National Statement on Ethical Conduct in Human Research

Developed jointly by
National Health and Medical Research Council
Australian Research Council
Australian Vice-Chancellors' Committee

Australian Government
National Health and Medical Research Council
Australian Research Council

AVCC
Australian Vice-Chancellors' Committee
the council of Australia's university presidents

Endorsed March 2007

Reprinted October 2007

ISBN Print: 1864962690

Online: 1864962755

To obtain details regarding NHMRC publications contact:
Email: nhmrc.publications@nhmrc.gov.au
Phone: Toll Free 13 000 NHMRC (13 000 64672) or call 02 6217 9000
Internet: http://www.nhmrc.gov.au

CONTENTS

THE NATIONAL STATEMENT: A USER GUIDE

This *National Statement on Ethical Conduct in Human Research* ('National Statement') is intended for use by:

- any researcher conducting research with human participants;
- any member of an ethical review body reviewing that research;
- those involved in research governance; and
- potential research participants.

This brief guide describes the structure of the document and suggests how each of these groups might use it. Note that 'review body' refers both to Human Research Ethics Committees (HRECs) and to non-HREC review bodies.

The *Preamble* sets out the historical context of the National Statement. This is followed by a brief explanation of its purpose, scope and limits. The document then has five sections, with multiple chapters in Sections 2 to 5.

- *Section 1: Values and principles of ethical conduct* sets out values and principles that apply to all human research. **It is essential that researchers and review bodies consider these values and principles and be satisfied that the research proposal addresses and reflects them.**
- *Section 2: Themes in research ethics: risk and benefit, consent* discusses the concept of risk in research and the role of participants' consent – themes in all human research – and is again **essential for all users**.

  Chapter 2.1 will help **researchers** and **reviewers** to understand and describe the level of risk involved in the planned research, and how to minimise, justify and manage that risk, and (with reference to Chapter 5.1) what level of ethical review is suitable.

  Chapters 2.2 and 2.3 will help to identify the information that needs to be disclosed to participants. It will help **researchers** to draft information for participants and plan the consent process (or develop a proposal for waiver of consent). And it will help **reviewers** to assess the suitability of the proposed consent process.

  All of Section 2 will help **participants** understand what information they are entitled to receive, and what their participation in research will characteristically involve.
- *Section 3: Ethical considerations specific to research methods or fields* will help **researchers** and **reviewers** to identify ethical matters specific to the research methods proposed.
- *Section 4: Ethical considerations specific to participants* will help **researchers** and **reviewers** to identify ethical matters relating to specific categories of research participants. **Participants** in these categories will also find this Section valuable.
- *Section 5: Processes of research governance and ethical review* will help **those involved in research governance** to understand their responsibilities for research ethics and ethical review and monitoring of human research, and provides criteria for their accountability. Chapter 5.2 will help **researchers** and **reviewers** to identify their responsibilities in relation to the ethical review of research.

This National Statement does not exhaust the ethical discussion of human research. Even a single research field covers a multitude of different situations about which the National Statement will not always offer specific guidance, or to which its application may be uncertain. Where other guidelines and codes of practice in particular research fields are consistent with the National Statement, researchers and members of ethical review bodies should draw on them when necessary to clarify researchers' ethical obligations in particular contexts.

PREAMBLE

ETHICAL BACKGROUND

All human interaction, including the interaction involved in human research, has ethical dimensions. However, 'ethical conduct' is more than simply doing the right thing. It involves acting in the right spirit, out of an abiding respect and concern for one's fellow creatures. This National Statement on 'ethical conduct in human research' is therefore oriented to something more fundamental than ethical 'do's' and 'don'ts' – namely, an ethos that should permeate the way those engaged in human research approach all that they do in their research.

Human research is research conducted with or about people, or their data or tissue. It has contributed enormously to human good. Much human research carries little risk and in Australia the vast majority of human research has been carried out in a safe and ethically responsible manner. But human research can involve significant risks and it is possible for things to go wrong. Sometimes risks are realised despite the best of intentions and care in planning and practice. Sometimes they are realised because of technical error or ethical insensitivity, neglect or disregard. On rare occasions the practice of research has even involved the deliberate and appalling violation of human beings – notoriously, the Second World War experiments in detention and concentration camps.

This range of possibilities can give rise to important and sometimes difficult ethical questions about research participation. Two considerations give further weight to those questions. First, research participants may enter into a relationship with researchers whom they may not know but need to trust. This trust adds to the ethical responsibility borne by those in whom it is placed. Secondly, many who contribute as participants in human research do so altruistically, for the common good, without thought of recompense for their time and effort. This underscores the importance of protecting research participants.

Since earliest times, human societies have pondered the nature of ethics and its requirements and have sought illumination on ethical questions in the writings of philosophers, novelists, poets and sages, in the teaching of religions, and in everyday individual thinking. Reflection on the ethical dimensions of medical research, in particular, has a long history, reaching back to classical Greece and beyond. Practitioners of human research in many other fields have also long reflected upon the ethical questions raised by what they do. There has, however, been increased attention to ethical reflection about human research since the Second World War. The judgment of the Nuremberg military tribunal included ten principles about permissible medical experiments, since referred to as the Nuremberg Code. Discussion of these principles led the World Medical Assembly in 1964 to adopt what came to be known as the Helsinki Declaration, revised several times since then. The various international human rights instruments that have also emerged since the Second World War emphasise the importance of protecting human beings in many spheres of community life. During this period, written ethical guidelines have also been generated in many areas of research practice as an expression of professional responsibility.

But what is the justification for ethical research guidelines as extensive as this National Statement, and for its wide-reaching practical authority?

The National Statement has been extended to address many issues not discussed in the previous version, or discussed in less detail. This is in response to requests for clearer

guidance for those conducting research and those involved in its ethical review. At the same time, without compromising the protection of participants, the revised National Statement provides for greater flexibility in the practice of ethical review, depending on the type and area of research and the degree of risk involved.

Research often involves public interaction between people that serves a public good. There is, therefore, a public responsibility for seeing that these interactions are ethically acceptable to the Australian community. That responsibility is acknowledged and given effect in the wide-reaching authority of this National Statement, which sets out national standards for the ethical design, review and conduct of human research. Its content reflects the outcome of wide consultation with Australian communities who participate in, design, conduct, fund, manage and publish human research.

Research governance

The National Statement should be seen in the broader context of overall governance of research. It not only provides guidelines for researchers, Human Research Ethics Committees (HRECs) and others conducting ethical review of research, but also emphasises institutions' responsibilities for the quality, safety and ethical acceptability of research that they sponsor or permit to be carried out under their auspices.

Responsibility for the ethical design, review and conduct of human research is in fact exercised at many levels, by: researchers (and where relevant their supervisors); HRECs and others conducting ethical review of research; institutions that set up the processes of ethical review, and whose employees, resources and facilities are involved in research; funding organizations; agencies that set standards; and governments. While the processes of ethical review are important in this field, individual researchers and the institutions within which they work hold primary responsibility for seeing that their research is ethically acceptable.

In addition to this National Statement, the *Australian code for the responsible conduct of research 2007*[1] (the 'Research Code') has an essential role in promoting good research governance. The Research Code sets down the broad principles of responsible and accountable research practice, and identifies the responsibilities of institutions and researchers in areas such as data and record management, publication of findings, authorship, conflict of interest, supervision of students and research trainees, and the handling of allegations of research misconduct.

Authors of this National Statement

This National Statement has been jointly developed by the National Health and Medical Research Council (NHMRC), the Australian Research Council (ARC) and the Australian Vice-Chancellors' Committee (AVCC). This joint undertaking reflects a widely shared conviction that there is a need for ethical guidelines that are genuinely applicable to all human research; and it gives expression to the shared responsibility for ethically good research described above.

The *National Health and Medical Research Council Act 1992* (NHMRC Act) establishes the NHMRC as a statutory body and sets out its functions, powers and obligations. Section 10(1) of the Act requires the Chief Executive Officer to issue human research guidelines precisely as developed by the Australian Health Ethics Committee (AHEC) and provided to the CEO by the Council. AHEC is established by the NHMRC Act as a Principal Committee of the NHMRC. All the guidelines in this National Statement that are applicable to the conduct of medical research involving humans are issued by the NHMRC in fulfilment of this statutory obligation.

[1] This is the proposed revision of the *Joint NHMRC/AVCC Statement and Guidelines on Research Practice* (1997).

The *Australian Research Council Act 2001* (ARC Act) establishes the ARC to provide the responsible Minister with advice and recommendations about research, including which research programs should receive financial assistance. The functions of the ARC also include administering the regimes of financial assistance for research and providing for the funding of research programs.

The *Australian Vice-Chancellors' Committee* (AVCC) is the council of Australia's university vice-chancellors (or presidents). Its purpose is to advance higher education through voluntary, cooperative and coordinated action, and to serve the best interests of Australia's universities and, through them, the nation. The AVCC acts as a consultative and advisory body for all university affairs, making submissions to public inquiries of interest to the university sector, and preparing statements on major issues.

PURPOSE, SCOPE AND LIMITS OF THIS DOCUMENT

PURPOSE

The purpose of this National Statement is to promote ethically good human research. Fulfilment of this purpose requires that participants be accorded the respect and protection that is due to them. It also involves the fostering of research that is of benefit to the community.

The National Statement is therefore designed to clarify the responsibilities of:

- institutions and researchers for the ethical design, conduct and dissemination of results of human research; and
- review bodies in the ethical review of research.

The National Statement will help them to meet their responsibilities: to identify issues of ethics that arise in the design, review and conduct of human research, to deliberate about those ethical issues, and to justify decisions about them.

Use of this National Statement

This National Statement must be used to inform the design, ethical review and conduct of human research that is funded by, or takes place under the auspices of, any of the bodies that have developed this National Statement (NHMRC, ARC, AVCC).

In addition, the National Statement sets national standards for use by any individual, institution or organisation conducting human research. This includes human research undertaken by governments, industry, private individuals, organisations, or networks of organisations.

What is research?

There is no generally agreed definition of research; however, it is widely understood to include at least investigation undertaken to gain knowledge and understanding or to train researchers. The British Research Assessment Exercise (RAE) definition of research is somewhat wider:

> 'Research'… includes work of direct relevance to the needs of commerce, industry, and to the public and voluntary sectors; scholarship; the invention and generation of ideas, images, performances, artefacts including design, where these lead to new or substantially improved insights; and the use of existing knowledge in experimental development to produce new or substantially improved materials, devices, products and processes, including design and construction. It excludes routine testing and routine analysis of materials, components and processes such as for the maintenance of national standards, as distinct from the development of new analytical techniques. It also excludes the development of teaching materials that do not embody original research.[2]

[2] Higher Education Funding Council for England, Scottish Higher Education Funding Council, Higher Education Funding Council for Wales, & Department for Employment and Learning Northern Ireland (2005) *RAE 2008: Guidance to Panels*, p.28. At http://www.rae.ac.uk/pubs/2005/01/rae0105.doc, accessed 27th October 2006

To enable comparative assessment of academic activity, this definition sought to include the widest range of creative and experimental activities. Many items in the definition are uncontentious, but there may be disagreement about some – for example, 'the invention and generation of new…images, performances, artefacts…where these lead to new or substantially improved insights' – since this could count poetry, painting and performing arts as research.

For the purposes of this National Statement, two further questions are more important than any definition of research:

- What is *human* research?
- When and by what means does human research, or other activities such as quality assurance or improvement, or clinical audit, need ethical review? (See *When does quality assurance in health care require independent ethical review?* NHMRC 2003.)

What is human research?

Human research is conducted with or about people, or their data or tissue. Human participation in research is therefore to be understood broadly, to include the involvement of human beings through:

- taking part in surveys, interviews or focus groups;
- undergoing psychological, physiological or medical testing or treatment;
- being observed by researchers;
- researchers having access to their personal documents or other materials;
- the collection and use of their body organs, tissues or fluids (eg skin, blood, urine, saliva, hair, bones, tumour and other biopsy specimens) or their exhaled breath;
- access to their information (in individually identifiable, re-identifiable or non-identifiable form) as part of an existing published or unpublished source or database.

The term 'participants' is therefore used very broadly in this National Statement to include those who may not even know they are the subjects of research; for example, where the need for their consent for the use of their tissue or data has been waived by a Human Research Ethics Committee (HREC).

In addition, the conduct of human research often has an impact on the lives of others who are not participants. When this impact is reasonably foreseeable, it may raise ethical questions for researchers and for those ethically reviewing research.

When is ethical review needed?

Institutions are responsible for establishing procedures for the ethical review of human research. That review can be undertaken at various levels, according to the degree of risk involved in the research (see *Section 2: Themes in research ethics: risk and benefit, consent,* and *Chapter 5.2: Responsibilities of HRECs, other ethical review bodies, and researchers*). Research with more than a low level of risk (as defined in paragraph 2.1.6, page 18) must be reviewed by an HREC. Research involving no more than low risk may be reviewed under other processes described in paragraphs 5.1.18 to 5.1.21 (page 79). Institutions may also determine that some human research is exempt from ethical review (see paragraphs 5.1.22 and 5.1.23, page 79).

A judgement that a human research proposal meets the requirements of this National Statement and is ethically acceptable must be made before research can begin and before full funding for the proposal is released.

Ethics and law in human research

Human research is governed by Australian law that establishes rights for participants and imposes general and specific responsibilities on researchers and institutions. Australian common law obligations arise from the relationships between institutions, researchers and participants. Contractual arrangements may impose obligations on research funders and institutions.

This National Statement focuses on the ethical aspects of the design, review and conduct of human research. Research ethics is only part of an institution's responsibilities for research governance. Compliance with legal obligations (statutory or otherwise) forms another part, which is not within the scope of the National Statement.

Some human research is subject to specific statutory regulation, at Commonwealth and State and Territory levels. The National Statement identifies some specific Commonwealth legislation that refers to the National Statement. The National Statement does not identify State and Territory laws that may be relevant to human research, such as those relating to use of information held by state or territory authorities, use of human tissues, guardianship, and illegal and unprofessional conduct.

The responsibilities set out in this National Statement are intended to be consistent with the international human rights instruments that Australia has ratified.

It is the responsibility of institutions and researchers to be aware of both general and specific legal requirements, wherever relevant.

SECTION 1: VALUES AND PRINCIPLES OF ETHICAL CONDUCT

INTRODUCTION

The relationship between researchers and research participants is the ground on which human research is conducted. The values set out in this section – respect for human beings, research merit and integrity, justice, and beneficence – help to shape that relationship as one of trust, mutual responsibility and ethical equality. For this reason, the National Statement speaks of research 'participants' rather than 'subjects'.

While these values have a long history, they are not the only values that could inform a document of this kind. Others include altruism, contributing to societal or community goals, and respect for cultural diversity, along with the values that inform *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research* (NHMRC 2003).

However, the values of respect, research merit and integrity, justice, and beneficence have become prominent in the ethics of human research in the past six decades, and they provide a substantial and flexible framework for principles to guide the design, review and conduct of such research. This National Statement is organised around these values, and the principles set out in paragraphs 1.1 to 1.13 give them practical expression.

Among these values, respect is central. It involves recognising that each human being has value in himself or herself, and that this value must inform all interaction between people. Such respect includes recognising the value of human autonomy – the capacity to determine one's own life and make one's own decisions. But respect goes further than this. It also involves providing for the protection of those with diminished or no autonomy, as well as empowering them where possible and protecting and helping people wherever it would be wrong not to do so.

Reference to these values throughout the National Statement serves as a constant reminder that, at all stages, human research requires ethical reflection that is informed by them. The order in which they are considered reflects the order in which ethical considerations commonly arise in human research.

Research merit and integrity are discussed first. Unless proposed research has merit, and the researchers who are to carry out the research have integrity, the involvement of human participants in the research cannot be ethically justifiable.

At a profound level, justice involves a regard for the human sameness that each person shares with every other. Human beings have a deep need to be treated in accordance with such justice, which includes distributive justice and procedural justice. In the research context, distributive justice will be expressed in the fair distribution of the benefits and burdens of research, and procedural justice in 'fair treatment' in the recruitment of participants and the review of research. While benefit to humankind is an important result of research, it also matters that benefits of research are achieved through just means, are distributed fairly, and involve no unjust burdens.

Researchers exercise beneficence in several ways: in assessing and taking account of the risks of harm and the potential benefits of research to participants and to the wider community; in being sensitive to the welfare and interests of people involved in their research; and in reflecting on the social and cultural implications of their work.

Respect for human beings is the common thread through all the discussions of ethical values. Turning to it as the final value is a reminder that it draws together all of the ethical deliberation that has preceded it.

The design, review and conduct of research must reflect each of these values.

GUIDELINES

Research merit and integrity

1.1 Research that has merit is:

(a) justifiable by its potential benefit, which may include its contribution to knowledge and understanding, to improved social welfare and individual wellbeing, and to the skill and expertise of researchers. What constitutes potential benefit and whether it justifies research may sometimes require consultation with the relevant communities;

(b) designed or developed using methods appropriate for achieving the aims of the proposal;

(c) based on a thorough study of the current literature, as well as previous studies. This does not exclude the possibility of novel research for which there is little or no literature available, or research requiring a quick response to an unforeseen situation;

(d) designed to ensure that respect for the participants is not compromised by the aims of the research, by the way it is carried out, or by the results;

(e) conducted or supervised by persons or teams with experience, qualifications and competence that are appropriate for the research; and

(f) conducted using facilities and resources appropriate for the research.

1.2 Where prior peer review has judged that a project has research merit, the question of its research merit is no longer subject to the judgement of those ethically reviewing the research.

1.3 Research that is conducted with integrity is carried out by researchers with a commitment to:

(a) searching for knowledge and understanding;

(b) following recognised principles of research conduct;

(c) conducting research honestly; and

(d) disseminating and communicating results, whether favourable or unfavourable, in ways that permit scrutiny and contribute to public knowledge and understanding.

Justice

1.4 In research that is just:

(a) taking into account the scope and objectives of the proposed research, the selection, exclusion and inclusion of categories of research participants is fair, and is accurately described in the results of the research;

(b) the process of recruiting participants is fair;

(c) there is no unfair burden of participation in research on particular groups;

(d) there is fair distribution of the benefits of participation in research;

(e) there is no exploitation of participants in the conduct of research; and

(f) there is fair access to the benefits of research.

1.5 Research outcomes should be made accessible to research participants in a way that is timely and clear.

Beneficence

1.6 The likely benefit of the research must justify any risks of harm or discomfort to participants. The likely benefit may be to the participants, to the wider community, or to both.

1.7 Researchers are responsible for:

(a) designing the research to minimise the risks of harm or discomfort to participants;

(b) clarifying for participants the potential benefits and risks of the research; and

(c) the welfare of the participants in the research context.

1.8 Where there are no likely benefits to participants, the risk to participants should be lower than would be ethically acceptable where there are such likely benefits.

1.9 Where the risks to participants are no longer justified by the potential benefits of the research, the research must be suspended to allow time to consider whether it should be discontinued or at least modified. This decision may require consultation between researchers, participants, the relevant ethical review body, and the institution. The review body must be notified promptly of such suspension, and of any decisions following it (see paragraphs 5.5.6 to 5.5.9, page 91–92).

Respect

1.10 Respect for human beings is a recognition of their intrinsic value. In human research, this recognition includes abiding by the values of research merit and integrity, justice and beneficence. Respect also requires having due regard for the welfare, beliefs, perceptions, customs and cultural heritage, both individual and collective, of those involved in research.

1.11 Researchers and their institutions should respect the privacy, confidentiality and cultural sensitivities of the participants and, where relevant, of their communities. Any specific agreements made with the participants or the community should be fulfilled.

1.12 Respect for human beings involves giving due scope, throughout the research process, to the capacity of human beings to make their own decisions.

1.13 Where participants are unable to make their own decisions or have diminished capacity to do so, respect for them involves empowering them where possible and providing for their protection as necessary.

Application of these values and principles

Research, like everyday life, often generates ethical dilemmas in which it may be impossible to find agreement on what is right or wrong. In such circumstances, it is important that all those involved in research and its review bring a heightened ethical awareness to their thinking and decision-making. The National Statement is intended to contribute to the development of such awareness.

This National Statement does not exhaust the ethical discussion of human research. There are, for example, many other specialised ethical guidelines and codes of practice for specific areas of research. Where these are consistent with this National Statement, they should be used to supplement it when this is necessary for the ethical review of a research proposal.

These ethical guidelines are not simply a set of rules. Their application should not be mechanical. It always requires, from each individual, deliberation on the values and principles, exercise of judgement, and an appreciation of context.

SECTION 2: THEMES IN RESEARCH ETHICS: RISK AND BENEFIT, CONSENT

Two themes must always be considered in human research: the risks and benefits of research, and participants' consent. For this reason, the two themes are brought together in this section, before discussion in the following sections of ethical considerations specific to different research methods and categories of participants.

CHAPTER 2.1: RISK AND BENEFIT

INTRODUCTION

The conduct of research in Australia is characterised by high ethical and scientific standards, and the dangers to participants have been few. The continued promotion of ethically good human research – the purpose of this National Statement – will help to maintain these standards.

Application of the values in Section 1, in particular the value of beneficence, requires that risks of harm to research participants, and to others, be assessed. Research will be ethically acceptable only if its potential benefits justify those risks.

While this chapter provides guidance on the assessment of risk, such assessment inevitably involves the exercise of judgment.

What is risk?

A risk is a potential for harm, discomfort or inconvenience (discussed below). It involves:

- the likelihood that a harm (or discomfort or inconvenience) will occur; and
- the severity of the harm, including its consequences.

Assessment of risk

Assessment of risks involves:

- identifying any risks;
- gauging their probability and severity;
- assessing the extent to which they can be minimised;
- determining whether they are justified by the potential benefits of the research; and
- determining how they can be managed.

Assessment of risks engages:

- researchers, who need to identify, gauge, minimise and manage any risks involved in their project;
- institutions, in deciding the appropriate level of ethical review for research projects;
- Human Research Ethics Committees (HRECs) and other ethical review bodies (see paragraph 5.1.7, page 78), in reviewing research proposals and making judgements on whether risks are justified by potential benefits; and
- participants' perceptions of risks and benefits. These perceptions are a factor to be considered by review bodies in deciding whether the risks are justified by the benefits.

Harm, discomfort and inconvenience

Research may lead to harms, discomforts and/or inconveniences for participants and/or others.

No list of harms can be exhaustive, but one helpful classification identifies the following kinds of potential harms in research[3]:

- physical harms: including injury, illness, pain;
- psychological harms: including feelings of worthlessness, distress, guilt, anger or fear related, for example, to disclosure of sensitive or embarrassing information, or learning about a genetic possibility of developing an untreatable disease;
- devaluation of personal worth: including being humiliated, manipulated or in other ways treated disrespectfully or unjustly;
- social harms: including damage to social networks or relationships with others; discrimination in access to benefits, services, employment or insurance; social stigmatisation; and findings of previously unknown paternity status;
- economic harms: including the imposition of direct or indirect costs on participants;
- legal harms: including discovery and prosecution of criminal conduct.

Less serious than harm is discomfort, which can involve body and/or mind. Discomforts include, for example, minor side-effects of medication, the discomforts related to measuring blood pressure, and anxiety induced by an interview.

Where a person's reactions exceed discomfort and become distress, they should be viewed as harms.

Less serious again is inconvenience. Examples of inconvenience may include filling in a form, participating in a street survey, or giving up time to participate in research.

[3] Adapted from National Bioethics Advisory Commission, Ethical and Policy Issues in Research Involving Human Participants, Bethesda, 2001 pp.71–72

Examples of risks to non-participants include the risk of distress for a participant's family member identified with a serious genetic disorder, the possible effects of a biography on family or friends, or infectious disease risks to the community. Some social research may carry wider social or economic risks; for example, research in a small community into attitudes to specific subpopulations may lead to unfair discrimination or have effects on social cohesion, property values, or business investment.

Harms that may arise from research misconduct or fraud, and harms to members of research teams from other forms of misconduct (for example, harassment or bullying) are addressed primarily in the *Australian code for the responsible conduct of research*. These forms of misconduct may, of course, also lead to potential harms to participants.

Low risk and negligible risk research

The expression 'low risk research' describes research in which the only foreseeable risk is one of discomfort. Research in which the risk for participants is more serious than discomfort is not low risk.

The expression 'negligible risk research' describes research in which there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience.

Requirements for the ethical review of low risk research and negligible risk research are set out in paragraphs 5.1.18 to 5.1.23, page 79.

Gauging risk

Gauging risk involves taking into account:

- the kinds of harm, discomfort or inconvenience that may occur;
- the likelihood of these occurring; and
- the severity of any harm that may occur.

These judgements should be based on the available evidence. The evidence may be quantitative or qualitative. In either case, the process needs to be transparent and defensible.

For those gauging the severity of the harm, the choices, experience, perceptions, values and vulnerabilities of different populations of participants will be relevant.

Minimising risk

In designing a research project, researchers have an obligation to minimise the risks to participants. Minimising risk involves an assessment of the research aims, their importance, and the methods by which they can be achieved.

Where a researcher or review body judges that the level of risk in a research proposal is not justified by the benefits, either the research aims or the methods by which they are to be achieved, or both, will need to be reconsidered if the research is to proceed.

Do the benefits justify the risks?

Research is ethically acceptable only when its potential benefits justify any risks involved in the research.

Benefits of research may include, for example, gains in knowledge, insight and understanding, improved social welfare and individual wellbeing, and gains in skill or expertise for individual researchers, teams or institutions.

Some research may offer direct benefits to the research participants, their families, or particular group/s with whom they identify. Where this is the case, participants may be ready to assume a higher risk than otherwise. For example, people with cancer may be willing to accept research risks (such as treatment side-effects) that would be unacceptable to well people. Those ethically reviewing research should take such willingness into account in deciding whether the potential benefits of the research justify the risks involved.

For ethical review bodies, there can be a profound tension between the obligation on the one hand to give maximum scope to participants' freedom to accept risk, and on the other to see that research is conducted in a way that is beneficent and minimises harm.

Managing risks

When risks have been identified, gauged and minimised, and the research has been approved, the risks must then be managed. This requires that:

- researchers include, in their research design, mechanisms to deal adequately with any harms that occur; and
- a monitoring process is in place and carried out (see *Chapter 5.5: Monitoring approved research*, page 91–92).

The greater the risk to participants in any research for which ethical approval is given, the more certain it must be both that the risks will be managed as well as possible, and that the participants clearly understand the risks they are assuming.

GUIDELINES

2.1.1 Institutions that choose to establish levels of ethical review other than by HREC for research that carries low or negligible risk (see paragraphs 5.1.18 to 5.1.23, page 79) should use this chapter (i.e. Chapter 2.1) to inform their identification of the level of risk.

2.1.2 Risks to research participants are ethically acceptable only if they are justified by the potential benefits of the research.

2.1.3 Steps to arriving at a judgement on the ethical acceptability of risks should include:

(a) identifying the risks, if any;

(b) assessing the likelihood and severity of the risks;

(c) identifying whom (participants and/or others) the risks may affect;

(d) establishing the means for minimising the risks;

(e) identifying the potential benefits; and

(f) identifying to whom benefits are likely to accrue.

2.1.4 In determining the existence, likelihood and severity of risks, researchers and those reviewing the research should base their assessments on the available evidence, whether qualitative or quantitative. They should consider whether to seek advice from others who have experience with the same methodology, population and research domain.

2.1.5 In considering whether the potential benefits of the research justify the risks involved, those reviewing research should take into account any willingness by participant populations to assume greater risks because of the potential benefits to them, their families, or groups to which they belong.

2.1.6 Research is 'low risk' where the only foreseeable risk is one of discomfort. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk.

2.1.7 Research is 'negligible risk' where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk.

2.1.8 The greater the risks to participants in any research for which ethical approval is given, the more certain it must be both that the risks will be managed as well as possible, and that the participants clearly understand the risks they are assuming.

CHAPTER 2.2: GENERAL REQUIREMENTS FOR CONSENT

INTRODUCTION

Respect for human beings involves giving due scope to people's capacity to make their own decisions. In the research context, this normally requires that participation be the result of a choice made by participants – commonly known as 'the requirement for consent'. This requirement has the following conditions: consent should be a voluntary choice, and should be based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it.

What is needed to satisfy these conditions depends on the nature of the project, and may be affected by the requirements of the codes, laws, ethics and cultural sensitivities of the community in which the research is to be conducted.

Variations of these conditions may be ethically justified for some research. Respect for human beings must, however, always be shown in any alternative arrangements for deciding whether potential participants are to enter the research.

It should be noted that a person's consent to participate in research may not be sufficient to justify his or her participation.

This chapter provides guidelines on the requirement for consent. *Chapter 2.3: Qualifying or waiving conditions for consent* then discusses and provides guidelines on conditions under which the requirement may be qualified or waived.

GUIDELINES

2.2.1 The guiding principle for researchers is that a person's decision to participate in research is to be voluntary, and based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it. For qualifications of this principle, see *Chapter 2.3: Qualifying or waiving conditions for consent,* page 23.

2.2.2 Participation that is voluntary and based on sufficient information requires an adequate understanding of the purpose, methods, demands, risks and potential benefits of the research.

2.2.3 This information must be presented in ways suitable to each participant (see paragraph 5.2.16, page 84).

2.2.4 The process of communicating information to participants and seeking their consent should not be merely a matter of satisfying a formal requirement. The aim is mutual understanding between researchers and participants. This aim requires an opportunity for participants to ask questions and to discuss the information and their decision with others if they wish.

2.2.5 Consent may be expressed orally, in writing or by some other means (for example, return of a survey, or conduct implying consent), depending on:

(a) the nature, complexity and level of risk of the research; and

(b) the participant's personal and cultural circumstances.

2.2.6 Information on the following matters should also be communicated to participants. Except where the information in specific sub-paragraphs below is also deemed necessary for a person's voluntary decision to participate,

it should be kept distinct from the information described in paragraphs 2.2.1 and 2.2.2:

(a) any alternatives to participation;

(b) how the research will be monitored;

(c) provision of services to participants adversely affected by the research;

(d) contact details of a person to receive complaints;

(e) contact details of the researchers;

(f) how privacy and confidentiality will be protected;

(g) the participant's right to withdraw from further participation at any stage, along with any implications of withdrawal, and whether it will be possible to withdraw data;

(h) the amounts and sources of funding for the research;

(i) financial or other relevant declarations of interests of researchers, sponsors or institutions;

(j) any payments to participants;

(k) the likelihood and form of dissemination of the research results, including publication;

(l) any expected benefits to the wider community;

(m) any other relevant information, including research-specific information required under other chapters of this National Statement.

2.2.7 Whether or not participants will be identified, research should be designed so that each participant's voluntary decision to participate will be clearly established.

Renegotiating consent

2.2.8 In some research, consent may need to be renegotiated or confirmed from time to time, especially where projects are complex or long-running, or participants are vulnerable. Research participants should be told if there are changes to the terms to which they originally agreed, and given the opportunity to continue their participation or withdraw (see paragraphs 5.2.16 and 5.2.17, page 84).

Coercion and pressure

2.2.9 No person should be subject to coercion or pressure in deciding whether to participate. Even where there is no overt coercion or pressure, consent might reflect deference to the researcher's perceived position of power, or to someone else's wishes. Here as always, a person should be included as a participant only if his or her consent is voluntary.

Reimbursing participants

2.2.10 It is generally appropriate to reimburse the costs to participants of taking part in research, including costs such as travel, accommodation and parking. Sometimes participants may also be paid for time involved. However, payment that is disproportionate to the time involved, or any other inducement that is likely to encourage participants to take risks, is ethically unacceptable.

2.2.11 Decisions about payment or reimbursement in kind, whether to participants or their community, should take into account the customs and practices of the community in which the research is to be conducted.

Where others need to be involved in participation decisions

2.2.12 Where a potential participant lacks the capacity to consent, a person or appropriate statutory body exercising lawful authority for the potential participant should be provided with relevant information and decide whether he or she will participate. That decision must not be contrary to the person's best interests. Researchers should bear

in mind that the capacity to consent may fluctuate, and even without that capacity people may have some understanding of the research and the benefits and burdens of their participation. For implications of these factors, see *Chapter 4.2: Children and young people*, *Chapter 4.4: People highly dependent on medical care who may be unable to give consent*, and *Chapter 4.5: People with a cognitive impairment, an intellectual disability, or a mental illness*.

2.2.13 Within some communities, decisions about participation in research may involve not only individuals but also properly interested parties such as formally constituted bodies, institutions, families or community elders. Researchers need to engage with all properly interested parties in planning the research.

Consent to future use of data and tissue in research

2.2.14 Consent may be:

(a) 'specific': limited to the specific project under consideration;

(b) 'extended': given for the use of data or tissue in future research projects that are:

(i) an extension of, or closely related to, the original project; or

(ii) in the same general area of research (for example, genealogical, ethnographical, epidemiological, or chronic illness research);

(c) 'unspecified': given for the use of data or tissue in any future research.

The necessarily limited information and understanding about research for which extended or unspecified consent is given can still be sufficient and adequate for the purpose of consent (see paragraph 2.2.2).

2.2.15 Extended or unspecified consent may sometimes need to include permission to enter the original data or tissue into a databank or tissuebank (see paragraph 3.2.9, page 31).

2.2.16 When unspecified consent is sought, its terms and wide-ranging implications should be clearly explained to potential participants. When such consent is given, its terms should be clearly recorded.

2.2.17 Subsequent reliance, in a research proposal, on existing unspecified consent should describe the terms of that unspecified consent.

2.2.18 Data or tissue additional to those covered by the original extended or unspecified consent will sometimes be needed for research. Consent for access to such additional data or tissue must be sought from potential participants unless the need for this consent is waived by an ethical review body.

Declining to consent and withdrawing consent

2.2.19 People who elect not to participate in a research project need not give any reason for their decision. Researchers should do what they can to see that people who decline to participate will suffer no disadvantage as a result of their decision.

2.2.20 Participants are entitled to withdraw from the research at any stage. Before consenting to involvement in the research, participants should be informed about any consequences of such withdrawal.

CHAPTER 2.3: QUALIFYING OR WAIVING CONDITIONS FOR CONSENT

INTRODUCTION

Consent to participate in research must be voluntary, and based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it.

The requirement for consent may sometimes be justifiably waived. In this case research participants will characteristically not know that they, or perhaps their tissue or data, are involved in the research.

'Limited disclosure' to participants of the aims and/or methods of research may also sometimes be justifiable. This is because in some human research (for example, in the study of behaviour), the aims of the research cannot be achieved if those aims and/or the research method are fully disclosed to participants.

Research involving limited disclosure covers a spectrum, from simply not fully disclosing or describing the aims or methods of observational research in public contexts, all the way to actively concealing information and planning deception of participants. Examples along the spectrum include: observation in public spaces of everyday behaviour; covert observation, for example of the hand-washing behaviour of hospital employees; undisclosed role-playing by a researcher to investigate participants' responses; telling participants the aim of the research is one thing when it is in fact quite different. At the beginning of that spectrum (for instance, observation in public spaces), limited disclosure research shades into research for which waiver of consent might be sought.

GUIDELINES

Limited disclosure

2.3.1 Where limited disclosure does not involve active concealment or planned deception, ethical review bodies may approve research provided researchers can demonstrate that:

(a) there are no suitable alternatives involving fuller disclosure by which the aims of the research can be achieved;

(b) the potential benefits of the research are sufficient to justify both the limited disclosure to participants and any risk to the community's trust in research and researchers;

(c) the research involves no more than low risk to participants (see paragraph 2.1.6, page 18), and the limited disclosure is unlikely to affect participants adversely;

(d) the precise extent of the limited disclosure is defined;

(e) whenever possible and appropriate, after their participation has ended, participants will be:

(i) provided with information about the aims of the research and an explanation of why the omission or alteration was necessary; and

(ii) offered the opportunity to withdraw any data or tissue provided by them.

2.3.2 Where limited disclosure involves active concealment or explicit deception, and the research does not aim to expose illegal activity, researchers should in addition demonstrate that:

(a) participants will not be exposed to an increased risk of harm as a result of the concealment or deception;

(b) a full explanation, both of the real aims and/or methods of the research, and also of why the concealment or deception was necessary, will subsequently be made available to participants; and

(c) there is no known or likely reason for thinking that participants would not have consented if they had been fully aware of what the research involved.

2.3.3 Where research involving limited disclosure aims to expose illegal activity (see paragraph 4.6.1, page 67), the adverse effects on those whose illegal activity is exposed must be justified by the value of the exposure.

2.3.4 Only a Human Research Ethics Committee (HREC) can review and approve research that:

(a) involves active concealment or planned deception; or

(b) aims to expose illegal activity.

Waiver

2.3.5 Only an HREC may grant waiver of consent for research using personal information in medical research, or personal health information. Other review bodies may grant waiver of consent for other research.

2.3.6 Before deciding to waive the requirement for consent (other than in the case of research aiming to expose illegal activity), an HREC or other review body must be satisfied that:

(a) involvement in the research carries no more than low risk (see paragraphs 2.1.6 and 2.1.7, page 18) to participants;

(b) the benefits from the research justify any risks of harm associated with not seeking consent;

(c) it is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records);

(d) there is no known or likely reason for thinking that participants would not have consented if they had been asked;

(e) there is sufficient protection of their privacy;

(f) there is an adequate plan to protect the confidentiality of data;

(g) in case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them (for example, *via* a disease-specific website or regional news media);

(h) the possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled;

(i) the waiver is not prohibited by State, federal, or international law.

2.3.7 Before deciding to waive the requirement for consent in the case of research aiming to expose illegal activity, an HREC must be satisfied that:

(a) the value of exposing the illegal activity justifies the adverse effects on the people exposed (see paragraph 4.6.1, page 67);

(b) there is sufficient protection of their privacy;

(c) there is sufficient protection of the confidentiality of data; and

(d) the waiver is not otherwise prohibited by State, federal, or international law.

2.3.8 Given the importance of maintaining public confidence in the research process, it is the responsibility of each institution to make publicly accessible (for example in annual reports) summary descriptions of all its research projects for which consent has been waived under paragraphs 2.3.6 and 2.3.7. Waiver decisions under paragraph 2.3.7 should not be made publicly accessible until the research has been completed.

SECTION 3: ETHICAL CONSIDERATIONS SPECIFIC TO RESEARCH METHODS OR FIELDS

This section discusses various research methods and fields. Some chapters are a result of the further expansion of this revised National Statement beyond health and medical research. The focus is on general principles – the section is not intended to be exhaustive. It reflects the interdisciplinary nature of many types of research and the use, in some research projects, of a number of different research methods.

Human research may be conducted only with ethical approval. Section 5 describes the processes that institutions may use to provide that approval. Those processes include ethical review by Human Research Ethics Committees (HRECs) or other ethical review bodies, according to the risks of the research (see paragraphs 5.1.6 to 5.1.8, page 78).

Ethical review by an HREC is required for any research that involves more than low risk (paragraph 5.1.6, page 78). It is also required for research discussed in *Chapter 3.3: Interventions and therapies, including clinical and non-clinical trials, and innovations*, *Chapter 3.5: Human genetics*, and *Chapter 3.6: Human stem cells*, as well as for research discussed in several chapters of Section 4.

As stated at the end of Section 1, this National Statement does not exhaust the ethical discussion of human research. Even a single research field covers a multitude of different situations about which the National Statement will not always offer specific guidance, or to which its application may be uncertain. Where other guidelines and codes of practice in particular research fields are consistent with the National Statement, researchers and members of ethical review bodies should draw on them when necessary to clarify researchers' ethical obligations in particular contexts.

CHAPTER 3.1: QUALITATIVE METHODS

INTRODUCTION

Qualitative research involves disciplined inquiry that examines people's lives, experiences and behaviours, and the stories and meanings individuals ascribe to them.[4] It can also investigate organisational functioning, relationships between individuals and groups, and social environments.

This approach to research can involve the studied use and collection of a variety of empirical materials such as case studies, personal experience, life stories, interviews, observations, and cultural texts. It may bring new insights into the experiences of individuals, groups or communities, or into issues such as environmental change, public policies and planning. Qualitative research may also have quantitative elements or aspects.

Qualitative research contributes to the development of new knowledge by:

- enabling researchers to gain a better understanding of complex concepts or social processes;
- investigating how communities and individuals interpret and make sense of their experiences;

4. Denzin NK & Lincoln YS (eds) 2000 Handbook of Qualitative Research, Sage: California

- eliciting contextual data in order to improve the validity of quantitative tools such as surveys.

Commonly used approaches to data collection in qualitative research

Data in qualitative research can be collected using a range of approaches. The following are some common examples.

- **Interviews** involve researchers talking to one or more participants, where the categories of response are focused but not necessarily pre-determined. Interviews are usually recorded by audio- or video-tape, or notes. These records are research data in themselves, but also may be transcribed. Interviews are usually conducted in locations mutually acceptable to participants and interviewers.

  Interviews can take many forms, including:

  > *structured interviews,* which follow a set list of questions;

  > *semi-structured interviews*, which use an interview guide listing a set of issues to be explored;

  > *unstructured interviews,* which involve spontaneous generation of questions in the natural flow of interaction, and where the interview is driven by the interviewee rather than the interviewer.

  The reason for choosing an 'informant' for interview may vary. For example:

  > *Key informant interviews* are conducted with individuals or groups with specific knowledge or expertise about the issue being investigated; for example, interviews with political leaders about historical events in which they played important roles.

  > *Sample informant interviews* are conducted with people whose experience or expertise is taken as representative of a broader group; for example, interviews with ordinary people about their experiences during a time of social turmoil or difficulty, or interviews with employees of a particular firm.

- **Life story or oral history** can involve structured, semi-structured or unstructured interviews. This is a form of research commonly undertaken in the humanities.

- **Focus groups** of participants discuss a set of research questions or topics. This may entail the researcher acting as a moderator for the discussion**.**

- **Observation** involves the researcher observing participant/s in their own environment, or in the environment being studied. Data collection through observation can be structured or unstructured, with the observer as a collaborative participant (participant observation) or external to the environment.

- **Archival research** refers to materials that are usually but not necessarily deposited in official or private libraries or archives.

- **On-line research** includes conducting on-line real-time group discussions using web-based chat-room technology (also known as E-groups) through the use of electronic bulletin boards and moderated email groups. On-line recruitment of participants provides the opportunity for extensive global participation in research. Data collection and dissemination can also be utilised on-line.

- **Action research** is often community- or organisation-based and is carried out in the field. This approach involves testing ideas in practice as a means of improving social, economic or environmental conditions and increasing knowledge. Action research proceeds in a spiral of steps consisting of planning, action, and evaluation. It provides a basis for further planning of critically informed action.

Values, principles and themes that must inform the design, ethical review and conduct of all human research are set out in Sections 1 and 2 of this National Statement. The guidelines and headings below show how those values, principles and themes apply specifically in research that is the subject of this chapter.

GUIDELINES

Research merit and integrity

3.1.1 A range of relationships between participants and researchers may develop as a result of the duration and nature of the interaction. Where such relationships threaten to compromise the research role, researchers must consider whether to modify those relationships, or to modify or even discontinue the research.

3.1.2 Where a researcher has professional skills (for example, counselling) that become relevant to the relationship with a participant, the researcher needs to decide, when continuing the research, whether:

(a) it is ethically acceptable to exercise those skills; or

(b) to refer that participant to another professional.

3.1.3 Researchers have a duty to inform participants whenever they are acting in a non-research professional role.

3.1.4 Qualitative research emphasises the significance of particular contexts and settings. It is not necessary to be able to generalise the results of qualitative research. Even so, qualitative research should aim to provide a sufficiently detailed account and/or analysis to enable others to determine whether there are other circumstances to which the findings may be applicable.

3.1.5 If a sampling strategy is used, the most common type is purposive sampling, which aims at the selection of information-rich cases relevant to the research question. While random and representative sampling are not precluded in qualitative studies, many sampling frames are grounded in the specific aims of the research question.

3.1.6 The rigour of a qualitative study should not be judged on sample size. When sampling is appropriate, the objectives and theoretical basis of the research should determine the size of the sample and the sampling strategy. For example, some qualitative methods use a principle of 'saturation', where sampling occurs until no new information is being obtained. This is only one of several criteria for assessing sample size.

3.1.7 Research proposals that include sampling should clearly describe the recruitment strategy and criteria for selecting participants.

3.1.8 The rigour of qualitative research should be assessed primarily by criteria of quality and credibility of data collection and analysis, and not by matters of validity and reliability as defined in research designs that employ quantitative methods.

Justice

3.1.9 The criteria for inclusion and exclusion of participants in qualitative research are often complex. For this reason, researchers should state these criteria clearly and be able to justify them (*see also* paragraphs 3.1.14 to 3.1.16).

Beneficence

3.1.10 Participants are often easily identifiable (for example, as members of small communities or groups, or as key informants), and the information they provide may be sensitive. For these reasons, care should be taken that participants are not identifiable by the information they provide, unless they have agreed to be identified. Special care

should be taken to protect the identity of participants when disseminating information and storing material.

3.1.11 Where possible, participants should be informed about any potential to be identified in the results of research even if identifiers, such as name and address, are removed.

3.1.12 Qualitative research that explores sensitive topics in depth may involve emotional and other risks to both participant and researcher. There should be clear protocols for dealing with distress that might be experienced by participants.

3.1.13 Predicting what topics are likely to lead to distress will not always be easy. Researchers should have sufficient training to help them in making such predictions.

3.1.14 Qualitative research may involve methods of data collection that require the development of personal relationships with participants. Researchers should reflect on the impact that they may have on the participants and vice versa, and as far as possible should describe in the research proposal any anticipated impact of this nature.

Respect

3.1.15 Researchers should consider whether respect for the participants requires that the accuracy or completeness of each interview transcript should be verified by the relevant participant before analysis is complete.

3.1.16 The method of providing consent in qualitative research depends on various factors, including the type of research, its level of sensitivity, its cultural context, and the potential vulnerability of the participants. In some contexts, the protection of vulnerable participants may favour a formal, written process of consent; in other contexts, an oral process.

3.1.17 In some circumstances, consent may be implied by participation, for example the return of a survey, or the answering of a verbal question (*see also* paragraph 2.2.5, page 19).

CHAPTER 3.2: DATABANKS

INTRODUCTION

This chapter covers a wide range of data types and methodologies. Given that the nature of data, data collection, research methodologies and data usage may change over time, the chapter presents principles rather than prescriptions.

Types of research that commonly make use of databanks include epidemiology, pathology, genetics and social sciences.

The term 'databanks', as used in this National Statement, includes databases.

What are data?

Data are pieces of information, for example:

- what people say in interviews, focus groups, questionnaires, personal histories and biographies;
- analysis of existing information (clinical, social, observational or other);
- information derived from human tissue such as blood, bone, muscle and urine.

Data identifiability

Data may be collected, stored or disclosed in three mutually exclusive forms:

- **individually identifiable data**, where the identity of a specific individual can reasonably be ascertained. Examples of identifiers include the individual's name, image, date of birth or address;
- **re-identifiable data**, from which identifiers have been removed and replaced by a code, but it remains possible to re-identify a specific individual by, for example, using the code or linking different data sets;
- **non-identifiable data**, which have never been labelled with individual identifiers or from which identifiers have been permanently removed, and by means of which no specific individual can be identified. A subset of non-identifiable data are those that can be linked with other data so it can be known that they are about the same data subject, although the person's identity remains unknown.

This National Statement avoids the term 'de-identified data', as its meaning is unclear. While it is sometimes used to refer to a record that cannot be linked to an individual ('non-identifiable'), it is also used to refer to a record in which identifying information has been removed but the means still exist to re-identify the individual. When the term 'de-identified data' is used, researchers and those reviewing research need to establish precisely which of these possible meanings is intended.

Tissue and data

With advances in genetic knowledge and data linkage, and the proliferation of tissue banks of identified material, human tissue samples should always be regarded as, in principle, re-identifiable.

The increased ability to link data has greatly enhanced the contribution that collections of data can make to research, as it enables researchers to match individuals in different data sets without being able to identify the person. For example, in epidemiological research (concerned with the study of populations), information about individuals and groups may be collected so that features of groups of people can be investigated. These data may or may not have originally been obtained for research purposes.

Banking

While most data are collected, aggregated and stored for a single purpose or activity. Permission may sometimes be sought from participants to 'bank' their data for possible use in future research projects.

'Banked' data may be deposited in a warehouse, similar to an archive or library, and aggregated over time. The Australian Social Science Data Archive, for example, collects computer-readable data on social, political and economic affairs and makes them available for further analysis. Archived data can usually be made available for secondary analysis, unless access is constrained by restrictions imposed by the depositor/s.

Use of the National Statement's values and principles

The values and principles of this National Statement apply to data collection by researchers, and by others whom they authorise to collect data or to whom they outsource the collection.

These ethical principles for the use of databanks should be applied in the guidelines and procedures established by institutions for the setting up of data collections.

Values, principles and themes that must inform the design, ethical review and conduct of all human research are set out in Sections 1 and 2 of this National Statement. The guidelines and headings below show how those values, principles and themes apply specifically in research that is the subject of this chapter.

GUIDELINES

Research merit and integrity

3.2.1 When planning a databank, researchers should clearly describe how their research data will be collected, stored, used and disclosed, and outline how that process conforms to this National Statement, particularly the requirements for consent set out in paragraphs 2.2.14 to 2.2.18, page 21.

3.2.2 To promote access to the benefits of research, such data should be collected, stored and accessible in such a way that they can be used in future research projects.

Data usage

3.2.3 Researchers' use of data from databanks must comply with conditions specified by the providers of the data; in particular, any conditions on the identifiability of the data (see paragraphs 2.2.14 to 2.2.18, page 21).

3.2.4 Where research involves linkage of data sets, approval may be given to the use of identifiable data to ensure that the linkage is accurate, even if consent has not been given for the use of identifiable data in research. Once linkage has been completed, identifiers should be removed from the data to be used in the research unless consent has been given for its identifiable use.

3.2.5 It is the duty of the custodian to ensure that the data are used responsibly and respectfully, and that the privacy of participants is safeguarded.

3.2.6 Whenever research using re-identifiable data reveals information that bears on the wellbeing of participants, researchers have an obligation to consider how to make that information available to the participants. Where individual notification is warranted, the custodian of the data will need to take all reasonable steps to re-identify those data.

3.2.7 In most situations, the custodian of data will be the individual researcher or agency who collected the information, or an intermediary such as a data warehouse that manages data coming from a number of sources. In some cases, an independent custodian may be necessary. For example, when coded data are stored in a databank, a custodian independent of both the data collectors and the researchers may be appointed, to maintain the data in coded form while enabling individual participants to access their own identified results or data.

3.2.8 Some uses of data in a databank may be detrimental to people to whom the data relate. Researchers and/or custodians should consider denying or restricting access to some or all of the data for those uses.

Consent

3.2.9 When collecting data for deposit in a databank, researchers should provide clear and comprehensive information about:

(a) the form in which the data will be stored (identifiable, re-identifiable, non-identifiable);

(b) the purposes for which the data will be used and/or disclosed; and

(c) whether they will seek:

(i) specific, extended or unspecified consent for future research (see paragraphs 2.2.14 to 2.2.16, page 21); or

(ii) permission from a review body to waive the need for consent (see paragraphs 2.3.5 and 2.3.6, page 24).

3.2.10 Researchers should recognise that data stored in an identifiable form cannot be used in research that is exempt from ethical review.

3.2.11 Any restrictions on the use of participants' data should be recorded and the record kept with the collected data so that it is always accessible to researchers who want to access those data for research.

3.2.12 Researchers and custodians of the databank should observe any confidentiality agreement about stored data with the participant, and custodians should take every precaution to prevent the data becoming available for uses to which participants did not consent.

CHAPTER 3.3: INTERVENTIONS AND THERAPIES, INCLUDING CLINICAL AND NON-CLINICAL TRIALS, AND INNOVATIONS

INTRODUCTION

Clinical research

Clinical research increasingly involves a range of different health professionals studying a wide range of matters, including disease prevention and causation, diagnostic methods, treatments, and effects of and response to illness. Such research can occur in a number of settings, including public and private hospitals and clinics, other institutions or organisations, community settings, and general or specialist medical practices.

This chapter focuses especially on randomised clinical trials, even though clinical trials are not always randomised. Further, as noted below, randomisation may be used in other areas of human research (eg education research) and therefore some of the ethical issues outlined will be relevant to such research.

At times it may be difficult to distinguish clinical and related research from quality improvement and clinical audit. In such situations, guidance is available from the NHMRC publication *When does quality assurance in health care require independent ethical review?* (NHMRC 2003).

Innovations in clinical practice

Innovations in clinical practice and complementary medicine include new diagnostic or therapeutic methods that aims to improve health outcomes but have not yet been fully assessed for safety and/or efficacy. The spectrum of innovations may range widely from minor variations or extensions of existing methods, to new indications, through to completely novel technologies. Where a proposed intervention is innovative and/or experimental, this should always be made clear to those who might be subject to it.

Whether a change in an individual's investigation or treatment is simply an innovation or actually constitutes clinical research is generally a matter for the responsible clinician's judgement, guided by institutional policies. Systematic evaluation of an innovation is research and requires ethical review.

Clinical and other trials

A clinical trial is a form of human research designed to find out the effects of an intervention, including a treatment or diagnostic procedure. A clinical trial can involve testing a drug, a surgical procedure, other therapeutic procedures and devices, a preventive procedure, or a diagnostic device or procedure.

Clinical trials of new therapeutic substances are typically categorised into Phase I, II , III or IV trials. The following definitions, adapted from the Therapeutic Goods Administration (TGA), describe these phases in trials of medications:

- Phase I studies involve the first administration of the medicine to humans. Medicines are usually given to small numbers of healthy volunteers, but sometimes to people affected by the disease the medicine is intended to treat. The purpose may be to determine the medicine's safety, pharmacokinetics, pharmacological activity, side effects, preferred routes of administration, or appropriate doses (for later studies). The studies are usually undertaken in centres equipped for specialised monitoring and a high degree of surveillance.

- Phase II studies are typically the first trials of the medicine in people with the health condition for which the medicine is intended. The principal aim is to determine efficacy and safety and establish an appropriate dosing regimen. These studies are undertaken in a small number of closely supervised patients and conducted by researchers regarded as specialists in the health condition and its treatment.
- Phase III studies are undertaken if the Phase II studies indicate the medicine has potential benefits that outweigh any hazards. The studies involve greater numbers of patients with the health condition under study, and aim to determine whether the medicine confers clinical benefit in that health condition and whether the incidence and nature of adverse effects are acceptable.
- Phase IV studies are those undertaken after the medicine has been approved for marketing for the treatment of a particular disease or for a particular indication. They may include studies to compare the medicine with a wider range of therapies, and may also further investigate the use of the medicine in the normal clinical setting of the disease (which may differ markedly from the conditions under which pre-marketing trials were conducted). Such studies also gather more comprehensive safety data, adding to the information known from the pre-marketing studies.

In pharmaceutical and medical device trials there are established codes of good clinical research practice that define clearly what is meant by a clinical trial for those purposes (see the *Australian code for the responsible conduct of research*). This chapter's main application is to biomedical clinical trials, but it also applies to any other interventions claiming therapeutic benefit. Trials involving experimentation with therapeutic goods, whether drugs or devices, that are not yet registered, listed or entered on the Australian Register of Therapeutic Goods (ARTG) are subject to regulation by the TGA.

Application of randomised trial methods to other areas of human research

Research methods intended to avoid or reduce bias include randomisation and 'blinding' participants and researchers to the identity of agents being compared. These research methods were first applied to the study of new therapies, and are now used in various other fields including, for example, psychology and education. Researchers who propose to use such methods should be aware of the ethical issues that may arise in the design and conduct of such research. In particular, paragraphs 3.3.3 and 3.3.6 will apply in all situations, while other paragraphs may be relevant depending on the nature of the research and the relationship between the researcher and potential participants.

Research to which this chapter applies must be reviewed and approved by a Human Research Ethics Committee (HREC) rather than by one of the other processes of ethical review described in paragraphs 5.1.7 and 5.1.8 (page 78).

Values, principles and themes that must inform the design, ethical review and conduct of all human research are set out in Sections 1 and 2 of this National Statement. The guidelines and headings below show how those values, principles and themes apply specifically in research that is the subject of this chapter.

GUIDELINES

Research merit and integrity

3.3.1 Health care and medical institutions should establish standards to determine when an innovative intervention requires systematic investigation to determine its safety and efficacy.

3.3.2 When such systematic investigation is required, it should be treated as clinical research needing formal consideration by an HREC.

3.3.3 Researchers should show that:

(a) the research is directed to answering a specific question or questions;

(b) there is a scientifically valid hypothesis being tested that offers a realistic possibility that the interventions being studied will be at least as beneficial overall as standard treatment, taking into account effectiveness, burdens, costs and risks;

(c) the size and profile of the sample to be recruited is adequate to answer the research question; and

(d) the research meets the relevant requirements of the *CPMP/ICH Note for Guidance on Good Clinical Practice* (CPMP/ICH-135/95), *ISO 14155 Clinical Investigation of Medical Devices*, and the TGA.

3.3.4 Researchers must inform the HREC of:

(a) any business, financial or other similar association between a researcher and the supplier of a drug or surgical or other device to be used in the trial;

(b) any other possible conflicts of interest; and

(c) any restrictions on publication.

3.3.5 In any clinical research, especially clinical trials, an HREC should be satisfied that:

(a) funding is sufficient to conduct and complete the trial as designed;

(b) any payment in money or kind, whether to institutions, researchers or participants, will not adversely influence the design, conduct, findings or publication of the research; and

(c) the facilities, expertise and experience available are sufficient for the trial to be conducted safely.

Justice

3.3.6 The research methodology should provide a rationale for the selection of participants and a fair method of recruitment (see paragraph 1.4, page 12).

Risks

3.3.7 In research without likely benefit to participants, any known risk to participants should be lower than would be ethically acceptable where there are such likely benefits. In 'first-time-in-humans' research projects, risks are uncertain, and recruitment into the study should therefore be gradual and monitored with special care.

3.3.8 In clinical research, where patient care is combined with intent to contribute to knowledge, any risks of participation should be justified by potential benefits to which the participants attach significance.

3.3.9 The prospect of benefit from research participation should not be exaggerated, either to justify to an HREC a higher risk than that involved in the participant's current treatment or to persuade a participant to accept that higher risk.

3.3.10 The use of a placebo alone or the incorporation of a non-treatment control group:

(a) is ethically unacceptable in a controlled clinical trial where:

(i) other available treatment has already been clearly shown to be effective; and

(ii) there is known risk of significant harm in the absence of treatment;

(b) may be considered if there is genuine uncertainty as to whether currently available treatments have a net clinical benefit.

Records

3.3.11 Data should be accurately recorded in a durable and appropriately referenced form that complies with established legislation, policies and guidelines. Where a trial is using materials of biological origin, or other materials where there is limited experience of their long-term use, records should be preserved for long enough to enable participants to be traced in case evidence emerges of late or long-term effects (see *Australian code for the responsible conduct of research,* paragraph 2.1.1).

3.3.12 Before beginning the clinical phase of the research, researchers should register clinical trials in a publicly accessible register.

Respect

3.3.13 Due to the potential complexity of information to be provided to participants, the requirements of paragraphs 2.2.2 to 2.2.6 (page 19) should be carefully considered and followed. Written information should not be unduly long or complex. Adequate time should be allowed for prospective participants to read and take in what is proposed, and they should be encouraged to ask questions.

3.3.14 Particular care should be taken in clinical trials to make it clear to participants whether there is intended to be any therapeutic benefit to them from the trial.

3.3.15 It should always be made clear to those who might be subject to a proposed intervention whether it is innovative and/or experimental.

3.3.16 In clinical research, where patient care is combined with an intent to contribute to knowledge, the following matters should be carefully weighed:

(a) the seriousness of the condition being treated;

(b) the risks involved in the proposed research; and

(c) the possible effects of an unequal or dependent relationship between the treating health professional or researcher and the potential participant (see *Chapter 4.3: People in dependent or unequal relationships*).

3.3.17 Where the researcher is also the treating health professional, it should be considered whether an independent person should seek the consent of potential participants.

3.3.18 An HREC should be satisfied that:

(a) payment in money or incentives of any kind, whether to researchers or participants, does not result in pressure on individuals to consent to participate (see paragraphs 2.2.10, and 2.2.11, page 20);

(b) research participants are adequately informed of the funding arrangements of the research and given the option of knowing the details of any capitation payments to researchers or clinicians; and

(c) it has been made clear to participants whether they will have continued access after the trial to treatments they have received during the trial, and on what terms.

Monitoring of approved clinical research

3.3.19 The ultimate responsibilities of institutions for monitoring the conduct of approved research are described in *Chapter 5.5: Monitoring approved research* (page 91–92). In clinical research, and especially clinical trials, research sponsors also have such responsibilities.

3.3.20 Institutions responsible for the conduct of clinical research should require that:

(a) monitoring arrangements are commensurate with the risk, size and complexity of the trial;

(b) for each project, there are mechanisms for reporting and reviewing:

(i) serious adverse events at any site for which the institution is responsible;

(ii) serious adverse drug reactions (ADRs), serious unexpected suspected adverse reactions (SUSARs), and serious adverse device events from any site for which the institution is responsible;

(c) for a large multi-centre trial, a Data and Safety Monitoring Board (DSMB) is used and there is a mechanism for informing the HREC of any relevant emerging data from the DSMB;

(d) for a local trial, there is an identified person/s or committee with suitable expertise to assist and advise the HREC about reports of serious adverse events.

3.3.21 HRECs should review approved projects in light of information provided to them under paragraph 3.3.20.

3.3.22 In addition to the requirements outlined in *Chapter 5.5: Monitoring approved research* (page 91–92), the granting and continuation of ethical approval of clinical research must be on the condition that, for any trial site under the HREC's responsibility, the researcher:

(a) conducts the trial in compliance with the approved protocol;

(b) provides reports of the progress of the trial to the HREC, at a frequency directed by the HREC (but at least annually), and related to the degree of risk to participants;

(c) informs the HREC, and seeks its approval, of amendments to the protocol including amendments that:

(i) are proposed or undertaken in order to eliminate immediate risks to participants;

(ii) may increase the risks to participants; or

(iii) significantly affect the conduct of the trial;

(d) notifies, in the manner and form specified by the HREC, any serious adverse events at any of those trial sites;

(e) informs the HREC as soon as possible of any new safety information from other published or unpublished studies that may have an impact on the continued ethical acceptability of the trial or may indicate the need for amendments to the trial protocol;

(f) informs the HREC, giving reasons, if the trial is discontinued before the expected date of completion; and

(g) for trials with implantable medical devices, confirms the existence of, or establishes, a system for

(i) tracking the participant, with consent, for the lifetime of the device; and

(ii) reporting any device incidents to the TGA.

Discontinuance of trials

3.3.23 It may be unethical for a researcher to continue a trial if:

(a) there are or have been substantial deviations from the trial protocol;

(b) side-effects of unexpected type, severity, or frequency are encountered; or

(c) as the trial progresses, one of several treatments or procedures being compared appears to be so much better or worse than the other/s that the continuation of the trial would disadvantage some of the participants.

The clearer it becomes that one treatment is substantially better or worse than the others, the stronger the need to consider discontinuing the trial.

Insurance

3.3.24 Institutions must be satisfied that sponsors of trials have made the indemnity or insurance and compensation arrangements required by *CPMP/ICH Note for Guidance on Good Clinical Practice* (CPMP/ICH-135/95), *ISO 14155 Clinical Investigation of Medical Devices* and the TGA.

3.3.25 In addition to the requirements in paragraph 3.3.24, institutions must also have arrangements to compensate participants for harm resulting from negligence in research to which this chapter applies.

CHAPTER 3.4: HUMAN TISSUE SAMPLES

INTRODUCTION

Samples of tissue, including blood and other body fluids, are collected from people in hospitals and other health care institutions, and in field research. Samples collected for diagnostic purposes in the course of treatment have also traditionally been used for teaching or quality assurance activities and for research. Directors of Pathology have traditionally exercised discretion in the use of clinical samples in testing and developing laboratory procedures, and should continue to do so.

Hospitals and pathology laboratories are required by law to retain archival samples for diagnostic or forensic purposes. This means that most hospitals have collections of stored samples whose use in research may lead to important advances in the understanding and treatment of disease.

State and Territory laws also regulate collection and some uses of human tissue.

This chapter provides ethical guidance for any research involving human tissue samples. *Chapter 3.5: Human genetics*, *Chapter 3.6: Human stem cells*, and *Chapter 4.1: Women who are pregnant and the human foetus* offer additional guidance on specific aspects of such research.

Research involving the use of gametes or embryos is governed by *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research* (NHMRC 2007).

Values, principles and themes that must inform the design, ethical review and conduct of all human research are set out in Sections 1 and 2 of this National Statement. The guidelines and headings below show how those values, principles and themes apply specifically in research that is the subject of this chapter.

GUIDELINES

Institutional policy

3.4.1 Institutions should develop a policy for the collection, storage, use and disposal of human tissue in research. This policy should cover:

(a) what information needs to be recorded about the source, nature and reason for collection of the tissue;

(b) requirements about participant consent (see *Chapter 2.2: General requirements for consent*), including circumstances where waiver of consent may be justified (see paragraphs 2.3.5 and 2.3.6, page 24);

(c) confidentiality;

(d) privacy of samples and information;

(e) access to samples and information;

(f) disposal of samples;

(g) socio-cultural considerations bearing on these issues.

3.4.2 This policy should conform to relevant legislation and be consistent with this National Statement.

3.4.3 Researchers should demonstrate that tissues will be collected, stored, used and disposed of in accordance with this policy.

Imported tissue

3.4.4 Where tissue is imported from another country for use in Australia, researchers should try to establish whether there are ethical and professional policies in that country, or the relevant institution,

governing the collection of tissue for use in research.

(a) Where such a policy exists, and reasonable enquiry reveals no reason to believe the collection of the tissue contravened it, a Human Research Ethics Committee (HREC) may consider waiving consent for the use of this tissue, in accordance with paragraph 2.3.6 (page 24).

(b) Where it cannot be established that a policy exists, or where it exists but enquiry reveals reason to believe the tissue was not collected in accordance with it, the tissue should not be used in research in Australia (*see also Chapter 4.8: People in other countries*).

(c) For research with tissues that were in collections either imported or existing overseas before the release of this National Statement, an HREC may consider waiving consent without reference to (a) and (b) (see paragraph 2.3.6, page 24).

Information and consent

3.4.5 Participants should receive clear information about whether their tissue samples will be identified, and if so, how.

3.4.6 If the research is likely to produce information relevant to the health and wellbeing of the person from whom the tissue was derived, procedures to allow participants to be identified for appropriate follow-up should, wherever possible, be included in the research proposal.

3.4.7 Consent for the use of tissue may be specific, extended or unspecified (see paragraph 2.2.14, page 21). When consent is given for the use of human tissue in specific research only, that tissue should not be used for any other purpose without the consent of the tissue donor unless an HREC or other review body has waived the requirement to seek further consent, in accordance with paragraph 2.3.6 (page 24).

Cadaveric tissue

3.4.8 Any wish expressed by a person about the use of his or her post-mortem tissue for research should be respected. If no such wish is discovered, consent for the use of the tissue should be sought from the senior available next of kin.

3.4.9 At the time of seeking this consent it should be agreed with the next of kin how the tissue is to be disposed of when the research has been completed. Researchers should try to accommodate any reasonable wishes of the next of kin about this.

Commercialisation

3.4.10 There should be no trade in human tissue for research purposes.

CHAPTER 3.5: HUMAN GENETICS

INTRODUCTION

The genome is an individual's biological inheritance. An individual's biological characteristics are determined by the interaction of his or her genome with the environment. An individual's genome contains all of his or her genes.

Genetics is the study of the structure, location, function, expression, interaction, abnormalities and effects of the genes or genetic material and their products, including but not limited to studies of the structure of the nucleic acids and other molecules that make up the genetic material.

Genes and genetic information are being studied increasingly in clinical, epidemiological and social research, as well as in basic research.

Genetic research may involve study of:

- single or multiple genes, gene-to-gene interaction or gene-environment interaction;
- acquired somatic variation;
- inherited gene sequences, and their variants or their products;
- gene expression, including the influence on those genes of environmental factors, pharmaceutics and other therapeutic products;
- the genes of individuals, families or populations;
- epigenetics;
- use of informatics and genetic information; and
- clinical phenotypes.

Some research that falls within this broad description of genetic research does not involve information that is relevant to the future health of the individual participant and does not generate sensitivities for the individual, or his or her family or community. The guidelines in this chapter differentiate between research that necessitates special precautions in that respect, and research that is unlikely to be of concern to individual participants, their families or their communities.

For genetic research using stored data, *see also Chapter 3.2: Databanks*; and for genetic research using human tissue samples, see *Chapter 3.4: Human tissue samples*.

There are ethical issues specific to genetic research because:

- many of an individual's genes are shared with close genetic relatives (commonly called 'blood relatives') and with unrelated people in the population; and
- genetic research can reveal information about predispositions to disease. Although people with such a predisposition may not develop the disease, the information may have implications for their access to employment and education and to benefits or services, including financial services such as banking, insurance and superannuation. The information may also have similar implications for blood relatives.

Research results and genetic material and information collected for genetic research may be significant for blood relatives of research participants. These family members may have an interest in their relatives' genetic material, or in information the research generates, because testing that material or acquiring that information may create new options for life decisions, including those with potential to improve health. However, some family members may prefer not to be given such information, or even not to know of its existence. In addition, other family members who are not blood relatives, such as partners and spouses, may have an interest because of concerns about the health of offspring. Genetic research can also

reveal information about previously unknown paternity or maternity. Genetic research also has uses outside health, such as for tracing migration patterns and in studies of cultural relatedness.

Research to which this chapter applies must be reviewed and approved by a Human Research Ethics Committee (HREC) rather than by one of the other processes of ethical review described in paragraphs 5.1.7 and 5.1.8 (page 78), except where that research uses collections of non-identifiable data and involves negligible risk, and may therefore be exempted from ethical review.

Values, principles and themes that must inform the design, ethical review and conduct of all human research are set out in Sections 1 and 2 of this National Statement. The guidelines and headings below show how those values, principles and themes apply specifically in research that is the subject of this chapter.

GUIDELINES

Research merit and integrity

3.5.1 Where research may discover or generate information of potential importance to the future health of participants, or their blood relatives, researchers must prepare and follow an ethically defensible plan to disclose or withhold that information.

3.5.2 This plan must take into account the clinical relevance of the research information, the types of genetic test used in the research, and the results of those tests. In addition:

(a) The plan should:

(i) enable participants to decide whether they wish to receive the information and who else may be given the information;

(ii) set out a process for finding out whether those other people want to receive information;

(iii) include procedures to inform participants that the information would remain potentially identifiable;

(iv) include measures to protect the degree of confidentiality that participants wish to maintain.

(b) When participants or their relatives are to be given or notified of genetic information that may be important for their health, the plan should either provide access to genetic and clinical advice and counselling, or clearly recommend to participants that they seek these services. Such advice and counselling should be provided by professionals with appropriate training, qualifications and experience.

(c) Where participants or relatives prefer not to receive genetic information that is important for their health, they should be advised that they will be approached to confirm this decision when the results of the research are available.

(d) Where the potential relevance of genetic information to participants' health is not clear until after interim analysis of the research information, participants should again be given:

(i) the option of being notified of the existence of that information;

(ii) the option of receiving the information; and/or

(iii) access to, or a recommendation to seek, advice or counselling about the implications of these decisions.

3.5.3 Advice about the results of genetic research needs to include a clear explanation of the difference between research and clinical testing, and to clarify any need for clinical testing of research results.

Justice in the use and disclosure of genetic information

3.5.4 Researchers should consider the potential psychological, social and cultural significance of their research. Where complex socially significant characteristics or the genetic characteristics of communities are being investigated, there is a risk that the research may be misrepresented or misused in ways that lead to prejudice, disrespect or other harm to participants or communities. In designing, conducting and reporting research of this nature, researchers should consider how to counter the possibility of such harm.

Beneficence

3.5.5 Identifiers of genetic material or related information:

(a) should not be removed without the consent of participants, if removal would make it difficult to communicate personal results;

(b) should be removed if participants request it, provided they have been informed that the material or information would remain potentially identifiable.

3.5.6 Genetic information can sometimes be misused to stigmatise people or to discriminate against them unfairly. Researchers should therefore take special care to protect the privacy and confidentiality of this information. Statutory or contractual duties may require participants to disclose the results of genetic tests or analysis to third parties (for example, insurance companies, employers, financial and educational institutions), particularly where results provide information about health prospects. Genetic research should be designed to minimise any resultant risk that participants will be deprived of benefits available to others in the community. Potential research participants should be advised of any such risks.

3.5.7 Researchers should not transfer genetic material or related information to any researcher not engaged in the research project unless:

(a) either

(i) participants have been informed about and have specifically consented to that transfer and, where the material or information is identified, there is a defensible plan as specified in paragraphs 3.5.1 and 3.5.2 for withholding or disclosing it; or

(ii) the provisions for extended or unspecified consent set out in paragraph 2.2.14 (page 21) have been met; or

(iii) an HREC has judged that the conditions for waiver of consent have been met (see paragraph 2.3.6, page 24), and has approved the transfer;

(b) the transferring and receiving researchers are conducting research that has been ethically approved in Australia or through an equally stringent process in another country; and

(c) the receiving researcher/s undertake/s not to permit attempts to re-identify the material or information or otherwise reduce the protection of the privacy of the participants or of the confidentiality of the information.

Family involvement

3.5.8 Where people are asked to consent to the collection of their genetic material or information for research, they should be given information required by paragraph 2.2.2 (page 19) and, in addition, be advised:

(a) that genetic material is in principle re-identifiable, even if identifiers are removed;

(b) that they are free to decline without giving reasons;

(c) about arrangements to ensure the privacy and confidentiality of their genetic information with regard to both family members and others, in accordance with the defensible plan for disclosing and withholding information (see paragraph 3.5.2);

(d) whether information from or about family members, in addition to that provided by participants, is required for the research;

(e) whether the research may reveal information of potential importance to their future health, or the future health of their blood relatives;

(f) that, if it is proposed to approach blood relatives, consent to do so will first be sought from the participant;

(g) that, if the research discloses that a family member may be at risk of a life-threatening or serious illness for which treatment is available or pending, this information may, with the approval of an HREC, be offered by a clinician to the family member, even if the research participant does not consent to this; and

(h) whether the research has the potential to detect previously unknown paternity or maternity, or non blood-relationship to siblings, and whether, how and to whom this information will be disclosed, according to the approved plan.

3.5.9 In deciding if relatives should be approached, researchers should consider:

(a) the privacy and any known sensitivities of the relatives;

(b) accepted habits of communication within the family; and

(c) whether the harms that might result from the relatives' participation in the research are justified by the potential benefits of their participation.

3.5.10 Where a participant has given consent to approach relatives, the opportunity to make initial contact should be given to the participant or someone else he or she chooses.

Community involvement

3.5.11 Consent should be sought from appropriate community representatives as well as from the individuals concerned (see paragraph 2.2.13, page 21), where:

(a) researchers propose to collect genetic material and information from individuals who are chosen because of their membership of a particular community;

(b) the research involves sensitivities for that community; and

(c) there is known to be a culturally relevant community structure involved in such matters.

Other information to be given

3.5.12 Those whose consent is being sought for collection of identified or potentially identifiable genetic material or related information should also be informed:

(a) if the research has potential to generate information that a participant may be legally required to disclose to a third party, for instance, for the purposes of insurance, employment, finance or education;

(b) that genetic material and data may have uses unrelated to research. Participants should be advised that their material and data will not be released for such uses without their consent, unless required by law;

(c) about any proposal, subject to participants' consent, to store their genetic material and data because it might be useful for as yet unspecified future research;

(d) that, if such consent is not given, the genetic material and data will be disposed of at the end of the research, once the sample storage and record-keeping requirements of good research practice have been met;

(e) that any wishes about the method of disposal will be recorded at the start of the research and taken into account at the time of disposal;

(f) that they are free to withdraw from the research at any time. Participants should be informed of any consequences of such withdrawal, including that they may request their genetic material and data to be disposed of, if the samples can be identified. They should also be clearly informed of any practical limitations on the granting of this request; and

(g) that, in research studying large numbers of genes simultaneously, participants will not be given the names of all the individual genes to be studied.

Confidentiality

3.5.13 Researchers must ensure the confidentiality and privacy of stored genetic information or research results relating to identified or re-identifiable participants. Such information or research results should be disclosed to treating clinicians only in accordance with the consent given for the research.

3.5.14 The rarity of some genetic disorders might allow certain families or individuals to be identified by other researchers, and in some cases by members of the community, even if information is given to others in non-identifiable form. For this reason, where genetic data are stored, confidentiality might sometimes require restrictions on the release of data for research use (see paragraph 3.2.8, page 31).