

NOTE: THIS GUIDANCE REPLACES THE FOLLOWING OHRP GUIDANCE: "Fetal Tissue Transplantation--Ban on Research Replaced by New Statutory Requirements" (OPRR REPORTS, April 29, 1994) [CLICK HERE] - THE GUIDANCE HAS BEEN UPDATED FOR FORMAT, AND REFERENCE TO THE NIH REPORT OF THE HUMAN FETAL TISSUE TRANSPLANTATION RESEARCH PANEL HAS BEEN REMOVED.

**Office for Human Research Protections
Department of Health and Human Services**

Fetal Tissue Transplantation

Date: February 7, 2003

Scope: This document describes the current human subjects protection requirements for research involving the transplantation of human fetal tissue.

Target Audience: Sponsors, research institutions, investigators, and institutional review boards (IRBs).

Guidance: 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of the superseding provisions contained in the law regarding fetal tissue transplantation, the interim guidelines were withdrawn.

To this end, your attention is directed to section 498A of the Public Health Service Act (42 U.S.C. 289g-1) added by P.L. 103-43. The provisions of this section, pertinent to the protection of human subjects in research involving the transplantation of human fetal tissue for therapeutic purposes, are described in the statute (<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/publiclaw103-43.htm>).

If your institution is conducting or planning to conduct research involving the transplantation of human fetal tissue for therapeutic purposes, or, if your IRB is reviewing or planning to review such research, your attention to the requirements outlined in the statute is essential. Adherence to your OHRP-approved Human Subject Assurance of Compliance requires that this legislative mandate be met.