

Campus Administrative Policy

Policy Title: Conducting Human Fetal Tissue Research

Policy Number: 6004 Functional Area: **Research**

Effective: March 15, 2016
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Supersedes: N/A

Approved by: Richard J. Traystman
 Vice Chancellor for Research

Prepared by: Office of Regulatory Compliance
Reviewing Office: Office of Vice Chancellor for Research
Responsible Officer: Vice Chancellor for Research

Applies to: University of Colorado Anschutz Medical Campus
 University of Colorado Denver

A. INTRODUCTION

Research performed on human fetal tissue (HFT) is part of the long history of scientific medicine. Human fetal cell research is important for the treatment of disease, valuable in basic research, and used for other applications. Until substitutes for HFT are found, these cells remain the only satisfactory source for promising progress in many fields of medicine. Concern over the procurement, storage, and final usage of HFT has prompted federal and state regulation for their use by researchers. This policy is not to prohibit the use of HFT but rather to direct that all research using HFT must be reviewed and approved in accordance with any applicable federal or state laws and regulations regarding such activity in addition to the requirements of this policy.

B. POLICY/GUIDELINES STATEMENT

This policy is to ensure that all researchers at the University of Colorado Denver and Anschutz Medical Campus who use human fetal tissue in their research acquire and use such tissue in accordance with legal requirements and it outlines the institutional process for overseeing the procurement/obtaining and use of HFT.

C. DEFINITIONS OF TERMINOLOGY FOR THE PURPOSES OF THIS POLICY

1. Fetus: The product of conception from implantation until delivery.
2. Human Fetal Tissue (HFT): Tissues or cells obtained from a dead human embryo or fetus after spontaneous or induced abortion, after a stillbirth, or from potentially viable fetus.
3. Human Fetal Surgery: Clinical surgery in utero in circumstances where any HFT obtained is for clinical purposes only.
4. Induced Abortion: Ending a pregnancy prematurely and purposefully.
5. Spontaneous Abortion: A naturally occurring loss of the fetus, usually before the 20th week of gestation.
6. Stillbirth: Delivery of a dead fetus at birth.
7. Human embryonic stem cells: cells derived from the inner cell mass of blastocyst human embryos.
8. Procurement: Obtaining directly or through a third party human fetal tissue regardless of whether the tissue was provided for free or for any level of financial remuneration.

D. SCOPE

This policy applies to research using human fetal tissue (identifiable, coded, de-identified or anonymous) including human embryonic stem cells not listed in the NIH embryonic stem cell registry.

This policy does not apply to the use or collection of placental or umbilical materials, amniotic fluid, human embryonic stem cells listed in the NIH embryonic stem cell registry. This policy does not apply to the clinical care of women and their fetus or the procurement of HFT for clinical purposes only.

E. PROCEDURES

Research involving HFT shall be conducted only 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 committee which may include Colorado Multiple Institutional Review Board (COMIRB), Institutional Animal Use and Care Committee (IACUC), Institutional Biosafety Committee (IBC), and / or the University of Colorado Denver | Anschutz Medical Campus Scientific Ethics Committee (SEC) as outlined below:

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 and as such require 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 COMIRB for review and on-going approval.

For HFT that uses an external IRB rather than COMIRB for review and approval to meet the regulatory obligations, then the research must also be reviewed and approved by the SEC in accordance with its written procedures.

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

All research using HFT or which 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 this is a commercial supplier or academic institution, clinic, hospital, for free or for pay, for any purpose, including research must first notify and obtain the approval of the SEC in accordance with its written procedures prior to procuring HFT.

Researchers who distribute HFT to an external third party regardless of whether this is a commercial supplier or academic institution, clinic, hospital, for free or for pay must be reviewed and approved by the SEC in accordance with its written procedures even if IRB/IACUC/IBC approval has been obtained.

Note: All research using HFT, which does not require COMIRB review, must be submitted to SEC for review and approval.

F. OTHER INSTITUTIONAL APPROVALS

Researchers procuring and/or using HFT for research purposes must also comply with all other applicable regulatory review processes at the University of Colorado Denver | Anschutz Medical Campus as well as institutional policies and procedures.

The following offices will include a requirement to identify that the research involves HFT:

- Office of Grants and Contracts (OGC)
- Colorado Multiple Institutional Review Board (COMIRB) and institutional review for use of external IRBs
- Institutional Biosafety Committee (IBC)
- Institutional Animal Care and Use Committee (IACUC)
- Colorado Procurement Services Center (PSC)
- Technology Transfer Office (TTO) or their equivalent

These offices will inform the Office for Regulatory Compliance if there is any research proposed that will procure and/or use HFT for research purposes.

G. INSTITUTIONAL REPORTING

The Associate Vice Chancellor for Regulatory Compliance will establish and maintain a centralized mechanism for tracking all procurement, use or external distribution of HFT by University of Colorado Denver | Anschutz Medical Campus faculty, employees or agents or if the institution is contracting with an external third party to obtain and or use HFT on behalf of the institution.

H. PROHIBITION

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

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

2. HFT collected by CU Denver | Anschutz or its affiliates 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.)

I. PROCUREMENT AND DISTRIBUTION OF HFT

A Materials Transfer Agreement (MTA) must be executed for HFT obtained from an external institution, clinic or hospital and must provide documentation that they are in compliance with the applicable Federal laws and policies or provide information on comparable restrictions in force in their country. A copy of the SEC approval must accompany the MTA in accordance with SEC procedures.

A Materials Transfer Agreement (MTA) must be executed for HFT to be distributed by the University of Colorado Denver | Anschutz Medical Campus to a commercial entity or an academic institution, clinic or hospital. A copy of the SEC approval must accompany the MTA in accordance with SEC procedures.

J. FINANCIAL TRANSACTIONS RELATED TO THE PROCUREMENT AND / OR DISTRIBUTION OF HFT

All commercial suppliers of HFT must provide documentation that they are in compliance with the applicable federal laws and policies and complete the SEC attestation form.

All commercial transactions for the procurement of HFT must be transacted through the University of Colorado Procurement Services Center (PSC) in accordance with relevant

PSC rules under Sensitive Expenditures.

PSC will require a copy of the following documents to complete the transaction:

A copy of the MTA

A copy of the approval from the SEC

PSC must maintain a copy of these documents with the related transaction records.

HFT cannot be purchased using a university procurement card regardless of the value of the proposed purchase.

Notes

1. Dates of official enactment and amendments:

March 15, 2016: Adopted and Approved by the Vice Chancellor of Research

June 10, 2019: Modified

2. History:

June 10, 2019: Modified to reflect a Campus-wide effort to recast and revitalize various Campus policy sites into a standardized and more coherent set of chartered policy statements organized around the several operational divisions of the university.

3. Initial Policy Effective Date: March 15, 2016

4. Cross References/Appendix:

1. Selected federal statutes, regulations, and policies

- 42 U.S.C.289g-1 and 289g-2 set forth specific requirements and prohibitions on research involving human fetal tissue. For example, among other prohibitions, 42 U.S.C. 289g-2 provides :

- *"Prohibitions regarding human fetal tissue*

- *(a) Purchase of tissue*

It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce."

- The full text of 42 U.S.C. 289g-1 is available at:

<https://www.govinfo.gov/app/details/USCODE-2017-title42/USCODE-2017-title42-chap6A-subchapIII-partH-sec289g-1>

- The full text of 42 U.S.C. 289g-2 is available at:

<https://www.govinfo.gov/app/details/USCODE-2017-title42/USCODE-2017-title42-chap6A-subchapIII-partH-sec289g-2>

- Code of Federal Regulations TITLE 45 PUBLIC WELFARE, DHHS, Part 46 Protection of Human Subjects (45 CFR 46 Subparts A & B)

<https://www.hhs.gov/ohrp/sites/default/files/ohrp/policy/ohrpregulations.pdf>

- §46.204 *Research involving pregnant women or fetuses.*
 - ~(a) - (g)
 - (h) *No inducements, monetary or otherwise, will be offered to terminate a pregnancy;*
 - (i) *Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and*
 - (j) *Individuals engaged in the research will have no part in determining the viability of a neonate.*
 - §46.206 *Research involving, after delivery, the placenta, the dead fetus or fetal material.*
 - (a) *Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable federal, state, or local laws and regulations regarding such activities.*
 - (b) *If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of this part are applicable.*
 - NIH Policy on Informed Consent for Human Fetal Tissue Research ([NOT-OD-16-033](#)) National Institutes of Health
2. University Administrative Policy Statements and Research Policies
- APS 4016, Fiscal Code of Ethics
<https://www.cu.edu/ope/aps/4016>
 - PSC Procedural Statement: Sensitive Expenditures
<https://www.cu.edu/psc/policies/psc-procedural-statement-sensitive-expenses>
 - COMIRB Policies and Procedures:
<http://www.ucdenver.edu/research/comirb/policies/Pages/default.aspx>
 - Scientific Ethics Committee Standard Operating Procedures
3. Campus Administrative Policy Statements
- Campus Policy 2013, Protected Class Data
http://www.ucdenver.edu/faculty_staff/employees/policies/Policies%20Library/1XXX%20Academic%20and%20Faculty%20Affairs/1023%20-%20Protected%20Class%20Data.pdf
 - Campus Policy 2009, Clinical Trials, 4-1
http://www.ucdenver.edu/faculty_staff/employees/policies/Policies%20Library/2XXX%20Finance/2009%20-%20Clinical%20Trials.pdf
 - Campus Policy 2013, Direct Charges to Federally Sponsored Projects, 4-7
http://www.ucdenver.edu/faculty_staff/employees/policies/Policies%20Library/2XXX%20Finance/2013%20-%20Direct%20Charges%20to%20Federally%20Sponsored%20Projects.pdf

- Campus Policy 2014, Roles and Responsibilities for Sponsored Project Administration, 4-13
http://www.ucdenver.edu/faculty_staff/employees/policies/Policies%20Library/2014%20Roles%20and%20Responsibilities%20for%20Sponsored%20Project%20Administration.pdf