



MCW Office of Research Standard Operating Procedure

USE OF HUMAN FETAL TISSUE IN RESEARCH

Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: Faculty and Staff involved in human research

PURPOSE:

Research involving a living fetus; a deceased fetus; macerated fetal material; or cells, tissue or organs excised from a deceased fetus; are defined as “human subjects research” by MCW, even if the specimens are de-identified or purchased from conventional commercial sources. Thus, research involving fetal or embryonic material requires prior IRB review and approval.

Fetuses, fetal biospecimens, or fetal/embryonic cell lines obtained from a commercial vendor also require prior IRB review and approval under this policy.

Research involving human fetal material shall be conducted only in accord with all applicable federal, state and local laws and regulations regarding such activities.

This policy and procedures outline additional state and federal regulations and institutional requirements for the use of fetal materials in research by Investigators.

This policy does not apply to placental, umbilical materials or non-fetal non-embryonic human stem cells.

DEFINITIONS:

Fetus: the product of conception from implantation until delivery. This term includes embryos (see definition below).

Fetal materials: includes the dead fetus, or cells, materials, or organs excised from a dead fetus.

Embryo: the product of conception from implantation until the end of the eighth (8) week of gestation. Note that within these definitions of “fetus” and “embryo”, an “embryo” is an early state of the fetus’ development. This includes human embryonic stem cells lines (hESCs), as they are derived from embryos.

POLICY:

General:

1. All research using human fetal materials must be submitted for review and ongoing approval to the MCW Institutional Review Board (IRB).
2. MCW IRB retains direct oversight of research in which Investigators are engaged in research collaborations, including when the research with fetal materials is conducted at other institutions or sites.

- a. Investigators who will access, analyze, or store human fetal material are required to notify the MCW HRPP office that their activities will include use of human fetal material before requesting a reliance with an external IRB per *IRB SOP: Reliance Agreements for Multi-Site Projects*.
- 3. If information associated the fetus or fetal material is recorded for research purposes in a manner that living individuals (i.e. the parents as well as the health information from the developing pregnancy) can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects too.
- 4. No MCW, FH, or Versiti employee or agent may knowingly acquire, receive or otherwise transfer any fetal material in exchange for valuable consideration.
 - a. Valuable consideration does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control or storage of human fetal material.

Transplantation Using Fetal Tissue Research

- 1. For purposes of this section fetal tissue means tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion or after a stillbirth.
- 2. Federal funds may only be used to support research involving the transplantation of fetal tissue for therapeutic purposes if all of the five following provisions are met.
 - a. Individuals donating the tissue for research involving transplantation must sign a written informed consent document declaring that:
 - i. They are donating the tissue for research involving transplantation for therapeutic purposes
 - ii. The donation is made without any restriction regarding the individuals who may be recipients of the transplanted tissue
 - iii. They have not been informed of the identity of the individuals who be the recipients of the transplanted tissue.
 - b. The attending physician who obtains the fetal tissue from the individual donating such material for transplantation must sign a written statement declaring that:
 - i. The tissue was donated with the informed consent of the donor, as describe above in 2.1.
 - ii. Full disclosure was made to the donor with regard to
 - 1. Such physician's interest, if any, in the research to be conducted with the tissue; and
 - 2. Any known medical risks to the donor or risks to their privacy that might be associated with the donation of the tissue and that are in addition to risks of such type that associated with their medical care.
 - c. In the case of tissue obtained pursuant to an induced abortion,
 - i. The consent of the individual for the abortion was obtained prior to requesting or obtaining consent for a donation of the tissue for use in the research;
 - ii. No alteration of the timing, method or procedures use 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.
 - d. The individual with principal responsibility for conducting the transplant research must sign a written statement declaring that they:
 - i. Is aware that the tissue is human fetal tissue; that it may have been obtained pursuant to a spontaneous or induced abortion or

1. A copy of the most recent IRB approval letter for the research which collected the materials
2. A copy of the IRB approved consent form
- ii. For de-identified specimens
 1. A copy of the most recent IRB approval letter for the research which collected the materials
 2. A copy of the IRB approved consent form
 3. If the materials are coming from an institution's tissue bank or core resource, provide a description of their de-identification process.
5. Investigators who are receiving fetal materials from a public repository or commercial vendor, the Investigator must upload the following documents to their submission to support the use of these materials.
 - a. Investigator should identify the exact materials (cell-lines etc.)
 - b. Investigator should include description of the ordering process & catalog # of items which will be purchases (if available).
6. The IRB will receive the application and confirm the above documents are present. In addition, IRB will ensure all federal, state and local laws have been followed and are being upheld.

For any research projects which propose transplantation using fetal tissue into humans, Investigators must contact the HRPP Director prior to starting the eBridge submission.

REFERENCES:

NATIONAL INSTITUTES OF HEALTH REVITALIZATION ACT OF 1993
 45 CFR 46.201 (Subpart B) Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research.

SUPPORTING DOCUMENTS:

IRB SOP: Submitting New Studies

Effective Date: 07/01/2023
 Version number: 2.0
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