

# **Biomedicine and Bioethics Innovation Grants**

## **Report to the Minnesota Legislature 2018**

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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 \$500.

## **Minnesota Biomedicine and Bioethics Innovation Grants Program Report**

### **Overview of TPDF implementation plan for FY18 funding under Minnesota Statutes 137.67**

#### **Administration**

Funds appropriated through this allocation will be 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 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 will be 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 will not be eligible for funding.

#### **Evaluation**

Evaluation of funding requests will be done according to current TPDF guidelines with the addition of a bioethics review (see below). 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 will also 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 will be 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.

<b>Allocation: Fund an additional Tier 1 project</b>
Estimated amount: \$79,500
<b>Progress: Awarded Tier 1 Project in June 2017</b>
“Treatment of Tension Pneumothorax Decompression with Needle Thoracotomy Colorimetric Capnography”. Martin Zielinski, MD and Jonathan 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 projects currently in review**

“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

Awarded: TBA - Amount awarded would be approx. \$1.2M if both projects in review are approved

**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

Timing of commitment: Initial investments beginning in Q4 2017

**Progress: Three projects identified for receipt of consulting funds**

Plans to initiate engagement of external consultants for two Tier 1 and two Tier 2 projects Q2 2018

Awarded: \$0

**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. Specific award amounts and eligibility criteria will be finalized by program implementation Q1 2018.

Estimated amount: \$350,000 - 400,000

Timing of commitment: establishment of program and funding Q1 2018

**Progress: Program fully established and operational; first project currently in review**

Application currently in review from CoreBiome, Inc. “Advancement of Microbiome Analysis Platform Technology”

Awarded: \$0

Total Funds Awarded: \$79,500

Total Funds Requested for Projects in Review: \$2,018,000

Estimated Balance Assuming Approval of Projects in Review: \$402,500

## **Attachment**

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

(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.

### **Sec. 55. [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.