

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.

At some institutions that process is referred to as 'reciprocal approval' however at WSU is referred to as External Ethics Recognition.

External Ethics Recognition is not the same as ethics approval. It is a process that allows Western Sydney to maintain a central record of ethics approvals obtained by staff and students. For approvals granted by overseas ethics committees, the process also allows Western Sydney to confirm that the process undertaken by the overseas ethics committee to review the research is equivalent to an ethics review that would be undertaken by the Western Sydney University HREC.

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 either an NHMRC accredited ethics review body; or the overseas ethics committee conducts ethical review that is equivalent to a WSU HREC review
- 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 / students 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.

When assessing a request for recognition of an overseas ethics approval, the WSU HREC will consider:

- Whether there is an ethics committee accreditation process in the jurisdiction
- Whether the research was reviewed against a set of ethical guidelines that align with the National Statement on Ethical Conduct in Research
- Whether the application submitted for review requires the researcher to discuss how the research aligns with the relevant ethical guidelines
- Whether the membership composition of the overseas ethics committee aligns with the requirements of the National Statement and the committee includes at least academic and lay members and expertise relevant to the research under review

The WSU HREC has reviewed the processes of ethical review in the following countries and or individual ethics committees and has determined that the ethical review is equivalent to an Australian review. If the country or committee is not listed here, the ethics review will need to be assessed by the Ethics Officer & Chair of HREC before acknowledgement of external recognition can be issued:

Country/Committee	Additional Information
Canada	Research Ethics Board (REB)
New Zealand	
United States	Institutional Review Board (IRB). Note that IRB exemption may be for a project that Australia considers to be under the low-risk category for research requiring ethical review. Check documentation to ensure that ethical approval was granted, and not an exemption.
South Africa	Institution Review Boards (IRB)
Scotland	
Fiji	
University of Malaya Medical Research Ethics Committee	
Tehran University of Medical Sciences	
College of Medicine Research and Ethics Committee, Malawi	
Germany	
India	Health or medical research that has ethical approval from a committee approved by the Central Drugs Standard Control Organisation. Other research to be considered on a case-by-case basis.
Nigeria	Health or medical research that has ethical approval from a committee approved by the National Health Research Ethics Committee of Nigeria, Federal Ministry of Health. Other research to be considered on a case-by-case basis.

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

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