Ethical Review of Observational Research, Audit and Related Activities

Discussion Document

September 2003
How to Respond

NEAC is asking stakeholders for their comments on this discussion document in order to assist the Committee to develop advice to the Minister of Health. There are questions in a tear-out section at the back of this document. You might like to use the questions as a way of organising and presenting your feedback. Please feel free to make additional comments if you wish. Your assistance is much appreciated.

There are three ways in which you can respond to this document:

1. Write your comments in the tear-out section at the back of this document and send them back to NEAC in the enclosed envelope.

2. Complete the questions as a Word document and either email it to NEAC or send it by post. The Word document is on the NEAC website at http://www.newhealth.govt.nz/neac.htm.

3. Write your comments as an email, or as a letter that you can send to NEAC in the enclosed envelope.

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1. Introduction

1.1 Background

The National Advisory Committee on Health and Disability Support Services Ethics (the National Ethics Advisory Committee or NEAC) was established under section 16 of the New Zealand Public Health and Disability Act 2000, and its members were appointed in December 2001. NEAC’s statutory functions are to:

• provide advice to the Minister of Health on ethical issues of national significance in respect of any health and disability matters (including research and health services)
• determine nationally consistent ethical standards across the health and disability sector and provide scrutiny for national health research and health services.

The Minister of Health has asked NEAC to address four matters arising from the Ministerial Inquiry into the Under-Reporting of Cervical Smear Abnormalities in the Gisborne Region (the Gisborne Inquiry). As part of its work programme to address these matters, NEAC has agreed with the Minister of Health to “develop guidelines on conducting observational studies in an ethical manner and establish the parameters for the ethical review of observational studies (including guidance regarding weighing up the harms and benefits of this type of health research)”.

The Gisborne Inquiry recommendation 11.21, that “Ethics committees require guidance regarding the weighing up of harms and benefits in assessing the ethics of observational studies”, highlights the concern raised by the Inquiry that there is a lack of consensus in New Zealand about the ethical considerations involved in observational studies, and that ethics committees require guidance to assess instances in research in which personal privacy may be overridden by the need to gain information to advance public health (Duffy, Barrett, et al, 2001).

This discussion document is part of a wider review NEAC is undertaking on the system of ethical review of health and disability research in New Zealand. The aim of this part of the review is to:

• Identify the ethical issues in the conduct of observational studies.
• Present and discuss options for the establishment of parameters for the ethical review of observational studies.
• Propose New Zealand guidelines on the ethical review of observational studies (draft guidelines are contained at the back of this document).
1.2 Definition of observational studies

The term ‘observational studies’ referred to in the Gisborne Inquiry has been clarified by NEAC as referring to epidemiological observational studies, as distinct from observation in social research, which may include observation of participants during an intervention.

In epidemiological research, observational studies are distinguished from interventional or experimental studies, as no intervention other than recording, classifying, counting, and analysing of data takes place.

This document uses the term ‘observational studies’ to refer to observational epidemiological methods and audit.

Audit and other related activities may use the same epidemiological methods as observational research, but they may not be required to have independent ethics committee approval. However, many of the same ethical considerations are relevant in such activities.

1.3 Ethical review of audit and related activities

This section discusses the distinction between research and audit and related activities, and the ethical issues raised by the latter. It then proposes three options for the ethical review of audit and related activities in New Zealand.

The Gisborne Inquiry raised the concern that there is a lack of clarity around the remit of ethics committees in relation to audit and related activities.

The role of ethics committees in the review of research is complicated by difficulties in defining which activities are research, and which are not.

Non-research activities, such as audit, can employ methods similar to those used in research, but they are considered to be distinct activities. These activities have the potential to raise the ethical issues that are also raised in research. However, the risks of harm associated with these activities may be lower, and the benefits more general and predictable than those of research.

The current New Zealand Operational Standard for Ethics Committees Section 4.1 (Ministry of Health, 2002a) defines ‘audit’ as an activity that measures practice against a standard. Current guidance is that ethics committee review is not required for audit or monitoring of quality of care, if these activities are carried out by those with professional obligations to maintain privacy, and no new information is to be gathered.
The Australian National Health and Medical Research Council (NHMRC) proposes that audit and related activities should proceed without ethics committee review if there is consent from all participants, or if the secondary use of data is related to the primary purpose of collection (and, for sensitive data, directly related to the primary purpose of collection), and the individual concerned would reasonably expect this use of the data. The activity also must not be likely to cause “burden or harm (physical, mental, psychological, spiritual, or social)” (NHMRC, 2003, p.5).

1.4 Draft Ethical Guidelines for Observational Studies

The Draft Ethical Guidelines for Observational Studies developed by NEAC (contained at the back of this document) consist of statements from New Zealand and international guidelines.¹ The majority of the guidelines referenced agree on major ethical issues relating to observational studies, and there are few instances where conflicting views are expressed.

The draft guidelines are structured around the process a researcher undertakes when designing and conducting a study, from consideration of the underlying values and ethics to the communication of study results.

Special issues such as specimen collection, storage and use, and genetic testing are not included. There will be a small number of observational studies that may need guidance on these matters, and reference to appropriate sources of advice will be included in any final set of guidelines.

In their current form, the guidelines draw on excerpts from published guidelines, and one purpose of this discussion document is to obtain views on the principles and issues that should be addressed in New Zealand guidelines. Responses to the draft guidelines will assist NEAC to construct a final set of guidelines.

¹ Health Research and Privacy Guidance Notes for Health Researchers and Ethics Committees (Health Research Council of New Zealand, 2002b); National Statement on Ethical Conduct in Research Involving Humans (National Health and Medical Research Council, Australia, 1999); International Guidelines for Ethical Review of Epidemiological Studies (Council for International Organisations of Medical Sciences, 1991); Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (Tri-Council, Canada, 1998); American College of Epidemiology Ethics Guidelines (American College of Epidemiology, 2000); Operational Standard for Ethics Committees (Ministry of Health, New Zealand, 2002); Code of Health and Disability Services Consumers’ Rights (Health and Disability Commissioner Act regulation, New Zealand, 1996).
2. Ethical Review of Audit and Related Activities

2.1 Introduction

Following the Gisborne Inquiry it was evident that parameters needed to be defined for the ethical review of audit and related activities. The Inquiry Committee was concerned that an ethics committee decision had prevented an independent audit of the cervical screening programme in New Zealand. The Committee believed that it is unethical to have a screening programme that is not evaluated, without informing women of the limitations of the programme arising from this lack of evaluation (Duffy, Barrett, et al, 2001). The Inquiry Report states:

“Today quality assurance and audit and evaluation are so much part of health delivery that it could be said that it is no more than one of the components of the original treatment, which happens to be carried out later on. On this view treatment which does not include a subsequent audit could be seen as incomplete treatment.” (Duffy, Barrett, et al, 2001, p.235).

The Inquiry also raised the concern that statements relating to audit in the National Guidelines for Ethics Committees in New Zealand [National Standard] were contradictory in respect of whether an independent team could audit the cervical screening programme (Duffy, Barrett, et al, 2001).

The report stated that clarification was necessary to determine the jurisdiction of ethics committees in relation to audit and related activities, as evidence was given that there is international consensus that ethical approval is not necessary for audit/quality assurance (Duffy, Barrett, et al, 2001).

Clause 11.18 of the Inquiry report recommends:

“[a] change to guidelines ... to make it clear that any (external and internal) audit, monitoring and evaluation of past and current medical treatment does not require the approval of ethics committees.” (Duffy, Barrett, et al, 2001, p.258).

In light of this recommendation the Ministry of Health included some further guidance on this matter in the Operational Standard for Ethics Committees (Ministry of Health, 2002a).

This NEAC project on observational studies also addresses recommendation 11.19 of the Inquiry Report:

“There should also be a review of the operation of ethics committees and the impact their decisions are having on independently funded evaluation exercises and on medical research generally in New Zealand.” (Duffy, Barrett, et al, 2001, p.259).

Independently funded evaluation exercises are often termed external audit. Therefore, any discussion of audit and related activities will be relevant to independently funded evaluation exercises.
Recommendation 11.20 is also relevant to this document:

“Ethics Committees require guidance regarding the application of the Privacy Act and the Privacy Health Information Code. Ethics Committees need to be informed that the interpretation of legislation relating to personal privacy is for the agency holding a patient’s data to decide. They would, therefore, benefit from having at least one legally qualified person on each regional committee.” (Duffy, Barrett, et al, 2001, p.259).

Section 2.2, below, examines the remit of research ethics committees in different countries, to determine how policy defines their task, and which activities are defined as research that requires ethics committee review. Section 2.3 describes other activities (termed ‘audit and related activities’) that use similar methods to research, but which are not considered to be research, and considers the ethical issues concerning these activities. Sections 2.4 and 2.5 discuss various ways of differentiating research from audit and related activities, and possible criteria for determining when ethics committee review is required. The final section discusses three proposed options for the ethical review of audit and related activities.

2.2 The remit of research ethics committees

The remit of research ethics committees is often addressed in the guidelines and standards for the operation of these committees. The following section contains excerpts from international guidelines and operational standards that address the remit of ethics committees.

One principal role of research ethics committees is to ensure the safety and protection of research participants, while facilitating high quality research for the benefit of individuals and society.

The United Kingdom’s Manual for Research Ethics Committees (Eckstein, 2003) highlights these roles:

“... [Research ethics committees] have the responsibility of ensuring that medical research on humans is conducted in an ethical manner ... On one hand there is the need to contribute to the evidence base upon which modern medicine is based, on the other is the need to protect those who participate in the research process.” (Eckstein, 2003, p.xvii).

The International Guidelines for Ethical Review of Epidemiological Studies (CIOMS, 1991) state:

“The primary functions of ethical review are to protect human subjects ... and to facilitate beneficial studies.” (CIOMS, 1991, p.20).

Definitions of research

A guide for institutional review boards in the United States draws on federal regulations to define research as:
“a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge” (Amdur and Bankert, 2002, p.120).

The United Kingdom’s Manual for Research Ethics Committees (Eckstein, 2003) states that medical research:

- May involve experiments on human subjects whether as patients, patients as volunteers, or healthy volunteers.
- Is a systematic investigation which aims to increase the sum of knowledge.
- May involve allocating patients randomly to different treatment groups.
- May involve a completely new treatment.
- May involve extra disturbance or work beyond that required for normal clinical management.
- Usually involves an attempt to test a hypothesis.
- May involve the application of strict selection criteria to patients with the same problem before they are entered into the research study. (Eckstein, 2003, p.60).

The Australian National Statement on Ethical Conduct in Research Involving Humans (NHMRC, 1999, p.6) defines research as including the following types of activities:

- systematic prospective collection of information to test an hypothesis
- a planned study of existing practices with a view to changing/improving practice in light of the study’s findings and/or to increase understanding, or
- the administration and analysis of data in response to surveys or questionnaires, interviews or opinion polling.

As these documents highlight, research can be defined in a variety of ways, which can be problematic. For example, upon defining research as above, the Australian National Statement then states:

“... such lists risk including activity that would not normally be included, like quality assurance activities or audits and excluding activity that probably should be included, such as research conducted as part of a course of education” (NHMRC, 1999, p.6).

Similarly, Institutional Review Board: Management and Function (Amdur and Bankert, 2002) states that the systematic investigation that characterises research may also be an element in other non-research activities. However, a systematic approach using the scientific method is not the same as research intent.

Given the difficulties associated with the definition of research, it is more useful to consider which activities require ethics committee review (NHMRC, 1999).
### 2.3 Audit and related activities

Audit and related activities often employ methods similar to those used in research, but are considered to be distinct from it.

The following categories of activities attempt to determine when an activity that uses identifiable medical data should not be considered research (Amdur and Bankert, 2002, p.119).

(i) **Personal health care practice**

Personal health care practice is an activity performed solely for the well-being of an individual. Innovative practice, in which an activity, which is not entirely proven, is used to benefit an individual patient, may appear to be similar to experimental research (Amdur and Bankert, 2002). It has been suggested that a better term for innovative practice would be non-validated practice (Amdur and Bankert, 2002). Guidance on innovative practice is often provided in guidance on experimental research.

(ii) **Personal health care practice for the benefit of others**

This is an activity in which the resulting benefit may not be for the individual, but will be for a well-defined group of people: for example, immunisation (when herd immunity applies) and blood donation. This activity differs from research as it aims to obtain a benefit for a particular group of people in a predictable manner (Amdur and Bankert, 2002).

(iii) **Public health practice**

Public health practice is similar to the previous category, as it may affect individuals who will not directly benefit (Amdur and Bankert, 2002). It has also been described as an operational tool that may have a direct effect on those involved (Lowrance, 2002). For example, an investigation into an outbreak of food poisoning may or may not stop further illness among those involved in the investigation, but it will protect public health by identifying the cause, thereby minimising the extent of the outbreak and preventing further similar events affecting others.

Public health practice includes activities such as the investigation of outbreaks of disease, analysis of vaccine safety and effectiveness, contact tracing for communicable diseases, analysing and reporting adverse drug reactions, auditing new treatments, evaluating screening policy and monitoring practice, eg, antenatal HIV screening (Verity and Nicoll, 2002).

Many of these efforts to protect public health are underpinned by public health surveillance, a form of public health practice that monitors risks to health. It may include adverse drug reaction monitoring, and notification of disease. The data
collected from disease notification produces vital information about disease occurrence in the community.

Public health surveillance does not usually require contact with individuals unless a response is required. However, for some diseases there will be a public health response that will need identifiable data, and will require contact with affected individuals (Verity and Nicoll, 2002). For example, notification of a case of meningococcal disease will require prophylactic treatment for contacts. Other public health responses may be at a population level. High rates of meningococcal infection may prompt strategies such as immunisation programmes, or education about the signs and symptoms of infection.

(iv) Quality assessment or improvement

Quality assessment or improvement activities are designed to improve medical practice. Usually a service or practice is measured against an established standard (Amdur and Bankert, 2002). Quality assessment activities aim to assess the adequacy of current care (Casarett, Karlawish, et al, 2000). Quality improvement has been described as, “cycles of interventions that are linked to assessment that have the goal of improving the process, outcome, and efficiency of complex systems of health care” (Casarett, Karlawish, et al, 2000).

(v) Outcome analysis

This activity differs from a quality assessment project, as it does not involve the comparison of practice against a standard (Amdur and Bankert, 2002). Practitioners may retrospectively examine medical notes to determine the outcome of medical treatment, or the course of a particular illness (Amdur and Bankert, 2002). They may perform descriptive analysis, but the activity is still considered a non-research activity (Amdur and Bankert, 2002).

An example of this type of activity is a 1983 New Zealand study, which analysed the survival of children with cancer, comparing survival rates across regional centres in New Zealand. Such studies are used to determine whether health service initiatives are maximising outcomes such as survival rates.

While this case is appropriately classed as an outcome analysis form of non-research activity, it is still clearly research. This illustrates the wider point that the term ‘non-research activity’ needs to be interpreted as ‘activity that has a non-research element’.

(vi) Resource utilisation review

Resource utilisation review is also referred to as ‘cost control’ or ‘utilisation review’ (Amdur and Bankert, 2002). This activity may involve the review of medical records to appraise resource use in a health care activity (Amdur and Bankert, 2002).
An example of this type of activity is where patient records are used to determine the health care inputs, for example chest x-rays, for patients with a particular diagnosis. This information may then be used to develop clinical care pathways.

(vii) Investigational activity

This term is used by the United States Food and Drug Administration (FDA) to describe activities such as the off-label use of medication, where a medication or device is used for a purpose other than that for which it has been approved (Amdur and Bankert, 2002).

Comment

Other international guidelines have also highlighted activities that would not be considered research. These activities include public health surveillance (CIOMS, 1991), programme evaluation (CIOMS, 1991) and quality assurance studies such as audit (Tri-council, 1998; NHMRC, 1999).

Although not explicit, the term ‘audit’ is often used for many of the activities contained in the categories above, particularly quality assessment, outcome analysis, and public health practice (eg, monitoring of screening programmes).

This document will use the term ‘audit and related activities’ to include all the activities outlined above except personal health care practice and innovative or non-validated practice. Ethical issues in personal health care are addressed by groups of health professionals according to their professional standards and in some countries by hospital ethics committees. Innovative practice or non-validated practice is addressed as part of the considerations that apply to experimental research.

Ethical issues raised by audit and related activities

Activities that use similar methods to those of research have the potential to raise similar ethical issues. The central question is whether or not policy should require these activities to receive independent ethics committee review.

Even without review by an ethics committee, those undertaking audit and related activities must consider ethical principles such as respect for persons, justice, beneficence and non-maleficence. This will include weighing up the risks and benefits of the activity.

Potential harms

The potential harms associated with audit and related activities depend on the methods employed, for example, whether previously collected information will be used, or whether further information will be collected from individuals. If confidentiality is breached in the use of identifiable medical data, then potential harms include psychological harm, problems with interpersonal relationships, stigmatisation, and
problems with employment or insurance or other discrimination (Amdur and Bankert, 2002). These harms will not occur if there are no breaches of confidentiality, involving someone outside the audit team being informed of identifiable medical information. However, it might be thought that access to patient data from which the audit team can directly approach patients could potentially cause harm simply as a breach of privacy. In such cases, the key issue is whether the conduct of such activity is part of high quality service delivery. There is further discussion of this below.

There are many safeguards in place for the protection of medical data, and there have been very few breaches of confidentiality in research in recent years (Lowrance, 2002). There are no known breaches of confidentiality for audit or related activities in New Zealand.

There are also various factors that make audit and related activities likely to cause less harm than research. According to the United Kingdom’s Manual for Research Ethics Committees, medical audit:

- *Never involves experiments, whether on healthy volunteers, or patients as volunteers.*
- *Is a systematic approach to the peer review of medical care in order to identify opportunities for improvement and to provide a mechanism for bringing them about.*
- *Never involves allocating patients randomly to different treatment groups.*
- *Never involves a completely new treatment.*
- *Never involves disturbance to the patients beyond that required for normal clinical management.*
- *May involve patients with the same problem being given different treatments, but only after full discussion of the known advantages and disadvantages of each treatment. The patients are allowed to choose freely which treatment they get.* (Eckstein, 2003, p.60).

Although the last bullet point describes health care practice, and audit would consist of the evaluation of such activity, this definition makes clear that medical audit does not involve any intrusive intervention.

In addition, in audit and related activities clinicians do not have the potential conflict of interest that can occur in a clinical trial, where they may feel that a patient would benefit from a particular medication, but where they also want to recruit large numbers of participants who will be randomised to treatment options, in order to get a result to benefit future patients.

*Potential benefits*

The benefits of audit are more general and predictable than those of research. The aim of audit and related activities is to improve the quality of health care, thereby improving health outcomes (Ministry of Health, 2002b). Audit and related activities protect the welfare of health care participants who are taking part in health care activities, by improving the delivery of that care. It has been argued in New Zealand that quality
assurance should be accepted as part of clinical care. If this were the case it could be considered unethical for medical care not to be audited (Duffy, Barrett, et al, 2001).

The consequences of not auditing can be overlooked when balancing the risks and benefits of audit and related activities. The Gisborne Inquiry highlighted the dangers of not auditing a complex service such as a cervical screening programme. Audit is a necessary requirement to ensure adequate quality and hence safety of such a programme, and it is especially important as screening is offered to a ‘well’ population. Conduct of such an audit in a timely manner can often be expected to save lives.

As for research, an audit or related activity will only be beneficial if it is designed properly and the skill of those involved is adequate. It is also important that the results of the audit are disseminated to those in the service that is being evaluated, and publication of results adds to the benefits of the activity for the wider population. Publication with resulting peer review may increase the quality of audit and related activities. Often independently funded (or external) evaluation exercises have academic input, which may increase the quality of these activities.

One benefit of externally conducted audits of health care services may be that these are the only audits that could be considered to be truly independent (Stone, 1990). However, external audits may have higher associated risks of breaching confidentiality of medical data. The risks will be reduced if those conducting the audit are operating under professional standards that oblige them to maintain the confidentiality of medical data.

Like research, ethical review of audit and other activities requires a weighing up of the risks and benefits of the activity. It is important, however, to remember the more predictable benefits and the reduced risks inherent in audit and related activities.

2.4 Differentiating audit and related activities from research

The ambiguity surrounding the distinction between research and audit has caused considerable concern. It has led to studies being declined for publication, as the authors believed they were undertaking audit, whereas journal editors considered it to be research that lacked ethics committee approval (Goodyear-Smith and Arroll, 2001). It has raised debate as to whether these situations warrant retrospective approval from ethics committees (NHMRC, 2003).

A recent article in the *Journal of the American Medical Association* (Casarett, Karlawish, et al, 2000) proposed that two criteria should be fulfilled before an activity is considered to be quality assurance rather than research: (i) the majority of those involved in an activity will directly benefit from it, and (ii) there is no increase in harm from a study design which aims to generalise the results. These criteria, however, provide a restricted definition of clinical audit. Although under such a definition the health service population may benefit, rarely will the majority of the same individuals directly benefit from an audit.
Research and audit can be distinguished by examining the justifications for the different activities. The justification for research is to gain knowledge that can be used to benefit others apart from the participants. While some participants may benefit from the activity, this is not the justification for it (Amdur and Bankert, 2002). The justification for audit and related activities is to improve health care delivery. While some non-research activities may produce data that is of value to others outside the study setting, this does not change the justification for the study (Amdur and Bankert, 2002).

Some institutional review boards in the United States define research according to whether the results will be publishable. It is argued, however, that this criterion is inappropriate, because not all information published in medical journals is obtained by research (Amdur and Bankert, 2002). It is also argued that the ethical standards applied to research may not be appropriate for some non-research activities that might be published. This is the case in outbreak investigations where the justification of the activity is important, and yet where the application of research ethical standards would be detrimental to public health (Amdur and Bankert, 2002).

It is suggested that if a study would proceed even if publication of the results or other academic recognition were prohibited, then the main intent of the study is not to add to general knowledge, and therefore is not research (Amdur and Bankert, 2002). However, it may still be appropriate to publish results of these studies.

The preferred distinction is that audit and related activities are “an essential and integral part of high-quality health care delivery”, whereas research is not.

This distinction is helpful in recognising the way in which quality assurance is integral to health care practice. However, given debate about which activities are essential to health care, this distinction should not be the only feature in determining whether an activity requires ethics committee review.

### 2.5 Ethics committee review of audit and related activities

**Do audit and related activities currently need ethics committee approval in New Zealand?**

The Gisborne Inquiry Report claimed that the 1996 *National Guidelines for Ethics Committees in New Zealand* were ambiguous with regard to whether audit and related activities required ethical approval, particularly in relation to external audit (Duffy, Barrett, et al, 2001). The Guidelines implied that external audit required ethical review, but internal audit did not. Another section allowed access to personal information for the monitoring of medical care without ethical approval, provided that those conducting the audit operated “under the same professional standard as the individual’s care giver” (Duffy, Barrett, et al, 2001).

Updated guidance on this issue for ethics committees is found in the *Operational Standard for Ethics Committees* (Ministry of Health, 2002a).
The Health Research and Privacy-Guidance Notes for Health Researchers and Ethics Committees (Health Research Council, 2002) also outlines the contents of the Health Information Privacy Code in regards to this matter, and gives advice on discretionary matters not directly dealt with by the law.

The following are excerpts from these documents that address audit and related activities.

(i) **Operational Standard for Ethics Committees (Ministry of Health 2002a)**

*Audit.*

135. Audit involves an investigation into whether an activity meets explicit standards, as defined in an auditing document, for the purpose of checking and improving the activity audited. An audit undertaken by or under the supervision of senior members of the health care or disability service directly responsible for the care of that group of health and disability service consumers would not require ethical review.

136. Access to confidential medical/personal information held by the service must be restricted to those individuals employed or contracted by the service provider, the funder of the service, or an agency responsible for overseeing the safety and quality of the service, and be used solely for the purpose of auditing a service. All information must be recorded in a non-identifiable manner and any report must not identify any individual.

137. Ethical review for an audit is required if it is intended to seek from patients additional information other than that which was collected by a service during the provision of health and disability care.

**Disclosure and use of personal health information for the purposes of monitoring the quality of care.**

138. At an institutional level, the disclosure and use of health information relating to identifiable individuals for the purposes of monitoring care may go beyond the processes involved in internal clinical audit. As part of such monitoring, expertise possessed by members not involved in the health care or disability services team (for example, expertise in statistical methods, pathological diagnosis or classification) may be required. Ethical review is not required for this process as long as all persons involved are operating under the same professional standards and confidentiality requirements as the individual caregiver.

139. Ethical review for monitoring the quality of care is required if it is intended to seek from patients additional information other than that which was collected during the provision of health and disability care. (Ministry of Health 2002a).

(ii) **Health Research and Privacy-Guidance Notes for Health Researchers and Ethics Committees (Health Research Council, 2002)**

Normally, ethics committee approval is not required for the use of health information for monitoring or internal audit undertaken by staff involved in the institution or service. Health information may be used for monitoring in accordance with rule 10(1)(b) as monitoring may be regarded as directly related to the purpose in connection with which the information was originally obtained. ... This exception may be relied on without having to seek ethics committee approval, provided of course that the information will not be published in a form that could reasonably be
Comment

The *Operational Standard’s* definition of audit, as an activity that measures practice against a standard, excludes audit that does not measure against a standard, e.g. outcome analysis. Ethics committee review is not required for audit as defined by the *Operational Standard*, if the audit is carried out by those with clinical responsibility for the patients. Access to confidential medical data is confined to those employed/contracted by the health service, funders of the service, or those responsible for the safety and quality of the service, for the purpose of audit. If new information is to be gathered from patients, then ethics committee review is required.

For ‘monitoring the quality of care’, expertise may need to be sought from outside the health care team. Ethics committee review is still not required provided that those involved in the activity operate under the same professional standards as the health care team. However, if new information is to be gathered the activity will require ethics committee approval. It is ambiguous, however, whether this review will be needed for the whole activity, or just the gathering of the extra information.

According to this document neither audit nor monitoring of quality of care activities require ethics committee review, provided that they are conducted by those with professional obligations to maintain privacy, and no new information will be gathered.

The *Health Research and Privacy-Guidance Notes for Health Researchers and Ethics Committees* reiterate that ethics committee review is not normally required for monitoring or internal audit undertaken by the health service. Health information can be used legally for monitoring as it is considered to be related to the purpose for which the information was gathered. This means that health information could also be used for external audit.

Possible criteria for establishing when activities need research ethics committee review

In a recently published document, the Australian Health Ethics Committee (AHEC) notes that “no authority or agency has been able to create definitions that clearly separate ‘quality assurance’ from ‘clinical research’” (NHMRC, 2003, p.1). The document focuses on the characteristic features that need to be considered when deciding whether quality assurance activities require independent ethical review.

The AHEC advised that activities can proceed without ethics committee review if there is consent from all participants, or if the secondary use of data is related to the primary purpose of collection (and, for sensitive data, *directly* related to the primary purpose of collection), and the individual concerned would reasonably expect this use of the data. The activity must not be likely to cause “burden or harm (physical, mental, psychological, spiritual, or social)” (NHMRC, 2003, p.5).
The document suggests questions as a guide to whether an activity requires ethics committee review, or whether it should at least be discussed with an ethics committee (NHMRC, 2003).

These questions, in a modified form, are set out below.

**Consent**
- Is there no consent from participants, or, is the secondary data use not related to the primary purpose of collection?

**Risks and burdens**
- Are there any risks or burdens beyond those expected for routine care? These may include psychological as well as physical harm, intrusiveness, and inconvenience such as persistent phone calls.

**Privacy and confidentiality**
- Will the medical records be viewed by a person who would not normally have access to them? This may be acceptable if someone who carries out the audit is bound by legislation or a professional code of conduct.
- Is there any added risk of a breach of confidentiality such as fax/email of personal health information?
- Has the data been anonymised? Will it be published in a form that could identify people?

**Overlap with research**
- Will clinical care be changed in any way?
- Is randomisation involved?
- Will information be gathered which is beyond that collected for routine care?

**Broader implications**
- Will the rights, privacy, or professional reputation of health care workers be infringed?

Even if some of these questions are answered in the affirmative, it will not necessarily mean that the audit or related activity requires full ethical review (NHMRC, 2003). Indeed, options for delegated responsibility for review, or expedited review, by ethics committees are suggested for most activities.

The Royal College of Physicians (1996) and CIOMS (1991) advise that ethics committee review should be pursued if there are numerous ethical considerations with an audit or related activity.
2.6 Options for the ethical review of audit and related activities

This section presents three options for the ethical review of audit and related activities. Questions relating to these options are listed at the end of the section, and space is provided in a tear-out section at the back of the document for you to respond.

The three options are:

1. No ethics committee review. Ethical matters are reviewed by those conducting the activity.
2. Ethics committee review is conducted when the activity reaches a threshold of risk. This option is similar to the guidance provided by the current Operational Standard for Ethics Committees.
3. Ethics committees review all audit and related activities.

Option 1: No ethics committee review

The consideration of the ethical issues would be undertaken by those conducting the activity.

Benefits

- No delay in initiation of audit and related activities that may identify problems in health care delivery.
- Encouragement for health professionals to evaluate and improve their practice.
- No risk to the public health from delay in investigation of communicable disease outbreaks or other threats to the public health.
- Assurance for those involved in screening programmes that the programme is being monitored for effectiveness as part of the programme itself.

Risks

- Some audit and related activities may have as much risk for those involved as some research activities. If ethical issues are considered only by those involved in the activity, harm might result for the participants.
- Ethical considerations may not always be well understood by those conducting these activities.
- Concern from the public about release of confidential health information to third parties, eg, for disease surveillance.

Recommendations if this option were to be implemented

- Education of those undertaking audit and related activities about the ethical issues involved and the evaluation of such issues.
- Public dialogue about the reasons for audit and other activities, the safeguards for individuals, and the benefits achieved by using these data.
Option 2: Ethics committee review is conducted when activity reaches a threshold of risk

Criteria are used to determine whether an activity requires ethics committee review.

Two questions need to be asked to determine the necessity of ethical review in these cases: (i) Is there a serious risk of harm if the activity is delayed? (ii) What are the risks to participants in the activity? If delays in the conduct of the activity will generate serious risk to public health or health service quality, and if ethics committee review is likely to cause such delays, then there should be no ethics committee review.

Benefits
- Safeguards participants when there is a risk of harm.
- Public confidence in the conduct of audit and related activities may be increased.

Risks
- Could delay timely investigation of threats to public health.
- Could dissuade health professionals or health services from examining practice.

Recommendations if this option were to be implemented
- Expedited review of audit and related activity that reaches a threshold but which still may not require full research ethics committee consideration.
- Development of an operational pathway for making the judgements as to threshold.
- The investigators should inform ethics committees when the decision is made not to seek ethics committee review.

Option 3: Ethics committees review all audit and related activity

Benefits
- Increased safeguards for the public against any possible harm from these activities.

Risks
- Decreased safeguards for the public if audits of health services are delayed or not undertaken.
- Inappropriate use of ethical standards that may apply to research but not to audit and related activity, as these activities usually have decreased risk and more predictable benefit when compared to research.
- Risks delaying public health practice with significant dangers to the health of the public.
- Potential to overload ethics committees and prevent their time being spent on research, which might raise substantial risks of harm.
Recommendations if this option were to be implemented

- Expedited review of audit and related activities, recognising that the risk of harm may be less than for research and the benefits may be greater.

Questions (please respond in the space provided at the end of the document)

(a) Looking at the benefits and risks of the options presented, please comment on the ethical review of audit and related activities.

(b) Should investigators be required to keep ethics committees informed of audit and related activities not considered to require ethical review? (Ref. Recommendations, Option 2).

(c) Is expedited ethical review, using delegated authority, an appropriate form of review for audit and related activities? (Ref. Recommendations, Option 3).
3. Privacy and the Secondary Use of Health Records for Research

3.1 Introduction

An important and controversial area in observational studies is the secondary use of data, where data, initially collected for a purpose such as health care, is then used for research (Lowrance, 2002).2

Until the 1980s, guidelines in New Zealand allowed secondary use of data as an extension of medical practice, without explicit consent in certain situations, subject to safeguards against breaches of confidentiality (MRCNZ, 1986).

The culture around the privacy of health records became more restrictive in the 1990s. In part this was due to the Health Information Privacy Code, although the Code allows the use and disclosure of health information in certain circumstances without the authorisation of the individual concerned. This change in culture has led to ethics committees becoming increasingly cautious about the secondary use of data for research without explicit consent. The current Operational Standard has no discussion on when such use might be justified.

In other countries concerns have been raised that research in the public interest – such as disease surveillance, evaluation of health care services and drug safety analyses – is impeded by an unbalanced emphasis on privacy (Lowrance, 2002).

Both in New Zealand and internationally there is a concern to resolve this controversy by finding a new and publicly acceptable balance between societal and individual interests.3

In finding a balance between societal and individual interests there are a number of features that are required of any public policy or regulatory framework, and some features where a choice between different approaches needs to be made.

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2 This form of research has made some important contributions to health. The following are three New Zealand examples: (1) The paper that led to the Cartwright inquiry (McIndoe, McLean, et al, 1984) would not have proceeded without the examination of hospital data that had been gathered for another purpose. (2) A study of health records determined there was a link between fenoterol, a drug used for asthma, and deaths in young New Zealanders (Crane, Pearce, et al, 1989). (3) The secondary use of health records was also used in a New Zealand study that linked fatal pulmonary embolism and oral contraceptive use (Parkin, Skegg, et al, 2000).

3 This section uses the Nuffield Trust document: Learning from experience. Privacy and the secondary use of data in health research. The document can be obtained from the URL: http://www.nuffieldtrust.org.uk/bookstore.
Required features (Lowrance, 2002):

- careful handling of identifiability (including anonymisation where possible, otherwise methods of coding, including ‘key-coding’)
- training of personnel
- controlling access and disclosure
- maintaining security
- arranging independent ethical oversight.

3.2 Approaches to the development of policy on the secondary use of data

There are a number of possible approaches to policy regarding the secondary use of data, as set out below (Lowrance, 2002):

1. Statutory sanctioning of research use without explicit consent (e.g., the New Zealand Cancer Registry Act).
2. Regulatory endorsement of research use for the common good without consent if necessary (as is provided for by the New Zealand Health Information Privacy Code, with ethics committee approval).
3. Presumption of implied consent to research use (as, some argue, has long held for the National Health Service data used for health services research in the United Kingdom – and may be similarly argued for data held by public health care providers in New Zealand).
4. Participant authorisation for broad research use (as in the New Zealand longitudinal health and development study cohorts).
5. Participant permission for research use for defined purposes, into the future (as is granted with most clinical trial data and voluntary registries).
6. Participant informed consent to each specific current research use.
### 3.3 Options for consideration

Drawing on the material above, five options are now proposed for policy on the secondary use of data. Questions relating to these options are listed at the end of this section, and space is provided in the tear-out section at the end of this document for you to respond.

**Option 1:** Move to statutory sanctioning of all research use of secondary data without explicit consent.

**Option 2:** Build on the regulatory endorsement of research use for the common good, without consent if necessary, by developing detailed guidance for ethics committees on when identifiable data can be used without consent. (See statement from NEAC’s ‘Draft Ethical Guidelines for Observational Studies’, Section 5.3 *Collection of Health Information from Records*.)

**Option 3:** Consult with the public about whether the presumption of implied consent for research use of data held by health care providers in New Zealand is justified. This must include a dialogue with the public about the need for data in the provision of health care and the protection of the health of the public.

**Option 4:** Seek broad authorisation from all users of health services for the secondary use of data for research. This would require an opt-out option.

**Option 5:** Move to requiring informed consent for all research uses of identifiable data.

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**Question** (please respond in the space provided at the end of the document)

Please provide your views on the secondary use of data for research. Which of the options presented would best protect participants from harm, while enabling high quality research to benefit the community? More than one option may be appropriate.


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Draft Ethical Guidelines for Observational Studies

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Note: In their current form, the guidelines draw on excerpts from published guidelines, and one purpose of this discussion document is to obtain views on the principles and issues that should be addressed in New Zealand guidelines. Responses to the draft guidelines will assist NEAC to construct a final set of guidelines.
1. Introduction

1.1 Definition of observational studies

The term ‘observational studies’ referred to in the Gisborne Inquiry has been clarified by NEAC as referring to epidemiological observational studies, as distinct from observation in social research, which may include observation of participants during an intervention.

In epidemiological research, observational studies are distinguished from interventional or experimental studies, as no intervention other than recording, classifying, counting, and analysing of data takes place.

This document uses the term ‘observational studies’ to refer to observational epidemiological methods and audit.

Audit and other related activities may use the same epidemiological methods as observational research, but they may not be required to have independent ethical approval. However, many of the same ethical considerations are relevant in such activities.

2. Underlying values and ethics

2.1 Treaty of Waitangi

- “The Treaty of Waitangi is the founding document of New Zealand. The principles of partnership and sharing implicit in the Treaty should be respected by all researchers and, where applicable, should be incorporated into all health research proposals” (HRC, 2002a).

Notes

“All issues relating to Māori cultural and ethical values should be resolved in discussion with the whānau, hapū or iwi concerned. The ownership rights of participants to personal data must be respected.” (HRC, 2002a).

2.2 Respect for persons

- “Respect for persons incorporates at least two other fundamental ethical principles, namely:
  a) autonomy, which requires that those who are capable of deliberation about their personal goals should be treated with respect for their capacity for self-determination; and
  b) protection of persons with impaired or diminished autonomy, which requires that those who are dependent or vulnerable be afforded security against harm or abuse.” (CIOMS, 1991).
Notes
“Individuals should be treated as autonomous agents and ... persons with diminished autonomy are entitled to protection. If respect for persons is equivalent to treating others as autonomous agents then we cannot show respect for those whose autonomy we recognise to be diminished. But we clearly can show such respect. That respect is for the inherent dignity and the rights of persons and is, at the same time, a commitment not to use a person only as a means to an end.” (NHMRC, 1999).

“Each research protocol must be designed to ensure that respect for the dignity and well being of the participants takes precedence over the expected benefits to knowledge”. (NHMRC, 1999).

2.3 Justice

• “The ethical value of justice requires that, within a population, there is a fair distribution of the benefits and burdens of participation in research and, for any research participant, a balance of burdens and benefits ....” (NHMRC, 1999).

Notes
“... Accordingly, a researcher must:
(a) Avoid imposing on particular groups, who are likely to be subject to over researching, an unfair burden of participation in research;
(b) Design research so that the selection, recruitment, exclusion and inclusion of research participants is fair; and
(c) Not discriminate in the selection and recruitment of actual and future participants by including or excluding them on the grounds of race, age, sex, disability or religious or spiritual beliefs except where the exclusion or inclusion of particular groups is essential to the purpose of the research.” (NHMRC, 1999).

“Weaker members of communities should not bear disproportionate burdens of studies from which all members of the community are intended to benefit, and more dependent communities and countries should not bear disproportionate burdens of studies from which all communities or countries are intended to benefit.” (CIOMS, 1991).

“Article 5.3 expresses the need for research that involves those who, though not competent to consent for themselves, are unique individuals who command all the respect, justice and inclusiveness that are accorded to competent individuals. The behaviour, psychology, biology and diseases of infants and children who are incompetent because of immaturity often differ markedly from those of adults; also, incompetence is often caused by disease, which cannot be studied only in those without the disease. However, the ethical imperative for research as expressed in Article 5.3 must be interpreted in the context of the safeguards expressed in Articles 2.6 to 2.8.” (Tri-council, 1998).
2.4 Beneficence and non-maleficence

- "... norms requiring that the risks of research be reasonable in the light of the expected benefits." (CIOMS, 1991).

Notes

“The REB [review ethics board] should adopt a proportionate approach based on the general principle that the more invasive the research, the greater should be the care in assessing the research.” (Tri-council, 1998).

“The purpose of ethical review is to consider the features of a proposed study in the light of ethical principles, so as to ensure that investigators have anticipated and satisfactorily resolved possible ethical objections, and to assess their responses to ethical issues raised by the study. Not all ethical principles weigh equally. A study may be assessed as ethical even if a usual ethical expectation, such as confidentiality of data, has not been comprehensively met, provided the potential benefits clearly outweigh the risks and the investigators give assurances of minimizing risks. It may even be unethical to reject such a study, if its rejection would deny a community the benefits it offers. The challenge of ethical review is to make assessments that take into account potential risks and benefits, and to reach decisions on which members of ethical review committees may reasonably differ.” (CIOMS, 1991).

Benefits

Notes

“Research methods that involve greater community participation and collaboration are more likely to provide long-term benefits to research participants and to the community. As part of some population-based studies, it may be feasible to impart some health care advantage to the community following completion of the study, such as epidemiologic research that leads to the establishment of a local disease registry or the training of members of a community in basic methods of population research, or a health care services program. Such indirect benefits of epidemiologic studies may be particularly important to consider in planning and carrying out studies in socioeconomically disadvantaged populations.” (American College of Epidemiology, 2000).

Risks

Notes

“The standard of minimal risk is commonly defined as follows: if potential subjects can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research then the research can be regarded as within the range of minimal risk. Above the threshold of minimal risk, the research warrants a higher degree of scrutiny and greater provision for the protection of the interests of prospective subjects.” (Tri-council, 1998).
2.5 Honest and thoughtful inquiry

- “The researcher’s commitment to the advancement of knowledge also implies duties of honest and thoughtful inquiry, rigorous analysis, and accountability for the use of professional standards.” (Tri-council, 1998).

2.6 Cultural diversity

- “Epidemiologists should respect cultural diversity in carrying out research and practice activities and in communicating with community members.” (American College of Epidemiology, 2000).

2.7 Conflict of interest

- “It is an ethical rule that investigators should have no undisclosed conflict of interest with their study collaborators, sponsors or subjects ....”

Notes

“... Investigators should disclose to the ethical review committee any potential conflict of interest. Conflict can arise when a commercial or other sponsor may wish to use study results to promote a product or service, or when it may not be politically convenient to disclose findings.” (CIOMS, 1991).

2.8 Lawful conduct

- “Researchers need to conform to relevant legal requirements ....” (NHMRC, 1999).

3. Design of the study and protocol

3.1 The research question

- “Epidemiologists should meet their obligations to communities by undertaking public health research and practice activities that address health problems including questions concerning the utilization of health care resources, and by reporting results in an appropriate fashion.” (American College of Epidemiology, 2000).

Notes

“Where research may have an impact on a specific community or population group, committees should require researchers to demonstrate what steps they have taken to
consult with those groups likely to be affected, and the feedback the researchers have received.” (Ministry of Health, 2002).

“Maintaining public trust is especially important in planning and carrying out community studies. In identifying public health problems to be studied, and their priority for study, epidemiologists should take into account the perceived importance of the problem to the people living in a community after information about the problem has been provided. However, if epidemiologists perceive that a health problem exists but is being ignored or its existence denied by the community, it may well be appropriate to proceed with a study of a health problem (or an outbreak investigation that must be initiated without delay to address an urgent public health concern) while simultaneously working with the community to gain their confidence and support.” (American College of Epidemiology, 2000).

3.2 The research design

- “Research subjects must not be subjected to unnecessary risks of harm, and their participation in research must be essential to achieving scientifically and societally important aims that cannot be realized without the participation of human subjects ....” (Tri-council, 1998).

Notes

“... In addition, it should be kept in mind that the principle of minimizing harm requires that the research involve the smallest number of human subjects and the smallest number of tests on these subjects that will ensure scientifically valid data.” (Tri-council, 1998).

“To the extent possible and whenever appropriate, epidemiologists should also involve community representatives in the planning and conduct of the research such as through community advisory boards.” (American College of Epidemiology, 2000).

Scientifically sound

- “Ethical considerations are as germane to good research as are scientific considerations. Ethical inadequacies in a research proposal are as significant as scientific inadequacies. But scientific inadequacies also have ethical implications. Projects without scientific merit are wasteful of resources and needlessly subject participants to risks ....” (NHMRC, 1999).

Notes

“... Accordingly, an essential condition of the ethical acceptability of research is the determination that the scientific quality of a proposal and the skill and experience of the researchers are such that the objectives of the proposal can reasonably be expected to be achieved.” (NHMRC, 1999).

“... the design of a research project that poses more than minimal risk ... [should be] capable of addressing the questions being asked in the research.” (Tri-council, 1998).
“Every research proposal must demonstrate that the research is justifiable in terms of its potential contribution to knowledge and is based on a thorough study of current literature as well as prior observation, approved previous studies, and where relevant, laboratory and animal studies.” (NHMRC, 1999).

“Kaupapa Māori and Māori-focused methodologies. Like most innovative approaches, these methodologies require validation and must demonstrate adherence to a set of standards set by professional peers. Researchers must demonstrate to ethics committees that they have consulted with appropriately skilled experts to determine the validity of approaches. Where methodological development is a component of the research, such development must be accompanied by mechanisms for respondent protection.” (Ministry of Health, 2002).

Skills and resources
• “... researchers [should] have the necessary skills in epidemiology and facilities for the research ....” (NHMRC, 1999).

Notes
“Research must be conducted or supervised only by persons or teams with experience, qualifications and competence appropriate to the research. Research must only be conducted using facilities appropriate for the research and where there are appropriate skills and resources for dealing with any contingencies that may affect participants.” (NHMRC, 1999).

3.3 Protocol
• “All epidemiological research ... should be conducted according to written protocols that state the aims of the study, the data needed and the way in which the data will be collected, used and protected.” (NHMRC, 1999).

Notes
“... adhering to the highest scientific standards (for example, by choosing an appropriate study design; writing a clear and complete protocol).” (American College of Epidemiology, 2000).

“Whatever the pattern of the procedure of ethical review, the investigator must submit a detailed protocol comprising: a clear statement of the objectives, having regard to the present state of knowledge, and a justification for undertaking the investigation in human subjects; – a precise description of all proposed procedures and interventions, ... [and] a statistical plan indicating the number of subjects to be involved ....” (CIOMS, 1991).
4. Independent ethical review

- “... the requirement that proposals for epidemiological studies be submitted to independent ethical review applies irrespective of the source of the proposals – academic, governmental, health-care, commercial, or other.” (CIOMS, 1991).

Notes

“Sponsors and investigators are expected to submit their proposals to ethical review, and this should not be overlooked even when sponsors have legal power to permit investigators access to data ....” (CIOMS, 1991).

4.1 Exceptions

- “... An exception is justified when epidemiologists must investigate outbreaks of acute communicable diseases. Then they must proceed without delay to identify and control health risks ....” (CIOMS, 1991).

Notes

“... [in the case of outbreaks of communicable disease] they cannot be expected to await the formal approval of an ethical review committee. Nevertheless, in such circumstances the investigator will, as far as possible, respect the rights of individuals, namely freedom, privacy, and confidentiality.” (CIOMS, 1991).

5. Collection of health information

5.1 Collection of health information directly from individuals

Approach

- “The use of medical records (including disease registries) to identify and approach individuals is another research purpose for which ethics committee approval is required.” (HRC, 2002b).

Notes

“The research protocol and the method of approach should be reviewed by the ethics committee. It should determine whether the approach may be made directly, or by the participant’s medical adviser. If the approach is to be made directly, the consent for the individual to be invited to take part should be sought from the participant’s medical adviser. In this circumstance, the individual should be informed of the name of the person who had given consent for them to be approached.” (Health Research Council of New Zealand, 2002b).
Free and informed consent

- “Epidemiologists should obtain the prior informed consent of research participants (with exceptions ...), in part by disclosing those facts and any information that patients or other individuals usually consider important in deciding whether or not to participate in the research.” (American College of Epidemiology, 2000).

Notes

“Where information is being collected by the researchers directly from any individual, the purpose of the research should be explained to the individual. This information should be as specific as possible without compromising the validity of the research.

There are many situations where providing very specific information about the study in advance of seeking consent would prejudice the purposes of the collection by compromising the scientific validity of the research. For example, if a mother is to be interviewed to establish whether she has been exposed to a particular medicine which might have caused a congenital abnormality in her baby, it would be wrong, when asking her to consent to the study, to give the name of the drug in question. If the name of the drug were disclosed this would have at least one scientifically unacceptable consequence.

If the mother in question had a baby with a birth defect, she would have both a reason and a longer period of time, in advance of the actual interview, to remember that she had been exposed to the drug. In contrast, a mother of a healthy baby would have less reason to remember past exposure, and would not reflect on possible past exposure during the period between the consent procedure and the actual interview. This effect could lead to a spurious association between birth defects and drug exposure in the mothers interviewed; thus if such an association were found, it could be scientifically invalid. In studies such as this, biased reporting can be minimised, and scientific validity assured, only by not disclosing in advance the complete details of the hypothesis under test.

Where specific information cannot be provided at the outset, the researcher should offer to provide results to participants, unless there are practical reasons to the contrary.” (HRC, 2002b).

“Where researchers collect information directly from individuals, [or seek their consent to access records] they should inform them that the supply of information is voluntary and (if in a health care context) that refusal to provide all or any part of the requested information will not affect the provision of health care to the individual in any way.” (HRC, 2002b).

“The requirement for free and informed consent should not disqualify research subjects who are not proficient in the language used by the researchers from the opportunity to participate in potential research. Such individuals may give consent providing that one or more of the following are observed to the extent deemed necessary by the REB, in the context of a proportionate approach to the harms envisaged in the research and the consent processes that are to be used:
• An intermediary not involved in the research study, who is competent in the language used by the researchers as well as that chosen by the research subject, is involved in the consent process.

• The intermediary has translated the consent document or approved an existing translation of the information relevant to the prospective subject.

• The intermediary has assisted the research subject in the discussion of the research study.

• The research subject has acknowledged in his or her own language, that he or she understands the research study, the nature and extent of his or her participation, including the risks involved, and freely gives consent (see exception in Article 2.1(c))." (Tri-council, 1998).

**Inducements**

• “Individuals or communities should not be pressured to participate in a study. However, it can be hard to draw the line between exerting pressure or offering inappropriate inducements and creating legitimate motivation ....” (CIOMS, 1991).

**Notes**

“... The benefits of a study, such as increased or new knowledge, are proper inducements. However, when people or communities lack basic health services or money, the prospect of being rewarded by goods, services or cash payments can induce participation. To determine the ethical propriety of such inducements, they must be assessed in the light of the traditions of the culture.” (The Council for International Organizations of Medical Science (CIOMS), 1991).

“Risks involved in participation should be acceptable to subjects even in the absence of inducement. It is acceptable to repay incurred expenses, such as for travel. Similarly, promises of compensation and care for damage, injury or loss of income should not be considered inducements.” (CIOMS, 1991).

“Traditionally, koha is an acknowledgement of the knowledge and/or hospitality extended by tangata whenua to manuhiri. Koha is presented as part of the powhiri onto a marae or other venue of the tangata whenua. Koha may be offered in line with the cultural norms of the researchers and/or participants in research.” (Ministry of Health, 2002).

**Documentation**

**Notes**

“Evidence of free and informed consent by the subject or authorized third party should ordinarily be obtained in writing. Where written consent is culturally unacceptable, or where there are good reasons for not recording consent in writing, the procedures used to seek free and informed consent shall be documented.” (Tri-council, 1998).

“Questionnaires, copies of which should be supplied to the REC [research ethics committee] are often innocuous and may even be offered by mail. The fact that the
subject completes the questionnaire can be taken as consent, provided that the letter of
invitation expressly leaves the subject free of obligation.

Some investigations may involve questionnaires that are intrusive and may cause
distress...For such questionnaires it is appropriate to seek the subject’s consent before
the questionnaire is offered.” (The Royal College of Physicians, 1996).

**Collective consent**

**Notes**

“When it is not possible to request informed consent from every individual to be studied,
the agreement of a representative of a community or group may be sought, but the
representative should be chosen according to the nature, traditions and political
philosophy of the community or group. Approval given by a community representative
should be consistent with general ethical principles. When investigators work with
communities, they will consider communal rights and protection as they would individual
rights and protection. For communities in which collective decision-making is
cust om Danny, communal leaders can express the collective will. However, the refusal of
individuals to participate in a study has to be respected: a leader may express
agreement on behalf of a community, but an individual’s refusal of personal participation
is binding.” (CIOMS, 1991).

“Investigators who initiate research within a whānau, hapū or iwi, where the research
investigators and research participants are members of that same group, may prefer to
provide, via a kaumatua or other person of authority in the group, a statement in the
research proposal that group consent for participation in the research was obtained
from the representatives/participants in hui.

An individual’s right to decline participation in the research, expressed in hui, should
also be noted. The statement of group consent obtained in hui should allow for
research participants to withdraw at any time from the investigation if they so wish.

Where research is initiated from outside the whānau, hapū or iwi or when the
investigators do not have a representative from that group within their number, the usual
procedures for informed consent to participate in the study will be expected. In addition,
a system of accountability of the investigators to the whānau, hapū or iwi concerned
should be instituted after full discussion with and agreement by the participants and
investigators. The group’s right to decline research to proceed within their whānau,
hapū or iwi if the research is unacceptable to them, is paramount.

Not all Māori have contact with whānau, hapū or iwi and the usual requirements for fully
informed consent to participate in a research proposal will be expected in such cases.”
(HRC, 2002a).
Those not competent to give consent

- “Ethical considerations around research involving those who are not competent to give a free and informed consent on their own behalf must seek to balance (1) the vulnerability that arises from their incompetence with (2) the injustice that would arise from their exclusion from the benefits of research.” (Tri-council, 1998).

Notes

“Where a consumer is not competent to make an informed choice and give informed consent, and no person entitled to consent on behalf of the consumer is available, the provider may provide services where –

a) It is in the best interests of the consumer; and
b) Reasonable steps have been taken to ascertain the views of the consumer; and
c) Either, –
   i. If the consumer’s views have been ascertained, and having regard to those views, the provider believes, on reasonable grounds, that the provision of the services is consistent with the informed choice the consumer would make if he or she were competent; or
   ii. If the consumer’s views have not been ascertained, the provider takes into account the views of other suitable persons who are interested in the welfare of the consumer and available to advise the provider.” (Code of Health and Disability Services Consumers’ Rights, Right 7(4)).

“Subject to applicable legal requirements, individuals who are not legally competent shall only be asked to become research subjects when:

- the research question can only be addressed using individuals within the identified group(s); and
- free and informed consent will be sought from their authorized representative(s); and
- the research does not expose them to more than minimal risks without the potential for direct benefits for them.” (Tri-council, 1998).

“For research involving incompetent individuals, the REB shall ensure that, as a minimum, the following conditions are met:

- The researcher shall show how the free and informed consent will be sought from the authorized third party, and how the subjects’ best interests will be protected.
- The authorized third party may not be the researcher or any other member of the research team.
- The continued free and informed consent of an appropriately authorized third party will be required to continue the participation of a legally incompetent subject in research, so long as the subject remains incompetent.
- When a subject who was entered into a research project through third-party authorization becomes competent during the project, his or her informed consent shall be sought as a condition of continuing participation.” (Tri-council, 1998).
“Where free and informed consent has been obtained from an authorized third party, and in those circumstances where the legally incompetent individual understands the nature and consequences of the research, the researcher shall seek to ascertain the wishes of the individual concerning participation. The potential subject’s dissent will preclude his or her participation.” (Tri-council, 1998).

**Interview/questionnaire**

- “Interviewers should be properly trained, suitable and culturally sensitive and, where appropriate, carry identification.” (HRC, 2002b).

**5.2 Collection of health information from another individual**

**Authorisation**

- “Where the researcher proposes to collect information from someone else, then this should be with the authority of the individual concerned, except in special circumstances ...” (HRC, 2002b).

**Notes**

- “... For instance if the researcher proposes to collect personal information from a relative or someone else, without the authority of the individual concerned, because that individual is deceased, untraceable, incapacitated, or for some other good reason, then this approach should be explained in the protocol for the ethics committee, and carried out in accordance with any conditions the committee specifies.” (HRC, 2002b).

**5.3 Collection of health information from records**

- “... access to medical or other records for research should be restricted to properly qualified researchers and research associates responsible to them ....” (NHMRC, 1999).

**Notes**

- “... the disclosure of personal records should only be made to persons who have given a written undertaking to ensure confidentiality. A named investigator of the research group to whom the records are disclosed should accept responsibility to ensure the safety and confidentiality of the records.” (HRC, 2002b).

- “... for records involving Māori health information, where a kaitiaki group has been established to act as guardian of Māori information in the area of research, the kaitiaki group should be consulted.” (HRC, 2002b).

**Consent (see above under 5.1 Collection of Health Information directly from individuals)**

- “Consent of participants should generally be obtained for the use of identified or potentially identifiable data for epidemiological research. A Human Research
Ethics Committee (HREC) may approve access to identified or potentially identifiable data without consent of those the data identifies ....” (NHMRC, 1999).

Notes

“Where the HREC is satisfied that:

(a) either the procedures required to obtain consent are likely either to cause unnecessary anxiety for those whose consent would be sought or to prejudice the scientific value of the research and there will be no disadvantage to the participants or their relatives or to any collectivity involved or it is impossible in practice, due to the quantity, age or accessibility of the records to be studied, to obtain consent;

AND

(b) the public interest in the research outweighs to a substantial degree the public interest in privacy.” (NHMRC, 1999).

“An investigator who proposes not to seek informed consent has the obligation to explain to an ethical review committee how the study would be ethical in its absence.” (CIOMS, 1991).

“Another justification for not seeking informed consent may be that subjects are made aware through public announcements that it is customary to make personal data available for epidemiological studies.” (CIOMS, 1991).

“Reasonable steps should be taken by the custodians of health records to publicise (through notices or pamphlets) the fact that health records may be used, under conditions of strict confidence, for research purposes.” (HRC, 2002b).

“The investigator will provide assurances that strict safeguards will be maintained to protect confidentiality and that the study is aimed at protecting or advancing health.” (CIOMS, 1991).

6. Use of information

• “Where identified or potentially identifiable data are used in the research, an HREC must be satisfied that the information: ... (b) will not be used so as to cause material, emotional or other disadvantage to any participant; and (c) will not be used for any purposes other than those specified in the approved protocol.” (NHMRC, 1999).

Notes

“If identified or potentially identifiable data are to be used for any research purposes or by any persons other than those specified in the approved protocol, a new protocol must be presented to an HREC for approval.” (NHMRC, 1999).
7. Confidentiality of data

- "Where personal information about research participants or a collectivity is collected, stored, accessed, used, or disposed of, a researcher must strive to ensure that the privacy, confidentiality and cultural sensitivities of the participants and/or the collectivity are respected. Any specific agreements made with the participants or the collectivity are to be fulfilled." (NHMRC, 1999).

Notes

“Privacy is concerned with the right of individuals to be left alone and not be forced to provide information about themselves except when, how, and to those to whom they choose to reveal this information. Confidentiality is concerned with preventing disclosure of information in ways that are inconsistent with the understanding under which the information was obtained.” (American College of Epidemiology, 2000).

“Epidemiological research includes the use of the following types of data:

- **Identified**: Data that allow the identification of a specific individual …Examples of identifiers may include the individual’s name, date of birth or address. In particularly small sets of data even information such as a postcode may be an identifier.

- **Potentially identifiable (coded, re-identifiable)**: Data may have identifiers removed and replaced by a code. In such cases it is possible to use the code to re-identify the person to whom the data relate so that the process of de-identification is reversible. In these cases the data are referred to as ‘potentially identifiable’.

- **De-identified, (not re-identifiable, anonymous)**: The process of de-identification can be irreversible if the identifiers have been removed permanently or if the data have never been identified. These data are referred to as ‘de-identified’. It should be recognised that the term ‘de-identified’ is used frequently, in documents other than this Statement, to refer to sets of data from which only names have been removed. Such data may remain ‘potentially identifiable’.” (NHMRC, 1999).

“Research may involve collecting and storing data relating to individuals and groups, and such data, if disclosed to third parties, may cause harm or distress. Consequently, investigators should make arrangements for protecting the confidentiality of such data by, for example, omitting information that might lead to the identification of individual subjects, or limiting access to the data, or by other means. It is customary in epidemiology to aggregate numbers so that individual identities are obscured. Where group confidentiality cannot be maintained or is violated, the investigators should take steps to maintain or restore a group’s good name and status.” (CIOMS, 1991).

“The implications of approved data linkage in which research subjects may be identifiable shall be approved by the REB.” (Tri-council, 1998).

“In research based on linkages between records, an HREC may permit personal information to be used to enable the record linkage without consent if it is satisfied that:
(a) the identity of participants is not disclosed except for the purposes of record linkage and is not retained once record linkage has been completed;
(b) identifying information is used with sufficient security; and
(c) the research has public benefit.” (NHMRC, 1999).

"Identifiable personal data will not be used when a study can be done without personal identification .... When personal identifiers remain on records used for a study, investigators should explain to review committees why this is necessary and how confidentiality will be protected." (CIOMS, 1991).

8. Professional relationships

- “Care should be taken not to interfere with health professional/patient relationships.” (HRC, 2002b).
- “Where it is proposed to involve persons in dependent or unequal relationships in research, the possibility that their relationship may impair their consent requires additional attention from the HREC in order for the HREC to be satisfied that their consent is both adequately informed and voluntary.” (NHMRC, 1999).

Notes

“It is not possible to define exhaustively all types of dependent relationships, but they include situations where unequal power relationships exist between participants and researchers or where participants occupy junior or subordinate positions in hierarchically structured groups. Examples include:
- persons with chronic conditions or disabilities and their carers;
- patients and health care professionals;
- students and teachers;
- prisoners and prison authorities; and
- employees (including members of the police force, defence forces and hospital and laboratory staff) and their employers or supervisors.” (NHMRC, 1999).

"Where research involves persons in dependent or unequal relationships the researcher must give an assurance that refusal to participate in, or a decision to withdraw from, the research will not result in any discrimination, reduction in the level of care or any other penalty.” (NHMRC, 1999).

9. When to reveal information obtained by research

- “If it is reasonably foreseeable that health problems previously unknown to the individual will be identified, then arrangements for referral, with the individual’s consent, should be made.” (HRC, 2002b).
- “Individuals’ privacy and confidentiality of information need to be ensured unless there is an overriding moral concern (e.g. health or safety) justifying the release of such information or if such release is required by law. If privacy or confidentiality
must be breached, the epidemiologist should first attempt to inform participants of such required infringements.” (American College of Epidemiology, 2000).

10. Communication of study results

- “All research findings and other information important to public health should be communicated in a timely, understandable, and responsible manner so that the widest possible community stands to benefit.” (American College of Epidemiology, 2000).

- “Results of research must not be published in a form that permits identification of individual participants and must be published in a form which gives due regard to cultural or other sensitivities.” (NHMRC, 1999).

Notes

“Part of the benefit that communities, groups and individuals may reasonably expect from participating in studies is that they will be told of findings that pertain to their health. Where findings could be applied in public health measures to improve community health, they should be communicated to the health authorities. In informing individuals of the findings and their pertinence to health, their level of literacy and comprehension must be considered. Research protocols should include provision for communicating such information to communities and individuals. Research findings and advice to communities should be publicized by whatever suitable means are available.” (CIOMS, 1991).

“The potential benefits of epidemiologic research include providing scientific data that policy makers can use to formulate sound public health policy. The responsibilities of epidemiologists to facilitate the development of health policy include publishing objective research findings in a form that can be utilized by policy makers. The publication of both positive and negative research findings is important, since it helps to prevent publication bias and allows for additional benefits to be gleaned through meta-analyses. Epidemiologists should submit their methods and findings to peer review (for example, review for publication). Peer review plays an important role in improving research protocols and scientific reports.” (American College of Epidemiology, 2000).

“Investigators may be unable to compel release of data held by governmental or commercial agencies, but as health professionals they have an ethical obligation to advocate the release of information that is in the public interest. Sponsors of studies may press investigators to present their findings in ways that advance special interests, such as to show that a product or procedure is or is not harmful to health. Sponsors must not present interpretations or inferences, or theories and hypotheses, as if they were proven truths.” (CIOMS, 1991).

“Although epidemiologists cannot always prevent the media or other parties from sensationalizing research results, epidemiologists should strive to ensure that, at a minimum, research findings are interpreted and reported on accurately and appropriately.” (American College of Epidemiology, 2000).
“Conflict may appear between, on the one hand, doing no harm and, on the other, telling the truth and openly disclosing scientific findings. Harm may be mitigated by interpreting data in a way that protects the interests of those at risk, and is at the same time consistent with scientific integrity. Investigators should, where possible, anticipate and avoid misinterpretation that might cause harm.” (CIOMS, 1991).

“The optimal time to disseminate the findings of epidemiologic studies is not always easy to discern. Both premature and unnecessarily delayed release of research findings can be more beneficial than harmful to individuals and to society. Study findings should be interpreted and made available to the public in accordance with the current scientific thinking about the utility and validity of the information. Nevertheless, it may be difficult to strike the right balance between the need to cautiously communicate findings to other scientists with appropriate peer review and validation of findings, and the need to expeditiously communicate results to other interested parties without undue delay. The appropriate peer review, replication and validation of study findings, and other safeguards to assure scientific validity are important, but they require time.” (American College of Epidemiology, 2000).

References


