DaCCoTA
DAKOTA COMMUNITY COLLABORATIVE ON TRANSLATIONAL ACTIVITY

Request for Applications DaCCoTA Feasibility Pilot Grant

Overview
The Dakota Community Collaborative on Translational Activity (DaCCoTA) Pilot Projects Program is requesting applications for **Feasibility** Pilot Grant Awards. The goal of the DaCCoTA is to bring together researchers and clinicians with diverse experience from across the region to develop unique and innovative means of combating disease in North and South Dakota. The mission of the Pilot Projects Program is to provide seed funding for highly innovative projects in clinical and translational research. For general information about the DaCCoTA program, see https://med.und.edu/daccota/.

The **Feasibility Award** is intended to provide support to allow a clinician/non-clinician team to form around a novel hypothesis. Applications can consider: 1) Behavioral health (including substance use disorder, mental health, suicidality, and overall wellness; 2) Food insecurity, nutrition, and food deserts; 3) Chronic disease (diabetes, cancer, hypertension, obesity and pain); 4) Culturally appropriate and trauma-informed healthcare and research; and 5.) Unresolved trauma (health impacts of trauma, toxic stress, adverse childhood experiences, disproportionate foster care experiences). Applications should focus on **T2-T4** translational research, although T1 studies will be considered if there is a clear plan to progress to T2-T4. The primary goal is to allow a team to form and connect with the CTR Biostatistics, Epidemiology, and Research Design Core; Clinical Research Resources and Facilities Core; Community Engagement and Outreach Core; and Pilot Projects Program to generate competitive proposals for the CTR Ready-to-Go Pilot Award mechanism.

Eligibility Criteria
Faculty and clinicians at participating DaCCoTA institutions who have applied and been accepted into the DaCCoTA Pathfinder network (https://pathfinder.med.und.edu/) are eligible to apply. Investigators with a Principle Investigator (PI) role from other NIH IDeA funding mechanisms are not eligible for a PI role on DaCCoTA awards.

All proposals must include a discussion of the relevance of the proposal to the DaCCoTA mission and identification of relevance to the research priorities listed above and vulnerable populations in North and South Dakota: American Indian (rural and urban), rural, New American, Immigrant, and Foreign born (NFI) communities, and the lesbian, gay, bisexual, transgender, & queer + (LGBTQ+) community. Additionally, participation in the DaCCoTA Pathfinder network is required.

Prior consultation with the CTR 1) Pilot Projects, 2) Biostatistics, Epidemiology and Research Design, 3) Community Engagement and Outreach, and 4) Clinical Research Resources and Facilities Cores is required. Demonstration of available research percentage effort for the PIs/co-Is and associated personnel on the proposal must be provided. Evidence of available research effort and salary support must be provided in the form of a letter from the departmental chair or clinical service unit chief for each PI/co-I. All proposals must have completed internal approval at their respective institution.

Team Requirements
Applications must be from a collaborative clinician/non-clinician team. The teams may or may not require mentoring and collaborative support to initiate and carry out a research project with the express goal of maintaining a research effort. All pilot awards must have a PI or co-I who is a clinician and a PI or co-I who is a non-clinician. If a potential PI needs but has not been able to identify a relevant teammate, the Pilot Projects

Program staff will assist in identifying one from among the collaborating academic institutions and hospital networks participating in the DaCCoTA program. The primary PI must also meet eligibility requirements for NIH funding. PIs should not have additional PI-level funding from an IDeA program award. Preparation of all pilot awards should involve extensive interaction pre-submission as well as post-award with the Pilot Projects Program, which will coordinate interactions with other cores to provide insight regarding research design, grant/publication preparation, and federal/non-federal funding mechanisms.

In accordance with NIH's guidelines for team roles and agreements, the PI will lead the project's scientific development or execution. The co-I will be involved with the PI in the project's scientific development or execution, but not quite at the level of a full PI. In your application's budget justificaiton, you must detail the activities/contributions of the PI, co-I, and any other key personnel.

Awardees are **required** to provide an **oral presentation at the annual DaCCoTA symposium** and provide biannual milestone reports, one of which will be submitted to NIH.

Funding
Funds up to $60,000 (direct+indirect costs) per award are anticipated to begin September 2023. Funds may not be used to support PI/co-I salaries, consultant/collaborator salaries, or to purchase capital equipment.

Depending on the institutions involved in the project, institutional Sponsored Programs Administrations (SPAs) may have additional requirements for budget and proposal approval. The University of North Dakota and North Dakota State SPAs require applications to be electronically routed through Novelution. The University of South Dakota SPA requires applications to be routed through Cayuse.

Projects will be evaluated primarily on potential for conversion to Ready-to-Go Pilot Awards and strength of the investigative team and any collaborators. All funded projects must have clearly established milestones. Milestone progression will be monitored by the Pilot Projects Program and the Tracking & Evaluation Core.

Application process and deadlines
Applications must be submitted as a PDF attachment and must use PHS 398 forms. Forms and detailed instructions can be found here: https://grants.nih.gov/grants/funding/phs398/phs398.html

The deadline for seeking assistance in finding a collaborator is October 14, 2022.
Letters of Intent (1 page maximum) are due October 21, 2022.
Letters of Intent acceptance will be determined by November 4, 2022.
Teams whose Letters of Intent are accepted must meet with all DaCCoTA Cores by December 2, 2022.
IRB/IACUC/IBC preparation must be initiated by December 2, 2022.
Budget and Grant Approval SPA is due January 13, 2023.
IRB/IACUC/IBC drafts for CRRFC consultation are due January 20, 2023.
Full applications will be due January 20, 2023.
Selected applicants following initial review will be invited to submit a completed grant by March 1, 2023.
Awards will be announced by September 2023.
Expected award period will be September 1, 2023-August 31, 2024.

Applications must be Arial 11-point font with 0.5-inch margins and include a:

- PHS 398 Forms
    - Form Page 1: Face Page

    - Form Page 2: Summary, Relevance, Project/Performance Sites
    - Form Page 2-continued: Senior/Key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells
    - Form Page 4: Detailed Budget for Initial Budget Period
    - Detailed Budget Justification
    - Biographical Sketches for PI, Co-I and Senior/Key Personnel
- Research Plan
    - Response to review if resubmission (0.5 page)
    - Specific Aims (1 page)
    - Significance (0.5 page)
    - Innovation (0.5 page)
    - Research Strategy (maximum 6 pages)
        - Rigor and transparency: As appropriate, a description of the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of project, and a description of the experimental design and methods proposed and how the investigator will achieve robust and unbiased results. If applicable, a brief description of the methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed project (see Notice NOT-OD-16-011 for details).
    - Bibliography and References Cited (use Continuation Format Page)
    - Vertebrate Animals Section (if applicable)
    - Consortium/Contractual Arrangements (if applicable)
- Letters of Support
    - from Department Head and/or Clinical Unit Chief, consortium participants, Senior/Key Personnel, and Other Significant Contributors included in application
    - from each DaCCoTA Core following core meetings
- Resource Sharing Plans(s) (if applicable)
- Authentication of Key Biological and/or Chemical Resources (if applicable)
- DaCCoTA Human Subjects Overview Checklist
- Community Engagement Relevance Survey
- PHS 398 Checklist

The letter of intent and subsequent full application should be submitted as a pdf to: Savannah Macias-Daugherty (Savannah.M.Daugherty@und.edu).

All applicants proposing studies involving human subjects or vertebrate animals must initiate the process of obtaining IRB or IACUC approval <u>prior to</u> submitting their applications and include a statement verifying submission.

All proposals recommended by the review panel will require prior approval by NIH prior to initiation. If the proposed study involves human subjects, the following documents will need to be submitted to Savannah Macias-Daugherty prior to application submission to NIH:

- Written protocol addressing the risks and protections for human subjects, in accordance with NIH's Instructions for Preparing the Human Subjects Section of the Research Plan
- Institutional Review Board (IRB) approval

- Human Subjects Training education courses through the Collaborative Institutional Training Initiative (CITI Program)
    - Certificates and completion reports must be included for PI and Key Personnel
- Create Inclusion Data Record (IDR) and enter inclusion data in Inclusion Management System (IMS)

If the proposed project involves clinical trials, in addition to above documents, the following documents must also be submitted to Savannah Macias-Daugherty before application submission to NIH:

- Specific plans for data and safety monitoring
- Good Clinical Practice (GCP) certification through the CITI Program
    - Certificates and completion reports must be included for PI and Key Personnel

If the proposed project involves animals, the following documents must be submitted to Savannah Macias-Daugherty before application submission to NIH:

- Animal Care and Use education courses through the CITI Program
    - Certificates and completion reports must be included for PI and Key Personnel

More information

Questions related to the **Feasibility Pilot Grant Awards** should be directed to Savannah Macias-Daugherty, Pilot Projects Program Core Coordinator (Savannah.M.Daugherty@und.edu)

DaCCoTA Grant Application
Human Subjects Overview

Investigator(s)/Co-Investigator(s)

Role	Name	Affiliation
Clinical Investigator	Click or tap here to enter text.	Click or tap here to enter text.
Non-Clinical Investigator	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.

Project Title: Click or tap here to enter text.

IRB Approval or Human Subjects Determination Status

- ☐ Approved
- ☐ Pending Approval/Submitted
- ☐ Not Submitted
- ☐ Not Required (project does not involve human subjects research) **FORM COMPLETE, Do Not Proceed**

IRB of Record (If multiple IRBs of record, please justify.)**:** Click or tap here to enter text.

IRB Application Type

- ☐ Determination of Human Subjects
- ☐ Record Review of Existing Specimens, Retrospective
- ☐ Investigator Initiated, Prospective

IRB Deadline(s) (Include pre-review deadlines, if available): Click or tap here to enter text.

Specimen Required (select all that apply)

- ☐ Serum
- ☐ Plasma
- ☐ DNA
- ☐ Tissue
- ☐ Archival
- ☐ Fresh
- ☐ None
- ☐ Other, please describe: Click or tap here to enter text.

Subject Characteristics (Describe the characteristics of the subjects. Criteria might include disease status, gender, age, race, ethnicity, comorbidities, treatments, date ranges, survival status, etc. Be as specific as possible.)
Click or tap here to enter text.

Number of Subjects: Click or tap here to enter text.

Do you require serial specimen?

- ☐ Yes, please describe: Click or tap here to enter text.
- ☐ No

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Community Engagement Relevance Survey for DaCCoTA Applications

Directions: The Community Engagement Relevance Survey is required for all DaCCoTA applications. The purpose of this survey is to identify relevant community engagement in prospective applications.

Applicant Name:
Core and Grant Funding Mechanism:
Project Name:

This identification is required for all DaCCoTA (AICoRN, BERDC, PDC, PPP) applications:

As part of your application, please identify which of the following communities is most relevant to your Community Engagement Scholars application (select all that apply):

☐American Indian (both rural and urban) communities

☐Rural communities

☐New American, Foreign-born, and Immigrant (NFI) communities

☐Lesbian, Gay, Bisexual, Transgender, & Queer + (LGBTQ+) communities

For PDC Community Engagement Scholars Applications Only!

As part of your application, please identify which of the following research priorities is most relevant to your Community Engagement Scholars application (select all that apply):

☐Behavioral health (including substance use disorder, mental health, suicidality, and overall wellness)

☐Food insecurity, nutrition, and food deserts

☐Chronic disease (including diabetes, cancer, hypertension, obesity, and pain)

☐Culturally-safe and trauma-informed healthcare and research (including integrative therapies such as traditional healing, and innovative prenatal and natal, and postnatal care)

☐Unresolved trauma (including health impacts of trauma and toxic stress, adverse childhood experiences, and disproportionate foster care experiences)