

Application for Exemption from Human Research Ethics Review

# Background

Certain activities can be exempted from the requirement to seek ethical review, including some research, quality assurance, evaluation and teaching/learning.

For **research** to be exempt, it must be negligible risk and involve the use of existing collections of data/records that contain only non-identifiable data.

**Quality assurance, evaluation and teaching** activities can be exempt from ethical review if:

* The data being collected and analysed is coincidental to standard operating procedures with standard equipment and/or protocols.
* The data is being collected and analysed expressly for the purpose of maintaining standards or identifying areas for improvement in the environment from which the data was obtained.
* The data being collected and analysed is not linked to individuals.
* The activity does not infringe the privacy or professional reputation of participants, providers or organisations
* The activity does not use data or analyses from QA or evaluation activities for another purpose.
* The activity does not gather information about the participant beyond that which is collected routinely.
* The activity does not involve testing of non-standard (innovative) protocols or equipment.
* The activity does not involve comparison of cohorts.

If your proposal to be exempted is approved, you will be issued with a letter stating that the proposed activity is exempt from ethical review. This letter is not an ethical approval letter, and you must not make any claim to any organisation, publisher etc that you have received ethics approval to conduct the activity.

# Section 1: Overview

* 1. Title of the Project:
	2. Approximate Start Date:

**1.3.** Names and IDs of key Western Sydney researchers (staff and students):

|  |  |
| --- | --- |
| Name | Student/Staff ID |
|  |  |
|  |  |
|  |  |

**1.4.** Are you claiming that:

 [ ]  The project is research but qualifies for an exemption from ethical review

 🡺 Complete Section 2 below

 [ ]  The activity is not research i.e., a quality assurance (QA), evaluation or learning and teaching activity

* Complete Section 3 below

**1.5.** A one-page summary of the research proposal or project outline must be attached to this form.

 [ ]  Research proposal / project outline is attached.

# Section 2: Research which is exempt from ethical review

**2.1.** Explain why you believe the research meets the National Statement requirements for exemption from ethics review. Refer to [National Statement Clauses 5.1.22/5.1.23](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018)

**2.2.** If the activity is research, does it meet all of the minimum standards for ethics review exemption?

 [ ]  The activity is negligible risk as defined in the National Statement

 [ ]  It involves the use of existing collections of data or records only

 [ ]  The data to be used is non-identifiable

**2.3** Basis for exemption. Select the appropriate option below:

[ ]  **All data to be used is already in the public domain**

Note: If the research will only use data, documents or records that are all publicly available, e.g. publicly accessible archives, publications or recordings, human research ethics review is generally not required. ‘Publicly accessible’ is the key issue and researchers shouldn’t presume that because data is easily available, for example via the internet, that it meets the requirements of ‘publicly accessible’.

For more information, see page 36 of the [National Statement](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018). If a waiver of consent for the use of the data is required, an ethics application will need to be made.

Describe the data you are using and publishing and its current location(s). Include whether the data is, or will be, identifiable at any stages – collection, analysis and publication.

[ ]  **Using existing database(s). Tick which apply**

[ ]  The research is Negligible risk. This is defined at NS 2.1.7 as “Research is ‘negligible risk’ where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk.”

[ ]  I am collecting, using or disclosing data from an agency, authority or organisation for the purpose of research.

[ ]  The disclosing agency, authority or organisation has indicated to the researchers that it is able / willing to supply the data without ethics review.

[ ]  The data to be accessed will be in non-identifiable form (and not able to be re-identified)\*

[ ]  The data to be used will be in non-identifiable form (and not able to be re-identified)\*

[ ]  The data to be published will be in non-identifiable form (and not able to be re-identified)\*

\* ‘Non-identifiable data’ that can be re-identified may contravene privacy legislation. When thinking through whether non-identifiable data could be re-identified the researcher should consider whether the information has been drawn from a ‘closed community’ or a small sample; whether the techniques used to de-identify the data can be considered adequate; and whether the datasets are large enough to avoid the possibility of re-identification based on certain characteristics of a participant.

[ ]  **Use of Western Sydney SFU or SFT survey data only**

[ ]  My project uses Western Sydney SFU or SFT survey data only

# Section 3: Activities which are not research (eg QA/Evaluations/teaching)

Please note that you are not required to make a formal exemption request for these activities, but you can do so if you wish your decision not to seek ethical review to be ratified by the university.

**3.1.** Explain why the activity is for the purposes of quality assurance, evaluation or teaching only. Why do you believe the activity meets the requirements for exemption from ethical review? Refer to [NHMRC: Ethical Considerations in Quality Assurance and Evaluation Activities](https://www.nhmrc.gov.au/about-us/resources/ethical-considerations-quality-assurance-and-evaluation-activities)

3.2 Basis for exemption. Select the appropriate option below:

[ ]  **Academic researcher**

 Teaching activity - the activity is for quality assurance or improvement of teaching.

 Evaluations of teaching and learning involve many of the same activities as conducting research. Such evaluations are treated as research only when the results will be published or disseminated outside Western Sydney University.

[ ]  **Undergraduate/Postgraduate Students**

 Activities conducted only for the purposes of assessment and not resulting in any publication/dissemination.

I confirm the activity is being undertaken by undergraduate or postgraduate students for the purposes of course assessment only, and that results of the activity will not be distributed beyond Western Sydney University.

[ ]  **Quality Assurance Activity/Evaluation**

The NHMRC has released *Ethical Considerations in Quality Assurance and Evaluation Activities* to assist in determining whether an activity can be classified as QA or an evaluation activity, and therefore not research and therefore exempt from human ethics review. Researchers should note that, even if the activity can be classified as QA or evaluation the activity must be conducted in a way that meets the ethics principles in the National Statement.

[ ]  I confirm have read *Ethical Considerations in Quality Assurance and Evaluation Activities* and determined that the activity is quality improvement only and that results of the activity will not be distributed beyond Western Sydney University.

# Section 4: Declaration

**I understand that:**

* **A statement of ethics exemption is not equivalent to ethics approval. (The project will not be given an ‘approval’ ID.)**
* **Further or different use of the data may require ethics approval, alternately, further or different use may not be possible because ethics review has not been sought.**
* **Western Sydney University does not grant retrospective ethics approval.**

Name of Signatory:

Signature: Date:

**Forward the completed and form to the Human Ethics Officer –** **humanethics@westernsydney.edu.au**