

Guidance on Ethics Review Exemption

Guiding statements

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

For an activity to be exempt, it must be lower risk and satisfy one of a number of criteria (see below).

Before conducting the activity, you must apply to the Ethics Committee to be granted an exemption. An exemption cannot be granted retrospectively.

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 will not be an ethics approval letter, and you must not make any claim to any organisation, publisher etc that you have received ethics approval to conduct the activity.

More information can be found on page 87 of the [National Statement on Ethical Conduct in Human Research 2023](#).

Overview

In determining the need for ethical review of research involving humans the NS identifies two key issues for initial consideration:

- What is human research?
- When, and by what means, does human research, or other activities such as quality assurance or improvement, or clinical audit, need ethical review?

What is human research?

Human research is conducted with or about people, or their data or tissue.

Human research includes activities that may be considered obvious, such as participants taking part in surveys, interviews or focus groups, through to the less obvious, such as accessing information from existing published or unpublished sources or databases.

Importantly, the term 'participants' includes people even if they don't know they are being included in the research.

What is QA/Evaluation?

These activities are characterised by:

- 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

While QA/Evaluation activities generally do not require ethical review, they do require oversight by the University. At Western Sydney, there are two review pathways:

- Full ethical review;
- Exemption from ethical review

Criteria for Exemption

To be eligible for an exemption, the activity must be lower risk:

“Research in which there is no risk of harm, but in which there is a risk of discomfort and in which there may also be a foreseeable burden (low risk research) OR research in which there is no risk of harm or discomfort, but which includes a potential for minor burden or inconvenience (minimal risk research).”
National Statement, Section 2.1)

The activity must then align with one of the following exemption categories.

Standard Exemption Categories

Category A: Use of pre-existing data/information

The research involves the use of collections of information or data from which all personal identifiers have been removed prior to being received by the researchers. For example, this may include non-identifiable datasets obtained from databanks or other researchers.

When using pre-existing data from an agency, authority or organisation you should consider:

- Has the disclosing agency, authority or organisation indicated to the researchers that it is able / willing to supply the data without ethics review?
- Will the data you access be in non-identifiable form (and not able to be re-identified)?
- Will the data you use be in non-identifiable form (and not able to be re-identified)?
- Will the data you publish be in non-identifiable form (and not able to be re-identified)?

Category B: Non-Identifiable Surveys and Observational Research

The research is restricted to surveys and observation of public behaviour using information that was or will be collected and recorded without personal identifiers and is highly unlikely to cause distress to anyone associated with the information or the outcomes of the research.

Category C: Educational Training Program

The activity will be conducted as part of an educational training program in which the research activity is for training purposes only and where any outcomes or documentation are provided for program use only.

Category D: Use of Publicly Available Information

The research uses only information that is publicly available through a mechanism set out by legislation or regulation that is protected by law, such as mandatory reporting information, information obtained from registries of births and deaths, coronial investigations, Australian Bureau of Statistics data, Western Sydney University SFU or SFT survey data.

There are 3 key issues when considering this type of data:

- ‘Publicly accessible’ – 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 on Ethical Conduct in Human Research 2023](#).
- Research requiring a waiver of consent for the use of the data cannot be exempted from ethical review.
- Non-identifiable data – refers to the state of the data at the point it is received or collected by the researcher. If the researcher needs to manipulate the data to remove identifiers, then the data is considered to be “re-identifiable”, not “non-identifiable”..

Category E: Quality Assurance/Evaluations/Teaching

Some QA and Evaluation activities can be exempted from ethical review if they satisfy the following criteria:

- The data being collected and analysed is coincidental to standard operating procedures with standard equipment and/or protocols; and
- 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; and

- The data being collected and analysed is not linked to individuals.

If any of the following triggers apply, you must apply for full ethics approval:

- The activity potentially infringes the privacy or professional reputation of participants, providers or organisations
- Secondary use of data - using data or analysis from QA or evaluation activities for another purpose
- Gathering information about the participant beyond that which is collected routinely. Information may include biospecimens or additional investigations
- Testing of non-standard (innovative) protocols or equipment
- Comparison of cohorts
- Randomisation or the use of control groups or placebos
- Targeted analysis of data involving minority/vulnerable groups whose data is to be separated out of that data collected or analysed as part of the main QA/evaluation activity.

The NHMRC guidelines on [Ethical Considerations in Quality Assurance and Evaluation Activities](#) is a useful resource that can help you to determine whether an activity can be classed as QA or an evaluation activity.

Researchers are advised to review section 2(e) Triggers for consideration of ethical review when determining if their activity may be exempt.

Researchers should note that, even if the activity can be classified as QA or evaluation, the activity must be conducted in a way that complies with the ethics principles in the National Statement.

Western Sydney University Specific Requirements

Students as potential participants

- Western Sydney SFU and SFT surveys advise students that if they submit the survey, they are consenting to the data being used for research purposes, therefore, further ethical review is not required.
- Academic staff should note that access to student records for teaching purposes does not grant access for research purposes. Requests to use student data which forms part of the student's academic record should be directed to the Western Sydney Chief Student Experience Officer. The project will require an ethics application.

Students' collecting and using data about others

Undergraduate activities conducted only for the purposes of assessment and not resulting in any publication/dissemination do not require ethical review. Note that if the output has received funding or can be counted as part of Higher Education Research Data Collection (HERDC) reporting then it is research and may require ethics approval.

Undergraduate Honours research may require ethical review unless the research satisfies the exemption criteria.

Making a Decision about whether a project needs ethics review

If you are conducting research involving human participants and/or their data and tissue you must either:

- Apply for full ethics approval; or
- Apply to be exempted from ethical review.

An [Exemption Decision Tree](#) has been developed to assist you to determine whether your research can be exempted from ethical review.

You must not commence the research until you have received approval from the Ethics Committee for one or the other.

Researchers may need to consider whether the research reporting avenues will expect the activity to have received ethical clearance i.e. some journals will not publish unless ethical review has been undertaken. This should be considered very carefully because retrospective ethics approval cannot be granted. Once the activity has commenced it is not possible to apply for ethics approval.

How to apply for Exemption from Ethical Review

This request should be made on the [Exemption from Ethical Review Form](#). A one-page outline of the activity should also be attached. If the committee declines your request, you will be directed to submit a full ethics application.

Resources about this topic

How to apply for human ethics review – risk level

https://www.westernsydney.edu.au/research/research_ethics_and_integrity/human_ethics/apply_for_human_research_ethics_review

Ethical Considerations in Quality Assurance and Evaluation Activities, NHMRC 2014

<https://www.nhmrc.gov.au/about-us/resources/ethical-considerations-quality-assurance-and-evaluation-activities>

Australian Law Reform Commission, Australian Privacy Law and Practice, 64. Research: Current Arrangements

<http://www.alrc.gov.au/publications/For%20Your%20Information%3A%20Australian%20Privacy%20Law%20and%20Practice%20%28ALRC%20Report%20108%29%2064-research>

NHMRC Guidelines approved under Section 95 of the Privacy Act 1988, 2014

<https://www.nhmrc.gov.au/about-us/publications/guidelines-approved-under-section-95a-privacy-act-1988>

NHMRC Flowchart for determining whether the S95 Guidelines apply

<https://www.nhmrc.gov.au/sites/default/files/documents/attachments/flow-chart-s95-guidelines.pdf>

The De-Identification Decision-Making Framework

<https://www.oaic.gov.au/privacy/guidance-and-advice/de-identification-decision-making-framework/>

UK ICO's Anonymisation Code of Practice, 2012

<https://ico.org.uk/media/1061/anonymisation-code.pdf>

Sax Institute (45 and Up Study) Governance and Ethics

<https://www.saxinstitute.org.au/our-work/45-up-study/governance/>

Other Western Sydney University Guidance Documents:

A series of Guidance Documents on a range of topics is available on the web.

<https://www.westernsydney.edu.au/research/forms>

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