

Business Plan

September 14, 2020

Vision

Improving the health of Minnesotans by advancing regenerative medicine research, clinical translation, and commercialization.

Mission

- Support Minnesota regenerative medicine research that has the potential to improve patient care.
- Translate research into clinical advances in regenerative medicine by funding clinical trials in Minnesota.
- Accelerate commercialization by supporting Minnesota biobusinesses that bring regenerative medicine products and services to market.

Governance

Recommendations governing the Regenerative Medicine Minnesota (RMM) funding will be made by an up to seven-person Board. The Regenerative Medicine Minnesota Board (Board) will have one representative each from the University of Minnesota and Mayo Clinic as co-chairs. Up to five additional Minnesotans representing statewide stakeholders, including industry and others with expertise in regenerative science and medicine, clinical translation and application, commercialization, and medical venture who are not currently affiliated with the University of Minnesota or Mayo Clinic will also serve on the Board.

The Board is responsible for approving the annual Business Plan that outlines the RMM's vision, mission, funding priorities, and outreach 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 the quality of applications received.

The Board is responsible for overseeing the progress of funded projects. An audit is submitted to the Minnesota State Legislature every other year in line with the appropriation bill (<u>Minnesota Regenerative Medicine Act</u>, CHAPTER 312, ARTICLE 1, SECTION 4) OF LAWS OF MINNESOTA 2014). RMM grant award results are made public and available to Minnesotans via the dedicated website <u>www.regenmedmn.org</u>.

Board information can be found in the document: Board Organization and Operations.

The oversight of RMM lies with senior officials of the University of Minnesota (Vice President for Research and Vice President for Clinical Affairs) and Mayo Clinic (Executive Dean for Research and Dean 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 utilizes the body's own ability to heal. Restoring form and function is at the essence of a regenerative outcome. 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 rejuvenate 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 focus on research, clinical translation, and biobusiness development. Eligible institutions must be based in the state of Minnesota, and funds must remain in Minnesota. Awardees are strongly encouraged to seek matching funds or in-kind contributions. Funds that remain unspent are returned to RMM, and the RMM Board will decide how to repurpose them.

Categories

DISCOVERY SCIENCE AND TRANSLATIONAL RESEARCH:

RFP released 9/14/2020, proposals due 11/11/2020, awards announced 1/18/2021

- One- or two-year projects (2nd year renewal contingent on adequate progress) with the potential to advance regenerative medicine. Awarded based on scientific peer review.
- Maximum award \$125,000/year (\$250,000 total; includes direct and indirect costs).

CLINICAL TRIALS:

RFP released 9/14/2020, proposals due 11/11/2020, awards announced 1/18/2021

- Two-year projects (2nd year renewal contingent on adequate progress) with the potential to advance regenerative medicine. Awarded based on scientific peer review.
- Maximum award \$250,000/year (\$500,000 total; includes direct and indirect costs).*

BIOBUSINESS DEVELOPMENT:

RFP released 1/25/2021, proposals due 3/8/2021, awards announced 4/26/2021

- One-year projects to develop Minnesota businesses and technologies that deliver regenerative medicine products, devices, and services. Awarded based on scientific peer review.
- May include purchase of non-expendable research equipment, creation of jobs, and/or development of infrastructure to produce regenerative biotechnology products, devices, and services.
- Maximum award \$100,000/year (\$100,000 total; includes direct and indirect costs except for equipment purchases, which do not have indirect costs).

Proposed Annual Budget

Discovery Science and Translational Research/Clinical Trials	\$3,500,000
Biobusiness Development	\$800,000
Outreach Expense	\$50,000
Total (Annual State Appropriation)	\$4,350,000

Outreach Expense

RMM budgets \$50,000 annually for the expense of maintaining, hosting, and designing the <u>www.regenmedmn.org</u> website. This website is used to track activity and outcomes of all RMM programs, to promote funding opportunities, and to provide information to the general public about the program. This contract was initially put out for competitive bid in 2015. Renewal of contract is dependent on favorable Board review of contractor performance and annual report demonstrating excellence of design, consistent maintenance, continual improvement, and responsiveness to RMM requests.

Regenerative Medicine MINNESOTA