Guide to Barwon Health HREC Applications

When does a research project require ethics committee review?

The National Statement on Ethical Conduct in Human Research 2007 (NS) Section 5.1 states that research which is no more than low risk research (including QA and negligible risk research):

- Must be reviewed by people who are familiar with the NS and have an understanding of the ethical issues that can arise; and have due regard to privacy regulations (laws) and is reviewed to ensure that it does not require review by the Human Research Ethics Committee (HREC).

Many QA and negligible risk projects can be exempted from full HREC review, however these will be reviewed by the REGI Unit with advice from the Barwon Health HREC, where appropriate.

Projects submitted to the REGI Unit will be assessed to determine whether or not the project:

- Qualifies for the exemption from ethics committee review; and
- Meets the requirements of all applicable legislation, codes of practice and Barwon Health policy.

Projects that are accepted as exempt from ethics committee review will be approved out of session and ratified by the Barwon Health HREC.

Any project that is not exempt must be submitted for ethics committee review.

Which projects are exempt from ethics committee review?

Ethics committee review may not be necessary and projects may be eligible for an exemption from full HREC review, where the research involves only:

- The use of existing collections of data that contain only **non-identifiable data** about humans
    - ***"Non-identifiable data** is data that has never been labelled with individual identifiers or from which identifiers have been permanently removed, and by means of which no specific individual can be identified. A subset of non-identifiable data is one that can be linked with other data so it can be known they are about the same data subject, although the person's identity remains unknown."*
- The use of information that would ordinarily be collected as part of patient management from a patient, either in person or through a survey/questionnaire;
- Negligible risk research
    - ***"Negligible risk research** is where there is no foreseeable risk or 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."*
- Does not involve the collection of new raw data, sensitive information, identifying information, or external researchers; and
- Is not instigated by an external person.

Which projects are NOT exempt from ethics committee review?

The NHMRC's advice outlined below for QA/audit activities states that where one or more of the triggers below apply, ethical review should be sought.

"Triggers for consideration of ethical review:

- Where 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 bio-specimens or additional investigations);
- Testing of non-standard (innovative) protocols or equipment;
- Comparison of cohorts;
- Randomisation or the use of control groups or placebos; and
- Targeted analysis of data involving minority/vulnerable groups."

Where ethical review by a HREC is not required, the REGI Unit will provide a statement which affirms that an alternative approach to ethical review was considered to be appropriate for the specific QA/evaluation activity.

How to apply for exemption from ethics committee review

If you think your research is exempt from ethics committee review, please view the Negligible Risk Application Guide found on the Audits, QA & Negligible risk applications webpage for information on the document requirements for your application.

Procedure for low and great than low risk research projects (that are not exempt from ethics committee review)

Low risk research

If the research does not meet the requirement for exemption from ethics committee review, and is **negligible** or **low risk,** the project will be reviewed by the Human Research Ethics Committee (HREC).

Low risk research is where the only foreseeable risk is one of discomfort. Where the risk, even if unlikely, is **more serious than discomfort, the research is not low risk.** If you think your research fits into this category, please view the Low Risk Application Guide found on the Low risk applications webpage.

For information on Participant Information and Consent Forms (PICFs) and waivers of consent, please visit the Consent, Waivers & PICFs webpage. Please be aware that many sections of the PICF templates may be inappropriate or irrelevant for a low risk project. You do not need to strictly adhere to the template wording and should edit and delete sections where necessary.

Greater than low risk research

For all research that involves greater than low risk, full ethical review is required and a full application to the HREC should be submitted for review and approval. Please see the Greater Than Low Risk Application Guide found on the Greater than low risk applications webpage for information on submission requirements.

Guidelines and advice on seeking consent or a waiver of consent are available on the Guidelines and advice webpage.