

# SECTION 4: ETHICAL CONSIDERATIONS SPECIFIC TO PARTICIPANTS

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

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

Human research may be conducted only with ethical approval. Section 5 describes the processes that institutions may use to provide that approval. Those processes include ethical review by Human Ethics Research Committees (HRECs) or other ethical review bodies, according to the risks of the research (see paragraphs 5.1.6 to 5.1.8, page 78).

Ethical review by an HREC is required for any research that involves more than low risk (see paragraph 5.1.6, page 78). It is also required for research discussed in several chapters of

Section 3, as well as for research discussed in the following chapters of this section: *Chapter 4.1: Women who are pregnant and the human foetus*, *Chapter 4.4: People highly dependent on medical care who may be unable to give consent*, *Chapter 4.5: People with a cognitive impairment, an intellectual disability, or a mental illness*, *Chapter 4.6: People who may be involved in illegal activities*, *Chapter 4.7: Aboriginal and Torres Strait Islander Peoples* and *Chapter 4.8: People in other countries*.

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

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## CHAPTER 4.1: WOMEN WHO ARE PREGNANT AND THE HUMAN FOETUS

### INTRODUCTION

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

- research on the woman who is pregnant and the foetus *in utero*; and
- research on the separated human foetus or on foetal tissue.

This chapter does not apply to research involving:

- gametes, embryos and/or participants in assisted reproductive treatments – this research is covered by the

*Ethical guidelines on the use of assisted reproductive technology in clinical practice and research* (NHMRC 2004);

- embryos excess to the needs of those for whom they were created using assisted reproductive technology – this research is covered by Australian legislation.

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

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

After separation, the following chapters of this National Statement may also be relevant to the design and conduct of research involving foetal tissue: *Chapter 3.4: Human tissue samples* and *Chapter 3.6: Human stem cells*.

**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

### The woman who is pregnant and the foetus *in utero*

- 4.1.1 The wellbeing and care of the woman who is pregnant and of her foetus always takes precedence over research considerations.
- 4.1.2 The research participation of a young person who is pregnant should be guided by the requirements of *Chapter 4.2: Children and young people*.
- 4.1.3 Research involving the woman may affect the foetus, and research involving the foetus will affect the woman. The risks and benefits to each should be carefully considered in every case, and should be discussed with the woman. This must include the effect of the research on the foetus *in utero* (including consideration of foetal stress) and on the child who may subsequently be born.
- 4.1.4 The possibility of providing access to counselling for the woman about these issues should be part of this discussion.
- 4.1.5 Researchers should ask the woman whether, in her decisions about the research, she wishes to involve others for whom the research may have implications.
- 4.1.6 Except in the case of therapeutic innovative therapy, the process of providing information and obtaining consent for involvement in research should be separate from clinical care. Information about research projects should also be separate from information about routine clinical care.
- 4.1.7 If it is consistent with promoting the life and health of the foetus, research on the foetus *in utero* may be ethically acceptable. Such research may, for example, provide information about the health of the foetus.

- 4.1.8 Research should be designed so as to minimise pain or distress for the foetus, and should include steps for monitoring for signs of foetal pain or distress, and steps for suspending or ceasing the research if necessary.
- 4.1.9 'Innovations in clinical practice' (page 39), in *Chapter 3.3: Interventions and therapies, including clinical and non-clinical trials, and innovations*, should be considered for any innovative therapy involving the foetus. *See also* paragraph 3.3.15 (page 36).
- 4.1.10 It is ethically unacceptable to conduct non-therapeutic research that involves administering drugs or carrying out a procedure on the woman or her foetus, where the research carries risk for the foetus.

### The human foetus, or foetal tissue, after separation

- 4.1.11 Those conducting research involving the human foetus *ex utero* or foetal tissue, after termination of pregnancy, should have no involvement in the clinical care of the woman from whom the foetus or foetal tissue was derived, and no financial or legal relationships with those who are so involved. Such research should be conducted in a location that maintains a separation of the woman's clinical care from research.
- 4.1.12 Researchers should demonstrate that there are no suitable alternatives by which the aims of research using the separated human foetus or foetal tissue can be achieved.
- 4.1.13 There should be no trade in human foetal tissue.
- 4.1.14 Those who conscientiously object to being involved in conducting research with separated fetuses or foetal tissue should not be compelled to participate, nor should they be put at a disadvantage because of their objection.
- 4.1.15 Where research involves a separated foetus, researchers should ask the woman whether, in her decisions about the research, she wishes to involve others for whom the research may have implications.
- 4.1.16 A foetus or foetal tissue may become available for research as the result of termination. The process through which the woman is approached, informed about, and her consent sought for research on that foetus should be separate from the process under which she decides whether to terminate her pregnancy, and should not begin until a decision to terminate has been made. Consenting to the research must not compromise the woman's freedom to change that decision.
- 4.1.17 Where research involves her separated foetus or its foetal tissue, arrangements should be made for the woman to have access to counselling and support.
- 4.1.18 Research on a terminated foetus or its tissues, including the timing and content of the process of seeking the woman's consent for the research, should be designed so as not to compromise the woman's decisions about the timing and method of termination.
- 4.1.19 Consideration of a woman's wishes and her physical, psychological and emotional welfare should inform:
- a decision whether to approach her about proposed research involving her, her separated foetus or its tissue; and
  - if she is approached, the way information is provided about the research and her consent for it sought.
- 4.1.20 In addition to information required to be disclosed under paragraphs 2.2.2 and 2.2.6 (page 19) of this National Statement, the woman should also be informed:

- (a) that she should consider whether to seek consent to the proposed research from any other person (see paragraphs 4.1.5 and 4.1.15);
- (b) whether it is possible to store the foetus or foetal tissues for later use in research;
- (c) that she is free to withdraw her consent to the research at any time, whether before or after a termination or other loss of a foetus;
- (d) whether there is potential for commercial application of outcomes of the research, including the development of cell lines;
- (e) that she will not be entitled to a share in the profits of any commercial applications; and
- (f) whether foetal organs or stem cell lines developed from them will be exported to another country.

4.1.21 A foetus delivered alive is a child, and should be treated as a child and receive the care that is due to a child.

4.1.22 Organs and tissues may be removed from a foetus delivered dead and used for research only if the conditions of paragraphs 4.1.11 and 4.1.12 are met, and:

- (a) the woman and any others she wishes to involve (see paragraph 4.1.15) have given consent to the removal and the research;
- (b) the foetus is available for research only as a result of separation by natural processes or by lawful means; and
- (c) death of the foetus has been determined by a registered medical practitioner who has no part (or financial interest) in the research.

4.1.23 If, for research purposes, foetal cells are to be derived from the foetal tissue and stored or propagated in tissue culture, or tissues or cells are to be used in human transplantation, the woman's consent is required. Others whom the woman identifies (*see also* paragraph 4.1.15) may also need to be involved in decisions about these matters.