

Request for Funding Proposals – Cycle 2, 2018

Northern New England Clinical & Translational Research Network

NIH Grant First IDeA-CTR (1U54GM115516-01) Directors: Jane B. Lian (UVM) and Douglas B. Sawyer (MMC)

Proposal Documents should be submitted to Meredith Oestreicher at MBOestreic@mmc.org

DUE on APRIL 30, by 5 pm

April 30, 2018	Full Proposal due
May 2018	Review panel meets
June 2018	Award Notification

Description of Pilot Project Program (PPP) Award.

We expect to approve a total of 5 awards in this round of the PPP.

The expectation of the PPP awards is that these 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), and Cardiovascular Disease (including affected by obesity and diabetes). Research that addresses health care issues relevant to rural communities is an additional priority of the NNE-CTR and PPP.

Pilot Project Program Research Awards

There is a total of \$250,000 for Awards in 2018-2019. Proposals requesting from \$10K to \$50K for a one year award for scientists and physician-investigators will be considered.

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 two central institutions (MMC 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 also encouraged. Prior recipients of a "Practice Stipend" award within the Rural Health Research and Delivery Core are encouraged to work with faculty at UVM or MMC to develop full Pilot Project Applications.

Eligibility Requirements for Awards

- 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 must be registered with the NNE-CTR, http://nne-ctr.net/

Full Proposal Requirements

A complete proposal will include, as one consolidated PDF, the following sections in order:

- 1. NIH PHS Forms (attached) in the following order:
 - a. **Cover Page Form** signed by Institutional Official (NOTE: your proposal must go through your institutional approval process)
 - b. Project Summary, Relevance and Performance Sites (text must fit within boxes)
 - c. **Senior/Key Personnel Page** (Senior/Key Personnel includes PI, Co-Is, must have measurable time on project. Other significant Contributor does not need measurable time (mentors, consultants fit here; era commons name not required)
 - d. **Budget and Budget Justification**: A detailed budget must be provided and justified commensurate with the work proposed. Awards may not be used merely to supplement existing grants, to provide support for ongoing projects, or to support previously funded research. For a grant that initiates new translational research by partnering with a collaborator at another institution, the budget should clearly indicate how funds will be allocated between the collaborating institutions or investigators. Indicate which expenses of the studies support health care initiatives to rural New England.

Budget guidelines are:

- If you are submitting a collaborative proposal involving more than one institution, please include the applicant institution budget first, with the total amount for the collaborating institution included in the "subaward" line. Include the detailed collaborating institution budget on a second budget page.
- The direct budget cost is limited to \$50,000 (including all collaborator budgets). Indirect costs should be added at the federally negotiated rate of the institution.
- No salary support for PI or Co-Pi is allowed.
- Any travel request must be related to the study and justified
- Equipment requests must be below \$3,000.
- Please use additional pages for Budget Justification if needed.
- 2. **Biosketches** (attached): For PI, Mentor and all Key Personnel (Co-PI, Co-Investigators) are required, as well as Other Significant Contributors (5 page limit for each Biosketch).
- 3. Specific Aims: One page limit
- 4. Research Plan: Six page limit.

Proposals should follow the guidelines of the Public Health Service Form 398 with the following: a) <u>Background</u> and <u>Significance</u> (literature review, premise, (importance of subject); b) <u>Hypotheses</u>, Impact of the studies; c) <u>Innovation</u> statement; d) <u>Study Design for each aim</u> with Rationale and Approach to include Data Collection (how will the data be obtained) and Analyses (assays, statistical methods, bioinformatics) and; e) <u>Outcomes</u> of aims/proposal and future directions.

- 5. Data Sharing and Dissemination Plan
- 6. References/Bibliography
- 7. Letters of Support

8. **Signed Attestation** (attached) 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.

Additional Requirements if Applicable

- Vertebrate Animal description: If you will be using vertebrate animals, provide the four-point NIH description. Include your IACUC approval letter (or information as to when you expect approval; approval must be received prior to funding). Direction for the vertebrate animal section are attached, if needed.
- **Protection of Human Subjects description**: If you are conducting a human subjects study, or are using human biospecimens data, you must complete a Protection of Human Subjects form.

The form has drop down menus and also required upload of narrative documents. NOTE: The NIH human subjects section was significantly revised in January 2018 and is detailed. Please fill out the entire form, following the accompanying instructions carefully. **Include your IRB approval letter** and documentation of completion of CITI training in human subjects research (or information as to when this is expected; approval and education documentation must be received prior to funding).

NOTE: As with all CTRs, funding is dependent upon review and approval by the NNE-CTR Internal and External Advisory Committees, and by the NIGMS. Since NIGMS and academic Institutions require, prior to funding, approvals for animal (IACUC) and human studies (IRB), applicants are strongly urged to have obtained or commenced the regulatory approval process at the time of submission of the application.

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
- Training and expertise of the co-PIs and their ability to perform the proposed research; and for junior faculty, the expertise of their mentor
- Project environment, including facilities and adequacy of patient population
- Likelihood that the project will lead to external funding for scientific merit including significance, investigators, innovation, and approach

Awardee Requirements

Awardees of the 2018 Pilot Projects Program are expected to adhere to the following requirements:

- Participate in meetings: monthly conferences for newly funded grantees with PPP Directors to assure operational procedures are running smoothly and that Co-PIs are taking advantage of Cores; quarterly meetings with NNE-CTR leadership, Core directors and Internal Advisory Board members 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- translational research seminar series.
- Present a poster at the annual NIH IDeA Symposium and a talk, if invited.
- 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 the IDeA-CTR (1U54GM115516-01) in all publications resulting from proposed studies. 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 will 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.