



Albert Einstein College of Medicine

Fetal Tissue Research Procedure

I. Purpose

This Procedure is to ensure that all researchers at Albert Einstein College of Medicine (“Einstein”) and Montefiore Medical Center (“MMC”) who use Human Fetal Tissue (“HFT”) in their research acquire and use such tissue in accordance with legal and ethical requirements. It outlines the institutional process for overseeing the procurement and use of HFT.

II. Scope

This procedure applies to all research using human fetal tissue (whether identifiable, coded, de-identified, or anonymous).

This policy does not apply to the use or collection of tissue or cells obtained from a placenta, umbilical materials, or amniotic fluid. This policy does not apply to the clinical care of women and their fetus or the procurement of HFT for clinical purposes only.

III. Definitions

Fetus: The product of conception from implantation until delivery.

Human Fetal Tissue (“HFT”): Tissues or cells obtained from a dead human embryo or fetus after spontaneous or induced abortion or stillbirth. Human fetal tissue does not include tissue or cells obtained from a placenta, umbilical cord or amniotic fluid.

Induced Abortion: Ending a pregnancy prematurely and purposefully.

Spontaneous Abortion: A naturally occurring loss of the fetus, usually before the 20th week of gestation.

Stillbirth: Delivery of a dead fetus at birth.

IV. Procedure

Research involving HFT shall be conducted in accordance with any applicable federal and state laws and regulations regarding such activities. In addition, all research involving HFT or collaborations with external third parties that involves obtaining, procuring, collecting, storing, or using HFT must be reviewed by the appropriate research committees. These may include the Fetal Tissue Research Committee, Institutional Review Board (“IRB”), Institutional Animal Use and Care Committee (“IACUC”), and/or Institutional Biosafety Committee (“IBC”), as outlined below:

All research utilizing HFT must be submitted to the Office of Human Research Affairs (“OHRA”) using its electronic protocol submission system for review by the Fetal Tissue Research Committee to ensure that the use of fetal tissue is appropriate and scientifically justified.

If information associated with the HFT is recorded for research purposes in a manner that living individuals (e.g. living donor(s) of the material) can be identified, directly or indirectly through identifiers linked to those individuals (i.e. coded), those individuals are research subjects. As such, the research requires IRB review.

All research using HFT derived from fetuses considered clinically viable or which otherwise meets the criteria for IRB review must be submitted to the IRB for review and on-going approval.

All use of fetal tissue for transplantation into humans is considered experimental and requires full IRB review.

For HFT research that uses an external IRB rather than the Einstein IRB, the research must still be submitted to the OHRA for review by the Fetal Tissue Research committee.

All research using HFT that otherwise meets the criteria for IACUC review must be submitted to IACUC for review and on-going approval.

All research using HFT that otherwise meets the criteria for IBC review must be submitted to IBC for review and on-going approval.

Researchers who wish to obtain HFT from an external third party, regardless of whether it is a commercial supplier or academic institution, clinic, hospital, and whether the HFT is obtained with or without consideration, must first notify and obtain the approval of Einstein Montefiore Fetal Tissue Research Committee prior to procuring HFT.

Consent

Informed consent from the donor is required for research use of HFT collected at sites under the auspices of the Einstein HRPP.

Consent process for induced abortion: The consent process for an induced abortion, and the consent process to use the fetal tissue for research, are two distinct decisions and are required to be conducted by separate people. The person obtaining the research consent may not be involved in the clinical care of the patient.

Procurement and distribution of HFT

A Materials Transfer Agreement (“MTA”) must be executed for HFT obtained from an external institution, clinic, or hospital. The source must provide documentation that they are in compliance with the applicable Federal and state laws, regulations, and policies, or provide information on comparable restrictions in force in their country. Receipt of these samples must also be documented in the protocol and in the electronic application made to the OHRA. Receipt of additional samples after the initial approval may be approved by an amendment.

The OHRA does not approve the distribution of HFT to external entities.

Prohibitions

No Einstein or MMC faculty, employee, or agent may knowingly acquire, receive, or otherwise transfer any human fetal material in exchange for valuable consideration.¹

HFT collected at sites under the auspices of the Einstein IRB for clinical purposes cannot be used for research purposes unless prospective, informed consent for research was obtained from the donor (i.e. HFT stored for clinical purposes cannot be used as discarded tissue for research purposes).

Institutional Reporting

The OHRA will establish and maintain a mechanism for tracking all procurement or use of HFT by Einstein and Montefiore faculty, employees, or agents, or if the institution is contracting with an external third party to obtain and/or use HFT on behalf of Einstein Montefiore.

Commercial Use

Use of fetal tissue for the development of cell lines for potential commercial purpose (e.g. diagnostic or therapeutic uses) is permissible, if in accordance with this Policy and with prior approval from the appropriate institutional official as determined by the Executive Dean.

Fetal Tissue Research Committee

The Fetal Tissue Research Committee (“FTRC”) meets on an ad-hoc basis to review research involving HFT. The FTRC shall have a minimum of five members, including the OHRA Director, the Executive Chair of the IRB, and an ethicist.

The OHRA Director and Executive Chair of the IRB will identify potential candidates for FTRC membership as needed. Members are appointed by the OHRA Director in consultation with the Executive Chair of the IRB.

The membership of the FTRC may include both primary members and designated alternate members. The appointment and function of alternate members is the same as that for primary members. The function of alternate members is to serve as a voting member of the panel when the regular member is unavailable to attend a meeting.

Minutes of FTRC meetings are circulated to all members who attended the meeting. Minutes are approved via email.

¹ Valuable consideration does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal material.

There are no set term periods for appointments. Members may resign by providing notice to the OHRA office.

V. Effective Date

Effective as of: 11 August 2019

VI. Policy Management and Responsibilities

Einstein's Office of Human Research Affairs is the Responsible Office under this Procedure. The Executive Dean is the Responsible Executive for this Procedure. The OHRA Director is the Responsible Officer for the management of this Procedure.