

Human Research Ethics Committee

Quality Assurance Guidelines

Human research requires review by the HREC but a project undertaken to 'monitor, evaluate or improve the quality'¹ (p3) of an existing program, delivered by an appropriate agent(s) or agency, represents quality assurance (QA) and does not. Differentiating quality assurance from research is difficult and 'no authority or agency has been able to create definitions that clearly separate 'quality assurance' from 'clinical research''.¹

These guidelines apply to all examples of quality assurance, not just health care projects. The NHMRC QA document¹ expressly indicates that 'the information (it contains) may be adapted and applied to non-health quality assurance activities'.

Quality assurance activities are viewed as 'essential and integral part' of service delivery and of developing and improving standards of care or of professional practice ¹(p2). This helps differentiate them from research and from needing review and approval by an HREC unless it is a condition of funding or otherwise of the University for the project to proceed.

Identification of a quality assurance project

The identification of a quality assurance activity in these guidelines is based on the headings and process identified in the NHMRC QA (2003) booklet (p.6-7). The process was modified to include all projects whether offering health or other care, programs or professional activities. All nine points below must be answered positively for the project to be considered as a quality assurance project. If not, the project cannot be considered as quality assurance and must be submitted to the HREC for review.

Consent

1. Adequate consent is obtained from participants or any institutions involved and the activity is consistent with National Privacy Principle 2.1(a).² 'Adequate' consent may be explicit (for example, in writing) or implied (for example, by completing a survey). The NPP 2.1 (a) requires that any secondary purposes for using the information relate to the primary purpose for collecting it and that the person whose information it is could reasonably expect that this information would be used for the secondary purpose concerned.

Risks and burdens

2. There is no added risk to persons (eg. physical, psychological, spiritual or of social harm or distress) beyond that entailed in their participation in the existing care/program/professional activity.
3. No additional burden (eg. extensive interviews or lengthy questionnaires, persistent reminders or intrusive questions) is imposed on participants beyond that implicit in their participating in the relevant care/program/professional activity.

Privacy and confidentiality

4. Any participants' records or information (eg. in databases, databanks, tissue banks) used in a quality assurance activity are accessed only by those with usual access for care or professional practice or access for a directly related secondary purpose and any person reviewing such information is bound by legislation or a code of ethics.
5. Access to any personal information is not beyond that required for the relevant care or professional practice and there is no risk of breach of confidentiality of an individual's personal information.

Overlap with research

6. There is no significant departure from the routine care or professional practice provided to the participant (eg. the use of new interventions or devices that are not a routine part of current practice require an application to the HREC for approval).
7. There is no randomisation of groups of participants, use of placebo interventions or of control groups.
8. The information being collected about participants in the relevant care/program/professional activity does not go beyond that which would be routinely collected (eg. any requirement for more extensive information necessitating additional testing such as additional blood, tissue, physical or psychological testing, will necessitate an application for approval by the HREC).

Broader implications

9. There is no infringement or risk of any infringement of any of the rights, the privacy or professional reputation of any person or institution involved in providing the care/program/professional activity.

Confirmation from HREC

Many journals require confirmation that a review was not required by an HREC. If formal confirmation is required that a project is a quality assurance activity and not research, submit a brief overview of the project **and** address all nine points listed. This will enable the HREC to provide the necessary confirmation.

References

1. NHMRC. *When does quality assurance in health care require independent ethical review?* Endorsed 20 February 2003 ed: Commonwealth of Australia; 2003.
2. National Privacy Principles: <http://www.privacy.gov.au/publications/>

Guidelines endorsed by HREC 15 October 2008