HREC Approved Subject Information Statement and Consent Form for research involving the use of human foetal tissue in medical research.

PARTICIPANT INFORMATION STATEMENT

USE OF HUMAN FETAL TISSUE FOR MEDICAL RESEARCH

Scientists generally use animal models to study the causes of human diseases, to develop new treatments and to discover cures. In many cases, however, the animal models used to investigate a human disease are not good models for a particular disease in humans.

Examples of differences between animals and humans are found in many diseases, such as in eye diseases including those which most commonly cause blindness in the aged and in premature infants. Other examples are in multiple sclerosis, Alzheimer’s disease, herpes infection, diabetes and some kidney diseases.

Consequently human tissue is the most relevant to acquire information vital to the disease process that occurs in humans. Human fetal tissue in particular has many advantages because it permits tissue development and disease mechanisms to be investigated.

Some of the research involves maintaining the tissue in culture within the laboratory. Other research may transplant the tissue into animals.

Such research will not be used to develop cell or tissue lines for commercial purposes. The tissue will be used for research and will not be sold. The research carried out with this tissue may help to develop new therapies to improve the quality of treatment given to patients, but you will not be paid.

Human fetal tissue will only be used with the fully informed consent of the donor. Such tissue is only used for research which has received approval from the relevant human research ethics committee. The decision to donate tissue is confidential and no personal information is available to the researcher, except for fetal age and for any potential infection of the tissue.

This is a very difficult time for you, however, to assist in scientific research your permission is sought to use fetal material obtained from your termination of pregnancy. This fetal tissue will not be used without your consent. You may withdraw your approval for the use of this fetal tissue for research up to the time of induction of the anaesthetic or sedation. Should you decline to approve the use of this fetal tissue for research, your wishes will be adhered to and your clinical management will not be disadvantaged in any way.
CONSENT FORM

USE OF HUMAN FETAL TISSUE FOR MEDICAL RESEARCH

Human fetal tissue is currently being used in Australia for a number of research studies which may increase our understanding of the causes of human diseases, and improve the quality of treatment given to patients. These include, for example, the use of pancreatic tissue in attempts to cure diabetes, the use of eyes, liver and bone to study growth and development, and muscle, nerves and kidneys to understand what happens in various disorders involving these tissues.

This is a very difficult time for you, however, to assist in scientific research your permission is sought to use fetal material obtained from your termination of pregnancy. This tissue may be utilised by a number of different research groups, and may involve maintaining the tissue in culture within the laboratory, and/or transplanting it into animals. All such projects have approval from the ethics committee of the institution where the research is being conducted.

I/we ____________________________________________________________

of ____________________________________________________________

have read and understood the above statement, and agree that the tissue obtained from termination of this pregnancy may be used for medical research as detailed above and in the patient information sheet provided. I/we acknowledge that I/we will not receive any direct benefit from such studies.

I/we understand:-

- no information about the medical history will be provided to the researchers under any circumstances, except for fetal age and for any potential infection of the tissue
- the fetal tissue will not be identifiable with me/us in any way
- the tissue will not be used to develop cell or tissue lines for commercial purposes.

Date: ____________________________________________________________

Signature(s): ____________________________________________________

Witness: _________________________________________________________
OPERATING SURGEON/ATTENDING PHYSICIAN CERTIFICATION

I hereby certify that patient permission has been given for this batch of fetal tissue to be used for research in ethically approved medical research.

Signature: ____________________________________________________________

Name: ______________________________________________________________

Date: ________________________________________________________________