

National Center of Neuromodulation for Rehabilitation (NC NM4R) at the Medical University of South Carolina

Request for Application for Pilot Project Grants and Submission Guidelines 2024-2025 Funding Cycle

Key Dates

RFA Release Date: August 1, 2023

Letter of Intent (LOI) Due: September 1, 2023 (11:59 pm EDT)

Invitation to Submit Sent By: September 11, 2023

Send Budget for Review: October 16, 2023

Application Due Date: November 3, 2022 (5:00 pm EDT)

Anticipated Award Date: May 1, 2024

Overview: The National Center of Neuromodulation for Rehabilitation (NM4R) at the Medical University of South Carolina (http://musc.edu/ncnm4r) is pleased to announce that it will fund four pilot grants for up to \$37,500 for a 12-month period. Submission of a Letter of Intent (LOI) is required. Only individuals who receive an Invitation to Submit may submit a full proposal for consideration.

Through these Pilot Grants, NC NM4R will provide short-term funding for studies designed to promote translational or clinical rehabilitation neuroscience research that uses neuromodulatory techniques and methodologies, or which may increase understanding of the underlying neurobiological mechanisms of NM4R. Projects must include a clear neurobiological rational for the methods and techniques used in the proposal.

This year we will give special consideration to projects that explore personalization of neuromodulation through measurement of biological variables.

The goal of the Pilot Grants is to support projects that will generate critical data used to develop fundable and sustainable research lines through competitive NIH research grant applications or through similar extramural funding mechanisms.

Objective: The principal goal of the NC NM4R Pilot Studies Program is to provide short-term funding for scientifically meritorious, new, and innovative projects through a competitive program with open solicitation and peer review. The program will focus on development of junior faculty by expanding their areas of biomedical research and enabling mid-level or senior

faculty to explore an area that is distinct from their currently-funded research, all using neuromodulatory methodologies supported by the NC NM4R.

Eligibility: The Principal Investigator should have a full-time faculty appointment and a doctoral

degree. The PI must be eligible to submit an NIH R01 application or equivalent at their institution. The PI should not have other resources adequate for pilot studies in this area. A strong preference is given to applicants that have not been funded previously through

this program.

Letter of The prospective applicant is **required** to submit an online Letter of Intent (LOI).

Intent: https://chp.musc.edu/research/nc-nm4r/funding-opportunities/pilot-grants/letter-of-intent.

LOIs will be reviewed and only those applicants that receive an Invitation to Submit full

applications are asked to submit a preliminary Budget and full proposal.

Budget: Investigator(s) are required to submit preliminary budget to Cynthia Gittinger at

gittinck@musc.edu by October 16, 2023. All preliminary budgets must be reviewed and

approved for accuracy and to guarantee budgetary compliance.

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Key Elements of the NC NM4R Pilot Project Program

Pilot Grants will support basic, translational, or clinical rehabilitation neuroscience research in new directions or innovative applications of neuromodulatory methods/technologies. They are designed to promote the growth of rehabilitation neuroscience that utilizes neuromodulatory techniques and methodologies, by providing NC NM4R research resources and expertise towards the development of potential new projects that are fundable and sustainable through extramural funding mechanisms. Each project should include a scientific rationale for the proposed neuromodulatory methods/technologies and their neurobiological mechanisms of action. The pilot project program is not designed to provide ongoing support for a long-term project or to provide supplemental support to ongoing funded research projects. Please note that pilot projects that are selected for potential funding will be required to complete necessary protocols as required by NIH to initiate the release of funds. This will include 1) studies involving animals will have to have institutional IACUC protocols accepted and approved, and 2) studies involving human participants will have to follow the updated Human Subjects guidelines, including Clinical Trial registration and reporting in clinicaltrials.gov. This information will be requested at the time of Just in Time notification.

Pilot Projects Must Aim To:

 Address an important question in basic, translational, and/or clinical research that impacts recovery from stroke, spinal cord injury, or other neurological damage.

- Generate critical preliminary data to support submission of a competitive extramural grant application that will directly utilize a neuromodulatory method or technology.
- Focus on a research or technological or methodological area that is distinct from investigators other research or expands the areas of biomedical rehabilitation research using neuromodulatory methodologies and technologies supported by the NC NM4R.
- Develop or acquire a new method or technology that will directly enhance, advance, or replace one or more currently available neuromodulatory methods or technologies supported by NC NM4R.
- Provide greater understanding of the neurobiological mechanisms underlying neuromdulatory methods/techniques.

Additional Information

Review the application process and review criteria below for more information.

Application Process

Proposal submission will involve two rounds: an initial Letter of Intent (LOI) followed by an invitation to submit a full proposal. The invitation will include the link to submit your full application as described below.

Round I: Letter of Intent (LOI) Due September 1, 2023

A Letter of Intent is required and will be used to determine which projects will be invited for full consideration of funding. Prospective applicants are required to submit a LOI (https://chp.musc.edu/research/nc-nm4r/funding-opportunities/pilot-grants/letter-of-intent) that includes the following information:

- Descriptive title of proposed research.
- Name, title, email address, and telephone number of the PI.
- Three to five descriptive keywords
- Complete listing of the investigating team with each individual's academic title, primary department, institution, and proposed role on the project.
- Hypotheses and objective of the project (max 500 words)
- Overview of the study design/methods (max 500 words)
- Relevance to the scientific field of Neuromodulation for Rehabilitation Research (max 100 words)
- Is the work proposed utilizing a new technique, technology, or area of work for the PI? If so, please provide a brief statement on the inclusion of mentors, collaborators, and/or consultants the PI will work with for successful completion of the proposed studies. (max 200 words)

For Resubmissions, additional information is required: If this LOI is a first resubmission of a previously reviewed but not funded full grant application, a response to reviewers' comments needs to be included (max 500 words).

Round 2: Pilot Grant Full Proposal Due November 3, 2023

*Note: Only use Word documents and then save and upload as PDFs (fillable PDFs will not work). *

1. Project Summary and Relevance

- 30 lines of text for Project Summary, Arial font size 11, at least 0.5-inch margins, convert the Word document to PDF.
- The Project Summary should serve as a succinct and accurate description of the proposed work when separated from the application. State the application's broad, long-term objectives and specific aims, relating them to those of the NC NM4R. Describe concisely the research design and methods for achieving the stated goals. This section should be informative to others working in the same or related fields and understandable to a scientifically or technically literate reader. Using no more than two or three sentences, describe the Relevance of this research to public health. The Relevance statement should be succinct and written using plain language that can be understood by a general, lay audience.

2. Research Plan

- o 6-page limit (1 page for Specific Aims, 3 pages for Research Strategy and 2 pages for Additional Review Criteria), font size 11, ≤ 15 characters per linear inch, ≤ 6 lines per vertical inch. We recommend but do not require the following font types: Arial, Georgia, Helvetica, and Palatino Linotype.
- at least 0.5-inch margins. Revised applications must include a 1-page Introduction at the beginning of the Research Plan (see **Resubmission of an Application** section for further details). All sections of the Research Plan and any Letters of Support should be combined and converted into a single PDF.
- The **Specific Aims** should state concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved. List succinctly the specific objectives of the research proposal, e.g., to test a stated hypothesis, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop a new technology. **The Specific Aims section must be limited to one page**.
- The Research Strategy section should describe how the data will be analyzed and used to make inferences regarding the Specific Aims. The Research Strategy section must be limited to three pages.
 - The Research Strategy should follow the standard NIH format which includes Significance, Innovation, and Approach. Further information can be found in <u>Section G.400</u> of General Application Guide for NIH, and in Instructions and Form Files for PHS 398
 - The research proposal should be informative enough for reviewers to understand the proposed research without any supporting documents.
 - Applicants should include all the required details based on the grant category and its review criteria within the proposal without referring to additional pages/documents.
 - Include a scientific rational for the proposed neuromodulatory methods/technologies and how and why they will be used in your study. Describe the known or neurobiological mechanisms of action of the neuromodulatory methods/technologies that will be utilized and how these studies may further the fields understanding.
- The Additional Review Criteria section should include a response to the five points listed below. The Additional Review Criteria section must be limited to a maximum of 2 pages, and should address all the following:
 - State if the work proposed utilizing a new technique, technology, or area of work for the Pl.
 - Provide information on potential mentors, collaborators, and consultants the PI would work with for successful completion of the proposed studies.
 - State how you plan to use the NC NM4R methods and/or technologies in this proposal.

- State how you plan to secure future extramural funding and how you plan to utilize the NC NM4R methods and/or technologies in future grant proposals. Please be sure to state funding agency, mechanism, and timeline.
- Each proposal must include a realistic timeline for completing the proposed project, preparing, and submitting at least one manuscript to an appropriate professional journal, and preparing and submitting a competitive grant application by or shortly after the end of the award period.
- o A **Biostatistical Justification** of sample size should be included for all studies.
 - The Biostatistical Justification should be placed at the end of the Research Strategy and is not included in the page limit.
- The Literature Cited section should be placed at the end of the Research Strategy and is not included in the page limit.
- Support Letter(s) should be placed at the end of the Research Strategy and not included in the page limit.

3. Address Compliance Issues (not included in the page limit)

- Human studies must include a Human Subjects Protection Plan section.
- Animal studies must include a Vertebrate Animals section.
- Assurance of IACUC, hSCRO and/or IRB approval and of completion of NIH-mandated responsible conduct or research training, where indicated, must be furnished after Award notice and before funds can be released.

4. Budget Justification and Statement of Intent

- Please Note: Institutions must agree to an 8% indirect cost rate. This is approved by NIH for
 this Pilot Program. It will be at the discretion of the receiving institution to execute the option to
 waive F&A costs so that full funding of \$37,500 can be applied towards the pilot project or direct
 costs will be \$34,722 with F&A of \$2,778.
- Statement of Intent to Enter into a Consortium Agreement: Applicants external to the Medical University of South Carolina must submit a Statement of Intent to Enter into a Consortium Agreement along with their budget. The Statement of Intent must be signed by the Institution's Signing Official and should include information contained on the Statement of Intent template which follows this RFA.
- For the budget, please use PHS 398 Form Page 4: Detailed Budget for Initial Budget Period in MS Word Version (1 page) at http://grants.nih.gov/grants/funding/phs398/phs398.html. Use continuation pages as needed for the budget justification. The NC NM4R Executive Committee reserves the right to reduce requested award amounts.
- **Personnel Support:** Salary and fringe benefits must be requested to cover the Pl's effort to conduct the proposed research. Additional salary support may cover faculty, staff, and trainees.
- Non-Personnel Research Expenses: Allowable expenses include research supplies, animal
 purchase and per diem, institutional core service fees, research subject compensation and
 transportation, and data analysis/statistical support. All expenses must be directly related to the
 proposed research.

- Unallowable Costs: General office supplies, computers and laptops, capital equipment, tuition, membership dues and fees, publication costs greater than \$2,500, subscription costs, mailing costs, and rent.
- Facilities and Administrative Costs: Facilities and administrative costs, also known as indirect costs, are not permitted for internal MUSC applicants.
- In-kind budgetary items will be considered as cost-share, and the PI's primary department will be required to provide a letter of support confirming the commitment.
- Funding to external investigators will be provided based on monthly invoices under a Sub-contract/Consortium Agreement to the Receiving Institution. Post-award management of pilot project funds awarded to internal MUSC applicants will be managed by the NC NM4R Grant Administrator and the College of Health Professions Research Administration team. An individual UDAK will be established for funded pilot projects, and instructions for the process of funding personnel and ordering supplies will be provided upon official notification of award. Internal applicants are not allowed to include F&A in their pilot budgets. Also note that the source of funding for internal pilots is considered cost share and Affiliate salary will not charge to the project; only the MUSC portion will be charged.

5. NIH-formatted Biosketch

Provide a NIH-formatted Biographical Sketch Format Page. Please use NIH Biographical Sketch
Format Page (non-fellowship) found at: (https://grants.nih.gov/grants/forms/biosketch.htm) for
all key personnel. Convert the Word document to PDF.

The Round 2 application deadline is **November 3, 2023**. Award Notification will be sent out by January 22, 2023, for a May 1, 2024, start date.

NOTE: The applicant will automatically receive an email confirmation that their proposal has been successfully uploaded into the system.

Project completion dates are within 12 months of the date of funding.

For reference, here is the link to submit a full application: <u>InfoReady</u>. This link will be provided to you via email if you are selected to submit a full application.

For questions or assistance with submission, please contact Cynthia Gittinger at gittinck@musc.edu or 843-792-6236.

Application Review Criteria and Process

Each application will be reviewed by a two to three reviewers with appropriate expertise. Applications will be scored on the 1-9 point NIH scale and recommendations for funding will be primarily based on these scores. Scoring will focus on four areas: 1) quality of the research (scientific merit, innovation, and impact); 2) relevancy to the mission of the NC NM4R and direct involvement of one or more the NC NM4R resources in the research plan; and 3) qualifications of the research team to lead the research effort toward securing extramural funding. The reviewers will provide a concise, one-page written review of the application's strengths and weaknesses, as well as recommendations for improvement. The Summary Statement will be sent to the the NC NM4R Program Director, Co-Director, Pilot Program Directors, and the Executive Committee for final decision, and also forwarded to the applicant. In order to maximally fund external applications through the Pilot Studies Program, an extensive effort will be made to utilize the MUSC institutional funds for supporting the top applications from MUSC investigators.

We aim to fund four proposals per year. Funding recommendations will be made by the Executive Committee, then must be approved by the External Advisory Board and then by NIH program staff. Investigators who are not funded on the initial submission will have the opportunity to submit one revision application in the following RFA cycle.

Resubmission of an Application

Applicants will have the opportunity to submit a revised application in response to review comments. Revised applications should be submitted during the following NC NM4R RFA cycle. Investigators submitting an amended application will be expected to address the review critiques using the NIH-modeled Introduction to Resubmission Application, limited to 1 page. The Introduction must summarize all substantial additions, deletions, and changes to the application. The Introduction also must include a response to the issues and criticism raised in the Summary Statement. Please indicate major scientific revisions in the text of the application by bracketing, indenting or changing typography. Do not underline or shade the changes. If the changes are so extensive that essentially all of the text would be marked, explain this in the Introduction. Additional guidance can be found in the NIH Application Guide (https://grants.nih.gov/grants/how-to-apply-application-guide.html).

Place on Subrecipient Institution's Letterhead

Date:

STATEMENT OF INTENT TO ESTABLISH A CONSORTIUM AGREEMENT

[Subrecipient Name]	PI:		
Application Title:			
Period of Support:			
Total Direct Costs: Total F&A Costs: Total Costs:	\$ \$ \$		
The appropriate programmatic and administrative personnel of each institution involved in this grant application will establish written inter-institutional agreements that will ensure compliance with all pertinent Federal regulations and policies in accordance with the "PHS Grant Policy Statement for Establishing and Operating Consortium Grants".			
The inter-institutional agreements will be consistent with the attached subcontract proposal which consists of a clear description of the work to be performed by the subrecipient institution, along with a corresponding budget and budget justification, and will take in consideration any budget recommendations by the granting agency.			
Medical University of South Carolina (Prime Institution)		(Consortium Institution)	
(Signature) Official Authorized to R. David Azbill, Assis	•	(Signature) Official Authorized to sign for	(Date) Institution