Request for Funding Proposals

Northern New England Clinical & Translational Research Network

NIH Grant First IDeA-CTR (1U54GM115516-01)

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

Dates of Submission, Review and Award Notice for Year 1 July 2017- July 2018

Cycle 1 – 2017 LOI – Sept 15; Full application - October 25; Award Notice – December 4

Cycle 2 – 2018 LOI – April 4; Full application - May 16; Award Notice - June 19

The Letter of Intent (LOI; one page) is to include contact information + affiliation/academic appointment, description of problem to be addressed and a brief delineation of the specific aims. Send to jane.lian@uvm.med.edu and identify in subject line NNE-CTR. Those Investigators that need assistance in developing a proposal can send a “letter of interest" at any time during the year.

Description of Pilot Project Program (PPP) Awards

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 would include development of novel monitoring systems and/or interventions that could impact patient awareness or health needs. NNE-CTR is particularly interested in pilot studies in Addiction Medicine, Cancer (lung, prostate, breast and others), and Cardiovascular Disease (including affected by obesity and diabetes). Research that addresses issues in rural communities is an important priority of the NET-CTR and PPP.

Pilot Project Research Awards (up to $50,000/1 year for scientists and physicians). Projects should be designed to produce publishable results and provide preliminary data for an external grant application. We anticipate receiving proposals that involve, for example, 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

Pilot Project Rural Physician Awards (up to $50,000 for rural clinicians). This award is for pilot studies that reach beyond the conceptual phase and can become operational within the NNE-CTR. This will include budgeting for clinical studies in rural communities and/or funds for integrating bench research (e.g. genetic sequencing, biomarkers) in target populations. These funds are independent of conceptual development awards from the Rural Health Delivery and Research Core. But those physicians who developed a research “concept" and project using a “Practice Stipend" award within the Rural Health Research and Delivery Core are eligible. Physician investigators or those that have used the Clinical Research Design Core in preparing an application will be given priority consideration.
The Scholars Training Award (2/yr up to $2500) is an innovative mechanism to support either young or established investigators in obtaining skills necessary for building a CTR multidisciplinary program. This award is designed as a mini-sabbatical to join an ‘off-site’ laboratory or other research environment to learn a new technique or how to establish a model system, and engage in intellectual project development with a mentor or a potential collaborator.

Travel and Publication Awards (up to $2K each). Pilot Project grantees will be eligible for this award to attend a national meeting to present an accepted abstract of their work.

**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 this Pilot Project funding, they must have an affiliation appointment and/or a collaborating partner/academic researcher from either UVM, MMC or USM.

**Pre-Submission applications**

Letter of Intent (LOI): One page to include contact information (affiliation/academic appointment), description of problem to be addressed and how it is related to the community. Indicate if assistance is needed in preparing the full application. Other cores can assist in developing a proposal and identifying a clinical or basic scientist collaborator. Cores that could assist include - Rural Health Research and Delivery Core; Clinical Research Design, Epidemiology and Biostatistics Core.

**Criteria for Full Submitted Proposals:** A complete proposal will include

1. **Cover Letter** - one-page which should show title, Principal Investigator and email contact. Briefly explain a) the Research Pilot Project goal b) innovation, c) potential for extramural funding sources, and d) relevance to NNE-CTR;

2. **Research Plan**, up to six pages for Pilot Project, and 3 pages for all other Awards (i.e. PP Research and PP rural Physician Proposals). Proposals should generally follow the guidelines of the Public Health Service Form 398) with the following: a) Specific Aims and (if appropriate) Hypotheses, b) Background (literature review); c) Significance (importance of subject); d) Study Design and Rationale; e) Measurements and Outcomes); f) Data Collection (how will the data be obtained) and analyzed (statistical methods, bioinformatics); also indicate Data Sharing and Dissemination plan; g) References.

3. **Biographical Sketches of Key Personnel in current NIH format**; **Technical Appendices** (up to two), which may include up to two peer-reviewed journal articles from which the proposed research directly takes its lead.

4. **Budget**: A 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. Funds may be budgeted at an awardee’s discretion but should not include funds for her/his own salary support, travel not related to the conduct of the
research, alterations and renovations of physical plant, purchase of unrelated office equipment or supplies, or research equipment costing $3,000 or more.

5- **Letters of Support** (e.g., from a Hospital or Practice Group Leader, Dean, Chair, Key Personnel); and **Signed Attestation** 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.

6- If applicable, please provide:

**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).

**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 description, including Planned Enrollment Tables. 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).

Additional information on completing Vertebrate Animals and Protection of Human Subjects descriptions will be sent to those whose LOI is selected for a full application.

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 health care problems of regional communities in Northern New England
- Scientific soundness of the experimental design, including plans for data analysis
- 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 2017 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.