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NATIONAL STATEMENT

National Statement on Ethical Conduct in Human Research 2007

(Updated May 2015)

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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.

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.

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

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]

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 *Ethical Considerations in Quality Assurance and Evaluation Activities, NHMRC 2014)*

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,) 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. Institutions may also determine that some human research is exempt from ethical review (see paragraphs 5.1.22 and 5.1.23).

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.

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[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

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).

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), 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;
- determining whether they are justified by the potential benefits of the research; and
- 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.

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.

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)*.

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) 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.

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

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*.

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).

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).

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).

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.

'Limited disclosure' to participants of the aims and/or methods of research may 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.

Depending upon the circumstances of an individual project it may be justifiable to employ an opt-out approach or a waiver of the requirement for consent, rather than seeking explicit consent.

A single research project may involve discrete elements or participant groups where different recruitment approaches can be used. For example, a project may involve some elements or participant groups where explicit consent must be sought and other elements where an opt-out approach may be considered or where a waiver of the consent requirement may be applied.

The opt-out approach is a method used in the recruitment of participants into research where information is provided to the potential participant regarding the research and their involvement and where their participation is presumed unless they take action to decline to participate.

While an opt-out approach makes it possible for people to make an informed choice about their participation, this choice can only be made if participants receive and read the information provided, and they understand that they are able to act on this information in order to decline to participate.

Importantly, the opt-out approach is unlikely to constitute consent when applying commonwealth privacy legislation to the handling of sensitive information, including health information. Therefore, where it is impracticable to obtain an individual's explicit consent to the use of their information and the purpose of the research cannot be served by using non-identifiable information, researchers must comply with the *Guidelines under Section 95 of the Privacy Act 1988* (s95 guidelines) or the *Guidelines approved under Section 95A of the Privacy Act 1988* (s95A guidelines) (as applicable)

to ensure that their handling of personal information does not breach the *Privacy Act 1988*. Where researchers need approval to use an opt-out approach for research to which the s95 or 95A guidelines apply, only an HREC may grant this approval. Other review bodies may approve an opt-out approach for other research.

The Australian Privacy Principles Guidelines contain further information about consent and the handling of personal information.

When neither explicit consent nor an opt-out approach are appropriate, the requirement for consent may sometimes be justifiably waived. When an HREC or, where appropriate, another review body grants a waiver of consent for research conducted prospectively or retrospectively, research participants will characteristically not know that they, or perhaps their tissue or data, are involved in the research.

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

(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

(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), 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.

Opt-out approach

2.3.5 An opt-out approach to participant recruitment to research may be appropriate when it is feasible to contact some or all of the participants, but where the project is of such scale and significance that using explicit consent is neither practical nor feasible.

2.3.6 Before approving the use of an opt-out approach for research, an HREC or, where appropriate, another 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 public interest in the proposed activity substantially outweighs the public interest in the protection of privacy

(c) the research activity is likely to be compromised if the participation rate is not near complete, and the requirement for explicit consent would compromise the necessary level of participation

(d) reasonable attempts are made to provide all prospective participants with appropriate plain language information explaining the nature of the information to be collected, the purpose of collecting it, and the procedure to decline participation or withdraw from the research

(e) a reasonable time period is allowed between the provision of information to prospective participants and the use of their data so that an opportunity for them to decline to participate is provided before the research begins

(f) a mechanism is provided for prospective participants to obtain further information and decline to participate

(g) the data collected will be managed and maintained in accordance with relevant security standards

(h) there is a governance process in place that delineates specific responsibility for the project and for the appropriate management of the data

(i) the opt-out approach is not prohibited by State, federal, or international law.

2.3.7 For guidance on the use of an opt-out approach in activities other than research, such as quality assurance and evaluation, refer to *Ethical Considerations in Quality Assurance and Evaluation Activities, 2014*.

2.3.8 When considering the provision of information to prospective participants and the mechanism by which individuals can decline participation, the ethical review body should consider the sensitivity and the risks, the potential participant pool, the context in which the research and opt-out approach will occur, and whether withdrawal from participation is feasible once identifiers have been removed from data.

Waiver

2.3.9 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.

2.3.10 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.

2.3.11 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

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

2.3.12 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 2.3.10 and 2.3.11. Waiver decisions under paragraph 2.3.11 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).

Ethical review by an HREC is required for any research that involves more than low risk (paragraph 5.1.6). It is also required for research discussed in *Chapter 3.3: Interventions and therapies, including clinical and non- clinical trials, and innovations*, and *Chapter 3.5: Human genetics,* 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 prcesses;
- investigating how communities and individuals interpret and make sense of their experiences;
- 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** nvolves 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 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:

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.

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).

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[4] Denzin NK & Lincoln YS (eds) 2000 Handbook of Qualitative Research, Sage: California(1997)

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.

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).

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); or

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

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 *Ethical Considerations in Quality Assurance and Evaluation Activities, NHMRC 2014*.

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.

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 Risks 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 3.3.8 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).

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.

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 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);

(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. 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) or 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*, 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 BIOSPECIMENS IN LABORATORY BASED RESEARCH

INTRODUCTION

'Human biospecimens' is a broad term that, for the purposes of this chapter, refers to any biological material obtained from a person including tissue, blood, urine, sputum and any derivative from these including cell lines. It does not include non-human biological material such as micro-organisms that live on or in a person.

Research involving human biospecimens often involves special ethical considerations because of:

- the way that human biospecimens are obtained;
- the information that may be derived from human biospecimens and the implications of that information for the individual donor, their blood relatives and their community; and
- the significance that may be attached to the human biospecimens by individuals donors and/or communities.

This chapter provides guidance to researchers, institutions and HRECs on the matters that require ethical consideration.

Specific considerations for human embryos, gametes and fetal tissue

Specific requirements for research involving fetal tissue are detailed in *Chapter 4.1: Women who are pregnant and the human fetus*.

Research involving human embryos and gametes, including the derivation of human embryonic stem cell lines, is separately governed by the *Research Involving Human Embryos Act 2002* (Cth) and the *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research* (2007) (ART guidelines), issued by the NHMRC. Research involving the derivation of embryonic stem cell lines or other products from a human embryo must be considered by a Human Research Ethics Committee (HREC) as part of a licence application to the Embryo Research Licensing Committee (see Part C of the ART guidelines). The legislation and ART guidelines do not regulate the use of these products after they have been derived.

Once human biospecimens have been derived from human embryos, gametes or fetuses, the requirements of this Chapter apply for any subsequent use in research.

Sources of human biospecimens

Sources of human biospecimens include voluntary donation, material taken for clinical purposes, and material collected post-mortem (after death).

Human biospecimens are commonly collected, stored and distributed by researchers, biobanks, clinical pathology services, health care providers, research institutes and commercial entities, such as pharmaceutical and biotechnology companies.

Other chapters, legislation and documents that should be considered

Additional ethical guidance that may be relevant to research uses of human biospecimens is provided in this National Statement at:

- Chapter 3.2: Databanks
- Chapter 3.3: Interventions and therapies, including clinical and non-clinical trials, and innovations, which provides ethical guidance on the use of human biospecimens for therapeutic purposes
- Chapter 3.5: Human genetics, which offers additional guidance on specific aspects of the use of human biospecimens for research purposes
- Chapters 4.1 – 4.8: Ethical consideration specific to participants, which offer additional guidance on ethical issues arising from collecting human biospecimens from particular categories of participants

and in

- Values and Ethics - Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (NHMRC, 2003).

Researchers and institutions must also meet any relevant legislative requirements that relate to the collection, retention, use and disposal of human biospecimens, including the general prohibition on trade in human tissue.

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 and are applicable to research involving human biospecimens.

GUIDELINES

Prospective collection of human biospecimens for research

3.4.1 Those proposing to collect human biospecimens for research should:

(a) ensure that the burdens of the biospecimen collection on the donor(s) are justified by the

potential benefits of the proposed research;

(b) ensure that those involved in the collection of the biospecimens are suitably qualified or experienced, and follow current best practice; and

(c) ensure that suitable provisions, including financial and governance arrangements, have been made for the intended processing, storage, distribution and/or use, and disposal of the biospecimens.

3.4.2 The consent of donor(s) should be obtained and recorded when collecting human biospecimens specifically for research in order to meet the requirements of *Chapter 2.2: General requirements for consent*.

3.4.3 Before potential participants consent to donation of their biospecimens, they should be given sufficient information about:

(a) the research for which their biospecimens are to be used and, where extended or unspecified consent is sought, sufficient information to meet the requirements of paragraphs 2.2.1 and 2.2.16;

(b) how their biospecimens will be stored, used and disposed of, including any processes to be adopted to respect their personal or cultural sensitivities;

(c) the extent to which their biospecimens will be reasonably identifiable, and how their privacy and confidentiality will be protected;

(d) whether or not research using their biospecimens is likely to provide information that may be important to their health or to the health of their blood relatives or their community;

(e) if information of the kind referred to in (d) is likely to be revealed, whether or not they will have the choice to receive this information, and how this will be managed (see paragraph 3.4.10);

(f) if information of the kind referred to in (d) is likely to be revealed, whether or not they will have the choice for it to be provided to their blood relatives or their community; and how this will be managed (see paragraph 3.4.10);

(g) whether their biospecimens and associated data may be distributed to other researchers, including those outside Australia (see paragraphs 3.4.13 – 3.4.15);

(h) their right to withdraw consent for the continued use of their biospecimens or associated data in research (see paragraph 2.2.6(g)), and any limitations that may be relevant to their withdrawal of consent; for example, as a consequence of the removal of identifiers, or the prior distribution and/or use of their biospecimens;

(i) any relevant financial or personal interests that those engaged in the collection, processing, storage and distribution and use of their biospecimens may have (see *Chapter 5.4: Conflicts of interest*); and

(j) any potential for commercial application of any outcomes of the research involving their biospecimens, how this will be managed and to whom the benefits, if any, will be distributed.

3.4.4 For human biospecimens collected for research purposes (including biobanks), there should be ethical review and approval by an HREC of the proposed consent, collection, processing, storage and distribution or disposal.

Human biospecimens obtained after death for research

3.4.5 Any wish expressed by a person about the use of their biospecimens post- mortem should be respected. If no such wish is discovered, researchers seeking to obtain human biospecimens post-mortem should obtain consent from the person(s) authorised by relevant legislation.

Ethical review of research involving human biospecimens

3.4.6 Institutions, researchers and other organisations that conduct research involving the use of human biospecimens have a responsibility to ensure that the research is designed, reviewed, approved and conducted in accordance with this National Statement and other relevant guidelines and legislation.

3.4.7 The ethical review of proposed research involving the use of human biospecimens must consider the circumstances in which the biospecimens were obtained and any known limitations the donor(s) placed on their use during the consent process.

3.4.8 In determining the level of ethical review appropriate for the research involving the use of human biospecimens, the responsible institution and researcher should consider:

(a) whether the research involves any risks to the donors, their blood relatives or their community that are more serious than discomfort (see *Chapter 2.1: Risk and Benefit*); and

(b) whether the research may give rise to information that may be important for the health of the donors, their blood relatives or their community where the identity of the donors will be known to, or can reasonably be ascertained by, those conducting the research or with access to health or research data related to donors.

3.4.9 If the research involves no more than low risk, then the provisions of paragraphs 5.1.18 – 5.1.21 for non-HREC levels of review may apply.

3.4.10 Where proposed research involving the use of human biospecimens may reveal information that may be important for the health of the donor(s), their blood relatives or their community, whether anticipated or incidental to the scope of the research, researchers should prepare an ethically defensible plan to describe the management of any proposed disclosure or non-disclosure of that information. This plan must be approved by an HREC and should include consideration of the following:

(a) The circumstances in which the biospecimens were obtained, including the type of consent provided (see paragraph 2.2.14) and the manner in which the consent was obtained;

(b) the likelihood of the research generating information that may be important for the health of the donor(s), their blood relatives or their community;

(c) whether a recognised intervention exists that can benefit or reduce the risk of harm to the

donor(s), their blood relatives or their community from any health impact revealed by this information;

(d) the resource requirements and infrastructure in place to support the return of information of the kind referred to in (b) and (c) in an ethically appropriate manner;

(e) whether participants will be given a choice to receive such information;

(f) whether there is a pathway to identify and recontact the donor(s), their blood relatives or their community, taking into account the relationship between the researchers and the donor(s), if any;

(g) the potential for sampling or coding errors that may compromise the certainty that the biospecimens came from a particular donor;

(h) whether the findings of specific tests being undertaken as part of the research have been produced or validated in an accredited laboratory; and

(i) who will take responsibility for any subsequent care requirements.

Use of human biospecimens collected for clinical purposes

3.4.11 Where human biospecimens were obtained for clinical purposes and have been retained by an accredited clinical pathology service, the biospecimens may be used for research purposes if:

(a) the identity of the donor is not necessary for the activity (see paragraph 3.4.9); or

(b) where the identity of the donor is required for the purposes of the research, a waiver of consent (see paragraph 3.4.12) has been obtained.

Waiver of consent

3.4.12 Where it is contemplated that proposed research will involve the use of human biospecimens that have been obtained without specific consent for their use in research (e.g. where biospecimens were collected for clinical investigation), or where the proposed research is not consistent with the scope of the original consent, the biospecimens may be used only if an HREC is satisfied that the conditions for waiver of consent are met (see *Chapter 2.3: Qualifying or waiving conditions for consent*). Particular consideration should be given to:

(a) whether there is a pathway to identify and recontact the donor(s) in order to seek their informed consent to the use of their biospecimens in research; and

(b) whether there is a known or likely reason for thinking that the donor(s) would not have consented if they had been asked.

Importation and exportation of human biospecimens for research

3.4.13 Where it is intended that human biospecimens will be, or where the biospecimens have been imported from another country for use in research in Australia, researchers must establish

whether these human biospecimens were obtained in a manner consistent with the requirements described in this National Statement and relevant Australian legislation.

3.4.14 Where it cannot be established that the human biospecimens described in paragraph 3.4.13 were obtained in a manner consistent with the requirements described in this National Statement and relevant Australian legislation the biospecimens should not be used for research in Australia.

3.4.15 Human biospecimens obtained for research in Australia may be sent overseas for research in accordance with institutional policy, if:

(a) ethical approval by an appropriate ethical review body for importation of the biospecimens is submitted; or

(b) the exportation of the biospecimens is consistent with the original consent and ethical approval is provided by an HREC.

Transition provisions for existing biospecimens

3.4.16 Where biospecimens were obtained domestically or via importation prior to the effective date of this guideline (December 2013), the biospecimens may continue to be used in Australia for approved research provided that the researcher's institution ensures that:

(a) there is sufficient evidence that the samples were obtained in a manner consistent with any prior guidelines and/ or the accepted ethical practice at the time of collection; and

(b) the proposed research for which the biospecimens will be used is within the scope of the consent provided by the donor(s).

Conscientious Objection

3.4.17 Those who conscientiously object to being involved in conducting research using human biospecimens derived from human embryos, gametes, fetuses or embryonic or fetal tissue should not be obligated to participate, nor should they be put at a disadvantage because of their objection.

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 biospecimens in laboratory based research*.

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, 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 have been met; or

(iii) an HREC has judged that the conditions for waiver of consent have been met (see paragraph 2.3.6), 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 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, 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

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

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).

SECTION 4: ETHICAL CONSIDERATIONS SPECIFIC TO PARTICIPANTS

In addition to the ethical considerations pertaining to all research participants, specific issues arise in the design, conduct and ethical review of research involving the categories of participants identified in this section.

The Introduction to this National Statement contains a definition of participants and notes that the impact of research on wider populations is an important ethical consideration in the design, review and conduct of human research.

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).

Ethical review by an HREC is required for any research that involves more than low risk (see paragraph 5.1.6). It is also required for research discussed in several chapters of Section 3, as well as for research discussed in the following chapters of this section: *Chapter 4.1: Women who are pregnant and the human fetus, Chapter 4.4: People highly dependent on medical care who may be unable to give consent, Chapter 4.5: People with a cognitive impairment, an intellectual disability, or a mental illness, Chapter 4.6: People who may be involved in illegal activities, Chapter 4.7: Aboriginal and Torres Strait Islander Peoples and Chapter 4.8: People in other countries.*

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 4.1: WOMEN WHO ARE PREGNANT AND THE HUMAN FETUS

INTRODUCTION

This chapter provides guidelines for the ethical conduct of research involving women who are pregnant, the human fetus ex utero, and human fetal tissue after the separation of the fetus from the woman. The chapter is arranged to reflect the following established categories of such research:

- research on the woman who is pregnant and the fetus in utero; and
- research on the separated human fetus or on fetal tissue.

This chapter does not apply to research involving:

- gametes, embryos and/or participants in assisted reproductive treatments – this research is covered by the *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research* (NHMRC 2004);
- embryos excess to the needs of those for whom they were created using assisted reproductive technology – this research is covered by Australian legislation.

For the purpose of this chapter, the term fetus applies to the developing human being from fertilisation to delivery, and whether alive or dead at delivery.

Fetal tissue includes membranes, placenta, umbilical cord, amniotic fluid, and other tissue that contains the genome of a fetus. Fetal tissue is regarded as part of the fetus prior to separation of the fetus from the woman.

After separation, the following chapters of this National Statement may also be relevant to the design and conduct of research involving fetal tissue: *Chapter 3.4: Human biospecimens in laboratory based research*.

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, 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

The woman who is pregnant and the fetus *in utero*

4.1.1 The wellbeing and care of the woman who is pregnant and of her fetus always takes precedence over research considerations.

4.1.2 The research participation of a young person who is pregnant should be guided by the requirements of *Chapter 4.2: Children and young people*.

4.1.3 Research involving the woman may affect the fetus, and research involving the fetus will affect the woman. The risks and benefits to each should be carefully considered in every case, and should be discussed with the woman. This must include the effect of the research on the fetus *in utero* (including consideration of fetal stress) and on the child who may subsequently be born.

4.1.4 The possibility of providing access to counselling for the woman about these issues should be part of this discussion.

4.1.5 Researchers should ask the woman whether, in her decisions about the research, she wishes to involve others for whom the research may have implications.

4.1.6 Except in the case of therapeutic innovative therapy, the process of providing information and obtaining consent for involvement in research should be separate from clinical care. Information about research projects should also be separate from information about routine clinical care.

4.1.7 If it is consistent with promoting the life and health of the fetus, research on the fetus *in utero* may be ethically acceptable. Such research may, for example, provide information about the health of the fetus.

4.1.8 Research should be designed so as to minimise pain or distress for the fetus, and should include steps for monitoring for signs of fetal pain or distress, and steps for suspending or ceasing the research if necessary.

4.1.9 'Innovations in clinical practice', in *Chapter 3.3: Interventions and therapies, including clinical and non-clinical trials, and innovations*, should be considered for any innovative therapy involving the fetus. See also paragraph 3.3.15.

4.1.10 It is ethically unacceptable to conduct non-therapeutic research that involves administering drugs or carrying out a procedure on the woman or her fetus, where the research carries risk for the fetus.

The human fetus, or fetal tissue, after separation

4.1.11 Research involving a fetus or fetal tissue should be conducted in a manner that maintains a clear separation between the woman's clinical care and the research. Where a treating health professional is also involved in the research, any conflict of interest (for example, one which may arise from a financial or contractual relationship) will need to be managed in accordance with paragraph 5.4.3 of this National Statement. In cases where pregnancy is to be terminated, the possibility of contributing fetal tissue to research must not be raised until a decision to terminate has been made. Proposals for research must include procedures to ensure that the process of providing information and obtaining consent for involvement in the research is clearly separated from clinical care. For example:

- A researcher who is also the treating health professional should not be the person who seeks the consent of the potential participant unless there is a specific justification for doing so (see paragraph 3.3.17).
- Information sheets for research projects must be completely separate from, and capable of being read independently of, written information provided to a patient in the course of routine clinical care.

4.1.12 Researchers should demonstrate that there are no suitable alternatives by which the aims of research using the separated human fetus or fetal tissue can be achieved.

4.1.13 There should be no trade in human fetal tissue.

4.1.14 Those who conscientiously object to being involved in conducting research with separated fetuses or fetal tissue should not be compelled to participate, nor should they be put at a disadvantage because of their objection.

4.1.15 Where research involves a separated fetus, researchers should ask the woman whether, in her decisions about the research, she wishes to involve others for whom the research may have implications.

4.1.16 A fetus or fetal tissue may become available for research as the result of termination. The process through which the woman is approached, informed about, and her consent sought for research on that fetus should be separate from the process under which she decides whether to terminate her pregnancy, and should not begin until a decision to terminate has been made. Consenting to the research must not compromise the woman's freedom to change that decision.

4.1.17 Where research involves her separated fetus or its fetal tissue, arrangements should be made for the woman to have access to counselling and support.

4.1.18 Research on a terminated fetus or its tissues, including the timing and content of the process of seeking the woman's consent for the research, should be designed so as not to compromise the woman's decisions about the timing and method of termination.

4.1.19 Consideration of a woman's wishes and her physical, psychological and emotionalwelfare should inform:

(a) a decision whether to approach her about proposed research involving her, her separated fetusor its tissue; and

(b) if she is approached, the way information is provided about the research and her consent for it sought.

4.1.20 In addition to the information required to be disclosed under paragraph 2.2.2 and 2.2.6 of this National Statement, the woman should also be informed:

(a) that she should consider whether to seek consent to the proposed research from any other person (see paragraphs 4.1.5 and 4.1.15);

(b) whether it is possible to store the fetus or fetal tissues for later use in research;

(c) that she is free to withdraw her consent to the research at any time, whether before or after a termination or other loss of a fetus;

(d) whether there is potential for commercial application of outcomes of the research, including the development of cell lines;

(e) that she will not be entitled to a share in the profits of any commercial applications; and

(f) whether fetal organs or stem cell lines developed from them will be exported to another country.

4.1.21 A fetus delivered alive is a child, and should be treated as a child and receive the care that is due to a child.

4.1.22 Organs and tissues may be removed from a fetus delivered dead and used for research only if the conditions of paragraphs 4.1.11 and 4.1.12 are met, and:

(a) the woman and any others she wishes to involve (see paragraph 4.1.15) have given consent to the removal and the research;

(b) the fetus is available for research only as a result of separation by natural processes or by lawful means; and

(c) death of the fetus has been determined by a registered medical practitioner who has no part (or financial interest) in the research.

4.1.23 If, for research purposes, fetal cells are to be derived from the fetal tissue and stored or propagated in tissue culture, or tissues or cells are to be used in human transplantation, the woman's consent is required. Others whom the woman identifies (see also paragraph 4.1.15) may also need to be involved in decisions about these matters.

CHAPTER 4.2: CHILDREN AND YOUNG PEOPLE

INTRODUCTION

Research involving children and young people raises particular ethical concerns about:

- their capacity to understand what the research entails, and therefore whether their consent to participate is sufficient for their participation;
- their possible coercion by parents, peers, researchers or others to participate in research; and
- conflicting values and interests of parents and children.

These considerations apply to all research involving children and young people. However, they assume special prominence in educational and health research, where there are particular tensions between not placing children at risk in studies of new interventions and the need for knowledge about how such interventions are best used for children.

Researchers must respect the developing capacity of children and young people to be involved in decisions about participation in research. The child or young person's particular level of maturity has implications for whether his or her consent is necessary and/or sufficient to authorise participation. Different levels of maturity and of the corresponding capacity to be involved in the decision include:

(a) infants, who are unable to take part in discussion about the research and its effects;

(b) young children, who are able to understand some relevant information and take part in limited discussion about the research, but whose consent is not required;

(c) young people of developing maturity, who are able to understand the relevant information but whose relative immaturity means that they remain vulnerable. The consent of these young people is required, but is not sufficient to authorise research; and

(d) young people who are mature enough to understand and consent, and are not vulnerable through immaturity in ways that warrant additional consent from a parent or guardian.

It is not possible to attach fixed ages to each level – they vary from child to child. Moreover, a child or young person may at the one time be at different levels for different research projects, depending on the kind and complexity of the research. Being responsive to developmental levels is important not only for judging when children or young people are able to give their consent for research: even young children with very limited cognitive capacity should be engaged at their level in discussion about the research and its likely outcomes.

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

4.2.1 The research and its methods should be appropriate for the children or young people participating in the research.

4.2.2 In the research design researchers should:

(a) specify how they will judge the child's vulnerability and capacity to consent to participation in research;

(b) describe the form of proposed discussions with children about the research and its effects, at their level of comprehension; and

(c) demonstrate that the requirements of this chapter will be satisfied.

4.2.3 In educational research, discussion with the school community should be built into the research design.

Justice

4.2.4 When children and young people are not of sufficient maturity to consent to participation in research, it is justifiable to involve them only when:

(a) it is likely to advance knowledge about the health or welfare of, or other matters relevant to, children and young people; or

(b) children's or young people's participation is indispensable to the conduct of the research.

Beneficence

4.2.5 The circumstances in which the research is conducted should provide for the child or young person's safety, emotional and psychological security, and wellbeing.

Respect

4.2.6 Researchers should be attentive to the developmental level of children and young people when engaging them in understanding the nature and likely outcomes of research, and when judging their capacity to consent to the research.

4.2.7 Except in the circumstances described in paragraphs 4.2.10 and 4.2.11, specific consent to a child's or young person's participation in each research project should be obtained from:

(a) the child or young person whenever he or she has the capacity to make this decision; and

(b) either

(i) one parent, except when, in the opinion of the review body, the risks involved in a child's participation require the consent of both parents; or where applicable

(ii) the guardian or other primary care giver, or any organisation or person required by law.

4.2.8 An ethical review body may approve research to which only the young person consents if it is satisfied that he or she is mature enough to understand and consent, and not vulnerable through immaturity in ways that would warrant additional consent from a parent or guardian.

4.2.9 A review body may also approve research to which only the young person consents if it is satisfied that:

(a) he or she is mature enough to understand the relevant information and to give consent, although vulnerable because of relative immaturity in other respects;

(b) the research involves no more than low risk (see paragraph 2.1.6);

(c) the research aims to benefit the category of children or young people to which this participant belongs; and

(d) either

(i) the young person is estranged or separated from parents or guardian, and provision is made to protect the young person's safety, security and wellbeing in the conduct of the research (see paragraph 4.2.5). (In this case, although the child's circumstances may mean he or she is at some risk, for example because of being homeless, the research itself must still be low risk); or

(ii) it would be contrary to the best interests of the young person to seek consent from the parents, and provision is made to protect the young person's safety, security and wellbeing in the conduct of the research (see paragraph 4.2.5).

Standing parental consent

4.2.10 'Standing parental consent' enables parents to give standing consent (for example at the beginning of each school year) to their child's involvement in certain types of research in the school setting during that year. Under standing consent, parents are notified of each project, but are not required to give further consent for each project. They should be reminded with each notification that they may withdraw their consent for that project, and also may withdraw their standing consent at any time.

4.2.11 Schools may arrange for standing parental consent to be given for a child's participation in research that:

(a) is for the benefit of children; and

(b) comprises no more than overt observation in school classrooms or anonymous or coded (potentially identifiable) questionnaires or surveys on subject matters not involving

sensitive personal information or personal or family relationships.

4.2.12 For any other research, except under the conditions described in paragraphs 4.2.8 and 4.2.9, specific parental consent is needed for each project.

Best interests of the child

4.2.13 Before including a child or young person in research, researchers must establish that there is no reason to believe that such participation is contrary to that child's or young person's best interest.

4.2.14 A child or young person's refusal to participate in research should be respected wherever he or she has the capacity to give consent to that same research (see levels of maturity (c) and (d) in the Introduction to this chapter). Where a child or young person lacks this capacity, his or her refusal may be overridden by the parents' judgement as to what is in the child's best interest.

CHAPTER 4.3: PEOPLE IN DEPENDENT OR UNEQUAL RELATIONSHIPS

INTRODUCTION

This chapter is about pre-existing relationships between participants and researchers or between participants and others involved in facilitating or implementing the research. These relationships may compromise the voluntary character of participants' decisions, as they typically involve unequal status, where one party has or has had a position of influence or authority over the other. Examples may include relationships between:

- carers and people with chronic conditions or disabilities, including long-term hospital patients, involuntary patients, or people in residential care or supported accommodation;
- health care professionals and their patients or clients;
- teachers and their students;
- prison authorities and prisoners;
- governmental authorities and refugees;
- employers or supervisors and their employees (including members of the Police and Defence Forces);
- service-providers (government or private) and especially vulnerable communities to whom the service is provided.

Those mentioned first in each of these examples will sometimes be involved as researchers, as well as being involved in facilitating or implementing the research.

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

4.3.1 Being in a dependent or unequal relationship may influence a person's decision to participate in research. While this influence does not necessarily invalidate the decision, it always constitutes a reason to pay particular attention to the process through which consent is

negotiated.

4.3.2 In the consent process, researchers should wherever possible invite potential participants to discuss their participation with someone who is able to support them in making their decision. Where potential participants are especially vulnerable or powerless, consideration should be given to the appointment of a participant advocate.

4.3.3 In the research design, researchers should identify and take steps to minimise potentially detrimental effects of:

(a) an unequal or dependent relationship on the conduct of the research; and

(b) the research on participants involved in the relationship.

Justice

4.3.4 People in the categories of relationship described in the Introduction to this chapter are vulnerable to being over- researched because of the relative ease of access to them as research populations. Researchers should take account of this vulnerability in deciding whether to seek out members of these populations as research participants.

4.3.5 Where participants are in a relationship of dependency with researchers, researchers must take particular care throughout the research to minimise the impact of that dependency.

Beneficence

4.3.6 Researchers need to be mindful that in some relationships of dependency, participants may have an unrealistic expectation of the benefits of research.

4.3.7 A person declining to participate in, or deciding to withdraw from, research should not suffer any negative consequences, such as unfair discrimination, reduction in the level of care, dismissal from employment, or any other disadvantage (see paragraphs 2.2.19 and 2.2.20).

Respect

4.3.8 The design of research involving those in dependent relationships should not compromise respect for them.

4.3.9 Where the researcher has a pre-existing relationship with potential participants, it may be appropriate for their consent to be sought by an independent person.

4.3.10 Researchers should take special care to safeguard confidentiality of all information they receive, particularly in settings such as shared workplaces, hospital rooms or rooms in residential care.

CHAPTER 4.4: PEOPLE HIGHLY DEPENDENT ON MEDICAL CARE WHO MAY BE UNABLE TO GIVE CONSENT

INTRODUCTION

Medical care increasingly offers interventions or treatment for people at times of serious risk to their life or wellbeing. These risks may be temporary or permanent. People can become highly dependent on those interventions and treatments and may be incapable of comprehending their situation or of communicating about it. At the same time, research on those interventions and treatments is necessary to assess and improve their efficacy.

This chapter describes conditions under which research involving people highly dependent on medical care might proceed although their capacity to give consent is limited or non-existent.

In every instance, relevant jurisdictional laws will need to be taken into account.

Significant ethical issues are raised by research conducted in the following settings:

- neonatal intensive care;
- terminal care;
- emergency care;
- intensive care; and
- the care of unconscious people.

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, 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

4.4.1 Research involving people who are highly dependent on medical care may be approved where:

(a) it is likely that the research will lead to increased understanding about, or improvements in, the care of this population;

(b) the requirements of relevant jurisdictional laws are taken into account; and

(c) either

(i) any risk or burden of the proposed research to this particular participant is justified by the potential benefits to him or her; or

(ii) where participants have capacity to consent, any risk or burden is acceptable to them and justified by the potential benefits of the research.

Justice

4.4.2 People highly dependent on medical care may be exposed to severe threats to their lives, so that recruiting them into research might seem unfair. However, those people are entitled to participate in research and, when the conditions of paragraph 4.4.1 are met, their involvement is not unfair.

Beneficence

4.4.3 The distinguishing features of *neonatal intensive care research* are the small size and unique developmental vulnerability of the participants and the potential for very long-range impact on their growth, development and health. In this research, risks and potential benefits should be assessed with particular care by individuals or groups with relevant expertise.

4.4.4 The distinguishing features of *terminal care research* are the short remaining life expectancy of participants and their vulnerability to unrealistic expectations of benefits. Terminal care research should be designed so that:

(a) the benefits of research to individual participants or groups of participants, or to others in the same circumstances, justify any burden, discomfort or inconvenience to the participants;

(b) the prospect of benefit from research participation is not exaggerated;

(c) the needs and wishes of participants to spend time as they choose, particularly with family members, are respected; and

(d) the entitlement of those receiving palliative care to participate is recognised.

Respect

4.4.5 People involved in research to which this chapter applies may have impaired capacity for

verbal or written communication. Provision should be made for them to receive information, and to express their wishes, in other ways.

4.4.6 In *emergency care research,* recruitment into a research project often has to be achieved rapidly. Where the research involves emergency treatment and meets the requirements of 4.4.1, consent for the research may be waived provided the conditions of paragraph 2.3.6 are satisfied.

4.4.7 In *intensive care research*, heavy sedation may impair participants' cognition, and communication is difficult with people receiving ventilatory assistance. Whenever possible, consent to intensive care research, based on adequate information, should be sought from or on behalf of potential participants before admission to that level of treatment. When prior consent to research is not possible, the process described in paragraphs 4.4.9 to 4.4.14 should be followed.

4.4.8 In *research with unconscious people*, the participants cannot be informed about the research and their wishes cannot be determined. Those who are unconscious should be included only in minimally invasive research, or in research designed both to be therapeutic for them and to improve treatment for the condition from which they suffer.

Process to be followed

4.4.9 Consent should be sought from people highly dependent on medical care wherever they are capable of giving consent and it is practicable to approach them.

4.4.10 Where it is not practicable to approach a person highly dependent on medical care, or the person is not capable of making such a decision, consent should be sought from the participant's guardian, or person or organisation authorised by law, except under the circumstances described in paragraph 4.4.13.

4.4.11 When consent is to be sought, either from the potential participant or another on his or her behalf, steps should be taken to minimise the risk that:

(a) stress or emotional factors may impair the person's understanding of the research or the decision to participate; and

(b) the dependency of potential participants and their relatives on the medical personnel providing treatment may compromise the freedom of a decision to participate.

4.4.12 Where the researcher is also the treating health professional, it should be considered whether an independent person should make the initial approach and/or seek consent from potential participants or from others on their behalf.

4.4.13 When neither the potential participant nor another on his or her behalf can consider the proposal and give consent, an HREC may, having taken account of relevant jurisdictional laws, approve a research project without prior consent if:

(a) there is no reason to believe that, were the participant or the participant's representative to be informed of the proposal, he or she would be unwilling to consent;

(b) the risks of harm to individuals, families or groups linked to the participant, or to their financial or social interests, are minimised;

(c) the project is not controversial and does not involve significant moral or cultural sensitivities in the community;

and, where the research is interventional, only if in addition:

(d) the research supports a reasonable possibility of benefit over standard care;

(e) any risk or burden of the intervention to the participant is justified by its potential benefits to him or her; and

(f) inclusion in the research project is not contrary to the interests of the participant.

4.4.14 As soon as reasonably possible, the participant and/or the participant's relatives and authorised representative should be informed of the participant's inclusion in the research and of the option to withdraw from it without any reduction in quality of care.

CHAPTER 4.5: PEOPLE WITH A COGNITIVE IMPAIRMENT, AN INTELLECTUAL DISABILITY, OR A MENTAL ILLNESS

INTRODUCTION

The three kinds of condition discussed in this chapter are different. They are discussed in the one chapter, however, because many of the ethical issues they raise about research participation are very similar.

People with a cognitive impairment, an intellectual disability, or a mental illness are entitled to participate in research. While research involving these people need not be limited to their particular impairment, disability or illness, their distinctive vulnerabilities as research participants should be taken into account.

The capacity of a person with any of these conditions to consent to research, and the ability to participate in it, can vary for many reasons, including:

- the nature of the condition;
- the person's medication or treatment;
- the person's discomfort or distress;
- the complexity of the research project;
- fluctuations in the condition. For example, while intellectual disability is usually permanent, cognitive impairment and mental illness are often temporary or episodic.

Even when capable of giving consent and participating, people with these conditions may be more-than-usually vulnerable to various forms of discomfort and stress.

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, 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

4.5.1 The research design should take into account factors that may affect the capacity to receive information, to consent to the research, or to participate in it. These factors may be permanent or may vary over time.

4.5.2 Care should be taken to determine whether participants' cognitive impairment, intellectual disability or mental illness increases their susceptibility to some forms of discomfort or distress. Ways of minimising effects of this susceptibility should be described in the research proposal.

Justice

4.5.3 People with a cognitive impairment, an intellectual disability, or a mental illness are entitled to participate in research, and to do so for altruistic reasons.

Beneficence

4.5.4 Because of the participants' distinctive vulnerability, care should be taken to ensure that the risks and any burden involved in the proposed research are justified by the potential benefits of the research.

Respect

4.5.5 Consent to participation in research by someone with a cognitive impairment, an intellectual disability, or a mental illness should be sought either from that person if he or she has the capacity to consent, or from the person's guardian or any person or organisation authorised by law.

4.5.6 Where the impairment, disability or illness is temporary or episodic, an attempt should be made to seek consent at a time when the condition does not interfere with the person's capacity to give consent.

4.5.7 The process of seeking the person's consent should include discussion of any possibility that his or her capacity to consent or to participate in the research may vary or be lost altogether. The participant's wishes about what should happen in that circumstance should be followed unless changed circumstances mean that acting in accordance with those wishes would be contrary to the participant's best interests.

4.5.8 Consent under paragraph 4.5.6 should be witnessed by a person who has the capacity to understand the merits, risks and procedures of the research, is independent of the research team and, where possible, knows the participant and is familiar with his or her condition.

4.5.9 Where consent has been given by a person authorised by law, the researcher should nevertheless explain to the participant, as far as possible, what the research is about and what

participation involves. Should the participant at any time recover the capacity to consent, the researcher should offer him or her the opportunity to continue participation (under the terms of paragraph 4.5.6) or to withdraw.

4.5.10 Researchers should inform HRECs how they propose to determine the capacity of a person with a cognitive impairment, an intellectual disability, or a mental illness to consent to the research. This information should include:

(a) how the decision about the person's capacity will be made;

(b) who will make that decision;

(c) the criteria that will be used in making the decision; and

(d) the process for reviewing, during the research, the participant's capacity to consent and to participate in the research.

4.5.11 Refusal or reluctance to participate in a research project by a person with a cognitive impairment, an intellectual disability, or a mental illness should be respected.

CHAPTER 4.6: PEOPLE WHO MAY BE INVOLVED IN ILLEGAL ACTIVITIES

INTRODUCTION

Research may in some instances discover illegal activity (including notifiable activity) by participants or others, or may discover information indicating future illegal activity. Such research may:

- be intended to study, and perhaps to expose, illegal activity;
- be not specifically intended to discover illegal activity, but likely to do so;
- discover illegal activity inadvertently and unexpectedly.

In the first category there may be particular ethical questions about participants' consent (see *Chapter 2.2: General requirements for consent*). In all three categories both ethical and legal questions for researchers and institutions might arise from:

- what researchers might be obliged to disclose;
- the vulnerability of participants and researchers because of discovery of participants' illegal activity (see paragraph 5.1.2(b)(ii)).

Legal implications may include:

- a statutory obligation for a researcher to disclose information revealed or discovered;
- legal orders that compel disclosure of information obtained by a researcher.

This chapter is not concerned with investigation conducted as part of law enforcement. Nor does it contain information or guidance about legal obligations of researchers arising from their conduct of any research that discovers illegal activity. Further, it is not the role of a Human Research Ethics Committee (HREC) or other ethical review body to provide legal advice on the existence or performance of any of those obligations.

Research that is intended to study or expose illegal activity or that is likely to discover it 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, 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

4.6.1 Research designed to expose illegal activity should be approved only where the illegal activity bears on the discharge of a public responsibility or the fitness to hold public office. Variation of consent requirements for such research must comply with either paragraph 2.3.3 or paragraph 2.3.7.

4.6.2 Participants may be subject to risks because of their involvement in research that discovers illegal activity. It should be clearly established that these risks are justified by the benefits of the research. Where the research is designed to expose illegal activity under paragraph 4.6.1, that exposure may sometimes be benefit enough.

Justice

4.6.3 Where research discovers information about illegal activity by participants or others, researchers and institutions may become subject to orders to disclose that information to government agencies or courts. Decisions by researchers and institutions about how to respond to those orders should have regard to values and principles set out in this National Statement and to scholarly values of academic freedom and inquiry.

Beneficence

4.6.4 Consideration should be given to the use of pseudonyms, or to the removal of links between names and data, for participants whose illegal activity may be revealed or discovered in research.

Respect

4.6.5 Researchers may have contact with those participants in other professional roles. Where this is the case, researchers should make every effort to ensure both that the research is not compromised by contact in those other roles, and that other obligations to participants are not compromised by the research activity. In research that is likely, but not designed, to discover illegal activity, researchers should also make clear to participants when a contact or intervention is part of research and when it is not.

4.6.6 In research that may foreseeably discover illegal activity but is not designed to expose it, researchers should explain to participants as clearly as possible:

(a) the likelihood of such discovery and of any resulting legal obligation of disclosure the researcher may incur; and

(b) the extent to which the researcher will keep confidential any information about illegal activity by participants or others, and the response the researcher will make to any legal obligation or order to disclose such information.

4.6.7 Researchers should be satisfied that participants who are subject to criminal justice processes:

(a) are aware that the research may discover illegal activity; and

(b) do not have unrealistic expectations of benefit from their participation.

CHAPTER 4.7: ABORIGINAL AND TORRES STRAIT ISLANDER PEOPLES

INTRODUCTION

Research with Aboriginal and Torres Strait Islander Peoples spans many methodologies and disciplines. There are wide variations in the ways in which Aboriginal and Torres Strait Islander individuals, communities or groups are involved in or affected by research to which this chapter applies. The variations depend on the scope of the project, the demographics of participants, the illnesses or social phenomena under study, and their historical, social and cultural context and connections.

Researchers should address relevant issues of research design, ethics, culture and language. Depending on the field of study and complexity of the proposed research, these issues might be addressed in numerous ways. A cornerstone of an ethical research relationship with Aboriginal and Torres Strait Islander Peoples is respect for and valuing of cultural and language diversity.

For health research fitting the above description, researchers must consult *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (NHMRC 2003) ('Values and Ethics')*.

Other documents that might provide useful guidance for researchers are *Keeping research on track: A guide for Aboriginal and Torres Strait Islander peoples about health research ethics* (NHMRC 2005) and the *Guidelines for Ethical Research in Indigenous Studies* (Australian Institute of Aboriginal and Torres Strait Islander Studies 2002).

Human Research Ethics Committees (HRECs) are also required to apply the Values and Ethics guidelines as the basis for assessing proposals for health research with Aboriginal and Torres Strait Islander participation.

In applying Sections 1 and 2 of this National Statement, researchers from other disciplines, HRECs and other ethical review bodies may also find the Values and Ethics guidelines informative.

The Values and Ethics guidelines are based on six core values identified as being important to Aboriginal and Torres Strait Islander Peoples. The message for researchers is that there is great diversity across the many Aboriginal and Torres Strait Islander cultures and societies. Application of these core values, and of additional cultural and local-language protocols, should be determined by the Aboriginal and Torres Strait Islander communities or groups involved in the research. The six core values are:

- Reciprocity
- Respect

- Equality
- Responsibility
- Survival and protection
- Spirit and integrity.

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. The HREC process must have included assessment by or advice from:

- **people who have networks with Aboriginal and Torres Strait Islander Peoples and/or knowledge of research with Aboriginal and Torres Strait Islander Peoples; and**
- **people familiar with the culture and practices of the Aboriginal and Torres Strait Islander people with whom participation in the research will be discussed.**

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

4.7.1 The researcher should ensure that research methods are respectful and acknowledge the cultural distinctiveness of discrete Aboriginal and Torres Strait Islander communities or groups participating in the research – including national or multi-centre research.

4.7.2 There should be evidence of support for the research project from relevant Aboriginal and Torres Strait Islander communities or groups and the research methodology should engage with their social and cultural practices.

Justice

4.7.3 The researcher should ensure that research methods provide for mutually agreed mechanisms for such matters as:

(a) appropriate recruitment techniques;

(b) suitable information about the research;

(c) notification of participants' consent and of research progress; and

(d) final reporting.

4.7.4 The researcher should seek to identify any potential negative consequences of the proposed research, to design processes to monitor them, and to advise steps for minimising them.

Justice

4.7.5 The research methods and processes should provide opportunities to develop trust and a sense of equal research partnerships.

4.7.6 Where:

(a) the geographic location of the research is such that a significant number of the population are likely to be Aboriginal and Torres Strait Islander, and/or

(b) the research is focused on a topic or disease/health burden identified as being of specific concern to Aboriginal and Torres Strait Islander Peoples and the population base has a significant proportion of Aboriginal and Torres Strait Islander people, the research should provide fair opportunity for involvement of Aboriginal and Torres Strait Islander Peoples, and the guidelines in this chapter apply to those participants.

Beneficence

4.7.7 The benefits from research should include the enhancement or establishment of capabilities, opportunities or research outcomes that advance the interests of Aboriginal and Torres Strait Islander Peoples.

4.7.8 The described benefits from research should have been discussed with and agreed to by the Aboriginal or Torres Strait Islander research stakeholders.

4.7.9 The realisable benefits for Aboriginal and Torres Strait Islander participants from the research processes, outcomes and outputs should be distributed in a way that is agreed to and considered fair by these participants.

Respect

4.7.10 The research proposal should demonstrate evidence of respectful engagement with Aboriginal and Torres Strait Islander Peoples. Depending on the circumstances, this might require letters of support from Aboriginal and/ or Torres Strait Islander community Councils or other organisations accepted by the participating communities (see *Chapter 2.1: Risk and benefit and Chapter 2.2: General requirements for consent*, especially paragraph 2.2.13). The research processes should foster respectful, ethical research relationships that affirm the right of people to have different values, norms and aspirations.

4.7.11 The research approach should value and create opportunities to draw on the knowledge and wisdom of Aboriginal and Torres Strait Islander Peoples by their active engagement in the research processes, including the interpretation of the research data.

4.7.12 National or multi-centre researchers should take care to gain local level support for research

methods that risk not respecting cultural and language protocols.

CHAPTER 4.8: PEOPLE IN OTHER COUNTRIES

INTRODUCTION

When a researcher from an Australian institution proposes to conduct research in another country, additional ethical considerations may arise. In some situations, regard for the beliefs, customs and cultural heritage of participants will require recognition of values other than those of this National Statement. Sometimes these values will be in tension with one or more of the ethical values of this National Statement. Sometimes the legal, regulatory or ethical review processes of another country may also demand conduct that is in tension with the ethical values of this National Statement. The guidelines in this chapter must inform any resolution of these tensions.

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

4.8.1 Research conducted overseas by researchers from Australian institutions must comply with this National Statement.

4.8.2 Local cultural values should be acknowledged in the design and conduct of the research. It should be clearly established that such acknowledgement will result in participants being accorded no less respect and protection than this National Statement requires.

4.8.3 As far as is necessary to satisfy the requirements of paragraphs 1.10 to 1.13, the design and conduct of the research should reflect continuing consultation with the local participant population and the communities to which they belong (paragraph 4.8.19).

4.8.4 Researchers should inform ethical review bodies in Australia:

(a) whether, in the country in which they intend to do research, there are ethics approval processes that are relevant to that research, and whether any such processes are mandatory or voluntary in relation to the proposed research; and

(b) how such processes function, the values and principles on which they rely, and whether they require reporting of the Australian review body's approval.

4.8.5 Where there are no ethics approval processes in an overseas country, this National Statement may provide the only applicable process for ethical approval. In this case, the Australian ethical review body should take account of the available resources and means to conduct the

research and avoid imposing unrealistic requirements, providing always that research participants are accorded no less respect and protection than this National Statement requires.

4.8.6 Some funding or national requirements will direct researchers and review bodies to conform to the ethics guidelines of local institutions or to recognised international guidelines or instruments. Research conducted under those guidelines or instruments should be approved only if participants will be accorded no less respect and protection than this National Statement requires.

4.8.7 Researchers should have enough experience or access to expertise to enable them to engage with participants in ways that accord them due respect and protection.

4.8.8 When research is to be conducted overseas by a researcher who is subject to academic supervision, researchers should inform the Australian ethical review body of how that supervision is to be effected so that due respect and protection will be accorded to participants.

4.8.9 When co-researchers are to be recruited in an overseas country, researchers should inform a review body of how the capacity and expertise to conduct that part of the research assigned to the co-researchers will be established.

4.8.10 It is the responsibility of researchers to satisfy themselves that those co- researchers will carry out the research in a way that accords participants no less respect and protection than this National Statement requires.

Justice

4.8.11 The distribution of the burdens and benefits of research in overseas countries, for the participants and in some instances the broader community, should be fair and the research should not be exploitative.

4.8.12 The conduct of the research in other countries should take into account the opinions and expectations of participants and their communities about the effect of any limits of resources on:

(a) the way the research will be conducted;

(b) participants' post-research welfare; and

(c) application of the results of the research.

4.8.13 Institutions and researchers should find out whether research they are planning to do in another country is lawful in that country.

Beneficence

4.8.14 Researchers need to inform review bodies when participants will be in dependent relationships with researchers, whether through previous or proposed arrangements (see *Chapter 4.3: People in dependent or unequal relationships*).

4.8.15 Researchers need to know enough about the communities, and how to engage with them, to be able to assess the burdens and benefits of their research to the communities. Political and social factors that may jeopardise the safety of participants need to be taken into account. Researchers should inform review bodies about these likely burdens and benefits.

4.8.16 A local, readily accessible contact should be available to participants to receive responses, questions and complaints about the research. Responses and questions should be handled by the researcher. Researchers should ensure that there is a process independent of the researcher for dealing with complaints (see *Chapter 5.6: Handling complaints*).

4.8.17 In proposing mechanisms for monitoring research, researchers should take account of local circumstances.

4.8.18 Conducting research in other countries can expose researchers to risks of harm. Institutions and researchers should try to identify and evaluate any such risks, and make provision for dealing with them, for instance by establishing local academic or institutional affiliations.

Respect

4.8.19 Respect for participants in other countries requires having due regard for their beliefs, customs and cultural heritage, and for local laws.

4.8.20 Local beliefs and practices regarding recruitment, consent, and remuneration to participants or contributions to communities for participating in research should be taken into account in the design and the conduct of the research, and in the ethical review process.

4.8.21 It should be clearly established that the processes to be followed in recruiting participants and through which they choose whether to be involved are respectful of their cultural context.

SECTION 5: PROCESSES OF RESEARCH GOVERNANCE AND ETHICAL REVIEW

Human research encompasses a wide range of activities with an equally wide range of risks and potential benefits. The National Statement allows for different levels of ethical review of research, reflecting the difference in degree of risk involved (see *Chapter 2.1: Risk and benefit*).

This Section sets out the processes by which institutions establish, conduct and oversee those different levels of ethical review, and includes the operations of Human Research Ethics Committees (HRECs). The section also describes other processes of research governance that must be in place if the ethical review of research is to be undertaken well. These are considered only briefly, as they are more fully set out in the *Australian code for the responsible conduct of research*.

CHAPTER 5.1: INSTITUTIONAL RESPONSIBILITIES

GUIDELINES

Research governance

5.1.1 Institutions must see that any human research they conduct or for which they are responsible is:

(a) designed and conducted in accordance with the *Australian code for the responsible conduct of research*; and

(b) ethically reviewed and monitored in accordance with this National Statement.

5.1.2 Each institution needs to be satisfied that:

(a) its human research meets relevant scholarly or scientific standards;

(b) those conducting its human research:

(i) are either adequately experienced and qualified, or supervised;

(ii) understand the need to assess risks to their own safety and that of participants; and

(iii) are free to withdraw from research on conscientious grounds.

5.1.3 Institutions may establish their own processes for ethical review of research, or use those of another institution.

5.1.4 Whichever option under 5.1.3 is adopted, institutions need to be satisfied that processes are in place for:

(a) managing conflicts of interest (Chapter 5.4);

(b) monitoring research (Chapter 5.5);

(c) handling complaints (Chapter 5.6); and

(d) ensuring accountability (Chapter 5.7).

5.1.5 Institutions should use and promote clearly formulated, documented, accessible and current policies and procedures for research governance and ethical review.

Processes for ethical review

5.1.6 The following types of research require review by a Human Research Ethics Committee (HREC):

(a) all research that involves more than low risk;

(b) research falling under the following chapters (except where research on collections of non-identifiable data under these chapters satisfies the conditions for exemption from review – see paragraphs 5.1.22 and 5.1.23): *Chapter 3.3: Interventions and therapies, including clinical and non-clinical trials, and innovations Chapter 3.5: Human genetics, Chapter 4.1: Women who are pregnant and the human fetus, Chapter 4.4: People highly dependent on medical care who may be unable to give consent, Chapter 4.5: People with a cognitive impairment, an intellectual disability, or a mental illness, Chapter 4.7: Aboriginal and Torres Strait Islander Peoples, and some categories of research falling under Chapter 4.6: People who may be involved in illegal activities* (see first bolded paragraph for details).

5.1.7 For research that carries only low risk (see paragraph 2.1.6) and does not fall under any of the chapters listed in paragraph 5.1.6, institutions may choose to establish other levels of ethical review. These levels are described in paragraphs 5.1.18 to 5.1.21.

5.1.8 Research that carries only negligible risk (see paragraph 2.1.7) and meets the requirements of paragraphs 5.1.22 and 5.1.23 may be exempted from ethical review.

Legal protection for those involved in ethical review of research

5.1.9 Institutions should provide an assurance of legal protection to all those involved in ethical review of research, for liabilities that may arise in the course of bona fide conduct of their duties in this capacity.

Oversight and review of ethical review procedures

5.1.10 Institutions that set up levels of ethical review other than HREC, as described in paragraphs 5.1.18 to 5.1.23, must establish criteria for allocating research to these different levels of review (including exemption from review), taking into account *Chapter 2.1: Risk and benefit*. These criteria must be readily accessible to all those involved in the conduct and review of research.

5.1.11 The ethical values and principles in this National Statement should be the basis on which institutions establish different levels of ethical review, allocate different kinds of research to them, and review those allocations.

5.1.12 Institutions must monitor any processes of ethical review of low risk research to ensure those processes continue to provide sufficient protection for participants.

5.1.13 Institutions should regularly assess all their ethical review processes, including the criteria for allocating research to different levels of review, to ensure that those processes continue to enable the institution to meet its responsibilities under this National Statement.

5.1.14 Where possible this assessment should be informed by the documented experience of research participants and/ or by involving participants or the wider community in the assessment.

5.1.15 Institutions should also remain alert to emerging ethical issues in any area of human research that may warrant changing the level of ethical review required.

5.1.16 To enable assessment of their ethical review processes, institutions should prepare and make readily accessible regular reports on all of those processes.

5.1.17 Institutions should have in place an auditing process to confirm that:

(a) research in their institution is being reviewed at the levels of review their criteria require;

(b) research is being exempted from review only in accordance with the criteria set out in paragraphs 5.1.22 and 5.1.23.

Research involving no more than low risk

5.1.18 Institutions that establish any non- HREC levels of ethical review for low risk research must have the resources and capacity to carry out such review competently and professionally.

5.1.19 Where institutions establish such non- HREC levels of ethical review for low risk research, that review must:

(a) be carried out by people who are familiar with this National Statement and have an understanding of the ethical issues that can arise in the research under review;

(b) be informed by *Section 1: Values and Principles of Ethical Conduct, Section 3: Ethical Considerations Specific to Research Methods or Fields and Section 4: Ethical Considerations Specific to Participants*;

(c) take account of researchers' judgements as to whether their research is suitable for review by a non-HREC process;

(d) have due regard to relevant privacy regulation.

5.1.20 The levels of ethical review referred to in paragraph 5.1.18 may include, but need not be limited to:

(a) review or assessment at departmental level by the head of department;

(b) review or assessment by a departmental committee of peers (with or without external or independent members);

(c) delegated review with reporting to an HREC; or

(d) review by a subcommittee of an HREC.

5.1.21 Those reviewing research at a non-HREC level must refer to an HREC any research they identify as involving more than low risk.

Research that can be exempted from review

5.1.22 Institutions may choose to exempt from ethical review research that:

(a) is negligible risk research (as defined in paragraph 2.1.7); and

(b) involves the use of existing collections of data or records that contain only non-identifiable data about human beings.

5.1.23 Institutions must recognise that in deciding to exempt research from ethical review, they are determining that the research meets the requirements of this National Statement and is ethically acceptable.

HRECs: research involving more than low risk

5.1.24 Each institution that conducts human research involving more than low risk must ensure that this research is reviewed and approved by an HREC that is constituted and functioning in accordance with this National Statement, whether or not that HREC is established by the institution.

5.1.25 Institutions[5] that establish HRECs are responsible for ensuring that those HRECs are established and continue to operate in accordance with this National Statement.

Establishment of HRECs

5.1.26 Institutions that individually or jointly establish HRECs should adequately resource and maintain them. Resourcing should be sufficient to enable HRECs:

(a) to satisfy the requirements for sound ethical review (see paragraph 5.1.37);

(b) to communicate well with researchers (see paragraphs 5.2.13 to 5.2.15);

(c) not to charge fees where doing so would discourage research the institution has an obligation to support.

5.1.27 When establishing an HREC, an institution should set out and publicise its terms of reference, including:

(a) the scope of its responsibilities for ethical review;

(b) its relationship to other processes of research review;

(c) its relationship to non-affiliated researchers;

(d) its institutional accountability;

(e) its mechanisms of reporting;

(f) not to charge fees where doing so would discourage research the institution has an obligation to support.

(g) remuneration, if any, for members.

5.1.28 Where an institution has established an HREC, the institution is responsible for ensuring that:

(a) members have relevant experience and/or expertise;

(b) members undertake:

(i) appropriate induction, which could include mentoring by a current HREC member, and

(ii) continuing education;

(c) review of research proposals is thorough;

(d) review processes and procedures are expeditious;

(e) decisions are transparent, consistent, and promptly communicated;

(f) actual and potential conflicts of interest that may affect research and its review are identified and managed (see *Chapter 5.4: Conflicts of interest*);

(g) membership of the HREC is made public in annual reports or by other routine processes, and is available to researchers submitting research proposals to that HREC;

(h) good communication between the institution/s, the HREC and researchers is promoted;

(i) the workload of the HREC does not compromise the quality and timeliness of ethical review; and

(j) any institution using the HREC can be assured the HREC is operating in accordance with this National Statement.

Composition of HRECs

5.1.29 The minimum membership of an HREC is eight. As far as possible:

(a) there should be equal numbers of men and women; and

(b) at least one third of the members should be from outside the institution for which the HREC is reviewing research.

5.1.30 This minimum membership is:

(a) a chairperson, with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under this National Statement;

(b) at least two lay people, one man and one woman, who have no affiliation with the institution and do not currently engage in medical, scientific, legal or academic work;

(c) at least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people; for example, a nurse or allied health professional;

(d) at least one person who performs a pastoral care role in a community, for example, an Aboriginal elder, a minister of religion;

(e) at least one lawyer, where possible one who is not engaged to advise the institution; and

(f) at least two people with current research experience that is relevant to research proposals to be considered at the meetings they attend. These two members may be selected, according to need, from an established pool of inducted members with relevant expertise.

5.1.31 No member may be appointed in more than one of the categories listed in paragraph 5.1.30, but institutions are encouraged to establish a pool of inducted members in each category. These members may attend meetings as needed to meet minimum HREC requirements, and may also be available to provide expertise for the research under review.

5.1.32 Wherever possible one or more of the members listed in 5.1.30 should be experienced in reflecting on and analysing ethical decision-making.

5.1.33 The institution should ensure that the HREC has access to the expertise necessary to enable it to address the ethical issues arising from the categories of research it is likely to consider. This may necessitate going outside the HREC membership.

Appointment of HREC members

5.1.34 Members should be appointed to an HREC using open and transparent processes. Institutions should consider reviewing appointments to the HREC at least every three years.

5.1.35 Members should be appointed as individuals for their knowledge, qualities and experience, and not as representatives of any organization, group or opinion.

5.1.36 Members should be provided with a formal notice of appointment.

HREC procedures

5.1.37 An institution that establishes an HREC should ensure that the HREC establishes, implements and documents working procedures to promote good ethical review, including procedures for:

(a) frequency of meetings;

(b) attendance at meetings;

(c) conduct and structure of meetings and deliberations;

(d) preparation of agendas and minutes;

(e) timely distribution of papers before meetings;

(f) presentation of applications for ethical review;

(g) timely consideration and review of applications;

(h) managing conflicts of interest (see paragraphs 5.4.1 to 5.4.6);

(i) communicating with researchers, including face to face, by telephone and in writing (including email) (see paragraphs 5.2.13 to 5.2.15);

(j) reporting on its activities to the institution;

(k) methods of decision making;

(l) prompt notification of decisions;

(m) record keeping (see paragraphs 5.2.23 to 5.2.27);

(n) monitoring of approved research (see paragraphs 5.5.1 to 5.5.5);

(o) reporting and handling of adverse events;

(p) receiving and handling of complaints (see paragraphs 5.6.1 to 5.6.7);

(q) advising the institution/s of decisions to withdraw ethical approval of a research project (see paragraphs 5.5.7 to 5.5.9);

(r) attendance, as observers, of people other than members or researchers (see paragraph 5.2.18) at meetings;

(s) fees, if any, to be charged; and

(t) appropriate confidentiality of the content of applications and the deliberations of review bodies.

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[5] Where the context is the establishment and maintenance of an HREC, 'institutions' also includes any body or agency that establishes an HREC but does not conduct human research.

CHAPTER 5.2: RESPONSIBILITIES OF HRECS, OTHER ETHICAL REVIEW BODIES, AND RESEARCHERS

GUIDELINES

Review body procedures

5.2.1 Institutions that set up non-HREC levels of ethical review should ensure that they have good working procedures for those levels. These should include the procedures from paragraph 5.1.37 and paragraphs 5.2.24 to 5.2.27 that are necessary for sound review at each of those levels.

Review body member responsibilities

5.2.2 Each member of an ethical review body is responsible for deciding whether, in his or her judgement, a proposal submitted to the review body meets the requirements of this National Statement and is ethically acceptable.

5.2.3 To fulfil that responsibility, each member of a review body should:

(a) become familiar with this National Statement, and consult other guidelines relevant to the review of specific research proposals;

(b) prepare for and attend scheduled meetings of the review body or, if unavailable, provide opinions on the ethical acceptability of research proposals before meetings, subject to institutional policies on absences; and

(c) attend continuing education or training programs in research ethics at least every three years.

5.2.4 Members of a review body should disclose to it any actual or potential conflict of interest, including any financial or other interest or affiliation, that bears on any research coming before the review body (see paragraph 5.4.5).

Researcher responsibilities

5.2.5 In each research proposal, the researcher/s should demonstrate that the research has merit and reflects the ethical values of justice, beneficence and respect for humans (see paragraph 1.1).

5.2.6 Research proposals should be clear and comprehensive, and written in lay language.

5.2.7 A researcher should disclose to the review body the amount and sources or potential sources of funding for the research.

5.2.8 A researcher developing or designing a research proposal involving two or more institutions should inform them all at an early stage in this process.

5.2.9 A researcher should keep an auditable record of any research he or she is undertaking that is exempted from ethical review in accordance with paragraphs 5.1.22 and 5.1.23.

5.2.10 A researcher should disclose to the review body any actual or potential conflicts of interest, including any financial or other interest or affiliation, that bears on the research (see *Chapter 5.4: Conflicts of interest*).

5.2.11 When reporting the research, a researcher should again disclose any actual or potential conflicts of interest, including any financial or other interest or affiliation, that bears on the research.

5.2.12 For researcher responsibilities in relation to monitoring, see *Chapter 5.5: Monitoring approved research.*

Good communication between review bodies and researchers

5.2.13 Good ethical review requires open communication between review bodies and researchers, and a shared commitment to the review process. The process should not be adversarial. Institutions should encourage this shared commitment by promoting:

(a) awareness of this National Statement among researchers; and

(b) ready accessibility of review bodies and their staff to researchers.

5.2.14 Misunderstandings can often arise when only written communication is used. From the outset review bodies should encourage informal communication with researchers, and should consider face-to-face meetings to resolve issues about research proposals that have not been resolved by written or telephone communication.

5.2.15 Open communication of these kinds has implications for the resourcing of review bodies (see paragraphs 5.1.18, and 5.1.26).

Participants' interests

5.2.16 Information about research should be presented to participants in ways that help them to make good choices about their participation, and support them in that participation. These ways must take into account:

(a) whether the information is best communicated through speech, writing, some other way, or a combination of these;

(b) the need for accurate and reliable translation (written and/or oral) into a participant's first language or dialect;

(c) culture and its effects on how language (English or other) is understood;

(d) educational background and level;

(e) age;

(f) visual, hearing or communication impairment.

5.2.17 A review body should consider consulting a participant advocate to help it assess whether a proposal under consideration adequately provides for participants' decision making and understanding.

Researchers or experts at review body meetings

5.2.18 A review body (HREC or other) may invite researcher/s, and researchers may request, to be present for discussion of their proposed research.

5.2.19 A review body may seek advice from experts to help in considering a research proposal (eg, as in paragraph 5.1.33). Such experts should be bound by the same confidentiality requirements as the review body members. Any conflicts of interest they may have should be disclosed and managed (see paragraphs 5.4.1 to 5.4.6).

5.2.20 Communication between a research sponsor and a review body should be avoided where it may, or may be perceived to, influence the ethical review and approval of the project.

Making and communicating decisions

5.2.21 A review body may approve, request amendment of, or reject a research proposal on ethical grounds.

5.2.22 The review body must clearly communicate its decision to the researcher/s:

(a) Where a proposal is approved, communication must be in writing (which may include email) and should include an explicit statement that the proposal meets the requirements of this National Statement.

(b) Where amendments are requested, communication may be written or, where appropriate, informal (see paragraph 5.2.14). Reasons should be given for the requested amendments.

(c) Where a proposal is rejected, communication of the rejection must be in writing (which may include email) and should include reasons linked to this National Statement.

Documents and records

5.2.23 All documents and other material used in recruiting potential research participants, including advertisements, letters of invitation, information sheets and consent forms, should be approved by the review body.

5.2.24 A review body should maintain a record of all research proposals received and reviewed, including at least the:

(a) name/s of the institution/s to which the research approval is provided;

(b) project identification number/s;

(c) name/s of principal researcher/s;

(d) title of the project;

(e) correspondence between the review body and the researcher about the review;

(f) acceptance or rejection of any changes to the proposal;

(g) proposed date of completion of the proposal;

(h) formal advice of final ethical approval or non-approval, with date;

(i) terms and conditions, if any, of approval of any proposal;

(j) duration of the approval;

(k) name of any other review body whose opinion was considered;

(l) mechanisms to be used to monitor the conduct of the research; and

(m) relevance, if any, of the Commonwealth, State or Territory legislation or guidelines relating to privacy of personal or health information.

5.2.25 In addition, a review body should retain on file a copy of each research proposal and application for ethical approval, including any information sheets, consent forms or relevant correspondence, in the form in which they were approved.

5.2.26 A review body should record decisions about approval, amendment or rejection of proposals in written or electronic form, with reasons for those decisions, linking those reasons to this National Statement.

5.2.27 Where more than one review body has reviewed a research proposal, each such review body should record, as far as possible (see paragraph 5.3.3):

(a) details of other review body/ies involved;

(b) the decision/s of each other review body; and

(c) details of any amendments required by each other review body.

HREC meetings

5.2.28 As far as possible, each HREC meeting should be arranged to enable at least one member in each category to attend (see paragraphs 5.1.29 to 5.1.32). Meeting papers should be provided enough in advance to enable members to be fully informed.

5.2.29 Decisions by an HREC about whether a research proposal meets the requirements of this National Statement must be informed by an exchange of opinions from each of those who constitute the minimum membership (see paragraph 5.1.30). This exchange should, ideally, take place at a meeting with all those members present.

5.2.30 Where there is less than full attendance of the minimum membership at a meeting, the Chairperson should be satisfied, before a decision is reached, that the views of those absent who belong to the minimum membership have been received and considered.

5.2.31 An HREC should endeavour to reach decisions by general agreement. This need not involve unanimity.

CHAPTER 5.3: MINIMISING DUPLICATION OF ETHICAL REVIEW

INTRODUCTION

Research projects that may generate duplication of ethical review in Australia include:

- a research project conducted at more than one institution, either by the same or different researchers;
- a research project conducted jointly by researchers affiliated with different institutions;
- a research project conducted at one institution by a researcher affiliated (c) with another institution, for example, a university-based researcher conducting research at a hospital;
- a research project approved at one (d) institution and transferred to another, for example, when a researcher changes institutions; and
- any other research for which more than one institution has responsibility for ethical review and approval.

GUIDELINES

5.3.1 Wherever more than one institution has a responsibility to ensure that a human research project is subject to ethical review (see paragraph 5.1.1), each institution has the further responsibility to adopt a review process that eliminates any unnecessary duplication of ethical review.

5.3.2 Different institutions that regularly have review responsibilities for the same research (for example, universities and related teaching hospitals) should agree on a single review body to review the research.

5.3.2 Where an institution decides to rely on ethical review by a body it has not established, it should undertake:

(a) to identify any local circumstances relevant to the ethical review of its research, disclose these circumstances to the review body/ies, and provide for their management;

(b) to exchange relevant information and advice with the review body/ies;

(c) not to duplicate an existing, duly authorised scientific/technological/ methodological assessment of the research;

(d) to establish the roles, if any, the institution and the review body/ies may have in monitoring the research;

(e) to inform participants if the research is discontinued; and

(f) to adopt any other administrative procedures that will avoid unnecessary duplication of ethical review.

5.3.4 Where paragraphs 5.3.1 to 5.3.3 apply, researchers should inform the ethical review body that reviews and approves the research:

(a) of all other sites at which the research will be conducted, and of the name and location of any other body that will conduct an ethical review of the research; and

(b) of any previous decisions made about the research by other review bodies (in Australia or elsewhere).

CHAPTER 5.4: CONFLICTS OF INTEREST

INTRODUCTION

A conflict of interest in the context of research exists where:

- a person's individual interests or responsibilities have the potential to influence the carrying out of his or her institutional role or professional obligations in research; or
- an institution's interests or responsibilities have the potential to influence the carrying out of its research obligations.

While a conflict may relate to financial interests, it can also relate to other private, professional or institutional benefits or advantages that depend significantly on the research outcomes.

A conflict of interest may compromise the research process itself and/or the institutional processes governing research, and may lead researchers or institutions to base decisions about the research on factors outside the research requirements.

A perception that a conflict of interest exists can be as serious as an actual conflict, raising concerns about an individual's integrity or an institution's management practices.

GUIDELINES

5.4.1 Institutions should establish transparent processes to identify and manage actual and potential conflicts of interest involving:

(a) the institution itself;

(b) researchers; or

(c) ethical review bodies, their members or advisors.

5.4.2 An institution with a conflict of interest bearing on research should inform relevant ethical review bodies about the conflict.

5.4.3 Ethical review bodies should see that measures are adopted to manage conflicts of interest involving researchers (see paragraph 5.2.10). These measures may include requiring that:

(a) the information be disclosed to research participants;

(b) a person other than the researcher make the initial approach to participants;

(c) the information be disclosed in any report of the research;

(d) the research be conducted by another researcher; or

(d) the research not be conducted.

5.4.4 Where an ethical review body becomes aware that there may be a conflict of interest involving the institution, the review body should notify the institution.

5.4.5 An ethical review body should require its members, and also any experts whose advice it seeks, to disclose any actual or potential conflict of interest in research to be reviewed, including any:

(a) personal involvement or participation in the research;

(b) financial or other interest or affiliation; or

(c) involvement in competing research.

The review body should adopt measures to manage such conflicts. In the case of members these measures may include exclusion from a meeting, or from some or all of the body's deliberations, or in the case of expert advisors, requesting only written advice from them.

5.4.6 Sometimes a researcher who discloses the fact that he or she has a conflict of interest may have an ethically acceptable reason for not disclosing what the conflict is, for example, that this might breach another person's privacy. The researcher may then remain involved in the research only if the review body is satisfied that the conflict can be managed without its nature being disclosed.

CHAPTER 5.5: MONITORING APPROVED RESEARCH

INTRODUCTION

Monitoring of research here refers to the process of verifying that the conduct of research conforms to the approved proposal. Responsibility for ensuring that research is reliably monitored lies with the institution under which the research is conducted.

Mechanisms for monitoring can include:

(a) reports from researchers;

(b) reports from independent agencies (such as a data and safety monitoring board);

(c) review of adverse event reports;

(d) random inspections of research sites, data, or consent documentation; and

(e) interviews with research participants or other forms of feedback from them.

GUIDELINES

Monitoring approved research

5.5.1 Each institution has ultimate responsibility for ensuring, via its research governance arrangements, that all its approved research is monitored.

5.5.2 The frequency and type of monitoring should reflect the degree of risk to research participants.

5.5.3 Researchers have a significant responsibility in monitoring, as they are in the best position to observe any adverse events or unexpected outcomes. They should report such events or outcomes promptly to the relevant institution/s and ethical review body/ies, and take prompt steps to deal with any unexpected risks. For monitoring of approved clinical research, see paragraphs 3.3.19 to 3.3.22.

5.5.4 Researchers are responsible for notifying the review body that mechanisms for monitoring are in place, and for satisfying the review body that the mechanisms are appropriate to the research.

5.5.5 At regular periods – reflecting the degree of risk, and at least annually and at the completion of the project – researchers should provide reports to the relevant review body/ies and institution/s, including information on:

(a) progress to date, or outcome in the case of completed research;

(b) maintenance and security of records;

(c) compliance with the approved proposal; and

(d) compliance with any conditions of approval.

Suspension or cessation of research

5.5.6 Researchers should inform the relevant institution/s, the review body/ies that approved the research and, wherever possible, the research participants, if the research project is to be discontinued before the expected date of completion, and why. For research at more than one site, or research where there has been multiple ethical review, it must be clearly established, before the research begins, how this information will be communicated.

5.5.7 Where a review body finds reason to believe that continuance of a research project will compromise participants' welfare, it should immediately seek to establish whether ethical approval for the project should be withdrawn. This process should ensure that researchers and others involved in the project are treated fairly and with respect.

5.5.8 Where ethical approval for a research project is withdrawn:

(a) the researcher, the institution/s and, where possible, the participants should be informed of the withdrawal;

(b) the institution must see that the researcher promptly suspends the research and makes arrangements to meet the needs of participants; and

(c) the research may not be resumed unless either

(i) the researcher subsequently establishes that continuance will not compromise participants' welfare; or

(ii) the research is modified to provide sufficient protection for participants, the modification is ethically reviewed, and the modified research is approved.

5.5.9 If an institution or review body considers that urgent suspension of research is necessary before the process described in paragraphs 5.5.7 and 5.5.8 is undertaken, the instruction to stop should come *via* the management of the institution.

5.5.10 In the light of reports received under paragraph 5.5.3 and paragraph 5.5.5, review bodies may require researchers to amend research procedures to protect participants. If such amendments cannot achieve that end, a review body may rely on the provisions of paragraphs 5.5.6 to 5.5.9.

CHAPTER 5.6: HANDLING COMPLAINTS

INTRODUCTION

Institutions may receive complaints about researchers or the conduct of research, or about the conduct of a Human Research Ethics Committee (HREC) or other ethical review body. Complaints may be made by participants, researchers, staff of institutions, or others. All complaints should be handled promptly and sensitively.

The *Australian code for the responsible conduct of research* describes 'research misconduct' and specifies institutional processes for dealing with it. Where complaints about researchers or research raise the possibility of misconduct fitting this description, they should be dealt with under those processes. Where complaints about researchers are serious and fall outside that description of research misconduct, they should be handled under institutional processes for dealing with other forms of misconduct, for example harassment or bullying.

There can be justifiable differences of opinion as to whether a research proposal meets the requirements of this National Statement. For this reason, while this chapter provides for complaints about the process of review, it does not provide for appeals by researchers against a final decision to reject a proposal.

GUIDELINES

5.6.1 To handle complaints about researchers or the conduct of research, institutions should:

(a) identify a person, accessible to participants, to receive these complaints; and

(b) establish procedures for receiv ing, handling and seeking to resolve such complaints.

5.6.2 Where such complaints raise the possibility of 'research misconduct' as described in the *Australian code for the responsible conduct of research*, they should be handled in accordance with the 'research misconduct' processes specified in that document.

5.6.3 Where complaints about researchers allege serious misconduct that falls outside the range of 'research misconduct' as described in the *Australian code for the responsible conduct of research*, they should be dealt with under institutional processes for dealing with other forms of misconduct, for example harassment or bullying.

5.6.4 Institutions should also establish procedures for receiving, handling and seeking to resolve complaints about the conduct of review bodies in reviewing research proposals.

5.6.5 Where these complaints cannot be readily resolved by communication between the complainant and the review body that is the subject of the complaint, complainants should have access to a person external to that review body to handle the complaint.

5.6.6 Institutions should identify a person or agency external to the institution to whom a person can take a complaint that has not been resolved by the processes referred to in paragraphs 5.6.1 to 5.6.5.

5.6.7 Institutions should publicise their complaints-handling procedures.

CHAPTER 5.7: ACCOUNTABILITY

INTRODUCTION

Responsibility for the ethical design, review and conduct of human research is exercised at different levels, from the detail of research conduct to the more general oversight of review and funding. Accordingly, responsibility is exercised at the different levels by:

- researchers (and where relevant their supervisors);
- an institution's interests or responsibilities have the potential to influence the carrying out of its research obligations.
- institutions whose employees, resources or facilities are involved;
- funding organisations;
- agencies that set standards; and
- governments.

The line of accountability for these responsibilities runs:

- from researchers to review bodies and institutions;
- from review bodies and institutions to funders and other agencies;
- from agencies to government; and
- from government to the Australian public.

Typically, this accountability involves reporting from one level to the next.

GUIDELINES

5.7.1 Researchers have responsibilities for the ethical design and conduct of research. The measures of accountability by which researchers demonstrate, to institutions and to review bodies, fulfilment of those responsibilities appear in *Chapter 5.1: Institutional responsibilities, Chapter 5.2: Responsibilities of HRECs, other ethical review bodies and researchers*, and paragraph 3.3.22, on the monitoring of approved clinical research. Researchers also have responsibilities under the Australian code for the responsible conduct of research.

5.7.2 Review bodies have responsibilities for the ethical review of research. The measures of accountability by which review bodies demonstrate to institutions their fulfilment of those

responsibilities appear in *Chapter 5.2: Responsibilities of HRECs, other ethical review bodies, and researchers*.

5.7.3 Institutions have responsibilities:

(a) to ensure that ethical review of research occurs. These responsibilities are set out in *Chapter 5.1: Institutional responsibilities*; and

(b) for the conduct of research. These responsibilities are set out in the *Australian code for the responsible conduct of research*. They include ensuring that research is both sound and lawful, and is conducted or supervised by educated and experienced researchers.

5.7.4 In addition to providing information annually, institutions shall, on reasonable request, provide other information about their ethical review processes to the NHMRC.

5.7.5 Institutions that are in receipt of NHMRC research funding, or intend to remain eligible for it, must be registered with the NHMRC. Registration will include information about any HREC/s or other review bodies which the institution has decided to use or has established.

5.7.6 The deed of agreement attached to any NHMRC funding requires that institutions attest annually to the NHMRC in writing that their research governance and ethical oversight processes remain compliant with this National Statement and the *Australian code for the responsible conduct of research*.

APPENDIX: PROCESS REPORT

BACKGROUND

The *National Statement on Ethical Conduct in Research Involving Humans* ('the National Statement') 1999 has been revised in line with the National Health and Medical Research Council (NHMRC) policy that all its guidelines be reviewed at least every five years. In September 2003 the Australian Health Ethics Committee (AHEC), a principal committee of the NHRMC, established a working committee to review the National Statement. The revision was undertaken jointly by the NHMRC, the Australian Research Council (ARC), and the Australian Vice Chancellors' Committee (AVCC), and the Working Committee consisted of the following members from AHEC, the ARC and the AVCC:

Working Committee

Dr Christopher Cordner (Chair)	Member of AHEC 2003 - 2006 triennium
Dr Kerry Breen	Chair of AHEC 2003 - 2006 triennium
Mr Christopher Coyne	Member of AHEC 2003 - 2006 triennium, Member of AHEC 2006 - 2009 triennium
Professor Joy Damousi	AVCC Nominee
Associate Professor Terry Dunbar	Member of AHEC 2003 - 2006 triennium, Member of AHEC 2006 - 2009 triennium
Professor Graeme Hugo	ARC Nominee
Reverend Professor John Morgan	Member of AHEC 2003 - 2006 triennium
Professor Elim Papadakis	ARC Nominee
Associate Professor Wendy Rogers	Member of AHEC 2003 - 2006 triennium
Professor Doreen Rosenthal AO	Member of AHEC 2003 - 2006 triennium
Mr Noel Spurr OAM	Member of AHEC 2003 - 2006 triennium
Professor Jane Stein-Parbury	AVCC Nominee
Ms Fiona Stoker	Member of AHEC 2003 - 2006 triennium
Professor Colin Thomson	NHMRC consultant 2003 - 2006 triennium, Chair AHEC 2006 - 2009 triennium
Dr Nicholas Tonti-Filippini	Member of AHEC 2003 - 2006 triennium, Member of AHEC 2006 - 2009 triennium

Reverend Bill Uren	Member of AHEC 2003 - 2006 triennium

Secretariat

Ms Nerida Lawrentin	September 2003 - June 2005
Ms Nicola Cooper	June 2005 - December 2006
Mr Matthew Sammels	May 2006 - March 2007

Consultant

Dr Angela Kirsner	Technical Writer

Process

Following the development of a first draft, and in accordance with section 13 of the National Health and Medical Research Council Act 1992, Australian Health Ethics Committee (AHEC) undertook public consultation from January to March 2005. This consultation resulted in 178 submissions. A second draft was then prepared taking into account the submissions received.

A further consultation was undertaken from January to March 2006, which resulted in 184 submissions. These submissions informed the final draft. Details of the submissions that were not confidential were placed on the website during the revision process at:
http://www.nhmrc.gov.au/ethics/human/ahec/ consultation/submissions/statement.htm

http://www.nhmrc.gov.au/ethics/human/ahec/ consultation/submissions/statementsec.htm.

Experts were consulted throughout the redrafting process on a number of issues. A workshop was also held with several institutions that are known to have developed models for devolving review of low risk research, to determine the methods of streamlining ethical review of research.

After completion of the final draft and agreement by the AHEC from the 2006 – 2009 triennium, both the Australian Research Council and the Australian Vice Chancellors' Committee were invited to approve the final draft. This agreed version was then presented to the Council of the NHMRC at its 164th Session in March 2007 for consideration.

At that Session the Council agreed to advise the CEO that the final draft should be issued.

GLOSSARY

accountability

The measures by which researchers, review bodies and institutions can demonstrate that their responsibilities have been, or are being, fulfilled. Typical accountability measures involve reporting from one level of the hierarchy to a higher (or more general) level.

adverse device event

A clinical sign, symptom or condition that is causally related to the device implantation procedure, the presence of the device, or the performance of the device system.

adverse drug reaction

Any noxious and unintended response to an unapproved medicinal product, related to any dose. The phrase "response to an unapproved medicinal product" means that a causal relationship between the product and an adverse event is at least a reasonable possibility, i.e. the relationship cannot be ruled out. ('Unapproved medicinal product' here includes approved products used at levels or in ways that are unapproved).

or

A noxious and unintended response to a drug that occurs at doses of marketed medical products normally used in humans for prophylaxis, diagnosis or therapy of diseases or for modification of physiological function.

adverse event (device)

Any undesirable clinical occurrence in a subject, whether it is considered to be device-related or not, that includes a clinical sign, symptom or condition and/or an observation of an unintended technical performance or performance outcome of the device.

beneficence

Doing good to others: here also includes 'non-maleficence', avoiding doing harm.

benefit

That which positively affects the interests or welfare of an individual or group.

blood relatives

Close genetic relatives.

capitation payments

Per capita payments to researchers, usually from sponsors of clinical trials, for recruiting participants for research.

cell line

A term used by scientists to describe cells grown in the laboratory over an extended period. Cell lines can be created from many different types of tissues and include those that will only grow for a limited period of time as well as those that may become 'immortal' through alteration of their genomes either through mutations arising naturally or induced artificially. Cell lines usually comprise a stable population of cells, although some heterogeneity is generally present and changes in the characteristics of the cells may occur over time.

child

Subject to law in the relevant jurisdiction, a minor who lacks the maturity to make a decision whether or not to participate in research. See also young person

clinical trial

A form of research designed to find out the effects of an intervention, including a treatment or diagnostic procedure.

community

A collection of individuals, which may extend from the whole population to a smaller grouping associated by cultural, ethnic, geographical, social or political factors or some other commonality.

confidentiality

The obligation of people not to use private information – whether private because of its content or the context of its communication - for any purpose other than that for which it was given to them.

conflict of interest

In the research context: where a person's individual interests or responsibilities have the potential to influence the carrying out of his or her institutional role or professional obligations in research; or where an institution's interests or responsibilities have the potential to influence the carrying out of its research obligations.

consent

A person's or group's agreement, based on adequate knowledge and understanding of relevant material, to participate in research.

data

Pieces of information.

databank

A systematic collection of data, whether individually identifiable, re-identifiable or non-identifiable.

deception

Where relevant material is withheld from research participants. and/or they are intentionally misled about procedures and/or purposes of research.

discomfort

A negative accompaniment or effect of research, less serious than harm.

ethical / unethical

Right or morally acceptable / wrong or morally unacceptable.

ethical review

Review of research by an HREC or other body.

ethical review body

Body set up to carry out ethical review of human research.

ethics

The concepts of right and wrong, justice and injustice, virtue and vice, good and bad, and activities to which these concepts apply.

genetic material

Any source of DNA or RNA that can be tested to obtain genetic information. It includes cells (whether isolated or as part of tissues) and extracted DNA and RNA.

harm

That which adversely affects the interests or welfare of an individual or a group. Harm includes physical harm, anxiety, pain, psychological disturbance, devaluation of personal worth and social disadvantage.

HREC

Human Research Ethics Committee.

human tissue

The substance, structure, and texture of human organs or body parts when separated from human beings; includes blood, blood components and waste products.

identifier

Details attached to data, such as name and/or contact information, that identify an individual. (It may remain possible to identify an individual even after all identifiers have been removed, if a code number has been assigned and there is access to the code, or if the data or tissue can be cross-linked to other data or tissue banks).

inconvenience

A minor negative accompaniment or effect of research, less serious than discomfort.

individually identifiable data

Data from which the identity of a specific individual can reasonably be ascertained.

integrity

Honesty and probity as qualities of character and behaviour.

justice

Regard for the human sameness shared by all human beings, expressed in a concern for fairness or equity. Includes three aspects of justice: procedural justice, involving fair methods of making decisions and settling disputes; distributive justice, involving fair distribution of the benefits and burdens of society; and corrective justice, involving correcting wrongs and harms through compensation or retribution.

limited disclosure

Not disclosing to research participants all of the aims and/or methods of the research.

low risk (research)

Research in which the only foreseeable risk is one of discomfort.

monitoring (of research)

The process of verifying that the conduct of research conforms to the approved proposal.

negligible risk

Research in which there is no foreseeable risk of harm or discomfort, and any foreseeable risk is of inconvenience only.

non-identifiable data

Data that 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 they are about the same data subject, although the person's identity remains unknown.

non-therapeutic (intervention)

An intervention not directed towards the benefit of the individual but rather towards improving scientific knowledge or technical application, or the benefit of others.

Opt-out approach

A method used in the recruitment of participants into research where information is provided to the potential participant regarding the research and their involvement and where their participation is

presumed unless they take action to decline to participate.

participant (in research)

Anyone who is the subject of research in any of the ways set out in *Purpose, scope and limits of this document*.

personal information

Information by which individuals can be identified.

placebo (in research)

A substance not containing an active agent under study, administered to some participants to compare the effects of the active agent administered to other participants.

privacy

A domain within which individuals and groups are entitled to be free from the scrutiny of others.

protocol

A document that provides the background, rationale and objectives of the research and describes its design, methodology, organisation and the conditions under which it is to be performed and managed.

qualitative research

Research involving the studied use of empirical materials such as case studies, personal experience, life stories, interviews, observations, and cultural texts.

re-identifiable data

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.

research

Includes at least investigation undertaken to gain knowledge and understanding or to train researchers.

research misconduct

Includes fabrication, falsification, plagiarism or deception in proposing, carrying out or reporting the results of research, and failure to declare or manage a serious conflict of interest. Also includes failure to follow research proposals approved by a research ethics committee, particularly where this failure may result in unreasonable risk or harm to humans, other animals or the environment. Also includes the wilful concealment or facilitation of research misconduct by others.

respect for human beings

Recognition that each human being has value in himself or herself.

risk

The function of the magnitude of a harm and the probability that it will occur.

serious adverse event

Any untoward medical occurrence that:

- results in death;
- is life-threatening (NOTE: The term "life-threatening" refers to an event/ reaction in which the patient was at risk of death at the time of the event/reaction; it does not refer to an event/reaction which hypothetically might have caused death if it were more severe);
- requires inpatient hospitalisation or prolongation of existing hospitalisation;
- results in persistent or significant disability/incapacity;
- is a congenital anomaly/birth defect; or
- is a medically important event or reaction.

serious unexpected suspected adverse reaction

A serious adverse event (see definition above) for which there is some degree of probability that the event is an adverse reaction to the administered drug, and the adverse reaction is unexpected.

sponsor

An individual, company, institution or organisation that takes responsibility for the initiation, management, and/or financing of research.

therapeutic (intervention)

Intervention directed towards the wellbeing of the individual concerned.

unexpected adverse drug reaction

An adverse reaction, the nature or severity of which is not consistent with the applicable scientific information (e.g. Investigator's Brochure for an unapproved investigational product or Product Information (PI) document or similar for an approved, marketed product).

voluntary participation

Participation that is free of coercion and pressure.

young person

In the context of this National Statement, a minor who (subject to the law in the relevant jurisdiction) may have the maturity to make a decision whether or not to participate in research. *See also* child

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