

The Great Plains IDeA-Clinical Translational Research (GP IDeA-CTR) Network is pleased to announce that funding through a NIH/NIGMS grant is available to support <u>one faculty member</u> who is in the early stages of their career. The GP IDeA-CTR is a collaboration of 8 eligible institutions within Nebraska which include: University of Nebraska Medical Center (UNMC), University of Nebraska Omaha (UNO), University of Nebraska-Lincoln (UNL), University of Nebraska Kearny (UNK), Boys Town National Research Hospital (BTNRH), Children's Hospital and Medical Center (CHMC), Creighton University (CU), and the Omaha-VA Medical Center (O-VAMC).

Purpose: The goal of the Scholars Program is to develop successful clinical translational research (CTR) investigators by providing them with the protected time and seed grant funding to develop competitive CTR R01, K, or equivalent funding.

Description: The candidate accepted into the program will receive salary support of up to 50% FTE (25% supported by NIGMS and 25% supported by the applicant's institution, including fringe benefits consistent with the applicant's institution) as well as up to \$25,000 annually to support preliminary research efforts for two years.

Applicable Research: 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 <u>does not fund basic research projects</u>. As broadly defined by the NIH IDeA-CTR Program, "clinical research" comprises studies and trials in human subjects as defined by <u>NIH</u> <u>Regulations and Policies</u>, and "translational research" includes projects that aim 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, <u>here</u>, to provide further clarity for researchers in determining whether their projects fall on the translational research spectrum.

- <u>Basic Research</u> Basic research involves scientific exploration that can reveal fundamental mechanisms of biology, disease, or behavior. Basic science projects (e.g., those using only animal models or cell lines that are not of direct relevance to human health/disease).
- <u>Pre-Clinical Research</u> 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.

- <u>Clinical Research</u> 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.
- <u>Clinical Implementation</u> 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.
- <u>Public Health</u> 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 fits the definition of CTR, please contact your local institutional program coordinator (see 'Eligible Institutions and Contacts' below). Alternatively, you may also contact one of the co-directors of the Professional Development Core, Dr. Ted Mikuls, tmikuls@unmc.edu or Dr. Lani Zimmerman, lzimmerm@unmc.edu.

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, defined as "emotions and behaviors that affect your overall wellbeing" (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)

In addition, applications focused on the leading causes of death in Nebraska (as determined by the <u>CDC</u>) are encouraged.

<u>Highest priority will be given to the strongest science and most promising applicants</u>. Additional priority will be given to 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. Note: applicants proposing CTR outside of the scientific areas and/or populations outlined above are still eligible to apply.

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 <u>Practice-Based Research Networks</u> (PRBN).

Eligibility:

- Member of the GPCTR via our <u>website</u>.
- Full-time, early-career faculty at participating institutions (see below), who have initiated CTR, but have not received independent federal funding. Preference will be given to individuals at the rank of Assistant Professor (MD, PhD, or equivalent).
- Eligible to apply for NIH R or K awards or equivalent funding.
- Has an established focus of relevant clinical, clinical translational, or community translational research <u>without</u> previous NIH R01 or equivalent funding, is not on a currently mentored K award or a funded Center of Biomedical Research Excellence (COBRE) or IDeA Networks of Biomedical Research Excellence (INBRE).
- Current and former PD/PIs of a NIH Small Grant (R03), Exploratory/Developmental Grant (R21), Dissertation Award (R36), or SBIR/STTR (R41, R42, R43, R44) remain eligible.
- Please note that the application requires a support letter from a department chair (or other appropriate institutional representative) attesting to the availability of 25% FTE support from the institution.

Participating Institutions and Contacts:

- Boys Town Natl. Research Hospital (BTNRH) Ryan McCreery (<u>ryan.mccreery@boystown.org</u>)
- Children's Hospital and Medical Center (CHMC) Ann Anderson Berry (<u>alanders@unmc.edu</u>)
- Creighton University (CU) Joan Lappe (joanlappe@creighton.edu)
- Omaha-VA Medical Center (O-VAMC) Fred Hamel (<u>fghamel@unmc.edu</u>)
- 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) Ted Mikuls (<u>tmikuls@unmc.edu</u>) & Lani Zimmerman (<u>lzimmerm@unmc.edu</u>)
- University of Nebraska at Omaha (UNO) Deepak Khazanchi (<u>khazanchi@unomaha.edu</u>)

Program Expectations:

Awardees will be required to:

- Take the UNMC Mentored Scholars Program (MSP) Seminars CTR 901 and CTR 903, two sequential grant writing courses (to begin Fall 2024), if needed, or completion of a comparable training.
- Devote at least 50% effort to the program (25% funded by NIGMS, 25% funded by applicant's institution). Institutions on a 9-month calendar must agree to pay 25% FTE support during the summer months for investigators to be able to continue their research.
- Remain current on all required regulatory training based on your project and institutional requirements.
- Complete Responsible Conduct of Research (RCR) training within first year of funding (if not already completed).
- Maintain all IRB/IACUC documentation and approval status, as applicable, and provide all updated approvals to the GP IDeA-CTR program coordinator.
- In addition to the reporting required for adverse events, we ask that you notify the GP IDeA-CTR program coordinator if the study has any adverse events (AE's).
- Submit an Individual Development Plan (IDP) upon acceptance to the program.
- Mentoring:

- a) Meet with your primary mentor at least once every two weeks and other mentors as needed to discuss progress and concerns.
- b) Meet with your full mentoring team at least every 6 months.
- c) Meet (along with your mentor[s]) with the Scholars Program leadership team twice a year.
- Submit an electronic progress report twice a year.
- Participate in a Research Studio for an external grant submission during the program. For more information on the studio process please visit our website, <u>here</u>.
- Attend the Annual Scientific Meeting where you will present your project and progress to date to the External Advisory Committee and meet with NIGMS program officers as requested.
- Attend monthly lectures offered by the Great Plains IDeA-CTR Network.
- Awardees and co-investigators are required to attend one engagement and dissemination plan meeting with the Community Engagement and Outreach (CEO) core to be held at the beginning of your award (within months 1-2). This meeting will result in the development of a communication and dissemination plan to share the results of your work in both community and academic settings. At the end of your funding period, you will be asked to complete a progress report about this in a REDCap survey.
- Submit an R01, K or equivalent extramural grant application within the funding period.
- Complete post-graduation evaluations and assist with post-award tracking (e.g., papers, promotions, grants, etc.).
- Cite the GP-CTR/NIGMS grant in all publications and presentations as appropriate. Click <u>here</u> for citation wording.
- Maintain engagement with the Great Plains IDeA-CTR after graduation via regular communications. For example, this might include possible participation in future Annual Scientific Meetings, Research Studios, providing invited presentations or acting as a mentor.

Application Deadline:

Applications are due by 5pm on <u>October 2nd, 2023</u> Applicants will be notified by <u>October 30th, 2023</u> Earliest funding start date (pending all required approvals) is January 1st, 2024

Application Requirements:

- 1. Full curriculum vitae (CV) of applicant
- 2. NIH biosketch of applicant and primary mentor to include other support.
- 3. NIH Face Page (download and complete Form Page 1, <u>here</u>). If the applicant is from UNMC, this form <u>does not</u> 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.
- 4. Personal summary of no more than <u>3 pages that</u> describes the applicant, career development plan, and interactions with mentors.

This summary will be evaluated by the following criteria:

- I. <u>Candidate</u> Relevant review criteria will include:
 - a) Does the candidate have the potential to develop as an independent and productive researcher?

- b) Is the candidate's prior training and research experience appropriate for this award?
- c) Is the candidate's academic, clinical (if relevant), and research record of high quality?
- d) Is there evidence of the candidate's commitment to meeting the program objectives to become an independent investigator in research?
- e) Do the two letters of recommendation required (see below) address the above review criteria, and do they provide evidence that the candidate has a high potential for becoming an independent investigator?
- II. <u>Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring</u> Relevant review criteria will include:
 - a) What is the likelihood that the plan will contribute substantially to the scientific development of the candidate and lead to scientific independence?
 - b) Are the content, scope, phasing, and duration of the career development plan appropriate when considered in the context of prior training/research experience and the stated training and research objectives for achieving research independence?
 - c) Are there adequate plans for monitoring and evaluating the candidate's research and career development progress?
- III. <u>Mentor(s)</u>, Co-Mentor(s), Consultant(s), Collaborator(s):
 - a) Potential mentor(s) and their area(s) of expertise.
 - b) Mentors may be chosen from any of the participating institutions, but at least one must be identified near (or at the same institution) to the applicant to assure adequate observation of Scholar progress. Scholars should have a project that is independent of their mentor's ongoing research.

Criteria to evaluate the mentor:

- c) Are the mentor's research qualifications in the area of the proposed research appropriate?
- d) Do(es) the mentor(s) adequately address the candidate's potential and his/her strengths and areas needing improvement?
- e) Click <u>here</u> to see additional K criteria for evaluating a mentor.
- Research Plan to include a research proposal that follows the NIH guidelines (e.g., Specific Aims, Significance, Innovation, and Methods - design, sample (including sample size calculation), measures, procedures, and data analysis). The <u>Aims (1-page) plus Research Plan (6-pages) should</u> <u>not exceed 7 pages in total.</u> (References not part of page limit).

The Research Plan will be evaluated by the following criteria:

- a) Are the proposed research question(s), design, and methodology of significant scientific and technical merit?
- b) Is the research plan relevant to the candidate's research career objectives?
- c) Is the research plan appropriate to the candidate's stage of research development and as a vehicle for developing the research skills described in the career development plan?
- d) Is there a strong scientific premise and scientific rigor and reproducibility for the project?
- e) Has the candidate presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?
- f) Has the candidate presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?
- g) References

6. <u>Community Impact</u>: Write a brief narrative in plain language (<u>limited to 30 lines or less</u>), 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). Comments and questions from the CAB member(s) will be provided to the applicant at the end of the review process.

Include the following:

- a) Project's broad, long-term objectives and specific aims.
- b) Briefly describe the research design and methods for achieving the stated goals.
- c) Clearly describe the potential long-term community impact.
- 7. <u>Environment and Institutional Commitment to the Candidate</u>: Current resources (e.g., equipment, lab or office space, research resources, clinical coordinator, or statistical support) available to support the pilot research project and lead to submission of an R01, K grant application or equivalent, as applicable.

Criteria to evaluate:

- a) Is there a clear commitment of the sponsoring institution to ensure that the required minimum effort (50% FTE) will be devoted directly to the Scholars Research Program?
- b) Is the institutional commitment to the career development of the candidate appropriately strong?
- c) Are the research facilities, resources and training opportunities, including faculty capable of productive collaboration with the candidate, adequate and appropriate?
- d) Is the environment for scientific and professional development of the candidate of high quality?
- e) Is there assurance that the institution intends the candidate to be an integral part of its research program as an independent investigator?
- 8. Letters of Recommendation/approval:
 - a) A <u>letter from the primary mentor</u> detailing their commitment to the applicant throughout the training period (see above criteria under Mentor(s)). The mentor should have current or a history of external research funding and should not be the applicant's immediate supervisor (e.g., Division Chief, Chair, Dean). Scholars should have a project that is independent of their mentor's ongoing research.
 - b) A <u>letter from senior faculty member</u> who can attest to the applicant's ability to succeed as a Scholar in this program. This could come from internal or external mentor who can attest to your ability to be successful in the program.
 - c) An <u>administrative approval letter</u> from one of the following: the appropriate Division Chief, Department Chair and/or Dean confirming the applicant will have 50% or more protected time for research (with at least 25% FTE coming from their institution), if selected, throughout the training period (which will be re-confirmed annually).

9. <u>Regulatory Requirements</u>:

 a) If your project meets the NIH definition of human subjects research <u>and</u> meets the new NIH definition of a clinical trial, you must check "Yes" to the clinical trial question on the <u>NIH</u> <u>Face</u> Page. If you are unsure whether your project meets the 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 on clinical trials and grants click here.

- b) 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, and your project is human subjects, you are required to complete Biomedical or Human Subjects education (e.g., Collaborative IRB Training Initiative (CITI) training) and submit a copy of the full report to the GP IDeA-CTR. If your project is clinical, you must also submit Good Clinical Practice (GCP) documentation.
- c) If IRB approval is not needed, an exemption letter or email from the IRB is still required. Funding will not be released until all regulatory and NIGMS approvals are obtained.
- d) 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). This is not included in the 7-page limit.
- e) If your project involves a potentially new or existing invention, you must notify the appropriate tech transfer/commercialization office at your institution - UNeMed (Matthew Boehm for UNMC and UNO investigators), NUtech Ventures (Cheryl Horst for UNL investigators), Stuart Martens for CU investigators, or Ryan McCreery for BTNRH investigators.
- f) 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 SRC website. For questions regarding this process, contact the Protocol Review and Monitoring System (PRMS) office at 402-559-8885. Applicants from a partner institution that requires a scientific review for cancer research must follow their institutional process for this approval.

Budget and Budget Justification: 10.

The budget sheet can be found at the bottom of the REDCap survey. Please download and complete the form, then attach it to your full submission.

- a) Budget should assume up to \$25,000/year in direct costs to cover research. The award will cover 25% FTE of the applicant's effort (with an additional 25% FTE required by the applicant's institution), plus benefits and indirect costs.
- b) Complete a separate budget for Years 1 and 2 of your project.
- c) Include indirect costs on NIH face page and budget sheet.
- d) 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. **Budget Guidelines:**

a) 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.).

- b) No faculty salary support is allowed. Student/post-doctoral stipend is not allowed. For postdocs or students to be include on your budget proposal, they must be paid through your institution's payroll system. 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) 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.
- 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 funded by partner institutions, rather than NIH, and these institutionally designated awards will not include indirect costs.
- h) Provide a completed budget from subcontractor(s), <u>only if applicable</u>. If applicable, use the same budget template included below. Make sure to include subcontract indirects in your direct costs.
- i) Appendices <u>will not</u> be accepted.
- j) <u>Any budget related questions</u> should be sent to either <u>Johna Belling</u> (402-559-5483) or your departmental grant administrator.

Application Process:

- 1. You should be working very closely with your mentor(s) on the application. Your institutional program coordinator is also available for consultation and should read your materials. See coordinators listed by site on page 3.
- 2. <u>Applicants must consult with a biostatistician in preparation of your application</u>. If a biostatistician or other statistical support is not available at your institution, or if you are located at UNMC, please complete a request for services through CCORDA, <u>here</u>, so that we can identify the appropriate Biostatistics, Epidemiology & Research Design (BERD) statistical consultant for your work. If you have questions, please contact <u>Dr. Fang Yu</u>, or call 402-559-9436. There is no need to budget the statistician time for your pilot proposal. The BERD Core is funded to support the pilot project investigators on developing the pilot proposals and data analysis for the awarded pilot projects.
- 3. Applications will receive a review in accordance with NIH K23 guidelines for Career Development K-awards. The five criteria (identified above) considered in providing an overall assessment will include: 1) Qualifications of candidate; 2) Career Development Plan/Goals; 3) Research Plan; 4) Mentor(s); and 5) Environment & Institutional Commitment. The Professional Development Leadership Committee (PDLC), with membership from all partner sites and led by the PDC Director (with additional ad hoc review as needed), will review applications. Top applicants will be invited for an in-person (or web-based) interview. Based on review panel evaluations, the director and co-director will make their program recommendations to the Steering Committee, External Advisory Committee, and NIGMS for final approval.
- 4. After a Scholar has received R01 or equivalent funding or a K award, the applicant will "graduate" from the program.
- 5. Once all documents are finalized, submit your application in REDCap <u>as a single PDF</u>. The application may be completed in more than one sitting.

Application to the program is done centrally through UNMC's REDCap portal (we recommend using the Chrome browser to complete the survey). If you are new to REDCap or have any difficulties during the application process, please contact the Research Information Technology Office (RITO) at 402-559-9072.

To submit your application, click <u>here</u>.

- CV of applicant
- NIH biosketch of applicant and primary mentor to include other support. Please do not provide biosketches for any other members on your project.
- NIH Face Page
- Personal summary (no more than 3 pages to include: candidate, career development goals and Mentor(s))
- Research Plan (no more than 7 pages to include: aims (1 page), significance, innovation, and methods (6 pages))
- References (not included in page limits)
- Community Impact (30 lines or less)
- Environment and Institutional Commitment to the Candidate
- Letters of Recommendation (3)
- Regulatory Documents, if available/applicable
- Budget and budget justification If your budget includes subcontracts, <u>you must complete a separate budget</u> sheet which is located in REDCap. Make sure to include subaward indirects in your direct costs.

Once your application has been submitted, you will receive a confirmation email from REDCap.

Questions arising during preparation of the application may be sent directly to the Program Coordinator, <u>heather.braddock@unmc.edu</u> or 402-559-9870.