



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: MCW/FH Faculty and Staff involved in human research

PURPOSE:

Research involving a living fetus; a dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead 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.

This policy and procedure outlines additional state and federal regulations and institutional requirements for the use of fetal materials in research by MCW/FH faculty, staff and students.

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 does not apply to placental or 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 below definition).

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 week of gestation. Note that within these definitions of "fetus" and "embryo," an "embryo" is an early stage of the fetus' development. This includes human embryonic stem cell lines (hESCs), as they are derived from embryos.

POLICY:

General:

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

2. 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.
3. All research using human fetal materials must be submitted for review and ongoing approval to the MCW/FH Institutional Review Board (IRB).
 - o MCW/FH IRB does not does permit this research to qualify for exemption under 45 CFR 46.101(b).
4. MCW/FH IRB retains direct oversight of research in which MCW and/or FH employees or agents are engaged in research collaborations, including when the research with fetal materials is conducted at other institutions or sites. MCW/FH investigators who will access, analyze, or store human fetal material are required to notify the MCW/FH IRB office that their activities will include use of human fetal material before seeking or relying on the IRB review/approval of a different institution.
5. No MCW or FH employee or agent may knowingly acquire, receive or otherwise transfer any fetal material in exchange for valuable consideration.
 - o "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.
 1. The woman donating the fetal tissue for transplantation must sign a written informed consent document declaring that:
 - She is donating the tissue for research involving transplantation for therapeutic purposes;
 - The donation is made without any restriction regarding the individuals who may be the recipients of the transplanted tissue;
 - She has not been informed of the identity of the individuals who may be the recipients of the transplanted tissue.
 2. The attending physician who obtains the fetal tissue from the woman donating such material for transplantation must sign a written statement declaring that:
 - The tissue was donated with the informed consent of the donor, as described above in 2.1.
 - Full disclosure was made to the donor with regard to,
 - Such physician's interest, if any, in the research to be conducted with the tissue; and
 - Any known medical risks to the donor 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 her medical care.
 3. 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 the 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.
4. The individual with principal responsibility for conducting the transplant research must sign a written statement declaring that he or she:
 - Is aware that the tissue is human fetal tissue; that it may have been obtained pursuant to a spontaneous or induced abortion or pursuant to a stillbirth; and that the tissue was donated for research purposes;
 - Has informed other individuals with responsibilities for the research that the tissue is human fetal tissue; that it may have been obtained pursuant to a spontaneous or induced abortion or pursuant to a stillbirth; and that the tissue was donated for research purposes;
 - Will require, prior to obtaining the consent of an individual receiving transplantation of the tissue, written acknowledgement of the recipient that he or she has received the information that the tissue is human fetal tissue; that it may have been obtained pursuant to a spontaneous or induced abortion or pursuant to a stillbirth; and that the tissue was donated for research purposes;
 - 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.
 5. MCW/FH must certify to the Secretary of Health and Human Services that the required statements will be available for audit by the Secretary.
3. No MCW or FH faculty, employee or agent may 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 tissue will be or is obtained pursuant to an induced abortion, and
 - 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 or relative of the donating individual.

The person who solicits or knowingly acquires, receives, or accepts the donation has provided **valuable consideration** for the costs associated with such abortion and as stated under this policy:

1. No MCW or FH employee or agent may knowingly acquire, receive or otherwise transfer any fetal material in exchange for **valuable consideration**.

PROCEDURE:

1. Research involving fetal materials as identified in this policy must be submitted for IRB review and approval as outlined in *IRB SOP: Submitting New Studies*.
 - Investigators must complete an eBridge PRO submission even if the research only involves the use of de-identified fetal cells or tissue, and even if the fetal specimen was purchased from conventional commercial sources. MCW/FH IRB will not accept a non-human subject application for this research.
2. Investigators must select in the subject population (Section 12) of the eBridge application that the project involves fetuses or fetal tissue from the list of potentially vulnerable subjects.
 - When “fetuses or fetal tissue” is checked, an additional section of questions will be presented to ensure federal regulations, state and/or local laws are addressed by the Investigator with regards to the acquisition, and use of fetal material for their research.

3. If MCW/FH investigators will be involved in the collection these materials, consent must be obtained prospectively.
4. For MCW/FH Investigators receiving fetal materials from a collaborating institution, the investigator must upload the following documents to their submission to support the use of these materials.
 - Completed & executed materials transfer agreement (MTA)
 - For identified specimens:
 - i. A copy of the most recent IRB approval letter for the research which collected the materials
 - ii. A copy of IRB approved consent form
 - For de-identified specimens
 - i. A copy of the most recent IRB approval letter for the research which collected the materials
 - ii. A copy of IRB approved consent form
 - iii. If the materials are coming from an institution's tissue bank or core resource, provide a description of their de-identification process.
5. For MCW/FH Investigators receiving fetal materials from a public/commercial vendor, the investigator must upload the following documents to their submission to support the use of these materials.
 - Investigator should identify the exact materials (cell-lines etc.)
 - Investigator should include description of the ordering process & catalog # of items which will be purchased (if available).
6. MCW/FH IRB will review the application and confirm the above documents are present. In addition MCW/FH 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, MCW/FH Investigator must contact the HRPP Director prior to starting the eBridge submission.

REFERENCES:

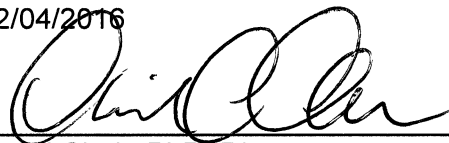
NATIONAL INSTITUTES OF HEALTH REVITALIZATION ACT OF 1993
 45 CFR 46.201 (Subpart B) Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research

SUPPORTING DOCUMENTS:

IRB SOP: Submitting New Studies.

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Approved By
 HRPP Authorized Official:



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