

Joint Ethics Application 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) but you also need ethics approval from the Western Sydney University HREC you can request review under the ‘joint approval’ ethics review pathway.

To be eligible for this review pathway:

* the project must already have at least one approval from an NHMRC accredited HREC or an international equivalent
* the need for approval by more than one HREC must be evident
* the Western Sydney University staff/student must be listed on the approved ethics application, and/or named in the approval letter (or an approved amendment letter).

If these criteria cannot be met the researcher should make an ethics application to the Western Sydney University HREC under a new application review pathway.

Projects which are granted joint approval will need to report annually to all approving HRECs and any amendments will need to be approved by all HRECs. Western Sydney University will provide a Western Sydney University approval ID number which must be quoted on all correspondence with this ethics team.

Joint approval applications may be reviewed by the Executive committee if considered appropriate. Western Sydney will review the risk level and assign according to its requirements. If the committee decides that joint approval isn’t appropriate for any reason, the researchers will need to make a new application.

**SUBMISSION**

Submit this completed cover sheet (along with the documents listed in the checklist) 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.**

# Rationale

Why is joint approval required for this project?

# Checklist

This cover sheet

The original application to the approving HREC

The approval letter from the approving HREC

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 7**

# Section 2: Western Sydney University Investigators

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

Family Name: First Name: Title:

WSU Unit: E-mail Address:

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

Family Name: First Name: Title:

WSU Unit: E-mail Address:

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

Family Name: First Name: Title:

WSU Unit: E-mail Address:

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

Family Name: First Name: Title:

WSU 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

None of the above

**3.3.** Is the inclusion of Aboriginal or Torres Strait Islander participants an intent of your research?

**3.4.** Are your participants under 18 and / or have an impaired ability to provide free and voluntary consent on their own behalf?

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

Written  Verbal  Implied  Assent  Waiver  Opt-Out

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

Specific  Extended  Unspecified

# Section 4: If the Project is a Clinical Trial

**4.1.** Does the nature of the study or research require that the investigator or any assistant must be a registered medical practitioner or other registered qualified health service provider:

If Yes:

4.1.1. Is the study or research to find out whether an intervention, such as treatments or diagnostic procedures, that are believed may improve a person's health, actually do so?

4.1.2. Is the study or research to:

test a drug, a surgical or other therapeutic or preventative procedure?

test a therapeutic, preventative or diagnostic device or service?

# Section 5: Approval Period of Existing/Approved Protocol

**5.1.** Approved Commencement Date: **5.2.** Approved Expiry Date:

**5.3.** Has data collection / involvement of human participants already commenced?

# Section 6: Funding

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

No

Yes

6.1.1. 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 7: 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:

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

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

Mandatory  Voluntary

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

Yes  No

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

E.g. Are applications peer reviewed and assessed by a 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)