

Exemption Process for Research Projects

Introduction

This document outlines the process for requesting an exemption from ethical review as per the guidelines in Section 5.1 of the National Statement on Ethical Conduct in Human Research. Exemptions are rarely granted and are only considered under specific circumstances where the research meets certain criteria.

Circumstances for Exemptions

As per the National Statement the decision as to whether to grant an exemption from review for a research project is the responsibility of the institution — it is not the responsibility of the researcher.

Research that may be eligible for exemption from ethics review includes research that carries a lower risk to participants or the community AND satisfies ONE or MORE of the conditions in (a)–(d), below:

- (a) 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 and where researchers explicitly;
 - (i) agree not to attempt to re-identify those with whom the information or data is associated;
 - (ii) to take all reasonable steps to prevent re-identification of the information or data for unauthorised purposes or access to the information or data by those who are not authorised; and
 - (iii) that any sharing of any research data during or after the project will not create any additional risks of re-identification of the information or data;
- (b) 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;
- (c) is 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 for program use only;
- (d) the research uses only information that is publicly available through a mechanism set out by legislation or regulation and that is protected by law, such as mandatory reporting information, information obtained from registries of births and deaths, coronial investigations or reports of the Australian Bureau of Statistics.

The committee may also give an exemption when the study is an audit or quality assurance activity that does not extend beyond the scope of standard practice and where the results will not be published.

NOTE: Please be advised that any research involving Aboriginal or Torres Strait Islander participants are not considered to be low risk

NOTE: Research that involves the use of personal information without consent cannot be granted an exemption from ethics review because, to conduct such research, a waiver of the requirement for consent would need to be granted by an appropriate ethics review body. (National Statement 5.1.16)

Exemption Request Requirements and process

To apply for an exemption, researchers must submit the following:

Written Rationale: A written statement detailing why an exemption is being requested, including the specific section(s) of the National Statement that support the request.

Research Protocol: A full protocol document that includes a description of the project, aim, objectives, an outline of who the participants and recruitment (if applicable), methodology, analysis plan and reporting of results. The research protocol helps the Committee understand the nature and scope of the project.

All exemption requests must be submitted in writing to the Ethics Committee.

Review and Decision-Making

Upon receiving a request, the Ethics Committee will review the submitted documents to assess whether the exemption criteria are met.

The decision will be communicated to the applicant in writing, along with any additional recommendations or requirements.

Approval and Notification

If an exemption is granted, the researcher will receive a written approval. Exemption from ethical review does not negate the researcher's responsibility to uphold ethical standards and comply with relevant institutional and legal requirements.

If at any stage, the project is amended, the exemption will be void and either the researchers will need to reapply for an exemption or for full ethics approval.