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
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

pursuant to a stillbirth; and that the tissue was donated for research purposes.

ii. 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.

iii. 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.

iv. 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.

e. MCW 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, FH or Versiti faculty, employee, or agent may solicit or knowingly acquire, receive or accept a donation for human fetal tissue for the purposes of transplantation of such tissue into another person if:
   a. The tissue will be or is obtained pursuant to an induced abortion and
   b. 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.

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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, FH or Versiti employee, agent may knowingly acquire, receive or otherwise transfer any fetal material 03 Twcwcwc5.14irth andnonatiora2.6067 0 TD34eyby th7 or 69

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