

REQUEST FOR APPLICATIONS:



LOI Due Date: September 13th, 2019

The Great Plains IDeA-CTR Network is pleased to announce an opportunity for 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.

We are requesting a Letter of Intent (maximum of two pages) using the template provided on page 8 of the attached RFA. The LOI application process is outlined on page 3. Those invited to submit full proposals will be notified by September 27th, 2019. Solicited applications will be due November 15th, 2019. The requirements for invitees are also detailed in the RFA.

Please email your LOI 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 8 institutions eligible for funding which include: Boys Town National Research Hospital, North Dakota State University, University of Nebraska Kearney, University of Nebraska Lincoln, University of Nebraska Medical Center, University of Nebraska Omaha, University of North Dakota, and University of South Dakota.

The goal of the Pilot Program is to provide support to 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 in direct costs for a one year project, as well as access to resources of the GP IDeA-CTR to support their research efforts.

Applicable Research: Proposed projects must 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' below). 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. 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 engage in new or existing interdisciplinary collaborations, inter-institution proposals, 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:

- Current full-time faculty appointment at a participating institution
- Eligible to apply for NIH funds (i.e. US citizen or a permanent resident)
- 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 at the time of this award.

Eligible Institutions and Contacts:

- Boys Town Natl. Research Hospital (BTNRH) – Walt Jesteadt (walt.jesteadt@boystown.org)
- North Dakota State University (NDSU) – Mark McCourt (mark.mccourt@ndsu.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)
- University of North Dakota (UND) – Jonathan Geiger (jonathan.geiger@med.und.edu)
- University of South Dakota (USD) – Lee Baugh (lee.baugh@usd.edu)

Full Application Deadline: November 15th, 2019

Earliest Funding Start Date: July 1, 2020 (pending review, NIH, and all other regulatory approvals)

Letter of Intent Application Process:

1. Applicants must consult with biostatistics or trial design in preparation of this application. If a biostatistician or other statistical support is not available at your institution, or you are located at UNMC, please complete a request through CCORDA/BERD [here](#), so that we can identify the appropriate BERD statistical consultant for your work. Projects must be reviewed by a biostatistician prior to submission. If you have questions, please contact Dr. Fang Yu by email, fangyu@unmc.edu, or by phone, 402-559-9436. BERD KCA is funded to support the pilot project investigators on developing the pilot proposals, and data analysis for the awarded pilot projects. There is no need to budget the BERD statistician time for your pilot proposal.
2. The letter of intent should be submitted via email to gpctr@unmc.edu in a PDF format by 5pm CST on September 7th, 2018. Late letters will not be accepted.

Letter of Intent Required Application Materials:

1. PDF Letter of Intent using the provided template included at the end of this document (maximum of 2 pages).
2. NIH format Biosketch (download [here](#)) for the applicant and other key personnel.
3. Project summary (limited to 30 lines or less of text, .5 margins, Arial size 11)
 - a. Include the project's broad, long-term objectives and specific aims. Include a description of the research design and methods for achieving the stated goals. Write in plain language, so even a non-scientist can understand the importance of the project.
4. Note: Appendices will not be accepted.

Review Process:

1. Letters will be reviewed by a scientific committee with representation across the translational research spectrum. Letters will be evaluated for their significance, scientific merit and to determine their suitability as preclinical, clinical, clinical implementation or public health research projects. Projects that align with the emphasis areas in the call for proposals 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.

Full Application Process:

1. Only investigators who have submitted the required letter of intent and have been invited to submit a full proposal are eligible.
Applicants must consult with a biostatistician in preparation of this 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 CCORDA, [here](#), so that we can identify the appropriate Biostatistics, Epidemiology & Research Design (BERD) statistical consultant for your work. Projects must be reviewed by a biostatistician prior to submission. If you have questions, please contact [Dr. Fang Yu](#), or call 402-559-9436.
 - The BERD KCA is funded to support the pilot project investigators on developing the pilot proposals and data analysis for the awarded pilot projects. There is no need to budget the statistician time for your pilot proposal.
2. Applying to the program is done centrally through UNMC's REDCap portal. The portal will be activated for full proposals by October 1st, 2019. The link to submit an application will be sent via email by October 1st to individuals who are invited to apply.
3. If you are new to REDCap or have any difficulties during the application process, please contact the Research Information Technology Office (RITO) at 402-559-4838.
4. 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. You must review the document carefully to ensure that all pages have been received and reply to the email whether or not the document is accurate.

Full proposal required application materials:

Compile the documents listed below in REDCap in the following order:

1. NIH Face Page (download and complete Form Page 1 [here](#)). This does not need to be signed by an institutional official but we strongly encourage you to work with your Grants Administrator or Sponsored Programs office to ensure that **all fields on the NIH Face Page are complete and correct.**
 - a. Project dates will be July 1, 2020 – June 30, 2021.
2. NIH format Biosketch (download [here](#)). A biosketch must be included for the applicant and all other key personnel.
3. Project summary (limited to 30 lines or less of text, .5 margins, Arial size 11)
 - a. Include the project's broad, long-term objectives and specific aims. Include a description of the research design and methods for achieving the stated goals as well as the potential long-term impact the study could have on population health. Write in plain language, so even a non-scientist can understand the importance and impact of the project. This will be critiqued by a member(s) of the Great Plains IDeA-CTR Community Advisory Board (CAB) as well as 3 scientific reviewers. Comments and questions from the CAB member(s) will be shared with scientific reviewers and provided to the applicant at the end of the review process.
4. Research Plan: this portion is limited to **five pages in total**
 - a. Specific Aim(s) (one page maximum)
 - b. Research Strategy
 - i. Significance: a) the scientific premise of the proposed research--the strengths and weaknesses of the research that is used to form the basis for the proposed research question; b) can include preliminary data, although not required.
 - ii. Innovation: a brief summary of how the research project moves the current field forward and incorporates novel concepts, approaches, methodologies, instrumentation or interventions.
 - iii. Approach: Experimental design, including steps taken to ensure scientific rigor (robust and unbiased experimental design, sample, measures, procedures, analysis, interpretation and reporting of results, explained as appropriate for a pilot project, and consideration of key biological variables, if applicable (please see guidelines [here](#)).

- c. Plans for extramural funding applications (e.g. to NIH or other agencies, please specify) upon successful completion of this project.
5. Literature cited (not part of the 5 pages).
6. If your project meets the NIH definition of [human subjects](#) research, you must include a Protection of Human Subjects section (as required by NIH grants; follow the “A Protection of Human Subjects section” which can be accessed via the link above). The Protection of Human Subjects section should also include sections for Inclusion of Women & Minorities and Inclusion of Children. You are also required to complete Human Subjects education (e.g., Collaborative IRB Training Initiative (CITI) training) and submit a copy of the certificate to the GP IDeA-CTR.
7. If your project meets the NIH definition of human subjects research *and* meets the new NIH definition of a clinical trial, you must check “Yes” to the clinical trial question on the NIH face page. If you are unsure whether your project meets the new NIH clinical trial definition, answer the four questions below. If the answer to all four questions is “Yes”, then your project is a clinical trial.
 - a. Does the study involve human participants? Yes / No
 - b. Are the participants prospectively assigned to an intervention? Yes / No
 - c. Is the study designed to evaluate the effect of the intervention on the participants? Yes / No
 - d. Is the effect being evaluated as a health-related biomedical or behavioral outcome? Yes / No

For additional information [click here](#).
8. If your project meets the NIH definition of vertebrate animal research, you are required to include the Vertebrate Animals items for NIH grants (Click [here](#) for instructions).
9. 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.
Protocols must be submitted to IRB for approval within 30 days of notification of award and final approval sent to us within 60 days.
10. If you are conducting a cancer study at UNMC, your protocol must be submitted simultaneously with the IRB and Scientific Review Committee (SRC). Please complete the “SRC New Project Form” that can be downloaded from the SRC [website](#). For questions regarding this process, contact the Protocol Review and Monitoring System (PRMS) office at 402-559-4232. Any partner institution that requires a scientific review for cancer research must follow their institutional process for this approval.
11. Budget – complete form on page 7 of this document.
 - a. Budget Justification document outlining the rationale for all research costs is required (NIH format; on a separate page, explain all expenses that appear in the budget including duties of personnel, use of supplies, other expenses, subaward costs, etc.).
 - b. No faculty effort nor 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.
 - c. Equipment (>\$5,000 per item) is not allowed.
 - d. Renovation is not allowed.
 - e. Honorariums are not allowed.
 - f. Travel is limited to strictly what is necessary to perform research (e.g., no conference travel). Travel to locations outside of the US & Canada is not allowed. Approved travel must be conducted during the time of the awarded funding.
 - g. Indirect costs (F&A) associated with pilot grants will be awarded to the investigator’s institution for NIH-funded pilots. *Please work with your Sponsored Programs office to ensure that your proposal budget includes your institution’s correct F&A rate.* Additional pilot funds may be contributed by partner institutions, rather than NIH, and these institutionally designated awards will not include indirect costs.
 - h. Provide a completed budget from subcontractor(s), only if applicable. If applicable, use the same budget template included below.
12. Appendices will not be accepted.

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 reviewers, including 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.
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.

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 (March 2020).
6. Become a member of the GP IDeA-CTR via our [website](#).
7. Attend the 2 day Annual Scientific Meeting (October 2020) 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.

DETAILED BUDGET

FROM
07/01/2020

THROUGH
06/30/2021

- List PERSONNEL (*Applicant organization only; no faculty effort nor faculty salary support is allowed*)
- Use Calendar, Academic, or Summer to enter months devoted to project
- Enter Dollar Amounts Requested (*omit cents*) for Salary Requested and Fringe Benefits

NAME	ROLE ON PROJECT	Cal. Months	Acad. Months	Summer Months	INST.BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTAL
SALARY & FRINGE SUBTOTALS →								
CONSULTANT COSTS								
SUPPLIES (<i>Itemize by category</i>)								
TRAVEL (<i>only what is necessary to perform research; no conference or training travel</i>)								
OTHER EXPENSES (<i>Itemize by category</i>)								
CONSORTIUM/SUBAWARD COSTS (<i>Include subaward F&A as a direct cost</i>)								
SUBTOTAL DIRECT COSTS (<i>Item 7a, Face Page</i>)								\$
Institutional F&A Rate:							FACILITIES & ADMINISTRATIVE COSTS	
TOTAL COSTS FOR PROJECT (<i>Item 7b, Face Page</i>)								\$

PRINCIPAL INVESTIGATOR(s):
CO-INVESTIGATORS:
COLLABORATORS/MENTORS:
INSTITUTION:
EMAIL:



REQUIRED LETTER OF INTENT (LOI) TEMPLATE: GREAT PLAINS IDeA-CTR PILOT GRANTS

TITLE OF PROPOSED STUDY:

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 upon which the proposal is built upon) of your study based on existing research findings.

APPROACH:

Study Population and Setting: Describe inclusion and exclusion criteria and provide characteristics of the population that your sample is intended to represent (e.g., the study will recruit participants who have hypertension, are Latino, and over the age of 40). Describe the study setting, including, if applicable information on healthcare or community settings where the research will be conducted.

Describe the preventive, therapeutic, or diagnostic strategy to be tested and the translational level: A brief description of the independent variable and, if applicable, any comparators (e.g., standard care). Include a sentence that indicates where on the translational spectrum the study falls (pre-clinical, clinical, clinical implementation, or public health).

Describe the study outcomes: Provide information on the primary outcome(s) of the study and, if applicable, secondary outcomes.

Study Design: Provide an overview of the study design including timing of assessments.

Analytic plan: Provide a brief overview of the analytic plan.

Sample Size and Power: Where appropriate, provide sample size and power calculations. (e.g., a sample size of X subjects per arm will provide Y% power to detect a between-arm effect size of Z in primary outcome measures, assuming a two-tailed α of 0.025. Assuming a 20% attrition rate, the final sample size is estimated at A subjects per arm).

INVESTIGATORS: Describe *relevant* prior research of the PI and team providing references to key publications.

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.