BIOBUSINESS Grant Applications DUE 2/12/2018

Who can apply?

Small businesses (the Entity) that are 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).

What is being funded?

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

- Development of commercial products and services.
- 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).
- Implementing Quality Management System & GMP standards.

What criteria are used to evaluate the applications?

1. Does this project demonstrate innovation with technical and/or commercial feasibility?
2. 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?
3. 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)?
4. 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?
5. 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?
6. Does the Project Director have adequate experience to ensure that the most critical factors for success are identified and addressed?
7. Are 1:1 matching funds available?
8. What does this project contribute to regenerative medicine (and patients) in Minnesota?

What else should applicants know?

- Maximum request is $100,000.
- Grants are for one year.
- Applications can have only one Project Director. Previous awardees can reapply.
- Awards must be made to a Minnesota-registered business entity and cannot be made to an individual.
- 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.
- Awards will be announced on April 10, 2018.

Partnering

- 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.

Intellectual Property

- 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.

Proposals as Public Data

Per Minn. Stat. §13.599:

- Names and addresses of grant applicants will be public data once proposal responses are opened.
- All remaining data in proposal responses (except trade secret data as defined and classified in §13.37) will be public data after the evaluation process is completed (for the purposes of this grant, when all grant agreements have been fully executed).

How do I apply? (Two steps)

STEP 1: Begin an application by answering the following questions via the Biobusiness grant application form found online at http://www.regenmedmn.org/apply-grant

1. ***Applicant Information*** *(Project Director and Responsible Party)*
   a. Project Director Name
   b. Position at Entity
   c. Email
   d. Phone number
   e. Mailing address
2. ***Entity Information*** *(responsible for receiving and disbursing grant funds)*
   a. Entity Name
   b. County (in which located)
   c. Financial Contact Name (usually an accountant)
   d. Financial Contact Email
   e. Financial Contact Phone number
3. ***Grant Information***
   a. Descriptive title of proposed activity
   b. Direct costs requested
   c. 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%).
   d. Total costs requested (combined direct and indirect costs)
   e. Start date requested (between May 1, 2018, and September 1, 2018)
   f. Names of key personnel on project
   g. Goals (About three sentences describing the goals of the project in lay language).

STEP 2: Email grant proposal to RegenMedMN@gmail.com

Proposals must use 1" margins on all sides, 12 pt Arial font, and *a minimum of single line spacing. Do not use URLs. Include Project Director name and page number in footer.*

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

A proposal that results in an RMM award will be available to the public on request, except for privileged information or material that is personal, proprietary or otherwise exempt from disclosure under law. Please highlight information that you feel should be withheld from public disclosure to the extent permitted by law, including the Freedom of Information Act. Without assuming any liability for inadvertent disclosure, RMM will seek

to limit disclosure of such information to its employees and to outside reviewers when necessary for merit review of the proposal, or as otherwise authorized by law.

A proposal that does not result in an RMM grant will be retained for three years, but will be released to the public only with the consent of the proposer or to the extent required by law.

Submit as a single pdf file in the following order:

Page 1	The 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 will fit into existing operations (if applicable).
Page 2	Project Summary (Elevator Pitch) *Do not include proprietary information* • Briefly describe 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?
Page 3	Detailed Project Description • 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?
Page 4	Technical and 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.
Page 5	Facilities, Equipment, and Other 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.
Page 6	Detailed documentation of all budget line items is required and must be listed on the Budget Justification page (see page 6 for optional format).
As needed	Biographical Sketch of no more than two pages for the Project Director and senior personnel (individuals with critical expertise working on the project who are employed at the Entity or at a subaward institution). Information should include (in reverse chronological order): • Education: institution, location, major/concentration, degree, and year. • Relevant Experience: Include technical and/or commercial experience. • Track Record: Include patents, publications, etc. Up to 5 may be listed that are related to the proposed work and up to 5 that are significant but not related to the proposed work.
As needed	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	Estimate(s)
If applicable	Bibliography

Add lines as needed, limit to two pages

Budget and SubawardTemplate

Personnel	**Year 1**		**Description**
Name	**Effort**	**Salary & Fringe**	
Other Direct Costs			
Supplies			
Services			
Travel			
Total Direct Costs			
Indirect Costs (% by entity)			
TOTAL COSTS			

Give justifications for budget items:

Describe commitment of matching funds: