

**Request for Funding Proposals – Cycle 5, 2021**

**Northern New England Clinical & Translational Research Network**

NIH IDeA-CTR (1U54GM115516)

Pilot Project Directors: Jane B. Lian (UVM) and Douglas B. Sawyer (MMC)

**Full Proposals are due January 18, 2021.**

**Proposal Documents should be submitted via email to Meredith Oestreicher** [**mboestreic@mmc.org**](mailto:mboestreic@mmc.org)

**Expectation:**

Awards will have a highly significant impact through novel approaches that can ultimately improve health care to at-risk populations. Such pilots could include development of novel monitoring systems and/or interventions that could impact patient awareness or health needs. Pre-clinical and clinical translational proposals that are related to the mission of the NNE-CTR are also welcome. NNE-CTR is particularly interested in pilot studies addressing questions related to:

* Addiction Medicine.
* Cancer(lung, prostate, breast and others).
* Cardiovascular Disease (including disease affected by obesity and diabetes).
* Research that addresses health care issues relevant to rural communities.

**Pilot Project Program Research Awards**

Direct costs are capped at $50,000. The direct costs from all collaborating sites may not exceed $50,000. Indirect costs may be requested at the federal negotiated rate of the institution, up to a cap of 55.6% (see detailed budget guidelines). The proposed project period should be 7/1/21-6/30/22.

Projects should be designed to produce publishable results and to provide preliminary data for an external grant application. We encourage proposals that involve collaborations between investigators at the member institutions (MMC, USM and UVM), between basic scientists and clinical investigators, or between population health scientists and community practitioners. Collaborations across institutions within the NNE-CTR, and development of multidisciplinary teams are encouraged.

**Eligibility**

* At least one member of the team must hold a faculty or affiliation appointment at MMC, UVM or USM. Junior faculty are encouraged to apply, but must involve a senior mentor in the application.
* For senior faculty with established research extending into NNE-CTR with a community-based physician, the research must be distinct from their current funded projects.
* For community-based physicians to be eligible for Pilot Project Research Awards, they must have an affiliation appointment and/or a collaborating partner/academic researcher from either UVM or MMC.
* The PI and all members of the study team must be registered with the NNE-CTR, <http://nne-ctr.net/>

**INSTRUCTIONS FOR FULL PROPOSALS**

**The proposal form accompanying these instructions must be completed, assembled, and made into a single PDF for submission.**

**COVER PAGE:**  This page must be filled out and signed by the lead PI’s institutional official. Note the Proposed Period of Performance is 7/1/21-6/30/22. Please contact your grants/sponsored programs office to obtain institutional information needed on this page and to complete your required institution’s proposal submission process.

For UVM proposers: <https://www.uvm.edu/sites/default/files/Sponsored-Project-Administration/spa_proposal_preparation_review_and_submission_procedure.pdf>

**PROJECT SUMMARY, RELEVANCE, PERFORMANCE SITE AND SENIOR/KEY PERSONNEL PAGES**: Please fill out these pages as follows:

* Project Summary: Describe the overall project, including aims and outcomes, within the space provided.
* Relevance: In no more than four lines, briefly describe in lay language the impact of the project on public health.
* Project Performance Sites: The first site should be the site of the Project PI. Then fill in for all collaborating sites. It is important to include DUNS numbers for the sites. The DUNS number for all MaineHealth member organizations is 071732663. The DUNS number for UVM is 06-681-1191. Other organizations should contact their business or sponsored research office.
* Senior/Key Personnel: List Project PI, lead Co-Investigators at other sites, and any other personnel deemed Senior/Key. Note that mentors and collaborators/consultants who are not giving “measurable” time should be listed under “other significant contributors.” Please note that Co-PI is not a term recognized by NIH, and multiple PIs are not permitted for these pilot project applications. Also note that Senior/Key personnel must have measurable time on the project.

**BUDGET AND BUDGET JUSTIFICATION**: A detailed budget is required for the lead site and each collaborating site for which funds are requested. A detailed budget justification is also requested for each site. Budget guidelines are as follows:

* Personnel: Funds may not be requested for salary support for any investigator with a faculty level appointment, and may not be requested for buying out protected research time for a physician. Funds may be requested for research coordinators, research assistants, technical staff, graduate students, postdoctoral fellows, etc. Additionally, resources for data analysis and/or statistical support will be provided by the NNE-CTR’s Clinical Research Design and Biostatistics Core and therefore should not be requested in the budget. In the justification, explain what each person will be responsible for on the project.
* Travel: Travel must be related to the conduct of the research. In the justification, specify who will travel and to where, and how it is related to the project. Mileage and meals should be budgeted at the federal rate. Please note that if you are funded, federal reimbursement rates at the time the travel occurs will need to be used for reimbursement. **Travel simply for presentation and/or attendance at a scientific or medical conference will not be approved for these pilot project applications.**
* Equipment and software: Equipment and software requests are limited to $3,000. (Note that at MMC items that cost less than $2,500 should be budgeted in supplies, not capital equipment). Specify the equipment to be purchased, the cost, and why it is needed in the budget justification. NOTE: If you wish to request more than $3,000, prior approval is required. Please email your request and justification to [**mboestreic@mmc.org**](mailto:mboestreic@mmc.org) for prior approval.
* Consultants: Specify who the consultant is and what he/she will be responsible for. Include the hourly rate for the consultant (a letter of support from each paid consultant should be included).
* Supplies: Please detail types of supplies and cost.
* Other: Typical expenses in this category may include: incentives for patients to enroll (e.g., gift cards), travel reimbursement for patients, core facility charges, or animal purchase and care. Patient procedure costs may also be budgeted, such as tests and blood draws. Note that tests must be for research purposes and not standard of care, and must be budgeted at the Medicare rate. In the justification, explain how each item in this category was calculated.
* Indirect Costs: Each site may request its federally negotiated indirect cost rate up to a maximum of 55.6%, which is the amount that has been awarded from NIH for pilot projects. If a site does not have a federally negotiated rate, then 10% indirects should be requested. Explain in the budget justification whether you have a negotiated rate or whether the minimum 10% is being used. Please budget at 55.6% if your rate exceeds 55.6%.

**Please note: Meals for meetings outside of travel reimbursements are not allowable under federal grants, per NIH policy.**

**INTRODUCTION** (applies to resubmissions only – 1 page limit). If this is a **resubmission**, on one page indicate your re*s*ponses to the critique and major changes that have been made to the proposal.

**SPECIFIC AIMS**: (1 page limit)

**RESEARCH PLAN** (6 page limit)

The Research Plan should include:

a) **Significance and Background -** literature review, premise, (importance of subject)

b) **Hypotheses and Impact**

c) **Innovation** **statement**

d) **Approach –** To include the study design for each aim with rationale and method, data collection method and plan for analysis (assays, statistical methods, bioinformatics)

e) **Outcomes** and **Future Directions**.

**BIBLIOGRAPHY** (no page limit, not counted in the 6 page Research Plan page limit)

**LETTERS OF SUPPORT** These may include letters from a Hospital or Practice Group Leader, Dean, Chair, Significant Contributor, or Consultant.

**BIOGRAPHICAL SKETCHES** Include Biographical sketches for all senior/key personnel and other significant contributors in the required NIH format. If guidance is needed, attached you will find a sample biosketch form and instructions.

**VERTEBRATE ANIMALS** (if applicable, no page limit). If your project proposes the use of vertebrate animals, please write the following four part descriptions:

**1. Description of Procedures.** Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the Research Strategy section. Identify the species, strains, ages, sex and total number of animals by species to be used in the proposed work. If dogs or cats are proposed, provide the source of the animals.

**2. Justifications.** Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).

**3. Minimization of Pain and Distress.** Describe the interventions, including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain and injury.

**4. Euthanasia.** State the method of euthanasia and whether the method is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If not, describe the method and provide a scientific justification.

**HUMAN SUBJECTS** (if applicable). If your project proposes human subjects studies or the use of human specimens, please follow the attached human subjects instructions, and fill out the “Human Subjects/Clinical Trials” section of the application. Please read carefully, as the instructions are complex.

**PRINCIPAL INVESTIGATOR ATTESTATION:** At the end of the proposal, please include the Signed Attestation of the Principal Investigator, taking responsibility for the accuracy of the application, the ethical conduct of the research, honest management of the funds and the responsibility of submitting written progress reports, commitment to meetings, and the appropriate acknowledgement of NNE-CTR support in any publication or presentation of results.

**COLLABORATING SITE ASSURANCES:** Following the PI Attestation, please include the approval pages for each collaborating site. (Note the lead site is already approved via the cover page signature).

**CHECKLIST**: Please fill out the checklist at the end of the proposal and ensure you have included all required sections.

**CRITERIA FOR SELECTION**

Applications will be reviewed by a Pilot Project Program Advisory Committee with participating members in the NNE-CTR network from Maine, Vermont and collaborating health network organizations in New Hampshire plus selected additional expert reviewers, using the following review criteria:

* Responsiveness to the program announcement to clinical and/or translational nature of the research related to health care problems of regional communities in Northern New England.
* Scientific soundness of the experimental design, including plans for data/statistical analysis.
* Use of Core resources available through NNE-CTR.
* Innovation and Significance.
* Project environment, including facilities and adequacy of patient population.
* Likelihood that the project will lead to additional external funding.
* Reviewers will also note the adequacy of human subjects and/or vertebrate animal sections. Any inadequacy must be addressed prior to funding.

**FUNDING PROCESS AND MECHANISM**: If your project is selected for funding by the Pilot Project Program review panel and approved by the NNE-CTR External Advisory Committee (EAC), the next steps are as follows:

* IRB or IACUC approval (if applicable) must be obtained and all Senior/Key investigators who will work with human subjects must submit evidence that they have a current human subjects education certificate (e.g., CITI certificate). It is important that you begin this process immediately. The NNE-CTR will assign a research navigator to assist you through this process, if needed.
* Once regulatory approvals and training certifications are received, the Maine Medical Center Research Grants office will review your proposal for NIH compliance, and may be in contact with you for additional information or with questions. MMC will submit your proposal to NIGMS for final approval.
* Final funding approval is dependent upon review and approval by the NIGMS. Once approved by NIGMS, Maine Medical Center will issue a subaward to each site on the project that has received funding (MMC sites will have an internal account set up for its funds). All funding to sites outside of MMC/MaineHealth will occur via subaward from MMC, regardless of which site serves as the lead site.

**AWARDEE REQUIREMENTS**

Awardees of the 2021 Pilot Projects Program are expected to adhere to the following requirements:

* Participate in meetings: regular conferences for newly funded grantees with PPP Directors to assure operational procedures are running smoothly and that projects are making use of NNE-CTR Cores; quarterly meetings with NNE-CTR leadership and Core Directors to present a short talk and discuss project productivity and directions.
* Submit a progress report at 6 and 12 months, and present near the end of the first year the project and results in the NNE-CTR translational research seminar series.
* Present a poster or platform presentation at the annual NIH IDeA Symposium.
* Respond to questionnaires and surveys from the Tracking and Evaluation Core.
* Complete a NNE-CTR survey at the end of the funding year.
* Report all presentations, publications, and extramural funding that arise from the Pilot Project Award, and acknowledge sponsorship from NNE-CTR, supported by NIGMS (U54GM115516), in all publications resulting from pilot project study.
* All publications must be compliant with the NIH Public Access Policy (including ensuring submission of publications to PubMed Central and obtaining a PMCID number).

The CTR and PPP reserve the right to further standardize the requirements of the PPP and the format of the application, and to reject applications outright that do not follow the published guidelines (for example, eligibility). This is necessary to achieve the goals of the CTR, to be fair to all Pilot Project applicants, and to enable efficient review of the applications.