Tech Transfer Pilot Grant
Request For Applications

GREAT PLAINS
IDeA | Clinical and
Translational Research

Deadline: October 21st, 2020 by 5 PM

The Great Plains IDeA-CTR Network is pleased to announce an opportunity for Tech Transfer Pilot funding through an NIH/NIGMS grant. Successful applicants will receive up to $50,000 in direct costs for a one-year project, as well as access to resources of the Great Plains IDeA-CTR to support their research efforts. This funding is dependent upon the renewal of the Great Plains IDeA-CTR grant. Earliest starting date will be July 1, 2021.

We are requesting a **Letter of Intent (LOI)** (maximum of two pages) using the template provided on page 5 of this document. Those invited to submit full applications will be notified by October 30th, 2020 and at that time will be provided with the instructions for the full application. Solicited applications will be due November 30th, 2020.

Please email your LOI document and NIH biosketch as a single PDF document to the Great Plains IDeA-CTR Office at gpctr@unmc.edu.

To learn more about the GP IDeA-CTR please visit our website. If you have any questions contact Heather Braddock or call 402.559.9870.

The Great Plains IDeA-CTR (GP IDeA-CTR) is a collaboration of 6 institutions eligible for funding which include: Boys Town National Research Hospital, Creighton University, University of Nebraska Kearney, University of Nebraska-Lincoln, University of Nebraska Medical Center, and University of Nebraska Omaha.

The Tech Transfer Pilot Program will provide up to $50,000 over one year to support projects that are focused on translation of intellectual property into clinical and/or community applications. Funds would be used to support investigators obtaining additional data to support patent applications, SBIR/STTR applications, other sponsored research, and/or licensing agreements. Funds may enable the advancement of the project along the translational spectrum. Priority will be placed on CTR projects focused on developing innovative tools and technologies that will support the remote conduct of CTR or improve health outcomes.

Applicable Research: Research projects must address at least one of the research priority areas (page 2) and fall along the translational research spectrum encompassing pre-clinical research, clinical research, clinical implementation research and public health research. The GP IDeA-CTR does **not** fund basic research projects. As broadly defined by the NIH IDeA-CTR Program, "Clinical research" comprises studies and trials in human subjects as defined by NIH Regulations and Policies, and "Translational research" includes research that aims to convert basic research advances to practical applications in humans and research aimed at the adoption of best practices in community healthcare. In addition, we note the following definitions, here, to provide further clarity for researchers in determining whether their projects fall on the translational research spectrum.

> **Basic Research** - Basic research involves scientific exploration that can reveal fundamental mechanisms of biology, disease or behavior. (**This research will not be funded by the Great Plains IDeA-CTR Pilot Grant program**).

Pre-Clinical Research - Pre-clinical research connects the basic science of disease with human medicine. During this stage, scientists develop model interventions to further understand the basis of a disease or disorder and find ways to treat it. Testing is carried out using cell or animal models of disease; samples of human or animal tissues; or computer-assisted simulations of drug, device or diagnostic interactions within living systems.

Clinical Research - Clinical research includes studies to better understand a disease in humans and relate this knowledge to findings in cell or animal models; testing and refinement of new technologies in people; testing of interventions for safety and effectiveness in those with or without disease; behavioral and observational studies; and, outcomes and health services research.

Clinical Implementation - The clinical implementation stage of translation involves the adoption of interventions that have been demonstrated to be useful in a research environment into routine clinical care for the general population. This stage also includes implementation research to evaluate the results of clinical trials and to identify new clinical questions and gaps in care.

Public Health - In this stage of translation, researchers study health outcomes at the population level to determine the effects of diseases and efforts to prevent, diagnose and treat them. Findings help guide scientists working to assess the effects of current interventions and to develop new ones.

Applicants are required to identify the level of research as pre-clinical, clinical, clinical implementation or public health.

For additional questions regarding whether your research satisfies this definition, please contact your local institutional program coordinator (see 'Eligible Institutions and Contacts' on page 3). Alternatively, you may also contact the director of the Pilot Projects Program, Dr. Sarah Holstein. Basic science projects (e.g., those using only animal models or cell lines that are not of direct relevance to human health/disease) will not be considered.

Research Priorities: Priorities include a combination of scientific and regional needs developed by the GP IDeA-CTR Scientific Team and Community Advisory Board. Priority areas are:

- Behavioral health including, mental health, substance abuse (e.g., opioids and alcohol), and violence as a public health issue
- Obesity treatment and prevention
- Aging and age-related cognitive impairment
- Injury prevention
- Technologies and models to improve health access including the evaluation of new or existing tools (e.g., telehealth) with a focus on rural populations
- Connecting clinical care and community services (e.g., schools, food banks, YMCA's)
- Addressing health disparities based on social determinants, race, ethnicity, and geography

Highest priority will be given to the strongest science and projects that focus on priority areas which are most likely to lead to successful extramural funding. Projects that make an impact on medically disadvantaged, underrepresented minority, and/or geographically or clinically isolated populations are of high interest. Projects that can introduce or evaluate new tools or technologies useful in these populations are strongly encouraged.

Interdisciplinary and collaborative approaches: To increase the likelihood of a strong scientific proposal, applicants are encouraged to build upon existing interdisciplinary collaborations and engage in new interdisciplinary or inter-institutional collaborations, and to develop links to other existing IDeA programs

(INBRE and COBRE) in the participating Great Plains region. Applicants are encouraged to consider recruitment of subjects or utilization of data from clinics or Practice-Based Research Networks (PRBN).

Eligibility:
- The Principal Investigator must be current full-time faculty appointment at a participating institution
- Eligible to apply for NIH research grants
- Has a focus on relevant clinical, clinical-translational, or community-translational research
- **Note:** You are not eligible if you have funding from any other IDeA-CTR program that will overlap <u>at the time of this award</u>.

Eligible Institutions and Contacts:
- Boys Town National Research Hospital (BTNRH) – Chris Stecker (chris.stecker@boystown.org)
- Creighton University (CU) – Peter Steyger (petersteyger@creighton.edu)
- University of Nebraska at Kearney (UNK) – Kimberly Carlson (carlsonka1@unk.edu)
- University of Nebraska-Lincoln (UNL) – David Hansen (dhansen1@unl.edu)
- University of Nebraska Medical Center (UNMC) – Sarah Holstein (sarah.holstein@unmc.edu)
- University of Nebraska at Omaha (UNO) – Sara Myers (samyers@unomaha.edu)

For those invited to submit a full proposal:
Full Application Deadline: November 30th, 2020
Earliest Funding Start Date: July 1st, 2021 (pending review, NIH, and all other regulatory approvals)

Funding will depend on the 1) Scientific and technical merit of the proposed project as determined by scientific peer review, 2) Availability of funds, 3) Relevance of the proposed project to the Great Plains IDeA-CTR program priorities, and 4) Approval by the officials funding the grant. Note that funding depends on receipt of Great Plains IDeA-CTR competitive renewal award. Otherwise, funds may be available for some pilots, and other applications can be updated for the next year's cycle if renewal is awarded.

Full Application Process:

1. Only investigators who have submitted the required letter of intent <u>and</u> have been invited to submit a full proposal are eligible.
2. Applicants <u>must</u> consult with a biostatistician in preparation of the <u>full application</u>. If a biostatistician or other statistical support is not available at your institution, or you are located at UNMC, please complete a request for services through CCORDA, here, so that we can identify the appropriate Biostatistics, Epidemiology & Research Design (BERD) statistical consultant for your work. <u>Projects must be reviewed by a biostatistician prior to submission</u>. If you have questions, please contact Dr. Fang Yu, or call 402-559-9436.
3. There is no need to budget the statistician time for your pilot proposal. The BERD Core is funded to support the pilot project investigators on developing the pilot proposals and data analysis for the awarded pilot projects. Applying to the program is done centrally through UNMC's REDCap portal. The portal will be activated for full proposals by October 28th, 2020. The link to submit an application and full RFA will be sent via email to individuals who are invited to apply.
4. If you are new to REDCap or have any difficulties during the application process, please contact the Research Information Technology Office (RITO) at 402-559-4878.
5. Once your application has been submitted, you will receive a confirmation email from REDCap. In addition, you will receive a copy of your submission within two business days from the Great Plains email address: gpctr@unmc.edu to confirm your application was received by our office.
6. The full proposal will include an NIH Face Page, NIH format biosketch (for all principal investigators, co-investigators and other key personnel), Project Summary, a Research Plan (five page maximum),

literature cited, Protection of Human Subjects (if applicable), Vertebrate Animals (if applicable), Budget Form and Budget Justification.

7. Note that no faculty salary support is allowed. Student/post-doctoral stipend is not allowed but student/doctoral salary/wages are permissible. Wages for technical personnel are permissible.

Review Process of Full Proposals

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. Three additional reviewers, including two content experts and one biostatistician, will provide critiques on each application and our Community Advisory Board will also provide feedback.
3. The Overall Impact Score will include other considerations, such as research priorities as stated on page 2, as well as potential for obtaining extramural funding, licensing agreements, establishment of start-up companies, and/or collaboration with industry and/or community partners to further develop the research product (tool, technology, etc.).
4. The Review Committee will suggest ranking to the Steering Committee.
5. The Steering Committee will make recommendations for funding, which will be forwarded to the External Advisory Committee and NIH Program Officers for final approval.
6. You will be notified by mid-February 2021 of your application status.

Expectations of Pilot Awardees

1. Remain current on all regulatory training and approvals and provide all updated approvals to the GP IDeA-CTR.
2. Meet with Pilot Program leadership at 6 and 12 months.
3. Complete a progress report at 6 months and a final report at the conclusion of the funding period.
4. Participate in a one-hour research studio at the end of your funding period.
5. Complete the NIH annual progress report.
6. Become a member of the GP IDeA-CTR via our website.
7. Attend the 2 day Annual Scientific Meeting where you will provide a poster to discuss during a networking session, as well as meet with and discuss your project and progress with our EAC members and NIGMS Program Officers.
8. Provide follow-up for the duration of the parent grant.
9. Cite the GPCTR/NIGMS grant in funding, publications, and presentations.
10. Awardees and co-investigators are required to attend two engagement and dissemination plan meetings with the Community Engagement and Outreach (CEO) core. The first will be held at the beginning of your award (within months 1-2) and the second at the end (between months 11-12). These meetings will result in the development of a communication and dissemination plan to share the results of your work in both community and academic settings.

REQUIRED LETTER OF INTENT TEMPLATE: GREAT PLAINS IDeA-CTR TECH TRANSFER PILOT GRANT

TITLE OF PROPOSED STUDY:

SPECIFIC AIMS: Provide aim statements. Be succinct. Only include the aims statements here, do not include any introductory content.
<u>**Aim 1:**</u>
<u>**Aim 2:**</u>

SIGNIFICANCE AND SCIENTIFIC PREMISE:

Research Priorities: Briefly describe how your project aligns with the GP IDeA-CTR priority areas and the significance of the proposed study.

Scientific Premise: Briefly describe the scientific premise (i.e., the strengths and weakness of the data and previously performed work which the proposal is built upon) of your study based on existing research findings.

APPROACH:
CTR Spectrum: Identify the level of research on the CTR spectrum as pre-clinical, clinical, clinical implementation or public health.
Study objective(s): Describe the primary (and secondary if applicable) objective(s) of the study.
Study design: Describe the design of the study, including the model or population that will be studied, as well as the major assessments that will be performed. Describe the study setting, including, if applicable information on healthcare or community settings where the research will be conducted.
Study outcome(s): Provide information on the primary outcome(s) of the study and, if applicable, secondary outcomes.
Analytic plan: Provide a brief overview of the analytic plan. Where appropriate, provide sample size and power calculations.

Investigators: Describe the identity and role of each team member (including all principal investigator(s), co-investigators (if applicable) and collaborators (if applicable)) will play in the proposed research project.

Tech Transfer: Describe the status of the intellectual property (IP) that will be the focus of the proposed research project. If applicable, describe plans for patent application, partnership with institutional technology transfer and commercialization offices, licensing agreements, establishment of start-up companies and/or new collaborations with industry and/or community partners. Describe whether the project involves innovative tools and/or technologies that will support remote conduct of CTR or improved health outcomes. Describe how the project will support translation of IP into clinical and/or community applications.

ANTICIPATED IMPACT: Describe the potential impact of the study with a focus on the priority areas described in the call for proposals. This section should be written for a broad audience, using lay language, similar to how you would describe your research to a neighbor or family member, who is unfamiliar with your research.

References (not included in 2-page count).

NOTE: DO NOT CHANGE MARGINS OR FONT SIZE WITHIN THE TEMPLATE.