University of Nebraska Medical Center

REQUEST FOR APPLICATIONS:
Great Plains IDeA-CTR Pilot Grant Program

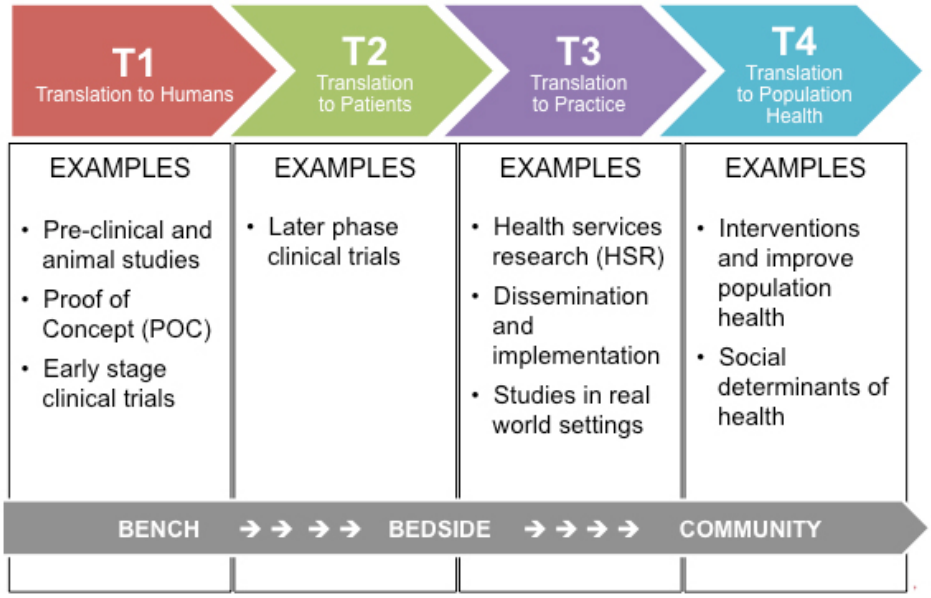
Application Deadline: January 17, 2017 (5 pm)

All Information also available online at
(https://unmcredcap.unmc.edu/redcap/surveys/?s=8YR9M7YN4T)

The IDeA-CTR Pilot Grant Program is administered through an NIH/NIGMS grant entitled "Great Plains IDeA CTR." The goal of the program is to provide a mechanism to test the most promising and novel clinical and translational research (CTR) projects, and help investigators obtain preliminary data necessary for successful investigator-initiated extramural grants. Successful applicants will receive up to $50,000 annually, as well as access to resources of the Great Plains IDeA-CTR to support these research efforts.

New interdisciplinary collaborations, inter-institution proposals, and links to existing other IDeA programs (INBRE and COBRE) in the participating Great Plains region are encouraged. Projects that make an impact on the medically disadvantaged or underrepresented groups will be prioritized, as will those that can introduce or evaluate new tools or technologies useful in isolated (e.g. rural or home-bound) patients. Work on factors that affect health, disease, and aging across the lifespan will be accepted. Highest priority will be given to the strongest science and those projects most likely to lead to successful extramural funding.

Proposed projects must fall in the realm of the definition of clinical and translational research. While there are many definitions of CTR, these can be conceptualized as in the figure at right. Purely basic research does not qualify for this pilot program.



Eligibility

- Current full time faculty appointment at a participating institution
- Eligible to apply for NIH funds (i.e. US citizen or a permanent resident)
- Project relevant to clinical and translational research

Participating Institutions:
University of Nebraska Medical Center (UNMC)
University of Nebraska Omaha (UNO)
University of Nebraska Lincoln (UNL)
University of Nebraska Kearney (UNK)
Boys Town National Research Hospital (BTNRH)
University of South Dakota (USD)

University of North Dakota (UND)
North Dakota State University (NDSU)

Application Deadline: January 17, 2017

Earliest Funding Start Date: March 1, 2017 (pending review, NIH and all regulatory approvals)

Funds Available: Up to seven awards of $50,000 (for one to two years, with second year, if requested, dependent upon evidence of significant progress.

Application Process:

1. Compile the below application materials and combine into one PDF file
2. Note that assistance with topics such as biostatistics or trial design in preparation and execution of this application is supported by the Great Plans CTR. Applicants are encouraged to contact the UNMC Center for Collaboration on Research Design and Analysis (CCORDA): https://www.unmc.edu/publichealth/centers/ccorda/ for such assistance. CCORDA personnel may be contacted by email or by phone, 402-559-4112
3. On the Great Plains IDeA-CTR REDCap portal, navigate to the Pilot Grant program and complete the online "Great Plains IDeA-CTR Pilot Face Sheet" (https://unmcredcap.unmc.edu/redcap/surveys/?s=8YR9M7YN4T)
4. Upload the PDF file containing the completed grant application on the above Great Plains IDeA-CTR REDCap website

Required application materials:

1. NIH format Face Page (download and complete Form page 1 from https://grants.nih.gov/grants/funding/phs398/phs398.html
2. Lay summary of project, including disease/health relevance: one paragraph on separate page. Include on this page a separate sentence/paragraph explaining which phase (T1-T4) of CTR research this project represents
3. Research Plan: this portion is limited to five pages in total
    a. Specific Aim(s)
    b. Research Strategy (be sure to include the scientific premise of the proposed research: the strength and weaknesses of the research that is used to form the basis for the proposed research question)
        i. Significance
        ii. Innovation
        iii. Approach
            1. Include the scientific premise of the proposed research (the strength and weaknesses of the research that is used to form the basis for the proposed research question)
            2. Can include preliminary data, although not required
            3. Experimental design, including steps taken to ensure scientific rigor (robust and unbiased experimental design, methodology, analysis, interpretation and reporting of results, explained as appropriate for a pilot project) and consideration of key biological variables (please see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-011.html)
            4. Authentication of key biological and/or chemical resources (if applicable, please see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-011.html)
            5. Plans for extramural funding applications (e.g. to NIH or other agencies, please specify) upon successful completion of this project
4. Literature Cited
5. Regulatory approvals: If your project includes human subjects or vertebrate animals, your institutional IRB or IACUC (respectively) approval is required before funds can be released.

While approval is not required at time of application, submission for approval is **strongly recommended** to avoid delays in timely beginning of projects. In addition, you must include the following sections in the application:

   a. Human Subjects: If your project meets the NIH definition of human subject research (https://humansubjects.nih.gov/walkthrough-investigator - tabpanel11), include the Protection of Human Subjects items for NIH grants (follow the "A Protection of Human Subjects section" link on the above web site). Please note that those doing human subject research need to complete Human Subjects education (e.g. Collaborative IRB Training Initiative (CITI) training)
   b. Vertebrate Animals: Include the Vertebrate Animals items for NIH grants (instructions at https://grants.nih.gov/grants/olaw/vertebrate_animal_section.htm)

6. NIH format Biosketch (download from https://grants.nih.gov/grants/forms/biosketch.htm) for applicant and other key personnel
7. Budget (download and complete Form page 4 from https://grants.nih.gov/grants/funding/phs398/phs398.html)
   a. Faculty salary support is not allowed, student/post-doctoral stipend is not allowed but salary/wages are permissible
   b. Equipment (>$5,000 per item) purchase is not allowed
   c. Travel is limited to what is necessary to perform research
   d. Indirect costs (F&A) associated with pilot grants will be awarded to investigator's institution for NIH-funded pilots (note some of the pilot funds are institutional and thus do not have NIH indirects)
8. Budget Justification (on separate page, explain duties of personnel, use of supplies, other expenses, etc.)
9. Appendices will not be accepted

Review Process

1. The Pilot Project Scientific Review Committee will review all applications, using the NIH review criteria (*Significance, Investigator(s), Innovation, Approach, Environment),* modified as appropriate for this Pilot grant program.
2. The Overall Impact Score will include other considerations, as stated in the introduction above, such as new interdisciplinary collaborations, inter-institution proposals, and links to existing other IDeA programs (INBRE and COBRE) in the participating Great Plains region. Projects that make an impact on the medically disadvantaged or underrepresented groups will be prioritized, as will those that can introduce or evaluate new tools or technologies useful in isolated (e.g. rural or home-bound) patients. Highest priority will be given to the strongest science and those projects most likely to lead to successful extramural funding.
3. The Review Committee will suggest ranking to the Steering Committee.
4. The Steering Committee will make recommendations for funding, which will be forwarded to the External Advisory Board and NIH Program Staff for Final Approval.

Funding

Following final approval, funding will be made available to your institution following above approvals and documentation of all necessary regulatory approvals.

Great Plains IDeA CTR Annual Meeting

All recipient of Pilot Awards will be required to attend the Annual Scientific Meeting, and present their project/results. For those outside of the region in which the meeting is held, travel funds will be provided.

Questions

Please direct questions to the Pilot Grant Director, Dr. Howard Fox, hfox@unmc.edu or the Great Plains IDeA-CTR Education Coordinator, Heather Braddock, heather.braddock@unmc.edu.

RFA Frequently Asked Questions:

Q: Are stipends allowed in Scholar and Pilot Program budgets for graduate students and post-doctorate fellows?
A: Although stipends for graduate students and post-doctoral trainees are NOT allowed, wages and salary support for students ARE allowed.

Q: Can a non-citizen/non-permanent resident lead a Pilot or Scholar project?
A: A non-citizen/non-permanent resident is eligible to lead a Pilot or Scholar project if s/he is faculty, has a project relevant to the CTR and his/her own institution allows him/her to apply for NIH grants.

Q: Can projects involve collaborators from non-IDeA-CTR sites?
A: There are no restrictions per se in where collaborators are from. For the Scholar and Pilot Programs, the only IDeA CTR restrictions would apply to the Scholar and the primary mentor. Collaborators and co-mentors from different sites are encouraged.

Q: Is an individual eligible to apply for the Scholar or Pilot Program if s/he was the recipient of a COBRE grant?
A: Individuals are eligible to apply if they will not be funded by a COBRE during grant award period.

Q: Fringe benefit rates - the RFA allows a fringe benefit rate of 23% for UNMC faculty but other institutions have different (higher) rates. Can we utilize the fringe benefit rate of our institutions?
A: It is fine to utilize a fringe benefit rate that varies from the 23% rate. The individual should follow his/her institution's policy.

Q: Will institutions of Pilot and Scholar awardees receive indirect payments?
A: All moneys coming from the NIH for the Scholar and Pilot Program will have indirect costs payable the participating institution. Salaries will pay the locally accepted fringe benefit rate at the participating institution.

Q: Can a PI submit more than one Pilot grant?
A: A PI can only submit one Pilot grant application. However, the individual can also be a collaborator on someone else's research. In addition, an individual can submit an application for both the Pilot and Scholar Programs.

Q: The Pilot RFA states that equipment purchase is not allowed (This disallowance of equipment purchase does NOT apply to the Scholar Program). Are items such as, wristband monitors that monitor physiological stress, sleep and physical activity considered equipment?
A: The definition for equipment, as stated in 45 CFR Parts 74 and 92, is an article of tangible nonexpendable personal property having a useful life of more than one year and an acquisition cost of $5,000 or more per unit. (45 CFR Part 74.2 and 74.34 and NIHGPS)(Frequently Asked Questions Equipment Under NIH Grants, retrieved 12/20/2016 from NIH)

Q: The NIH face page form requires institutional signature when it is used for official NIH submissions. Is the institutional signature a requirement for the Pilot Program submissions?
A: This signature is not required at the time of application submission. Individuals who are awarded funding will be asked to complete this step after the applicant selection process.

Q: The Scholar Program application requests that I provide a CV. Can I simply provide an NIH biosketch instead?
A: No, a CV is required.

Q: What qualifies as Clinical and Translational Research?
A: Clinical and Translational research is research that impacts human health. It is incumbent on the applicant to demonstrate how his/her research project affects human health. Below are some helpful definitions and a schematic of the different phases of translational research.

Q: I'm applying for the IDeA-CTR Scholar Program. I read that the funds cannot be used for graduate student or postdoctoral stipends. Can I use the budget to compensate my mentor and for consultant's that offer knowledge outside of the topics offered by the core?
A: Mentor(s) can have cumulative support of up to 1.0 person-month. Thus, if two mentors are listed, their total/sum FTE supported by the grant cannot exceed 1 person-month. As for other consultants/co-investigators, there are no restrictions beyond the typical NIH and local guidelines, however, the intent of the Scholar Program is to support the Scholar. Please keep this in consideration while preparing your application. A budget that disproportionately supports senior personnel/faculty may be critiqued on those grounds.

NIH defines Clinical and Translational research as per below:

Clinical Research

Research with human subjects that is:

1. Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. It includes: (a) mechanisms of human disease, (b), therapeutic interventions, (c) clinical trials, or (d) development of new technologies.
2. Epidemiological and behavioral studies.
3. Outcomes research and health services research

Studies falling under 45 CFR 46.101(b) (4) (Exemption 4) are not considered clinical research by this definition. (NIH. Glossary and acronym list. 2013b. [February 13. 2013]. NIH.)

Translational Research

Translational research includes two areas of translation. One is the process of applying discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials and studies in humans. The second area of translation concerns research aimed at enhancing the adoption of best practices in the community. Cost-effectiveness of prevention and treatment strategies is also an important part of translational science. (NIH. Glossary and acronym list. 2013b. [February 13. 2013]. NIH.)

Q: I'm applying for the IDeA-CTR Scholar Program. I read that the funds cannot be used for graduate student or postdoctoral stipends. Can I use the budget to compensate my mentor and for consultant's that offer knowledge outside of the topics offered by the core?

A: Mentor(s) can have cumulative support of up to 1.0 person-month. Thus, if two mentors are listed, their total/sum FTE supported by the grant cannot exceed 1 person-month. As for other consultants/co-investigators, there are no restrictions beyond the typical NIH and local guidelines, however, the intent of the Scholar Program is to support the Scholar. Please keep this in consideration while preparing your application. A budget that disproportionately supports senior personnel/faculty may be critiqued on those grounds.