

Transplantation of Human Fetal Tissue

On January 22, 1993, President Clinton issued a directive to the Secretary of Health and Human Services ending a five-year moratorium on Federal funding of transplantation research that uses human fetal tissue derived from induced abortions. In March 1993, NIH published interim guidelines for research involving human fetal tissue transplantation. These guidelines were based on the recommendations of the 1988 Human Fetal Tissue Transplantation Research Panel and were designed to ensure that Federal funding of human fetal tissue transplantation research would not encourage the choice of abortion. On June 10, 1993, the NIH Revitalization Act of 1993 (Public Law 103-43) was enacted, and, because of the superseding provisions contained in the law regarding fetal tissue transplantation, the interim guidelines were withdrawn.

42 USC §498A(b)(1) and (2)

(a) ESTABLISHMENT OF PROGRAM

(1) **IN GENERAL** - The Secretary may conduct or support research on the transplantation of human fetal tissue for therapeutic purposes.

(2) **SOURCE OF TISSUE** - Human fetal tissue may be used in research carried out under paragraph (1) regardless of whether the tissue is obtained pursuant to a spontaneous or induced abortion or pursuant to a stillbirth.

(b) INFORMED CONSENT OF DONOR

(1) **IN GENERAL** - In research carried out under subsection (a), human fetal tissue may be used only if the woman providing the tissue makes a statement, made in writing and signed by the woman, declaring that--

(A) the woman donates the fetal tissue for use in research described in subsection (a);

(B) the donation is made without any restriction regarding the identity of individuals who may be the recipients of transplantations of the tissue; and

(C) the woman has not been informed of the identity of any such individuals.

(2) **ADDITIONAL STATEMENT** - In research carried out under subsection (a), human fetal tissue may be used only if the attending physician with respect to obtaining the tissue from the woman involved makes a statement, made in writing and signed by the physician, declaring that--

(A) in the case of tissue obtained pursuant to an induced abortion--

(i) 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;

(ii) no alteration of the timing, method, or procedures used to terminate the pregnancy was made solely for the purposes of obtaining the tissue; and

(iii) the abortion was performed in accordance with applicable State law;

(B) the tissue has been donated by the woman in accordance with paragraph (1); and

(C) full disclosure has been provided to the woman with regard to--

(i) such physician's interest, if any, in the research to be conducted with the tissue; and

(ii) 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.

(c) INFORMED CONSENT OF RESEARCHER AND DONEE

In research carried out under subsection (a), human fetal tissue may be used only if the individual with the principal responsibility for conducting the research involved makes a statement, made in writing and signed by the individual, declaring that the individual--

(1) is aware that

(A) the tissue is human fetal tissue;

(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.

(d) AVAILABILITY OF STATEMENTS FOR AUDIT

(1) **IN GENERAL** - In research carried out under subsection (a), human fetal tissue may be used only if the head of the agency or other entity conducting the research involved **certifies to the Secretary** that the

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statements required under subsections (b)(2) and (c) will be available for audit by the Secretary.

(2) CONFIDENTIALITY OF AUDIT - Any audit conducted by the Secretary pursuant to paragraph (1) shall be conducted in a confidential manner to protect the privacy rights of the individuals and entities involved in such research, including such individuals and entities involved in the donation, transfer, receipt, or transplantation of human fetal tissue. With respect to any material or information obtained pursuant to such audit, the Secretary shall--

- (A) use such material or information only for the purposes of verifying compliance with the requirements of this section;
- (B) not disclose or publish such material or information, except where required by Federal law, in which case such material or information shall be coded in a manner such that the identities of such individuals and entities are protected; and
- (C) not maintain such material or information after completion of such audit, except where necessary for the purposes of such audit.

(e) APPLICABILITY OF STATE AND LOCAL LAW

(1) RESEARCH CONDUCTED BY RECIPIENTS OF ASSISTANCE - The Secretary may not provide support for research under subsection (a) unless the applicant for the financial assistance involved agrees to conduct the research in accordance with applicable State law.

(2) RESEARCH CONDUCTED BY SECRETARY - The Secretary may conduct research under subsection (a) only in accordance with applicable State and local law.

(f) REPORT- The Secretary shall annually submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the activities carried out under this section during the preceding fiscal year, including a description of whether and to what extent research under subsection (a) has been conducted in accordance with this section.

(g) DEFINITION- For purposes of this section, 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.'

SEC. 112. PURCHASE OF HUMAN FETAL TISSUE; SOLICITATION OR ACCEPTANCE OF TISSUE AS DIRECTED DONATION FOR USE IN TRANSPLANTATION.

PROHIBITIONS REGARDING HUMAN FETAL TISSUE `SEC. 498B.

(a) PURCHASE OF TISSUE- It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce.

(b) SOLICITATION OR ACCEPTANCE OF TISSUE AS DIRECTED DONATION FOR USE IN TRANSPLANTATION - It shall be unlawful for any person to solicit or knowingly acquire, receive, or accept a donation of human fetal tissue for the purpose of transplantation of such tissue into another person if the donation affects interstate commerce, the tissue will be or is obtained pursuant to an induced abortion, and--

- (1) the donation will be or is made pursuant to a promise to the donating individual that the donated tissue will be transplanted into a recipient specified by such individual;
- (2) the donated tissue will be transplanted into a relative of the donating individual; or
- (3) the person who solicits or knowingly acquires, receives, or accepts the donation has provided valuable consideration for the costs associated with such abortion.

(c) CRIMINAL PENALTIES FOR VIOLATIONS-

(1) IN GENERAL - Any person who violates subsection (a) or (b) shall be fined in accordance with title 18, United States Code, subject to paragraph (2), or imprisoned for not more than 10 years, or both.

(2) PENALTIES APPLICABLE TO PERSONS RECEIVING CONSIDERATION - With respect to the imposition of a fine under paragraph (1), if the person involved violates subsection (a) or (b)(3), a fine shall be imposed in an amount not less than twice the amount of the valuable consideration received.

(d) DEFINITIONS - For purposes of this section:

(3) The term `valuable consideration' does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue.'