NORTHERN NEW ENGLAND
CLINICAL & TRANSLATIONAL
RESEARCH NETWORK

Instructions for Submitting a Full Proposal

NNE-CTR Pilot Projects Program

Due Date: November 1, 2024

Congratulations! You have been invited to submit a full proposal to the NNE-CTR's pilot project program. Full proposals are submitted electronically via our REDCap system. The link you have received is unique to you to begin the application process.

NOTE: If you need assistance or have questions, please email nne-ctr@med.uvm.edu

Before you begin your application, for guidance with study design, data analysis, statistical needs or human subjects section, please submit a request for the Navigation services through our website.

IMPORTANT: We are requiring you to answer a number of questions in the on-line system and upload several components of the application. All required forms can be found on our website.

REQUIRED SECTIONS OF THE APPLICATION

A. NIH forms The NIH forms should be downloaded from our website. They are all in one word document and once they are filled out, please save as a single PDF and upload as directed with the file name: ApplicantLastName_SectionA_NIH_Forms

Components in Section A:

1) **COVER PAGE**: The Project Lead's institutional official must sign this page. Please contact your sponsored programs office to obtain institutional information needed on this page and to complete your required institution's proposal submission process. For additional sites, please see "Collaborating Site Assurances" at the end of these instructions.

2) **PROJECT SUMMARY, RELEVANCE, PERFORMANCE SITES**

- Project Summary – describe the overall project, including aims and outcomes.
- Relevance – in no more than three sentences, 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 Lead. If there are collaborating sites, fill in for all collaborating sites. It is important to include Unique Entity Identifier ((UEI). The UEI number for all MH member organizations is MAYKB1LWD5U9. The UEI number for UVM is Z94KLERAG5V9. Other organizations should contact their business or sponsored research office.

3) **SENIOR/KEY PERSONNEL and EMBRYONIC STEM CELLS**

Senior/Key Personnel – list Project Lead and Co-Leads at other sites under Senior/Key. List mentors, consultants and collaborators under Other Significant Contributors. The correct role for leads at each site is Project Lead (for lead site), and Project Co-Lead (collaborating sites). Technical staff, including technicians, research coordinators, research assistants, and data analysts are typically not included as senior/key personnel or in other significant contributors, they will be listed in budget only.

Human Embryonic Stem Cells (HESC) - Please be sure to answer the yes/no question on HESC.

B. BUDGET & BUDGET JUSTIFICATION:

NORTHERN NEW ENGLAND
CLINICAL & TRANSLATIONAL
RESEARCH NETWORK

Upload this section as a PDF with the file name: ApplicantLastName_SectionB_Budget

Provide a detailed budget and budget justification for the lead site and for each collaborating site for which funds are requested. Use the NNE-CTR budget and justification form, which can be found in the FORMS section of our website. Each site has its own individual budget (note: there are no subawards allowed on a site budget. All subawards to sites will be issued from MaineHealth). One composite (cumulative) budget that shows total direct and indirect costs is required. The cap on direct costs is $40,000. **Direct costs for all sites when totaled must not exceed $40,000.** Each site may include indirects at their federally negotiated rate (not to exceed 72%). If a site does not have a federally negotiated rate, the site may use a 10% rate. Note that budgets should be approved by the institution's appropriate sponsored research office or equivalent. Budget guidelines are below.

- 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. (NOTE: For project leads and co-leads with measurable time, it is recommended that the effort be in the range of 1–5%. Since you cannot request salary support for faculty, this effort is "in kind" - please ensure that your proper institutional approvals are in place for any in-kind commitments. Remember that the 'other significant contributors' do not need measurable time or in-kind commitment approval - they contribute on an 'as needed' basis. Funds may be requested for research coordinators, research assistants, technical staff, data analysts, statisticians, etc. The NIH salary cap in effect at the time of the proposal applies.
- 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. To learn the current federal rate for mileage and per diem expenses, see https://www.gsa.gov/travel/plan-book/per-diem-rates
    - Travel for presentations and/or attendance at a scientific or medical conference is not allowable for these pilot project applications.
- Equipment & Software – Equipment and software requests are limited to $3,000. 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 Drs. Rob Koza and Janet Stein via nne-ctr@med.uvm.edu 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). Note there are strict rules for who can be paid as a consultant; a consultant cannot be an employee of your institution. Refer to your sponsored research office for details on your institution's policy on consultants. Questions on consultants may also be directed to the NNE-CTR Administrative contact via nne-ctr@med.uvm.edu
- 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 clinical tests and blood draws. Note that clinical procedures must be for research purposes and not standard of care and must be budgeted at the Medicare rate. Incentives are usually in the $25 to $50 range for participants in a study. We suggest you consult with your Clinical Trials office to obtain clinical procedure costs. 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 72%). 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 note the following restrictions:

***Meals**: Meals for meetings outside of travel reimbursements for per diem meals are not allowable under federal grants, per NIH policy. If your project proposes a technical meeting to disseminate information to non-employees (i.e. community residents) and the meeting must be held during a mealtime, these costs may be allowable per NIH policy. Please consult the NNE-CTR contacts with questions.*
***Publications**: Publications costs are not allowable. If your project is funded and you publish the work in the following year, you may apply to the NNE-CTR for funds to cover publication fees.*

C. BIOGRAPHICAL SKETCHES: Upload all biosketches as a single PDF with the file name: Applicant LastName_SectionC_Biosketches

Include NIH biographical sketches for all senior/key personnel and other significant contributors in the required NIH format. The first biosketch should be the Project Lead. The required format (instructions and sample) are on the NNE-CTR pilot project website. Note there is a field on the biosketch for an eRA commons ID. This is NOT required at time of submission. If the proposal is recommended for funding, we will ensure the Project Lead has an eRA commons registration (this is done by the home institution). Other members of the team are not required to have an eRA commons ID.

D. RESEARCH PLAN: Make a single PDF of all sections of the research plan and upload with the file name: Applicant LastName_SectionD_ResearchPlan Make sure to use the order of sections below.

Formatting for Research Plan
The following sections are submitted as NARRATIVE and do not go on a specific form. Please use **Arial 11-point font and ½ inch margins** all the way around and follow the guidelines for subheadings. Make a single pdf of all components when complete.

- ***INTRODUCTION** (if applicable, applies to resubmissions only):* (1 page limit) If this is a **resubmission**, on one page indicate your responses to the critique and major changes that have been made to the proposal.

- ***SPECIFIC AIMS*:** (1 page limit) 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 proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.

- ***RESEARCH STRATEGY*:** (6-page limit) The Research Strategy should include:
  - Significance and Background – literature review, premise, importance of subject
  - Hypotheses and Impact
  - Innovation Statement
  - Approach – to include the study design for each aim with rationale and, data collection method and plan for analysis (assays, statistical methods, bioinformatics)
  - Outcomes and Future Directions

- ***BIBLIOGRAPHY:*** (No page limit, not counted in the 6-page Research Strategy page limit)

- ***VERTEBRATE ANIMALS***: (If applicable, no page limit.) If your project proposes the use of vertebrate animals, please include a header "Use of Vertebrate Animals" and address the following four points.
  - 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.
- Justification. 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).
- Minimization of Pain and Distress. Describe the interventions, including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain and injury.
- Euthanasia. State the method of euthanasia and whether the method is consistent with the recommendation of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If not, describe the method and provide a scientific justification.

- ***LETTERS OF SUPPORT*** (optional): These may include letters from a hospital or Practice Group Leader, Dean, Chair, Significant Contributor, or Consultant.

- ***DATA SHARING PLAN*** (2-page limit)**:**

If any of the proposed research in the application involves the generation of scientific data, a Data Management and Sharing Plan is required. If the proposed research in the application will generate large-scale genomic data, the Genomic Data Sharing Policy also applies and should be addressed in this Plan (see link below for instructions). The data sharing plan should include the following information:

Data Type: Summarize the types and estimated amount of scientific data expected to be generated in the project. Describe which scientific data from the project will be preserved and shared and provide the rationale for this decision. Briefly list the metadata, other relevant data, and any associated documentation (e.g., study protocols and data collection instruments) that will be made accessible to facilitate interpretation of the scientific data.

Related Tools, Software and/or Code: State whether specialized tools, software, and/or code are needed to access or manipulate shared scientific data, and if so, provide the name(s) of the needed tool(s) and software and specify how they can be accessed.

Standards: State what common data standards will be applied to the scientific data and associated metadata to enable interoperability of datasets and resources and provide the name(s) of the data standards that will be applied and describe how these data standards will be applied to the scientific data generated by the research proposed in this project. If applicable, indicate that no consensus standards exist.

Data Preservation, Access, and Associated Timelines. Provide the name of the repository(ies) where scientific data and metadata arising from the project will be archived.
Describe how the scientific data will be findable and identifiable, i.e., via a persistent unique identifier or other standard indexing tools. Describe when the scientific data will be made available to other users (i.e., no later than time of an associated publication or end of the performance period, whichever comes first) and for how long data will be available.

Information on repositories can be found here:
https://sharing.nih.gov/data-management-and-sharing-policy/sharing-scientific-data/selecting-a-data-repository

Access, Distribution, or Reuse Considerations: NIH expects that researchers maximize the appropriate sharing of scientific data. Describe and justify any applicable factors or data use limitations affecting subsequent access, distribution, or reuse of scientific data related to informed consent, privacy and confidentiality protections, and any other considerations that may limit the extent of data sharing.

State whether access to the scientific data will be controlled (i.e., made available by a data repository only after approval).) If generating scientific data derived from humans, describe how the privacy, rights, and confidentiality of human research participants will be protected (e.g., through de-identification, Certificates of Confidentiality, and other protective measures).

Oversight of Data Management and Sharing: Describe how compliance with this Plan will be monitored and managed, frequency of oversight, and by whom at your institution (e.g., titles, roles).

Please see links below for further information on the required Data management and sharing policy including details on the genome wide data sharing requirements and examples of data sharing plans:

https://sharing.nih.gov/faqs#/data-management-and-sharing-policy.htm?anchor=11822

https://sharing.nih.gov/data-management-and-sharing-policy/planning-and-budgeting-for-data-management-and-sharing/writing-a-data-management-and-sharing-plan#after

E. HUMAN SUBJECTS SECTION (if applicable): Make a PDF of the form when completed and upload with file name: ApplicantLastName_SectionE_HumanSubjects

If your project proposes human subject studies or the use of human specimens, follow the human subjects instructions attached here and on the website. Please read carefully, as the instructions are complex. Please use the template provided, which NIH requires. NIGMS has offered additional guidance on how to fill this out and this guidance is on the website (Human Subjects Section Tips for PIs). It is critically important that this section be filled out correctly. Contact your research navigator if you need help. If you are unsure if your project is exempt or which exemption category your project falls in, contact your IRB directly. NOTE: if recommended for funding, IRB determinations and approvals will be required prior to issuing an award – it is highly encouraged to contact the IRB for the correct category prior to submission.

F. PROJECT LEAD ATTESTATION: PDF File name: Applicant LastName_SectionF_Attestation

Include the Signed Attestation of the Project Lead, 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 expectations
- Appropriate acknowledgement of NNE-CTR support in any publication or presentation of results.

G. COLLABORATING SITE INSTITUTIONAL ASSURANCES:
PDF File name: ApplicantLastName_SectionG_Assurances
Following the Project Lead Attestation, include the approval page for each collaborating site. (Note the lead site is already approved via the cover page signature and should not be included here.)

H. CHECKLIST: PDF File name: Applicant LastName_SectionH_Checklist
Please fill out and upload the Application Documents Checklist to ensure that you have included all required sections.

NORTHERN NEW ENGLAND
CLINICAL & TRANSLATIONAL
RESEARCH NETWORK

PROPOSAL REVIEW PROCESS

REVIEW CRITERIA: Applications will be initially reviewed by a Pilot Project Program Review Committee with participating members in the NNE-CTR network from Maine, Vermont and collaborating health network and partner organizations, using the criteria below.

- Project will take place in and consist of partners from only IDeA states (Vermont, Maine, New Hampshire). Non-IDeA state collaborators may be included but no funding may be requested.
- Project is clinical or translational in nature (basic research will ~~only~~ be considered if mechanisms are being pursued that relate to the diagnosis, prognosis, or targeting of disease and the translational nature is clearly justified)
- Responsiveness of the clinical or translational research approach to addressing health and health care challenges encountered in Northern New England communities
- Scientific rigor 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
- Identification of mentorship and guidance for development and pursuit of pilot project
- Potential of the project to provide credentials for external funding.
- Adequacy of human subjects' protections and/or vertebrate animal sections; inadequacies must be addressed prior to funding and can negatively impact the score of the application during review.

NOTICE OF RECOMMENDATION TO FUND

FUNDING PROCESS & MECHANISM: If the Pilot Project Review Committee and the NNE-CTR Leadership recommend your project for funding, you will receive a "Notice of Recommendation to Fund" letter with instructions on next steps. The Notice will include an administrative review of your project which may require additional information, revisions to sections, or questions to be answered. This level of review is similar to the "Just in Time" request that NIH issues prior to funding. This Notice is not a guarantee of funding, as two more levels of review are required: 1) review and approval by the NNE-CTR External Advisory Committee (EAC), and 2) approval by NIGMS. Prior to NIGMS approval, all regulatory approvals must be obtained, and other documents as follows:

- IRB or IACUC approval (if applicable). If your project is a multi-site non-exempt human subjects study, there must be one IRB of record who will oversee the study at all sites. Please work on regulatory approvals immediately; your research navigator is available to provide support as needed.
- All Senior/Key investigators who will work with human subjects must provide a copy of their current human subjects education certificate (e.g., CITI certificate). If your project is a clinical trial, all senior/key must have certification in Good Clinical Practice.
- The Project Lead must provide a list of other sources of support and certify that he/she has no other IDeA program funding or duplicative funding for the project.

Once all administrative review information, regulatory approvals and training certifications are received, the project will be submitted to our External Advisory Committee (EAC) for approval, and then NIGMS for final approval. Once all approvals are in place, funding will be awarded as follows:

If the project is at MaineHealth, the accounting department will set up an account for the MH Project Lead, who may begin to access funds; if there are sites outside of MaineHealth, the MH grants office will issue a subaward to each site on the project that has been approved for funding.

POST-AWARD REQUIREMENTS: Awardees will be expected to adhere to the following requirements.

- Submit progress reports as requested twice per year, including the CTR Annual report. You will be contacted by the NNE-CTR administrators who will provide reporting requirements. *Note that the annual report also requires an update in the enrollment table for all human subjects work. Please keep*

records for each enrollee including, gender, race, ethnicity and age.

- Present your project to the NNE-CTR leadership and Core Leads to review progress, challenges encountered and future directions (virtual, as requested)
- Deliver an NNE-CTR Seminar at the completion of the Pilot Project
- Give a poster or platform presentation at the annual NIH IDeA Symposium IF SELECTED
- Respond to questionnaires and surveys from the Tracking and Evaluation Core
- 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 and presentations resulting from pilot project study
- All publications supported by the award must be compliant with the NIH Public Access Policy (including ensuring submission of publications to PubMed Central and obtaining a PMCID number). Publications must acknowledge support of NNE-CTR (U54GM115516)
- If your project is an NIH-defined Clinical Trial, there are additional requirements including registration in clinicaltrials.gov, appointment of an independent medical monitor, reporting of adverse events to NIH, and reporting results in clinicaltrials.gov. We will provide a detailed list of federal requirements for clinical trials.

The NNE-CTR and Pilot Projects Program reserve the right to further standardize the requirements and the format of the application. Applications that do not comply with the published guidelines will not be reviewed. This is necessary to be fair to all Pilot Project applicants, and to enable efficient review of the applications.