**Center for Heart and Vascular Research Pilot**

**Full Submission Guidelines**



 **Deadline: November 24th, 2021 by 5 PM**

 If you have any questions, contact Heather Braddock or call 402.559.9870.

The Center for Heart and Vascular Pilot will provide up to $40,000 over one year to support projects that are related to heart and vascular research, including but not limited to cardiac pathology, hypertension, stroke, kidney disease, and vascular focused research. Projects must fall along the translational research spectrum encompassing pre-clinical research, clinical research, clinical implementation research and public health research.

**Full Application Deadline:** November 24th, 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. Note that funding depends on receipt of Great Plains IDeA-CTR competitive renewal award. Otherwise, funds may be available for some pilots, and other applications can be updated for the next year’s cycle if renewal is awarded.

**Full Application Process:**

* + - 1. Applying to the program is done centrally through UNMC’s REDCap portal. To submit your application, please click [here](https://unmcredcap.unmc.edu/redcap/surveys/?s=YCN9KHAD7NWPN9XC).
			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. Applicants must 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 CCORDA, [here](https://www.unmc.edu/publichealth/centers/ccorda/request.html), so that we can identify the appropriate Biostatistics, Epidemiology & Research Design (BERD) statistical consultant for your work. Projects must be reviewed by a biostatistician prior to submission. 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 BERD Core is funded to support the pilot project investigators on developing the pilot proposals and data analysis for the awarded pilot projects.
			4. 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 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)). 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**.
				1. Project dates will be July 1, 2021 – June 30, 2022.
1. NIH format Biosketch (for current version, download [here](https://grants.nih.gov/grants/forms/biosketch.htm)). The recently updated NIH biosketch format must be included for the principal investigators and all other key personnel.
2. Project summary (limited to 30 lines or less of text, .5 margins, Arial size 11)
	1. 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. Write in plain language, so even a non-scientist can understand the importance and 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.
3. Research Plan: this portion is limited to ***five pages in total***
4. Specific Aim(s) (one page maximum)
5. Research Strategy
	* 1. 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; c) relevance to clinical translational research.
		2. Innovation: a brief summary of how the research project moves the current field forward and incorporates novel concepts, approaches, methodologies, instrumentation or interventions.
		3. 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 guidelines [here](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-228.html)).
6. Plans for extramural funding applications (e.g., to NIH or other agencies, please specify) upon successful completion of this project.
7. Literature cited (not part of the 5 pages).
8. 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 (e.g., Collaborative IRB Training Initiative (CITI) training) and submit a copy of the certificate to the GP IDeA-CTR, if awarded.
9. 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 [click 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 or IACUC (respectively) approval 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. Budget
5. Complete the budget form on page 4 of this document.
6. 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.).
7. 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.
8. Equipment (>$5,000 per item) is not allowed.
9. Renovation is not allowed.
10. Honorariums are not allowed.
11. 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.
12. 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.
13. 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, including 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 relevance to the Great Plains IDeA-CTR program research priorities, the strength of the interdisciplinary team based-approach and the potential for future extramural funding.
			4. The Pilot 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.

**Expectations of Pilot Awardees**

1. Remain current on all regulatory training and approvals and provide all updated approvals to the GP IDeA-CTR.
2. Meet with Pilot Program leadership at 6 and 12 months.
3. Complete a progress report at 6 months and a final report at the conclusion of the funding period.
4. Participate in a one-hour research studio at the end of your funding period.
5. Complete the NIH annual progress report.
6. Become a member of the GP IDeA-CTR via our [website](https://gpctr.unmc.edu/membership/).
7. Attend the GPCTR Annual Scientific Meeting where you will provide a poster to discuss during a networking session, as well as meet with and discuss your project and progress with our EAC members and NIGMS Program Officers.
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.

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

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| --- | --- | --- | --- |
| DETAILED BUDGET (Direct costs only) | FROM 7/1/2022 | THROUGH 6/30/2023 | 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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