

### 2025 Regenerative Medicine Minnesota (RMM) RFP

# Establishing Minnesota as a Leader in Regenerative Medicine

The mission of RMM is to bring breakthrough regenerative medicine therapies to patients in Minnesota and beyond. In the 2025 RFP, RMM is calling for transformative proposals aimed at overcoming barriers that currently prevent or hinder regenerative medicine therapies from getting into patients. Key barriers to translation in regenerative medicine include availability of preclinical models and human microphysiological systems, lengthy and expensive development timelines, scalability of manufacturing processes and product consistency. RMM aims to support projects that leverage strengths in Minnesota to overcome these barriers and position the state at the forefront of regenerative medicine.

## **Project Eligibility**

### Projects must:

- Clearly identify and address a specific challenge that hinders progress in the regenerative medicine field in MN
- Lead to capabilities that will be broadly accessible to other organizations in the regenerative medicine field in MN
- Be sustainable beyond the funding period

Projects that include collaborations (e.g. private-public or cross-institutional) to advance approaches that cannot be accomplished through traditional research or by a single institution are encouraged. For more information on how RMM is supporting teaming efforts, see the Teaming section at the end of this document.

Examples of responsive projects may include, but are not limited to:

### Availability of Preclinical Models and Materials:

- Broaden access to regenerative medicine-based models or research tools (e.g. sharing expertise, specialized equipment/technologies, models, cell lines, facilities)
- Establish or improve standards and reproducibility, characterization or development of regenerative medicine-based models
- Develop or implement approaches to share cell lines, banks or repositories

### Scalable Development and Manufacturing Processes

- Develop or implement innovative manufacturing or analytical technologies, models or processes
- Establish models or processes to share resources/equipment/platforms for process development and manufacturing

- Establish or operationalize networks/partnerships to support process development and GMP manufacturing (with academic and industry manufacturing partners)
- Develop GMP-compatible manufacturing processes or capabilities suitable for IND/IDE-enabling preclinical studies and clinical trials
- Establish or enhance in-house or partnered capabilities for analytical assays, process development, technology transfer, product characterization, identification of critical quality attributes and critical process parameters, and process control strategies
- Develop systems for sharing manufacturing protocols, data, and analytics
- Develop readily accessible, scalable, and reproducible device-based platforms for enabling preclinical studies and clinical trials
- Develop or implement innovative processes/approaches to improve quality assurance

### Translational and Clinical Research Efficiency:

- Establish or operationalize networks/partnerships to support preclinical research, IND/IDE enabling studies, clinical research/trials, regulatory filings and meetings (with academic and industry partners)
- Develop or implement processes/approaches to support clinical trial operations and sites
- Develop tools or methods to improve patient identification, recruitment and enrollment in clinical studies, particularly for unserved populations, such as patients in rural communities and/or with rare diseases.

This RFP is not intended to support discovery, development, translation or commercialization of a specific regenerative medicine-based innovation.

## **Applicant Eligibility**

Minnesota-based academic institutions and small businesses performing scientific and/or medical research in the state of Minnesota are eligible for this opportunity. Small businesses must be based, owned (≥50%), and operating in the state of Minnesota. For this definition, a small business must have at least 2 and no more than 100 affiliated full- or part-time employees. Entities must be registered with the state of Minnesota's Secretary of State Office (http://www.sos.state.mn.us/business-liens) prior to the application being submitted.

- The PI(s) must be an employee of the applicant organization and authorized by the applicant organization to conduct the research and assume the responsibilities of the PI.
- PI(s), key personnel and any business leadership of small businesses must be in good standing (not have been convicted of, or are under investigation for, crimes involving fraud/misappropriation or research misconduct).
- The funding history and performance of applicants previously supported through the RMM program will be taken into account in funding decisions.

### **Award Information**

RMM will fund total project costs (direct and indirect) up to \$2,000,000 over the span of up to 3 years. RMM anticipates awarding at least 3 projects in 2025.

## **Application Process**

Letters of Intent (LOIs) must be submitted online through the InfoReady system through the following link:

#### **LOI Content:**

- PI(s), collaborator and organization information
- What is the barrier that hinders progress in the field of regenerative medicine in MN that you are trying to address?
- Briefly describe the project and how it will address the translational barrier in MN?
- How would the proposed project/solution be made broadly accessible to regenerative medicine organizations (academic institutions, companies) throughout MN?
- How could the proposed capabilities be sustained in the long-term (after completion of this project) to accelerate regenerative medicine in MN?
- Briefly describe how the team/collaborators are uniquely positioned and qualified to complete this project.
- Estimate the cost and timeframe for completion (up to \$2M/up to 3 years)

LOIs must be less than 2 pages, single spaced, 12 point Arial font, 1 inch margins. Figures are allowed if they are contained within the 2 page limit.

LOIs will be reviewed by the RMM Leadership Team for eligibility, alignment with the RFP, potential for impact, strength of the research team, and feasibility.

Applicants invited to submit a full proposal will be notified by December 12, 2024 and will be provided with additional information on the full proposal submission and review process at this time.

### **RFP Timeline**

Launch RFP	9/23/24
LOI due	11/8/24
LOI Review	11/8/24-12/11/24
Proposals Invited	12/12/24
Proposals Due	1/17/25
Proposal Review	1/21/25-2/17/25

Decisions	March 2025
Award start	June 2025

## **Teaming**

RMM anticipates that applicants may need to form collaborations with organizations with varied technical expertise to be competitive for this funding opportunity. <u>Applicants are encouraged (but not required)</u> to form teams of two or more MN-based entities to propose transformative <u>projects</u>. To help facilitate connections between prospective applicants, RMM has created a <u>Teaming Form</u>.

The following information is included in this form:

- Organization and contact information
- Describe you or your organization's current research focus area (<200 words).
- Describe what you or your organization are looking for in potential teaming partners (<200 words).</li>
- Which technical areas within the RFA do you or your organization have the capacity to address?

Information submitted in the Teaming Form will be reviewed and added to this <u>RMM Applicant</u> <u>Resources webpage</u> on a continuous basis for prospective applicants to identify potential collaborations.

Program Contact Information regenmedmn@gmail.com