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

https://gpctr.unmc.edu

LOI is Required
LOI Due Date: September 7th, 2018

The Great Plains IDeA-CTR Network is pleased to announce an opportunity for pilot funding through an NIH/NIGMS grant.

We are requesting a Letter of Intent (maximum of two pages) using the template provided at the end of this document. The LOI application process is explained on page 3.

Those invited to submit full applications will be notified by September 28th, 2018. Solicited applications will be due November 16th, 2018. The RFA and requirements for invitees are detailed below. Please email your LOI and NIH biosketch as a single PDF document to the Great Plains IDeA-CTR Office at gpctr@unmc.edu. If you have any questions, contact Heather Braddock at heather.braddock@unmc.edu or 402.559.9870.

The Great Plains IDeA-CTR (GP IDeA-CTR) is a collaboration of 8 eligible institutions 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 be clinical and translational research. While there are many definitions of CTR, the GP IDeA-CTR uses the following definitions:

Clinical Research is 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. Clinical research that will be supported by this granting mechanism includes clinical trials, the development of new technologies, epidemiological and behavioral studies, and outcomes and health services research.

Translational Research is about moving research on treatments, diagnostics and prevention from the laboratory and pre-clinical settings to patient-and population-based settings. Applicants are required to identify the level of translational research proposed using the T1 to T4 descriptions below.

T1 Translation to humans: Seeks to move fundamental discovery into health application.
T2 Translation to patients: Develops health applications with implications for evidence-based practice.
T3 Translation to practice: Investigates the movement of evidence-based guidelines to health practices.
T4 Translation to communities: Investigates the impact of evidence-practice and policies to population health impact/investigators providing communities with the optimal intervention.
For additional questions regarding whether your research satisfies this definition, please contact your local institutional program coordinator (see ‘Eligible Institutions and Contacts’ below). Alternatively, if you have questions about whether your research applies, you may also contact Dr. Sarah Holstein, sarah.holstein@unmc.edu. Basic science projects (e.g. those using only animal models or cell lines in the absence of patient level data) will not be considered.

**Research Priorities:** Priorities include a combination of scientific and regional priorities 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 those projects most likely to lead to successful extramural funding. In addition, projects that make an impact on medically disadvantaged, underrepresented minority, and/or geographically or clinically isolated populations—and can introduce or evaluate new tools or technologies useful in these populations—are of high interest.

**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-institutional proposals, and to develop links to other existing IDeA programs (INBRE and COBRE) in the participating Great Plains region.

**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
- GP IDeA-CTR faculty with pilot funding with projects that are competitive and have demonstrated good progress on the current award are eligible
- **Note:** You are not eligible if you currently have funding from any IDeA-CTR program

**Eligible Institutions and Contacts:**
- Boys Town Natl. Research Hospital (BTNRH) – Lori Leibold (lori.leibold@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) – Robin Miskimins (robin.miskimins@usd.edu)

**Required Letter of Intent Due Date:** September 7th, 2018
**Notification of Request for Full Proposal:** September 28th, 2018
**Application Deadline:** November 16th, 2018
**Earliest Funding Start Date:** July 1, 2019 (pending review, NIH and all regulatory approvals)
Letter of Intent Application Process:
1. If needed, applicants may consult with a biostatistician in the letter of intent development. If a biostatistician or other statistical support is not available at your institution, or you are located at UNMC, please contact Dr. Fang Yu by email, fangyu@unmc.edu or by phone, 402-559-9436, to discuss who the appropriate statistical consultant would be for your work. Identify that you are preparing a GP IDeA-CTR pilot letter of intent.
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 2 pages).
2. NIH format Biosketches (download from https://grants.nih.gov/grants/forms/biosketch.htm) for 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 and research spectrum. Letters will be evaluated for their significance and scientific merit and to determine their suitability as clinical or translational 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.

2. 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 contact Dr. Fang Yu by email, fangyu@unmc.edu or by phone, 402-559-9436, to discuss who the appropriate statistical consultant would be for your work. Projects are to be reviewed by a biostatistician prior to submission.

3. Application to the program is done centrally through UNMC’s REDCap portal. The portal will be activated for full proposals by October 1st, 2018. This portal is best supported through Chrome: https://unmcredcap.unmc.edu/redcap/surveys/?s=AKT49X4H8R

4. If you are new to REDCap or have any difficulties during the application process, please contact Satya Lalam at the Research Information Technology Office (RITO) at 402-559-4838.

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). You must review the document carefully to ensure that all pages have been received and reply to the email whether or not it is accurate.

Full proposal required application materials:
Compile the below application materials in REDCap.

1. NIH Face Page (download and complete Form Page 1 from https://grants.nih.gov/grants/funding/phs398/phs398.html). 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, 2019 – June 30, 2020.

2. NIH format Biosketch (download from https://grants.nih.gov/grants/forms/biosketch.htm) for 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. Research Plan: this portion is limited to five pages in total (sections included in italics)
   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
      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 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-011.html).
   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 (https://humansubjects.nih.gov/walkthrough-investigator - tabpanel11), you are required to include a Protection of Human Subjects section (as required by NIH grants; follow the “A Protection of Human Subjects section” link on the above web site). 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).
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, visit: https://grants.nih.gov/policy/clinical-trials.htm

8. If your project meets the NIH definition of vertebrate animal research, you are required to include the Vertebrate Animals items for NIH grants (for instructions: https://grants.nih.gov/grants/olaw/vertebrate_animal_section.htm).

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 funding and final approval sent to us within 60 days. If you are conducting a cancer study at UNMC, your protocol must be submitted simultaneously to the Scientific Review Committee (SRC). This also applies to any partner institution that requires a scientific review for cancer research. In addition, you must include the following sections in the application:

   a. Budget Justification document outlining the rational 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. Faculty effort is not allowed and faculty salary support is not 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.
   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.

11. Note: 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 will provide critiques on each application.
3. The Overall Impact Score will include other considerations, as stated in the introduction above.
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 Staff for Final Approval.

Funding

Provided all regulatory approvals (IRB, IACUC, NIGMS) have been obtained, funding will be made available to your institution on July 1, 2019.
List PERSONNEL (Applicant organization only; no faculty effort nor faculty salary support is allowed)
Use Cal, Acad, or Summer to Enter Months Devoted to Project
Enter Dollar Amounts Requested (omit cents) for Salary Requested and Fringe Benefits

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**SALARY & FRINGE SUBTOTALS**

**CONSULTANT COSTS**

**SUPPLIES** *(Itemize by category)*

**TRAVEL** *(only what is necessary to perform research; no conference or training travel)*

**OTHER EXPENSES** *(Itemize by category)*

**CONSORTIUM/SUBAWARD COSTS** *(Include subaward F&A as a direct cost)*

**SUBTOTAL DIRECT COSTS** *(Item 7a, Face Page)* $  

Institutional F&A Rate: **FACILITIES & ADMINISTRATIVE COSTS**

**TOTAL COSTS FOR PROJECT** *(Item 7b, Face Page)* $
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 (i.e., T1, T2, T3, T4).

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: 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. Where appropriate, provide sample size and power calculations.

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.