



REQUEST FOR APPLICATIONS

Great Plains IDeA-CTR Pilot Grant Program Cancer Related Research RFA

Application Deadline: January 31, 2018 | 5:00 PM

<https://gpctr.unmc.edu/>

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 cancer-related, clinical-translational research (CTR) projects and help investigators obtain preliminary data necessary for successful investigator-initiated extramural grants. The pilot project application can have a budget adding up to \$100,000 to be spent in 24 months, but must have a strong explanation as to why this project would benefit from two years instead of one year. The first \$50,000 will be given for 12 months and at the end of month 12, a progress report will be due. The second \$50,000 for months 13-24 is contingent upon submission of a progress report where sufficient progress has been shown in Year 1 (as determined by Pilot Projects KCA leadership). Resources of the GP IDeA-CTR to support their research efforts are also available.

Applicable Research: Proposed projects must be clinical-translational research and pursue research questions related to cancer prevention and control. 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 applications for treatments, diagnostics and prevention from pre-clinical work to population level impact. 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' on page 2). Alternatively, if you have questions about whether your research applies, you may also contact Dr. Howard Fox at hfox@unmc.edu or Dr. Paul Estabrooks at paul.estabrooks@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.**

Additional Research Priorities: Priorities include a combination of scientific and regional priorities developed by the GP IDeA-CTR Scientific Team and Community Advisory Board. Responsive applications will be cancer-focused and may or may not address these additional priority areas:

- 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, YMCAs, etc.)
- 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-institution 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, cancer research.
- GP IDeA-CTR faculty with pilot funding with projects that are competitive and have demonstrated good progress on the current award are eligible.

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) – Paul Estabrooks (paul.estabrooks@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)

Full Application Process

1. Applicants are encouraged to consult with their institutional program coordinator, listed on page 2 of this document.
2. Note that assistance with topics such as biostatistics or trial design in preparation and execution of this application is supported by the GP IDeA CTR. 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. For those at UNMC, you must contact Fang Yu even if you have consulted with a different biostatistician.

3. Application to the program is done centrally through UNMC's REDCap portal. This portal is best supported through Chrome: <https://unmcredcap.unmc.edu/redcap/surveys/?s=T4LHHCC4MN>
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 or satyakumar.lalam@unmc.edu.
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 one business day from the Great Plains email address: gpctr@unmc.edu. Review the document carefully to ensure that all pages have been received.

Full proposal required application materials:

Compile the below application materials below in redcap.

1. NIH Face Page (download and complete Form page 1 from <https://grants.nih.gov/grants/funding/phs398/phs398.html>)
2. NIH format Biosketch (download from <https://grants.nih.gov/grants/forms/biosketch.htm>) for applicant and other key personnel
3. Research Plan: this portion is limited to **five pages in total** (sections included in italics)
 - a. *Specific Aim(s)*
 - b. *Research Strategy*
 - i. *Significance: a) the scientific premise of the proposed research--the strength 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.*
4. Literature Cited (not part of the 5 pages)
5. Inclusion enrollment report, if applicable, <https://grants.nih.gov/grants/forms/inclusion-enrollment-report.pdf>.
6. 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. While approval is not required at time of application, submission for approval is **strongly recommended** to avoid delays in timely beginning of projects. **If selected to receive a pilot grant, awardee is required to submit to IRB/IACUC/SRC within 7 days of notification.**
7. In addition, you must include the following sections in the application:
 - a. Human Subjects: If your project meets the NIH definition of human subject research (<https://humansubjects.nih.gov/walkthrough-investigator-tabpanel11>), include the Protection of Human Subjects items for NIH grants (follow the "A Protection of Human Subjects section" link on the above web site). Please note that those doing human subject research need to complete Human Subjects education (e.g. Collaborative IRB Training Initiative (CITI) training).
 - b. Vertebrate Animals: Include the Vertebrate Animals items for NIH grants (instructions at https://grants.nih.gov/grants/olaw/vertebrate_animal_section.htm).
8. Budget (see pages 5 and 6)

- a. Faculty salary support is not allowed. Student/post-doctoral stipend is not allowed but salary/wages are permissible.
 - b. Equipment (>\$5,000 per item) purchase is not allowed.
 - c. Travel is limited to what is necessary to perform research.
 - d. Indirect costs (F&A) associated with pilot grants will be awarded to investigator's institution for NIH-funded pilots. Additional pilot funds may be contributed by partner institutions, rather than NIH, these institutionally designated awards will not include indirect costs.
9. Budget Justification (on a separate page, explain duties of personnel, use of supplies, other expenses, etc.).
 10. Lay summary of project, including the rationale for the project, specific aims, approach, and potential impact (one page limit .5 margins, Arial font size 11). You should consider that you are writing this summary for one of your neighbors or family members, who are unfamiliar with your research.
 11. 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. Written critiques will be reviewed using a study-section format to determine the highest impact projects.
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 Board and NIH Program Staff for Final Approval.

Funding

Earliest Funding Start Date: June 2018 (pending review, EAC, funding institutions, NIH and all regulatory approvals). Funding will be made available to your institution following the approvals listed above, and upon receiving all necessary regulatory approval documentation.

Post-Selection Requirements

- Great Plains IDeA-CTR Annual Scientific Meeting
All recipients of Pilot Awards will be required to attend the Annual Scientific Meeting, and present their project/results. For those outside of the region in which the meeting is held, travel funds will be provided.
- Meet with Pilot Program leadership team every 6 months.
- Submit an annual written report.
- Annual follow-up for the duration of the parent grant.

Questions

Please contact the Great Plains IDeA-CTR Office at gpctr@unmc.edu or 402.552.2260. Additionally, a list of frequently asked questions (FAQ) is available on our website: https://gpctr.unmc.edu/about/pilot-projects/pilot_program_application_faqs.html.

DETAILED BUDGET FOR FULL PROPOSAL <u>YEAR 1</u>		Dates: FROM		THROUGH
NAME	Fringe Rate*	SALARY REQUESTED	FRINGE BENEFITS *	TOTAL COST
<i>*Not to exceed fringe allowable rate from applicant's institution; Must provide institutional documentation of fringe rate</i>				
SALARY SUBTOTAL →				\$
RESEARCH EXPENSES <i>(Itemize by category)</i> **				
CONSULTANT COSTS				
EQUIPMENT				
SUPPLIES				
TRAVEL				
OTHER EXPENSES				
BUDGET JUSTIFICATION:				
OTHER EXPENSES SUBTOTAL →				\$
TOTAL DIRECT COSTS FOR BUDGET PERIOD (NOT TO EXCEED \$ 50,000)				\$
<p>Applications must include an itemized budget. Up to \$50,000 per applicant per year may be requested for research costs. Please note: a) Faculty salary support is not allowed. Student/post-doctoral stipend is not allowed but salary/wages are permissible; (b) Equipment (>\$5,000 per item) purchase is not allowed; (c) Travel is limited to what is necessary to perform research; (d) Indirect costs (F&A) associated with pilot grants will be awarded to investigator's institution for NIH-funded pilots. Additional pilot funds may be contributed by partner institutions, rather than NIH, these institutionally designated awards will not include indirect costs.</p> <p>For questions concerning the budget or budget justification, contact Melissa Welch-Lazoritz at m.welchlazoritz@unmc.edu or 402.552.6579.</p>				

DETAILED BUDGET FOR FULL PROPOSAL <u>YEAR 2</u>		Dates: FROM		THROUGH
NAME	Fringe Rate*	SALARY REQUESTED	FRINGE BENEFITS *	TOTAL COST
<i>*Not to exceed fringe allowable rate from applicant's institution; Must provide institutional documentation of fringe rate</i>				
SALARY SUBTOTAL →				\$
RESEARCH EXPENSES <i>(Itemize by category)</i> **				
CONSULTANT COSTS				
EQUIPMENT				
SUPPLIES				
TRAVEL				
OTHER EXPENSES				
BUDGET JUSTIFICATION:				
OTHER EXPENSES SUBTOTAL →				\$
TOTAL DIRECT COSTS FOR BUDGET PERIOD (NOT TO EXCEED \$ 50,000)				\$
<p>Applications must include an itemized budget. Up to \$50,000 per applicant per year may be requested for research costs. Please note: a) Faculty salary support is not allowed. Student/post-doctoral stipend is not allowed but salary/wages are permissible; (b) Equipment (>\$5,000 per item) purchase is not allowed; (c) Travel is limited to what is necessary to perform research; (d) Indirect costs (F&A) associated with pilot grants will be awarded to investigator's institution for NIH-funded pilots. Additional pilot funds may be contributed by partner institutions, rather than NIH, these institutionally designated awards will not include indirect costs.</p> <p>For questions concerning the budget or budget justification, contact Melissa Welch-Lazoritz at m.welchlazoritz@unmc.edu or 402.552.6579.</p>				