

The background of the slide is a complex, abstract pattern of overlapping, semi-transparent blue shapes. These shapes include various polygons, circles, and curved lines, creating a sense of depth and movement. The colors range from light sky blue to a darker, muted blue. The overall effect is a modern, digital aesthetic.

2.0 WHEN DO I NEED ETHICS APPROVAL?

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All human research requires ethics approval. Human research is any research that is conducted with or about people, their data and/or their tissues. There are a few exceptions listed in the following section.

This diagram provides some examples of activities that count as human research.³



What types of research do not always require ethics approval?

The following activities do not always require human research ethics approval:

- Research that does not involve humans, their data, or tissues/fluids but that meets the National Statement's conditions for exemption ([s5.1.22](#)). You must still apply for an exemption before commencing the research.

- Research using certain types of publicly available information.
- Some quality assurance and evaluation activities.

In 2014, the NHMRC issued a new three-page statement concerning 'ethical considerations' of both quality assurance and evaluation.⁴ The document recognised that ethics review of quality assurance and evaluation activities may not always be required, but emphasised that whatever an activity is called, participants must be 'afforded appropriate protections and respect'; that the activity must be conducted ethically with consideration given to, for instance, risk, consent and privacy; and that organisations should develop policies for the oversight, and where necessary ethics review of quality assurance and evaluation activities. The NHMRC provided seven 'triggers', the presence of any one of which should occasion formal ethics review according to the requirements in the National Statement:

1. Infringement of privacy;
2. Use of data collected for a different purpose;
3. Gathering information from participants that is beyond that which would normally be collected during the participants' involvement with the service (to which could be added requiring the participant to do something that would not normally be part of the participants' involvement with the service);
4. Use of non-standard protocols or equipment;
5. Comparison of cohorts of participants;
6. Randomisation of participants or the use of control groups or placebos; and
7. Identification of minority or vulnerable groups in the analyses (this is a common situation for health promotion workers because the identification of disadvantage and the promotion of equity are often priorities in their programs, and there is a constant risk that stigmatisation of disadvantaged and minority groups may occur as a result).

What are quality assurance activities?

The National Health and Medical Research Council guidance on [Ethical Considerations in Quality Assurance and Evaluation Activities](#)⁴ provides the following definitions for Quality Assurance Activities and Evaluation:

Quality assurance activities are "...where the primary purpose is to monitor or improve the quality of service delivered by an individual or an organisation. Terms such as 'peer review', 'quality assurance', 'quality improvement', 'quality activities', 'quality studies' and 'audit' are often used interchangeably" (Page 2).

Evaluation activities "...generally encompass the systematic collection and analysis of information to make judgements, usually about the effectiveness, efficiency and/or appropriateness of an activity. The term is used in a broad sense to refer to any set of procedures, activities, resources, policies and/or strategies designed to achieve some common goals or objectives" (Page 2).

Projects aiming to monitor, evaluate or improve services by a provider may be deemed to be "Quality Assurance" if they:

- Do not impose any risk on participants.
- Use existing data already collected by that organisation in the conduct of their work.
- Ensure analysis is conducted by either members of that organisation or someone working with the organisation who is bound by a professional code of ethics.
- Do not infringe the rights or reputation of the carers, providers or institution.
- Do not violate the confidentiality of the client.⁵

Additional resources:

- [Development and oversight of ethical health promotion quality assurance and evaluation activities involving human participants.](#)
- [Office of Research Ethics and Integrity - quality assurance activities.](#)

