

Regenerative Medicine Minnesota Infrastructure Award Program

APPLICATIONS DUE 3/10/2023

Objective of Infrastructure Awards

The objective of the Regenerative Medicine Minnesota (RMM) Infrastructure Award program is to enhance the organization's ability to develop commercializable regenerative medicine-based therapeutics, diagnostics, medical devices, or tools.

Award Information

What is the award amount and duration?

RMM will fund total (direct and indirect) costs of up to \$100,000. Larger budgets may be allowable with adequate justification and approval of RMM. Proposed project periods should be 12 months from the award start date. Longer project periods may be allowed if justified. Project costs must be adequately justified and are subject to adjustment prior to the issuance of an award.

How will the funds be awarded?

An RMM award is a formal contract that defines the terms and conditions of an award and documents the commitment of the funds from RMM. 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.

Costs resulting from a delay or failure to meet milestones will be the sole responsibility of the recipient. Successful applicants will have thoughtfully accounted for foreseeable project risks and developed contingency plans that do not involve additional funding from RMM.

What activities will RMM support?

RMM has special interest in broadening the portfolio of research that can help relieve chronic, genetic, and/or rare disorders that impact patients and health care costs in Minnesota.

RMM funds will support activities under this opportunity including, but not limited to:

- Development of infrastructure, including personnel, equipment, supplies, and/or services required to establish the design, development, testing (including clinical), and manufacturing of a product(s) or provision of a service(s).
- Purchase of non-expendable advanced scientific equipment or instrumentation that contributes to an improved infrastructure for developing commercializable regenerative medicine-based therapeutics, diagnostics, medical devices, or tools.
- Implementing Quality Management System and GMP standards.

RMM resources cannot be used to support the following activities under this opportunity:

- Development of infrastructure or purchase of equipment to support research activities not directly related to commercialization of a regenerative medicine-based therapeutic, diagnostic, medical device, or tool.
- Development of infrastructure or purchase of equipment to be used outside of Minnesota.

Eligibility

What types of projects are eligible for funding?

To be eligible, the proposed project must satisfy the following requirements:

- (1) The applicant must be developing for commercial use a stem cell technology or genetic therapy that significantly improves patient care or addresses a critical bottleneck to the discovery, development, or use of stem cell-based therapies.
- (2) The applicant must be ready to initiate work on the funded project within 90 days of approval.
- (3) Co-funding is not required.

If the project does, however, require funding over and above that which RMM provides, documentation demonstrating the commitment of funds to cover the proposed co-funding amount must be provided at the time of application submission.

- (4) In keeping with the spirit of this program, 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.
- (5) Partnerships with other institutions are allowed.

Collaborations may include research subcontracts or consulting agreements with laboratories, universities, medical centers, industry partners, etc. in the state of Minnesota. If planning to use a portion of requested funds to support a project at another institution, such as the University of Minnesota or Mayo Clinic, then the application must include that institution's indirect cost rate. The submitted budget should reflect this and include separate indirect costs for the primary organization and any other institution with a different indirect rate. Other institution budgets should be shown separately.

- (6) Application must be accurate and complete.

Who can apply for RMM funding?

- (1) Only 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 (the "Entity") must be based, owned ($\geq 50\%$), 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.
- (2) The PI and applicant 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 Review Board). A copy of the approval document(s) must be available upon request.
- (3) Applicant must be in "good standing"

The PI, key personnel named in the application and any business leadership of small businesses must not have been convicted of, or are under investigation for, crimes involving fraud/misappropriation or research misconduct. The performance of applicants previously supported through the RMM program will be taken into account in funding decisions.

Who can serve as the Principal Investigator (PI)?

RMM encourages early stage investigators from diverse backgrounds to apply. To be eligible, the PI must:

- Be an employee of the applicant organization.
- Be authorized by the applicant organization to conduct the research and assume the responsibilities of the PI.

- Applications can have **only one PI**.
- PIs can only hold one RMM award at a time.
- Not currently have another application pending review or approval under this funding opportunity.
- Not currently have another application that is substantially similar or has overlapping activities pending review or approval under any RMM opportunity.

Schedule and Deadlines

Applications Due	March 10, 2023 at 5 pm
Application Review	March through May 2023
Awards Announced	Late May 2023
Earliest Start Date	July 1, 2023

Application Components and Submission

How does one apply?

Applications must be completed and submitted online at <https://umnodat.infoready4.com/#competitionDetail/1893450>

Any prospective PI must create a login in the system to access application materials and apply. A PI may submit only one RMM application in a given review cycle.

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

- 1. Principal Investigator Information** (Responsible Party; there can only be one principal investigator)
- 2. Institution Information** (responsible for receiving and disbursing grant funds)
- 3. Application Preview Page/Abstract:** This section will be utilized by reviewers to prescreen applications and select a subset to move forward to the next stage of the review process.
 - a. Project Summary
 - b. Unmet Infrastructure Need
 - c. Plan for Sustaining Infrastructure Beyond Funding Period
- 4. Resubmission Statement:** If this application is a resubmission from previous RMM review cycles, the applicant will provide a brief statement on how this application addresses the previous reviewers' critiques.
- 5. Entity:** Briefly describe the operational history of the Entity, including its goals, company founders, and key participants. Include a description of the Entity's business structure and revenue history (if any) for the past three years, including any government funding and/or private investment. Explain how the proposed effort/equipment will fit into existing operations (if applicable).
- 6. Commercial Development:** What stem cell technology or genetic therapy that significantly improves patient care or addresses a critical bottleneck to the discovery, development, or use of stem cell-based therapies will be supported through this award? What is novel or transformative about this product or approach compared to the state of the art? Provide a timeline with technical milestones that must be met to get the product or service to market.

7. **Resources and Environment:** Specify the availability and location of significant equipment, instrumentation, computers, and physical facilities supporting the commercial development of the product or service.
8. **New Jobs:** An estimate of the number of new jobs that will be created with this funding (if awarded) and plan for sustaining these jobs after the award has ended.
9. **Intellectual Property:** A brief summary of any intellectual property related to the proposed project, including protection status and ownership/assignment.
10. **References**
11. **Budget Information:** Completed budget form (template provided in online application portal).
 - a. **Direct** costs requested
 - b. **Indirect** costs requested (see: <https://oamp.od.nih.gov/dfas/indirect-cost-branch/indirect-cost-submission/indirect-cost-definition-and-example>. These should be included in the budget at the established NIH-negotiated rate or, in the absence of a federally-negotiated rate, at 10 %.)
 - c. **Total combined** costs requested (must be \leq \$100,000 total)
 - d. Start date requested (between July 1, 2023 and July 30, 2023)
 - e. Length of award (up to 12 months)
12. **Estimates:** Estimate(s) for new equipment (3 sources if possible) and institutional letter of support confirming that the equipment/instrumentation will be installed, housed, and maintained at the Entity.
13. **Biographical Information:** Brief biographical sketch for the PI and each senior personnel (individuals with critical expertise working on the project who are employed at the Entity or at a subaward institution). An NIH biosketch is a suitable template.

Application Review Information

What criteria are used to evaluate the applications?

- 1) *Does the project hold the necessary significance and potential for impact?*
 - a. Will the infrastructure funding support the commercialization of a new stem cell technology or genetic therapy that significantly improves patient care or addresses a critical bottleneck to the discovery, development, or use of stem cell-based therapies?
 - b. Is the approach likely to provide an improvement over the standard of care for the intended patient population?
 - c. To what extent does the proposed treatment address chronic disorders that impact patients and health care costs in Minnesota?
- 2) *Is the rationale sound?*
 - a. Does the proposed effort/equipment fit into existing operations?
 - b. Does the proposed product or new approach supported through this infrastructure demonstrate innovation with technical and/or commercial feasibility?
 - c. Do the commercial development milestones indicate advanced capability or offer progress toward commercialization?
- 3) *Is the project well planned and designed?*
 - a. Will there be space and adequate maintenance for any new equipment or resources?
 - b. Does the PI have adequate experience to ensure that the most critical factors for success are identified and addressed?

- c. Is the stage of commercial development clearly described (e.g., pilot, low-volume versus commercial-grade process validation, qualification, and compliance standards), and is it possible to implement?
- 4) *Is the project feasible?*
- a. Are the intended objectives likely to be achieved within the proposed timeline?
 - b. Does the team have a viable contingency plan to manage risks and delay?

What is the process for evaluating an application?

Pre-submission Consultation

RMM is committed to helping develop promising stem cell-based technologies by partnering with researchers. Therefore, prospective applicants are encouraged to contact RMM with questions or to discuss their project's eligibility before applying.

Eligibility Review

RMM will assess whether the proposed project meets eligibility requirements sought under this program. If RMM determines that an application does not meet the eligibility requirements of the program, RMM will notify the applicant of its decision and, if RMM deems it is appropriate, allow an opportunity to remedy. If RMM deems it inappropriate, or if the applicant does not remedy the error in a timely manner, RMM will remove the application from further review and funding consideration.

Scientific Review

The scientific merit of each application will be assessed by RMM Board members and scientific reviewers from outside Minnesota. Applications will be evaluated according to scientific and technical merit, applying the review criteria described above. The review will be conducted in three stages. In the first stage, RMM program leadership and Board members will conduct a pre-review of applications to identify applications that the Board believes are most responsive to the funding opportunity and hold the most potential for impact. Since the selection process is focused on quickly identifying promising proposals rather than identifying deficiencies in applications, no reviewer comments are collected at this stage.

Selected applications advance to the second stage of review, which involves assignment to specific scientific reviewers outside of Minnesota. Applications are scored according to the review criteria and review comments are collected and discussed by the Application Review Committee, which is made up of the RMM Board and RMM program leadership.

In the final stage of the review, all applications will undergo a review by the Application Review Committee in which applications of high scientific and technical merit will be carefully scrutinized to allocate the funds available to support the award mechanism as wisely as possible. 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) will be selected for funding. Although the evaluations of the scientific reviewers are a key factor, the additional consideration of programmatic intent 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 information from a previously funded and related RMM award as part of its review. This includes but is not limited to achievement of specific milestones, data, and outcomes for a related RMM award or awards. A "related RMM award" includes: (1) an award for which the applicant PI served as the PI, a co-investigator, or otherwise substantially participated in the conduct of the award; (2) an award involving the same research project or product; or (3) an award that includes overlapping team members.

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, milestones (both technical and financial), success criteria, timelines, and budgets prior to issuance of the NOGA/Subaward Contract. RMM reserves the right to review whether an applicant has satisfied the eligibility criteria set forth in this program announcement and, if RMM determines that an applicant has failed to satisfy one or more criteria, to refrain from issuing a NOGA/Subaward Contract.

Payments and Reporting

Payments are made on a cost-reimbursement basis. For University awards, this is done automatically up to the award amount. For non-University 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.

Grantees 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 through access to both internal experts and the ability to enlist the help of external subject matter experts when needed. Grantees will have ongoing communication with the RMM Program Manager throughout the duration of the award.

Award Conditions

The PI is 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.

No-Cost Extensions

Timeline progress on funded projects is of critical importance to RMM. Therefore, RMM will consider a No-Cost Extension (NCE) request, submitted at least 30 days before the project end date. Such request should properly justify how such an extension will advance the project towards its expected outcome, but Grantees should not assume RMM will approve a NCE request.

Contacts

For questions not answered in the RFP, email RegenMedMN@gmail.com.

