Clinical Trial Grant Applications DUE 11/17/2021

Who can apply?

Applicants should be performing scientific and/or medical research in the state of Minnesota. Principal Investigators can be of any professional rank. RMM encourages early stage investigators from diverse backgrounds to apply.

What kind of clinical trial is being funded?

Funding is available for clinical trials that test regenerative therapeutics in patients to help people return to better health. The clinical trial must take place in the state of Minnesota. In the case of multi-site trials, RMM funding can only apply to Minnesota sites. Funding is available to conduct and support FDA approved clinical trials under a single IND or IDE, including the manufacture and release of clinical grade products and prototype devices required to run the proposed clinical trial. Additional information on the manufacturing clearances needed must also be provided.

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.

Are there conditions on the awards? YES

- 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 Review Board and Use Committee). A copy of the approval document(s) must be available upon request.
- If the principal investigator of the grant leaves the institution where the award is funded, unused funds will revert to RMM.
- If the principal investigator 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 should be noted in the budget.

What criteria are used to evaluate the applications? PLEASE SEE BELOW

NIH Principles of Rigor and Reproducibility

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** for:
        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? THESE THINGS ARE IMPORTANT

- Maximum request (including both direct and indirect costs) 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.
- Avoid overlap with other proposals.
- 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 in January 2022.

How do I apply? VIA THE WEBSITE: www.regenmedmn.org

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. ***Principal Investigator Information*** *(Responsible Party; there can only be one principal investigator)*
   a. Investigator's name
   b. Investigator's degree(s)
   c. Based on the NIH guidelines, is the Investigator an Early Stage Investigator? (see https://grants.nih.gov/grants/new_investigators/investigator_policies_faqs.htm)
   d. Investigator's position at institution
   e. Investigator's email
   f. Investigator's phone number
   g. Investigator's mailing address
2. ***Institution Information*** *(responsible for receiving and disbursing grant funds)*
   a. Institution name
   b. County (Anoka, White Earth, etc.) in which institution is located
   c. Financial Contact's name (usually an accountant)
   d. Financial Contact's email
   e. Financial Contact's phone number
3. ***Grant Information***
   a. Title
   b. Scientific subject of proposal (e.g., kidney disease, cartilage replacement, etc.)
   c. Trial Phase: I, II, or III
   d. Identifying Number (IND or protocol number if applicable)
   e. Names of Co-investigators (please separate names with commas, not returns)
   f. Names of Collaborators (please separate names with commas, not returns)
   g. Does this proposal contain trade secret* information exempt from disclosure under law?
   h. If awarded, how many new jobs will be created by the grant project? (can be zero)
   i. Goals (3-5 sentences describing the goals of the project in lay language).
4. ***Budget Information***
   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 ≤ $250,000/year, $500,000 total)
   d. Start date requested (between March 1, 2022 and May 30, 2022)
   e. Length of grant (one year or two)

5. *Scientific Proposal*

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. Please use the format below to make the grants easier to review and compare. Missing information may negatively impact review. Upload 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 2-8 **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 9 **References**	Maximum of 20 references.
Page 10 **Resources**	Description of resources and environment available for the project.
Page 11 **Budget**	Budget outline, please use format given on page 5, Word template available online.
As needed **Approval Status**	• Statement describing the status of scientific advisory and/or protocol approval from investigator's institution (SAB, IRB, etc.). • Relevant FDA correspondence.
As needed **Biosketches**	Current NIH-format biosketch for each investigator (max 5 pages each).

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 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):