§ 289g–1. Research on transplantation of fetal tissue

(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) of this section, 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) of this section;

(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) of this section, 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) of this section, 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) of this section, 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 statements required under subsections (b)(2) and (c) of this section 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) of this section 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) of this section 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) of this section has been conducted in accordance with this section.

(g) “Human fetal tissue” defined
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.

Change of Name

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.


Nullification of Moratorium

Section 113 of Pub. L. 103–43 provided that:

“(a) In General.—Except as provided in subsection (c), no official of the executive branch may impose a policy that the Department of Health and Human Services is prohibited from conducting or supporting any research on the transplantation of human fetal tissue for therapeutic purposes. Such research shall be carried out in accordance with section 498A of the Public Health Service Act [this section] (as added by section 111 of this Act), without regard to any such policy that may have been in effect prior to the date of the enactment of this Act [June 10, 1993].

“(b) Prohibition Against Withholding of Funds in Cases of Technical and Scientific Merit.—

“(1) In general.—Subject to subsection (b)(2) of section 492A of the Public Health Service Act [section 289a–1 (b)(2) of this title] (as added by section 101 of this Act), in the case of any proposal for research on the transplantation of human fetal tissue for therapeutic purposes, the Secretary of Health and Human Services may not withhold funds for the research if—

“(A) the research has been approved for purposes of subsection (a) of such section 492A;

“(B) the research will be carried out in accordance with section 498A of such Act [this section] (as added by section 111 of this Act); and

“(C) there are reasonable assurances that the research will not utilize any human fetal tissue that has been obtained in violation of section 498B(a) of such Act [section 289g–2 (a) of this title] (as added by section 112 of this Act).

“(2) Standing approval regarding ethical status.—In the case of any proposal for research on the transplantation of human fetal tissue for therapeutic purposes, the issuance in December 1988 of the Report of the Human Fetal Tissue Transplantation Research Panel shall be deemed to be a report—

“(A) issued by an ethics advisory board pursuant to section 492A(b)(5)(B)(ii) of the Public Health Service Act (as added by section 101 of this Act); and

“(B) finding, on a basis that is neither arbitrary nor capricious, that the nature of the research is such that it is not unethical to conduct or support the research.

“(c) Authority for Withholding Funds From Research.—In the case of any research on the transplantation of human fetal tissue for therapeutic purposes, the Secretary of Health and Human Services may withhold funds for the research if any of the conditions specified in any of subparagraphs (A) through (C) of subsection (b)(1) are not met with respect to the research.

“(d) Definition.—For purposes of this section, the term ‘human fetal tissue’ has the meaning given such term in section 498A(f) of the Public Health Service Act [subsec. (f) of this section] (as added by section 111 of this Act).”

Report by General Accounting Office on Adequacy of Requirements

Section 114 of Pub. L. 103–43 provided that, with respect to research on the transplantation of human fetal tissue for therapeutic purposes, the Comptroller General of the United States was to conduct an audit for the purpose of determining whether and to what extent such research conducted or supported by Secretary of Health and Human Services had been conducted in accordance with this section and whether and to what extent there have been violations of section 289g–2 of this title and directed the Comptroller General to complete the audit and report the findings to Congress, not later than May 19, 1995.