

“WHEN DOES QUALITY ASSURANCE IN HEALTH CARE REQUIRE INDEPENDENT ETHICAL REVIEW?”

Research seeks to extend scientific knowledge that might be applied in everyday practice, and audit seeks to extend the knowledge of practitioners about their own practice. Clinical audit is a systematic and critical analysis of the quality of patient care, the ultimate aim of which is to improve the delivery of patient care. The questions or aims of an audit are usually specific to a particular setting and motivated by local circumstances. Often it is prompted by perceived or actual deficiencies in care, or the need to set up a new service, whereas research starts with a clear statement of a problem in the form of questions, aims or hypotheses. Audit may draw on theory, but does not generate or test it. Theory generation and/or testing are essential characteristics of research, which distinguish it from quality assurance / audit activities”.

You may also like to refer to the Victorian Government Health Information, Human Research Ethics. There is a very good explanation at this site and the Mater Health Services gratefully acknowledges The Department of Human Services HREC in allowing us access this information to assist our researchers: <http://www.health.vic.gov.au/ethics/single/research.htm>

*(Study Exempt from Human Research Ethics Committee Review Policy). Please refer to **“When does quality assurance in health care require independent ethical review?”***
<http://www.nhmrc.gov.au/publications/files/e46.pdf>

ALL RESEARCH PROTOCOLS MUST BE SUBMITTED TO THE HUMAN RESEARCH ETHICS COMMITTEE FOR REVIEW AND APPROVAL. IN ADDITION ANY CLINICAL REVIEW OR QUALITY ASSURANCE STUDY, WHICH MEETS ONE OR MORE OF THE FOLLOWING CRITERIA MUST BE SUBMITTED TO THE COMMITTEE FOR CONSIDERATION.

- Studies in which patients are required to undergo an additional procedure or investigation, e.g., venepuncture, which would not be necessary for normal investigation and treatment.
- Studies in which the investigation or treatment to be used is selected by a means other than the method regarded by the treating medical officer as the most appropriate for the particular patient, e.g., random allocation between two or more groups.
- Studies in which contact is to be made with a patient of the Mater Misericordiae Health Services by a research worker not involved with the treatment of the patient.
- Studies in which identifiable patient information is to be collected and forwarded to an external person or authority other than within the operations of the Mater Misericordiae Health Services.
- Studies which intend to be presented or published – please contact the Research Ethics Coordinator to discuss if this is your only requirement.

QUESTIONS TO BE CONSIDERED FOR QUALITY ASSURANCE STUDIES

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.

		YES	NO
1.	<p>Consent Is the consent from participants <i>inadequate</i>, or is the activity <i>inconsistent</i> with National Privacy Principle 2.1(a)? <u>(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:</u> <u>(a) both of the following apply:</u> <u>(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;</u> <u>(ii) the individual would reasonably expect the organisation to use or disclose the information for the secondary purpose:)</u></p> <p>Participants may include patients, carers, health care providers and the institution involved.</p>		<input checked="" type="checkbox"/>
	Please provide a detailed response		
2.	<p>Risks and burdens Does the proposed quality assurance activity pose any risks for patients beyond those of their routine care?</p> <p>Risks include not only physical risks, but also psychological, spiritual and social harm or distress, eg stigmatisation or discrimination.</p>		<input checked="" type="checkbox"/>
	Please provide a detailed response		
3.	<p>Does the proposed quality assurance activity impose a burden on patients beyond that experienced in their routine care?</p> <p>Burdens may include intrusiveness, discomfort, inconvenience or embarrassment, eg persistent phone calls, additional hospital visits or lengthy questionnaires.</p>		<input checked="" type="checkbox"/>
	Please provide a detailed response		

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4.	<p>Privacy and confidentiality 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?</p> <p>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.</p>		<input checked="" type="checkbox"/>
	Please provide a detailed response		
5.	<p>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?</p> <p>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.</p>		<input checked="" type="checkbox"/>
	Please provide a detailed response		
6.	<p>Overlap with research Does the proposed quality assurance activity involve any clinically significant departure from the routine clinical care provided to the patients?</p> <p>Application and evaluation of a new technology not previously used in the health service may need further consideration.</p>		<input checked="" type="checkbox"/>
	Please provide a detailed response		
7.	<p>Does the proposed quality assurance activity involve randomisation or the use of a control group or a placebo?</p> <p>Proposals involving comparison with published or prior treatment results with other groups are acceptable if the</p>		<input checked="" type="checkbox"/>

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	proposals do not involve randomisation.		
	Please provide a detailed response		
8.	<p>Does the proposed quality assurance activity seek to gather information about the patient beyond that collected in routine clinical care?</p> <p>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.</p>		<input checked="" type="checkbox"/>
	Please provide a detailed response		
9.	<p>Broader implications</p> <p>Does the proposed quality assurance activity potentially infringe the rights, privacy or professional reputation of carers, health care providers or institutions?</p> <p>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.</p>		<input checked="" type="checkbox"/>
	Please provide a detailed response		
	<i>If you answer yes <input checked="" type="checkbox"/> to any one of the above questions contact the Research Ethics Coordinator for further advice, your study may require full ethical review.</i>		<input checked="" type="checkbox"/>