CLINICAL TRIAL Grant Applications DUE 10/25/2016

Who can apply?

Applicants (investigator, cooperative group, institution, network) must be qualified and capable of conducting the proposed study in compliance with the U.S. Food & Drug Administration's Good Clinical Practices and applicable Institutional Ethics Committees/Review Boards. The Principal Investigator (PI), who assumes sponsorship of the study, must comply with all applicable legal and regulatory requirements and must not be subject to any legal or regulatory restrictions or sanctions. Applicants should be performing scientific and/or medical research in the state of Minnesota and must be at a rank of Assistant Professor **or** must have received a doctoral degree (MD, PhD, DO, or equivalent) within the past 12 years (June 1, 2004 or later) in a field pertinent to the award. If the applicant has more than one relevant doctoral degree, the date the most recent doctoral degree was obtained will be used to determine eligibility. *Exceptions to the June 1, 2004 cutoff may be requested for investigators who had to spend time away from research related to medical concerns, disability, family care responsibilities, natural disasters, active duty military service, clinical training after the doctoral degree, or comparable factors. The NIH FAQs regarding these exceptions for Early Stage Investigators offer a guideline for the kinds of exceptions RMM will accept. Requests may be submitted with an application or, for prior approval, sent to regenmedmn@gmail.com.*

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.

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?

- 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. A copy of the approval document(s) will be required prior to the release of funding.
- Awards will be announced January 30, 2017.

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. Name
   b. Degree(s)
   c. Date most recent pertinent doctoral degree was awarded (must be after 6/1/2004)
   d. Position at Institution
   e. Email
   f. Phone number
   g. Mailing address
2. ***Institution Information*** *(responsible for receiving and disbursing grant funds)*
   a. 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. Trial Phase: I, II, or III
   c. Identifying Number (if any; IND or protocol number)
   d. Direct costs requested
   e. 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%)
   f. Total costs requested (combined direct and indirect costs)
   g. Start Date requested (between March 1, 2017 and May 30, 2017)
   h. Length of Grant (one year or two)
   i. List of Co-investigators
   j. Number of Collaborators
   k. Goals (three sentences or less 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.* ***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	Five-page NIH-format biosketch for each investigator.

Questions?

Please go to our website's Frequently Asked Questions or email: RegenMedMN@gmail.com.

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):