

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

INTRODUCTION

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

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

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

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

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

Research to which this chapter applies must be reviewed and approved by a Human Ethics Research Committee (HREC) rather than by one of the other processes of ethical review described in paragraphs 5.1.7 and 5.1.8 (page 78), except where that research uses collections of non-identifiable data and involves negligible risk, and may therefore be exempted from ethical review.

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

Sections 1 and 2 of this National Statement. The guidelines and headings below show how those values, principles and themes apply specifically in research that is the subject of this chapter.

GUIDELINES

Research merit and integrity

- 4.4.1 Research involving people who are highly dependent on medical care may be approved where:
- (a) it is likely that the research will lead to increased understanding about, or improvements in, the care of this population;
 - (b) the requirements of relevant jurisdictional laws are taken into account; and
 - (c) either
 - (i) any risk or burden of the proposed research to this particular participant is justified by the potential benefits to him or her; or
 - (ii) where participants have capacity to consent, any risk or burden is acceptable to them and justified by the potential benefits of the research.

Justice

- 4.4.2 People highly dependent on medical care may be exposed to severe threats to their lives, so that recruiting them into

research might seem unfair. However, those people are entitled to participate in research and, when the conditions of paragraph 4.4.1 are met, their involvement is not unfair.

Beneficence

- 4.4.3 The distinguishing features of *neonatal intensive care research* are the small size and unique developmental vulnerability of the participants and the potential for very long-range impact on their growth, development and health. In this research, risks and potential benefits should be assessed with particular care by individuals or groups with relevant expertise.
- 4.4.4 The distinguishing features of *terminal care research* are the short remaining life expectancy of participants and their vulnerability to unrealistic expectations of benefits. Terminal care research should be designed so that:
- the benefits of research to individual participants or groups of participants, or to others in the same circumstances, justify any burden, discomfort or inconvenience to the participants;
 - the prospect of benefit from research participation is not exaggerated;
 - the needs and wishes of participants to spend time as they choose, particularly with family members, are respected; and
 - the entitlement of those receiving palliative care to participate is recognised.

Respect

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

- 4.4.6 In *emergency care research*, recruitment into a research project often has to be achieved rapidly. Where the research involves emergency treatment and meets the requirements of 4.4.1, consent for the research may be waived provided the conditions of paragraph 2.3.6 (page 24) are satisfied.
- 4.4.7 In *intensive care research*, heavy sedation may impair participants' cognition, and communication is difficult with people receiving ventilatory assistance. Whenever possible, consent to intensive care research, based on adequate information, should be sought from or on behalf of potential participants before admission to that level of treatment. When prior consent to research is not possible, the process described in paragraphs 4.4.9 to 4.4.14 should be followed.
- 4.4.8 In *research with unconscious people*, the participants cannot be informed about the research and their wishes cannot be determined. Those who are unconscious should be included only in minimally invasive research, or in research designed both to be therapeutic for them and to improve treatment for the condition from which they suffer.

Process to be followed

- 4.4.9 Consent should be sought from people highly dependent on medical care wherever they are capable of giving consent and it is practicable to approach them.
- 4.4.10 Where it is not practicable to approach a person highly dependent on medical care, or the person is not capable of making such a decision, consent should be sought from the participant's guardian, or person or organisation authorised by law, except under the circumstances described in paragraph 4.4.13.
- 4.4.11 When consent is to be sought, either from the potential participant or another on his or her behalf, steps should be taken to minimise the risk that:

- (a) stress or emotional factors may impair the person's understanding of the research or the decision to participate; and
- (b) the dependency of potential participants and their relatives on the medical personnel providing treatment may compromise the freedom of a decision to participate.
- (f) inclusion in the research project is not contrary to the interests of the participant.

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

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

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

- (a) there is no reason to believe that, were the participant or the participant's representative to be informed of the proposal, he or she would be unwilling to consent;
- (b) the risks of harm to individuals, families or groups linked to the participant, or to their financial or social interests, are minimised;
- (c) the project is not controversial and does not involve significant moral or cultural sensitivities in the community;

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

- (d) the research supports a reasonable possibility of benefit over standard care;
- (e) any risk or burden of the intervention to the participant is justified by its potential benefits to him or her; and

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

INTRODUCTION

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

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

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

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

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

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uses collections of non-identifiable data and involves negligible risk, and may therefore be exempted from ethical review.

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

GUIDELINES

Research merit and integrity

- 4.5.1 The research design should take into account factors that may affect the capacity to receive information, to consent to the research, or to participate in it. These factors may be permanent or may vary over time.
- 4.5.2 Care should be taken to determine whether participants' cognitive impairment, intellectual disability or mental illness increases their susceptibility to some forms of discomfort or distress. Ways of minimising effects of this susceptibility should be described in the research proposal.

Justice

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

Beneficence

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

Respect

4.5.5 Consent to participation in research by someone with a cognitive impairment, an intellectual disability, or a mental illness should be sought either from that person if he or she has the capacity to consent, or from the person's guardian or any person or organisation authorised by law. Where the impairment, disability or illness is temporary or episodic, an attempt should be made to seek consent at a time when the condition does not interfere with the person's capacity to give consent.

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

4.5.7 Consent under paragraph 4.5.5 should be witnessed by a person who has the capacity to understand the merits, risks and procedures of the research, is independent of the research team and, where possible, knows the participant and is familiar with his or her condition.

4.5.8 Where consent has been given by a person authorised by law, the researcher should nevertheless explain to the participant, as far as possible, what the research is about and what participation involves. Should the participant at any time recover the capacity to consent, the researcher should offer him or her the

opportunity to continue participation (under the terms of paragraph 4.5.6) or to withdraw.

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

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

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