University of Minnesota

Human Fetal Tissue Research

Report to the Minnesota Legislature
2018

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 Academic Health Center 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 Statue 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 the 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 and was to be in lieu of FTR Committee approval.

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

The University of Minnesota has 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 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 publically 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.

Approved Research:

Since February 2016, there have been four applications approved by the FTR. Each application was approved for access to human fetal tissue which was donated following an elective pregnancy termination.

- FTR Application number 001-Zika Virus Infection of Human Fetal Brain Cells
- FTR Application number 002- AAV to CNS for MPS I (Mucopolysaccharidosis research)
- FTR Application number 003: Expression of Cyp26b1 and Slc6a4 in Developing Human Brains (depression and schizophrenia research)
- FTR Application number 004: Stem Cell Model of Neurofibromatosis

All of the applications are ongoing research projects with exception of the Mucopolysaccharidosis study which has not been funded or acquired human fetal tissue.

In addition to the four applications, two amendments to FTR 001 were approved. Only one FTR action, the FTR's approval of an amendment to application number 001 (amendment 2), commenced after the provisions of Minnesota Statute 137.47 went into effect on July 1, 2017. Going forward all applications reviewed by the FTR and IRB will include a written narrative from the researcher justifying not only the use of human fetal tissue, but also specifically fetal tissue from induced abortions.

To date, none of the approved protocols have resulted in a publication. The researchers in FTR application numbers 001, 003, and 004 are currently analyzing their compiled data. The existence of other publicly available information regarding these research projects is difficult to determine. However, none of the projects have been awarded funding through the National Institutes of Health.

FTR Application Number and Title	Date of Application Approval	Research Goal	Funding Source	Tissue Procurement Source
001-Zika Virus Infection of Human Fetal Brain Cells	5/18/16 3/30/2017[1] 10/27/2017[2]	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
002- AAV to CNS for MPS I	5/18/2016	The goal of our work is to determine the serotype of AAV that will most efficiently transduce human fetal brain cells in delivering therapeutic genes. We will grow human fetal neuronal progenitor cells and astrocytes in tissue culture and transfect cells with AAV5, AAV8, AAV9 and AAV10.	Not funded	None
003: Expression of Cyp26b1 and Slc6a4 in Developing Human Brains	5/18/2016	Many genes have been identified whose mutations increase the risk of psychiatric disorders such as schizophrenia, autism and depression. In mouse brains, many of these genes are expressed during development, suggesting that abnormal development of certain brain structures underlie the cause of many psychiatric disorders. Based on these assumptions, mouse models for these mutations have been made. However, little is known about when and where these disease-associated genes are expressed in developing human brains. Without knowing this, it is difficult to determine how useful mouse models are for studying the causes and therapies for human psychiatric disorders.	Privately funded	Human Developmental Biology Resource-Newcastle University
004: Stem Cell Model of Neurofibromatosis	3/3/2017	Our previous work generating human stem cells from neurofibromatisis (NF) developed methods to generate Schwann cells from NF- as well as non-NF stem cells. In doing this, we have found no tumor formation in Schwann cells generated from NF donor stem cells. This addresses our original hypothesis that the NF mutation confers a tendency to transform Schwann cells to generate Schwannomas, but is not sufficient to do so without additional changes. We have obtained RNA from normal adult Schwann cells, but require RNA from fetal tissue as expression controls for the developmental stages.	Privately funded	Birth Defects Research Laboratory -University of Washington

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

[1]-Amendment to application requesting to add Newcastle as a procurement source

[2]-Amendment to application requesting to add additional types of tissue to project