SECTION 4: ETHICAL CONSIDERATIONS SPECIFIC TO PARTICIPANTS IN RESEARCH

INTRODUCTION

Anyone can be at increased risk of harm as a result of their participation in research, in different ways, at different times and to different degrees. However, some potential participants may be at increased risk of harm because of specific characteristics or circumstances, the nature of particular research projects and/or how these interact.

The inclusion or exclusion of individuals in research who may experience increased risk of harm from participating in the research project raises ethical issues about self-determination and agency, fairness, and the equitable distribution of benefits, risks and burdens. Assessment of the possible risk of their participation in research involves comparison with some implicit norm about 'usual' levels of risk. While this norm is difficult to quantify, the inclusion of some potential participants in research requires additional consideration arising from:

(a) the nature, design or other contextual factors of the research,

(b) sources of risk of harm specific to potential participants as individuals or by virtue of their group membership or other circumstances, and/or

(c) interaction between (a) and (b).

Traditional approaches to addressing the potential for increased harm to participants in research have commonly involved labelling certain groups of people as 'vulnerable' based on physical, cognitive, social, economic or cultural factors. These factors are often thought to predispose members of certain groups to an increased risk of harm. The National Statement recognises that individuals who identify or who are identified as members of these groups will not necessarily experience the increased risk that is attributed by others to them.

The National Statement requires researchers and reviewers to consider potential sources of increased risk arising from the characteristics and circumstances of individual participants, when viewed in the context of a specific research project. This approach is based on the understanding that increased risk is not an "either/or" binary state, nor is vulnerability a fixed characteristic of individuals or groups. Rather, they are a matter of degree; both increased risk and vulnerability exist on a spectrum and arise from multiple sources. Increased risk also may vary over time as a participant's circumstances change and/or a research project progresses.

Actions to reduce the impact of harm arising from the research on participants may be required.

This section of the National Statement addresses the issues and factors that should be taken into account and provides guidance on how research should, accordingly, be designed, reviewed and conducted in order to minimise risks to certain groups of participants.

In considering the potential inclusion of participants who may be at increased risk in a research project, researchers and reviewers should refer to the principles in Section 1 of this document as well as to Chapters 2.1 and 2.2 for guidance on risk and benefit and the general requirements for consent in research. Researchers and reviewers should also refer to the information under the sub-headings for Elements 1, 2 and 3 of Chapter 3.1 for additional guidance on the themes of research merit, recruitment and consent before considering the guidance in this section.

This section has nine chapters:

1. Ethical issues in recruitment and involvement of research participants who may experience increased risk
2. Pregnancy and the human fetus and human fetal tissue
3. Children and young people

4. People in dependent or unequal relationships
5. People experiencing physical and mental ill-health or disability
6. Research conducted in other countries
7. Research involving Aboriginal and Torres Strait Islander people and communities
8. Research conducted during natural disasters, public health emergencies or other crises
9. Research that may discover illegal activity.

Chapter 4.1: Ethical issues in recruitment and involvement of research participants who may experience increased risk

INTRODUCTION

Sources of increased risk

Characteristics associated with particular life stages or physical and cognitive states may increase a person's risk of harm when participating in research and/or decrease their ability to provide consent to research participation. These characteristics include, but are not limited to:

- an age or developmentally-based lack of capacity to make decisions
- the presence (or perception) of physical or mental ill-health or disability associated with impaired autonomy.

In the latter case, the relevant health condition, impairment or disability may be congenital or acquired, and it may be permanent, chronic, acute or temporary in nature – for example, an impairment might be episodic, fluctuating in severity or subject to environmental factors.

In addition, there are particular life circumstances that may increase risk. These include, but are not limited to:

- social or economic disadvantages that constrain the exercise of self-determination, including those resulting from limited communication skills or capacities, limited first or second language skills, illiteracy, educational or vocational skills deficits, poverty, employment conditions, systematic prejudice or stigmatisation based on disclosed or perceived identity, or being a victim of violence, abuse or other criminal activity.
- being involved in dependent or unequal relationships that increase the risk of exploitation or other harm or constrain the exercise of self-determination, including some employment, educational and service delivery relationships.
- being subject to restrictions imposed by institutions such as prisons, detention centres, youth justice facilities, hospitals, mental health facilities, rehabilitation centres, aged or residential care facilities, defence forces and out-of-home care for children
- participating in research while having an illegal, non-adjudicated or undetermined migrant status, such as being an asylum seeker, or being involved in illegal activities.

Many of these circumstances are present in people's lives in combination, rather than occurring independently. Together, or separately, they can result in compromised autonomy or a sense of alienation and powerlessness and can increase the risk of exploitation or other harm to a person's physical, mental or emotional wellbeing, or their interests.

As previously noted, a further complicating factor in understanding, assessing and responding to a research participant's increased risk is that the associated characteristics or circumstances may be permanent, chronic or temporary in nature or result from the legacy of past experiences.

The context of the research

Some of the increased risk that is associated with participation in research arises from the context of the research itself. This context can be associated with the nature of the research, the setting in which it will be conducted, the goals of the research, the social or political implications of doing the research, cultural factors or some combination of these and other factors.

Although there is a potentially infinite number of contexts in which research can be conducted, chapters 4.6, 4.7, 4.8 and 4.9 provide guidelines related to four such contexts: research conducted in other countries, research with Aboriginal and Torres Strait Islander people and

communities, research conducted during natural disasters or other crises, and research that may discover illegal activity.

Risk mitigation

If it is likely or foreseeable that a cohort of potentially eligible participants have characteristics or are in the circumstances outlined above that are likely to expose them to an increased risk of harm, the research proposal should include discussion of strategies to mitigate, minimise and manage this additional risk. However, if the project is not directed toward potential participants who may be at increased risk and the risks of their incidental inclusion are low, then it may not be necessary to create a risk mitigation strategy.

Where participants face increased risk of harm due to identified sources of vulnerability, there is an imperative to consider whether modifications to the design of the research project are warranted or whether additional safeguards are required to protect the interests of these individuals. Rather than defaulting to exclude such persons, strategies should be employed to enable their participation, support their agency and respect their right to self-determination.

During the development of a research project, researchers should consider consulting any other relevant individuals who are knowledgeable and/or experienced in conducting research with potential participants who may be at increased risk. Consultation with communities themselves, or advocacy or support groups who represent a prospective participant population where such groups exist, is optimal. In addition, consultation with professionals, carers, community workers, peers, elders or family members may be warranted.

When reviewing research involving participants who may be at increased risk of harm, reviewers should consider the level of expertise of the researchers in working with those whose participation in the research raises the issues addressed by the section and how that expertise may or may not mitigate the relevant risks.

Inclusiveness in research

The National Statement's core principles of research ethics – research merit and integrity, beneficence, justice and respect for persons – all support offering the opportunity for participation in research to all those who are eligible, including those who may be at increased risk. Increasingly, it is considered best practice, and a requirement of some research funding, for relevant communities to be involved in co-design or co-production of research – that is, involved from early in the process in the entire research process: from identifying research questions through to research design, implementation, interpretation and dissemination of the findings. This principle of maximising inclusion wherever possible extends to those who are physically or mentally ill, people with disability, or others who are traditionally excluded from research.

Human Research Ethics Committees (HRECs) and other review bodies have traditionally seen it as part of their role to protect potential participants from harm, especially where participants may be perceived to be at high risk of harms or are likely to incur significant burdens that might be associated with the research. While this is appropriate, researchers and HRECs also have a role in facilitating appropriate inclusion of a wide range of participants who are often inappropriately excluded from research because of assumed or potential vulnerabilities. Thus, these roles involve considering not only any potential harms of participation, but also any harmful long-term consequences of excluding participants who may be at increased risk.

Researchers have an obligation to design and conduct research in such a way that opportunities to participate in research are equitable and as inclusive as possible, within the constraints imposed by reasonable and appropriate eligibility criteria.

Consequently, it is the ethical responsibility of researchers and reviewers to find ways to minimise barriers to inclusion in research and to promote the principles and practice of fair selection into, and fair distribution of benefits resulting from, all research projects as they are developed and implemented.

Potential research participants should be offered the opportunity to engage with researchers from early in the process to inform research and discuss perspectives that may be useful in identifying the likelihood of harms and their impact and in accommodating participants' needs or interests at each stage of the research process. Such information may inform the design phase, the research activities affecting participants' experiences during the research, and processes after the research is completed (for example, being given the results or being advised of the outcomes of the research).

Review pathways

When additional consideration is warranted for research that may involve participants at increased risk, the question of which review pathway is appropriate for the research arises. In determining which review pathway is appropriate, researchers, administrators and reviewers should first consider the guidance in Chapter 2.1 on assessment of risk. As a rule, the determination that additional consideration is warranted does not, by itself, automatically require review by an HREC; a variety of factors must inform this judgment.

Having considered the information in the Introduction to this chapter, researchers can begin by asking themselves and each other the following questions:

- To which individuals or groups might our research be relevant?
- Whom do we plan to include in our research?
- Who else is likely to be included in the potential pool of participants for our research?
- Even if not likely, who else might foreseeably be included in the pool of potential participants for our research?
- Is there an increased risk of harm to potential participants in this project? If so, what is the nature and extent of that risk?
- How can we design, or modify the design of, and conduct our research so as to minimise, mitigate and manage the increased risk to potential participants (with consideration for recruitment, consent, ongoing participation and the potential outcomes of the research)?
    - If we cannot reduce these risks to an acceptable level, are we justified in excluding these individuals from our research?
- In addition to decreasing the risk to these potential participants, how can we accommodate the needs and interests of these participants and empower them as they consider participating in and as they participate in our research?

GUIDELINES

4.1.1 When planning to conduct research involving persons with one or more of the characteristics described in this section, researchers should:

(a) develop processes for engaging with the views or experience of those whose perspectives are relevant to their research.

(b) be inclusive in their recruitment of participants, consistent with the aims of the research (see also 1.4 and 3.1.14 - 3.1.16).

(c) provide adequate justification if there is planned exclusion of groups or individuals at increased risk and consider the impact of this exclusion on their research findings.

(d) where feasible and appropriate, include some members of the potential participant group as co-researchers and/or establish a reference group including these participants, so that the project can be informed by the experience, needs and goals of participants.

4.1.2 In considering whether additional measures are necessary to protect research participants who may be at increased risk when participating in the research, researchers and reviewers should consider the nature of potential harms that may arise given the participants' characteristics and circumstances, the nature of the research and how these

factors may interact. Understanding these harms should be informed by consultation with relevant individuals and/or groups during the design stage of the research process. If undertaken, these consultations do not require ethics review.

4.1.3 Some situations may limit potential participants' freedom to make decisions about research participation or may affect their perception of their freedom to make such a decision (see also 3.1.18). However, researchers should not assume an inability to provide consent based on health or disability status or group affiliation. Researchers should be aware that:

(a) where there is a reasonable expectation that an individual's capacity to consent is diminished, the consent process should aim to support the individual in making a free informed decision to the extent possible (e.g. where appropriate, through the use of supported decision making or a surrogate decision maker such as the person's guardian or any individual or organisation authorised by law)
(b) where an inability to consent is related to impairment and is episodic or temporary, recruitment should, where possible, be delayed until the potential participant is able to provide consent (see also 4.5.17-4.5.24)
(c) when there are signs of reluctance or distress from a participant whose capacity to consent may be diminished, this may not necessarily indicate a definitive desire to end participation. In this situation, researchers must consider pausing the research activity, exploring the sources of distress, which may include seeking advice from a guardian or relevant professional, and addressing it using strategies to calm or re-orient the participant. However, if the unwillingness to participate is sustained and unequivocal, then this should be respected.

4.1.4 Where there is potential for actual or perceived coercion, or where participants may not otherwise be freely able to consent, researchers should:

(a) consider appointing a participant advocate or other mechanism to support discussion of the proposed research and the making of voluntary and informed decisions
(b) describe the steps taken to minimise potentially detrimental effects of:
    i. any existing relationships on the conduct of the research
    ii. the research on participants involved in the relationship
(c) ensure that the research is justified in terms of balancing:
    i. the potential benefits to the participants
    ii. the risk of harms to the participants
    iii. the impact of the harms on the individual or their community.

4.1.5 Researchers and reviewers should be aware that conflicts of interest, both financial (e.g. arising from funding sources) and non-financial (e.g. arising from reputation or prestige) can be a source of increased risk of harm to participants including undue pressure to participate (see Chapter 5.4).

Chapter 4.2: Pregnancy and the human fetus and human fetal tissue

INTRODUCTION

Although pregnancy does not necessarily increase vulnerability, some research can pose serious risks to a pregnant woman[1] or the fetus. Attempts to avoid this risk has traditionally led to the exclusion of women, including pregnant women, from much clinical research, leading to lack of evidence for therapies used in pregnancy. Despite potential risks, the participation of pregnant women in research can be of value both to the individual woman and to society more generally, for example, where the research addresses matters that are directly related to reproductive health, pregnancy and childbirth, including clinical treatments.

Individuals choosing to participate in research may unknowingly be pregnant or become pregnant during the research. In clinical research, this may affect the safety or well-being of the participant, the fetus or the validity of the research.

Risks related to clinical research involving women who may be or may become pregnant during the research (or the fetus) include, but are not limited to, harms from infection, exposure to chemicals or radiation, medications or other environmental factors that put the body under increased stress.

GUIDELINES

Pregnancy

4.2.1 In research that carries a risk to pregnant women, researchers should ensure that potential participants are informed of any pregnancy-related risks of participation, unless the potential participants are known to not have, or no longer have, reproductive potential.

4.2.2 Researchers should advise potential participants or participants who are pregnant about the option of access to any counselling that may be relevant to them in making a decision to participate or to continue to participate in the research.

4.2.3 Researchers who are knowingly recruiting adults who are pregnant into their research should refer to the section below on the human fetus and human fetal tissue.

4.2.4 Researchers who are recruiting young women who are pregnant into their research should refer to the section below on the human fetus and human fetal tissue and Chapter 4.3.

The human fetus and human fetal tissue

This guidance addresses research involving the human fetus in utero and human fetal tissue after the separation of the fetus from the body of the woman carrying it.

This guidance does not apply to research involving:

- gametes, embryos (*ex utero*) 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 2017);

[1] The terms *pregnant woman/women* and *woman who has carried the fetus* will be used in the National Statement because women, including pregnant women, continue to be unfairly excluded from research or otherwise disadvantaged in many countries around the world, including Australia. However, we recognise that it is also important to avoid gendering birth, and those who give birth, as feminine, and the National Statement does not support exclusion of those who are or have been pregnant and do not identify as women.

- 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, whether alive or dead at delivery, inclusive of an embryo that has been transferred to a uterus.

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

Chapter 3.2: Human biospecimens in laboratory based research is also relevant to the conduct of research involving fetal tissue after separation.

GUIDELINES

4.2.5 Review of research to which this sub-section applies should be proportionate to the risk of the research. Most commonly, this research should be reviewed and approved by a Human Research Ethics Committee (HREC), rather than by processes for ethics review of lower risk research described in paragraphs 5.1.10 – 5.1.14.

4.2.6 Alternative processes for review of lower risk research may be used only when the research is highly unlikely to have any effect on the health of the fetus or the pregnant woman.

4.2.7 Research involving a fetus or fetal tissue cannot be determined to be exempt from ethics review; however, research using only data associated with fetuses or fetal tissue may be eligible for exemption from ethics review (see 5.1.15 – 5.1.18).

4.2.8 Research involving a fetus or fetal tissue should be conducted in a manner that maintains a clear separation between clinical care and research. Except in the case of innovative therapy, 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. This includes the use of information sheets for research projects that are completely separate from, and capable of being read independently from, written information provided to a patient in the course of routine clinical care.

4.2.9 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).

4.2.10 Where a treating health professional is also involved in the research, any conflict of interest that is identified must be appropriately disclosed and managed.

The human fetus in utero

4.2.11 The wellbeing and care of the pregnant woman and the fetus in utero always takes precedence over research considerations.

4.2.12 Research involving the fetus in utero may affect the pregnant woman and research involving the pregnant woman may affect the fetus. Researchers should discuss the risks and benefits of the research with the pregnant woman, including:

a) the likely and potential effects of the research on the fetus (including consideration of fetal stress) and on the child who may subsequently be born
b) the likely and potential effects of the research on the pregnant woman.

4.2.13 Research that has no prospect of direct benefit to the pregnant woman or the fetus and that involves significant risk to the fetus is ethically unacceptable.

4.2.14 Research on the fetus in utero is ethically acceptable only if:

a) it is consistent with promoting the life and health of the fetus, or
b) it provides necessary information about the health of the fetus

and it also

c) is designed so as to minimise harm to the fetus
d) includes steps for monitoring for signs of fetal harm, and
e) includes steps for suspending or ceasing the research if necessary.

4.2.15 The option of access to expert independent counselling for the pregnant woman about the risks and benefits of the research should be part of any discussion about participation in the research.

4.2.16 Researchers should ask the pregnant woman whether, in deciding whether to participate in the research, they wish to involve others for whom the research may have implications, such as partners, known donors of genetic material or family members and explain why this involvement may be advisable.

The human fetus, or fetal tissue, after separation

4.2.17 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.

4.2.18 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 disadvantaged because of their objection.

4.2.19 Research that involves a fetus or fetal tissue that has become available for research as the result of the termination of a pregnancy should meet the following conditions:

(a) the process used to approach, provide information to and obtain consent for the research from the woman who has carried the fetus is separate from the process supporting a decision to terminate the pregnancy (see 4.2.8 – 4.2.9)
(b) the approach to the woman who has carried the fetus should not begin until after the decision to terminate the pregnancy, and
(c) providing consent to participate in the research must not override or compromise decisions about the timing or method of termination or the freedom of the pregnant woman to change the decision to terminate the pregnancy
(d) where a treating health professional is also involved in the research, any conflict of interest that is identified must be appropriately disclosed and managed.

4.2.20 Consideration of the physical, psychological and emotional welfare and any expressed wishes of the woman who has carried the fetus should inform:

(a) a decision whether to approach the woman who has carried the fetus about proposed research involving the separated fetus or fetal tissue
(b) how and when the woman who has carried the fetus is approached, how information about the research is provided and how and when consent to participate is sought.

4.2.21 In addition to the information that must be disclosed under paragraphs 2.2.2 and 2.2.6, researchers should also inform the pregnant woman or the woman who has carried the fetus:

(a) that the woman's consent to participate in the research may be withdrawn before or after the loss of the fetus or the termination of the pregnancy

(b) that she may consent to store the fetus or fetal tissues for later use in research
(c) about any potential for commercial application of any outcomes of the research or the development of cell lines, including information that might be relevant to the woman's consent
(d) that the woman who has carried the fetus will not be entitled to a share in the profits of any commercial applications unless specified in the project information
(e) about any potential for fetal organs or stem cell lines developed from the organs to be exported to another country.

4.2.22 The option of access to expert independent counselling for the pregnant woman or the woman who has carried the fetus about the risks and benefits of the research should be part of any discussion about participation in the research.

4.2.23 Where research involves a separated fetus, researchers should ask the woman who carried the fetus whether, in deciding whether to participate in the research, they wish to involve others for whom the research may have implications, such as partners, known donors of genetic material or family members.

4.2.24 Biospecimens may be removed from a fetus that has been delivered dead and used for research only if the conditions of the relevant guidelines in Chapter 3.2 and in this chapter are followed, and:

(a) the woman who has carried the fetus and any others that have been consulted (see 4.2.23) have agreed to both the removal of the biospecimens and the research
(b) the biospecimens are available for research only as a result of separation of the fetus by natural processes or by lawful means, and
(c) the death of the fetus has been determined by a registered medical practitioner who has no role (or financial or other interest) in the research.

4.2.25 Researchers must be aware of the legislative requirements that relate to human biospecimens generally, including the prohibition on trade in human tissue, as well as those requirements that address the human fetus, or fetal tissue, after separation (see guidance in Chapter 3.2).

4.2.26 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 consent of the woman who has carried the fetus is required. Others whom she has identified as relevant to decisions about these matters may also need to be involved in the decisions.

Chapter 4.3: Children and Young People

INTRODUCTION

A 'child' is a person under the age of 18 and the term 'young person' is often used to describe older children. A child or young person may or may not have the maturity to make a decision that is sufficient to authorise participation in research. In Australia, when a person reaches 18, they are legally an adult who can make their own decisions about participation in research.

While the National Statement provides ethics guidance, state or territory legal requirements must also be considered and met when conducting research with children or young people.

Research with children or young people should be consistent with the National Principles for Child-Safe Organisations, endorsed by the Australian Council of Governments.[1] In particular, researchers have an obligation to respond appropriately if children or young people report any safety concerns or instances of harm, including reporting to the appropriate authorities, when necessary.

Assent

Although children and young people usually lack the maturity to provide valid and legal consent to participate in research, with exceptions as discussed below, they benefit from knowing what will happen in the research and having an opportunity to express their interest, their questions, their concerns and, potentially, their agreement to participate. Assent refers to the process of informing and seeking agreement to participate in research when valid and legal consent is not possible. A failure to object to participation should not be construed as assent.

Incorporating assent into the recruitment of children or young people for research demonstrates the principle of respect for persons. In obtaining assent, the emphasis is on respect for and communication and engagement with children or young people who are potential research participants.

Assent is not sufficient to authorise participation in research and should only be used in conjunction with parental/guardian consent or other protections, as described in the guidelines below.

Properly obtained assent involves providing as much information as the child or young person desires and is able to understand. This may include appropriately tailored information about:

- the nature and aims of the research
- what participation in the research will involve
- benefits and risks
- the right to decline to participate in some or all of the research during the conduct of a research project or to withdraw from it at any time
- other issues, as per the requirements for consent.

Developing maturity and capacity to provide valid consent

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

- their capacity to understand the nature of a research project and the implications of participation
- their level of maturity and consequent ability to make decisions regarding participation in research
- potentially conflicting values and interests of children/young people and their parents or guardians, and

[1] https://www.humanrights.gov.au/our-work/childrens-rights/national-principles-child-safe-organisations.

- the possibility of exploitation or coercion by parents, peers, researchers or others.

Capacity can refer to:

- the capacity to understand information related to the research
- the capacity to be involved in a decision to participate in research or to agree to participate (assent)
- the capacity to provide consent to participate
- the capacity to effectively participate in research

As the level of maturity of a child or young person increases and their capacity to understand and make decisions about participating in research develops, their involvement in these decisions should increase correspondingly. Increased levels of maturity and of the corresponding capacity to be involved in the decision to participate determine whether a child or young person's assent, together with parental/guardian consent, is the appropriate approach or whether the young person's consent alone is sufficient to authorise participation.

The development of maturity and the capacity to understand and make decisions regarding participation in research cannot necessarily be matched with the age of the child or young person, as there is significant variation among individuals. A child or young person may also have, at the one time, different levels of capacity with respect to different research projects, depending on the type and complexity of the research. For these reasons, it is critical to properly assess a child or young person's ability to be involved in discussions about participation in research, their capacity to understand the research and make decisions about participation, and their capacity to provide consent.

While this chapter provides that researchers must specify how they will assess the child or young person's maturity and capacity to provide assent or consent to participation in the research, it does not provide information, advice or guidance on how to interpret or apply relevant legislation or other legal requirements or relevant clinical guidelines for assessing maturity or capacity.

Researchers and reviewers should consult Figure 2 below for assistance in making the necessary distinctions regarding consent that arise from the developing maturity of children and young people.

GUIDELINES

4.3.1 All research involving children or young people should be designed to include methods and recruitment strategies that are appropriate for the children or young people participating in the research and should be conducted in such a way that promotes the safety, emotional and psychological security and wellbeing of the participants.

4.3.2 In all interactions with children or young people who are potential participants in research, researchers should be attentive to the level of maturity of a child or young person and their capacity to understand and make decisions about participating in the research.

4.3.3 Researchers must

(a) indicate whether they intend to obtain assent together with parental/guardian consent, or consent from the young person only
(b) specify how they will assess the child or young person's capacity to provide assent or consent to participation in the research and whether the assessment will be done on an individual basis or applied to a group

(c) describe the format and content of any proposed discussions with children or young people about the research and, if appropriate, the potential implications of participation (or not) in the research
(d) indicate how consent, assent or the outcome of any proposed discussions will be documented.

4.3.4 Except in the circumstances described in 4.3.5, agreement to a child's or young person's participation in research should be obtained from:

(a) the child or young person, whenever they have the capacity to provide their consent, or
(b) the child or young person, whenever they have the capacity and desire to provide their assent, and
(c) a parent, guardian or other authorised person via standard consent processes.

4.3.5 When a child or young person does not have sufficient maturity to provide assent or valid consent to participation, it is justifiable to involve them in research only when:

(a) the participation of children or young people is indispensable to the conduct of the research and
(b) the research is likely to directly benefit the child or young person or advance knowledge about the health or welfare of, or other matters relevant to, children and young people and
(c) there is no reason to believe that such participation is contrary to that child's or young person's interests.

4.3.6 A review body may determine that the risks associated with the participation of a child or young person in the research warrant a requirement to obtain consent from more than one parent (if available), guardian or other authorised person.

4.3.7 Where the research involves a child or young person who has a caseworker or other appropriate carer with ongoing involvement in a child or young person's decision-making, researchers should consider informing and consulting with this person in a manner appropriate to the context.

4.3.8 In very specific and limited circumstances, an HREC may approve research with young people of developing maturity who provide their assent, but for which no consent is provided by the parents/legal guardian or other authorised person (such as protective services staff). In these cases, the HREC must be satisfied that:

(a) obtaining consent from the parent(s), guardian or authorised person is not practicable or it would not be possible to conduct the research if their consent were required. This situation may arise when:

i. the young person is estranged or separated from their parent(s) or guardian, or
ii. it would be contrary to the interests of the young person to seek consent from the parent(s) or guardian (e.g. due to the confidential or sensitive nature of a survey).

(b) the young person is mature enough to understand the relevant information about the research and is capable of providing their assent to participate in the research
(c) researchers have put in place processes that ensure proper assessment of the young person's level of maturity and capacity to assent to participate in the research

(d) the research aims to benefit the category of children or young people to which this participant belongs
(e) the research has important social value (e.g. adolescent mental health, sexual health, addiction, etc.), and
(f) researchers have put in place provisions to protect the young person's safety, security and wellbeing in the conduct of the research.

4.3.9 As a general matter, researchers should respect the refusal of a child or young person to participate in research or their decision to withdraw from the research. A refusal may be overridden by a parent or guardian judgment where:

(a) the child is very young or immature, and
(b) the research includes the provision of treatment or therapy that is not available outside the context of the research and for which there is no medically acceptable alternative.

4.3.10 If the research will include the potential for researchers, or others involved in the research, to come into direct or indirect contact with children or young people, the following issues should be addressed in information provided to reviewers:

(a) how any foreseeable contact might occur (e.g. in person, by telephone, by email or on a website)
(b) the likelihood that unsolicited, incidental or unplanned contact with children and young people may arise from data collection methods such as where participants 'opt in' (for example, by completing online surveys, texting responses to an SMS service, or responding via email or social media sites)
(c) if there is potential direct contact, whether this contact and the collection of data and information will be supervised and by whom (e.g. by a senior researcher, teacher or parent)
(d) the credentials required for researchers, other project staff and any contractors engaged to assist with the research (e.g. fieldworkers conducting interviews, interpreters), such as legislative or organisational requirements for police clearances, working with children checks, child protection authorisation and/or mandatory reporting training
(e) how records of contact with children or young people and any safety issues that arise will be kept.

4.3.11 Researchers should describe how they will deal with any disclosure and/or suspicion of abuse, including:

(a) compliance with any legal requirements
(b) conformance to any limitations to the scope of confidentiality owed to the child or young person
(c) the circumstances under which confidentiality might be breached, especially if a researcher has a reasonable belief that a risk to self or others has arisen, and
(d) how and when they will communicate this information to participants and how they will confirm that it has been understood by the participant.

4.3.12 Where research involves contact with children (including research conducted in early childhood education, school or public settings where the participants may be a group of children), researchers should collect only personal information that is necessary for the project so as to minimise the potential for misuse (e.g. enabling contact with children outside of the research).

4.3.13 In educational, justice and child protection research, discussion with schools, government departments or other service providers should be built into the research design, where appropriate.

Standing consent

'Standing consent' is used in educational and youth service settings to enable a parent or guardian to provide ongoing consent to their child's involvement in research over a defined time period. This means researchers are not required to obtain further consent from the parent or guardian for individual research projects to which the standing consent applies.

4.3.14 A standing consent model may be established by researchers in educational or youth service settings for research that:

(a) is for the benefit of children or young people
(b) involves only observation in educational or youth service settings or surveys, questionnaires or interviews that:
    i. collect only information from which identifiers will be removed, and
    ii. do not collect sensitive personal information or information on personal or family relationships.

4.3.15 Having obtained standing consent and prior to the commencement of each project, researchers should ensure that:

(a) the parent(s) or guardian has been notified of the date of commencement of the project
(b) the parent(s) or guardian have been given details of the research project
(c) the parent(s) or guardian has been reminded that they may withdraw their consent for any individual project
(d) the parent(s) or guardian has been reminded that they may withdraw their standing consent at any time.

Figure 2: Guide to how participation of children and young people in research is authorised based on levels of maturity, requirements for consent and assent and other provisions

CATEGORY	Type of permission or agreement required			How research participation is achieved
	Child or young person ASSENT	Child or young person CONSENT	Parent/ guardian CONSENT	
Infants who are unable to take part in discussions	NO	NO	YES	Valid parental/guardian consent
Young children who are able to understand some relevant information and to take part in limited discussions	YES	NO	YES	Valid parental/guardian consent
Young people of developing maturity who are able to understand the relevant information, although more vulnerable because of a decreased ability to safeguard their own interests	YES	NO	YES	Valid parental/guardian consent
Young people of developing maturity who are able to understand the relevant information, and for whom parental/ guardian consent is not possible	YES	NO	NO	HREC approval per 4.3.8
Mature young people who are able to understand the relevant information and, due to their maturity, have the ability to safeguard their own interests	NO	YES	NO	Valid participant consent

Chapter 4.4: People in dependent or unequal relationships

INTRODUCTION

This chapter is about pre-existing relationships between participants and researchers, which typically involve unequal status or a power imbalance where one party has or has had a position of influence or authority. These relationships may compromise recruitment and the voluntary nature of participant decisions to provide consent. Unequal relationships may also lead to an increased risk of exploitation or other harm to participants.

Examples include, but are not limited to, relationships between:

- carers and people with chronic conditions or disabilities (including but not limited to 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;
- government authorities and asylum seekers or refugees;
- employers or supervisors and employees (including members of the Police and Defence Forces);
- service-providers (government or private) and individuals or communities to whom the service is provided.

In the above examples, those mentioned first will sometimes be involved as researchers, and may also be involved in facilitating or implementing the research. In these situations, the relationship between researcher and participant may exacerbate an already unequal relationship.

In some contexts, a power imbalance may be relevant to a specific aspect of a person's life, such as their educational, employment or residential circumstances. In other contexts, the power imbalance may be linked with economic, political, social or cultural factors that generate or are associated with systemic prejudice or stigmatisation, poverty, illiteracy, educational or skills deficits, legal status, homelessness, or being a victim of violence, abuse or other criminal activity.

Research participants in dependent or unequal relationships can be more likely to be under-represented or over-represented in research. Under-representation can be due to denial of opportunities to participate in research by the gatekeeping activity of those in the position of power or authority. Over-representation can be due to compromises in the participants' autonomy, when choosing to decline to participate in research may be difficult, and the ease of access to a particular population group, once a researcher has obtained access to the setting.

It is necessary to adopt strategies to mitigate and manage these relationships. Potential approaches may include disclosure of the nature and duration of the relationship and arranging for an independent person to make the initial approach to and/or obtain consent from the potential participant.

GUIDELINES

4.4.1 In the research design, conduct and dissemination of outcomes, researchers should identify and take steps to minimise, mitigate or manage any potentially detrimental effects of:

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

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

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

In the consent process, researchers and reviewers should consider:

(a) the potential for these people to be compromised in their ability to decline to participate
(b) whether the approach to the potential participant is being made by a person on whom they depend for care, daily services or other interactions.
(c) whether there is any direct, indirect or perceived benefit to those in the position of power or authority arising from the participation of one or more of the people with whom they are in an unequal relationship
(d) whether there is any potential for participants to be adversely affected by a decision to participate or decline to participate in the research
(e) whether there is any reason to believe that participation in the research is contrary to the person's best interests.

4.4.3 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. Consideration should be given to the appointment of a participant advocate to safeguard the participants' interests.

4.4.4 Where the researcher has a pre-existing relationship with potential participants that could be considered a potential conflict of interest, it may be appropriate for an independent person to engage in discussions about participation and/or obtain consent (see Chapter 5.4).

4.4.5 People in dependent or unequal relationships may be over-represented in research. because of the relative ease of access to some of these groups as research populations. Conversely, some groups may also be unfairly excluded from research. Researchers should consider these issues in deciding whether to seek out members of these populations as research participants.

4.4.6 Researchers need to be mindful that in some dependent or unequal relationships, some participants may be more likely to have an unrealistic expectation of the benefits of research.

4.4.7 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).

4.4.8 Researchers should respect the privacy of participants and ensure confidentiality of all information they receive, in settings such as shared workplaces, hospital rooms or residential care facilities.

4.5 People experiencing physical or mental ill-health or disability

INTRODUCTION

Physical and/or mental ill-health will have an impact on everyone at some stage. Ill-health (whether physical or mental) exists on a gradient of severity. It can be a permanent, chronic, episodic or temporary condition and can fluctuate in both severity and expression.

Similarly, disability exists on a gradient of severity and can vary significantly in its expression. Disability can be associated with illness, injury, inherited disorders, ageing and other factors. It can be experienced as limitations in mobility, dexterity, strength, energy, sensory perception, communication, cognition, memory, executive function and learning ability, and may sometimes be accompanied by pain. Frailty, physical disability or cognitive impairment are more common among older people and are potential sources of increased risk for older participants in research.

An individual's ability to provide valid consent for and effectively participate in research will depend on the nature and severity of the ill-health or disability, and on contextual factors. Nevertheless, disability, ill-health or age should not be a barrier to participating in research. Many people with disability or chronic illness will value the opportunity to participate in research and they have the right to do so.

In the past, the design, review and conduct of research have directly or indirectly caused people experiencing physical or mental ill-health or disability to be disempowered or excluded from research due to assumptions about their ability to make decisions or provide consent, or to misunderstandings of their ability to participate in research. Commonly, these assumptions and misunderstandings have been based on the use of a group category label (e.g. 'terminally ill', 'mentally ill' or 'disabled') to describe a person's status and situation rather than on a careful assessment of the capacities of individual participants in the context of the proposed research.

Therefore, it is important that the design and assessment of research take account of the range of relevant factors and not be limited to, or focus on, whether the participant has been diagnosed or labelled as physically or mentally ill or as a person with disability.

There is an ethical imperative to include people with physical or mental ill-health or disability in research and to facilitate their independent decision making. This includes considering ways to enable people with altered physical or mental abilities to provide consent. The assumption should always be that adults are able to provide consent for themselves unless an assessment of their individual ability or the context of the research indicates otherwise.

While physical or mental ill-health or disability may mean that, in some circumstances, people are more likely to experience certain harms, this does not mean that they are unable to understand these harms or the likelihood that they may occur.

GUIDELINES

4.5.1 Researchers should consider how the design of their research and the recruitment strategies and models of consent that they employ will facilitate the appropriate inclusion of people with ill-health or disability in their research.

4.5.2 Inclusion and the self-determination of people with ill-health or disability should be paramount in decision making about research. In planning and conducting research, researchers should consider consulting with people with physical or mental ill-health or disability, their representative organisations, or individuals that support them such as carers or family members.

4.5.3 Researchers should indicate how they will determine the impact of a potential participant's ill-health or disability on their:

(a) decision-making capacity

(b) capacity to provide valid consent

(c) ability to participate in research.

4.5.4 Researchers should indicate how they propose to determine the capacity of a potential participant with ill-health or disability to provide consent to take part. This information should include:

(a) how the decision about the person's capacity to provide consent will be made, including who will make that decision,

(b) the criteria that will be used in making the decision, and

(c) any process for reviewing (during the research) the participant's ability to continue participating in the research.

4.5.5 The process of seeking the consent of a potential participant with ill-health or disability should, where relevant, include discussion of the possibility that their capacity to provide consent or express ongoing agreement to participate may fluctuate or be lost altogether during recruitment into or participation in research. The potential participant's wishes about what should happen in that situation should be followed unless changed circumstances mean that acting in accordance with those wishes would be contrary to the participant's best interests.

4.5.6 Researchers and reviewers should consider the use of advance planning and advance directives to record the views of potential participants about their participation in research when their ill-health or disability is fluctuating or when a decline in the capacity to make decisions related to research is anticipated. Similar to the scope of consent more generally (see 2.2.14-2.2.18), advance directives may be project-specific, applicable to related future research ('extended') or broadly applicable to future research activities ('unspecified'). Any use of advance directives in research must not be used if their use is prohibited by relevant jurisdictional legislation.

4.5.7 Researchers should not assume that, once engaged in the research, signs of reluctance or distress from a participant with ill-health or disability indicate a definitive desire to end participation. In this situation, researchers should consider pausing the research activity, explore the source of the distress, and, if possible, address it using strategies to calm or re-orient the participant. However, if the unwillingness to participate is sustained or unequivocal, then any refusal to continue to participate must be respected and their decision to withdraw consent is binding.

4.5.8 Some research involving people with ill-health or disability may be low or negligible risk and should not automatically be deemed to require review by an HREC. The appropriate level of ethics review should be determined on a case-by-case basis.

Research involving people who are seriously ill or unconscious

4.5.9 Additional consideration may be necessary to ensure that research involving people who are seriously ill or unconscious is designed so that they are adequately protected from harm and that conditions are in place to enable valid consent and effective participation in research.

4.5.10 The general principle of inclusiveness in research applies to those people who are seriously ill (e.g. from trauma, infection or comorbidity) or unconscious (e.g. as a consequence of cardiac arrest or stroke).

4.5.11 It can be ethically appropriate to include people in research who are seriously ill or unconscious where the conditions set out in paragraphs 4.5.12 – 4.5.27 are met.

4.5.12 Research involving participants who are seriously ill or unconscious 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 legislation are met, and

(c) either

i. any risk or burden of the proposed research to/on an individual participant is justified by the potential benefit to them, or

ii. where the participant has the capacity to provide consent (including in the form of an advance directive), any risk or burden is acceptable to them and justified by the potential overall benefits of the research.

4.5.13 People who are seriously ill may have impaired capacity for verbal or written communication. Provision should be made for them to receive information tailored to their abilities and in ways that help them express their wishes.

4.5.14 When consent is sought, either from the potential participant or another person authorised to act on their 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.

4.5.15 Where the researcher is also the treating health professional, researchers and reviewers should consider whether an independent person should make the initial approach and/or seek consent from a potential participant or from their guardian or authorized representative.

Consent for emergency care research and intensive care research

In the National Statement, *consent* refers to a process that can only occur prior to commencing participation in research. This understanding of consent is the basis for the common ethical prohibition of delayed, deferred or retrospective consent and the preference in the National Statement for the use of the term 'agreement to continue participation' over 'consent to continue participation'. This means that informing participants and/or their relatives, guardian or authorised representative about participation is not equivalent to obtaining their consent to participate. Equally, seeking a participant's agreement to continue to participate in research when they have regained capacity is not a form of consent. This guidance does not override the requirement for ethics review to take into account relevant jurisdictional legislation and the terminology that may be used therein.

4.5.16 For emergency care or intensive care research, researchers must obtain ethics approval for the model of consent that they will use, or, alternatively, for a waiver of the requirement for consent (see 4.4.19) or use of the process set out in 4.4.20-4.4.21.

4.5.17 Obtaining valid consent from the research participant is the standard for all research, including emergency care research, intensive care research and research involving terminally ill participants, unless otherwise justified.

4.5.18 If it is not possible to obtain consent from the participant for the research, then researchers should seek consent from the participant's guardian or authorised representative, taking into account any relevant legal restrictions.

4.5.19 If obtaining consent from the participant's guardian or authorised representative is not feasible, then researchers should consider obtaining a waiver of the requirement for consent (see paragraphs 2.3.9 – 2.3.10).

4.5.20 If it is not possible to obtain consent from either the participant or the participant's guardian or authorised representative, and the waiver requirements of paragraph 2.3.10 cannot be met, then researchers should consider requesting approval from an HREC for the research to proceed without the requirement for consent, as per the requirements of paragraph 4.5.21.

4.5.21 Approval for research to proceed without consent can be granted by an HREC provided that it is satisfied that the following conditions have been met:

(a) obtaining consent from the participant, the participant's guardian or an authorised representative is not feasible, including when recruitment into the research project has to be achieved very rapidly in an emergency care setting

(b) in making the request for approval, researchers have provided adequate justification for

i. not seeking participant consent or consent from a participant's guardian, or authorised representative, and

ii. not requesting a waiver of the requirement for consent, as provided in paragraphs 2.3.9 – 2.3.10

(c) there is no known or likely reason for thinking that participants would have withheld their consent if they had been asked to provide it, including the absence of any known advance directive that precludes participation in the research

(d) the research carries a risk that is proportionate to the history of the participant's underlying condition(s)

(e) the potential future benefits from the research justify any risk of harm associated with the research

(f) there is sufficient protection of participants' privacy

(g) there is an adequate plan to protect the confidentiality of any data or information collected

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

(i) in making the request for approval, researchers are aware of and comply with any limitations imposed by state, federal or international law.

4.5.22 If approval for research to proceed without consent has been granted and research has commenced, the participant and/or the participant's relatives and guardian or authorised representative should be informed as soon as reasonably possible of the participant's inclusion in the research and of the option to withdraw from it without affecting the quality of care that the participant is receiving.

4.5.23 If the participant regains the capacity to make decisions regarding participation after the research has commenced and they are contactable, then the researchers should explain what ongoing participation involves and seek agreement from the participant that they are willing to continue to participate. Participant decisions not to continue should be respected.

4.5.24 The practice of seeking delayed or deferred consent to participation in research or seeking retrospective consent after some or all components of the research have been completed is not ethically permissible.

Research involving terminally ill participants

4.5.25 As with any person experiencing ill-health, people who are dying may be more likely to experience to certain harms; however, this does not mean that they are unable to

understand the nature of those harms or the likelihood of those harms occurring, nor that they lack insight into their own condition and life expectancy. In addition, many people who are dying may value the opportunity to participate in research, even when there is no hope of cure or any prospect that the research will prolong their own lives. Therefore:

(a) people who are dying should not be routinely excluded from research, and

(b) researchers should consider and apply the general guidance provided for participants with ill-health when designing and conducting research involving terminally ill participants.

4.5.26 The distinguishing features of research involving terminally ill participants are the short remaining life expectancy of participants and their vulnerability (and the vulnerability of family members, guardians or authorised persons) to unrealistic expectations of benefits. Therefore, this research should be designed so that:

(a) the benefits of the research to participants or to others with the same condition justify any risk, burden, discomfort or inconvenience to the participants

(b) the prospect of benefit from the research to participants is not exaggerated

(c) the needs and wishes of participants to spend time as they choose, particularly with family members, are respected and given priority over the research.

Research involving people with disability

4.5.27 Researchers should design and conduct their research in such a way that people with disability can participate. Measures to achieve this include:

(a) adapting the process and timing of obtaining consent to any restrictions imposed by the potential participant's disability, and/or

(b) using data collection methods, research spaces and schedules of research-related activities that are 'user friendly' (e.g. wheelchair accessible), are adapted to the capacity of participants and that accommodate other requirements (e.g. rest breaks).

4.5.28 Unless adequately justified, exclusion of people with disability from research is unethical. Researchers who design a research project that explicitly excludes people with disability must disclose this to reviewers and should include this disclosure in research outputs that are made available publicly, including, but not limited to, academic presentations or publications.

4.5.29 In planning and conducting their research, researchers should consider the need to consult disability representative organisations or individuals, such as carers or family members, who support the specific participants, as appropriate.

4.5.30 In designing and conducting their research and in developing suitable information materials, researchers who are less experienced in working with people with disability should consult with potential research participants who have a relevant disability, as well as any guidelines for the inclusion of people with disability in the research.

4.5.31 Researchers should consider the physical and cognitive status and living conditions of participants living with disability in research and develop strategies to facilitate their participation in research. These strategies might include (but are not limited to):

(a) home-based assessment prior to recruitment and/or commencement of research

(b) consent processes and materials, such as short videos, illustrations and written material with easy readability (e.g. simple vocabulary and syntax, larger text size, line height and length)

(c) appropriate modifications to research procedures

(d) provision or facilitation of transport to the research site.

4.5.32 In seeking consent from people living with disability who are able to make their own decisions about participation in research, researchers should consider which measures to support the consent process are appropriate for the specific circumstances of each potential participant.

4.5.33 Where the participant does not have the capacity to provide consent and consent has been provided by a guardian or authorised representative, the researchers should nevertheless explain to the participant, to the extent possible, what the research is about and what participation in the research involves and seek their agreement.

4.5.34 If the participant regains the capacity to make decisions about participation after the research has commenced, then the researchers should check that the participant is willing to continue to participate and understands that they have the right to withdraw from the research with no penalty.

Review pathways

4.5.35 Research involving participants who are seriously ill or unconscious, including (but not limited to) emergency care research, intensive care research and research involving terminally ill participants will ordinarily require review by an HREC. Researchers advocating for an alternative review pathway must provide adequate justification for this approach.

4.5.36 Some research involving people living with disability may be lower risk and should not automatically be deemed to require review by an HREC. The appropriate level of ethics review should be determined on a case-by-case basis.

Chapter 4.6: Research conducted 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 values, beliefs, customs and cultural heritage of participants in other countries will require recognition of values other than those in the National Statement. There may be times when these values will be in tension with one or more of the values of the National Statement. The legal, regulatory or ethics review processes of another country may also demand conduct that is in tension with the values of the National Statement. The guidelines in this chapter must inform any resolution of these tensions.

It is important that appropriate and sufficient respect is accorded to participants involved in research taking place in other countries and that appropriate and sufficient measures are in place to safeguard the well-being and interests of these participants.

Those with responsibility for oversight of research conducted in other countries must ensure that appropriate research governance processes are in place to authorise and monitor this research.

GUIDELINES

4.6.1 When conducting research overseas, Australian researchers must adhere to the requirements of the National Statement.

4.6.2 The design and conduct of the research should also recognise local cultural values and expectations, in particular what researchers and research participants expect from one another. This recognition should demonstrate that participants will be accorded no less respect and protection than the National Statement requires.

4.6.3 Researchers should demonstrate respect and satisfy the requirements of 1.10 to 1.13 in the design, conduct and monitoring of overseas research by:

(a) taking into account local beliefs and practices, including those related to recruitment, consent and remuneration of participants or contributions to communities for participating in research, and
(b) engaging in ongoing consultation with the local participant population and the communities to which they belong.

4.6.4 The distribution of the benefits, risks and burdens of overseas research for the participants and the broader community should be equitable and should be considered acceptable by local standards.

4.6.5 Researchers should be familiar with the communities in which they plan to conduct their research, know how to engage with the potential participants, and be able to assess the benefits of their research to these participants and communities and the risks and burdens that may be placed upon them. Researchers need to take account of any political, social and cultural factors that may jeopardise the safety, well-being or interests of the participants.

4.6.6 The conduct of research overseas should take into account the opinions and expectations of participants and their communities about the impact of any limits of resources on:

(a) the way the research will be conducted
(b) the well-being of participants after the research is completed, and
(c) application of the outcomes of the research.
This guidance applies to resources brought to the project by the research team or the existing local resources or both.

4.6.7 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, local networks or other support structures.

4.6.8 Researchers conducting research overseas should inform ethical review bodies in Australia:

(a) whether, in the country in which they intend to do research, there are ethics approval or other authorisation processes that are relevant to that research
(b) whether any such processes are mandatory or voluntary in relation to the proposed research, and, to the extent appropriate, how such processes operate, and
(c) whether any reporting of the Australian review body's approval is required by such processes.

4.6.9 Where there are no relevant ethics approval processes in the country where the research will be conducted, the Australian ethics review body should apply the principles and relevant guidelines of the National Statement, with additional regard for the outcomes of consultation with the local participant population and the communities to which they belong.

4.6.10 Researchers conducting overseas research should comply with any requirements set by funders or government bodies that direct them to conform to the standards of overseas institutions or to recognised international guidelines or instruments.

4.6.11 Researchers should ensure that they are aware of and comply with any relevant legal requirements for research or engagement with local populations in the country in which they intend to do their research.

4.6.12 Researchers who plan to diverge from local expectations and requirements in the conduct of their research must disclose and justify this to reviewers, who will consider the rationale provided.

4.6.13 When co-researchers are to be recruited overseas, Australian researchers should inform the review body of the co-researchers' capacity and expertise to conduct that part of the research assigned to them or how such capacity and expertise will be established. There should also be consideration of the benefits for the co-researchers during and after the project.

4.6.14 Australian researchers should satisfy themselves that any overseas co-researchers will carry out the research in a way that accords participants the respect and protection required by the National Statement.

4.6.15 Reviewers should consider:

(a) whether researchers have sufficient experience or access to expertise to enable them to engage with participants in ways that accord participants the respect that they are due and the protection to which they are entitled

(b) whether the researchers' plan for engagement with the potential participants, and their assessment of the benefits, burdens and risks of their research are adequate and properly reflect the values of the National Statement and any local standards and expectations.

4.6.16 To address any questions, concerns or complaints from participants, reviewers should ensure that arrangements have been made for:

(a) a local, readily accessible contact who is available to participants to receive questions and complaints about the research
(b) clear communication between the local contact and the research team so that the researchers can promptly respond to any questions, concerns or complaints
(c) a process for participants to contact the research team and/or the reviewing HREC if there is no viable local contact available
(d) a process independent of the research team for dealing with any complaints (see Chapter 5.6 and the *Australian Code for the Responsible Conduct of Research, 2018*).

Chapter 4.7: Research with Aboriginal and Torres Strait Islander people and communities

INTRODUCTION

Much research has been undertaken in Australia into many aspects of Aboriginal and Torres Strait Islander people's lives. While some of this research has been of benefit to Aboriginal and Torres Strait Islander people and communities, a lot of it has had significant adverse impacts. It is therefore important that appropriate processes are in place and strengths-based approaches are used to ensure that this research is considered, meaningful, ethical and beneficial to Aboriginal and Torres Strait Islander people and communities.

Recognising and respecting cultural needs, actively engaging with people and communities and acknowledging diversity throughout the research journey help to initiate, develop and sustain partnerships and relationships with Aboriginal and Torres Strait Islander people and communities that are based on trust, respect, mutual responsibility and sound ethical principles.

It is important that research with Aboriginal and Torres Strait Islander people and communities is led and governed by Aboriginal and Torres Strait Islander people and communities, and that meaningful engagement with participants and communities is undertaken and ongoing. This helps to ensure that research and its priorities are driven and guided by the Aboriginal and Torres Strait Islander people and communities with whom the research will take place and on whom the research will have an impact.

Researchers must address the principles and guidance outlined in the National Statement and the six core values as described in NHMRC's *Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders*. The six core values are:

- Spirit and integrity
- Cultural continuity
- Equity
- Reciprocity
- Respect
- Responsibility

These six core values help ensure that all human research undertaken with Aboriginal and Torres Strait Islander people and communities:

- respects the diverse values of Aboriginal and Torres Strait Islander people and communities
- reflects Aboriginal and Torres Strait Islander priorities, needs and aspirations
- contributes to the development of long-term ethical relationships among researchers, institutions and sponsors
- is consistent with best practice ethical standards of research.

For this research, researchers must consult NHMRC's *Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (2018)* and *Keeping Research on Track II (2018),* and the *Code of Ethics for Aboriginal and Torres Strait Islander Research (2020)* and *A Guide to applying The AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research (2020)*, produced by the Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS).

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

The guidelines in this chapter apply to (but are not limited to) research where:

(a) the geographic location of the research is such that a significant number or proportion of the population is likely to be Aboriginal and Torres Strait Islander people, and/or
(b) the research is focused on a topic identified as being of specific benefit for or identified as a priority by Aboriginal and Torres Strait Islander people and communities, and the research cohort has a significant proportion of Aboriginal and Torres Strait Islander people and/or
(c) the data gathered in the research will include analysis that specifically identifies Aboriginal and Torres Strait Islander people and communities and/or
(d) the research outcomes will have a specific impact on Aboriginal and Torres Strait Islander people and communities.

Values, principles and themes that must inform the design, review and conduct of all human research are set out in Sections 1 and 2 of the 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.

In applying other sections of the National Statement, researchers, HRECs and other ethics review bodies may also find these guidelines informative.

GUIDELINES

Engagement and consultation in the design and conduct of research

4.7.1 Researchers should ensure that all aspects of research appropriately engage with and incorporate relevant social and cultural preferences and acknowledge the cultural considerations of diverse Aboriginal and Torres Strait Islander people and communities participating in the research – including national or multi-centre research.

4.7.2 The research plan, design and proposal should demonstrate evidence of respectful and meaningful engagement with Aboriginal and Torres Strait Islander people and communities with whom the research will be conducted. Depending on the circumstances, this might include:

- a research agreement between the researchers and the participating groups, organisations and/or communities, or written confirmation of agreement from participating groups, organisations and/or communities, to engage in the research, including evidence of their understanding of their role and responsibilities in the research
- an engagement process whereby meetings are held with potential participants and communities to discuss the research (see Chapter 2.1: Risk and benefit and Chapter 2.2: General requirements for consent, especially 2.2.13).

The following guidelines provide further information about engagement and building cultural capability and must be consulted before planning and conducting research:

- NHMRC *Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (2018)*
- NHMRC *Keeping Research on Track II (2018)*
- The *AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research (2020)*
- *A Guide to applying The AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research (2020)*.

4.7.3 Researchers should ensure that the process of engagement and any agreements with the relevant people and communities provides for mutually agreed mechanisms for such matters as:

(a) community and other relevant consultation

(b) appropriate recruitment techniques, including consent strategies

(c) suitable information to be provided to participants about the research

(d) the progress of the research

(e) sharing of the research findings, outcomes and benefits.

4.7.4 The research approach should acknowledge, value and create opportunities to respectfully learn from the knowledge, wisdom and leadership of Aboriginal and Torres Strait Islander people and communities by actively engaging with them in aspects of the research processes, such as the interpretation of the research data.

4.7.5 The conduct of the research should foster respectful, ethical research relationships that affirm the rights of people and communities to have different values, priorities and aspirations.

4.7.6 Research methods and the conduct of the research should provide opportunities to develop trust and equitable partnerships between participants and researchers.

4.7.7 Researchers undertaking national or multi-centre research with Aboriginal and Torres Strait Islander people and communities should ensure that they gain local level support for their research.

Risks of and benefits from the research

4.7.8 The design of research should take account of risks, burdens and benefits of the research with reference to Chapter 2.1 of the National Statement.

4.7.9 In particular, researchers should seek to identify any potential negative outcomes of the proposed research, as these outcomes may increase the risk of the research. If potential negative outcomes cannot be eliminated, researchers should design processes to reduce or mitigate them, and propose steps for their ongoing monitoring and management.

4.7.10 The benefits from research should include the enhancement and/or establishment of capabilities, opportunities or outcomes that are relevant for the interests and priorities of Aboriginal and Torres Strait Islander people and communities.

4.7.11 The 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 and/or their communities.

4.7.12 The benefits from research should be discussed with and agreed to by Aboriginal or Torres Strait Islander research participants, communities and any relevant stakeholders during an engagement process conducted prior to and during the research.

Review pathways

4.7.13 While research to which this chapter applies may require review and approval by an HREC, some research to which this chapter applies may meet the criteria for lower risk research (see 5.1.10 and 5.1.14).

4.7.14 If review by an HREC is required, the review process must include assessment by or advice from:

- HRECs that have specialist expertise in reviewing ethics proposals for research with Aboriginal and Torres Strait Islander people and communities; or
- people who have networks with Aboriginal and Torres Strait Islander people and communities and/or knowledge of research with Aboriginal and Torres Strait Islander peoples and communities; or
- people who are culturally capable and competent, and aware of considerations specific to the Aboriginal and Torres Strait Islander people and communities with whom the research will be taking place.

The appropriate approach to the HREC review process will also depend on jurisdictional requirements and guidance.

4.7.15 If the research meets the criteria for review as lower risk research, appropriate consideration and incorporation of cultural needs must be part of the design, review and conduct of the research.

Chapter 4.8: Research conducted during natural disasters, public health emergencies or other crises

INTRODUCTION

Research conducted during or following natural disasters, public unrest, armed conflict, public health emergencies or other crises raises significant challenges and ethical issues.

The principal challenges are the balancing of important social priorities and ethical principles. Research conducted in these contexts can serve to protect the public and is often necessary to help manage the current crisis and/or to prevent, or mitigate the impact of, the next one. Such research must be scientifically valid and, ideally, able to be rapidly implemented. At the same time, this research must not:

- pose undue risks to participants
- take priority over participants safety, well-being and recovery from the disaster, conflict or emergency
- impede organised and coordinated responses to the crisis itself.

In planning, designing, reviewing, conducting and monitoring this research, researchers and reviewers should refer to the information and guidance in other sections of the National Statement and to the information and guidelines in other chapters in this section, as well as to the guidelines provided below.

The guidance in this chapter imposes additional requirements on researchers and reviewers who are developing or assessing proposals and/or conducting the research addressed in this chapter. It is designed to be used in specific and limited circumstances where the scale and significance of the disaster, emergency or other crisis require additional ethical consideration of issues in recruitment, consent and participation that arise in this research as a consequence of the nature of disasters, emergencies or other crises.

Research in the context of a humanitarian crisis carries not only risks of harm to participants, but also the potential for re-traumatisation, exploitation or stigmatisation of crisis victims or those responding to the crisis. It can also involve significant risks of physical and/or psychological harm to researchers.

In some cases, research following a disaster or other crisis can be more effective if delayed so as to enable relief efforts and the first stages of recovery from the trauma of the event.

Understanding and responding appropriately to the distinctive collection of factors that characterise research conducted in these circumstances require specific expertise and may require innovative approaches to its design, conduct and review. Nevertheless, the core principles of research ethics as set out in the National Statement still apply to this type of research, even if the research is being conducted overseas.

Researchers and reviewers may also benefit from referring to ideas and guidance available from specialised agencies and organisations that are committed to responding to natural disasters, public health emergencies or other crises throughout the world[1], including the need for rapid sharing of data amongst researchers and between researchers and affected communities in these situations.

[1] Examples of such agencies and organisations are Australia's National Emergency Management Agency (NEMA), the World Association for Disaster and Emergency Medicine (WADEM) and the World Health Organization's Health Cluster initiative.

GUIDELINES

4.8.1 Researchers should consider whether or how their research should be conducted taking into account timing, available resources, the physical and psychological condition of the potential participants in the research and whether the research will hinder responses to the crisis.

4.8.2 Researchers should demonstrate to reviewers that their research is responsive to a genuine crisis and can only be conducted during the crisis to which they are responding.

4.8.3 Researchers should coordinate their research with humanitarian organisations and government agencies responding to the relevant crisis, where possible and appropriate.

4.8.4 Researchers should plan, design and conduct their research so that it:

(a) satisfies requirements for merit and integrity, including recognition that the conditions in which the research will take place will lack stability and may evolve rapidly

(b) is responsive to the needs and priorities of those individuals and/or communities affected by the crisis, with consideration for advice sought and received on this issue from those affected, to the extent possible

(c) employs selection, recruitment and consent strategies and processes that are respectful, fair and appropriately tailored to the participants and the conditions under which they are presently existing

(d) distributes the benefits, burdens and risks of participation in research equitably, including realistic assessments of both short- and long-term benefits and burdens and the risks of unproven interventions

(e) involves community engagement, including effective communication of the aims and implications of the research and its projected benefits, burdens and risks to the participants, with attention to clarifying the distinction between humanitarian aid and research

(f) includes provisions for sharing and dissemination of the data, the results and the outcomes of the research with the affected communities, unless otherwise explicitly justified.

4.8.5 Researchers should make every effort to ensure that the urgency of the situation and/or the duress experienced by victims of the crisis is not used as a justification for any failure to effectively communicate with or obtain consent from participants in their research.

4.8.6 Reviewers of research into natural disasters, public unrest, armed conflict, public health emergencies or other crises have a significant role in facilitating such research and in ensuring that research conducted in these conditions is conducted ethically. Responsibilities of institutions and reviewers include:

(a) developing processes that enable the rapid review of research proposals. These processes could include

  i. preparedness plans for researchers, research institutions and reviewers
  ii. pre-review of standard operational plans, 'generic' protocols or partial protocols
  iii. use of technology and triage strategies to expedite review
  iv. ensuring that adequate review expertise is available on short notice
  v. referring review to equivalent review bodies or specialised expert panels
  vi. delegated and/or 'on call' review arrangements
  vii. other forms of proportionate, accelerated and streamlined review, where appropriate

(b) developing policies for researchers on when review processes for lower risk research may be suitable for their research

(c) careful assessment of the need for the research and justifications offered by researchers regarding its timing, use of resources, coordination with crisis response efforts and engagement with affected individuals and communities
(d) requiring researchers to describe the measures that will be in place to support themselves psychologically and logistically and protect themselves physically
(e) ensuring that appropriate and proportionate monitoring of the research is planned and implemented.

4.8.7 Researchers, reviewers and research institutions should collaborate in making timely determinations about what level of oversight is required for needs assessments, monitoring or surveillance activities and program evaluations related to a crisis and what body will be responsible for the oversight activity (e.g. institution and/or review body).

Chapter 4.9: Research that may discover illegal activity

INTRODUCTION

In some instances, research may discover illegal activity by participants or others, or may discover information that indicates or suggests the possibility of future illegal activity (including activity that is subject to notification, by law, to relevant authorities). Such research may:

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

With respect to research that may discover illegal activity, ethical and legal questions for researchers and institutions relate to:

- whether the consent obtained included provision of sufficient notice or warning of the potential for discovery of illegal activity
- the scope of what researchers might be obliged (for legal, contractual or professional reasons) to disclose and the likelihood of this disclosure occurring
- the possibility that researchers may feel a moral obligation to disclose and the likelihood of this disclosure occurring, and/or
- the implications for participants and researchers arising from the discovery of participants' illegal activity.

The legal obligation of a researcher to disclose information that the research has revealed may arise from a statutory obligation or from legal orders that compel disclosure of information obtained by a researcher.

This chapter is not concerned with investigation conducted as part of law enforcement. It also does not contain guidance about the specific legal obligations of researchers arising from their conduct of 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.

GUIDELINES

4.9.1 Participants may be subject to risks because of their involvement in research that discovers illegal activity. Researchers should establish that these risks are justified by the benefits of the research (see 2.3.3), which may include the exposure itself; for example, where the illegal activity bears on the discharge of a public responsibility or the fitness to hold public office.

4.9.2 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, law enforcement bodies, or courts. In such circumstances, researchers and institutions should consider seeking legal advice.

4.9.3 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 possibility and/or likelihood of such discovery and of any resulting legal or other obligations of disclosure the researcher may incur
(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 or other obligations or order to disclose such information, and

(c) which interactions and activities are part of the research and which are not.

4.9.4 Researchers must consider the use of pseudonyms, or the removal of links between names and data, for participants whose illegal activity may be revealed or discovered in research.

4.9.5 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.

4.9.6 Research that is intended to study or expose illegal activity or that is likely to discover it must be reviewed and approved by an HREC (see 2.3.4), except where that research uses collections of non-identifiable data and may be eligible for lower risk research review processes.