

REDI HUMAN RESEARCH ETHICS

RESEARCH | ENGAGEMENT | DEVELOPMENT | INNOVATION

Guidance for Researchers New to Human Ethics Review

The Context

An ethics application is made when University researchers, staff and/or students, are conducting research with human participants. This includes their actual participation, such as being interviewed by a researcher, and/or use of participants' data and / or tissue.

To complete the application the researcher needs to be aware of, and apply to their research, the principles in the:

- National Statement on Ethical Conduct in Human Research (2007, 2015 update) <http://www.nhmrc.gov.au/guidelines-publications/e72>
- Australian Code for the Responsible Conduct of Research <http://www.nhmrc.gov.au/guidelines-publications/r39>
- Western Sydney Research Code of Practice <http://policies.uws.edu.au/view.current.php?id=00166>

Doctoral Candidates, Master of Philosophy and Master of Research Students

It is necessary to first successfully pass your Confirmation of Candidature (Doctorates, MPhil) or Presentation of Proposal (MRes students). Please discuss this with your Supervisor or the Graduate Research School if you require clarification. Evidence of completion of the CoC or PoP must be submitted with the ethics application.

http://www.westernsydney.edu.au/graduate_research_school/grs/higher_degree_research_students

The Application

All human ethics applications are made on the standard national application form - the Human Research Ethics Application (HREA).

You should enter the HREA website, create an account and then work through the dynamic form. The form is administered by the National Health and Medical Research Council (NHMRC), not Western Sydney University. The ethics team at Western Sydney University are unable to offer advice about functionality issues. However, the HREA website provides a range of helpdesk services including a comprehensive guidance document. Once you have completed the form you will download a set of documents including the HREA form and your attachments. Please send the form and the attachments to the relevant ethics committee.

The application must be signed by all the researchers listed in the application before sending it to the ethics team. Some schools also require the Dean to review the application before it is submitted to the ethics team.

The Human Research Ethics Application is available at <https://hrea.gov.au>
Send to Western Sydney ethics team at humanethics@westernsydney.edu.au

Medical Research

Medical research to be conducted in a public health facility or with public health patients or their data must have applications approved by the relevant Local health District HREC. If you are seeking ethics clearance from an LHD HREC you need to talk to them about their requirements.

Western Sydney U Attachments

One of the key attachments is the bespoke Western Sydney University Project Description. Other attachments required depend on the project. There are templates for the most common attachments, Guidance for Researchers New to Human Ethics Review – V2 – August 2017
HEO

including the Project Description, on the Western Sydney website at <http://www.westernsydney.edu.au/research/researchers/forms>

Western Sydney U Assessment Process

When the application is received the ethics staff will do an initial screening. During that process staff will check that all required attachments are included and that the application reads coherently, without ambiguity and doesn't include known unacceptable processes. The researcher will be contacted if the application would benefit from revision before being assigned to a committee meeting. The application will not be assigned to a meeting until the researcher submits a 'review ready' version.

The application is then assigned to the next available meeting for review. Western Sydney operates two research ethics review committees, one for very low or negligible risk research (LNR) and one for research involving risk greater than low risk (HREC), as set out in the National Statement on Ethical Conduct in Human Research.

Following committee review, a Human Ethics Officer will send any comments back to the researchers for action, or process the approval.

For more information on the Western Sydney human ethics review process

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

Common misconceptions and problems with ethics applications

- Thinking the application assessors will presume or infer information.
- Not writing for the audience. The Committees include researchers and appointments from the general community and these members are unlikely to have any research experience or expertise in your field. The research participants in your project will usually also be members of the general community and must be able to understand all public documents e.g. the information sheet.
- Having information in the application that conflicts with other statements in the application or the attachments.
- Thinking the application and ethics process is intuitive - you need to understand the principles of ethics review, as per the documents noted above, and any legal issues relating to your research.
- Failing to address the practical 'how' of the required steps to make the project work and then failing to address the ethical issues raised by the 'how'. This includes requirements for additional clearances and the need to provide evidence of those.

Human Research Ethics Guidance Documents available from REDI

- Guidance for Researchers New to Human Ethics Review
- Guidance on Choosing the most appropriate PIS and Consent
- Guidance on Levels of Risk and the Ethical Review Process
- Guidance on Making an Amendment to an Approved Project
- 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 Data Storage and Retention Questions
- Guidance on Ethics Review Exemption
- Guidance on Research Involving Young People
- Guidance on Using Focus Groups in Research
- Guidance on Complaints
- Guidance on Research being done with, or for, Organisations

Human Research Ethics Team Contact: humanethics@westernsydney.edu.au