

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

INTRODUCTION

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

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

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

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

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

Research to which this chapter applies must be reviewed and approved by a Human Research Ethics Committee (HREC) rather than by one of the other processes of ethical review described in paragraphs 5.1.7 and 5.1.8 (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

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

Justice

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

Beneficence

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

Respect

4.5.5 Consent to participation in research by someone with a cognitive impairment, an intellectual disability, or a mental illness should be sought either from that person if he or she has the capacity to consent, or from the person's guardian or any person or organisation authorised by law.

4.5.6 Where the impairment, disability or illness is temporary or episodic, an attempt should be made to seek consent at a time when the condition does not interfere with the person's capacity to give consent.

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

4.5.8 Consent under paragraph 4.5.6 should be witnessed by a person who has the capacity to understand the merits, risks and procedures of the research, is independent of the research team and, where possible, knows the participant and is familiar with his or her condition.

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

opportunity to continue participation (under the terms of paragraph 4.5.7) or to withdraw.

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

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

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