Specialty Pilot Funding Announcement:
Biostatistics, Epidemiology, and Data Science Methodology Pilot Award

Full Submission Guidelines

GREAT PLAINS IDeA | Clinical and Translational Research

Deadline: JANUARY 19, 2024 AT 5:00 PM CST

The Great Plains IDeA-CTR Network is pleased to announce an opportunity for Biostatistics, Epidemiology, and Data Science Methodology Pilot funding through an NIH/NIGMS grant. Successful applicants will receive up to $30,000 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 potential project start date will be **July 1, 2024**.

To learn more about the GP IDeA-CTR please visit our website.
If you have any questions, contact Heather Braddock (heather.braddock@unmc.edu or call 402.559.9870).

The Great Plains IDeA-CTR Network (GP IDeA-CTR) is a collaboration of 8 eligible institutions which include: Boys Town National Research Hospital, Children's Hospital and Medical Center, Creighton University, Omaha Veterans Administration Medical Center, University of Nebraska Kearney, University of Nebraska Lincoln, University of Nebraska Medical Center, and University of Nebraska Omaha.

This funding program aims to promote the development and use of novel statistical, epidemiological, and data science methods to address a clinical or translational research issue. The goal is to support investigators in obtaining further extramural funding.

Examples of relevant topics that this pilot would support include, but are not limited to:

- Drug target evaluation
- Mechanisms of action of therapeutics
- Optimization of clinical trials
- Subject identification, recruitment, and/or retention
- Improving the diversity, equity and inclusiveness in biomedical research and its outcomes
- Social determinants of health
- Prediction of disease subtypes
- Developing diagnostic tools using deep learning algorithms
- Disease survival and risk prediction using AI/ML
- Disease surveillance
- Acquisition and analysis of real-world, health-relevant data (e.g., wearables/smart devices)
- Healthcare workflow
- Clinical decision support systems

This grant will provide up to $30,000 for a one-year project. Awards may pay for wages and salaries of faculty, graduate student, software, datasets, travel, or other appropriately justified expenses. **Please reference the budget description below for a full list of allowable and unallowable expenses.**

Applicable Research: The project 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**).
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> **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.
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> **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; outcomes and health services research.
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> **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.
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> **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, if you have questions about whether your research will be considered eligible, you may contact Elizabeth Reisher (ereisher@unmc.edu). 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, defined as "emotions and behaviors that affect your overall wellbeing" –CMS (e.g., mental health, substance use (opioids and alcohol), sexual health, and suicide)
- Chronic diseases and leading causes of death (e.g., heart disease, cancer, chronic lower respiratory disease, cerebrovascular disease, Alzheimer's disease and age-related cognitive impairment, COVID-19) and associated risk factors (e.g., obesity, diabetes, hypertension). For State-specific data, please visit Nebraska (cdc.gov)
- Injury prevention and violence (e.g., sex trafficking, abduction of women in native populations)
- Telehealth and innovative technology to improve health access to rural and underserved populations
- Connecting clinical care and community services (e.g., schools, food banks, YMCA's)

- Addressing health disparities based on race, ethnicity, gender, sexual orientation, and geography
- Addressing health disparities based on food insecurity, economic instability, education access and quality, health care access and quality, neighborhood and built environment, social and community context

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 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 have a 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 to submit as a Principal Investigator if you are currently funded by the GP IDeA-CTR

Eligible Institutions and Contacts:

- Boys Town National Research Hospital (BTNRH) – Chris Stecker (chris.stecker@boystown.org)
- Children's Hospital and Medical Center (CHMC) – Ann Anderson-Berry (aberry@childrensnebrasks.org)
- Creighton University (CU) – Peter Steyger (petersteyger@creighton.edu)
- Omaha Veterans Administration Medical Center (O-VAMC) – Frederick Hamel (Frederick.Hamel@va.gov)
- 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) – Ying Zhang (ying.zhang@unmc.edu)
- University of Nebraska at Omaha (UNO) – Roni Reiter-Palmon (rreiter-palmon@unomaha.edu)

Full Application Deadline: JANUARY 19, 2024
Earliest Funding Start Date: July 1, 2024 (pending review, NIH, and all other regulatory approvals)
Application Process:

1. Applying to the program is done centrally through UNMC's REDCap portal. **Please submit your proposal here: https://go.unmc.edu/berdpilot24**
2. 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.
3. Once your application has been submitted, you will receive a confirmation email from REDCap. 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 1st, 2024 – June 30th, 2025.

2. NIH format Biosketch (download here). A biosketch must be included for all principal investigators, co-investigators 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. Include a description of the composition of the research team and indicate how this research project is interdisciplinary in nature.
4. Research Plan: this portion is limited to ***three pages in total***
    a. Specific Aim(s)
    b. Research Strategy
        i. Significance: 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.
        ii. Innovation: A brief summary of how the research project moves the current field forward and incorporates novel concepts, approaches, methodologies, instrumentation or interventions. Describe how the newly formed multidisciplinary team will provide a novel approach to the research.
        iii. Approach: Experimental design, including steps taken to ensure scientific rigor, 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).
        iv. Team Development: Describe the leadership structure of the team. Describe the role of each team member in the proposed research project. Describe the plan for interaction and communication between team investigators.
    c. Future directions. Describe how successful completion of the proposed studies will lead to further project development, including plans for seeking additional funding opportunities.
5. Literature cited (not part of the 3 pages). Please include with the Research Plan.
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 "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. If awarded, 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, if awarded.
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 approval (respectively) is required before funds can be released.
10. To reduce potential funding delays, protocols should be submitted to the IRB for approval within 15 days of notification of award, with final approval sent to our office within 60 days. If your projects is exempt from IRB approval an exemption letter or email from the IRB is still required.
11. If you are conducting a cancer study at UNMC that involves human subjects research, your protocol must be submitted simultaneously to the IRB and Scientific Review Committee (SRC) for approval from both. Please complete the "SRC New Project Form" that can be downloaded from the Protocol Review and

Monitoring System (PRMS) website. For questions regarding this process, contact the PRMS office at 402-559-4232. Applicants from partner institution's that require a scientific review for cancer research must follow their institutional process for this approval.

12. Budget – complete form on page 6 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.).
    a) Faculty salary support is allowed. Student/post-doctoral stipend is not allowed (they must be paid through your institution's payroll system) but student/doctoral salary/wages are permissible. Wages for technical personnel are permissible.
    b. Equipment (>$5,000 per item) is not allowed.
    c. Renovation is not allowed.
    d. Honorariums are not allowed.
    e. Domestic travel is allowed if it is directly related to the conduct of the research project and not for presentation of the results. International travel is not permissible.
    f. 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.
13. Use the budget template on page 6 to provide a separate budget sheet for subaward(s), only if applicable. Make sure to include subcontract indirects in your direct costs Appendices will not be accepted.

Review Process and Scoring

1. Proposals will be reviewed and scored by reviewers selected by the IDeA-CTR Biostatistics, Epidemiology and Research Design Core and Biomedical Informatics, Bioinformatics and Cyberinfrastructure Enhancement Core.
2. Proposals and scores will be submitted to the GP IDeA-CTR Steering Committee and External Advisory Committee for approval.
3. Highest reviewed proposals will be sent to NIH for final approval.
4. Selections will be announced in Mid-April.

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. Complete a final report at the conclusion of the funding period.
4. Complete the NIH annual progress report and other reports as requested.
5. Attend the Annual Scientific Meeting and provide progress on your project which will be shared with our EAC members and NIGMS Program Officers, as requested.
6. Complete an engagement and dissemination E-module hosted by the Community Engagement and Outreach (CEO) core.
7. Provide follow-up for the duration of the parent grant.
8. Cite the GPCTR/NIGMS grant in funding, publications, and presentations.
9. Awardees and investigators are encouraged to participate in a one-hour research studio.
10. 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.
11. 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).

Questions

If you have any questions regarding this process, contact Elizabeth Reisher at ereisher@unmc.edu or the Great Plains IDeA-CTR Office at gpctr@unmc.edu or 402.552.2260.