



UnitingCare

Fact Sheet: Research with Vulnerable Groups

The information contained in this Fact Sheet has been extracted from the National Statement on Ethical Conduct in Human Research 2007 (updated 2018) available here [National Statement](#). Please refer to the full National statement for additional, detail.

The [UnitingCare Vulnerable Clients/Residents involved in Research Activities Policy](#) includes definitional material and principles relating to research with vulnerable persons

National Statement Excerpt – Section 4

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

(The National Statement addresses consideration of the following vulnerable groups:

- a. Women who are pregnant and the human fetus
- b. Children and Young people
- c. People independent or unequal relationships
- d. People highly dependent on medical care who may be unable to give consent
- e. People with a cognitive impairment, an intellectual disability, or a mental illness
- f. People who may be involved in illegal activities
- g. Aboriginal and Torres Strait Islander peoples
- h. People in other countries.

This fact sheet will introduce aspects of the groups highlighted in yellow above.)

Children and Young People

Research involving children and young people raises particular ethical concerns about: their capacity to understand what the research entails, and therefore whether their consent to participate is sufficient for their participation; their possible coercion by parents, peers, researchers or others to participate in research; and conflicting values and interests of parents and children.

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

People in Dependent or Unequal Relationships

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

- carers and people with chronic conditions or disabilities, including long-term hospital patients, involuntary patients, or people in residential care or supported accommodation;
- health care professionals and their patients or clients; • teachers and their students;
- prison authorities and prisoners;
- governmental authorities and refugees;

- employers or supervisors and their employees (including members of the Police and Defence Forces);
- service-providers (government or private) and especially vulnerable communities to whom the service is provided.

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

People Highly Dependent on Medical Care who may be Unable to Give Consent

Medical care increasingly offers interventions or treatment for people at times of serious risk to their life or wellbeing. These risks may be temporary or permanent. People can become highly dependent on those interventions and treatments and may be incapable of comprehending their situation or of communicating about it. At the same time, research on those interventions and treatments is necessary to assess and improve their efficacy. This chapter describes conditions under which research involving people highly dependent on medical care might proceed although their capacity to give consent is limited or non-existent. In every instance, relevant jurisdictional laws will need to be taken into account. Significant ethical issues are raised by research conducted in the following settings:

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

People with a Cognitive Impairment, an Intellectual Disability, or a Mental Illness

The three kinds of condition discussed in this chapter are different. They are discussed in the one chapter, however, because many of the ethical issues they raise about research participation are very similar. People with a cognitive impairment, an intellectual disability, or a mental illness are entitled to participate in research. While research involving these people need not be limited to their particular impairment, disability or illness, their distinctive vulnerabilities as research participants should be taken into account. The capacity of a person with any of these conditions to consent to research, and the ability to participate in it, can vary for many reasons, including:

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

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

Aboriginal and Torres Strait Islanders

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

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

For health research fitting the above description, researchers must consult Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders. Other documents that might provide useful guidance for researchers are Keeping Research on Track II and the Guidelines for Ethical Research in Australian Indigenous Studies (Australian Institute of Aboriginal and Torres Strait Islander Studies 2012).

Human Research Ethics Committees (HRECs) are also required to apply the Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders as the basis for assessing proposals for health research with Aboriginal and Torres Strait Islander participation.

In applying Sections 1 and 2 of this National Statement, researchers from other disciplines, HRECs and other ethical review bodies may also find the Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders informative.

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

The six core values are:

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

Disability Worker Screening

After 1 February 2021, researchers working with NDIS participants will need to apply for the NDIS Worker Screening check, not the Yellow Card. The Yellow Card is now for state funded disability providers only.

For researchers who do not have their own provider number, the employer ID that will be used to link **Blue Care approved projects** with the organisation is: **Employer ID: 264230** - this will prefill the remainder of the employer details and include the name of the organisation - Blue Care.

Key Inclusions for RAG/HREC application

Considerations relevant to RAG/HREC applications at UnitingCare:

<input type="checkbox"/>	Clear inclusion and exclusion criteria
<input type="checkbox"/>	Provision of Blue Cards for researchers working with children
<input type="checkbox"/>	Provision of Disability Worker screening checks for researchers involved with NDIS participants
<input type="checkbox"/>	<p>Clear acknowledgment of any power differentials between researchers/staff and participants and what measures are in place to mitigate this risk.</p> <p>As consumers of Uniting Care services, participants drawn from this population are generally accepted to be in a relationship where a power differential is evident, despite overt mechanisms that promote and govern a participant focused quality approach to service provision.</p> <p>Research that targets UnitingCare staff as participants should also consider potential power differentials between staff and managers/supervisors.</p>
<input type="checkbox"/>	<p>Statement about how the researchers will specifically address, as relevant (for example when a particular group is the target of a research project and/or is likely to require specific considerations given the methodology), the cultural needs of groups (such as those people with a Aboriginal and Torres Strait Islander backgrounds), <i>in relation to their methodology</i>. This may include :</p> <ul style="list-style-type: none"> - access to support people from the person's own cultural background - consideration of recruitment approaches that build trust and demonstrate respect.
<input type="checkbox"/>	<p>Statement about how the researchers will specifically address, as relevant, the needs of people with a cognitive impairment or intellectual disability <i>in relation to their methodology</i>. This may include a statement illustrating an understanding the impact of dementia on the process of consent, and acknowledgement that a diagnosis of dementia does not necessarily preclude an individual from making decisions across all aspects of their life, including participation in research.</p>
<input type="checkbox"/>	A brief (approximately 2 pages), referenced literature review that indicates a knowledge of the research area and links the research question to the review.
<input type="checkbox"/>	A clear statement of benefits and risks to (any) participants with specific consideration of those from vulnerable groups or who may be particularly impacted by the research methodology or area.