BIOBUSINESS DEVELOPMENT Grant Applications DUE 2/24/2020

Who can apply?

Applicant should be a small business (the "Entity") that is based, owned (≥50%), and operating in the state of Minnesota. For this definition, 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.

What is being funded?

Projects to develop Minnesota businesses and technologies that deliver regenerative medicine products, devices, and services. This can include:

- Development of infrastructure, including personnel, equipment, supplies, and/or services required to establish the design, development, testing (preclinical or clinical), and manufacturing of a product(s) or provision of a service(s).
- Development of commercial products and services.
- Purchase of non-expendable advanced scientific equipment or instrumentation that contributes to an improved infrastructure for regenerative medicine.
- Device testing to support PMA or NDA for FDA approval or approval from other notified bodies.
- Implementing Quality Management System & GMP standards.

Are there restrictions on the awards? YES

- Funding must remain primarily in Minnesota unless used to purchase equipment (then equipment must remain and be used in Minnesota).

What criteria are used to evaluate the applications? SEE BELOW

1. Does this project fill a demonstrable need? How?
2. Does this project demonstrate innovation with technical and/or commercial feasibility?
3. Is this project clearly explained by stage (e.g., pilot, low-volume versus commercial-grade process validation, qualification and compliance standards), and is it possible to implement?
4. Does the application describe applicable regulatory and industry standards that demonstrate that its underlying technology, processes or systems comply with industry standards (e.g., ISO, FDA, MDR)?
5. Do this project's milestones indicate advanced capability or offer progress toward commercialization—i.e., does the project represent a pathway to scalability of production and maturation of development, testing, and/or manufacturing processes to support potential therapeutic use?

6. Does this project have adequate support and resources? Is the application supported by a clear project plan with timelines, resources, and funding needed for each stage and the ability to meet those resource and funding requirements? If applicable, is there space and maintenance for any equipment?
7. Does the Project Director have adequate experience to ensure that the most critical factors for success are identified and addressed?
8. Are 1:1 matching funds available?
9. What does this project contribute to regenerative medicine (and patients) in Minnesota?

What else should applicants know? THESE THINGS ARE IMPORTANT

- Maximum request (including both direct and indirect costs unless for equipment) is $100,000 for one year.
- Awards must be made to a Minnesota-registered business entity and cannot be made to an individual.
- Applications can have only one Project Director. Previous awardees can reapply.
- The Project Director is responsible for obtaining all necessary approvals from regulatory agencies (FDA, IRB, etc.). If needed, a copy of the approval document(s) will be required prior to the release of funding.
- The Project Director must be legally employed by the entity at the time of the award and for the entire duration of the project. The Project Director must not have any conditions that prevent him/her from meeting this legal employment requirement (including residency status or other policy).
- All funded projects are subject to an audit; therefore, it is strongly advised that awardees retain associated receipts and maintain detailed records of expenses incurred.
- For questions not answered in the RFP, see Frequently Asked Questions. If you can't find the answer there, email RegenMedMN@gmail.com.
- Awards will be announced on April 6, 2020.

Can applicants partner with other organizations? YES, WITH LIMITS

A minimum of two-thirds of the research (as measured by the budget) must be performed by the Entity, but collaborations may include research subcontracts or consulting agreements with regional laboratories, universities, medical centers, etc.

Who retains intellectual property rights? THE ENTITY, WITH LIMITS

Inventions arising from RMM-funded research 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 upon licensing for the benefit of public health.

How do I apply? VIA THE WEBSITE

The application form can be found online at Apply for a Grant. **The application questions are listed below.** Before starting the online application form, please have the answers and a single pdf file of the final proposal ready.

1. ***Applicant Information*** *(Project Director and Responsible Party)*
   a. Applicant's name
   b. Applicant's position at Entity
   c. Applicant's email
   d. Applicant's phone number
   e. Applicant's mailing address
2. ***Entity Information*** *(responsible for receiving and disbursing grant funds)*
   f. Entity Name
   g. County or counties (Blue Earth, Hennepin, etc.) in which Entity is located.
   h. Financial Contact Name (usually an accountant)
   i. Financial Contact Email
   j. Financial Contact Phone number
3. ***Grant Information***
   a. Descriptive title of proposed activity
   b. Names of key personnel on project
   c. Goals (About three sentences describing the goals of the project in lay language).
4. ***Budget Information***
   a. **Direct** costs requested
   b. **Indirect** costs requested (should be included in the budget at the established NIH-negotiated rate or, in the absence of a federally-negotiated rate, at 10%). Indirect costs are not needed for equipment purchases.
   c. **Total combined costs** requested (direct + indirect must be ≤$100,000).
   d. Start date requested (between May 4, 2020, and August 31, 2020)
5. ***Proposal***

Proposals must use 1" margins on all sides, 12 pt Arial font, and a minimum of single line spacing. Please include Program Director name and the page number in footer. Please use the format below to make the grants easier to review and compare. Please do not exceed suggested page length of each section. Missing information may negatively impact review. Upload as a single pdf file in the following order:*

1 page **Entity**	• Briefly describe the operational history of the Entity, including its goals, company founders, and key participants. • Describe the Entity's business structure. • Describe the 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).
1-2 pages **Project summary***	• Summarize the project: what will be done, by whom, how, where, and when. • What is the main project innovation? • Who is the expected customer for this innovation? • What customer needs will be addressed? • What competitors exist? • What is original, novel, or transformative about this project compared to the state of the art? • How does this project relate to regenerative medicine?
1-2 pages **Project details**	• Describe the project in sufficient technical depth for a knowledgeable reviewer to understand why it is innovative and how it benefits the targeted applications. • If applicable, describe scientific data related to the project, including preliminary studies, proof-of-concept data, and images of prototypes. • Describe the business economics and market drivers in the target industry. • Describe the key technical challenges and risks in bringing this innovation to market. Which of these will be the focus of this project. • Describe the status of the intellectual property associated with this project (if any) and the plans to protect it. • Describe the source of the matching funds available. • Will this proposal create new jobs?
1 page **Technical/Business Plan**	• Describe critical technical milestones that must be met to get the product or service to market. • Include a timeline that includes objectives and what experiments, computations, etc. are planned to reach those objectives. • Outline any validation and verification plans for processes and protocols used to develop or manufacture products. • Identify obstacles to success that might occur and contingency plans to surmount them. • Describe the roles of the Project Director and key personnel and their expected contributions. • How will the entity proceed after the RMM grant has been spent? Include plans for future research, commercialization, additional investment sources, etc.

1 page **Resources**	• Specify the availability and location of significant equipment, instrumentation, computers, and physical facilities necessary to complete the portion of the research that is to be carried out by the proposing firm. • If the equipment, instrumentation, computers, and facilities for this research are not the property (owned or leased) of the proposing firm, include a statement signed by the owner or lessor which affirms the availability of these facilities for use in the proposed research, reasonable lease or rental costs for their use, and any other associated costs.
1-2 pages **Budget**	Detailed documentation of all budget line items is required and must be listed on the Budget Justification page (see budget template on page 6 of RFP; available for download online).
As needed **Biographical info**	Brief (≤5 pages each) biographical sketch for Project Director 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.
As needed **Letters of support**	Include institutional letter(s) of support confirming that the Entity has initiated dialogue with potential customers, strategic partners, or investors for the proposed innovation and that a legitimate business opportunity may exist should the proposed technology/service prove feasibility. Letter(s) should be on institution/business letterhead and provide contact information for the signatory stakeholder.
If applicable **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.
If applicable **References**	Maximum of 20 references

**Important Note:*

RMM is state funded and subject to the Freedom of Information Act (FOIA).

After awards are made, all proposals will be available to the public on request, except for information or material that are evaluated as being trade secrets and therefore exempt from disclosure under law. Please highlight information that you feel should be withheld from public disclosure to the extent permitted by Minnesota law, including the FOIA. Without assuming any liability for inadvertent disclosure, RMM will seek to limit disclosure of such information to its employees and to outside reviewers except when necessary for merit review of the proposal, or as otherwise authorized by law.*

Add lines as needed, limit to two pages

Budget Template **Project Director Name**

Personnel	**Year 1**		**Description**
Name	**Effort**	**Salary & Fringe**	
Other Direct Costs			
Supplies			
Services			
Travel			
Total Direct Costs			
Indirect Costs **(not applicable for equipment purchase)**			
TOTAL COSTS			

Give justifications for budget items:

Describe commitment of matching funds: