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 Hospital and Medical Center (CHMC), 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).

**Team Development Pilot**

**Full Submission Guidelines**

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 **Deadline:** November 1, 2021

The Great Plains IDeA-CTR Network is pleased to announce an opportunity for Team Development Pilot funding through an NIH/NIGMS grant. Successful applicants will receive up to $25,000 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 starting date will be July 1, 2022.

To learn more about the GP IDeA-CTR, please visit our [website](https://gpctr.unmc.edu/). If you have any questions, contact Heather Braddock or 402-559-9870.

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The Team Development Pilot grant will provide up to $25,000 over one year to foster new team formation with cross-disciplinary and cross-institutional integration of basic, preclinical, clinical, clinical implementation, and public health research. Single investigators working in isolation are not eligible for this funding mechanism. Instead, there should be evidence of a team-based approach involving two or more investigators from different disciplines. The goal of this funding mechanism is to provide initial funds to facilitate formation of a new multidisciplinary research team and generate preliminary data to support subsequent grant applications. Established research teams with prior history of joint publications and/or grant funding are not eligible for this funding mechanism, but instead should consider applying for the Team Research Pilot funding opportunity.

**Applicable Research:** Team Development 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](https://grants.nih.gov/grants/guide/pa-files/PAR-18-265.html#_Part_1._Overview), 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](https://ncats.nih.gov/translation/spectrum), 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 Community Advisory Board. Priority areas are:

* Behavioral health including mental health, substance use, and violence as a public health problem
* Obesity across the lifespan
* Aging and age-related cognitive impairment
* Injury prevention
* 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

In addition, applications focused on the leading causes of death in Nebraska (as determined by the [CDC](https://www.cdc.gov/nchs/pressroom/states/nebraska/ne.htm)) are encouraged.

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:**

* At least one of the Principal Investigators must be current full-time faculty 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 at the time of this award.

**Eligible Institutions and Contacts:**

* Boys Town National Research Hospital (BTNRH) – Chris Stecker (christ.stecker@boystown.org)
* Children’s Hospital and Medical Center (CHMC) – 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) – 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)

**Full Application Deadline:** November 1st, 2021

**Earliest Funding Start Date:** July 1st, 2022 (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.

**Application Process:**

1. Applicants are encouraged to 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 the Center for Collaboration on Research Design and Analysis (CCORDA), [here](https://www.unmc.edu/publichealth/centers/ccorda/request.html), 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.
* There is no need to budget the statistician time for your pilot proposal. The Biostatistics, Epidemiology & Research Design (BERD) core of the GP IDeA-CTR is funded to support the pilot project investigators on developing the pilot proposals and data analysis for the awarded pilot projects.
1. Applying to the program is done centrally through UNMC’s REDCap portal. The application can be accessed via this link: <https://unmcredcap.unmc.edu/redcap/surveys/?s=YKK7TT47DL37DKTM>
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. 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 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](https://grants.nih.gov/grants/funding/phs398/fp1.pdf)). For UNMC applicants, this form 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. For applicants outside of UNMC, please ensure that your documents are signed by the appropriate institutional official(s) and are reviewed by your Grants Administrator or Sponsored Programs Office.
1. NIH format Biosketch (download [here](https://grants.nih.gov/grants/forms/biosketch.htm)). A biosketch must be included for all principal investigators, co-investigators and all other key personnel and must include other support currently being received.
2. Project summary (limited to 30 lines or less of text, .5 margins, Arial size 11)
	1. Include the following:
		1. Project’s broad, long-term objectives and specific aims.
		2. Briefly describe the research design and methods for achieving the stated goals.
		3. Clearly describe the potential long-term community impact.

 Write the project summary in plain language, so even a non-scientist can understand the importance and potential community 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.

1. Research Plan: this portion is limited to ***three pages in total***
2. Specific Aim(s)
3. Research Strategy
	* 1. 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.
		2. 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.
		3. 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 NIH guidelines [here](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-228.html)).
		4. 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.
4. 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).
6. If your project meets the NIH definition of [human subjects](https://humansubjects.nih.gov/walkthrough-investigator%20-%20tabpanel11) 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 training (e.g., Collaborative IRB Training Initiative (CITI)) 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.
	1. Does the study involve human participants? Yes / No
	2. Are the participants prospectively assigned to an intervention? Yes / No
	3. Is the study designed to evaluate the effect of the intervention on the participants? Yes / No
	4. Is the effect being evaluated as a health-related biomedical or behavioral outcome? Yes / No

For additional information visit the NIH clinical trial requirements webpage, [here](https://grants.nih.gov/policy/clinical-trials.htm).

1. 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](https://grants.nih.gov/grants/olaw/vertebrate_animal_section.htm) for instructions).
2. Regulatory approvals: If your project includes human subjects or vertebrate animals, your institutional IRB and/or IACUC approval (respectively) is required before funds can be released.
3. 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 IRB approval is not needed, an exemption letter or email from the IRB is still required.
4. 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](https://www.unmc.edu/cancercenter/clinical/prms.html). For questions regarding this process, contact the 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.
5. Budget
6. Complete the budget form on page 7 of this document.
7. Complete 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.).
8. No 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.
9. Equipment (>$5,000 per item) is not allowed.
10. Renovation is not allowed.
11. Honorariums are not allowed.
12. Travel is allowed if travel is directly related to the conduct of the research project and not for presentation of the results. International travel is not permissible.
13. 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.
14. Provide a completed budget from subcontractor(s), only if applicable. If applicable, use the same budget template included below. Make sure to include subcontract indirects in your direct costs.
15. 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 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 the strength of the research team and potential for obtaining extramural funding.
			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 2022 of your application status.

**Expectations of Pilot Awardees**

1. Become a member of the GP IDeA-CTR via our [website](https://gpctr.unmc.edu/membership/).
2. Remain current on all regulatory training and approvals and provide all updated approvals to the GP IDeA-CTR.
3. Meet with Pilot Program leadership at 6 and 12 months.
4. Complete a progress report at 6 months and a final report at the conclusion of the funding period.
5. Complete the NIH annual progress report.
6. Attend the Annual Scientific Meeting where you will provide a poster of your project and progress to discuss with attendees as well as with our EAC members and NIGMS Program Officers, as requested.
7. Participate in a one-hour research studio at the end of your funding period.
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.
11. Applicants should notify UNeMed (Matthew Boehm for UNMC and UNO investigators) or NUtech Ventures (Cheryl Horst for UNL and UNO investigators), Stuart Martens for CU investigators, or Ryan McCreery for BTNRH investigators, if your project involves an existing or potentially new invention.
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).

Questions? Contact Heather Braddock via email or by phone: 402.559.9870

Program Director/Principal Investigator (Last, First, Middle):

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| --- | --- | --- | --- |
| DETAILED BUDGET (Direct costs only) | FROM7/1/2022 | THROUGH6/30/2023 | GRANT NUMBER      |

List PERSONNEL *(Applicant organization only)*

Use Cal, Acad, 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.Mnths | Acad.Mnths | SummerMnths | SALARY REQUESTED | FRINGE BENEFITS | TOTALS |
|       | PD/PI |       |       |       |       |       |       |
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| SUBTOTALS |  |  |  |  |       |       |       |
| CONSULTANT COSTS      |       |
| EQUIPMENT *(Itemize)*      |       |
| SUPPLIES *(Itemize by category)*      |       |
| TRAVEL      |       |
| INPATIENT CARE COSTS |       |       |
| OUTPATIENT CARE COSTS |       |       |
| ALTERATIONS AND RENOVATIONS *(Itemize by category)*      |       |
| OTHER EXPENSES *(Itemize by category)*      |       |
| SUBTOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD | **$** |       |
| CONSORTIUM/CONTRACTUAL COSTS | DIRECT COSTS |       |
| CONSORTIUM/CONTRACTUAL COSTS | FACILITIES AND ADMINISTRATIVE COSTS |       |
| TOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD *(Item 8a, Face Page)* | **$** |       |

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