

## UNIVERSITY OF MINNESOTA

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April 1, 2019

Senator Michelle R. Benson, Chair  
Health and Human Services Finance and Policy Committee  
3109 Minnesota Senate Bldg.  
St. Paul, MN 55155

Senator John Marty, Ranking Minority Lead  
Health and Human Services Finance and Policy Committee  
2401 Minnesota Senate Bldg.  
St. Paul, MN 55155

Representative Tina Liebling, Chair  
Health and Human Services Finance Division  
477 State Office Building  
St. Paul, MN 55155

Representative Joe Schomacker, Ranking Minority Lead  
Health and Human Services Finance Division  
209 State Office Building  
St. Paul, MN 55155

Dear Legislators,

Per Chapter 6, Article 10, Section 55 of Laws of Minnesota 2017, please accept our final report on the Biomedicine and Bioethics Innovation Grants. The grants were administered jointly by the University of Minnesota and Mayo Foundation Partnership, with the University of Minnesota acting as the fiscal agent.

Thank you for your support of the partnership. We look forward to a productive and exciting future as we work to improve the health of Minnesotans across the state.

Sincerely,



Jakub Tolar, MD, PhD  
Vice President for Academic Clinical Affairs  
University of Minnesota

# **Biomedicine and Bioethics Innovation Grants**

**Report to the Minnesota Legislature 2019**

## **Biomedicine and Bioethics Innovation Grants**

### **Report to the Minnesota Legislature**

As required by Minnesota Statutes 137.67 which went into effect on July 1, 2017.

#### **Submitted by:**

University of Minnesota and Mayo Foundation partnership

#### **Prepared by:**

The report was prepared by staff in the Office of Discovery and Translation Clinical and Translational Science Institute with the assistance of staff in the Academic Health Center at the University of Minnesota.

#### **Report Preparation Costs:**

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

## Minnesota Biomedicine and Bioethics Innovation Grants Program Report

### Overview of TPDF implementation plan and funding activities under Minnesota Statutes, section 137.67

#### Administration

Funds appropriated through this allocation are administered through the Translational Product Development Fund (TPDF), a joint program through the Mayo Clinic Center for Clinical and Translational Science (CCaTS) and the University of Minnesota (UMN) Clinical and Translational Science Institute (CTSI). The University of Minnesota Office of Discovery and Translation (ODAT) and the Mayo Clinic Office of Translation to Practice (OTP) share joint responsibility for program oversight and operations. The TPDF is funded through the Minnesota Partnership for Biotechnology and Medical Genomics (Minnesota Partnership) which provides overall program oversight and review.

#### Eligibility

Funding is allocated according to current TPDF guidelines, which awards funding to Mayo investigators, to UMN investigators, or to a collaboration between Mayo and UMN investigators. Projects that include the acquisition or use of human fetal tissue are not eligible for funding.

#### Evaluation

Evaluation of funding requests is done according to current TPDF guidelines with the addition of a bioethics review (see below). The rigorous protocol review committees in place at Mayo Clinic and the University of Minnesota govern the use of animals and human subjects in TPDF-supported projects. Evaluation criteria include potential for commercialization, readiness of the technology to advance to the next stage of translation from the proposed activity, and strength of the investigative team and any partners.

#### Bioethics

In addition to the evaluation criteria stated above, projects selected for funding through this allocation receive a bioethics review through Mayo Clinic and/or UMN. Any issues or questions raised during the bioethics review must be resolved prior to award of funding. The TPDF program is open to biomedical and bioethics projects focused on developing a new therapeutic, diagnostic, device, software, or treatment approach.

#### Consultation

Existing TPDF processes are used to seek advice and recommendations on project milestones and funding decisions from external experts in therapeutics, diagnostics, health-related software, and medical device development.

#### **Allocation: Fund an additional Tier 1 project**

Estimated amount: \$79,500

#### **Progress: Awarded Tier 1 Project in June 2017**

“Treatment of Tension Pneumothorax Decompression with Needle Thoracotomy Colorimetric Capnography”. Martin Zielinski, MD and Jonathon M. Aho, MD, Mayo Clinic, Rochester

Awarded: \$79,500

**Allocation: Fund up to three additional Tier 2 projects**

Estimated amount: \$1.8M - \$1.9M

**Progress: Three Tier 2 Projects Approved**

“Preclinical Development of Beta-hydroxybutyrate/Melatonin (BHB/M) for the Treatment of Trauma-induced Acute Blood Loss" Gregory Beilman, M.D., University of Minnesota

“Fiber-Optic Tube Thoracostomy Trocar for Improved Patient Chest Drainage" Johnathon M.E. Aho, MD PhD, Mayo Clinic, Rochester

“Development of hexyl-benzyl-biguanide (HBB) for breast cancer therapeutics” David A. Potter, M.D., Ph.D. and Robert Schumacher, Ph.D., University of Minnesota

Total Awarded: \$1,868,000

**Allocation: Provide TPDF funding for expert consultants and technical troubleshooting**

Consulting funds to offer directed expert guidance to Tier 1 and Tier 2 approved projects as needed. Technical troubleshooting funds utilized to overcome unanticipated research and development barriers; funds allocated as needed for projects with consistently positive scientific and commercialization indicators.

Estimated amount: \$100,000 - \$150,000

**Progress: Consulting Funds Allocated**

Consulting funds allocated to ODAT and OTP for engagement of consultants on three TPDF Tier 2 projects

Awarded: \$100,000

**Allocation: Establish start-up incubator matching fund**

Funds to support recently incorporated (within 2 years) Minnesota-based start-up companies that have previously received TPDF Tier 2 funding. Funding is intended to match funds the company has attracted to advance development efforts to the point of securing sustainable investment such as SBIR or similar funding. Estimated amount: \$350,000 - 400,000

**Progress: Program fully established and operational; first project approved June 2018**

CoreBiome, Inc. “Advancement of Microbiome Analysis Platform Technology”

Awarded: \$220,000

Total Funds Awarded: \$2,267,500

Balance: \$232,500 (allocated for remaining award to one Start-up Incubator Matching Fund project and possibly additional Consulting Funds)

**Project Highlights:**

- CoreBiome was acquired in Q1 2019 by OraSure Technologies, a leader in point-of-care diagnostics, to expand its position in the rapidly growing microbiome market.
- An Investigational New Drug application to the FDA is in preparation for the project “Preclinical Development of Beta-hydroxybutyrate/Melatonin (BHB/M) for the Treatment of Trauma-induced Acute Blood Loss” to be filed in early 2020.
- A prototype for the project “Fiber-Optic Tube Thoracostomy Trocar for Improved Patient Chest Drainage” is in development with preclinical testing to begin Q2 2019. The market potential of this device has been validated by an independent consulting firm.
- 500 prototypes for the project “Treatment of Tension Pneumothorax Decompression with Needle Thoracotomy Colorimetric Capnography” are being distributed to aerial medical emergency teams and Mayo emergency rooms for an initial usage study, with additional interest from the military medical community.

## **Attachment**

### **Language from Health and Human Services Omnibus Bill, SF 2, 2017**

(i) **Transfer; Minnesota Biomedicine and Bioethics Innovation Grants.** \$2,500,000 in fiscal year 2018 is from the general fund for transfer to the Board of Regents of the University of Minnesota for Minnesota biomedicine and bioethics innovation grants under Minnesota Statutes, section 137.67. The full amount of the appropriation is for grants, and the University of Minnesota shall not use any portion for administrative or monitoring expenses. The steering committee of the University of Minnesota and Mayo Foundation partnership must submit a preliminary report by April 1, 2018, and a final report by April 1, 2019, on all grant activities funded under Minnesota Statutes, section 137.67, to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services finance. This is a onetime appropriation and is available until June 30, 2021.

### **[137.67] MINNESOTA BIOMEDICINE AND BIOETHICS INNOVATION GRANTS.**

Subdivision 1. **Grants.** (a) The steering committee of the University of Minnesota and Mayo Foundation partnership shall award grants to entities that apply for a grant under this subdivision to fund innovations and research in biomedicine and bioethics. Grant funds must be used to fund biomedical and bioethical research, and related clinical translation and commercialization activities in this state. Entities must apply for a grant in a form and manner specified by the steering committee. The steering committee shall use the following criteria to award grants under this subdivision:

- (1) the likelihood that the research will lead to a new discovery;
- (2) the prospects for commercialization of the research;
- (3) the likelihood that the research will strengthen Minnesota's economy through the creation of new businesses, increased public or private funding for research in Minnesota, or attracting additional clinicians and researchers to Minnesota; and
- (4) whether the proposed research includes a bioethics research plan to ensure the research is conducted using ethical research practices.

(b) Projects that include the acquisition or use of human fetal tissue are not eligible for grants under this subdivision. For purposes of this paragraph, "human fetal tissue" has the meaning given in United States Code, title 42, section 289g-1(f).

Subd. 2. **Consultation.** In awarding grants under subdivision 1, the steering committee may consult with interested parties who are able to provide technical information, advice, and recommendations on grant projects and awards. Interested parties with whom the steering committee may consult include but are not limited to representatives of private industries with expertise in biomedical research, bioethical research, clinical translation, commercialization, and medical venture financing.