

Observational Studies: Application Process for Expedited Ethics Committee Review

Introduction

- Investigators must have read the Ethical Guidelines for Observational Studies: Observational research, audits and related activities (the Guidelines), National Ethics Advisory Committee, December 2006. This three-page guidance sheet 'Observational Studies: Application Process for Expedited Ethics Committee Review' summarises the key points.
- The primary responsibility for determining whether an observational study is appropriate for the expedited review process, as set out in the Guidelines, lies with investigators.
- Applicants must submit two hard copies of the Expedited Review of Observational Studies application form **or** a pdf file of the completed form, including the signed declaration/s, to the relevant ethics committee administrator.

Part A

Question 3: Brief description of the project and study design

Applicants should provide a brief description of the study and the study design in lay language. The information about the study design should be written with paragraphs 5.1–5.10 of the Guidelines in mind.

Question 4(iii): Expected reporting date

A summary of the study results is required for studies that have been given ethical approval. If the study is longer than 12 months, an annual progress report is also required. The report form is available at <http://www.newhealth.govt.nz/ethicscommittees>.

Question 5(a) and (b): Is expedited review appropriate or required?

The Guidelines recognise two principal categories of observational studies:

- a) observational research
 - b) audit and related activity.
- a) All observational research requires ethics committee review (Guidelines, paragraph 11.3). However, low-risk observational research may qualify for expedited rather than full review. Low-risk observational research includes (Guidelines, paragraph 11.13):
 - case reports and case series
 - descriptive studies
 - questionnaires or surveys for research purposes that do not involve the collection of sensitive, personal information.
 - b) Audits and related activities generally do not require any ethics committee review (Guidelines, paragraph 11.3). There are, however, some audits or related activities that do require review, because they reach a threshold of risk specified in the Guidelines. If the audits or related activities that reach a threshold of risk do not meet any of the exceptions to the requirement for ethics committee review (Guidelines, paragraphs (11.7–11.11), they qualify for expedited review (Guidelines, paragraph 11.14).

Investigators whose audit or related activities do not involve any factors that reach the threshold of risk, or that fall under one or more of the relevant exceptions, may request written confirmation from

the committee that no review is required. The Expedited Review of Observational Studies application form makes provision for such requests.

If an audit or related activity does not require ethics committee review, then there is no requirement to submit an application. Investigators should note, however, that organisations that fund, host, or publish observational studies may also set their own requirements. For example, the Health Research Council of New Zealand (HRC) requires written ethics committee confirmation for any study that it funds that does not require ethics committee review. Note also that the Guidelines, paragraph 12.1, provide guidance to investigators who are considering publication of their observational studies.

- c) Expedited review may also be appropriate for an observational study that is undertaken as part of an educational qualification, and that requires timely ethics committee review (Guidelines, paragraph 11.15). Note that whereas studies that fall under questions 5(a) or (b) will qualify for expedited review, paragraph 11.15 of the Guidelines requires the ethics committee to judge whether expedited review is appropriate for studies falling under question 5(c). Applicants who wish to use this provision should seek a preliminary indication from the ethics committee that expedited review is appropriate, before completing the application form.

Part B

Question 6: Overall risk and benefit

One of the primary motivations for the expedited review process is the recognition that observational studies are typically relatively low-risk. The Guidelines also recognise that the acceptable level of risk in a study must be assessed in light of the study's expected benefits (paragraphs 4.8–4.13). Question 6 asks investigators to identify expected benefits and risks, and to comment on the balance between the two.

Question 7(a): Collection of information

The Guidelines recognise three possible sources of information (individuals, third parties and health records (paragraphs 6.5–6.7, 6.35–6.40)) and raise different issues for each source. Question 7(a) asks investigators to identify the source of the information in their study, and to address the issues raised about that source in the Guidelines.

Question 7(b): Identifiability

An important part of the risk that observational studies might pose is that individuals may be 'identifiable' from the information gathered by investigators. Question 7(b) asks whether the data gathered in a study is, on the one hand, identified, potentially identifiable, or partially de-identified; on the other, de-identified or anonymous (Guidelines, paragraph 6.4). In short, identified, potentially identifiable, and partially de-identified data raise a greater risk of identification. Investigators using such data are asked to justify doing so. De-identified or anonymous data carry few risks. An applicant whose study accesses only data of these sorts should consequently go straight to question 10.

Question 8: Consent

The consent of participants should generally be obtained for using identified or potentially identifiable data for research (Guidelines, paragraph 6.41). Question 8(a) asks if and how such consent will be obtained. The Guidelines recognise (paragraph 6.42) that the presumption that consent should be obtained may be set aside. Question 8(b) asks for a justification for any decision to do so.

Question 9: Confidentiality and storage of information

Questions 9(a)–(c) ask what provisions have been made to protect patient confidentiality, who will have access to data, and how it will be stored (Guidelines, paragraphs 8.1–8.10).

Question 10: Māori and ethical issues

The Guidelines recognise a range of issues of particular relevance to Māori: see for instance, paragraphs 4.3–4.5, 5.7, 6.39. Question 10 asks whether the study raises issues under these sections, and, if so, how they will be addressed and what consultation has taken place.

Expedited review will normally be carried out by one or more committee members under delegation from the full ethics committee. When delegating authority, ethics committees must ensure appropriate Māori participation in the expedited review of any observational studies that raise issues of particular relevance to Māori.

Question 11: Any other ethical issues

The Guidelines address ethical issues not explicitly raised in the Expedited Review of Observational Studies application form. Investigators should draw to the reviewer's attention any significant ethical issues about their proposed studies that are not otherwise addressed in the application form.

Document checklist

Study protocol

Observational studies will normally require appropriate written protocols (Guidelines, paragraphs 5.11–5.12).

Information sheets and consent forms

Observational studies may require information sheets and consent forms. Refer to the Guidelines for Completion of the National Application Form for Ethical Approval of a Research Project (NAF-2005 v1) available at <http://www.newhealth.govt.nz/ethicscommittees/documents/nafg.doc>, pages 15-20, for guidelines on writing information sheets and consent forms. The statements on compensation are **not** required for observational studies.

Informing locality organisation(s)

Locality assessment is not needed for observational studies that receive expedited ethics committee review. The investigator should nevertheless inform the locality organisation(s) about conduct of the study, and should also note that such organisations might also set their own requirements (Guidelines, paragraphs 12.5–12.6).