State of Minnesota

HOUSE OF REPRESENTATIVES

NINETIETH SESSION

H. F. No. 1633

02/23/2017 Authored by Whelan, Knoblach, Grossell, McDonald, Heintzeman and others
The bill was read for the first time and referred to the Committee on Higher Education and Career Readiness Policy and Finance

A bill for an act

relating to higher education; imposing requirements for fetal tissue research at the University of Minnesota; appropriating money for a program in ethical fetal tissue research; proposing coding for new law in Minnesota Statutes, chapter 137.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. **[137.45] FETAL TISSUE RESEARCH.**

Subdivision 1. **Definition.** "Fetal tissue" means any part of an unborn child or fetus, including a body part, cell, tissue, or organ.

Subd. 2. **Approval by institutional review board (IRB).** The University of Minnesota must obtain approval from an institutional review board (IRB) or stem cell oversight committee before conducting research using fetal tissue. In its approval process, the IRB must consider whether adult or nonhuman tissue would be sufficient for the research.

Subd. 3. **Fetal tissue sources.** The university must attempt to identify sources for procurement of fetal tissues that are available due to the natural death of the fetus and are suitable for use in academic research. The university may consider engaging an outside consultant to assist in identifying such sources. When appropriate sources are identified, recommendations must be made to the Board of Regents of the University of Minnesota for updates to university policies and procedures to encourage use of these sources in all university research activities where fetal tissue is requested to be used. Sources that are identified must be submitted to the Association of American Medical Colleges.

Subd. 4. **Legislative report.** No later than January 15, 2018, the Board of Regents must submit a report to the chairs and ranking minority members of the legislative committees with jurisdiction over higher education policy and finance and health and human services

policy and finance. The report must describe all activities under subdivision 3, including the identification of suitable fetal tissue sources, any recommended updates to university policies and procedures, and whether the Board of Regents adopted the recommended updates. The report must also contain a list of all new or ongoing fetal tissue research projects at the university. For each research project, the list must include:

(1) the date that the research was approved by an IRB or stem cell oversight committee;

(2) the source of funding for the research;

(3) the goal or purpose of the research;

(4) the source of the fetal tissue used;

(5) references to any publicly available information about the research such as National Institutes of Health grant award information; and

(6) references to any publications resulting from the research.

Subd. 5. **Institutional review board procedures.** The university shall:

(1) further develop and clarify existing university policies and procedures related to the lawful and ethical treatment of human subjects and fetal tissue in research activities, including enhancement of applicable penalties for violation of these policies and procedures;

(2) institute a system of frequent, random, unannounced inspections and audits of research activities involving fetal tissue to verify compliance with applicable federal and state laws, university policies and procedures, and other professional standards related to purchasing, handling, and disposing of fetal tissue;

(3) conduct education and outreach programs, including instituting a required comprehensive training program, on applicable federal and state laws, university policies and procedures, and other professional standards related to the respectful, humane, and ethical treatment of human subjects and fetal tissue in research, for all students and employees engaged in these activities; and

(4) establish an anonymous reporting system to receive complaints of activities that may violate applicable federal and state laws, university policies and procedures, and other professional standards in research involving human subjects and fetal tissue by the university, university students or employees, or any other person engaged in research activities in university facilities.

EFFECTIVE DATE. This section is effective the day following final enactment.

Sec. 2. **APPROPRIATION; CENTER FOR ETHICAL RESEARCH.**

Subdivision 1. **Appropriation provided.** $1,000,000 in fiscal year 2018 is appropriated from the general fund to the Board of Regents of the University of Minnesota to establish a program in ethical fetal tissue research within the Center for Bioethics on the Twin Cities campus.

Subd. 2. **Program in ethical fetal tissue research.** (a) The program in ethical fetal tissue research must:

(1) provide oversight of all research activities at the university that request the use of fetal tissue;

(2) ensure compliance with applicable laws and policies governing the ethical acquisition, sale, handling, and disposal of fetal tissue;

(3) procure fetal tissue for use in applicable university research activities, provided that the program may only purchase fetal tissue for use in research if the tissue is available due to the natural death of the fetus; and

(4) advance research on stem cells derived from sources other than fetal or embryonic tissue, including adult somatic cells, cord blood, and related sources.

(b) In advancing nonembryonic and nonfetal stem cell research, the program may:

(1) produce clinical grade stem cells from adult tissues, cord blood, and related materials for use in clinical trials and therapies;

(2) facilitate the delivery of adult, cord blood, and related stem cell therapies to area hospitals where appropriate;

(3) partner and collaborate with other institutions to foster a regional network of physicians trained in adult, cord blood, and related stem cell therapy applications;

(4) create and maintain a database resource for physicians and patients that provides a comprehensive global list of available stem cell clinical trials and therapies;

(5) initiate clinical trials with adult, cord blood, and related stem cells;

(6) create education modules to train and educate physicians and research scientists about peer-reviewed adult, cord blood, and related stem cell therapy applications for patients;

(7) distribute information to physicians about methods for successful treatments with adult, cord blood, and related stem cells through basic and clinical research; and

(8) inform the public on available adult, cord blood, and related stem cell therapeutic options.

Subd. 3. **Certification required.** By the end of fiscal year 2018, the Board of Regents must submit a report stating whether the program in ethical fetal tissue research has been established and is operational consistent with the requirements of subdivision 2. The report must be submitted to the chairs and ranking minority members of the legislative committees with jurisdiction over higher education policy and finance and health and human services policy and finance.