

Guidance on Levels of Risk and the Ethical Review Process

The following is intended to help researchers by clarifying:

- How HREC understands the intent of the ethics review process and risk categorisation
- How risk assignment dictates which committee will review the application and subsequent amendments

Western Sydney University operates 3 human research ethics review committees – the Human Research Ethics Committee (HREC); the Executive of the HREC; and the Low and Negligible Risk Committee (LNR).

Under the National Statement on Ethical Conduct in Human Research (NS) guidelines, the risk level of the research activity determines which Committee may review the project. The risk level of a project is assigned after screening by the Human Ethics Officers.

The types of risk and which Committee is able to review and issue an approval is as follows:

High Risk

This is defined as any research that can cause severe harm to a participant psychologically, physically, socially, economically, cause legal harm or devalue a person's self-worth (NS 2.1).

Moderate Risk

This is defined as where the foreseeable risk to participants is greater than discomfort or where there are risks to the researcher or the participants are particularly vulnerable (NS 5.1.6).

Under the National Statement, High and Moderate risk new applications must be reviewed by the full Human Research Ethics Committee (HREC). HREC meetings are held on the third Monday of every month, except January (no meeting) and when public holidays cause a meeting to be rescheduled. Responses to HREC assessments and/or amendments may be reviewed at the HREC Executive meeting. The HREC will determine this when it first reviews the application.

Low Risk

This is defined as where the only foreseeable risk is one of discomfort (NS 2.1.6).

Negligible Risk

This is defined as where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk (NS 2.1.7).

Under the National Statement, Low and Negligible risk applications may be considered by the LNR Committee. The LNR assesses weekly except in weeks with public holidays and during the holiday closure.

Ethical Review based on the level of risk

The National Statement lists particular types of research that require HREC review regardless of whether they may otherwise be considered less than High risk. There are also additional categories of research that the Western Sydney University requires to have HREC review.

The following research characteristics mean that the new application MUST be reviewed by the HREC, not the LNR.

- Interventions and therapies, including clinical and non-clinical trials, and innovations
- Collection of samples such as blood, bodily fluids, etc.
- Physical screening or physical exertion
- Children
- Aboriginal and Torres Strait Islander peoples
- Human genetics or human stem cells
- Women who are pregnant and the human foetus
- People highly dependent on medical care who may be unable to give consent
- People with a cognitive impairment, an intellectual disability, or a mental illness
- Topics that may cause distress to participants due to past traumatic experiences
- Limited disclosure involving active concealment and/or planned deception
- Study or exposure of illegal activity, or research that is likely to discover illegal activity
- Research that could jeopardise a participant's employment
- Research that poses a risk to the physical or emotional safety or welfare of a University of Western Sydney student researcher
- Research that seeks a waiver of consent for the use of health information
- Research that will use 'opt out' as the form of consent
- Autoethnography

In addition, a combination of factors in a project may increase its risk rating.

Meeting Dates

The HREC meets monthly, except for January each year. The LNR and the Executive meet weekly except for weeks with public holidays and, for the Executive, weeks in which there is an HREC meeting. Committee meeting dates and the corresponding dates for application submissions to the meeting are on the website.

http://www.westernsydney.edu.au/research/research_ethics_and_integrity/human_ethics/apply_for_human_research_ethics_review

Human Research Ethics Guidance Documents available from Research Services

- Guidance for Researchers New to Human Ethics Review
- Guidance Human Research Ethics Protocols for Coursework Masters
- Guidance on Choosing the most appropriate PIS and Consent
- Guidance on Completing the Project Description
- Guidance on Creating Research Project Flyers
- Guidance on Data Storage and Retention Questions
- Guidance on Ethics Review Exemption
- Guidance on Issues with Informed Consent in Research
- Guidance on Levels of Risk and the Ethical Review Process
- Guidance on Making an Amendment to an Approved Project
- Guidance on Organisations in Research
- Guidance on Questions Related to Cultural Sensitivities
- Guidance on Questions Related to Restrictions on Publication of Results
- Guidance on Receiving and Responding to Ethics Committee Assessor Comments
- Guidance on Research Projects Seeking to use Western Sydney Staff as Participants
- Guidance on Reimbursements
- Guidance on The use of 'Opt Out' or Passive Consent in Human Research
- Guidance on Writing Participant Information Sheets and Consent Forms
- Guidance on Research Involving Young People
- Guidance on Research Projects and DFAT Advice
- Guidance on Using Focus Groups in Research

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