POLICYI026 QUALITY ASSURANCE AND ETHICAL REVEIW

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PURPOSE

To assist researchers in identifying when a quality assurance (QA) activity may require Human Research Ethics Review (HREC).

Preamble

There can often be disagreement about clearly distinguishing research from QA activities.

Many QA activities can be closely related to routine clinical practice or service delivery and may not pose additional ethical risks. Just as occurs in clinical research, there needs to be consideration of the potential risks, suffering or inconvenience related to the activity.

QA activities can be conducted using individually identifiable, re-identifiable or non-identifiable data. Some have the potential to generate information of a sensitive nature e.g. HIV status, genetic disease or social issues relating to a particular demographic. An important part of the HREC review is to protect participant anonymity and privacy.

The following checklist has been developed to assist the researcher and/or the HREC in determining if the QA activity should be subject to ethical review.

Following review of an application, Bellberry HREC will respond to the researcher advising whether the study does or does not require full HREC review and why.

The Checklist

This checklist has been designed to assist in identifying when a proposed QA activity entails ethical 'risks'.

If the researcher answers 'Yes' to any of the questions on the checklist then it is likely full review from an HREC may be required.

1. Does my activity require ethical review?

Consider the National Statement on Ethical conduct in Human Research 2007 (National Statement) definition of research.

- Is the activity required to undergo ethical review as defined in the National Statement (5.1.6b)?
- Is the activity more than low or negligible risk as defined in the National Statement (2.1.6 and 2.1.7)?
- The activity does not fit the description as defined in the National Statement (5.1.22) to be exempt from ethical review.

2. What is the reason/s for conducting the activity?

Consider the application of the values and principles in the National Statement. The process should not be a mechanical application but should weigh up the risks and benefits and burdens to the participants as per the National Statement 2.1.

- Is the activity being conducted for reasons other than the sole purpose of assessing a service for internal purpose only?
- Does the proposed activity require consent to be sought from potential participants as per the National Statement 2.2?
- Does the project involve direct contact with patients, consumers, or members of the public?
- Does the project pose additional risks or burdens to the patient beyond their routine care e.g. a patient to attend an extra appointment or complete a questionnaire that is not part of routine care?

3. Does the use of the data/sample comply with Commonwealth Privacy Principles?

Consider the National Privacy Principles (see s95A guidelines)
Consider the Information Privacy Principles (see s95 guidelines)

- Is the data to be collected of a sensitive nature or application?
- Is the purpose of the activity not 'directly related' to the patient's disease, illness and or management?
- Will the data be used or available in such a way that may identify individuals?
- Will access to personal information 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?
- Will the project involve data on rare conditions or a small community?
- Will data be selected or identified by; Aboriginal or Torres Strait Islander peoples or ethnic, religious or minority groups?
- Will data be collected beyond that which is normally collected in routine care?

4. Other considerations

- Will the project use 'new' interventions, protocols or equipment?
- Will the project involve allocation of patients to groups to enable comparisons?
- Will the project involve genetic testing/tests?
- Will the project potentially infringe the rights, privacy or professional reputation of carers, health professionals or institutions?
- Does the project involve the use of a placebo?

5. Publication

- Is the project likely to generate data that may lead to publication?

If the response to any of the above statements in the checklist is 'yes', full review by the HREC may be required.

If all of the answers to the above questions are 'no' then it is likely the activity is for quality assurance or clinical audit purposes.

Other useful information is available at:

- '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
- National Statement on Ethical Conduct in Human Research NHMRC (2007)
  http://www.nhmrc.gov.au/publications
- NHMRC Considerations in determining if an activity such as quality assurance requires ethical review.

This document has been adapted from the 'NHMRC Considerations in determining if an activity such as quality assurance requires ethical review' document.