Terms of Reference – Low and Negligible Risk (LNR) 2017

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 and has undergone ethical review in accordance with the National Statement on Ethical Conduct in Human Research (2007) (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 Low and Negligible Risk Committee (LNR) operates under the requirements of the National Statement Section 5.1.

These Terms of Reference should be read in conjunction with Section 5 of the National Statement which provides further Terms with which the Low and Negligible Risk Committee is compliant.

The Low and Negligible Risk 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 University facilities doing low or negligible risk research.

**Summary of Committee responsibilities**

The LNR Committee has responsibility to consider the ethical implications of proposed human research studies conducted under the auspices of the University and determine whether or not they are acceptable on ethical grounds. These responsibilities include monitoring the ethical aspects of all research studies involving human participants undertaken by the staff and students of Western Sydney University.

Western Sydney University LNR Committee is delegated by the Human Research Ethics Committee to:

- Review proposals for very low (Low 1) and negligible risk 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 Low 1 and negligible 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 Low 1 and negligible risk 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 Low 1 and negligible risk research proposals where review has determined that they are not ethically acceptable and/or are not in accordance with relevant standards and guidelines.

**Definitions**

Staff includes conjoint appointments and 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 Higher Education Research Data Collection (HERDC) reportable and these projects will be registered on the University’s research management database within Research Engagement, Development and Innovation (REDI).

Confirmation of Candidature and Masters of Research Proposal of Project 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 Low and Negligible Risk 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) examine low and negligible risk proposals which involve the use of humans as participants in the research of staff and students and to advise the Human Research Ethics Committee on whether the proposals comply with the ethical guidelines adopted by the University and the Human Research Ethics Committee, and

d) facilitate ethical research through efficient and effective review processes.

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 of:

- risk and benefit, and
- participant’s consent.

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

- review and approve proposals for research involving human participants that involve no more than Low 1 risk to be undertaken by staff and students or on the premises of the University or its affiliates;
- refer to the Human Research Ethics Committee (HREC) any proposals it considers involves more than low risk;
- 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 and the NSW Privacy and Personal Information Protection Act, 1998;
- conduct research merit and integrity review unless the research has been awarded external research funding which is held in a Western Sydney University research account with REDI or where a higher degree research student has successfully completed a Confirmation of Candidature or a Masters of Research Proposal of Project. If the LNR 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 approval of a written approval by the Committee;
- monitor the progress of research projects to ensure continued compliance with approved ethical standards;
- report its reviews and approvals to Human Research Ethics Committee, and
- refer to and defer to the decision of the Chair of the Human Research Ethics Committee, if it cannot agree on if a proposal is ethically acceptable and/or not in accordance with the relevant standards and guidelines.

Membership of the Committee

Members are appointed by the Deputy Vice-Chancellor (Research Engagement, Development and International) and membership of the Committee is in accordance with the requirements of the National Statement.

Membership of the Committee shall be as follows:

- the Chairperson who is also the Chairperson of the HREC or their designated representative,
- up to 13 members with current research experience. At least two members must have current research experience that is relevant to a research proposal to be considered at a meeting by the Low and Negligible Risk Committee, and
- additional members may be appointed from time to time.

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.
All appointments are for three years, subject to meeting the Conditions of Appointment, and may be renewable.

Members are not offered remuneration. The University has agreed to the following workload allocation for LNR committee members – 5% for LNR committee members**. Researchers wanting to claim the workload allocation should discuss this with the Supervisor or School/Institute Head of Department.

Members shall receive a formal notice of appointment 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 policy.

Members of the LNR Committee shall maintain the confidence of applicants and their proposals, ensuring that they do not discuss or disclose details of submissions apart from discussion undertaken with another member of the LNR or HREC, the Chair 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 will undergo an induction process. All members will be eligible to attend training arranged through the ethics secretariat.

Membership will lapse if a member:

- is unable to make themselves available for reviews for an extended period;
- consistently does not provide adequate notice of unavailability to review or is unavailable without apology or reasonable excuse;
- 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, or
- does not provide ‘timely’ reviews in line with the advertised schedule of LNR meeting dates.

**Conduct of business**

The LNR Committee undertakes weekly reviews electronically.

The LNR will also meet face to face up to five times per annum to discuss general issues relating to the ethical review of low and negligible risk research and/or for training. A quorum for such meetings will be seven members, including the Chair.

Projects will be reviewed and approved by a minimum of two reviewers and approved by circulation between meetings.

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

a) Where further information is sought from applicants, only the final version of the application will be considered by the Chair for approval
b) Discussions of significant issues and decisions are recorded in the Minutes.
c) Where members wish, a record of their formal dissent from the decision of the Chair is recorded in the Minutes.
d) To emphasise the collegiate character of the LNR 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
Report its reviews and approvals to Human Research Ethics Committee via the meeting Minutes.

REDI will 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
The LNR committee is a designated Committee of the Human Research Ethics Committee (HREC). The HREC, and the LNR, are independent decision making bodies and decisions are not subject to ratification by Western Sydney University.

The Human Research Ethics Officers act as its complaints officer. Members of the public, students and staff may contact the HREC 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 Engagement, Development and International) on the recommendation of the Chair of Human Research Ethics Committee.