TRANSPLANTATION OF FETAL TISSUE

Definition

For the purposes of this law, the term "human fetal tissue" means tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth.

Description

If an investigator is planning to conduct research involving the transplantation of human fetal tissue for therapeutic purposes, the law (Public Law 103-43) must be followed. The investigator must meet the requirements outlined in the statute. This document outlines the information which must be submitted to the IRB in any application which proposes research on the transplantation of human fetal tissue for therapeutic purposes.

The informed consent document from the woman and statements from the physician, researcher and recipient must be obtained and must include information as detailed below. Additional stipulations regarding availability and confidentiality of records is found in Public Law 103-43 (see link below). Any study falling under this guidance must also adhere to state and local law. The Office of General Counsel will be contacted for assistance in applying any applicable laws.

Documents must be provided to the IRB as follows:

Consent Document From the Woman:	The human fetal tissue may only be used if the woman providing the tissue makes a statement, made in writing and signed by the woman, declaring that: **1.** the woman donates the fetal tissue for use in research involving the transplantation of the fetal tissues for therapeutic purposes; **2.** the donation is made without any restriction regarding the identity of individuals who may be the recipients of transplantations of the tissue; and **3.** the woman has not been informed of the identity of any such individuals.
Statement from the Physician:	The human fetal tissue may only be used if the attending physician with respect to obtaining the tissue from the woman involved makes a statement in writing and signed by the physician, declaring that: **1.** In the case of tissue obtained pursuant to an induced abortion **a.** the consent of the woman for the abortion was obtained prior to requesting or obtaining consent for a donation of the tissue for use in such research; **b.** no alteration of the timing, method, or procedures used to terminate the pregnancy was made solely for the purposes of obtaining the tissue; and **c.** the abortion was performed in accordance with applicable State law; **2.** The tissue has been donated by the woman in accordance with the terms in the woman's consent document (see above); and **3.** Full disclosure has been provided to the woman with regard to **a.** such physician's interest, if any, in the research to be conducted with the tissue; and **b.** any known medical risks to the woman or risks to her privacy that might be associated with the donation of the tissue and that are in addition to risks of such type that are associated with the woman's medical care.
Statement of Researcher and Recipient :	The human fetal tissue may be used only if the individual with the principal responsibility for conducting the research involved (the PI) makes a statement, made in writing and signed by that researcher, declaring that he/she: **1.** Is aware that **a.** the tissue is human fetal tissue;

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b. the tissue may have been obtained pursuant to a spontaneous or induced abortion or pursuant to a stillbirth; and

c. the tissue was donated for research purposes;

2. Has provided such information to other individuals with responsibilities regarding the research;

3. Will require, prior to obtaining the consent of an individual to be a recipient of a transplantation of the tissue, written acknowledgment of receipt of such information by such recipient; and

4. Has had no part in any decisions as to the timing, method, or procedures used to terminate the pregnancy made solely for the purposes of the research.

References & Links

NIH Revitalization Act of 1993, Public Law 103-43	~~*http://www.hhs.gov/ohrp/humansubjects/guidance/publiclaw103-43.htm*~~. *http://www.hhs.gov/ohrp/policy/publiclaw103-43.htm.html*

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