GREAT PLAINS
IDeA | Clinical and
Translational Research

# Tech Transfer Pilot Grant
# Letter of Intent Announcement

Deadline: September 9th, 2024, by 5 PM

The Great Plains IDeA Clinical and Translational Research (GP IDeA-CTR) Network is pleased to announce an opportunity for tech transfer pilot funding through an NIH/NIGMS grant for the 2025-2026 grant cycle. 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. Earliest start date will be July 1st, 2025.

We are requesting a **Letter of Intent (LOI)** (maximum of two pages) using the template on page five of this document. Those invited to submit full applications will be notified by September 23rd, 2024, and provided with instructions for the submission process. Solicited applications will be due November 4th, 2024.

***Please upload your LOI and NIH biosketches for the PI and Co-PI(s) only as a combined PDF by clicking here.**

Questions? Email the Great Plains IDeA-CTR Pilot Projects Coordinator or call 402.559.9870

To learn more about the GP IDeA-CTR visit our website.

The Great Plains IDeA-CTR (GP IDeA-CTR) is a collaboration of 8 institutions eligible for funding which include: Boys Town National Research Hospital (BTNRH), Children's Nebraska, Creighton University (CU), Omaha VA Medical Center (O-VAMC), University of Nebraska Kearney (UNK), University of Nebraska-Lincoln (UNL), University of Nebraska Medical Center (UNMC), and University of Nebraska Omaha (UNO).

The Tech Transfer Pilot award 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 for 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 clinical and translational projects focused on developing innovative tools and technologies that will support the remote conduct of CTR or improve health outcomes.

**Applicable Research:**
Tech Transfer 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 the 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 Community Advisory Board. Priority areas are:

- **Mental health**, defined as "emotional, psychological, and social well-being across every stage of life, from childhood and adolescence through adulthood." For more information, including data and statistics, please visit About Mental Health (cdc.gov)
- **Nutrition, physical activity, and weight**; for more information, visit About the Division of Nutrition, Physical Activity, and Obesity | National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) | CDC
- **Social determinants of health**, such as economic stability, education access and quality, healthcare access and quality, neighborhood and built environment, and social and community context. For more information, visit Social Determinants of Health - Healthy People 2030 | health.gov
- **Leading causes of death** (e.g., heart disease, cancer, accidents, chronic lower respiratory disease, COVID-19, stroke, Alzheimer's disease, diabetes, hypertension, and suicide). For State-specific data, please visit Nebraska (cdc.gov).

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. In addition, 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 at a participating institution.
- Postdoctoral fellows, research associates, visiting personnel and students are not eligible.
- Eligible to apply for NIH research grants.
- Has a focus on relevant preclinical, clinical, clinical implementation or public health research.
- PI's, Co-PI's and Co-I's must be from IDeA-CTR awarded states. Click here to see eligible states.
- **Note:** You are not eligible if you have funding from any other IDeA-CTR program (e.g., COBRE, INBRE) that will overlap at the time of this award.

**Eligible Institutions and Contacts:**

- Boys Town National Research Hospital (BTNRH) – Chris Stecker (chris.stecker@boystown.org)
- Children's Nebraska – Ann Anderson Berry (alanders@unmc.edu)
- Creighton University (CU) – Peter Steyger (petersteyger@creighton.edu)
- Omaha VA Medical Center (O-VAMC) – Fred Hamel (fghamel@unmc.edu)
- University of Nebraska at Kearney (UNK) – Kimberly Carlson (carlsonka1@unk.edu)
- University of Nebraska-Lincoln (UNL) – Jennifer Nelson (jnelson18@unl.edu)
- University of Nebraska Medical Center (UNMC) – Sarah Holstein (sarah.holstein@unmc.edu)
- University of Nebraska at Omaha (UNO) – Roni Reiter-Palmon (rreiter-palmon@unomaha.edu)

**Additional Information:**

1. More than one PI is allowed on this award, if desired.
2. The investigator whose name is listed first and who submits the LOI will be considered the contact PI through the application process and during the award period, if funded. Funding will be awarded to the contact PI's institution and subawards will go to collaborating institutions, if applicable.
3. PI's, Co-PI's and Co-I's must be from IDeA-CTR awarded states. Click here to see eligible states.
4. IRB/IACUC approval titles must match the project title of your pilot award.
5. For projects that need to be registered with clinicaltrials.gov, it is the responsibility of the PI to complete this process. Please contact your IRB if you have any questions.

**For those invited to submit a full proposal:**

- **Full Application Deadline:** November 4th, 2024
- Earliest Funding Start Date: July 1st, 2025
  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, 4) Approval by the officials funding the grant, and 5) Submission of all regulatory approvals and required documents.

**Full Application Process:**

6. Only investigators who have submitted the required letter of intent and have been invited to submit a full proposal are eligible.
2. Applicants are required to consult with a biostatistician in preparation of the full application. 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 the Center for Collaboration on Research Design and Analysis (CCORDA), here, so that we can identify the appropriate statistical consultant for your work. If you have questions, please contact Dr. Fang Yu or call 402-559-9436.
   a) There is no need to budget the statistician's time for review and feedback of your pilot proposal. The Biostatistics, Epidemiology & Research Design (BERD) core of the GP IDeA-CTR is funded to support pilot project investigators with developing their proposals and data analysis for the awarded pilot project.
3. Applying to the program is done centrally through UNMC's REDCap portal. The portal will be activated for full proposals after applicants have been notified that they are eligible 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.
6. The full proposal will include: 1) NIH Face Page, 2) NIH format biosketch (for all principal investigators, co-investigators, and other key personnel), 3) Project Summary, 4) Research Plan (three page maximum), 5) Literature cited, 6) Protection of Human Subjects (if applicable), 7) Vertebrate Animals (if applicable), 8) Budget Form and Budget Justification.
7. Do not include any letters of support.

**Review Process of Full Proposals**

- Three reviewers, including two content experts and one biostatistician, will each provide a critique of your application using the NIH review criteria (*Significance, Investigator(s), Innovation, Approach, Environment),* modified as appropriate for this pilot grant program.
- 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.).
- A study section will be held in mid-January to assess the scientific merit, feasibility, and impact of research proposals.
- Applicants will be notified by mid-February 2025 of their application status.

**Approval Process of Awarded Applications**

- The Pilot Program Review Committee will suggest ranking to the Steering Committee.
- The Steering Committee will make recommendations for funding, which will be forwarded to the External Advisory Committee (EAC) and NIH Program Officers for final approval, as applicable.

**Expectations of Pilot Awardees**

1. Become a member of the GP IDeA-CTR via our website.
2. Remain current on all regulatory training and approvals and provide all updated approvals to the GP IDeA-CTR Pilot Program Coordinator.
3. Respond to short quarterly surveys with updates on significant progress and any barriers until project completion.
4. Complete a final report at the conclusion of the funding period.
5. Complete the NIH annual progress report.
6. Attend the Annual Scientific Meeting in October 2025 and provide progress, as requested.
7. Awardees and investigators are encouraged to participate in a one-hour research studio which are designed to help refine upcoming grant applications or resubmissions by meeting with a team of content experts.
8. Cite the GPCTR/NIGMS grant in funding, publications, and presentations.
9. Watch the pre-recorded webinar on dissemination and consult with the Community Engagement and Outreach Core for additional dissemination and implementation assistance, here.
10. Create a community-friendly product to be disseminated to the community highlighting your pilot findings and solicit input from the Community Advisory Board during your funding period. Examples include a video, policy brief, fact sheet, infographic, poster, podcast, promotional product, interview, or social media advertisement.
11. If your project involves an existing or potentially new invention, you must notify the appropriate commercialization office at your institution (UNeMed (Matthew Boehm for UNMC and UNO investigators), (NUtech Ventures (Cheryl Horst for UNL and UNK investigators), (Stuart Martens for CU investigators), or (Ryan McCreery for BTNRH investigators.
12. In addition to the reporting required for any adverse event, as a courtesy, we ask that you notify the GP IDeA-CTR program coordinator if the study has any adverse events (AE's).

➢ LOI documents must be submitted via REDCap, here.

**Questions?** Contact Heather Braddock via email or by phone: 402-559-9870.

**REQUIRED LETTER OF INTENT TEMPLATE**
**TECH TRANSFER PILOT GRANT**
2-page maximum

*Investigator names and contact information will be requested when submitting documents in REDCap and do not need to be included in the LOI.

**TITLE OF PROPOSED STUDY:**

**IS THIS A RESUBMISSION?**

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

**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 each team member (including all principal investigator(s), co-investigators 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 outlined in the call for proposals. This section should be written for a broad audience, using simple language, similar to how you would describe your proposal to someone who is unfamiliar with research.

**References (not included in 2-page count)**

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