SECTION 4: ETHICAL CONSIDERATIONS SPECIFIC TO PARTICIPANTS

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

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

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

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

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

Chapter 4.1: Women who are pregnant and the human fetus

Introduction

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

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

This chapter does not apply to research involving:

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

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

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

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

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

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

**Guidelines**

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

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

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

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

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

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

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

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

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

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

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

**The human fetus, or fetal tissue, after separation**

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

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

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

4.1.13 There should be no trade in human fetal tissue.

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

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

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

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

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

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

a. a decision whether to approach her about proposed research involving her, her separated fetus or 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 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:

i. the woman and any others she wishes to involve (see paragraph 4.1.15) have given consent to the removal and the research;
ii. the fetus is available for research only as a result of separation by natural processes or by lawful means; and
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

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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:
Justice

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

Beneficence

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

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

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

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

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

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

Respect

4.4.5 People involved in research to which this chapter applies may have impaired capacity for verbal or written communication. Provision should be made for them to receive information, and to express their wishes, in other ways.

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

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

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

Process to be followed

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

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

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

a. stress or emotional factors may impair the person’s understanding of the research or the decision to participate; and

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

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

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

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

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.
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;
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 4.5.7) or to withdraw.

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

   a. how the decision about the person’s capacity will be made;
   b. who will make that decision;
   c. the criteria that will be used in making the decision; and
   d. the process for reviewing, during the research, the participant's capacity to consent and to participate in the research.

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

Chapter 4.6: People who may be involved in illegal activities

Introduction

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

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

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

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

Legal implications may include:

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

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

Research that is intended to study or expose illegal activity or that is likely to discover it must be reviewed and approved by a Human Research Ethics Committee (HREC) rather than by one of the other processes of ethical review described in paragraphs 5.1.7 and 5.1.8, except where that research uses collections of non-identifiable data and involves negligible risk, and may therefore be exempted from ethical review.
Values, principles and themes that must inform the design, ethical review and conduct of all human research are set out in Sections 1 and 2 of this National Statement. The guidelines and headings below show how those values, principles and themes apply specifically in research that is the subject of this chapter.

**Guidelines**

**Research merit and integrity**

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

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

**Justice**

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

**Beneficence**

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

**Respect**

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

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

   a. the likelihood of such discovery and of any resulting legal obligation of disclosure the researcher may incur; and
   b. the extent to which the researcher will keep confidential any information about illegal activity by participants or others, and the response the researcher will make to any legal obligation or order to disclose such information.

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

   a. are aware that the research may discover illegal activity; and
   b. do not have unrealistic expectations of benefit from their participation.

**Chapter 4.7: Aboriginal and Torres Strait Islander Peoples**

**Introduction**

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

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

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

Other documents that might provide useful guidance for researchers are *Keeping research on track: A guide for Aboriginal and Torres Strait Islander peoples about health research ethics* (NHMRC 2005) and the *Guidelines for Ethical Research in Indigenous Studies* (Australian Institute of Aboriginal and
Human Research Ethics Committees (HRECs) are also required to apply the Values and Ethics guidelines as the basis for assessing proposals for health research with Aboriginal and Torres Strait Islander participation.

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

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

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

Research to which this chapter applies must be reviewed and approved by a Human Research Ethics Committee (HREC) rather than by one of the other processes of ethical review described in paragraphs 5.1.7 and 5.1.8. The HREC process must have included assessment by or advice from:

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

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

**Guidelines**

**Research merit and integrity**

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

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

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 minimizing 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 (see also paragraph 4.8.19).

4.8.4 Researchers should inform ethical review bodies in Australia:

- a. whether, in the country in which they intend to do research, there are ethics approval processes that are relevant to that research, and whether any such processes are mandatory or voluntary in relation to the proposed research; and
- b. how such processes function, the values and principles on which they rely, and whether they require reporting of the Australian review body's approval.

4.8.5 Where there are no ethics approval processes in an overseas country, this National Statement may provide the only applicable process for ethical approval. In this case, the Australian ethical review body should take account of the available resources and means to conduct the research and avoid imposing unrealistic requirements, providing always that research participants are accorded no less respect and protection than this National Statement requires.

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

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

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

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

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

Justice

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

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

   a. the way the research will be conducted;
   b. participants' post-research welfare; and
   c. application of the results of the research.

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

Beneficence

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

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

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

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

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

Respect

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

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

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