CLINICAL TRIAL Grant Applications DUE 10/16/2017

Who can apply?

Applicants should be performing scientific and/or medical research in the state of Minnesota. Principal Investigators can be at any professional rank. Like the NIH, RMM believes that early stage investigators bring fresh ideas to existing research problems and help pioneer new areas of investigation. RMM will make funding decisions that ensure the success rates for early stage investigators are comparable to the success rates on similar applications from established investigators.

What kind of research is being funded?

Funding is available for planned or active clinical trials that develop ways to replace, restore, or regenerate damaged or malfunctioning cells, tissues, and organs to help people return to better health. The clinical research must take place in the state of Minnesota. Funding is available to conduct and support a Phase 1, Phase 2, or Phase 3 clinical trial under a single IND, including the ability to use relevant products (Chemistry, Manufacturing & Controls [CMC] for both the biologic agent and/or device to deliver such an agent, as appropriate) to supply the proposed clinical trial. Additional information on manufacturing clearances needed to support an IND must also be considered and justified in devising a clinical trial plan.

RMM has special interest in broadening the portfolio of research that can help relieve chronic disorders that strongly impact patients and health care costs in Minnesota, for example, kidney disease requiring dialysis, chronic obstructive pulmonary disease (COPD), and diabetic and other non-healing wounds (see *Chronic Conditions in Minnesota*: http://www.health.state.mn.us/divs/hpsc/hep/publications/costs/20160127_chronicconditions.pdf).

What criteria are used to evaluate the applications?

1) Significance and potential of clinical trial for impact.
    a. Does the proposed therapy use regenerative medicine to help patients return to better health?
    b. Does the proposed therapy fulfill an unmet medical need?
    c. Is the proposed therapy likely to improve standard of care for the intended patient group?
2) Sound scientific and/or clinical basis for research.
    a. Is the proposed therapy supported by the body of available data?
    b. Is there a report of prior investigation(s) to support the proposal?
    c. Is the project well planned and designed?
    d. Is the timeline appropriate and feasible?
3) The adequacy of the resources to successfully conduct the proposed research.
    a. Does the proposed team have appropriate qualifications, experience, and number of staff?
        i. Trial management

   ii. Data analysis and management
   iii. Regulatory compliance
b. Does the team have the facilities and institutional support in place to conduct the proposed research activities?
c. Is the budget realistic for the scope of the proposed project?
d. Does the team have a viable contingency plan to manage financial risks, and other risks and delays?
e. Does the recruitment strategy address ways to recruit from the broad diversity of Minnesota's population?

What else should applicants know?

- For questions, please go to our website's Frequently Asked Questions page. If you can't find the answer there, email: RegenMedMN@gmail.com
- Maximum request is $250,000 per year.
- Maximum grant period is two years, with the second year of funding contingent on demonstrated adequate progress in year one.
- Applications can have only one principal investigator (PI).
- PIs can only hold one RMM research grant at a time.
- The PI is responsible for obtaining approvals from all regulatory agencies (e.g., Institutional Review Board). A copy of the approval document(s) will be required prior to the release of funding.
- Awards will be announced January 8, 2018.

How do I apply? (Two steps)

STEP 1: Begin an application by answering the following questions via the Clinical Trial grant application form found online at www.RegenMedMN.org, "Apply for a Grant"

1. ***Applicant Information*** *(Principal Investigator and Responsible Party)*
   a. Investigator name
   b. Degree(s)
   c. Based on the NIH guidelines, are you an Early Stage Investigator? (see https://grants.nih.gov/grants/new_investigators/investigator_policies_faqs.htm)
   d. Position at institution
   e. Email
   f. Phone number
   g. Mailing address
2. ***Institution Information*** *(responsible for receiving and disbursing grant funds)*
   a. Institution 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. Title
b. Scientific subject of proposal
c. Trial Phase: I, II, or III
d. Identifying Number (IND or protocol number if applicable)
e. Direct costs requested
f. 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%)
g. Total costs requested (*combined direct and indirect costs* must be ≤$250,000/year)
h. Start date requested (between March 1, 2018 and May 30, 2018)
i. Length of grant (one year or two)
j. List of Co-investigators
k. Number of Collaborators
l. Does this proposal contain privileged information or material that is personal, proprietary or otherwise exempt from disclosure under law?
m. If awarded, how many new jobs will be created by the grant project?
n. Goals (3-5 sentences describing the goals of the project in lay language).

STEP 2: Email written research proposal to RegenMedMN@gmail.com

Proposals must use 1" margins on all sides, 12 pt Arial font, and a minimum of single line spacing. Please include PI name and page number in footer. Please do not include any letters of support.

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 Abstract	Introduction and overview: include the problem(s) to be investigated and how the aims, if achieved, are of significance to regenerative medicine and impact the targeted patient population. State the hypothesis being tested.
Pages 2-9 Research Plan	1) Scientific and/or clinical rationale for use of the proposed therapy in the target disease or injury. 2) Available preclinical and/or clinical safety and efficacy data that support moving forward with the proposed project at this stage. 3) Statistical methods and statistical analysis plan for trial. 4) Sample size and justification (power calculation) of sample size. 5) Study design and endpoints/outcomes (primary and secondary objectives. 6) Recruitment strategy 7) Clinical protocol synopsis (if applicable) 8) Team Organization: structure, leadership, and communications plan, including clinical trial management, clinical data management and regulatory compliance. 9) Contingency Plan: description of potential risks with costs and mitigation strategies, as well as a financial contingency plan outlining viable funding sources in the event that costs exceed the amount of the award.
Page 10	References
Page 11	Description of resources and environment for project.
Page 12	Budget outline, please use format given on page 5
As needed	• Statement describing the status of scientific advisory and/or protocol approval from investigator's institution (SAB, IRB, etc.). • Relevant FDA correspondence.
As needed	Current NIH-format biosketch for each investigator.

Add lines as needed, limit to one page

Budget Template **PI Name**

Personnel	**Year 1**		**Year 2**	
Name	**Effort**	**Salary & Fringe**	**Effort**	**Salary & Fringe**
Other Direct Costs				
Supplies				
Services				
Travel				
Patient Costs				
Total Direct Costs				
Indirect Costs (% by institution)				
TOTAL COSTS				

Justifications for budget items:

Explanation of overlap (if applicable):