

Human Research Ethics Committee

Guidelines for Expedited Ethical Review of Quality Assurance and Low Risk Studies

The Human Research Ethics Committee has developed a process for ethical review of studies, which do not need to go to the full committee, it is known as Expedited Ethical Review. The studies that may be appropriate for this process are Quality Assurance Projects or Research Studies that involve minimal or no risk to the study population.

The guidelines as to what is quality assurance and what is research are very subjective and non-specific. It is not possible to give a definitive description; all projects will need to be individually assessed.

Quality Assurance projects are essentially an evaluation or the monitoring of a current service or practice with the aim of improving that service or practice.

- Examples might include the evaluation of existing psychiatric services to young offenders, the evaluation of existing counselling services provided to victims of child abuse, or the evaluation of morbidity and mortality data from hospital services.

QA projects that do not breach confidentiality or privacy and are non interventional or QA projects that do not breach confidentiality and are interventional, but where the intervention does not present ethical issues, can be classified as low risk QA projects and do not require ethical review.

- An example of a non-interventional evaluation is counting the number of recorded wound infections after surgery. An example of an interventional evaluation is performing right heart catheter studies to examine some cardiological practice.
- An example of where an evaluation is interventional but does not present ethical issues is a brief questionnaire that does not ask questions that may adversely affect the well-being of participants (physically or psychologically), such as an anonymous patient satisfaction survey of inpatient stay administered as the patient is about to leave hospital.

Be aware that many QA projects include elements that could warrant ethical review or will incorporate elements that will, by their nature, put the project into the category of being higher risk; these projects should be submitted for ethical review.

- QA projects in which the National Privacy Principles apply are required by law to have ethical review.
- Example might also include the evaluation of a diagnostic technique that requires the collection of an extra blood sample or the evaluation of one service, which requires the collection of health information from another service.

If it is intended to publish the data collected in a QA project it is recommended that you submit the study for ethical review.

Research is a systematic investigation to establish facts or to test an hypothesis, or a study whose objective is to obtain or confirm knowledge. The purpose of research is usually the establishment of a new service or program.

Research can involve, amongst other things,

- evaluation of a new practice for example the introduction and evaluation of a new psychiatric service to young offenders.
- evaluation of the related issues of a group of patients for example assessing the psychological services required by HITH patients or a survey of drug users about the types of drugs they use.
- evaluation of an existing practice that is not a service for example evaluating the frequency of needle sharing amongst intravenous drug users, evaluating the use of natural therapies amongst a particular group of patients.

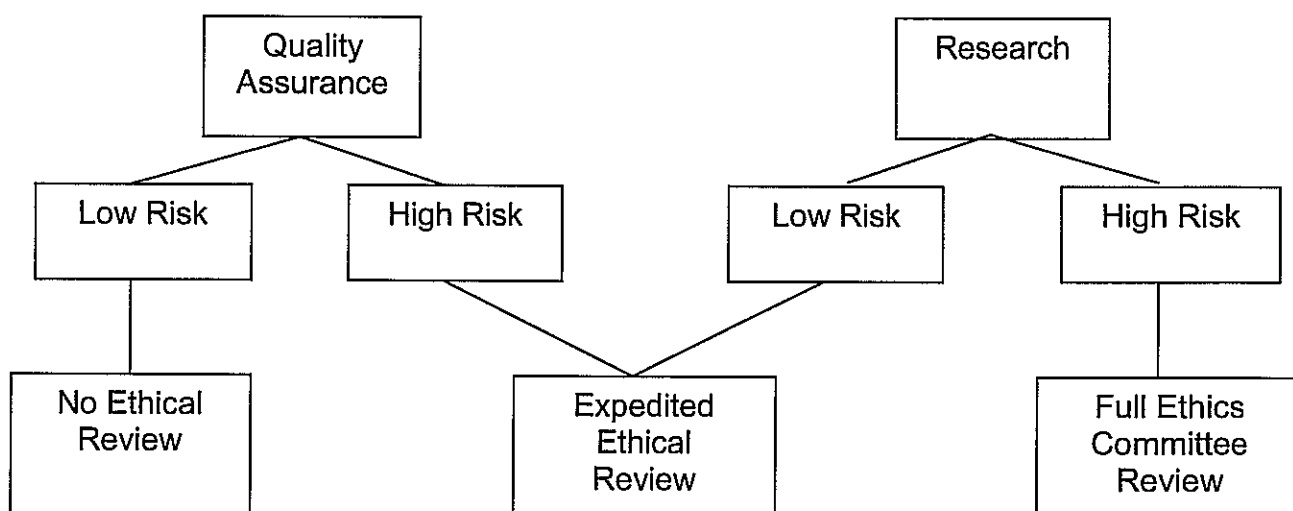
Low Risk Research Studies are studies that do not present any more than what could be considered a minimal risk and/or burden to participants including patients, carers, health care providers or institutions. Risks to participants include not only physical risks, but also research that may cause psychological, spiritual, social harm or distress. Burdens may include research that is intrusive, causes discomfort, inconvenience or embarrassment for the participants.

It is very important to realise expedited ethical review is a process that is available for appropriate studies only. It is not a process aimed at meeting a researcher's need for urgent review.

The Application Package contains a checklist for QA projects and another for low risk research studies, referring to them may assist you in deciding whether your project is appropriate for the expedited ethical review process. The NHMRC Guidelines are on the next page of this document and they may also assist you in the assessment of your study's suitability.

A description of the administrative process is also included in this document. Our aim is to keep this process as uncomplicated and as quick as possible, so it has been designed to operate electronically, hard copies will be accepted but this will slow down the process.

What level of ethical review does your study/project require?



NHMRC Guidelines

for

Expedited Ethical Review

Although circumstances may vary, examples of situations in which expedited ethical review might be permitted include:

- Social science questionnaires or non-controversial, non-personal issues.
- Observational studies in public situations which focus on non-sensitive issues
- Studies of existing de-identified data, documents, records, and pathological or diagnostic specimens.
- An activity where the primary purpose is to monitor, evaluate or improve health care delivery.
- Studies that do not involve an intervention that could result in significant harm to patients.
- Certain projects involving discarded tissue.
- Collection of certain biological specimens: including hair, nail clippings, or saliva.
- Applications for approval of amendments to previously approved research protocols.
- Studies that are substantially similar to another study already approved.

Things to be aware of:

- Social, cultural or religious issues related to any of those situations that might suggest the need for a full ethical review.
- Where a conflict of interest may arise such as those between the roles of clinician and researcher, or teacher and student.
- Expedited ethical review is never justifiable solely on the grounds of a researcher's claim to the need for urgent review of their study.
- If urgency is clearly identified a study may be submitted for provisional ethical review. As with expedited ethical review this will also require ratification by the Human Research Ethics Committee.

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Expedited Ethical Review

Quality Assurance and Low Risk Studies

The Process

STEP 1 Researchers assess whether the study is a Quality Assurance or a Low Risk Study by referring to the guidelines and the checklists.

STEP 2 If the study is considered a suitable - Complete the application form, include copies of the PIS&C, where you have them and complete the checklist(s). It is possible that some studies will have elements of both categories and if so, both checklists will need to be completed.

STEP 3 Submit the application to the Research Support Unit for review of suitability for Expedited Ethical Review. If possible please submit electronically.

STEP 4 If the study is accepted for Expedited Ethical Review it is sent to two members of the Human Research Ethics Committee (HREC) for a detailed review.

The reviewers' comments are then forwarded to the Chairman for sign off.

STEP 4 If the study is not accepted for Expedited Ethical Review, the Principal Investigator will be notified.

A full study application will need to be submitted to the Non-Drug Study Review Committee.

STEP 5 The Principal Investigator will be notified electronically, by the Admin Secretary of approval or non-approval, within two weeks, this may take longer if the study was not submitted electronically.

STEP 6 Chairman will present the study for ratification at the next HREC meeting and a full approval letter will be forwarded to the Principal Investigator once the study has been ratified.