Issuing Department: Human Subjects Protection Program
Policy Number: 2011-006.5
Policy Title: Additional Protections for Certain Populations - Fetal Tissue Transplants

Purpose

The purpose of the policy is to describe when human fetal tissue may be used in transplant research.

Definitions

See policy 2011-007.0 for definition of the following:

Fetus	Human Fetal Tissue

Policy

Human fetal tissue may be used in research involving transplant procedures regardless of whether the tissue is obtained pursuant to a spontaneous or induced abortion or pursuant to a stillbirth only if the procedures outlined below are satisfied.

All documentation related to this type of research is subject to audit and for DHHS supported research human fetal tissue may be used only if the head of the agency or other entity conducting the research certifies to the Secretary that the statements described below will be available for audit by the Secretary.

Procedure

The woman providing the tissue must provide a written signed statement declaring that:

- the woman donates the fetal tissue for use in the research,
- the donation is made without any restriction regarding the identity of the individuals who may be the recipients of transplantations of the tissue; and
- the woman has not been informed of the identity of any such individuals.

The attending physician with respect to obtaining the tissue from the woman involved must provide a written signed statement declaring that:

- in the case of tissue obtained pursuant to an induced abortion
    - 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;
    - no alteration of the timing, method, or procedures used to terminate the pregnancy was made solely for the purposes of obtaining the tissue; and
    - the abortion was performed in accordance with applicable State law
- the tissue has been donated by the woman accordance with the above section; and
- full disclosure has been provided to the woman with regard to
    - the physician's interest, if any, in the research to be conducted with the tissue and
    - 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.

The individual with the principal responsibility for conducting the research involved must provide a written, signed statement declaring that s/he:

- is aware that
  - the tissue is human fetal tissue,
  - the tissue may have been obtained pursuant to a spontaneous or induced abortion or pursuant to a still birth and
  - the tissue was donated for research purposes.
- has provided such information to other individuals with responsibilities regarding the research;
- 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
- 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.

Related Content

2011-007.0 – Definitions Applied to Policies

Basis

Public Law 103-43; June 10, 1993 https://www.hhs.gov/ohrp/regulations-and-policy/guidance/public-law-103-43/index.html

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Reviewed and Approved By:

Signed by Richard H. Simon ***3/8/2017***

Richard Simon, MD **Date**
Director Human Subjects Protection Office