Federal Privacy Act 1988](https://www.nhmrc.gov.au/guidelines-publications/pr1) and the [NSW Privacy and Personal Information Protection Act, 1998](http://www.legislation.nsw.gov.au/#/view/act/1998/133)
* conduct research merit and integrity review unless the research has been awarded external research funding which is held in a Western Sydney U research account with Research Engagement, Development and Innovation or where higher degree research student has successfully completed a Confirmation of Candidature. If the Human Research Ethics Committee does not have the relevant expertise to conduct research merit and integrity review of a project, it is able to seek expert review elsewhere.
* determine whether or not proposed research projects involving human participants are acceptable on ethical grounds - no research project may proceed without prior consideration and written approval by the Committee
* monitor the progress of research projects to ensure continued compliance with approved ethical standards
* review and approve amendments to approved projects
* delegate the review of ‘low risk’ or ‘negligible risk’ human research projects to the Low and Negligible Risk Committee as permitted by the National Statement.

**Membership of the Committee**

Membership of the Committee is in accordance with the requirements of the National Statement on Ethical Conduct in Human Research 2007. The quorum for meetings is at least one member from the minimum membership categories as specified in the National Statement, attending in person or via telephone or videoconference if agreed by the Chair. In circumstances where a member of each category of membership as designated in the National Statement cannot be present, members may provide written comments for consideration at the meeting.

Members are appointed by the Deputy Vice Chancellor Research and Development.

Membership shall be a:

* Chairperson (either internal or external to the institution)
* Deputy Chairperson
* at least one Laywoman (who has no affiliation with the institution)
* at least one Layman (who has no affiliation with the institution)
* someone who performs a pastoral care role in a community
* Lawyer
* Health Researcher
* Health Professional – care, counselling or treatment
* Medical Researcher with knowledge of Clinical Trials
* Biomedical Researcher
* Psychologist
* Educationalist
* Philosopher
* Sociologist
* additional members may be appointed from time to time.

***Minimum membership (National Statement 5.1.30) is***

* Chair
* At least two lay people
* One person with knowledge and current experience in the professional care, counselling or treatment of people
* A pastoral carer
* A lawyer
* At least two people with current research experience relevant to the research proposal under review

**Conditions of Appointment**

Selection of members follows an open and accountable procedure. Members are appointed as individuals for their knowledge, qualities and experience and not as representatives of any organisation, group or opinion. All appointments are for three years and may be renewable.

Community members will be reimbursed for legitimate expenses incurred in attending Human Research Ethics Committee meetings or in otherwise carrying out the business of the Human Research Ethics Committee.

Academic members will be allocated workload to conduct these important governance responsibilities.

Chair – 20%

Deputy Chair, also a member of the HREC Executive – 10%

Committee member – 5%

Membership will lapse if a member fails to attend three consecutive meetings or send comment without apology or reasonable excuse. Membership will also lapse if members fail to attend at least four meetings in a calendar year.

Members shall receive a formal notice of appointment and a guarantee that the institution accepts legal responsibility for decisions and advice from the Panel and indemnifies its members accordingly. Members are bound by the University’s Conflict of Interest policy. Members of the Human Research Ethics Committee shall maintain the confidence of applicants and their proposals, ensuring that they do not discuss or disclose details of submissions outside the meeting forum, apart from discussion undertaken with another member of the Committee or the Ethics Officers. If the committee seeks advice from experts in considering a proposal, these experts are bound by the same confidentiality requirements. All general discussions within the forum of the meetings must remain in confidence.

New members undergo an induction process, usually a half day workshop run by the Executive Officer.

The Chair will be ex officio member of the LNR committee.

**Meetings**

The Human Research Ethics Committee will meet face to face at least 10 times per calendar year. Decisions must be informed by an exchange of opinions from each of those who constitute the minimum membership and may, where it is deemed necessary by the Chair, be conducted electronically (National Statement 5.2.29).

The conduct of the business of the committee will enable all members reasonable opportunity to express relevant views on matters on the agenda.

1. The Human Research Ethics Committee endeavours to reach its decisions by general agreement based on review of the documents provided by researchers.
2. Where a unanimous decision is not reached, the Chair will facilitate the expression of opinion from all members, identify points of agreement and of disagreements and judge when a sufficient degree of general agreement has been reached.
3. Any significant minority view (i.e. 2 or more members) is noted in the minutes.
4. Discussions of significant issues and decisions are recorded in the minutes.
5. Where members wish, a record of their formal dissent from the decision of the Human Research Ethics Committee is recorded in the minutes.
6. Where further information is sought from applicants, the Chair will determine whether or not further HREC review is required or delegate further review to the Committee Executive.
7. To encourage free and open discussion and to emphasise the collegiate character of the Human Research Ethics Committee, particular views are not attributed to particular individuals in the minutes, except in circumstances where a member seeks to have their opinions or objections recorded.

**Records and Reporting**

The Human Research Ethics Committee will:

1. report to the Vice-Chancellor, through the Vice-Chancellor’s nominated representative, the Deputy Vice Chancellor Research and Development.
2. via Research Engagement, Development and Innovation (REDI), maintain a register of research projects involving human participants and communicate information on request to the Vice Chancellor and appropriate national bodies, including the NHMRC.

**Complaints and Review**

Human Research Ethics Committee is an independent decision making body and its decisions are not subject to ratification by Western Sydney University.

The Executive Officer of the Committee acts as its complaints officer. Members of the public, students and staff may contact the Human Research Ethics Committee regarding concerns about the conduct of research. If the Committee is unable to resolve the concern, the University's Complaints Resolution Unit can be contacted by the Committee or by any concerned member of the public, staff or student of the University.

These Terms of Reference can be amended by the Deputy Vice Chancellor, Research and Development on the recommendation of the Chair of Human Research Ethics Committee.