



## Procedures for Ethical Review of Quality Assurance (QA) Projects

*(This document accompanies the Human Research Ethics Policy – RGU 03 and the Human Research Ethics Procedures)*

This guidance is based on the NHMRC publication [\*Ethical Considerations in Quality Assurance and Evaluation Activities\*](#) which is designed to assist organisations in deciding the appropriate level of oversight for quality assurance (QA) and evaluation.

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 (QA) study. QA should be an integral part of all health care delivery.<sup>1</sup>

At Cancer Council Victoria, this would include Clinical Management Surveys, Clinical Audits, and other such projects, evaluations of CISS services, evaluations of professional training programs or cancer prevention policy and programs.

Quality assurance and research are activities that form a continuum. The ethical principles outlined in the *National Statement on Ethical Conduct in Human Research 2007*: integrity, respect for persons, beneficence and justice apply to all QA and research activities.

In many situations, while oversight of the QA or evaluation activity is required, ethical review is not necessary. However, there are certain situations where QA or evaluation activities should be ethically reviewed.

The Quality Assurance/evaluation checklist has been prepared to assist researchers in deciding whether the activity they wish to undertake can be categorised as a Quality Assurance/evaluation activity that does not require ethical review, or if the project needs to be ethically reviewed.

The NHMRC notes in [\*Ethical Considerations in Quality Assurance and Evaluation Activities\*](#) (2014) that 'Where ethical review by an HREC is not required, organisations should consider providing a statement which affirms that an alternative approach to ethical review was considered to be appropriate for the specific QA/evaluation activity if this is required for publication purposes.'

Please note that some journals expect evidence of ethical review of research irrespective of whether the research can be described as a quality assurance activity. The project leader should consider this prior to commencing the activity. In rare cases, a project leader may apply for retrospective approval of a QA activity in order to publish the findings.

The following process is to be followed:

1. The QA checklist is to be used by the project leader to assess the planned activity.
2. If the project meets all requirements for a QA/evaluation activity involving only negligible or low risk to participants, then the activity is noted in the Division where it is being conducted, and no record of the activity is lodged with RGU.

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<sup>1</sup> NHMRC advice 20 February 2003, "When does quality assurance in health care require independent ethical review?" (Archived November 2009)

3. If the project leader has a query regarding the checklist they will consult with RGU who will assist with a determination, in consultation with IRRC member/s as required. If the activity is considered to be a QA activity and no further review is required, no record will be kept by RGU.
4. For projects where it is intended that findings will be published, a completed QA checklist and a project plan are to be submitted to Karen Sharp, Ethics Officer, Research Governance Unit for submission to the Institutional Research Review Committee for ratification as a Quality Assurance activity not requiring ethical review.
5. If it is deemed that ethical review is required, a submission to the appropriate review committee – IRRC or HREC, depending on level of risk – is to be made.

For further information and assistance please contact Karen Sharp tel 9514 6307 or email [karen.sharp@cancervic.org.au](mailto:karen.sharp@cancervic.org.au).