

Expedited Ethical Review

QUALITY ASSURANCE STUDY CHECKLIST

Quality Assurance Studies involve an activity where the primary purpose is to monitor, evaluate or improve the quality of health care delivered by a health care provider. Terms such as 'peer review', 'quality assurance', 'quality improvement', 'quality activities', 'quality studies', and 'audit' are often used interchangeably. Quality assurance covers all of these terms. The ethical principles of respect for persons, beneficence, and justice apply to quality assurance and research activities.

1. Is the consent from participants *inadequate*, or is the activity inconsistent with National Privacy Principle 2.1(a)?
Yes No

Participants may include patients, carers, health care providers and the institution involved.

2. Does the proposed quality assurance activity pose any risks for patients beyond those of their routine care?
Yes No

Risks include not only physical risks but also psychological, spiritual and social harm or distress, e.g. stigmatisation or discrimination.

3. Does the proposed quality assurance activity pose a burden on patients beyond that experienced in their routine care?
Yes No

Burdens may include intrusiveness, discomfort, inconvenience or embarrassment. E.g. persistent phone calls, additional hospital visits or lengthy questionnaires.

4. 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?
Yes No

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.

5. 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?
Yes No

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.

6. Does the proposed quality assurance activity involve any clinically significant departure from the routine care provided to the participants?
Yes No

Application and evaluation of a new technology not previously used in the health service may need further consideration.

7. Does the proposed quality assurance activity involve randomization or the use of a control group or placebo?
Yes No

Proposals involving comparison with published or prior treatment results with other groups are acceptable if the proposals do not involve randomisation.

8. Does the proposed quality assurance activity seek to gather information about the patient beyond that collected in routine care?
Yes No

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.

9. Does the proposed quality assurance activity potentially infringe the rights, privacy or professional reputation of carers, health care providers or institutions?
Yes No

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.

10. Do you require review Expedited Ethical Review in order to publish your data?
Yes No

***If you answered No to all of the above questions,
the proposal does not need consideration by an HREC.***

***If you answered YES to any of the above
it does not mean that this is not a QA study
please give further details
for consideration as to suitability for
Expedited Ethical Review.***

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LOW RISK STUDY CHECKLIST

Low Risk Studies involve an activity where participants, including patients, carers, health care providers or institutions are unlikely to suffer burden or harm. These studies must not present any more than what could be considered a minimal risk and/or burden to participants. 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.

Does the proposed low risk study pose any risks for patients beyond those of their routine care?

Yes

No

Risks include not only physical risks but also psychological, spiritual and social harm or distress, e.g. stigmatisation or discrimination.

Does the proposed low risk study pose a burden on patients beyond that experienced in their routine care?

Yes

No

Burdens may include intrusiveness, discomfort, inconvenience or embarrassment. E.g. persistent phone calls, additional hospital visits or lengthy questionnaires.

Is the proposed low risk study 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?

Yes

No

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.

Does the proposed low risk study involve randomization or the use of a control group or placebo?

Yes

No

Proposals involving comparison with published or prior treatment results with other groups are acceptable if the proposals do not involve randomisation.

If you answered YES to any of the above, please give further details:

Is the research specifically about any of the following topics?

| | | |
|--|-----|----|
| • research about parenting | Yes | No |
| • research investigating sensitive personal issues | Yes | No |
| • research investigating sensitive cultural issues | Yes | No |
| • explorations of grief, death or serious/traumatic loss | Yes | No |
| • depression, mood states, anxiety | Yes | No |
| • gambling | Yes | No |
| • eating disorders | Yes | No |
| • illicit drug taking | Yes | No |
| • substance abuse | Yes | No |
| • self report of criminal behaviour | Yes | No |
| • any psychological disorder | Yes | No |
| • suicide | Yes | No |
| • gender identity | Yes | No |
| • sexuality | Yes | No |
| • race or ethnic identity | Yes | No |
| • any disease or health problem | Yes | No |
| • fertility | Yes | No |
| • termination of pregnancy | Yes | No |

If you answered YES to any of the above, please give further details:

Are any of the following procedures to be employed?

| | | |
|---|-----|----|
| • use of personal data obtained from Commonwealth or State Government Department/Agency | Yes | No |
| • deception of participants | Yes | No |
| • concealing the purposes of the research | Yes | No |
| • covert observation | Yes | No |
| • audio or visual recording with consent | Yes | No |
| • recruitment via a third party or agency | Yes | No |
| • withholding from one group specific treatments or methods of learning, from which they may “benefit” (eg in medicine or teaching) | Yes | No |
| • any psychological interventions or treatments | Yes | No |
| • administration of physical stimulation | Yes | No |
| • invasive physical procedures | Yes | No |
| • infliction of pain | Yes | No |
| • administration of drugs | Yes | No |
| • administration of other substances | Yes | No |
| • administration of ionizing radiation | Yes | No |
| • tissue sampling or blood taking | Yes | No |
| • collecting body fluid | Yes | No |
| • genetic testing | Yes | No |
| • use of medical records where participants can be identified or linked | Yes | No |
| • drug trials and other clinical trials | Yes | No |
| • administration of drugs or placebos | Yes | No |

If you answered YES to any of the above, please give further details:

Other Risks

Are there any risks to the researcher,
(e.g. research undertaken in unsafe environments or
trouble spots)?

| | | |
|--|-----|----|
| | Yes | No |
|--|-----|----|

If you answered YES, please give further details:

Participants – Vulnerability Assessment

Does the research target any of the following categories of people?

- | | | |
|--|-----|----|
| • suffering a psychological disorder | Yes | No |
| • suffering a physical vulnerability | Yes | No |
| • people highly dependent on medical care | Yes | No |
| • minors without parental or guardian consent | Yes | No |
| • people whose ability to give consent is impaired | Yes | No |
| • resident of a custodial institution | Yes | No |
| • unable to give free informed consent because of difficulties in understanding information statement (eg language difficulties) | Yes | No |
| • members of a socially identifiable group with special cultural or religious needs or political vulnerabilities | Yes | No |
| • those in dependent relationship with the researchers (eg lecturer/student, doctor/patient, teacher/pupil, professional/client) | Yes | No |
| • participants be able to be identified in any final report when specific consent for this has not been given | Yes | No |
| • indigenous | Yes | No |

If you answered YES to any of the above, please give further details:

Research In Overseas Settings

Does the research involve any of the following:

- | | | |
|--|-----|----|
| • research being undertaken in a politically unstable area | Yes | No |
| • research involving sensitive cultural issues | Yes | No |
| • research in countries where criticism of government and institutions might put participants and/or researchers at risk | Yes | No |

If you answered YES to any of the above, please give further details: