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National Statement on Ethical Conduct in Human Research

2007 (Updated 2018)

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Developed jointly by
National Health and Medical Research Council
Australian Research Council
Universities Australia

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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 in the design, development, review and conduct of research* 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*, 2018 (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 Universities Australia (UA). 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.

Universities Australia (UA) is the peak body representing Australia's 39 comprehensive universities in the public interest, both nationally and internationally. Its primary role is to advocate for regulatory, policy and fiscal settings conducive to a world-class university system.

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, UA).

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.[1]

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,

[1] 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

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.

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 *Ethical conduct in research with Aboriginal andTorres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders*.

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 5.5.7 to 5.5.10).

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[2]:

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

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

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

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

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.

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

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.

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 5.2.17).

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 5.2.17 and 5.2.19).

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, page 67), the adverse effects on those whose illegal activity is exposed must be justified by the value of the exposure.

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

a) involves active concealment or planned deception or

b) aims to expose illegal activity.

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 IN THE DESIGN, DEVELOPMENT, REVIEW AND CONDUCT OF RESEARCH

INTRODUCTION

The aim of this section is to provide guidance on the ethical considerations that are relevant to the way that research is designed, reviewed and conducted. This material should be read in conjunction with the Preamble (Purpose, scope and limits, p.6) and Section 2 (Themes in research ethics: risk and benefit, consent, pp 12-22).

This section aims to be compatible with and relevant for many different ways of doing human research. It requires those who conduct and approve human research to consider:

- how the research question/theme is identified or developed
- the alignment between the research aims and methods
- how the researchers and the participants will engage with one another
- how the research data or information are to be collected, stored, and used
- how the results or outcomes will be communicated, and
- what will happen to the data and information after the project is completed.

The guidance in this section identifies common ethical issues that arise in the various phases of research. It is up to each researcher and HREC to apply the guidance to each project, taking account of the four principles of research merit and integrity, justice, beneficence and respect. This guidance facilitates consideration of the risks and benefits of the research and the level of ethical oversight required.

The guidance in Chapter 3.1 is broadly applicable to **all fields of research**, including those types of research for which additional specific guidance is provided in Chapters 3.2, 3.3 and 3.4.

Chapter 3.1 is designed around seven elements that are common to most – if not all – forms of research. The chapter starts with considering the ethical issues associated with developing the research scope, aims, themes, questions and methods, and ends with ethical considerations that pertain after the project comes to an end.

The elements are:

Element 1 – Research Scope, Aims, Themes, Questions and Methods

Element 2 – Recruitment

Element 3 – Consent

Element 4 – Collection, Use and Management of Data and Information

Element 5 – Communication of Research Findings or Results to Participants

Element 6 – Dissemination of Research Outputs and Outcomes

Element 7 – After the Project

Researchers who are designing a research project should read all of Chapter 3.1, noting which parts of the guidance are relevant for their project. In addition, if research involves biospecimens, genomics or xenotransplantation, they should also consult the specific chapters on these topics.

Each subsequent chapter in this section provides guidance on additional ethical considerations that may apply to:

- the use of human biospecimens in laboratory based research (Chapter 3.2)
- genomic research (Chapter 3.3)
- xenotransplantation research (Chapter 3.4).

This guidance applies to research, but sometimes the distinction between research and innovative clinical practice is unclear. For example, innovative clinical practice occurs on a spectrum from minor changes at the border of established practice that pose little change in risk to patient safety to novel interventions that should only be introduced as part of an ethically approved research protocol.

Whether an innovative clinical practice should be undertaken only as clinical research may depend on the extent to which the procedure departs from established practice. Importantly, even if the introduction of an innovative practice falls within existing clinical guidance, its implementation and the associated collection of data for monitoring and reporting may require notification to the institutions where the practice is taking place.

When it is not clear whether an innovation should be implemented only as research, it may be necessary to seek advice from a Human Research Ethics Committee or other institutional review process on the review required for the new intervention.

Researchers planning to do any type of research involving Aboriginal and Torres Strait Islander peoples must consult and follow the advice in the most contemporary versions of *Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders* and *Keeping research on track II* as well as the *Guidelines for Ethical Research in Australian Indigenous Studies* (GERAIS) produced by the Australian Institute of Aboriginal and Torres Strait Islander Studies. These guidelines embody the best standards of ethical research and human rights and seek to ensure that research with and about Aboriginal and Torres Strait Islander peoples follows a process of meaningful engagement and reciprocity between the researcher and the individuals and/or communities involved in the research.

Researchers should also consult the most contemporary version of NHMRC's *Statement on Consumer and Community Participation in Health and Medical Research*.

CHAPTER 3.1: THE ELEMENTS OF RESEARCH

INTRODUCTION

Human research projects must adhere to the core ethical principles described in Section 1 of this National Statement. These principles apply at all stages of a research project from inception to post-completion.

Human research can involve a wide range of methods and practices: it can be qualitative, quantitative or mixed; interventional, experimental or observational in nature; and involve various degrees of collaboration between researchers and participants. Each research project is shaped by the field to which the research question relates, the research question itself, the desired outcome, and the context in which it is conducted.

Effective research ethics review incorporates appropriate expertise related to relevant methods or areas of practice. Reviewers should be aware of expectations and apply requirements that are relevant to the areas of practice or methods used in projects that they review. This requires becoming familiar with methods or areas of practice that are unfamiliar or novel.

A range of relationships between participants and researchers may develop as a result of the duration and nature of the research interaction. Some methodological approaches require careful boundaries to be maintained between researchers and research participants. In contrast, other research fields require data collection methods that involve the development of close personal relationships with participants, or degrees of collaboration that blur the lines between researcher and participant (e.g. co-researchers in action research).

Researchers may have an impact on research participants and vice versa and this impact may compromise a researcher's role or professionalism. If this is anticipated and/or occurs, it may become necessary to modify those relationships, or to modify or discontinue the research.

Additionally, a researcher may have other professional skills (for example, counseling or clinical care) that become relevant to the relationship with a participant. In this event, it is important to consider whether it is ethically acceptable to exercise those skills or, alternatively, to refer that participant to another professional.

The guidance provided in Chapters 4.3 and 5.4 is relevant to the researcher's duty to inform participants that they are acting in a professional role other than the research role.

Research may involve risks to participants. To the extent that it is appropriate, the development of clear protocols for managing any distress that might be experienced by participants during the process of data collection or conduct of research procedures is an important component of planning research. Predicting what topics are likely to lead to distress and how to manage this distress will not always be easy. Access to sufficient training to help researchers and reviewers in making such predictions is valuable. Refer to Chapter 2.1 for a further discussion about the identification and handling of risk in research.

This chapter discusses the manner in which the core principles of this National Statement should be reflected in the elements of research project design. The chapter should be considered as a whole; however, the order in which these elements are discussed does not imply a hierarchy or a sequence, or that all of these elements will have equal relevance in every design. The elements are:

- Element 1: Research Scope, Aims, Themes, Questions and Methods
- Element 2: Recruitment
- Element 3: Consent
- Element 4: Collection, Use and Management of Data and Information
- Element 5: Communication of Research Findings or Results to Participants
- Element 6: Dissemination of Research Outputs and Outcomes
- Element 7: After the Project

Chapter 3.1 should be read in conjunction with other sections of the National Statement and is supplemented by the guidance in Chapters 3.2, 3.3 and 3.4.

Researchers conducting clinical interventional research should also refer to additional guidance in Chapters 5.2 and 5.5.

GUIDELINES

Element 1: Research Scope, Aims, Themes, Questions and Methods

A critical feature of good research is clarity regarding how the research project will meet the ethical requirement that research has merit, as described in paragraph 1.1 of the National Statement. This Element of Chapter 3.1 offers advice and guidance about meeting this obligation.

Key questions include:

- What is the research theme or question that this project is designed to explore?
- Why is the exploration of this theme or answer to this question worth pursuing?
- How will the planned methods explore the theme or achieve the aims of the research?

3.1.1 In an application for review of their research, researchers should determine and state in plain language:

(a) the research question or questions that the project is intended to explore;

(b) the potential benefit of exploring the question or questions including:

(i) to whom that potential benefit is likely to flow, and

(ii) whether that benefit is a contribution to knowledge or understanding, improved social or individual wellbeing, or the skill and expertise of researchers;

(c) the basis for that potential benefit as described in either relevant literature or a review of prior research unless, due to the novelty of the question, there is scarce literature or prior research;

(d) how the design and methods of the project will enable adequate exploration of the research questions and achieve the aims of the research;

(e) how the design of the project will maintain respect for the participants;

(f) where relevant, that the research meets the requirements of any relevant regulations or guidelines authorised by law (such as those related to privacy and reporting requirements for disclosure of child abuse); and

(g) whether or not the project has been reviewed by a formally constituted academic, scientific or professional review process, and, if so, the outcome of that review.

3.1.2 The merit and integrity of research should be assessed by criteria and standards relevant to the research field/s and methodology/ies, such as:

(a) the objectives and conceptual basis of the research;

(b) the quality and credibility of data collection and analysis; and

(c) how to assure validity and reliability of results, taking account of relevant statistical, thematic and other forms of generalisability.

3.1.3 Reviewers should be aware that some research designs will be informed and shaped by the experience, insights and/or needs of participants. Such designs can be a valid and powerful way to collect qualitative information and to inform practice.

3.1.4 For interventional research conducted in the context of health care or public health, researchers should additionally determine and state:

(a) whether the project involves the systematic investigation of the safety, efficacy and/or effectiveness of an intervention;

(b) if the research involves exposure to an intervention for which the safety or efficacy, or both, is not well understood:

(i) whether it is likely or possible that the intervention will be of therapeutic benefit and

(ii) whether there is a realistic possibility that the intervention being studied will be at least as beneficial overall as standard treatment, taking into account effectiveness, burden, costs and risks;

(c) where patient care is combined with intent to contribute to knowledge, that any risks of participation should be justified by potential benefits to which the participants attach significance. The prospect of benefit from research participation should not be exaggerated, either to justify to the reviewing body a higher risk than that involved in the participant's current treatment or to persuade a participant to accept that higher risk;

(d) whether the intervention or other research procedures are without likely benefit to participants. For such research to be ethically acceptable, any known or emerging risks to the participants must not be greater than the risks that would be associated with the health condition and its usual care.

3.1.5 Where current and available treatments are known or widely believed to be effective and/or there is known risk of significant harm in the absence of treatment, placebo or non-treatment groups are not ethically acceptable. Non-treatment (including placebo alone) groups may only be used:

(a) where the existing standard of care comprises or includes the absence of treatment (of the type being evaluated); or

(b) where there is evidence that the harms and/or burdens of an existing standard treatment exceed the benefits of the treatment.

3.1.6 In health research involving an intervention, the risks of an intervention should be evaluated by researchers and reviewers in the context of the risks of the health condition and the treatment or treatment options that would otherwise be provided as part of usual care.

3.1.7 For any research project that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes, researchers must register the project as a clinical trial on a publicly accessible register complying with international standards (see information on the International Clinical Trials Registry Platform (ICTRP) on the World Health Organisation website) before the recruitment of the first participant.

3.1.8 Where the total project cannot be described in advance because the design and detail of successive stages will be informed by preceding stages, researchers should provide a description of the stages that are foreseen and how they intend to seek ethics approval for each stage.

3.1.9 Researchers should confirm and reviewers should be satisfied that:

(a) a plan is in place to ensure that resources are sufficient to conduct and complete the research as designed; and

(b) the facilities, expertise and experience available seem to be appropriately allocated and sufficient for the research to be completed safely.

3.1.10 Researchers should provide assurance that any proposed payment in money or kind, whether to institutions, researchers or participants, will not adversely influence the design, conduct, findings or publication of the research.

3.1.11 Researchers seeking approval for a program of research (i.e. a series of related research projects), or to establish infrastructure for research such as a database or a biobank, should adequately describe their plans to reviewers.

Element 2: Recruitment

When research will involve the direct participation of people (e.g. testing, surveys, interviews, focus groups, observation and health or behavioural interventions) the recruitment phase of a project is fundamental to the success of the research. Depending upon the design of a project, this element can include such matters as identifying individuals as potential participants, contact between the research team and potential participants, screening or exclusion of some individuals, and preparing to seek consent from the potential participants.

A single project may employ more than one recruitment strategy, especially where discrete cohorts are required to meet the objectives of the research. For some research designs, the recruitment and consent strategies occur concurrently; for others, they are separate. It is essential that recruitment strategies adhere to the ethical principles of justice and respect.

Key questions include:

- Who will be recruited?
- How will participants be identified and recruited?
- Will the potential participants be screened?
- What is the impact of any relationship between researchers and potential participants on recruitment?
- How will the recruitment strategy facilitate obtaining the consent of participants?
- How will the recruitment strategy ensure that participants can make an informed decision about participation?
- Are there any risks associated with the recruitment strategy for potential participants or for the viability of the project?

3.1.12 Research proposals should clearly describe the recruitment strategy and the criteria for the selection of potential participants.

3.1.13 The recruitment strategy for a project should be relevant to the research methodology, topic/subject matter, the potential participants and the context.

3.1.14 The criteria for the selection of potential participants for a project and the cohort that is recruited should align with both the objectives and theoretical basis of the research.

3.1.15 The inclusion/exclusion criteria for the potential participants in a project must be justifiable and should be fair. The exclusion of some groups may amount to unfair discrimination, and/or exclude individuals and groups from the potential benefits of research. Researchers should consider the degree to which including/excluding groups may limit (or compromise) the value of the results of a project, with consequent impact on the merit of the project.

3.1.16 Researchers and reviewers should consider the degree to which potential participant populations might be over-researched or may require special consideration or protection and the degree to which the flow of benefits to that population (or to individual participants) justify the burdens. Equally, people should not be denied the opportunity to exercise self-determination or obtain the potential benefits of research solely because they are a member of a population that might be over-researched or may require special consideration or protection, such as Aboriginal and Torres Strait Islander peoples.

3.1.17 The recruitment strategy must be respectful of potential participants and their culture, traditions and beliefs and facilitate their voluntary participation.

3.1.18 In developing and implementing their recruitment strategy, researchers should consider:

(a) the potential for coercion/exploitation;

(b) any risks to participants related to recruitment (see Chapter 2.1) and how the pattern of recruitment might be structured to mitigate any risks to participants;

(c) any privacy matters relating to the recruitment of participants;

(d) the potential impact of existing relationships on recruitment (including, but not limited to, hierarchical relationships that may generate an unequal or dependent relationship, such as teacher and student, manager and employee, supervisor and team member or treating health care professional and patient);

(e) the potential impact of participation on existing relationships;

(f) whether participants will be recruited by co-researchers or other members of the project team who are unfamiliar with the guidance provided by this National Statement; and

(g) whether the research requires community engagement or agreements related to the research to be in place prior to individual recruitment.

3.1.19 Researchers should describe and justify their approach to potential participants (i.e. how do they find out about the possibility of participating, or not, in the research). The level of detail that is required by reviewers should be proportional to the foreseeable risks and appropriate to the methodology selected.

3.1.20 For many research projects, researchers should provide reviewers with proposed recruitment materials (e.g. notices, flyers, advertisements, and social media posts) prior to use, including those materials that are developed subsequent to the initial review of the research proposal. However, for some research designs or where recruitment material needs to be ad lib, adapted or tailored to the context (such as some social media, radio or other oral communication) a description of the strategy and broad messages is sufficient.

3.1.21 Researchers and reviewers should consider the potential impact of the recruitment strategy upon the consent process (e.g. the degree to which the recruitment strategy might undermine the voluntary nature of the consent of individual potential participants).

3.1.22 Researchers and reviewers should consider the degree to which any payment in money or incentives of any kind, whether to researchers, participants or others involved in recruitment, could result in pressure on individuals to consent to participate (see paragraphs 2.2.10, and 2.2.11). This is especially important with respect to research that involves more than a low risk of harm.

Element 3: Consent

Well-designed consent strategies are appropriately tailored to the potential participants, the research design, the topic and the context. Obtaining consent in a manner that shows respect for participants facilitates valid consent. This may involve obtaining consent as part of an ongoing process. Obtaining consent may be a component of broader processes of consultation, engagement and negotiation, such as in the context of research involving Aboriginal and Torres Strait Islander Peoples (see Chapter 4.7).

The guidance in Element 3 should be considered in the context of the guidance provided in Chapters 2.2 and 2.3. These chapters provide essential guidance on the selection and framing of a consent strategy or alternatives to consent, such as an opt-out approach or waiver of the requirement for consent.

The guidance in Chapters 2.2, 2.3, and this Element should be considered in applying the guidance on consent included in Chapters 3.2, 3.3 and 3.4.

Key questions include:

- What strategy(ies) for obtaining consent, or alternatives to consent are appropriate for the specific project?
- Does the nature of the project design, the participants or the context necessitate the use of more than one strategy?
- Do the proposed strategy(ies) satisfy the relevant requirements of Chapters 2.2 and 2.3?
- Are there any project-specific matters that warrant specific attention (e.g. whether the research could generate results of significance to participants, whether the data will be added to an open or mediated access repository or whether the data or materials will be used for any other purpose)?

3.1.23 Researchers should ensure that any proposed consent strategy:

(a) provides all of the required information and assurances as set out in Chapters 2.2 and 2.3, as relevant to the proposed research; and

(b) uses tools and language that are appropriate, respectful and relevant to the research design, objectives, potential participants and context, including relevant cultural sensibilities.

3.1.24 Researchers and reviewers should recognise that research involving multiple methods or different groups of potential participants may require more than one consent strategy or may require consent to be revisited and renegotiated over time.

3.1.25 There is a range of strategies that may be appropriate for obtaining consent. While these may include the provision of a written information and consent document, other strategies may be more appropriate. It is not a requirement of the National Statement that participants' consent must, routinely, be witnessed.

3.1.26 An information and consent document or other consent strategy should be appropriate to the needs of the participants and proportional to the project's risks and ethical sensitivity. Specifically:

(a) information provided in any format should not be unnecessarily long or detailed, even for complex interventional research;

(b) strategies such as the use of staged or tiered information should be considered in order to address variations in the needs or characteristics of potential participants; and

(c) adequate time should be allowed for prospective participants to understand and consider what is proposed and for their questions and expression of concerns to be addressed by those obtaining their consent (See 2.2.2 – 2.2.6).

3.1.27 Researchers should ensure that participants understand whether or not third parties (including supervisors of participants) will know who has been approached about participating, who has been selected from the participant pool, and which individuals have chosen to participate.

3.1.28 In circumstances where there may be significant risks if the participatory status of individuals becomes known, researchers must select a consent strategy that masks the identity of participants.

3.1.29 When those who are recruiting participants will receive some form of payment per recruited individual or other benefit, this must be disclosed to potential participants during the consent process.

3.1.30 Researchers should explain to potential participants that their access to any services or supports normally provided by the person trying to recruit them will not be affected by their decision to accept or decline research participation.

3.1.31 In any information provided to potential participants during the consent process, researchers should include information on data management and storage and any relevant intellectual property and copyright arrangements.

3.1.32 Researchers should describe to potential participants any limitations on/ consequences of withdrawing consent and whether or not it will be possible to withdraw their data or information.

3.1.33 Where research may yield findings that are potentially significant for individuals, the consent strategy should clarify whether participants will be provided with these findings or whether individuals will have a choice about receiving the findings.

3.1.34 Researchers should disclose to potential participants whether, and under what circumstances, research results or information that has been collected may be reported to relevant authorities.

3.1.35 During the consent process, researchers should advise participants whether, and, if so, in what form, they will receive or can obtain access to a summary of the outcomes of the research.

3.1.36 If researchers are planning to add data obtained in a research project to an open or mediated access repository or make the data or materials available for re-use,

any implications of these plans should be provided to participants. The use of 'extended consent' or 'unspecified consent' (see 2.2.14 to 2.2.16) may be appropriate for this purpose.

3.1.37 When researchers seek consent to collect information that is considered to be of historical, cultural or other long term value, they should obtain consent for its perpetual retention, including any planned re-use and sharing with others.

3.1.38 When a project relates to a health intervention or treatment, researchers must make it clear to potential participants, if relevant:

(a) that it is a novel intervention that has not yet been approved for any health condition, or an intervention that is not used in the usual care of the relevant health condition, or an intervention that is being investigated for use in a new health condition or in a new or modified setting;

(b) whether there is likely to be any therapeutic benefit to them from the intervention and whether access to the intervention is available only through participation in the research; and

(c) whether they will have access after completion of the project or active treatment phase of the project to the intervention, treatment or information that they have received, and, if so, with what limitations, if any.

3.1.39 For research that is not explicitly or primarily genomic, but that may, during recruitment or data collection, generate information with hereditary implications, consent processes should be designed to take account of this potential (see Chapter 3.3: Genomic Research).

Element 4: Collection, Use and Management of Data and Information

This section addresses ethical issues related to generation, collection, access, use, analysis, disclosure, storage, retention, disposal, sharing and re-use of data or information.

Human research projects incorporate one or more methods to generate, collect, or access data or information so as to achieve the objectives of the research. Collection, use and management of data and information must be in accordance with the ethical principles discussed in Section 1 of this National Statement.

Research may involve access to large volumes of data or information not explicitly generated for research purposes. The size and accessibility of such sources make them attractive for some research designs, the use of which may raise difficult privacy and consent questions. However, because research using population-wide datasets is inclusive of all members of the population in question, it promotes the core principle of justice. In addition, benefits and burdens may be spread more evenly than research based on selected participants.

The increased ability to link data in ways that preserve privacy has greatly enhanced the contribution that collections of data can make to generating knowledge, as it enables researchers to match individuals in different data sets without explicitly identifying them.

Key questions include:

- What data or information are required to achieve the objectives of the project?
- How and by whom will the data or information be generated, collected and/or accessed?
- How and by whom will the data or information be used and analysed?
- Will the data or information be disclosed or shared and, if so, with whom?

- How will the data or information be stored and disposed of?
- What are the risks associated with the collection, use and management of data or information and how can they be minimised?
- What is the likelihood and severity of any harm/s that might result?
- How will the collection and management of the data or information adhere to the ethical principles in Section 1 of this National Statement?

What is data and what is information?

The terms 'data' and 'information' are often used interchangeably. Data can refer to raw data, cleaned data, transformed data, summary data and metadata (data about data). It can also refer to research outputs and outcomes. Likewise, information takes many different forms. Where information is in a form that can identify individuals, protecting their privacy becomes a consideration.

For the purposes of the National Statement, 'data' is intended to refer to bits of information in their raw form, whereas 'information' generally refers to data that have been interpreted, analysed or contextualised.

Data and information may include, but not be limited to:

- what people say in interviews, focus groups, questionnaires/surveys, personal histories and biographies;
- images, audio recordings and other audio-visual materials;
- records generated for administrative purposes (e.g. billing, service provision) or as required by legislation (e.g. disease notification);
- digital information generated directly by the population through their use of mobile devices and the internet;
- physical specimens or artefacts;
- information generated by analysis of existing personal information (from clinical, organizational, social, observational or other sources);
- observations;
- results from experimental testing and investigations; and
- information derived from human biospecimens such as blood, bone, muscle and urine.

Identifiability of information[3]

Researchers and reviewers must consider the identifiability of data and information in order to assess the risk of harm or discomfort to research participants or others who may be at risk.

The risks related to identifiability of data and information in research are greatest where the identity of a specific individual can reasonably be ascertained by reference to an identifier or a combination of identifiers (examples of identifiers include the individual's name, image, date of birth or address, attribute or group affiliation). Risk may also arise where identifiers have been removed from the data or information and replaced by a code, but where it remains possible to re-identify a specific individual (by, for example, unlocking the code or linking to other data sets that contain identifiers). Due to technological advances, risks may arise in relation to data and/or information that has never been labelled with individual identifiers or from which identifiers have been permanently removed.

The identifiability of information is a characteristic that exists on a continuum. This continuum is affected by contextual factors, such as who has access to the information and other potentially related information, and by technical factors that

[3] The National Statement does not use the terms 'identifiable', 'potentially identifiable', 're-identifiable', 'non-identifiable' or 'de-identified' as descriptive categories for data or information due to ambiguities in their meanings. Re-identification and de-identification are best understood as processes that change the character of information and are only used with this meaning.

have the potential to convert information that has been collected, used or stored in a form that is intended to protect the anonymity of individuals into information that can identify individuals. Additionally, contextual and technical factors can have a compound effect and can increase the likelihood of re-identifiability and the risk of negative consequences from this in ways that are difficult to fully anticipate and that may increase over time.

Furthermore, the identifiability of information may change during the life of a research project, e.g. data or information might initially be collected in a form that could identify individuals, then coded for analysis and correlation to other collected data or information, and, finally, once all the data or information has been collected, the code key might be destroyed, rendering the data or information anonymous. Therefore, it is important for researchers and reviewers to focus on the risk of harm to affected individuals if their identity is ascertained and the effort that would be required to achieve this at each stage of a research project.

Factors that should be taken into consideration when determining the degree of identifiability of information and when evaluating the associated risks include the type and quantity of the information, any other information held by the individual who receives the information and the capacity (skills and technology) available to the individual who receives it. Identifiability of information is also conditioned by contextual factors, such as whether only the person/s who collected the information could use it to identify (an) individual/s, or whether those to whom it is disclosed or with whom it is shared for research purposes could also use it for this purpose. Identifiability may also reflect features of the project such as the nature of the participant cohort: for example, whether it includes high-profile individuals or members of small communities versus larger populations.

Data and information that is contained in data sets, such as those held in government databases and by social media organisations, may be used (in sum or in part) to identify individuals. This potential is due to the impact of predictive analytics, machine learning, increased commercial accessibility, proliferation of data sets, data breaches or degradation of privacy protections and other developments on access to and use of data and information. In this increasingly complex environment, researchers are encouraged to consult guidance promulgated by expert bodies such as the Office of the Australian Information Commissioner and its state and territory equivalents, the Australian Bureau of Statistics and the Australian National Data Service in addition to this National Statement.

3.1.40 The removal of personal identifiers may or may not be ethically required. Some research projects may legitimately require the retention of personal identifiers, for example, to link information or data from a number of different sources or to return results to participants. In addition, some research populations (e.g. academics, activists and some public figures) are amongst those who may prefer to be identified in the collection, use, and reporting of research data. Where participants choose to be identified, researchers and participants should collaboratively determine and agree upon whether all research data or information collected from them will be identified, or only certain components of the collected data or information.

3.1.41 Researchers should adopt methods to reduce the risk of identification during collection, analysis and storage of data and information. Methods to reduce identifiability and the consequent risks may include:

(a) minimising the number of variables collected for each individual;

(b) separation and separate storage of identifiers and content information; and

(c) separating the roles of those responsible for management of identifiers and those responsible for analysing content.

3.1.42 In any publications, researchers should ensure that the identity of participants cannot be reasonably ascertained from the data or information that they use or report, unless they have agreed to be identified. This may require minimising, obscuring, or changing identifiers, either in the collection process or when presenting and publishing the research results.

3.1.43 Where research involves linkage of data sets with the consent of participants, researchers should advise participants that use of data or information that could be used to identify them may be required to ensure that the linkage is accurate. They should also be given information about the security measures that will be adopted, for example the removal of identifiers once linkage is completed.

Data management

3.1.44 When multiple researchers are collaborating on collection, storage and/or analysis of data or information, they should agree to the arrangements for custodianship, storage, retention and destruction of those materials, as well as to rights of access, rights to analyse/use and re-use the data or information and the right to produce research outputs based upon them. Researchers should consider whether any intellectual property will be generated by the project and agree on the ownership of any intellectual property created. Agreements on such arrangements and ownership need not necessarily be in the form of a contractual document, but should facilitate a clear resolution of these issues.

3.1.45 For all research, researchers should develop a data management plan that addresses their intentions related to generation, collection, access, use, analysis, disclosure, storage, retention, disposal, sharing and re-use of data and information, the risks associated with these activities and any strategies for minimising those risks. The plan should be developed as early as possible in the research process and should include, but not be limited to, details regarding:

(a) physical, network, system security and any other technological security measures;

(b) policies and procedures;

(c) contractual and licensing arrangements and confidentiality agreements;

(d) training for members of the project team and others, as appropriate;

(e) the form in which the data or information will be stored;

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

(g) the conditions under which access to the data or information may be granted to others; and

(h) what information from the data management plan, if any, needs to be communicated to potential participants.

Researchers should also clarify whether they will seek:

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

(j) permission from a review body to waive the requirement for consent (see paragraphs 2.3.9 and 2.3.10).

3.1.46 The security arrangements specified in the data management plan should be proportional to the risks of the research project and the sensitivity of the information.

3.1.47 Researchers must comply with all relevant legal and regulatory requirements that pertain to the data or information collected, used or disclosed as well as the conditions of the consent provided by participants.

3.1.48 In relevant research, particularly that which involves the use of materials of biological origin, records should be preserved for long enough to enable participants to be traced in the event that evidence emerges of late or long-term health-related effects, taking into account the conditions of consent that apply.

3.1.49 Data, information and biospecimens used in research should be disposed of in a manner that is safe and secure, consistent with the consent obtained and any legal requirements and appropriate to the design of the research.

3.1.50 In the absence of justifiable ethical reasons (such as respect for cultural ownership or unmanageable risks to the privacy of research participants) and to promote access to the benefits of research, researchers should collect and store data or information generated by research projects in such a way that they can be used in future research projects. Where a researcher believes there are valid reasons for not making data or information accessible, this must be justified.

Secondary use of data or information

Research may involve access to and use of data or information that was originally generated or collected for previous research or for non-research purposes, including routinely collected data or information. This is commonly called 'secondary use of data or information'. The main ethical issue arising from this use is the scope of consent provided or, alternatively, the impracticability of obtaining consent.

Administrative data or information is data or information routinely collected during the delivery of a service e.g. by a government department or private service provider and may involve collections of data or information from large numbers of people or whole populations. It is usually impractical to obtain consent from individuals for secondary use of this data or information. In these circumstances, respect for participants can be demonstrated in other ways, including, but not limited to, community consultation, ensuring that the research results are translated into improvements in services and practices, acknowledging the source of the data or information in publications and/or publishing the research results in a location and language suitable for the general community. In particular, using data or information without consent may undermine public trust in the confidentiality of their information.

Privacy concerns arise when the proposed access to or use of the data or information does not match the expectations of the individuals from whom this data or information was obtained or to whom it relates. These issues are especially complex in the context of the access to or use of information relating to individuals that is available on the internet, including social media posts, tweets, self-generated 'lifelogging' data emitted from mobile phones and other 'smart' appliances and data or information generated through applications and devices related to personal pursuits, such as fitness activity, gambling, dating and web-based gaming.

Data or information available on the internet can range from information that is fully in the public domain (such as books, newspapers and journal articles), to information that is public, but where individuals who have made it public may consider it to be private, to information that is fully private in character. The guiding principle for researchers is that, although data or information may be publicly available, this does not automatically mean that the individuals with whom this data or information is associated have necessarily granted permission for its use in research. Therefore, use of such information will need to be considered in the context of the need for consent or the waiver of the requirement for consent by a reviewing body and the risks associated with the use of this information.

3.1.51 For research involving the secondary use of data or information, researchers should make study designs publically available, including information about:

(a) the form in which the data or information will be stored (i.e. whether it can identify individuals); and

(b) the purposes for which the data or information will be used.

3.1.52 Unless a waiver of the requirement for consent is obtained, any research access to or use of publicly available data or information must be in accordance with the consent obtained from the person to whom the data or information relates.

3.1.53 Researchers should understand the context in which data or information was collected or disclosed, including the existence of any relationship of confidence or, if available on the internet, the privacy settings that apply. This includes avoiding the use or disclosure of information that was obtained unethically or illegally.

3.1.54 Researchers should take account of any terms and conditions applicable to social media platforms when using data or information from these sources or platforms and other web-based communities that do not permit the removal of the name of the author of a post or any changes to the wording of a post.

Sharing of data or information

While data or information may be collected, aggregated and stored for an initial purpose or activity, it is common for researchers to 'bank' their data or information for possible use in future research projects or to otherwise share it with other researchers. It is also increasingly common for funding agencies to require the sharing of research data either via open access arrangements or via forms of mediated access controlled by licenses.

To this end, data or information may be deposited in an open or mediated access repository or data warehouse, similar to an archive or library, and aggregated over time. Archived data or information can then be made available for later analysis, unless access is constrained by restrictions imposed by the depositor/s, the original data custodian/s or the ethics review body.

3.1.55 All data collections should have an identified custodian to enable access by researchers or participants to the data while maintaining it in a protected form. The custodian of the data may be the individual researcher or agency who collected the information, or an intermediary that manages data coming from a number of sources.

3.1.56 When planning to share data or information with other researchers or to establish or add them to a databank, researchers must develop data management plans in accordance with the guidance provided in 3.1.45. This plan should enable the sharing of data and information and propose appropriate conditions on the sharing of data and information.

3.1.57 Researchers must make data custodians aware of the data management plans for banking or sharing of the data or information, and, in particular, of any confidentiality agreements or other conditions on the identifiability or re-use of the data or information.

3.1.58 Any sharing of data or information between research collaborators and research sites must be secure and proportional to the risks associated with, and the ethical sensitivity of the information.

3.1.59 In any proposals to share or disclose research data or information, researchers should distinguish between disclosure to specific third parties, sharing with other researchers and disclosure to the public and clarify whether the sharing or disclosure of data or information is subject to participant consent, other voluntary agreements or mandatory requirements.

3.1.60 Researchers should be aware of expectations and policies regarding the sharing or re-use of participant data or information in any form and should consider the value of the data or information for future research. At the time of initial consent, participants should be informed of these expectations and given appropriate options, including the potential to provide extended or unspecified consent (see paragraphs 2.2.14 to 2.2.16). If consent to future use was not obtained at the time of collection, then reviewers considering the proposed re-use of this data or information in further research may consider a waiver of the requirement for consent or whether it is appropriate to seek additional consent for the sharing or re-use of the data or information. Whether there is an ongoing relationship with the participants and the burden on the participants of re-contact should be considered in this decision.

3.1.61 Before publishing data or information, or adding data or information to a repository, researchers should consider the degree to which it may be possible for the data or information to enable participants to be identified through efforts made by other researchers or third parties.

3.1.62 Shared or banked data or information that is stored in a form that can identify individuals can sometimes be used in research that qualifies as negligible or low risk research; however, it cannot be used in research that is exempt from ethics review (see paragraph 5.1.22).

Element 5: Communication of research findings or results to participants

Research across a range of fields and methodologies can generate findings or results of significance to participants and others. Some research (e.g. analysis of human biospecimens) can generate findings or results of significance to the health of individual participants, and, potentially, their relatives and other family members.

Providing research findings or results to participants can be a benefit, but it can also be a source of risk (e.g. psychological, social, legal). The approach taken to communicating findings and results should reflect principles of good science and adhere to the ethical principles of justice, respect and beneficence discussed in Section 1, including consideration of the values and preferences of traditional custodians, such as Aboriginal and Torres Strait Islander peoples.

Communicating findings or results may be required or optional, appropriate or inappropriate, and/or intentional or unintentional depending on the nature of the research and other circumstances.

Key questions include:

- Could the research generate findings or results of interest to participants?
- Could the findings or results be of significance to the current or future welfare or wellbeing of participants or others?
- Are potential participants in the research forewarned of this possibility?
- Will the consent of participants be obtained to enable any planned or necessary disclosure of findings or results?
- Who will communicate the findings or results and how?
- Will the findings or results be disclosed to third parties and/or the public?

3.1.63 In considering whether to return results of research, researchers should distinguish between individual research results and overall research results and, if individual and/or overall results will be provided to participants:

(a) how these results will be provided to participants;

(b) how the process of returning results will be managed; and

(c) the risks of the return of individual research results and overall research results.

3.1.64 Where information could be of significance to the health of participants, relatives or other family members, researchers should prepare and follow an ethically defensible plan to disclose or withhold findings or results of research (see Chapters 3.2: Use of Human Biospecimens in Laboratory Based Research and 3.3: Genomic Research). Ethically defensible plans may be required for other types of research addressing, for example, any significant social, economic or psychological implications of the research.

3.1.65 An ethically defensible plan for research other than that described in Chapters 3.2 and 3.3 should:

(a) indicate whether the research will be likely to generate findings or results of significance to participants or others;

(b) clarify whether the researchers intend to disclose any findings or results to participants directly and which types of findings or results, if any, are returnable to participants or others (e.g. clinicians or relatives);

(c) confirm that participants will be advised in advance whether they will be offered the option to receive their findings or results;

(d) if applicable, enable participants to decide whether they wish to receive the findings or results and who else may be given the findings or results;

(e) in appropriate circumstances, set out a process for finding out whether family members wish to receive the information;

(f) outline how the findings or results will be provided in a manner that is appropriate and accessible;

(g) include the relevant expertise of the person who may be communicating the findings or results; and

(h) include measures to protect the level of privacy desired by participants.

Disclosure to third parties of findings or results

There can be situations where researchers have legal, contractual or professional obligations to disclose findings or results to third parties. Additionally, researchers may believe that they have a moral obligation to disclose findings or results to third parties.

3.1.66 Where the potential disclosure of findings or results to third parties can be anticipated, researchers should identify:

(a) whether, to whom and under what circumstances the findings or results will be disclosed;

(b) whether potential participants will be forewarned that there may be such a disclosure;

(c) the risks associated with such a disclosure and how they will be managed; and

(d) the rationale for communicating and/or withholding the findings or results and the benefits and/or risks to participants of disclosure/non-disclosure.

3.1.67 Researchers should be aware of situations where a court, law enforcement agency or regulator may seek to compel the release of findings or results. In such circumstances, researchers should:

(a) have a strategy in place to address this possibility; and

(b) advise reviewers of the potential for this to occur.

3.1.68 In circumstances where the imperative to disclose findings or results emerges after the research has commenced, researchers must develop a strategy for addressing this and promptly advise and seek advice from reviewers.

Element 6: Dissemination of project outputs and outcomes

It is consistent with the ethical principles of respect, beneficence and justice to make the outputs or outcomes of research publicly available. Doing so is also a requirement for research merit and integrity. A principal goal of dissemination of outputs/outcomes is to make a contribution to knowledge or practice or to serve a public good. Common mechanisms for achieving this objective include publication in peer-reviewed journals or books, conference presentations, commissioned reviews for public bodies, or dissemination via other forms of media such as creative works and performances. The form of the disseminated outputs (e.g. a conference paper) will be shaped by the research field, the topic, the research design, researcher preference and experience. Publication of outcomes should not be withheld on the basis that they are negative or inconclusive. However, there may be justifiable reasons to delay or restrict the dissemination of the outputs or outcomes out of consideration for the privacy of the participants or other risk factors.

Key questions include:

- What is the plan for reporting, publishing or otherwise disseminating the outputs/outcomes of the research?
- Will participants in the research be offered a timely and appropriate summary of the project outputs/outcomes?
- How will the planned dissemination of the outputs/outcomes contribute to knowledge or practice or serve the public?

3.1.69 Researchers should consider and advise reviewers as to whether

(a) they intend to disseminate the outputs or outcomes widely in order to contribute to scientific, academic, professional or general knowledge or practice;

(b) there are any risk factors or commercial interests that might legitimately delay or restrict the dissemination of the outputs or outcomes; and

(c) the risks of dissemination of the outputs or outcomes are justified by the benefits of dissemination (e.g. the public interest).

3.1.70 Researchers should ensure that reports of their research outputs or outcomes adhere to prevailing standards for ethical reporting, referencing and authorship (e.g. the *Australian Code for the Responsible Conduct of Research*).

3.1.71 Researchers should advise participants on the format and medium or media that will be used to disseminate outputs or outcomes of research to them (such as a lay summary, a research manuscript or published paper, or both) and, to the extent known, when such information about the outcomes will be made available to them. Dissemination of outputs or outcomes of research should occur in a timely fashion.

3.1.72 Researchers should ensure that any outputs or outcomes disseminated to participants are provided in language that is clear and understandable to participants.

Element 7: After the project

Researchers continue to have ethical responsibilities after projects are completed. These responsibilities relate to disposal or retention of data and information, potential secondary (future) use of data or information and any necessary follow up or long term monitoring of research participants.

Key questions include:

- Will the data or information be retained only for the minimum period required by relevant policy?
- Do the data or information have cultural, historical or other significance that could warrant longer, or perpetual retention?
- Are the arrangements regarding intellectual property (individual, community, organisational, commercial) and copyright related to the outputs of the research clearly understood and communicated?
- Will the data or information be banked or added to a repository such as an open or mediated access facility, for future use?
- Is any follow up or monitoring of research participants required and is this clear in the research plan and consent information?

3.1.73 With respect to the retention, storage and subsequent disposal of the data and information, researchers:

(a) must adhere to the ethical principle of respect for persons (e.g. with regard to culture and beliefs of the participants);

(b) should maintain the confidentiality of individuals in accordance with any assurances made to them (e.g. during the consent process); and

(c) should be aware of and adhere to applicable national and/or state or territory codes and legislation, as well as to relevant international guidelines and regulation.

3.1.74 Data and information may be of cultural, historical or other significance such that they should be retained beyond the minimum retention period. Disposing of these data or information without consideration of these factors violates the ethical principle of respect. These matters should be appropriately addressed in the research plan and in consent processes and documentation.

CHAPTER 3.2: 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 and sputum; it also includes any derivative of these, such as 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 consideration 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 relatives and their community; and
- the significance that may be attached to the human biospecimens by individual donors and/or communities.

Chapter 3.2 should be read in conjunction with Chapter 3.1 and other parts of the National Statement.

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.

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 (2017)* (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.

Conscientious Objection

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.

Element 1: Research Scope, Aims, Themes, Questions and Methods

Ethical considerations related to laboratory based research involving human biospecimens vary according to whether the biospecimens are being collected prospectively for the research or whether the biospecimens to be used in the research are stored biospecimens that have been previously collected for research or non-research purposes.

Prospective collection of human biospecimens for research

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

Use of stored human biospecimens for research

3.2.2 In determining the level of ethics 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 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 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 or information related to donors.

3.2.3 If the research involves only the use of stored biospecimens and 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.

Element 2: Recruitment

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.

For the purposes of this chapter, the concept of 'recruitment' includes the acquisition or collection of human biospecimens.

Prospective collection of human biospecimens for research

3.2.4 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.

Human biospecimens obtained after death for research

3.2.5 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.

Use of human biospecimens collected for clinical purposes

3.2.6 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; or

(b) where the identity of the donor is required for the purposes of the research, a waiver of consent (see paragraph 3.2.14) has been obtained.

Importation and exportation of human biospecimens for research

3.2.7 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 of this chapter and relevant Australian legislation.

3.2.8 Where it cannot be established that the human biospecimens described in paragraph 3.2.7 were obtained in a manner consistent with the requirements described in this chapter and relevant Australian legislation, the biospecimens should not be used for research in Australia.

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

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

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

Transition provisions for existing biospecimens

3.2.10 Where biospecimens were obtained domestically or via importation prior to 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).

Element 3: Consent

Prospective collection of human biospecimens for research

3.2.11 Those involved in the collection of human biospecimens specifically for research should obtain and record the consent of donor(s) in order to meet the requirements of Chapter 2.2.

3.2.12 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 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 3.2.14);

(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 relatives or their community; and how this will be managed (see paragraph 3.2.14);

(g) whether their biospecimens and associated data may be distributed to other researchers, including those outside Australia (see paragraphs 3.2.7 – 3.2.9);

(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); 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.

Use of stored human biospecimens for research

3.2.13 Reviewers 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.

3.2.14 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). In particular, reviewers should consider:

(a) whether there is a pathway to identify and re-contact 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.

Element 5: Communication of research findings or results to participants

3.2.15 Where proposed research involving the use of human biospecimens may reveal information that may be important for the health of the donor(s), their 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, in reviewing this plan, the HREC should consider:

(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 relatives or their community;

(c) whether a recognised intervention exists that can benefit or reduce the risk of harm to the donor(s), their 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 re-contact the donor(s), their 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.

CHAPTER 3.3: GENOMIC RESEARCH

INTRODUCTION

This chapter is about generating, gathering, collecting, conveying or using genomic data or information that has hereditary implications and/or is predictive of future health in research involving participants, relatives and other family members. It applies irrespective of the nature of the source material for the research, such as data or biological materials such as germline/germ cells or somatic cells.

Genomic research is characterised by the original intention of the investigation and the potential hereditary and/or future health implications, if any, of the information that is collected or generated by the investigations. Genomic research is rapidly evolving and is not constrained by current methods or techniques for obtaining the information; however, a common element of genomic research is the sequencing of data or its use.

Genomic information can be predictive, unchanging, sensitive and familial. Genomic information has the unique character of being both specific to an individual and specific to relatives of that individual and, in some cases, of significance to human population groups such as groups that define themselves via their ancestral lineages.

Research results and information collected for genomic research may be significant for relatives of research participants. Relatives and other family members, such as partners and spouses, may have an interest in the participants' genomic 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 the potential to improve their health or the health of their offspring. However, some family members may prefer not to be given such information, or even not to know of its existence.

Genomic 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. Genomic information can sometimes be misused to stigmatise people or to discriminate against them unfairly. The information may also have similar implications for close relatives. In addition, genomic research can reveal information about previously unknown or misattributed paternity or maternity or familial relationship.

Genomic research is frequently considered to be greater than low risk, especially in the context of research involving Indigenous peoples. For this reason, relevant on-going community consultation and active agreement on the part of communities and traditional owners is an essential component of the planning and conduct of this research.

This chapter is relevant to different types of genomic research (e.g. family studies, clinical research, population health research, health service research). Some research that falls within the broad description of genomic 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. An example of this research is a population survey of preferences regarding disclosure of genomic information where identifiers related to survey results are not disclosed.

As a general principle, research including genomics will require review by an HREC; however, if no information that can identify an individual is used and no linkage of data is planned, the research may be determined to carry low risk.

In genomic investigations, there may be a strong relationship between the research and clinical contexts such that there may be clinical implications of research results or findings. Nevertheless, differences between results that are associated with research and results that are associated with clinical investigations should be clear, especially when the researcher is also a clinician and where clinical care is ongoing. Where appropriate, researchers should refer to clinical practice guidelines such as the NHMRC's *Principles for the translation of 'omics'–based tests from discovery to health care* and applicable legislation.

Chapter 3.3 should be read in conjunction with Chapter 3.1 and other parts of the National Statement.

GUIDELINES

Element 1: Research Scope, Aims, Themes, Questions and Methods

3.3.1 Genomic research that uses sequenced information should be designed with attention to what information is necessary to achieve the aims of the research and to ensure that ethical issues that arise from activity outside the intended scope of the research are minimised by, for example, developing a list of genes that are excluded from analysis.

3.3.2 Genomic research should be designed to minimise the potential for misunderstanding and misuse of genomic information by those who may wish to use it for unrelated purposes.

3.3.3 Methods used in genomic research are not a static set, but are constantly evolving and, as they are developed and applied, may require ethical consideration on an ongoing basis. Therefore, the ethical principles and guidance in this chapter should be considered with reference to the new technologies as they are developed and applied.

Element 2: Recruitment

3.3.4 In addition to participants in genomic research identified as index cases (probands), relatives of these individuals who provide information or biospecimens for genomic research become participants in the research in their own right. Therefore, researchers should be aware of the possibility of the involvement of relatives by virtue of association with a participant or other family member who has been recruited.

3.3.5 HRECs must consider the rationale for and review the information to be used in recruiting family members of a participant.

3.3.6 Where a potential research participant is not already known to the research team, it may be ethically preferable for the participant (rather than the researcher) to make the initial contact with a family member for purposes of recruitment into research.

3.3.7 Researchers should respect differences between and within families regarding the willingness to communicate health information, the relative importance of privacy versus sharing of health information and other matters that may reflect cultural values (whether shared within the family or not).

3.3.8 Where researchers propose to generate or collect genomic information from individuals who are chosen because of their membership of a particular community, they should consult with appropriate community representatives.

3.3.9 The recruitment process should avoid disclosure of genomic information to a potential research participant as an inadvertent consequence of that process.

Element 3: Consent

3.3.10 In considering the appropriate form and scope of consent and the most appropriate process for obtaining consent, researchers should consider:

(a) what information will be generated by the research;

(b) what may be discovered by the research;

(c) what will be deliberately excluded from the scope of the research;

(d) which, if any, of the findings of the research will be communicated to participants and, if so, how;

(e) what the health implications are of the information for participants and their relatives;

(f) whether there are any other implications for participants and their families of being given this information (e.g. insurance, employment, social stigma);

(g) the potential for the information generated by or used in the research to result in participants being re-identified;

(h) whether information generated by the research will be shared with other research groups; and

(i) potential future use of information and biospecimens, including commercial applications.

3.3.11 Participants should be advised that information that they may be given about the likely impact of the genomic information may change over time as new knowledge/insight is gained and how to obtain updated information.

3.3.12 Participants should be advised that publication or funding requirements may require submission of data or information to controlled access repositories that meet international security and safety standards for sharing with researchers globally.

3.3.13 Participants should be advised of the practical limitations associated with a decision to withdraw from genomic research after analysis of data has been conducted or biospecimens have been shared with other researchers as well as any other consequences that may follow from their withdrawal from the research.

3.3.14 Consent specific to the research may not be required or a waiver of the requirement for consent may be considered by an HREC if:

(a) the data or information to be accessed or used was previously collected and either aggregated or had identifiers removed; or

(b) prior consent for the use of the data or information was provided under the scope of a research program that encompasses the proposed research project; or

(c) prior consent for the use of the data or information was provided in the clinical context for research that encompasses the proposed research project; or

(d) unspecified consent has been provided.

3.3.15 An opt-out approach (see 2.3.5), should not be used in genomic research.

3.3.16 Collection of information about family history for genomic research may involve the collection of information about family members who are not aware that information about them is being collected and it may not be practicable to obtain consent from all family members in a pedigree. Therefore, researchers should consider documenting who provided the family history and any presentation of research outcomes should acknowledge that self-reported information about individuals and their families may not be accurate or complete.

3.3.17 Researchers should not presume that the decision to participate in genomic research includes a decision to receive the results of that research. Where researchers consider that the results must be provided to participants, the project should be designed to include the mandatory return of results and this condition should be clear in any information materials.

Element 4: Data Collection and Management

This section covers the access to and collection, use, analysis, disclosure, storage, retention, sharing and disposal of genomic data and information. The potential return of findings and results of genomic research is covered in 3.3.26 to 3.3.35, below.

3.3.18 Researchers should recognise and account for the potentially predictive and sensitive nature of genomic information.

3.3.19 Researchers should be sensitive to the contextual factors that determine the identifiability of genomic information, in particular the impact of the rarity of a genetic disorder or mutation on whether individuals or families could be identified.

3.3.20 For the purposes of a specific research project, the identification of individuals or family members can be considered impracticable if:

(a) there is no plan in the research proposal to link or match the information in such a way as to permit re-identification; and

(b) storage of biospecimens and project information is secure.

3.3.21 If inclusion of information in databases is a necessary component of the research or if information is to be shared for other research, efforts should be made to minimise the potential for re-identification.

3.3.22 Researchers receiving genomic information should not undertake nor permit attempts to re-identify the material or information or otherwise reduce the protection of the privacy of the participants.

3.3.23 Information generated or collected through genomic research should not be disclosed by researchers for uses unrelated to research; however, 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. Participants should be advised of these duties.

3.3.24 Researchers may share genomic data or information provided that:

(a) sharing information is consistent with the consent that has been obtained for the research project or for clinical purposes; or

(b) an HREC has judged that the conditions for waiver of the requirement for consent have been met (see 2.3.9 to 2.3.10); and

(c) the HREC has approved the transfer in principle, subject to any transfer agreement that has been established for this purpose.

3.3.25 Subject to the requirements of good research practice, genomic information and related biospecimens should be stored or disposed of in accordance with the project-specific consent provided or the governance policies of the relevant biobank.

Element 5: Communication of research findings or results to participants

3.3.26 In considering whether to return results of research, researchers should distinguish between individual research results and overall research results. Researchers should consider how these results will be provided to participants, how the process of returning results will be managed and the risks of the return of individual research results and overall research results.

3.3.27 Return of findings and results relating to an individual participant depends on the contextual relevance of the findings; some genomic research findings must be returned, some findings may be returned and some findings should not be returned.

3.3.28 While participants may have a strong interest in their own information, researchers are not expected to return raw genomic data to participants.

3.3.29 Once there is sufficient evidence and agreement that a finding or result is clinically significant, participants should be advised that research results or findings that may be returned will first need to be confirmed according to applicable guidelines, e.g. at a National Association of Testing Authorities (NATA)-accredited laboratory.

3.3.30 When designing the research project and in considering whether to return findings to participants, researchers should refer to the *Decision tree for the management of findings in genomic research and health care* for the principles/framework and then refer to the guidance in the section *Guidance for the Development and Evaluation of an Ethically Defensible Plan for the Potential Return of Findings and Individual Results from Genomic Research* that follows for developing an ethically defensible plan.

3.3.31 Any plan to return individual research results should include linkage with a clinical service and access to genetic counselling. The plan should specify any expertise to which the project team might require access.

3.3.32 The return of results or findings of significance for the health of the participant or relative is the responsibility of the appropriate clinical service or, where such a service is not available, the participant's clinician in consultation with the research team.

3.3.33 Where a result or finding may be of relevance to one or more relatives, it is the remit of the appropriate clinical service or the participant's clinician to discuss with the participant the appropriateness of communicating these results or findings to relatives.

3.3.34 Over time there may be a substantive change in the understanding of the significance of the research results or findings. For the duration of the research project, researchers have a responsibility to provide the research cohort with the opportunity for each participant to re-consider their decision related to receiving results or findings (see 3.3.53-3.3.55).

3.3.35 In all other cases, any obligation to further analyse or interpret genomic data related to participant information ceases at the end of the project.

Decision tree for the management of findings in genomic research and health care

Note 1: Clinicians who do not request an investigation or on whose behalf an investigation was not requested or who subsequently refer a patient to a different primary treating clinician do not have an obligation with respect to management of the findings of the investigation.

Note 2: The patient must be advised of the policy +/- options addressing the return of findings including incidental findings.

Note 3: A "no" answer includes scenarios in which a non-validated test is performed in a NATA accredited lab or overseas equivalent AND in which a validated test is performed in a non-accredited lab. Situations in which this might occur include the development of diagnostic tests and research testing that has not been approved as part of a research project. In the first situation (test development), findings should not be returned. The second situation (unapproved testing) is contrary to ethical standards.

Note 4: The criteria and process must specify: 1) that any findings must be verified by a NATA accredited lab; 2) which findings will be returned; 3) who will be consulted prior to the return of the findings; 4) who will return the findings; and 5) to whom the findings will be returned.

Note 5: If the findings are not pertinent findings, then any return of findings will be based on the policy established by the research protocol and/or by international standards.

Note 6: Refer to guidance in this chapter regarding requirements related to consent for the return of findings from genomic research.

Key Terms

Pertinent findings: Also known as primary findings, pertinent findings are those that were the primary objects of the investigation.

Secondary findings: Findings that were not the primary target of the investigation, but were either specifically sought or are related to the primary target and anticipated as likely to arise.

Incidental findings: Findings of potential clinical significance unexpectedly discovered during the investigation. NB: With respect to full spectrum 'discovery'investigations and direct-to-consumer testing, one is explicitly searching for any and all findings and so no findings can be considered 'unexpected'.

GUIDANCE FOR THE DEVELOPMENT AND EVALUATION OF AN ETHICALLY DEFENSIBLE PLAN FOR THE POTENTIAL RETURN OF FINDINGS AND INDIVIDUAL RESULTS FROM GENOMIC RESEARCH

General Requirements

3.3.36 Researchers must prepare and follow an ethically defensible plan to manage the disclosure or non-disclosure of genomic information of potential importance for the health of research participants or their relatives.

3.3.37 The ethically defensible plan must be approved by an HREC.

The Nature of Research Findings

3.3.38 Researchers should describe how potentially returnable findings may arise (where applicable). This description may include reference to the types of technologies that will be used to generate the findings.

3.3.39 As relevant, descriptions should include information on distinctions between:

(a) findings related to primary aims of the research (including individual test results); and

(b) findings related to secondary aims of the research or findings that are unintended, unanticipated, inadvertent, incidental to or beyond the aims of the research.

3.3.40 Researchers should include information on the difference between clinical and research testing/findings and the need for further validation of any research findings and assessment of their clinical significance.

Step 1: Determination of Whether Findings Will Be Returned

Genomic research falls into three categories:

(a) research with findings that must be returned;

(b) research with findings that may be returned; and

(c) research with findings that should not be returned.

The relevant factors to be considered to determine whether findings must, may or should not be returned include:

(a) analytic (scientific) and clinical validity;

(b) significance to the health of the participants/relatives; and

(c) clinical utility.

3.3.41 Where there will be any return of findings to participants, they should be advised as to which findings will be returned and which will not be returned, as follows:

(a) that researchers have an obligation to have a process in place for the return of findings that are of proven validity and of health significance to the participant or relative, subject to participant consent;

(b) that if researchers plan to return findings during the project that are of proven validity but are not of health significance to the participant or relative, they will need to justify this plan;

(c) that there is no obligation on researchers to look at or assess findings outside of the scope of the research; and

(d) that there is no ongoing responsibility on researchers to review findings of a research project after the project has been completed in order to discover or assess findings that may have become returnable due to later scientific advances.

3.3.42 Where unspecified collections by biobanks are involved, researchers should describe the role, if any, that any biobank involved in the collection, management or storage of any biospecimens used in genomic research will have in the return of findings. Researchers should note that there is no general expectation that there is a role for a biobank in the return of findings of genomic research.

3.3.43 Researchers must provide evidence in their research proposal of their awareness of any relevant institutional policies or procedures related to the return of findings to participants, including those of associated familial cancer centres or their equivalent.

3.3.44 Researchers should describe the resource requirements and infrastructure that are or will be put in place to support the process of return of findings, including resources that the research team, institution or external parties (e.g. clinicians and other experts) will need related to the provision of advice or counselling, the coordination of services and administrative matters.

Step 2: Validation and Assessment of Findings

This section applies to individual test results and any findings, whether primary, secondary or beyond the intended scope of the research.

3.3.45 Researchers should describe how any individual findings will be confirmed including reference to where the validated tests will ordinarily be conducted and any relevant distinctions between different types of validity (i.e. analytic (scientific) validity and clinical validity).

3.3.46 Researchers should describe how the validated findings will be assessed for their potential health significance and clinical utility for the participant and/or relatives, including:

(a) who will be responsible for making these judgements, including any intention to refer participants to a clinician for this purpose;

(b) recommendations for finding the necessary expertise for making these judgements, if not within the expertise of the research team – a process that must:

(i) include the involvement of a clinical service with qualified genetics practitioners before and/or after the assessment; and

(ii) be independent of the research team; and

(c) how the confirmed findings will be communicated to those whose expertise is required.

Step 3: Consent to Disclosure of Findings and Notification Requirements

3.3.47 Researchers should describe how consent for return of findings will be obtained and how it will enable participants' decisions to receive or not to receive findings, including when, how and by whom the consent will be obtained and with recognition of:

(a) the iterative character of consent (i.e. obtained at multiple time points) for return of this type of findings; and

(b) the familial character of information and the consequent implications for relatives.

3.3.48 Researchers should describe the proposed process for communication with

(a) the participant;

(b) the appropriate clinical service or participant's clinician (regarding the communication of the implications of the findings to the participant); and

(c) the authorised decision maker in the event of the death or incapacity of the participant.

3.3.49 The communication process should include:

(a) who will be involved in communicating with the participant/clinician/authorised decision makers;

(b) to whom the participant/clinician/authorised decision makers can address any follow up questions or concerns; and

(c) what mechanisms and formats will be used to communicate information (including potential notification, disclosure and referral).

3.3.50 Researchers should provide participants with qualitative and, if available, quantitative information regarding the likelihood that returnable findings will be discovered and whether an effective and beneficial (or harm reducing) intervention exists for the condition related to the findings.

3.3.51 If the participant has agreed to be notified of the existence of potentially relevant information and the option to receive this information, they should only be notified after the test validity and the potential utility of the information have been established.

3.3.52 Where feasible, researchers should indicate the timeframe for establishing the validity and potential utility of the relevant information.

3.3.53 Researchers should respect the decision of a participant not to receive information on the research findings, including information that is important for their health, and should not routinely seek to confirm the preference at a later point in time.

3.3.54 As the nature of information may change during a research project, researchers should be prepared to provide information to participants who, after indicating that they prefer not to receive information, later change their preference and request to receive the information (see 3.3.17 and 3.3.34).

3.3.55 Researchers should advise participants that, if they change their preference and wish to receive the information, they may contact the research team to request it and that the researchers will provide the information if it is practicable to do so.

3.3.56 Researchers should describe the access to genetic and clinical advice and counselling that will be provided, 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.

3.3.57 Researchers should specify where the genetic and clinical advice and counselling services are located and confirm that sufficient resources are available.

Privacy Issues Specific to Genetic Information

3.3.58 Researchers should consider the identifiability of information and data linkage issues in the context of the return of genomic research findings, with specific attention to the impact of the design and implementation of the research and other current or projected activities that may require the use of the information/findings that are potentially returnable.

3.3.59 Researchers should advise participants of the potential for genetic information to become re-identified.

3.3.60 Researchers should describe the process for protection of privacy in accordance with participant preferences, how differences in the preferences of participants will be accommodated and how any conflicts (e.g. between family members) will be managed.

3.3.61 Researchers should consider how genomic research data or information will be stored in the event of the need for future analysis/testing and disclosure to participants.

CHAPTER 3.4: ANIMAL-TO-HUMAN XENOTRANSPLANTATION

INTRODUCTION

Xenotransplantation includes any procedure that involves the transplantation, implantation or infusion of *live* cells, tissues or organs from another species, or body fluids, cells, tissues or organs that have ex vivo contact with live cells, tissues or organs from another species.

Some animal materials are already used to treat humans, such as porcine heart valves. However, in these cases the materials are chemically preserved so they contain no living cells or tissue. In contrast, xenotransplants are *living* cells that can perform the same functions as the organ, tissue or cells that they replace.

This chapter provides guidance for the ethical review and conduct of *animal-to-human* xenotransplantation research, hereafter referred to as xenotransplantation research. Researchers should seek advice from an HREC if they are unsure if their proposed research is covered by this chapter.

Chapter 3.4 should be read in conjunction with Chapter 3.1 and other parts of the National Statement.

In addition to the ethical considerations identified in Chapter 3.1 that are applicable to all research, there are ethical considerations that are particularly relevant to xenotransplantation research. These include:

- the potential risk of disease transmission from animals to humans (xenozoonosis), including the risk of novel xenozoonoses;
- the risk of the transmission of a xenozoonosis from the participant to their close contacts or other non-participants;
- the need to balance the interests and safety of close contacts and other non-participants with the interests of the participant;
- the requirement for long-term or lifelong monitoring for safety. Monitoring may include the participant and, potentially, their close contacts; and
- limitations on the participant's ability to withdraw consent. This may be due to the inability to remove the animal material or withdraw from long-term monitoring.

HRECs must adopt a cautious approach when assessing the ethical acceptability of xenotransplantation research. Xenotransplantation research will only be ethically acceptable if the potential benefits justify the risks. HRECs responsible for approving xenotransplantation research must consider the extent to which risks are unknown in the context of public safety and whether the proposed research should proceed in view of potential unknown risks. An assessment of the risks and benefits associated with xenotransplantation research may be particularly complex due to:

- the potential risk not just to the individual, but also to close contacts and other non-participants;
- the potential for catastrophic harm if an adverse event, such as xenozoonosis, were to eventuate; and
- unknown risks.

Specific considerations for xenotransplantation research

All research to which this chapter applies must be ethically reviewed and approved by an HREC, with consideration of any requirements of the Therapeutic Goods Administration (TGA).

Conscientious objection

Those who conscientiously object to being involved in xenotransplantation research should not be obligated to participate, nor should they be put at a disadvantage because of their objection.

The use of animals in research

The use of animals in research raises significant ethical issues. The care and use of animals in xenotransplantation research must comply with the requirements of the *Australian code for the care and use of animals for scientific purposes 8th edition, 2013* and relevant state and territory legislation, and also applies to animal materials imported for use in xenotransplantation research. Xenotransplantation research must be ethically reviewed and approved by an institutional animal ethics committee.

Source animals for xenotransplantation that are genetically modified are regulated by the Office of the Gene Technology Regulator (OTGR) under the *Gene Technology Act 2000* (Cth).

The use of hybrid embryos or chimeras

Research involving human embryos and gametes, including the creation of hybrid and chimeric embryos, is separately governed by the *Research Involving Human Embryos Act 2002* (Cth) and the *Prohibition of Human Cloning for Reproduction Act 2002* (Cth).

GUIDELINES

Element 1: Research Scope, Aims, Themes, Questions and Methods

Key questions include:

- Does the HREC have appropriate expertise to assess xenotransplantation research?
- What are the potential risks to participants, close contacts and other non-participants?
- Are there risks that are not currently known or not well understood?
- How is the research ethically justified in the context of these risks?
- How will the planned methods minimise the risks of the research?
- How are public interests balanced against private and/or commercial interests?
- What type of monitoring will be required?
- For how long will participants be monitored and under what circumstances, if any, would the monitoring plan change?
- How will adverse events be managed?
- Under what circumstances would the research be discontinued?

3.4.1 HRECs responsible for approving xenotransplantation research should be satisfied that:

(a) all necessary information, as outlined in this chapter, has been received;

(b) appropriate expertise is available for the assessment of the research (see paragraph 5.1.33);

(c) the proposed research is scientifically valid, and independent expert advice has been sought (see paragraph 5.2.21);

(d) the proposed research activities, level of risk and proposed benefits have been considered in relation to public interest and safety; and

(e) all possible mechanisms to reduce the risks to the participant, close contacts and to other non-participants have been explored and, where possible, introduced.

3.4.2 Researchers should develop a definition of 'close contacts' for each research proposal with consideration of an individual participant's circumstances. The definition of 'close contacts' may vary depending on the specific research and identified risks. Close contacts may include the participant's immediate family, close friends, work colleagues, or any person who is in intimate or frequent contact with the participant or the xenotransplantation material.

3.4.3 If there are options that pose less risk or greater benefit to the participant, the HREC must be satisfied that the research is ethically justified.

3.4.4 When assessing risk to the participant, close contacts and other non-participants, researchers and HRECs should consider:

(a) the type of material intended for transplantation, including whether the material will be encapsulated in synthetic, animal or human material;

(b) the measures in place to minimise the potential for xenozoonoses. These measures may include the use of specific pathogen-free herds or genetically modified animals;

(c) the anticipated level and duration of immunosuppression required for the participant;

(d) the likelihood of psychological and/or social harm to the participant;

(e) current clinical and/or theoretical evidence, including evidence of xenozoonoses and the likely disease types, associated severity, infectious potential and likely mode of transmission; and

(f) alternative treatment options available, including other clinical trials, which may pose greater benefit to the participant or less risk to the participant, close contacts and other non-participants.

3.4.5 An ethically defensible plan for the management of risks related to xenotransplantation research must be developed for consideration by an HREC. In reviewing this plan, the HREC should be satisfied that the following have been considered:

(a) the requirements outlined in this chapter;

(b) a risk management plan, including a plan for proposed monitoring and a justification for the proposed monitoring;

(c) the availability of the required resources to sustain the proposed research, including evidence of adequate financial resources for long-term monitoring (see 3.1.9);

(d) the likelihood of the research generating information, such as the diagnosis of a xenozoonosis, which may be relevant to the participant's close contacts and/or other non-participants;

(e) the circumstances under which the participant's personal information may be disclosed to close contacts and the process for managing such a disclosure;

(f) the procedure for the transfer of responsibility for monitoring and care, should the researchers move or discontinue the research activities, or in the event of institution closure;

(g) the procedure to be followed at the conclusion of the monitoring, including the conclusion of monitoring following the death of a participant;

(h) any required psychosocial assessment of the potential participant. For example, an assessment to determine the likelihood of long-term compliance by the participant, and their ability to cope with the identified risks; and

(i) the existence and availability of a recognised state or territory public health containment plan commensurate with the level of risk associated with the proposed research.

Element 2: Recruitment

Key questions include:

- How will participant suitability be assessed (including, potentially, an assessment of the likelihood of long-term compliance with the monitoring plan)?
- Will individuals who come into frequent or close contact with animals be excluded from the research?
- How will risks that are not currently known or not well understood be explained to potential participants?
- If a participant's close contact does not support the participant's involvement in the research, how will this be managed?

3.4.6 Prior to obtaining consent from potential participants, information relating to the research and the associated risks should be provided to close contacts.

Element 3: Consent

Key questions include:

- How will consent for long-term monitoring be managed?
- What are the limitations for withdrawal of consent?

3.4.7 Before potential participants consent to xenotransplantation research, researchers should provide them with sufficient written information regarding:

(a) the potential risks to the participant, including an explicit acknowledgment when the risks are unknown;

(b) alternatives to participation, including participation in other available clinical trials;

(c) the potential risks to the participant's close contacts or other non-participants;

(d) the proposed strategy for the management of these risks, including required monitoring, the reasons for monitoring and the expected duration of monitoring;

(e) the required action to be taken if an adverse event occurs, particularly in the event that a xenozoonosis is detected. This may include changes to participant monitoring, contact tracing and/or in extreme cases, participant isolation; and

(f) any requirement for the participant to disclose their participation in xenotransplantation research to close contacts, health professionals or others.

3.4.8 Researchers should provide participants involved in xenotransplantation research with information about their right to withdraw consent to participate in the research, including any limitations that may be relevant to their withdrawal of consent. Limitations may include:

(a) the requirement to agree to long-term monitoring for safety;

(b) the potential absence of an option to remove implanted materials; and

(c) cooperation with any required contact tracing.

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 3.2: 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' should be considered for any innovative therapy involving the fetus. *See also* paragraph 3.1.38.

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 Introduction to *Chapter 3.1: Elements of Research*).
- 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 emotional welfare 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 2.3.10 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 *Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders.*

Other documents that might provide useful guidance for researchers are *Keeping Research on Track II* and the *Guidelines for Ethical Research in Australian Indigenous Studies* (Australian Institute of Aboriginal and Torres Strait Islander Studies 2012).

Human Research Ethics Committees (HRECs) are also required to apply the *Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders* 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 *Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders* informative.

The *Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders* 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.[4]

[4] 'The six core principles in *Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders* have been updated as follows:
- Spirit and integrity
- Cultural continuity
- Equity
- Reciprocity
- Respect
- Responsibility

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.

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 for 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 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 4.8: 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 in the Design, Development, Review and Conduct of Research 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 5.2.14 to 5.2.16);

(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) categories of minimum membership; and

(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.

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

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 5.2.14 to 5.2.16);

(j) reporting on its activities to the institution;

(k) methods of decision making;

(l) prompt notification of decisions;

(m) record keeping (see paragraphs 5.2.25 to 5.2.29);

(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 5.2.20) at meetings;

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

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

Insurance

5.1.38 Institutions must be satisfied that sponsors of clinical trials have indemnity, insurance and compensation arrangements in accordance with applicable regulatory requirements.

5.1.39 Institutions must also have arrangements to compensate participants for harm resulting from negligence in 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 5.2.26 to 5.2.29 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 For relevant health research, researchers should show that the research meets the requirements of the CPMP/ICH Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95), ISO 14155 Clinical Investigation of Medical Devices, the World Health Organization International Clinical Trials Registry Platform and the TGA.

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

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

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

5.2.10 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.

5.2.11 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). Where applicable, this disclosure should specify:

(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 research; and

(b) any restrictions on publication or dissemination of research findings.

5.2.12 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.

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

Good communication between review bodies and researchers

5.2.14 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.

5.2.15 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.

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

Participants' interests

5.2.17 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.

5.2.18 In any clinical research, a review body should be satisfied that research participants are adequately informed of the funding arrangements of the research (see also 3.1.29).

5.2.19 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

5.2.20 A review body may invite researcher/s, and researchers may request, to be present for discussion of their proposed research..

5.2.21 A review body may seek advice from experts to help in considering a research proposal (e.g. 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).

5.2.22 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

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

5.2.24 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 5.2.15). 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

5.2.25 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.

5.2.26 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.

5.2.27 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.

5.2.28 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.

5.2.29 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

5.2.30 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.

5.2.31 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.

5.2.32 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.

5.2.33 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 with another institution, for example, a university-based researcher conducting research at a hospital;
- a research project approved at one 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.

5.3.3 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

(e) 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 Monitoring arrangements should be commensurate with the risk, size and complexity of the research.

5.5.3 For each clinical trial, institutions and review bodies should ensure that there are appropriate mechanisms for safety monitoring and reporting, including standard safety reporting and the use of a Data and Safety Monitoring Board (DSMB) or (an) identified person/s or committee with suitable expertise to assist and advise the institution and/or review body in carrying out their safety monitoring responsibilities. Researchers should refer to other published NHMRC guidance addressing these matters.

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.

5.5.6 The granting and extension of ethical approval for a research project must be on the condition that the researchers:

(a) conduct the research in compliance with the approved protocol or project description;

(b) provide reports of the progress of the trial and any safety reports or monitoring requirements as indicated in NHMRC guidance and in accordance with the manner and form specified by the review body;

(c) submit for approval any amendments to the project, including but not limited to 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 research;

(d) inform the review body as soon as possible of any new safety information from other published or unpublished research that may have an impact on the continued ethical acceptability of the research or that may indicate the need for modification of the project;

(i) for clinical trials with implantable medical devices, confirm the existence of, or establish, a system for enabling the tracking of the participant, with consent, for the lifetime of the device.

Discontinuation or suspension of research

5.5.7 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.

5.5.8 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.

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

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

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

(c) as the trial progresses, the continuation of the trial would disadvantage some of the participants as determined by the researchers or others monitoring the trial.

5.5.10 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.

5.5.11 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.

5.5.12 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 receiving, 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);
- Human Research Ethics Committees (HRECs) and other ethical review bodies;
- 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*.

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.

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.

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.

co-researcher
One or more participants (or a particular sub-group of participants) who make/s a significant contribution to the planning, design, implementation or outputs of a research project, including the collection, analysis or interpretation of data. Examples of co-researcher contributions include where participants contribute expertise, such as their cultural knowledge of mores and local practices, or their personal insights into local conditions, special interests (e.g., gaming), or social identities or contexts (e.g. young people living in out-of-home care, community activists or people who identify as LGBTIQ). (See Chapters 3.1 and 4.8.)

data

Data refers to bits of information in their raw form. Data can refer to raw data, cleaned data, transformed data, summary data and metadata (data about data). It can also refer to research outputs and outcomes. (See Chapter 3.1, Element 4). Note: Information generally refers to data that have been interpreted, analysed or contextualized.

databank

A systematic collection of data.

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.

ethics review

Review of research by an HREC or other body.

ethics review body

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

genomic data

Raw data, processed data or information that has been subject to a process of critical analysis and/or interpretation to assign meaning in the context of genomic research.

genomic research

Research with the potential for hereditary implications which may range from single gene genetic research to whole genome sequencing and any other 'omic' research (e.g. exomic, proteomic, etc) with potential hereditary implications. Genomic research includes the full scope of 'genetic' research..

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. (See also the definition for 'human biospecimens' in Chapter 3.2)

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.

index case

The original patient or participant in genomic research who stimulates investigation of other members of the family. This person is also referred to as the 'proband'.

innovation

In the research context, the introduction of one or more novel elements of an intervention that represent/s a substantive departure from the spectrum of standard care or service delivery. An innovation may apply modalities or strategies used and tested in one domain to a novel application. An innovation may or may not be therapeutic in intent or effect and may or may not be considered to be experimental; however, a condition of

research involving an innovation is that the safety, efficacy, or effectiveness of the innovation in the context in which it is used is not known at the onset of the research.

integrity

Honesty and probity as qualities of character and behaviour.

intervention

An intentional change in the circumstances of research participants. The aim of interventional research is to evaluate the impact of that change on one or more outcome measures. The intervention can be a health-related procedure or process or a behavioural, educational or social modification. It can involve a policy change, a therapeutic strategy, a change in service provision or an approach to provision of information that is introduced and manipulated, controlled or directed by the researcher.

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.

mutations

Genetic changes that can be investigated or discovered in the form of

- Germ line mutations, which involve inherited or de novo variations or mutations that occur in germ cells implicating one or more genes known to cause or predispose a person to disease (e.g. BRCA1)
- Somatic mutations, which involve acquired variations or mutations in one or more genes within tissues (e.g. tumours with BRAFV600E).

negligible risk

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

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 or an opinion about an identified individual, or an individual who is reasonably identifiable:

(a) whether the information or opinion is true or not; and

(b) whether the information or opinion is recorded in a material form or not.

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.

relatives
: Persons related by blood to the index case, as distinguished from family members who are persons who may or may not be related by blood, but who may be affected by information with hereditary implications.

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

research findings
: Information that becomes known as a result of the research. Research findings may take the form of

- Findings related to primary aims of the research (including individual test results)
- Findings related to secondary aims of the research or that are unintended, unanticipated, inadvertent or incidental to the aims of the research.

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. *See also Australian code for the responsible conduct of research*, 2018.

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.

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

validity
: In the context of genomic research findings or individual test results, a judgement about the likely accuracy of the findings or results, as measured by National Association of Testing Authorities (NATA) accredited testing or its equivalent. Validity may refer to the pathology processes establishing the analytic validity and clinical validity of a testing method and/or the use of an accredited test to confirm the presence of a variant found in the research.

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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