

External Ethics Recognition Cover Sheet

If you have received ethics approval from an NHMRC registered Human Research Ethics Committee other than Western Sydney University HREC (including health services) you may not be required to submit a new application to Western Sydney University HREC.

As of 2019, researchers who have an externally funded project (eg ARC, NHMRC), and who obtain ethics approval from an external Human Research Ethics Committee (Eg Local Health District) are required to notify WSU of that approval via this process.

To be eligible for Western Sydney University External Ethics Recognition:

* **the Western Sydney University staff / student must be named on the approved ethics application, and / or named in the approval letter (or an approved amendment letter)**
* where appropriate Western Sydney University must be listed as a research site
* the approving HREC must accept responsibility for the project at all sites, i.e. ongoing project monitoring including adverse event monitoring.

If these criteria cannot be met the researcher should make an ethics application to the Western Sydney University HREC.

**SUBMISSION**

Submit this completed cover sheet (along with the documents listed in the mandatory attachments list) to the Human Ethics Officer by email ([humanethics@westernsydney.edu.au](mailto:humanethics@westernsydney.edu.au)).

**If you are unable to use the tick boxes on this template, please delete the option/s which do not apply.**

# Mandatory attachments

This **cover sheet**

Copy of the **approved ethics application**

All **supporting documents** including project description, information sheets, consent forms and data collection tools

The **ethics approval letter** from the approving HREC (Note: we do not need public health SSA documents)

Any **amendments** and corresponding approval letters by the approving HREC

Any **other correspondence** with the approving HREC, including previous progress reports.

# Section 1: Overview

**1.1.**  Approved Protocol Title:

**1.2.** External Institution HREC Official Name:

**1.3.** External Institution Approval Number:

If the approval has been granted by a non-Australia NHMRC accredited HREC, complete questions at **Section 6**

# Section 2: Western Sydney University Investigators

**2.1.** **Chief Investigator**

Family Name: First Name: Title:

Western Sydney University Unit: E-mail Address:

**2.2.** **Other Western Sydney Researcher**

Family Name: First Name: Title:

Western Sydney University Unit: E-mail Address:

**2.3.** **Chief Student**

Family Name: First Name: Title:

Western Sydney University Unit: E-mail Address:

**2.4.** **Other Western Sydney Student**

Family Name: First Name: Title:

Western Sydney University Unit: E-mail Address:

# Section 3: Risk, Type of Research and Participant Involvement

**3.1.** Risk Level

High  No more than Low  Negligible

**3.2.** Does this project involve any of the following:

Select all that apply

Clinical Trials – including CTN/CTX

Clinical Trials – excluding CTN/CTX

Research conducted overseas

Aboriginal and/or Torres Strait Islander peoples

Children

None of the above

**3.3.** What is the approach to consent for this project?

Written  Verbal  Implied  Assent  Waiver  Opt-Out

**3.4.** What is the consent type for this project?

Specific  Extended  Unspecified

# Section 4: Approval Period of Existing/Approved Protocol

**4.1.** Approved Commencement Date: **4.2.** Approved Expiry Date:

**4.3.** Approval period if aligned with funded grant or longitudinal study beyond 5 years:

# Section 5: Funding

**5.1.** Does this research have external funding that is being administered in a Western Sydney University Research Account?

No

Yes

5.1.1. If Yes, provide the Project ID as it appears on the [Researcher Portal](https://research-report.westernsydney.edu.au/wpubs/Portal.asp) (E.g. P00000001):

# Section 6: Non-Australian Ethics Review Body

If the ethics review body is not an Australian NHMRC accredited HREC, the Western Sydney University HREC require evidence that its ethics review and monitoring processes can be considered equivalent to the Australian ethics review system. Western Sydney University HREC retains the right to determine whether a non-Australian ethics review process will be accepted.

Please complete the following:

**6.1.** In which country does the ethics review body operate?

**6.2.** Is the ethics approval mandatory or voluntary in the country the institution is governed by?

Mandatory  Voluntary

**6.3.** Is the ethics review body accredited nationally (in its own country)?

Yes  No

**6.4.** Summarise the ethics review body process:

E.g. Are applications peer reviewed and assessed by committee? Does the ethics review body refer to standardised or nationally accepted and documented values and principles statements (equivalent to the Australian National Statement on Ethical Conduct in Human Research)?

**Forward this completed form and all relevant documents to** [**humanethics@westernsydney.edu.au**](mailto:humanethics@westernsydney.edu.au)