University of Minnesota Human Fetal Tissue Research

Report to the Minnesota Legislature Calendar Year 2024

January 15, 2025

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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 from the Office of Academic Clinical Affairs and the Research & Innovation Office 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 following report is required to disclose specific information regarding university projects that access donated human fetal tissue for the purposes of research or education. The coverage period for information provided below is 1/1/2024 to 11/1/2024. Any subsequent FTR or IRB submissions received in 2024 will be included in the University's legislative calendar year 2025 report.

Background:

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

Per these 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 its 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.

Additionally, the January 2018 revisions specifically exempt "the use of cell lines derived from human fetal tissue that historically have been available and are widely used and distributed on a national basis" from review. In 2018, the Office of the Legislative Auditor performed a comprehensive review of the University's fetal tissue research policies in place at the time.

Report Requirements:

Per the requirements of Minnesota Statute 137.47, the following information must be included in the legislative 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 also 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.

New Fetal Tissue Research Proposals Submitted to the Fetal Tissue Research Committee and/or the Institutional Review Board:

There were no new fetal tissue related research proposals submitted to the FTR or IRB during the reporting period.

Previously Reported Research Update:

The FTR received one amendment during the reporting period relating to a previously reported, uninitiated proposal titled *Understanding Developmental Origins of Human Skull Base Tumors* (FTR Application Number 2002-37902B). A decision was made not to move forward with this research at this time.

All other previously reported research projects were either never initiated or were discontinued.