

Guidance on Ethics Review Exemption

Guiding statements

Sections 5.1.22 and 5.1.23 of the National Statement (NS) state that exemption from ethical review is a choice/decision of the University.

Section 5.1.23 clarifies that a decision to exempt research from ethical review is not an automatic result of the application of the NS. Rather, it is a determination of the University that the research (or the nature of the research) meets the requirements of the NS and is ethically acceptable.

The elements of a decision to exempt from review

The NS provides that to qualify for possible exemptions research must, at a minimum:

- be human research to which the NS otherwise applies;
- be **'negligible risk'** (as per definition in section 2.1.7) [5.1.22(a)];
- involve the **use of existing collections of data** / records (only) [5.1.22(b)]; and
- contain **only non-identifiable data** about human beings [5.1.22(b)]

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interviews or focus groups, through to the less obvious, such as accessing information from existing published or unpublished sources or databases.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.

Whilst the funding source of an activity is not the decider on whether or not the activity is research, at Western Sydney, an activity which has been funded as research and/or is recorded in ERA reporting is research and must be submitted for ethics review.

Standard Exemption Scenarios

Scenario 1

If the research will only use data, documents or records that are all publicly available, e.g. publicly accessible archives, publications or recordings, and the project is negligible risk, human research ethics review is generally not required. There are 2 key issues when considering this exemption:

- 'Publically accessible' – researchers shouldn't presume that because data is easily available, for example via the internet, that it meets the requirements of 'publically accessible'. For more information, see page 36 of the National Statement on Ethical Conduct in Human Research, updated 2018. If a waiver of consent for the use of the data is required, an ethics application will need to be made.
- Non-identifiable data – the identifiability of data is considered at the collection, use, storage and dissemination stages.

Scenario 2

If the research will use existing databases the following questions need to be asked, and each answer must be 'yes'.

- Is the research 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."
- Are you collecting, using or disclosing data from an agency, authority or organisation for the purpose of research?
 - 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 you the data you publish 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.

Other forms of Negligible risk research involving human participants must be submitted for ethics review.

Scenario 3

If the activity is for quality assurance or improvement of teaching, and is not research, it can be exempt from review.

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.

Scenario 4

If the activity is a quality assurance activity (QA).

The NHMRC has released Ethical Considerations in Quality Assurance and Evaluation Activities to assist in determining 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 meets 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 ERA reporting then it is research and will need ethics.

Undergraduate Honours research DOES require ethical review unless it is exempt because it meets standard exemption criteria - as outlined above.

Making a Decision about whether a project needs ethics review

It is the researchers' responsibility to determine the ethics review requirements of the project and it is possible that changes to the project may take it from being exempt to needing review for work going forward.

Researchers may need to consider whether the research reporting avenues will expect the activity to have received ethics clearance i.e. some journals will not publish unless ethical review has been undertaken.

The ethics committees have the authority to apply an exemption in relation to a waiver of consent for the use of personal information in research under privacy legislation. The committee requires a full ethics application to be made to determine if it is able to do this.

Researchers should be mindful that ethics approval will not be given retrospectively i.e. once the activity has commenced or been done it is not possible to get retrospective ethics review and approval for that project.

Research which *is* exempt from review

If the research is exempt it doesn't need to be submitted for ethical review. The activities, however, must comply with relevant University and national ethical standards and the activity may still require other types of approvals.

For formal recognition of ethics exemption researchers can submit an ethics exemption request which will be considered by the HREC Executive. This request should be made on the FORM: Exemption from human ethics review available at <https://www.westernsydney.edu.au/research/forms>. A one-page outline of the activity should also be attached. If the committee decides the activity is not suitable for exemption a full application will need to be made.

Resources on 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/>

Acknowledgement: *This material is an adaptation of Griffith University's research ethics arrangements.*

Thanks to Mr Nick Drew, Research Contracts Officer, Western Sydney University for additional material.

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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