

# NHMRC Statement on Human Experimentation and Supplementary Notes 1992

1. This Supplementary Note was previously part of the NHMRC Statement on Human Experimentation and Supplementary Notes (1992). The NHMRC Statement has been replaced by the National Statement on Ethical Conduct in Research Involving Humans with the exception of this Supplementary Note.
2. This Supplementary Note remains in force from the date they were originally issued in October 1983. It should be read in conjunction with the current National Statement Introduction

## ***Introduction***

This supplementary note, which should be read in conjunction with the NHMRC Statement on Human Experimentation and Supplementary Notes, is intended as a guide on ethical matters for research involving the human fetus or human fetal tissue. Included in this research is the possible usefulness of transplantation of fetal tissue for the treatment of disease.

For the purpose of these guidelines the terms fetus and fetal tissue include respectively the whole or part of what is called the embryo, fetus or neonate, from the time of implantation to the time of complete gestation, whether born alive or dead. The fetal membranes, placenta, umbilical cord and amniotic fluid are regarded as part of the fetus prior to separation; after separation they are also subject to certain guidelines.

## ***The fetus in utero***

1. There are two circumstances in which it may be ethical to carry out experiments on the fetus in utero:
  - where experiments are consistent with the promotion of life or health of the fetus;
  - where research on antenatal fetal diagnosis provides the mother with information about the health or normality of the fetus and so gives her choices between continuation of the pregnancy, treatment for the fetus, and lawful termination of the pregnancy.
2. There may be risks to both mother and fetus in research on the fetus in utero, and institutional ethics committees (IECs) should carefully consider the risks and benefits to both in every case.
3. It is unethical to administer drugs to, or to carry out any procedure on, the mother with the intention of ascertaining harmful effects that these may have on the fetus, whether in anticipation of induced abortion or otherwise. Some research procedures may be allowable once the physical process of abortion is irrevocably in train.

## ***The separated preivable fetus and fetal tissues***

1. For the purposes of medical research, a separated preivable fetus is at present regarded as one that has not attained a gestational age of 20 weeks and does not exceed 400g in weight. Adoption of this description will prevent inadvertent withholding of life-sustaining treatment from a separated fetus that may in fact be viable.
2. The following conditions should be observed:
  1. the fetus should be available for research only as a result of separation by natural processes or by lawful means;
  2. dissection of the fetus should not be carried out while a heart beat is still apparent or there are other obvious signs of life;
  3. research procedures should not be performed in the immediate area in which clinical procedures are carried out; and
  4. those concerned with research involving the use of tissue from a fetus should have no part in the management of either the mother or the fetus, or in deciding if the fetus is preivable.

## ***General conditions for research on the fetus and fetal tissue***

1. The research must be conducted only in institutions that have a properly constituted ethics committee, and only according to written protocols approved by the ethics committees of all institutions involved.
2. The consent of the mother and, whenever practicable that of the father, should be obtained before research is undertaken. If fetal cells including cells from fetal membranes, placenta, umbilical cord and amniotic fluid are to be stored or propagated in tissue culture, or tissues or cells are to be transplanted into a recipient human, consent for this should be obtained specifically.
3. The decisions (a) whether it is appropriate in a particular instance to approach the mother about the possible use of fetal tissue for research and (b) whether a fetus or its tissues in a category that may be used for research, must rest with the attending clinician and not with the intending research worker.
4. The obtaining of consent for research should also be through the attending clinician.
  - When an IEC is reviewing a proposal for research it should also take particular account of the following:
  - the required information should not be obtainable by other means or by using other species;
  - the investigators should have the necessary special facilities and skills;
  - there should be no element of commerce involved in the transfer of human fetal tissue;

- that the separation of clinical and research responsibilities that is crucial to the ethical basis for research in this area clearly exists; and
5. a record of all attempts to transplant human fetal tissue, including a description of the outcome, should be maintained by the institution.

In this, as in other experimental fields, those who conscientiously object to research projects or therapeutic programs conducted by institutions that employ them should not be obliged to participate in those projects or programs to which they object, nor should they be put at a disadvantage because of their objection.