

2026 Regenerative Medicine Minnesota (RMM) RFP

Bringing breakthrough regenerative medicine therapies to Minnesotans

The mission of RMM is to bring breakthrough regenerative medicine therapies to Minnesotans and the rest of the world. In the 2026 RFP, RMM is calling for proposals that advance groundbreaking regenerative medicine therapies and innovations that help them reach patients. RMM seeks projects that build off strengths and fill gaps in regenerative medicine in Minnesota to establish the state as a leader in the industry.

This RFP is designed to solicit two types of projects. Projects that aim to advance:

- 1. Novel regenerative medicine **therapies and products** with a clearly defined target use, indication or disease area towards **clinical application**
- 2. **Innovations** that improve the ability to discover, develop, or deliver regenerative medicine therapies and can be **generalizable beyond a single application**

This funding program may support a variety of projects such as identification, development, testing and real-world application of regenerative medicine innovations including therapeutics, diagnostics, devices, tools, platforms, approaches, methods, processes, models, etc.

Examples of responsive projects from previous RFP cycles include:

- Translational research infrastructure to enable more predictive preclinical testing of regenerative therapies
- Genome engineering consortium to establish quality and safety standards in gene-edited therapies
- Derivation of iPSC lines with less risk for immune rejection for manufacturing clinical cell therapy products in Minnesota
- · Automated microfluidic platform for decentralized CAR-T manufacturing
- Bioreactor for GMP manufacturing of tissue engineered vascular graft for pediatric regeneration
- Mesenchymal stem cell-derived exosome therapy targeting mitochondrial function for recovery of hibernating myocardium
- Cryopreservation of pancreatic islets to achieve diabetes cure through transplantation
- Gene therapy of Hereditary Tyrosinemia Type I using in vivo lentiviral vectors
- Novel cell-free peptide therapeutics for cardiac repair and regeneration

AWARD INFORMATION

The typical maximum award amount and duration is up to \$400,000 total (\$200,000/year) for up to two years. Award amount limits include both direct and indirect costs.

Budget requests beyond the typical maximum amount require additional and strong justification. If the budget request is not sufficient to complete the proposed project or is partial support of a larger project, applicants must demonstrate commitment and availability of funds from another matching or supplemental funding source for project activities that are not supported by the RMM budget request, but are necessary to achieve the goals of the project.

Funds will only be provided for work critical to advance a project. Only request the amount that is needed. The reasonableness of the budget requested will be factored into the funding decision as the program aims to support as many projects as possible. Project costs must be adequately justified and are subject to adjustment prior to the issuance of an award.

See Eligibility and Award Administration sections for more details on expenses, award issuance, and conditions.

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Project

- Projects must focus on regenerative medicine approaches that help the body replace, restore, or regenerate damaged cells, tissues, or organs. Eligible innovations include cell and gene therapies, tissue-engineered products, small molecules/biologics, and combination products, as well as diagnostics, medical devices, tools, platforms, processes, methods, and other enabling technologies that support the discovery, development, manufacturing, or clinical use of regenerative medicine therapies.
- Activities may include, but are not limited to: feasibility and proof-of-concept studies, preclinical and IND/IDE-enabling work, regulatory preparation, clinical trial start-up, diagnostic and biomarker development, therapeutic design and delivery strategies, creation of human-based disease models, Al/machine learning-driven discovery and optimization, development of innovative manufacturing, analytical, or data tools, improved clinical trial design and patient recruitment strategies.

Organization

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

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- If an application includes more than 1 PI, it must be clear who is designated as the primary PI
- 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 during the review process.

Expenses

- Direct and indirect expenses are allowed.
 - Eligible direct costs include all allowable NIH costs. Faculty salary requests should be based on the current NIH cap, if appropriate.
 - Indirect costs should be included at the established NIH-negotiated rate or 10% (in the absence of a federally-negotiated rate). Small businesses should confirm their indirect rate with their financial manager prior to submission as the rate cannot be changed if the award is issued. Indirect calculations for equipment, patient care costs, etc., should be consistent with NIH policies
- Partnerships with other organizations based within Minnesota are allowed.
 Collaborations may include research subcontracts or consulting agreements with laboratories, universities, medical centers, industry partners, etc.
 - Each organization's budget will need to be itemized separately with their institutional indirect rate.
 - RMM funding is administered through the University of Minnesota (UMN).
 Awards to UMN will be issued as a Notice of Grant Award (NOGA) and awards to organizations external to UMN will be issued as a Subaward Contract from UMN.
 - If an award to an external organization involves work being completed at UMN, administratively, a UMN PI will be required to serve as Primary PI and the budget will need to itemize the Subaward Contract to the external organization (not the UMN collaborator).
- Funds should remain and the work should be performed in Minnesota. Exceptions may be made for materials or services not available within the state, and such exceptions should be noted in the budget.
- Work to be completed by vendors should be based on accurate quotes.

APPLICATION PROCESS & CONTENT

Applications must be completed and submitted online through the InfoReady system at https://umnodat.infoready4.com/#freeformCompetitionDetail/1993737

The main components of the application include the following key sections:

- 1. Principal Investigator Information.
- 2. Institution Information (responsible for receiving and disbursing grant funds).
- 3. Application title.
- 4. Enter the total dollar amount requested for the duration of the project (including direct and indirect costs).

- 5. Provide a brief, jargon-free summary of the project that could be understood by a lay audience. Clearly state the overall goal of the project, how it will be accomplished, how it aligns with the goals of the RFP, and the potential for impact. *This may be made publicly available.*
- 6. If this application is a resubmission from previous RMM review cycles, provide a brief statement on how this application addresses the previous reviewers' critiques if applicable.
- 7. Describe the innovation (platform, solution, approach, product, tool, intervention, treatment, etc.) in development. Address the following:
 - What unmet medical need or a critical bottleneck to discovery, development, use, application or commercialization of regenerative medicine in Minnesota does it address?
 - o How does it improve upon current practice and why is it superior to currently available solutions or solutions in development?
 - What is the potential value for the intended patient or user population and why is it likely to be adopted?
- 8. Summarize prior research and preliminary data that supports the proposed scope of work. Include evidence that demonstrates feasibility or supports the approach. Figures may be uploaded as a separate file in the Additional Supporting Information section.
- 9. Detail the specific aims/milestones that will be completed to accomplish the overall goal of the project. For each aim/milestone outline:
 - Overall cost and time to complete.
 - o The work (e.g., tasks, experiments, activities, etc.) that will be performed. Include details on methods, tests, approaches, variables to be measured, etc.
 - Criteria for success, anticipated outcomes and how it will accomplish the overall goal of the project.
 - Potential pitfalls and alternative approaches.
- 10. Upload a visual/figure to show the anticipated timing for aim/milestone completion over the duration of the project. Indicate whether aims are sequential or overlapping.
- 11. List any current or pending funding related to this project. Include source, funding amount, award period and overlap with the proposed project. Indicate whether any funding is intended to be matching funds or supplemental support and if applicable, describe what activities will be completed through these additional funds and how they relate to the goals of the project.
- 12. Describe any plans to pursue additional support (e.g., future funding sources, partnerships, commercialization or other opportunities) to advance the innovation and/or to ensure long-term sustainability.
- 13. Describe how any data, protocols, processes, expertise, guidance or other project outputs will be captured and shared particularly with regenerative medicine organizations (academic institutions, companies) throughout Minnesota.
- 14. Describe the roles, expertise and responsibilities of the PI(s) and key personnel (include only individuals who will play a prominent role on the project).
- 15. If the project involves collaboration with another organization, explain why the collaboration is essential for project success and achieving the goals of the funding,

- which project components each organization will perform and how the collaboration leverages unique strengths of each organization.
- 16. Briefly describe the available facilities and resources, including collaborator or partner facilities and resources that will be utilized for the project.
- 17. Briefly describe any IP relevant to this project, including status (e.g., provisional filed, issued patent), ownership, and how it supports future translation or commercialization.
- 18. Describe the potential impact of the project on the State of Minnesota's health or economy? How might this work benefit patients, communities, public health, or the local innovation ecosystem? How could it establish Minnesota as a leader in Regenerative Medicine?
- 19. References uploaded as a single PDF.
- 20. Budget Information:
 - Include both direct and indirect costs.
 - For each expense category in the budget, provide a justification for what it will be used for and how it relates to the scope of work.
 - If a project includes multiple organizations, each organization will need to provide a separate budget that includes indirect costs calculated using their designated indirect rate.
 - If a project includes the UMN as a collaborator, the subcontract must be set up to go to the external organization (not the UMN). Download and complete the UMN Budget and Justification template and include the external organization subaward total as a line item.
 - Budgets must be provided for each individual year of the award.
- 21. CV/Biosketches/Resume for key personnel (uploaded as a combined PDF).
- 22. Letters of Support Limit letters to 1 page each may be uploaded as a combined PDF.
- 23. Additional supporting information, including figures may be uploaded as one PDF.

REVIEW INFORMATION

Criteria

Significance and impact

- Does the project have the potential to impact: an unmet medical need, a critical bottleneck to discovery and/or development, or use, application or commercialization in regenerative medicine.
- Does the proposed innovation (platform, solution, approach, product, tool, intervention or treatment) in development provide an improvement over current practice and is likely to be adopted by the intended patient or user population?

Team

- Is the proposed team appropriately qualified and have access to all the necessary resources to conduct the proposed activities?
- If the project involves a collaboration, is there sufficient rationale for why the project could not be completed solely by a single entity?

Project Plan

- Is the project appropriately planned and designed to meet the objective of the project and achieve meaningful outcomes?
- Are potential pitfalls identified and alternative approaches presented?
- Is the proposed plan well-constructed with appropriate milestones and timelines?

Feasibility

- Are the proposed aims/milestones/objectives and expected project outcome logical and likely to be achieved within the proposed timeline?
- Is the budget appropriate for the research proposed?

REVIEW PROCESS

<u>Pre-submission Consultation:</u> Prospective applicants are encouraged to contact RMM with questions or to discuss their project's eligibility before applying.

<u>Eligibility Review:</u> RMM program will assess whether the proposed project meets eligibility requirements and intent of the program and specific funding track. Projects that meet eligibility requirements will advance to further review and funding consideration. Projects that do not meet eligibility requirements will be removed from further review and funding consideration.

<u>In-depth Review:</u> The RMM Leadership Team and subject matter expert reviewers will evaluate each application according to the review criteria described above.

<u>Funding decision:</u> Applications that have the highest potential to help achieve the vision and goals of the RMM program (programmatic relevance, portfolio balance, adherence to the intent of the mechanism) and this specific RFP will be selected for funding. Although the evaluations of the subject matter expert reviewers are a key factor, the additional consideration of programmatic fit and portfolio balances means that applications are not funded using an established "pay line" based solely on a numeric scoring system.

Consideration of past RMM award information (if applicable): RMM may consider funding history and performance of applicants and projects previously supported through the RMM program as a part of the review process and funding decisions. This may include, but is not limited to, compliance with the program requirements, achievement of specific milestones, data, and outcomes for a previous or related RMM award involving the same applicants, project, or innovations.

Confidentiality and Data Privacy: RMM's confidentiality and conflict screening policies apply to everyone who will have access to applications or who will participate in any review meeting in which confidential information is discussed. Through administration of the RMM program, the University is committed to protecting the information submitted in your proposal as allowed under state data privacy laws and University policy. Minnesota's Government Data Practices Act contains specific provisions on public grant data and protected trade secret information. In the application, you will be asked to identify specific sections that you believe qualify as your trade secret information (https://mn.gov/admin/data-practices/data/types/tradesecrets/).

AWARD ADMINISTRATION

Issuance of Award

An RMM award is issued through the Sponsored Projects Office at the University of Minnesota, via a Notice of Grant Award (NOGA) and/or Subaward Contract document, which is a formal contract that defines the terms and conditions of an award and documents the commitment of the funds from RMM. RMM reserves the right to modify or establish funded project activities and the associated budget prior to issuance of a NOGA/Subaward Contract, including, when applicable, establishing project milestones, success criteria, and timelines at its sole discretion after consultation with the PI(s) and based on information provided in the application. The first year of funding will be issued at the time of award. Issuance of the second year of funding is contingent upon programmatic review and approval of an annual progress report demonstrating adequate progress as measured by achievement of specific aims or other milestones.

Payments and Reporting

Payments are made on a cost-reimbursement basis. For University of Minnesota awards, this is done automatically up to the award amount. For non-University of Minnesota awardees, invoices must be submitted per the contract document. Projects will be monitored by RMM for progress and adherence to the project milestones, timeline and budget. If at any time RMM determines that a project is not complying with the terms of the program, or is unable to advance the project, a project may be closed and the unused funds returned to RMM.

Awardees will be required to provide periodic written progress and financial reports to RMM. RMM will partner with the grantee to foster the success of the project. Grantees will have ongoing communication with the RMM Program throughout the duration of the award.

Award Conditions

The PI(s) and organization are responsible for being in compliance with federal, state, and institutional research regulations at all times during the funding period, including having active approvals from all regulatory agencies (e.g., Institutional Animal Care and Use Committee). A copy of the approval document(s) must be available upon request.

If the PI of the grant leaves the institution, a request for change in PI may be submitted for consideration. If no request is submitted or the request is denied, unused funds will revert to RMM.

If the PI of the grant is unable to use the funds for the research as proposed in application, funds will revert to RMM.

In keeping with the spirit of the awards, the funds should remain and the work be performed in Minnesota. Exceptions may be made for materials or services not available within the state, and such exceptions should be noted in the budget.

Intellectual Property

Inventions arising from RMM-funded projects are required to be reported to RMM. As with federal funding, RMM permits businesses and nonprofits (including universities) to retain ownership of the inventions, while also giving the Minnesota state government the license to practice the subject invention. In turn, the organizations are expected to file for patent protection

and to ensure commercialization for the benefit of public health. Awardees are responsible for ensuring that any and all intellectual property is properly disclosed to their institution's intellectual property office.

No-Cost Extensions and Change Requests

Awardees are expected to carry out the project activities as outlined in the approved work plan. Any changes to the project scope, timeline, or budget require prior authorization from RMM. Timeline progress on funded projects is of critical importance to RMM. RMM will consider a request for a No-Cost Extension (NCE), submitted at least 90 days before the project end date. Such a request should clearly justify how such an extension will advance the project towards its expected outcome, but awardees should not assume RMM will approve a NCE request.

PROPOSAL SUBMISSION TIMELINE

EVENT	DATE
Applications Due	November 20, 2025, 1:00 p.m. CT
Application Review	December 2025 through February 2026
Awards Announced	March 2026
Earliest Start Date	June 2026

PROGRAM CONTACT INFO

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