

## Terms of Reference

### Human Research Ethics Committee (HREC) 2020

Western Sydney University is a research-led University with regional, national and global impact. For all research at Western Sydney involving human participants 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](#) and has undergone ethical review in accordance with the [National Statement on Ethical Conduct in Human Research \(2007, updated 2018\)](#) (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](#) (Cth).

The Western Sydney University HREC is registered with the NHMRC.

These Terms of Reference should be read in conjunction with Section 5 of the National Statement and any additional terms and conditions as outlined in the member's Appointment Letter.

The HREC has jurisdiction over the research conducted by all Western Sydney University staff (paid and honorary) and students, and all visiting staff, including those using Western Sydney University facilities conducting moderate or high risk research.

### Summary of Human Research Ethics Committee responsibilities

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

- Review proposals for moderate and high risk research to be undertaken by staff and students of the University, including adjunct staff, to determine whether they are ethically acceptable and in accordance with relevant standards and guidelines.
- Conduct research merit and integrity review unless the research has been awarded research funding by an external Category 1 funding body or where a higher degree research student has successfully completed a Confirmation of Candidature or a Masters of Research Proposal of Project.
- Seek expert review elsewhere if the Committee does not have the relevant expertise to conduct the research merit and integrity review of a project.
- Grant approval for moderate to high risk research proposals and amendments to those proposals where review has determined that they are ethically acceptable and in accordance with relevant standards and guidelines.
- Withhold ethical approval for moderate to high risk research proposals where review has determined that they are not ethically acceptable and/or are not in accordance with relevant standards and guidelines.
- Recommend withdrawal of ethical approval for moderate to high risk 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.
- Abide by the Values and Principles of Ethical Conduct outlined in the *National Statement on Ethical Conduct in Human Research (2007, updated 2018)* issued by the National Health

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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](#) and the NSW Privacy and Personal Information Protection Act, 1998.

- Refer to, and defer to, the decision of the Chair of the HREC, if it cannot agree that a proposal is ethically acceptable and/or not in accordance with the relevant standards and guidelines.

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.

### Objectives of the HREC

The Committee is concerned in particular with ensuring 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, updated 2018)*.

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, updated 2018)*; and
- d) Facilitate ethical research through efficient and effective review processes.

### 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, updated 2018)*. The quorum for meetings is at least one member from the minimum membership categories as specified in the National Statement. 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, Enterprise and International) and membership of the Committee is in accordance with the requirements of the National Statement.

### 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. Members are expected to conduct their own research in ways that display their commitment to conducting research with integrity and the principles and values in the National Statement.

Members will receive a formal notice of appointment (Appointment Letter) and a guarantee that the institution accepts legal responsibility for decisions and advice from the Committee and indemnifies its members accordingly. Members are bound by the University's Conflict of Interest HREC ToR June 2020

policy – see <https://policies.westernsydney.edu.au/document/view.current.php?id=93>.

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 and will be paid an honorarium for each meeting attended.

Academic members are not offered remuneration, but will be allocated workload to conduct these important governance responsibilities. Researchers wanting to claim the workload allocation should discuss this with their Supervisor/Manager or Dean/Institute Director.

Chair – 20%

Deputy Chair / HREC Executive – 10%

Committee member – 5%

Members will be appointed for a designated term as outlined in the Appointment Letter. The Chair of the Committee will monitor performance to ensure the goals and objectives of the Committee are being met.

Members are expected to attend meetings in person at the nominated venue. Attendance via zoom is only acceptable in extraordinary circumstances and will require prior approval from the Chair of the Committee.

Membership will lapse if a member;

- Fails to attend three consecutive meetings and does not send written reviews without apology or reasonable excuse.
- Fails to attend at least seven meetings in a calendar year.
- Fails to conduct appropriate reviews in line with the principles and values of the National Statement;
- Does not provide reviews which are 'actionable' by the applicant;
- Does not provide 'timely' reviews in line with the advertised schedule of Executive meeting dates.

New members will undergo an induction process. All members will be eligible to attend professional development arranged through the ethics secretariat.

Senior members are encouraged to mentor early and mid-career members.

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.

### **Conduct of Business**

The Human Research Ethics Committee will meet face to face at least ten (10) times per calendar HREC ToR June 2020

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 5.2.30).

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

- a) The Human Research Ethics Committee endeavours to reach its decisions by general agreement based on review of the documents provided by researchers.
- b) 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.
- c) Any significant minority view (i.e. 2 or more members) is noted in the Minutes.
- d) Discussions of significant issues and decisions are recorded in the Minutes.
- e) Where members wish, a record of their formal dissent from the decision of the Human Research Ethics Committee is recorded in the minutes.
- f) 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.
- g) 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.
- h) The Executive Committee undertakes weekly electronic reviews of applications initially reviewed by the HREC, amendments for all projects which have been risk rated moderate or high risk and adverse events.

### **Records and Reporting**

The Human Research Ethics Committee will:

- a) report to the Vice-Chancellor, through the Vice-Chancellor's nominated representative, the Deputy Vice Chancellor & Vice President (Research, Enterprise & International).
- b) via Research Services, 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.

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### **Complaints and Review**

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

The Human Research Ethics Officers act as the ethics complaints officers. Members of the public, students and staff may contact the Human Research Ethics Committee regarding concerns about the conduct of research. If the Chair of the Committee is unable to resolve the concern, the matter will be referred to the Director, Research Impact and Integrity. If the Director, Research Impact and HREC ToR June 2020



Integrity is unable to resolve the matter it will be referred to the Pro Vice Chancellor, Research. At any stage of the process a decision may be made to refer the matter to the University's Complaints Resolution Unit. It is also acknowledged that any member of the public, member of staff or student of the university may contact the Complaints Resolution Unit at any time.

These Terms of Reference can be amended by the Deputy Vice Chancellor (Research, Enterprise and International) on the recommendation of the Chair of the Human Research Ethics Committee. Members will be notified when the Terms of Reference are updated, and continuing membership of the committee will be subject to the newly updated Terms of Reference.

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