

University of Minnesota

Human Fetal Tissue Research

Report to the Minnesota Legislature

2021

University of Minnesota Human Fetal Tissue Research

Report of the Minnesota Legislature

As required by Minnesota Statute 137.47 which went into effect on July 1, 2017.

Submitted by:

Board of Regents

Prepared by:

The report was prepared by staff in the Office of Academic Clinical Affairs with the assistance of staff in the Office of the Vice President for Research at the University of Minnesota.

Report Preparation Costs:

Per the requirements set forth in Minnesota Statute 3.197, the cost to prepare this report was \$300.

Purpose:

During the 2017 Minnesota legislative session, a law was passed requiring the Board of Regents of the University of Minnesota to submit an annual report to the chairs and ranking minority members of the higher education policy and finance, health and human services, and human services policy and finance committees. The report is required to disclose specific information regarding university research projects which access donated human fetal tissue (reporting requirements noted below).

Background:

In February 2016, the University of Minnesota instituted new requirements for researchers accessing donated human fetal tissue. Oversight of human fetal tissue research became administered jointly by the Office of the Vice President of Research and the Vice President of Academic Clinical Affairs (formerly Academic Health Center).

Per the new requirements, researchers requesting to access human fetal tissue were required to apply for permission to conduct research using human fetal tissue from the Fetal Tissue Research Committee (FTR) prior to commencing their studies. Approval from the Institutional Review Board (IRB) continued to be required if the research project met the criteria established under federal law.

The Anatomy Bequest Program, a university anatomical donation program, became responsible for the acquisition, tracking and final disposition of the tissue.

In January 2018, the University of Minnesota updated the fetal tissue policies to reflect the new requirements associated with the enactment of Minnesota Statute 137.47. The revisions also broadened the scope of the policies to include educational uses, clarified the responsibilities of researchers, delineated newly required duties among the administrative units, and provided an opportunity to make housekeeping changes.

Report Requirements:

Per the requirements of Minnesota Statute 137.47, the following information must be included in this report: all fetal tissue research proposals submitted to the FTR or IRB, including any written narrative required under 137.47, subd.2; whether the research proposal involved aborted fetal tissue; action by the FTR or IRB on all fetal tissue research proposals, including whether the proposal was approved by the FTR or IRB; and a list of all new or ongoing fetal tissue research projects at the university. The list must include the date the project was approved by the FTR or IRB, the source of funding for the project, the goal or purpose of the project, whether the fetal tissue used is aborted fetal tissue or non-aborted fetal tissue, the source of the fetal tissue used, references to any publicly available information about the project, and references to any publications resulting from the project.

Per Minnesota State Statute 137.47, all required disclosures relating to University of Minnesota research projects which access donated human fetal tissue can be referenced below and/or in the attached table.

New Research Requests Submitted to the Fetal Tissue Research Committee:

One new application was reviewed and subsequently approved by the FTR in 2020. The *Understanding Developmental Origins of Human Skull Base Tumors* research project (FTR Application Number 2002-37902B) was granted access to acquire human fetal tissue which was donated following an elective pregnancy termination. This research project has not yet begun. As such, no research expenses have been incurred nor has any fetal tissue been acquired.

As required under Minnesota law, the IRB reviewed the FTR's decision. The IRB concluded that the researcher and the FTR committee had considered all alternatives to the use of human fetal tissue.

The required reporting information regarding this study can be found in Table 1: *New or Ongoing University of Minnesota Research Projects Utilizing Donated Human Fetal Tissue*.

Previously Reported Research Update:

The following actions occurred in 2020:

- The *Zika Virus Infection of Human Fetal Brain Cells* (FTR Application Number: 001) research project has completed the genetic data analysis process since the last report. The active research is now complete, with possible publications to follow based on the research results. The Anatomy Bequest Program arranged for the cremation of the fetal tissue per university policy.
- The *Expression of Cyp26b1 and Slc6a4 in Developing Human Brains* (FTR Application Number: 003) research project remained discontinued in 2020 due to lack of funding. The Anatomy Bequest Program arranged for the return of the fetal tissue microscope slides to the Human Developmental Biology Resource located at the Newcastle University as previously determined by a material transfer agreement.
- To date none of the approved protocols have resulted in a publication.
- Public grant information remains unavailable since the research was privately funded.
- We are not aware of any references to other publicly available information about the projects.

FTR Application Number and Title	Application Approval Date	Research Goal	Funding Source	Tissue Procurement Source
001-Zika Virus Infection of Human Fetal Brain Cells	5/18/2016 ¹ 3/30/2017 ² 10/27/2017 ³ 5/3/2018 ⁴	The goal of this project is to determine whether the Zika virus can directly infect cells that are found in the human fetal brain. At the present time there is an association between the presence of the Zika virus and damage to the developing human brain, but no direct evidence. We will determine the ability of the Zika virus to infect each of the different types of cells that are found in the fetal brain. Once we identify what types of cells can be infected then we will study the molecular mechanisms that are involved in the infection process. An understanding of these molecular mechanisms will allow us to begin consider what drugs might prevent the Zika virus from infecting the brain.	Privately funded	Birth Defects Research Laboratory -University of Washington Human Developmental Biology Resource- Newcastle University (No tissue was received from this source)
2002-37902B- Understanding Developmental Origins of Human Skull Base Tumors	6/19/2020 (FTR and IRB)	Cancer occurs as a result of transformation from a previously normal cell. We use new technology (“single cell genomics”) that allows us to view all genes expressed in <i>individual</i> cells. Our goal is to compare the genes expressed in individual cells between human tumors and normal cells undergoing fetal development, so that we can map the origin of specific human cancers. Insights into the origin for cancer allows us to understand the underlying biology of cancer formation and provides a framework on how to prevent or treat these cancers in new ways.	No expenses have yet been incurred. This research will be privately funded once initiated.	None

Table 1: New or Ongoing University of Minnesota Research Projects Utilizing Donated Human Fetal Tissue

¹Application approved prior to MN Statute 134.47 effective date, IRB review of FTR decision was not required..

²Amendment to application requesting to add Newcastle as a procurement source

³Amendment to application requesting to add additional types of tissue to project

⁴Amendment to application requesting to remove 4 researchers from project