

Observational Studies and Ethics Committee Review

This guidance sheet summarises when ethics committee review of an observational study is appropriate and defines observational studies. It summarises the National Ethics Advisory Committee's *Ethical Guidelines for Observational Studies: Observational Research, Audits and Related Activities* (the Guidelines), which address all aspects of the ethical conduct required for observational studies. The Guidelines are available at <http://www.newhealth.govt.nz/neac/>.

What is an observational study? (Guidelines, paras. 2.1–2.7)

Observational studies:

- include observational research and also audits and related activities (see definitions overleaf)
- are studies where the investigator has no control over study variables and merely observes outcomes
- differ from intervention or experimental studies, in that no intervention other than the recording, classifying, counting and analysing of data takes place.

When does an observational study require ethics committee review? (Guidelines, paras. 11.1–11.11)

- All observational research requires ethics committee review.
- Public health investigations do not require ethics committee review.
- Audits and related activities do not require ethics committee review, unless they reach a threshold of risk by having one or more of the following features:
 - Departure from normal care.
 - Use of stored samples.
Exception: A health professional undertaking a recognised quality assurance programme, an external audit of services, or an external evaluation of services.
 - Secondary use of data without consent.
Exception: The secondary use of data for quality assurance, outcome analysis, or resource review done by people employed or contracted by the service provider holding the information.
 - Extra data collected in a health or disability support setting.
Exception: The collection of non-sensitive data or an observation in which participants remain anonymous, when undertaken by people employed or contracted by the service provider.
 - Extra data collected outside a health or disability support setting.
Exception: An innocuous questionnaire or focus group to discuss new forms of care delivery.

When is expedited ethics committee review appropriate? (Guidelines, paras. 11.12–11.17)

Expedited review is appropriate for observational research such as:

- case reports and case series
- descriptive studies
- questionnaires or surveys for research purposes that do not involve the collection of sensitive personal information.

Expedited review is also appropriate for an:

- audit or related activity that requires ethics committee review
- observational study undertaken as part of an educational qualification and that requires timely ethics committee review.

If in doubt

- consult the Guidelines
- consult the relevant ethics committee.

Observational Studies: Definitions

Observational research

Primarily observational research is to add to generalisable knowledge about a health or disability issue.

- **Case control studies** examine the relationship between an attribute and a disease, by comparing people with and without the disease with respect to the presence of the attribute or level of exposure to it.
- **Cohort studies** examine the relationship between exposure to a factor or factors and the probability of the occurrence of a disease, by observing large numbers of people over a long period and comparing incidence rates of the disease in relation to exposure levels (eg, a clinical cohort study where a group of patients with a given disease is followed to examine the prognosis).
- **Cross-sectional studies** examine the relationship between diseases (or other health-related characteristics) and other variables in a defined population at one particular point by collecting health and other information about members of the population, and include questionnaires or surveys done for research purposes.
- **Case reports** report cases from health or disability service or research settings.
- **Case series** describe a set of cases of a disease (or similar problem).
- **Descriptive studies** examine the existing distribution of variables in populations (eg, the analysis of cancer registry data or emergency department data by person, place or time).

Audits and related activities

Primarily an audit or related activity is to improve the delivery of the particular health or disability support service being studied or to control a threat to public health.

- **Audits** involve the systematic evaluation of aspects of health or disability support service delivery by considering measurable indicators of performance and/or quality.
- **Programme evaluation** is an audit where a whole programme is evaluated rather than specific interventions.
- **Evaluation studies** determine the relevance, effectiveness and impact of activities in the light of their objectives and may evaluate an activity's structure, process or outcome.
- **Quality assurance activities** aim to improve health and disability support services by assessing the adequacy of an existing practice against a standard.
- **Outcome analyses** involve assessing health and disability support service quality by reviewing health care information to evaluate outcomes, without comparing outcomes against standards.
- **Benchmarking** improves practice by comparing two or more health and disability support services.
- **Public health investigations** explore possible risks to public health, are often of an immediate or urgent nature, and are often required by legislation. They include investigations into outbreaks or clusters of disease, analyses of vaccine safety and effectiveness, and contact tracing for communicable conditions.
- **Public health surveillance** monitors health risks by, for example, systematically collecting, analysing and disseminating information about disease rates.
- **Pharmacovigilance** (post-marketing surveillance) involves monitoring the adverse effects of pharmaceuticals after their introduction into the general population by such methods as the spontaneous reporting of adverse events and the monitoring of all adverse events for a restricted group of medicines (prescription event monitoring).
- **Resource utilisation reviews** evaluate resource use in a particular health or disability service activity (eg, by reviewing health records to determine health care inputs).

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Note: For application forms for full review or expedited review, and for ethics committee contact details, see <http://www.newhealth.govt.nz/ethicscommittees/>