

**When does quality assurance in
health care require independent
ethical review?**

**Advice to Institutions, Human Research
Ethics Committees and
Health Care Professionals**

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NHMRC

*National Health &
Medical Research Council*

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1. INTRODUCTION

The National Health and Medical Research Council's (NHMRC's) *National Statement on Ethical Conduct in Research Involving Humans* (The *National Statement*) discusses the difficulties of precisely defining research, and notes in passing that lists of examples of research 'risk including activities that would not normally be included, like quality assurance activities or audits'. The *National Statement* also states that it 'is the responsibility of each institution and organisation to develop criteria to classify which of its activities are reviewable by its Human Research Ethics Committee (HREC) and which are not'.¹

While a small number of institutions and their HRECs have addressed this matter since the publication of the *National Statement* in 1999, many other HRECs have indicated their desire to be provided with advice on this issue centrally from the Australian Health Ethics Committee (AHEC). It has also become apparent that clinicians and others involved in performing audits and quality assurance (QA) studies would benefit from the provision of advice indicating how they should identify whether their proposed project has ethical issues that require review by the institution's HREC.

A related issue was raised when the *Medical Journal of Australia* published a clinical study that led to a debate about whether an HREC could retrospectively approve a study held by its author to be an audit but regarded by the journal editor as clinical research.² In addition, NHMRC funding for studies on implementing 'best practice' identified through the 'evidence based medicine' process, raised the need to consider how to classify such studies and whether they needed ethical review.³

In response to these needs, AHEC established a broadly representative working party to provide advice for HRECs concentrating especially on the question of how an individual or an HREC can decide whether a quality assurance proposal raises ethical issues that require some form of ethical review. The working party undertook this task by preparing a detailed discussion paper⁴ on the subject, including draft advice. That discussion paper was released for targeted consultation for the period 12 August – 20 September 2002. After consideration of the 44 submissions received from the consultation process, changes were made to the document. The final document was endorsed by AHEC and the NHMRC.

The focus of the document is on quality assurance activities in health care, consistent with the Working Party's terms of reference. However, AHEC considers that the information may be adapted and applied to non-health quality assurance activities.

AHEC noted that no authority or agency has been able to create definitions that clearly separate 'quality assurance' from 'clinical research.' While the advice

briefly addresses some of this debate, it focuses on central or characteristic features of any quality assurance proposal that may need to be considered when deciding whether the proposal requires independent scrutiny by an HREC.

AHEC noted that quality assurance is an area of changing expectations and attitudes. On the one hand, there is clearly an increasing appreciation of the need for health care institutions and health professionals to be more proactive in undertaking quality assurance, studying the findings and taking appropriate measures to minimise adverse events in health care. On the other hand, the community is concerned about privacy and that personal information held about individuals might be used inappropriately. The advice contained in this document is not intended to be a comprehensive overview of the privacy legislation as it relates to health care research and quality assurance or other important issues surrounding the delivery of quality health care. Those who are interested in the relevant State and Territory privacy legislation pertaining to health care research and quality assurance are advised to check the appropriate State and Territory government websites.

AHEC considers that QA activities are an essential and integral part of health care delivery that should be encouraged and facilitated.

The advice also recommends that institutions encourage HRECs to establish policies that allow efficient review of low risk quality assurance proposals. Delegates of HRECs could approve these proposals and this may avoid creating impractical and/or unnecessarily large workloads or delays.

2. WHAT IS MEANT BY QUALITY ASSURANCE IN HEALTH CARE?

An activity where the primary purpose is to monitor, evaluate or improve the quality of health care delivered by a health care provider (an individual, a service or an organisation) is a quality assurance study. QA should be an integral part of all health care delivery.

Terms such as 'peer review', 'quality assurance', 'quality improvement', 'quality activities', 'quality studies' and 'audit' (including all types of audit such as medical, clinical, surgical and record audit), are often used interchangeably. In this document the term 'quality assurance' is used to include all of these terms.

Quality assurance and research are activities that form a continuum. The ethical principles of integrity, respect for persons, beneficence and justice apply to all QA and research activities.

Attempts to clearly separate quality assurance from research are difficult, and can be artificial and unhelpful. What really matters is that:

- (a) quality assurance is undertaken for a valid purpose and its outcomes are used to improve health care; and
- (b) those who undertake quality assurance adhere to relevant ethical principles and State, Territory and Commonwealth legislation; and
- (c) where quality assurance proposals could infringe ethical principles that guide human research, independent ethical scrutiny of such proposals should be sought.

3. WHAT THIS ADVICE AIMS TO ACHIEVE

This advice is designed to assist HREC members, institutions, professional bodies and all those involved in planning or conducting health care quality assurance activities. In particular, the advice should help to:

- (a) decide when quality assurance in health care requires independent ethical review;
- (b) interpret the *National Statement* where it refers to those matters such as quality assurance 'not normally' needing ethical review;
- (c) protect the interests of patients, carers, health care providers and institutions;
- (d) protect the subjects of quality assurance from inadvertent exposure to potential risks;
- (e) facilitate the conduct of quality assurance; and
- (f) assist journal editors to assess articles submitted for publication.

4. ASSESSMENT OF QUALITY ASSURANCE PROPOSALS

AHEC recognises the necessity for health care providers to take steps to ensure that their service is of a high quality and consistent with the resources available to them. Not to do so would be unethical. Quality assurance activities should utilise valid methodology and tools and must not contravene any relevant State, Territory or Commonwealth legislation, including requirements relating to legal privilege for quality assurance committees.

AHEC therefore advises that an appropriately planned activity can proceed without review by an HREC if:

Both

- (a) the activity is undertaken with the consent of the patients, carers, health care providers or institutions involved;

or

is consistent with National Privacy Principle 2.1(a), which states:

‘An organisation must not use or disclose personal information about an individual for a purpose (the secondary purpose) other than the primary purpose of collection unless’ ... ‘both of the following apply:

- (i) the secondary purpose is related to the primary purpose of collection and, if the personal information is sensitive information, directly related to the primary purpose of collection;
- (ii) the individual would reasonably expect the organisation to use or disclose the information for the secondary purpose’;

and

- (b) it is an activity where participants, including patients, carers, health care providers or institutions are unlikely to suffer burden or harm (physical, mental, psychological, spiritual or social).

5. QUESTIONS TO BE CONSIDERED

In deciding whether or not a quality assurance proposal requires ethical review, the following questions should be asked. If all of these questions are answered in the **negative**, the proposal does **not** need consideration by an HREC.

If any questions are answered in the positive, further advice should be obtained from an HREC or its delegate. The delegate may be a member(s) of the HREC, a quality assurance committee, a senior administrator or professional health care worker designated to be responsible for the task.

Consent

1. Is the consent from participants *inadequate*, or is the activity *inconsistent* with National Privacy Principle 2.1(a)?

Participants may include patients, carers, health care providers and the institution involved.

Risks and burdens

2. Does the proposed quality assurance activity pose any risks for patients beyond those of their routine care?

Risks include not only physical risks, but also psychological, spiritual and social harm or distress, eg stigmatisation or discrimination.

3. Does the proposed quality assurance activity impose a burden on patients beyond that experienced in their routine care?

Burdens may include intrusiveness, discomfort, inconvenience or embarrassment, eg persistent phone calls, additional hospital visits or lengthy questionnaires.

Privacy and confidentiality

4. Is the proposed quality assurance activity to be conducted by a person who does not normally have access to the patient's records for clinical care or a directly related secondary purpose?

The involvement of a clinical student who is a member of the team in any clinical setting or involvement of an authorised quality assurance officer would be acceptable. However, the involvement of a student external to the clinical team would need further consideration.

Review of medical records by anyone who would not normally have access to information contained therein, unavoidably compromises the privacy of

individuals. However, authorised audit of records is an extremely valuable quality assurance activity. Provided the individual reviewing the records is bound by legislation or a professional code of ethics, the use is a directly-related secondary purpose and is within the expectations of the patient, this question can be answered in the negative.

5. Does the proposed quality assurance activity risk breaching the confidentiality of any individual's personal information, beyond that experienced in the provision of routine care?

A quality assurance activity that requires a letter, fax or email to a patient, that includes sensitive health information, could lead to a breach of confidentiality, if the communication is read by someone other than the proposed recipient.

Overlap with research

6. Does the proposed quality assurance activity involve any clinically significant departure from the routine clinical care provided to the patients?

Application and evaluation of a new technology not previously used in the health service may need further consideration.

7. Does the proposed quality assurance activity involve randomisation or the use of a control group or a placebo?

Proposals involving comparison with published or prior treatment results with other groups are acceptable if the proposals do not involve randomisation.

8. Does the proposed quality assurance activity seek to gather information about the patient beyond that collected in routine clinical care?

Information may include observations, blood samples, additional investigations etc. Genetic studies or others that seek information about family members, relatives or contacts as well as the individual patient, require further consideration.

Broader implications

9. Does the proposed quality assurance activity potentially infringe the rights, privacy or professional reputation of carers, health care providers or institutions?

These issues should be considered by management and may have legal implications. Consideration may need to be given to the relevant State or Territory legislation with respect to legal privilege for a quality assurance body.

6. OPTIONS FOR FURTHER REVIEW

Even where answers to some of these questions are positive, most quality assurance activities do not require a detailed application to, and review by, a full HREC. Institutions are encouraged to ensure that HRECs establish policies to allow efficient review of quality assurance proposals that involve minimal risk, burden, alteration of care or invasion of privacy. Such proposals could be approved by a delegate(s) of the HREC.

There are a number of different methods that institutions could adopt to handle delegated responsibility. They include delegating responsibility to:

- The Chairperson and/or one or more members of the HREC
- A QA committee that has a member who is also a member of the HREC
- An HREC with a subcommittee dealing with QA proposals
- An individual or individuals delegated this responsibility by an HREC.

Facilities or institutions with no regular access to an HREC should build a relationship with, and obtain advice from, an HREC regarding an appropriate delegate to undertake review on their behalf.

Any proposal causing unresolved concern to the HREC delegate should be referred for full review to an HREC constituted and operating in accordance with the *National Statement on Ethical Conduct in Research Involving Humans* (1999).

7. PUBLICATION OF QUALITY ASSURANCE ACTIVITIES

Where it is proposed that a report of a QA activity undertaken in accordance with this advice is to be published, an HREC may advise a journal editor that it is satisfied that the activity has been so undertaken. This will obviate any need for requests for retrospective approval.

8. EDUCATING STAFF

Because quality assurance is integral to health care, it is essential that institutions educate their staff about the ethical requirements for quality assurance.

APPENDIX 1

TERMS OF REFERENCE

The *National Statement on Ethical Conduct in Research Involving Humans* (preamble, p.8) recognises that institutions need to have policies indicating which activities require review by their Human Research Ethics Committees. In the light of the *National Statement* and of established professional practices, the terms of reference require the working party:

- 1) To develop advice for institutional policies indicating which activities involving humans require review and approval by an HREC, whether by full committee or by expedited procedures, with particular attention to audit and quality assurance processes.
- 2) To develop criteria related to –
 - i. the nature of human involvement in the activities;
 - ii. the need for use of identified/identifiable personal information;
 - iii. the need for consent for such involvement or use;
 - iv. the provisions of the *National Statement*;
 - v. established professional practices, including those developed by relevant Australian specialist medical colleges and practices established by other bodies including health professional, health management societies, and regulatory bodies;
 - vi. other relevant matters;to be used to distinguish reviewable from non-reviewable activities.
- 3) To propose if thought necessary, working definitions of key expressions, including clinical audit and quality assurance.
- 4) To ensure that the developed criteria reflect the balance of ethical considerations relevant to the collection and use of personal information, especially health information, in Australia.

Note: For the purposes of the advice contained in this document, the word quality assurance has been used to encompass all of the various activities designed to evaluate, monitor and improve the quality of health services. Such activities include monitoring of performance indicators, clinical audit including medical record audit, peer review, customer surveys, observational studies, quality reviews and quality improvement projects.

APPENDIX 2

MEMBERSHIP OF THE WORKING PARTY

Prof Bryan Campbell, AM (Chairperson)

Person with experience in health administration

NHMRC member & Chief Health Officer, Queensland Health

Dr Kerry Breen

AHEC member

AHEC Chairperson

Rev Bill Uren

AHEC member

AHEC member with knowledge of the ethics of medical research

Prof Phil Boyce

Representative of the Medical Colleges

President-elect, Royal Australian & New Zealand College of Psychiatrists

Mr Kingsley Faulkner

Representative of the Medical Colleges

President, Royal Australasian College of Surgeons

Prof Rosemary Ryall

Experienced HREC member

Member, Flinders Clinical Research Ethics Committee

Member, Calvary Health Care Inc (Adelaide) HREC

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Member, St. Vincent's Hospital (Melbourne) HREC

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Consumer representative

Representative of the Australian Council on Quality & Safety in Health Care

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Representative of the Consumers Health Forum

Ms Sharon Hill

NHMRC Secretariat

APPENDIX 3

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1. National Health and Medical Research Council (1991) *National Statement on Ethical Conduct in Research Involving Humans*. Canberra. p.6.
2. Grover SR. Morley R. (2001) Vitamin D deficiency in veiled or dark-skinned pregnant women. *Medical Journal of Australia* 175(5):251–2.
3. National Health and Medical Research Council (2000) *Report of the Evidence Based Clinical Practice Research Workshop*. Canberra.
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The National Health and Medical Research Council

The National Health and Medical Research Council (NHMRC) is a statutory body within the portfolio of the Commonwealth Minister for Health and Ageing, established by the *National Health and Medical Research Council Act 1992*. The NHMRC advises the Australian community and Commonwealth; State and Territory Governments on standards of individual and public health, and supports research to improve those standards.

The NHMRC advises the Commonwealth Government on the funding of medical and public health research and training in Australia and supports many of the medical advances made by Australians.

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