

Human Research Ethics Committees - Quality Improvement & Ethical Review: A Practice Guide for NSW

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Summary This Guideline assists health professionals undertaking quality improvement activities by helping identify when that activity may require ethical review by a Human Research Ethics Committee. The need for such review is based on identifying any ethical risks that such activities may pose to participants. This Guideline provides a checklist to assist in this task.

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Applies to Area Health Services/Chief Executive Governed Statutory Health Corporation, Board Governed Statutory Health Corporations, Affiliated Health Organisations - Non Declared, Affiliated Health Organisations - Declared, Public Health System Support Division, Dental Schools and Clinics, NSW Dept of Health, Public Health Units, Public Hospitals

Audience All clinical and research staff involved in development of research trial products

Distributed to Public Health System, Dental Schools and Clinics, Divisions of General Practice, Government Medical Officers, Health Professional Associations and Related Organisations, NSW Ambulance Service, NSW Department of Health, Public Health Units, Public Hospitals, Private Hospitals and Day Procedure Centres, Tertiary Education Institutes

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QUALITY IMPROVEMENT AND ETHICS REVIEW: A PRACTICE GUIDE FOR NSW

PREAMBLE

There are a number of methods of monitoring and evaluating health care with the aim of improving its delivery. These quality improvement (QI) activities include incident monitoring, root cause analysis, sentinel event monitoring, peer review, morbidity and mortality review and other forms of audit. There can be difficulty in, and disagreement about, clearly defining 'research' versus some QI activities. However, the role of ethics review, whether it is in research or quality improvement, is to champion consumers' interests when interventions are proposed that might incur risks, suffering or inconvenience to patients or carers where these may occur other than through direct patient care. While not wanting to discourage QI practice with unnecessary obstacles, it is nonetheless recommended that QI activities be subject to a routine and simple review process to identify ethical risks.

Many QI activities are closely related to the treatment of the individual patients involved and will not pose additional ethical risks. When risks, suffering or inconvenience resulting from a QI activity may be present, patients need to be provided with sufficient information in an environment free of undue pressure to enable them to decide whether they wish to be involved, just as occurs in clinical care or research. An important aim of ethics review is to protect patients' privacy and anonymity. Some QI activities can be conducted using only summary or otherwise de-identified data. Some projects have the potential however to generate information of a sensitive nature. Such information might be medical, such as HIV status or the identification of genetic disease, or it may be social, for example where a particular set of demographics, when applied in a small town or ethnic group, enable an individual or family to be identified.

NSW Health recognises that a number of Area Health Services (AHS) have established mechanisms for providing ethics review of QI projects. The process for screening and approving QI activities outlined in this practice guide is optional, but is hoped will assist health professionals undertaking QI activities. This review process may also be beneficial for on-going education of those conducting QI activities, and as an institutional record of those activities. This guide is based on, and should be read in conjunction with other relevant regulatory or advisory documents, specifically:

- *"When does quality assurance in health care require independent ethical review – Advice to Institutions, Human Research Ethics Committees and Health Professionals"*, NHMRC (2003)
<http://www.nhmrc.gov.au/publications>
- *NSW Health Privacy Manual (Version 2) 2005*
http://www.health.nsw.gov.au/policies/pd/2005/pdf/PD2005_593.pdf
- *National Statement on Ethical Conduct in Human Research, NHMRC (2007)*
<http://www.nhmrc.gov.au/publications>

1. ETHICS REVIEW PROCESS (SEE APPENDIX B)

- 1.1 Ethical review, quality improvement and clinical governance structures share a common aim of ensuring provision of safe, high quality care to patients. It may therefore be appropriate for institutions or AHS to have a 'designated body' such as a quality unit or clinical governance body as the group responsible for preliminary screening of QI projects using the 'Model Checklist' (see Appendix A).
- 1.2 Many QI activities will not have any ethical risks identified, and so should proceed without further review.
- 1.3 Some projects where the ethical risks are minimal (usually not involving patient interventions and only use of health data) may be adequately considered through an "expedited" or fast track review process. In expedited review, discussion about the identified ethical risks, as identified by the Checklist, should occur between the individual/team proposing the project and the Human Research Ethics Committee (HREC) delegate (see 2).
- 1.4 This will often result in project approval by the HREC delegate. Expedited review should be in place of, not additional to, full review by the HREC, unless the HREC delegate has unresolved concerns warranting consideration by the HREC.
- 1.5 Expedited review should preferably involve more abridged documentation than is required for full HREC application.
- 1.6 Upon consideration of the project's ethical risks by expedited review, a recommendation may still be made that formal approval be sought from the HREC. A full application as for a research proposal is then required.

2. DELEGATED RESPONSIBILITY FOR ETHICS REVIEW

Responsibility for ethics review of QI projects could be delegated, on behalf of the HREC, to:

- The Chairperson and/or one or more members of the Human Research Ethics Committee (HREC);
- A QI committee that has a member who is also a member of the HREC;
- A subcommittee of the HREC dealing with QI projects; or
- Another individual/s delegated this responsibility by an HREC.

3. CONSIDERATIONS WHEN REVIEWING QUALITY IMPROVEMENT PROJECTS

The following sections are intended to clarify the questions posed in the Checklist. These comments are grouped according to the question numbers as they appear on the Checklist.

Section 1: Issues that may require consent

General comments

The NSW *Health Records and Information Privacy Act 2002* (HRIPA) recognises that an organisation's quality improvement activities may be "directly related secondary purposes" (to the primary purpose of collecting information for clinical care), and that generally these do not require explicit patient consent additional to that elicited in the original clinical practice interaction. However, there are exceptions, and explicit consent is usually required when the QI activity requires direct contact with patients or relatives, if randomisation of interventions is required, or where identifiable or sensitive personal data is used. Consent may be demonstrated by various means including signed 'consent' forms, return of a self-administered survey, or recorded agreement for interview. Consent requires that sufficient information be provided for the person to make a decision, considering the risks and benefits, and that the decision is freely made.

In some cultural communities, consent to participate in QI activities may not only be a matter of individual agreement, but rather may involve other groups or 'collectives', such as community elders. Properly interested parties may need to be engaged in consent or other aspects of the quality improvement activity. This is not limited to, but has been common among Aboriginal and Torres Strait Islander communities. Community consent however, does not apply to, or replace, consent by individuals to their clinical care.

It is recommended that patients be routinely informed on hospital admission or at another early point during their care that their de-identified information might be used for quality improvement purposes, albeit in a manner that respects privacy of health information. This may be achieved through the use of patient information leaflets that may create a 'reasonable expectation' (HRIPA – principles 10-11, *NSW Privacy Manual*) that their own health information may be used legally and for legitimate purposes, such as quality improvement.

- Q 1. Direct contact with patients or families through phone calls or face-to-face interview may potentially create undue pressure or coercion, depending on how direct contact is planned. Patients or families may feel pressured firstly to participate, and secondly to respond in particular ways, depending on factors such as patient vulnerability or whether there is an ongoing treatment/care relationship. Patient surveys may legitimately ask about attitudes to aspects of care, but if these are not anonymous, may leave patients feeling compromised.
- Q.2 Additional harms or risks may be physical harm, psychological disturbance, risk of spiritual or social harm, or distress. Tests, blood samples, or medical interventions additional to the patient's routine clinical care will likely constitute burdens warranting express patient consent, as may persistent phone calls, additional visits to hospital, or lengthy or intrusive questionnaires. Potential exploitation of cultural

knowledge or property is considered another harm. There have been instances where such information has been damaging to some cultural minorities, such as contributing to discriminatory attitudes and stigmatisation.

- Q.3 A letter, fax or email sent to a patient that includes sensitive information could lead to a breach of confidentiality if such communication were to be read by another person. Examples of sensitive data include a diagnosis of HIV/AIDS or sexually transmitted disease, mental illness, sexual assault, domestic violence, drug and alcohol use, genetic testing or results, IVF or artificial insemination, or where a child is considered to be at risk.
- Q.4 Secondary use of health information (eg for research) that is not directly related to the primary purpose for which it was collected (i.e. to provide clinical care to the patient) must be approved by an HREC for it to comply with the Health Records and Information Privacy Act 2002 (NSW). If it is unclear whether the activity 'directly relates' to the patient's care, contact the local HREC delegate or consult the *NSW Health Privacy Manual (Version No.2, 2005)*.
- Q.5 Data that allow for identification of a specific individual are referred to as 'identified data'. Examples of identifiers are the individual's name, date of birth, address, or diagnosis where the condition is rare. In very small data sets, even information such as a postcode may be an identifier.

Section 2: Privacy and confidentiality

Q.6 & 7.

Some forms of audit may involve 'independent' third party assessment of provision of care using external observers and an audit tool. Interviews and observation give such parties direct contact with patients, often without their express consent, and access to information as events occur. This may require ethical review by an HREC in order to safeguard patients' privacy, and 'legitimise' the third party's presence while observing clinical care. As a general principle, QI activities data should be de-identified where possible before being given to third parties who would not normally have access to them. Multi-centre QI activities coordinated by an external organisation other than the participating institutions will also require ethics review by those institutions, unless patient information is de-identified before it is accessed by an external organisation.

The 'clinical care team' refers to the group of health professionals involved in provision of clinical care including nursing and medical clinicians, and allied health professionals. Student health professionals enrolled in recognised teaching institutions may have access to health records with the approval and direction of their supervisor if that access is sought in respect of their education program at the health facility.

- Q.8 Where patient numbers are limited or the diagnosis is rare, this may inadvertently result in the patient being identified, even where the data have been de-identified in the usual manner. Quality improvement activities that combine groups of similar patients from small units may assist in maintaining confidentiality, where this is feasible.
- Q.9 QI activities amongst religious, ethnic, or minority groups should be undertaken following appropriate consideration of cultural difference, as relevant to the activity. Some ethical issues associated with a QI activity may need to be considered in a broader context than the individual patient context, for example the notion of 'community privacy' often applies in Aboriginal communities.
- Q.10 No additional comment.

Section 3: Other Implications

- Q.11 Where new knowledge is being generated, this may create a greater potential risk of harm to subjects. This is more applicable to research but may also apply to some QI activities where new or alternate clinical interventions are undertaken. 'New' interventions refer to those not previously used for this purpose or in this institution. See also *Model Policy for the Safe Introduction of New Interventional Procedures Into Clinical Practice* - PD2005_333.
- Q.12 Randomisation, or allocation of patients to groups, to enable comparison of interventions will usually diminish treatment choice that may be unacceptable to the patient. Patients may choose not to participate in randomised quality activities. Interventional quality activities comparing one intervention with another should not involve provision of care inferior to the benchmark 'standard of care'.
- Q.13 Genetic testing may have an impact on not only the individual being tested, but also other family members. Quality improvement activities involving genetic information need informed consent, given the sensitive nature of the information and its potential implications.
- Q.14 There is increasing interest in comparison of patient outcomes or other performance indicators within, and more recently between units, departments or individual clinicians. However, these comparisons must be against agreed benchmark standards, and with appropriate consideration of the variables impacting on outcomes and performance, such as patient acuity. Where use of comparative data between individual clinicians or institutions occurs, this should be clearly grounded within the institution's clinical governance system.

There is a general obligation to feedback results of quality improvement activities to health professionals who have been directly involved in a QI activity, or affected locally by its results. There should also be

consideration given to providing results of QI activities to other participant groups.

- Q.15 Any project involving randomisation or other means of allocation to one of two or more treatment options requires ethics review.
- Q.16 Many professional journals require evidence of ethical review before quality improvement results will be published, especially where identifiable or sensitive data are audited, or potential harms or burdens exist. This also applies where the results of the QI activity are for publication as a conference abstract. If the Checklist identifies no 'ethical risks', and only intention to publish, then ethical review is not warranted. However, some, in particular international, journals may apply different standards for ethical review. Intending authors should explore this on an individual basis. Presentation of de-identified data at conferences does not require ethics review.

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Appendix A

THE CHECKLIST

Use of this Checklist is optional in NSW public hospitals. It is designed to assist in identifying when a proposed QI activity entails ethical 'risks'. For more detailed information related to each statement, please see *Considerations for reviewing QI activities*. This Checklist may be modified for use with local HRECs.

Section 1: ISSUES THAT MAY REQUIRE CONSENT

TRUE/FALSE

1. The project involves direct contact with patients, consumers, or members of the public.
2. The project poses additional risks or burdens to the patient beyond their routine care.
3. The data to be collected is of a sensitive nature or application.
4. The purpose of the activity is not 'directly related' to the patient's disease, illness or its management.
5. The data will be used or available in such a way that may identify individuals.

*If the response to any of the above statements is "true", you should contact your nominated HREC delegate (or designated institutional body) to discuss. **Informed consent** is usually required. If approval is required, you will need to provide a project outline, including a description of how you intend to gain consent, as well as a participant information statement.*

Section 2: PRIVACY and CONFIDENTIALITY

TRUE/FALSE

6. There is no process for de-identification of data.
7. Access to personal information will extend beyond those who are members of the clinical care team, or to others who normally do not have access to the patient's record, or to other data sets.
8. The project involves rare conditions or a small community.
9. Data will be selected or identified by:
 - Aboriginal or Torres Strait Islander status; or
 - Ethnic, religious or minority group.
10. Data will be collected beyond that which is normally collected in routine care.

*If the response to any of the above statements is "true", you will need to provide more information and you **may need full Ethics Committee approval**. Please provide a brief explanation and a description of the consent process with your application, and contact your nominated HREC or QI delegate to discuss.*

Section 3: OTHER IMPLICATIONS

TRUE/FALSE

11. The project uses 'new' interventions, protocols or equipment.
12. The project will involve allocation of patients to groups to enable comparisons.
13. The project will involve genetic tests/testing.
14. The project may potentially infringe the rights, privacy or professional reputation of carers, health professionals or institutions.
15. The project involves use of placebo.

*If the response to any of the above statements is "true", you will need to provide more information and it **is highly likely you will need full Ethics Committee approval** for your project. Contact your HREC representative.*

16. The project is likely to generate data that may lead to publication.

If responses to all of the above statements in the checklist are 'false', then no ethical risks have been identified with this project and no ethics review is required.

Appendix B

ETHICS REVIEW PROCESS

