

Guidance on External Ethics Recognition

Projects and researchers which have received ethics approval from an NHMRC registered Human Research Ethics Committee other than Western Sydney University HREC (including health services), and in some cases from overseas ethics review bodies, can apply to WSU for recognition of that approval.

Previously that process was referred to as 'reciprocal approval' however is now referred to as External Ethics Recognition.

This guidance sheet outlines what projects and existing ethics approvals are eligible for recognition.

What is External Ethics Recognition?

The recognition means that the documents you provided with the External Ethics Recognition Cover Sheet

- show that ethics approval for the project was obtained from an accredited ethics review body
- show that the approving ethics review body accepts responsibility for the project at all sites, ie ongoing project monitoring including adverse events monitoring
- name the Western Sydney University staff / student to be covered by WSU recognition
- where appropriate name Western Sydney University as a research site.

Australian HRECs

For projects which have external approval from an Australian accredited HREC ethics staff check that the conditions above are met.

Overseas ethics review entities

Researchers who have received ethics approval from an overseas ethics review body should not presume they will be eligible for External Ethics Recognition.

Under the [National Statement on Ethical Conduct in Human Research](#) the WSU HREC is required to ensure that any alternate ethics approval obtained for a project meets the following requirements:

*"4.8.4 (People on other countries) Researchers should inform ethical review bodies in Australia:
(a) whether, in the country in which they intend to do research, there are ethics approval processes that are relevant to that research, and whether any such processes are mandatory or voluntary in relation to the proposed research; and
(b) how such processes function, the values and principles on which they rely, and whether they require reporting of the Australian review body's approval*

4.8.6 (People on other countries) Some funding or national requirements will direct researchers and review bodies to conform to the ethics guidelines of local institutions or to recognised international guidelines or instruments. Research conducted under those guidelines or instruments should be approved only if participants will be accorded no less respect and protection than this National Statement requires.

Chapter 5.1

Research governance

*5.1.1 Institutions must see that any human research they conduct or for which they are responsible is:
(a) designed and conducted in accordance with the Australian code for the responsible conduct of research; and*

(b) ethically reviewed and monitored in accordance with this National Statement.

HRECs: research involving more than low risk

5.1.24 Each institution that conducts human research involving more than low risk must ensure that this research is reviewed and approved by an HREC that is constituted and functioning in accordance with this National Statement, whether or not that HREC is established by the institution.”

A request for external recognition by an overseas HREC will not be considered as approved until it is reviewed and considered appropriate by the HREC Chair.

When Recognition is provided

Recognition **DOES NOT** mean that the WSU HREC or LNR have considered the project and approved it and will act as an ongoing monitoring body for the project.

Given this, all future correspondence, amendments, time extensions etc must go through, and be approved by, the external review body. Western Sydney asks for copies of any additional approved documents to be provided for the project file, but again, does not assess and approve them. In addition, Western Sydney asks for a final report when the project is completed so that we can close off our file.

If circumstances change

It is important to note that if circumstances change and Western Sydney University ethics approval is required, the researchers will need to make one of the following:

- a joint approval application when the project going forward will have more than one ethics review approval and monitoring body;
- a transfer of ethics approval request when the CI is transferring to Western Sydney and bringing the project with them and the original HREC will be withdrawing its ongoing ethics role; or
- a new application to WSU which will be assessed in the same way as all new applications.

A copy of the External Ethics Recognition form is at:

<http://www.westernsydney.edu.au/research/researchers/forms>

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

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