

CP Institute fact Sheet

Quality Assurance & Ethics

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What is Quality Assurance?

Quality Assurance (QA) refers to an activity where the primary purpose is to monitor, evaluate or improve the quality of healthcare delivered by a healthcare provider (National Health and Medical Research Council, 2003).

Ethical Principles- What are they and how do they relate to QA activities?

The National Health & Medical Research Council (NHMRC) has drawn up ethical principle and guidelines to protect the welfare and rights of individuals.

There are 4 ethical principles for research involving humans:

- 1) **Integrity** – commitment to search for knowledge, recognise principles of research conduct, honest and ethical conduct of research, communication and dissemination of information.
- 2) **Respect for Persons**- regard for the welfare, rights, beliefs, perceptions and cultural heritage of research participants
- 3) **Beneficence** – the researchers responsibility to minimise the risks of harm or discomfort to participants
- 4) **Justice** –a balance of burdens and benefits for research participants and a even distribution of burdens and benefits to taking part in research for the wider community.

The 4 ethical principles apply to **both** QA activities and research activities.

Deciding Whether a Quality Assurance Proposal Needs Ethical Review

If you answer '**Yes**' to **ANY** of the following questions, you need to submit a proposal of your activities for ethical review:

- The National Privacy Principle states "An organisation must not disclose personal information about an individual for a secondary purpose other than the primary purpose of collection". In healthcare provision, the primary purpose is treatment, so for all activities other than treatment, you need to obtain additional consent. Do you need to obtain informed consent?
- Does the QA activity pose any risks for patients beyond that experienced in routine care? e.g. physical and psychological risks, social harm, distress
- Does the activity impose a burden (e.g. discomfort, embarrassment) on patients beyond that experienced in their routine care? e.g. additional hospital visits, questionnaires, persistent phone calls
- Will the activity be conducted by a person who does not normally have access to the patients' records for clinical care?
- Will the activity risk breaching the confidentiality of an individual's personal information, beyond that experienced in the provision of routine care? e.g. a letter or email to a patient that includes sensitive health information could lead to a breach of confidentiality
- Does the activity involve any clinically significant departure from the routine care provided to patients? e.g. application of a new technology or treatment.
- Does the activity involve randomisation or the use of a control group or placebo?
- Does the activity seek to gather information about the patient beyond that collected in routine clinical care? e.g. observations, blood samples, family information etc.
- Does the activity potentially infringe the rights, privacy or professional reputation of carers, healthcare providers or institutions?

If you are uncertain whether your proposed QA activity needs ethical review, err on the side of caution and contact the ethics committee.

References

National Health & Medical Research Council. 2003. When Does Quality Assurance in Health Care Require Independent Ethical Review? Advice to Institutions, Human Research Ethics Committees and Health Care Professionals.

National Health & Medical Research Council. 2005. Principles of Ethical Conduct.

www.nhmrc.gov.au/publications/hrecbook/01_commentary/01.htm