

Business Plan

March 29, 2017

Vision

Improving the health of Minnesotans by advancing regenerative medicine therapies.

Goals

- Advancing regenerative medicine research, education, industries, and care delivery to patients.
- Moving Minnesota to the forefront of regenerative medicine science and practice.

Objectives

- **Scientific:** Support Minnesota research that has the potential to translate into clinical advances in regenerative medicine.
- **Commercial:** Develop Minnesota businesses and infrastructure to deliver regenerative medicine products and services.
- **Educational:** Educate, recruit and retain a regenerative medicine workforce in Minnesota. Educate Minnesotans about the status and potential of regenerative medicine therapies.
- **Clinical:** Advance regenerative medicine therapies to the clinic.

Governance

Recommendations governing the Regenerative Medicine Minnesota (RMM) funding will be made by a five-person Board. The Regenerative Medicine Minnesota Board (Board) will have representatives from the University of Minnesota and Mayo Clinic as co-chairs, with three additional Minnesotans from fields as diverse as patient advocacy, industry, and health care. Members will also preferably have expertise pertinent to regenerative medicine, medical or basic science research, clinical translation, and/or business development.

The Board is responsible for approving a business plan that outlines the RMM's vision, goals, objectives, funding priorities, and marketing and communications efforts. The board is also responsible for overseeing the review of applications and providing recommendations for distribution of funds. The Board has the authority to recommend reallocating funding among RMM funding categories based on need or on the quality of applications received. The Board is responsible for overseeing the progress of funded

projects and for approving reports to be submitted to the State of Minnesota as mandated in the appropriations bill.

The oversight of RMM lies with senior officials of the University of Minnesota (Dean of the Medical School/Vice President for Health Sciences and the Senior Associate Dean for the Medical School) and Mayo Clinic (Executive Dean for Research and the Director of the Center for Clinical and Translational Science). To ensure that RMM meets the legislative intent of a broad statewide program and that the program meets all requisite legal and financial requirements, these four officials will act together to provide final oversight of the business plan and RMM board recommendations regarding funding and other strategic issues. RMM is independent of other University-Mayo collaborations.

Definition of Regenerative Medicine

Regenerative medicine assists the body's own ability to heal. Cell and developmental biology, regenerative pharmacology and immunology, medicine and surgery, biotechnology, bioengineering, and other relevant fields, are brought together to develop ways to replace, restore, or regenerate damaged or malfunctioning cells, tissues, and organs to help people return to better health.

Funding Opportunity Guidelines

Regenerative Medicine Minnesota **will engage a network of stakeholders to develop regenerative medicine assets throughout the state.** Funding opportunities will be balanced across needs in research, clinical practice, business development, and education, and will emphasize statewide access. Eligible institutions include public and private schools, colleges and universities, hospitals and clinics, health departments, research organizations, and biotechnology development or other companies/organizations that are based in the state of Minnesota. Matching funds or in-kind contributions are strongly encouraged.

Proposed Budget	Annual Years 3-10
Discovery Science, Translational Research, and Clinical Trials	\$3,000,000
Education & Outreach	\$650,000
Patient Care	\$200,000
Biotechnology/Biobusiness Development	\$500,000
Total	\$4,350,000
State Appropriation	\$4,350,000

RESEARCH:

RFP released 9/6/2016, proposals due 10/25/2016, awards announced 1/30/2017

One- or two-year projects (2nd year renewal contingent on adequate progress) with the potential to advance regenerative medicine. Awarded based on independent scientific peer review.

- Discovery science: maximum award of \$125,000/year (inclusive of indirect costs*).
- Translational research: maximum award of \$125,000/year (inclusive of indirect costs*).
- Clinical trials: maximum award of \$250,000/year (inclusive of indirect costs*). *Indirect costs should be included in the budget at the established NIH-negotiated rate or, in the absence of a federally-negotiated rate, at 10%.

EDUCATION:

RFP released 1/3/2017, proposals due 2/14/2017, awards announced 4/10/2017

- Improve student knowledge in regenerative science and medicine (grades 3-12).
 - Summer camps and other programs that teach students about biology, medicine, engineering, and other fields related to regenerative medicine, maximum award \$20,000/year.
- Recruit, educate, and retain students in regenerative science and medicine.
 - Programs designed to recruit non-traditional students, provide regenerative medicine-specific education, or to help retain students in areas related to regenerative medicine, maximum award \$100,000/year.

OUTREACH:

Annual report of progress due from vendor on 9/6/2016; If unsatisfactory, RFP will be released 10/3/2016, proposals due 11/1/2016, awards announced 12/1/2016

• Website: maintenance of website to track existing and future Minnesota regenerative medicine assets, educate the community, promote funding opportunities, and publicize the funded projects and their outcomes. Maximum budget \$50,000/year.

PATIENT CARE:

RFP released 1/3/2017, proposals due 2/14/2017, awards announced 4/10/2017

• Projects that benefit multiple patients by creating or updating access to regenerative medicine throughout the state, maximum request \$25,000/year.

BIOTECHNOLOGY/BIOBUSINESS DEVELOPMENT:

RFP released 1/3/2017, proposals due 2/14/2017, awards announced 4/10/2017

- Projects to develop Minnesota businesses and technologies that deliver regenerative medicine products, devices, and services, maximum request \$100,000/year.
 - May include purchase of non-expendable research equipment and/or development of infrastructure to produce regenerative biotechnology products, devices and services.