DaCCoTA
DAKOTA CANCER COLLABORATIVE
ON TRANSLATIONAL ACTIVITY

Request for Applications

DaCCoTA TREE Pilot Grant

Overview

The Pilot Projects Program and the Biostatistics, Epidemiology, and Research Design Core for the Dakota Cancer Collaborative on Translational Activity (DaCCoTA) are requesting applications for **Translating Epidemiology to Experiments (TREE) Pilot Grant Awards**. The goal of the DaCCoTA program is to stimulate the growth of expertise and engagement in health-related translational research (CTR) in the Dakota region. The focus of the TREE program is to provide seed funding for highly innovative projects that seek to translate promising epidemiological findings at the population level to relevant ***in vitro*** and/or ***in vivo*** experiments and/or the reverse, from ***in vitro*** and ***in vivo*** observations to a population setting. For general information about DaCCoTA, see https://med.und.edu/daccota/.

The **TREE Pilot Grant Award** is intended to provide support to allow a team comprised of a public health scientist and a laboratory scientist to form around important population health findings. Applications can consider findings from epidemiological studies at the population level (e.g., health surveys, ecological or analytic epidemiologic studies) and attempt to confirm and/or extend these in an experimental setting (e.g., cell cultures, mouse models). Conversely, applications could translate promising experimental results and apply them to population-level studies (e.g., findings from an animal experiment that found a risk of disease due to chemical or exposure "X" might be translated into an epidemiologic study in which rates of exposure to the chemical or exposure are examined in relation to disease rates).

Applications are envisioned to focus on **T0-T1** translational research, whereas **T2-T4** studies are a better fit for the general Pilot Project funding mechanism. 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 initial results in '**trench-to-bench**' (epidemiology to experiment), or '**bench-to-trench**' (experiment to epidemiology) research. Successful completion of these proposals should lead to peer-reviewed manuscript submissions and extramural grant submissions.

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 consideration of relevance for high-priority health issues relevant to populations in the Dakota region. 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 are 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 public health scientist/laboratory scientist 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 awards must have a PI or Co-I who is a public health scientist, defined broadly as a non-laboratory focused health researcher (e.g., epidemiologist, statistician, or other health scientists, including physical and occupational therapists) and a PI or Co-I who is a laboratory scientist (e.g., biomedical researcher). If a potential PI needs but has not been able to identify a relevant teammate, the Pilot Projects Program or BERDC staff will try to help by 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 cannot 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.

Awardees are **required** to provide an **oral presentation at the annual DaCCoTA symposium**, **quarterly survey reports**, and an **annual progress report** that will be submitted to NIH.

Funding

A maximum budget of $60,000 (direct+indirect costs) is allowed. Funds may not be used for PI/Co-I salaries, consultant/collaborator salaries, or to purchase capital equipment. PIs must have an eRA Commons username.

Projects will be evaluated primarily based on the potential for immediate implementation, the potential for extramural grant submission and peer-reviewed publication, the readiness of the proposed experiments to appropriately test the translational hypotheses, and the strength of the investigation team.

Application process and deadlines

Letters of intent (1-page maximum) are due February 11th, 2022. Letters of intent should provide a study title, a study overview, grant category targeted, and identify the public health scientist/laboratory scientist team. Full applications will be invited from selected applicants and will be due March 11th, 2022. Awards will be announced by August 2022. The expected award period will be September 2022-August 2022.

Proposed Timeline for TREE Pilot Grants

- **RFA Release Date:** January 3rd
- **Deadline for Assistance Finding a Collaborator:** January 31st
- **Letter of Intent Deadline:** February 11th
- **Letter of Intent Acceptance/Decline:** February 17th
- **Required DaCCoTA Core Meetings:** February 28th
- **IRB and IACUC Preparation (if applicable):** February 17th
- **IRB Draft Application Deadline for CRRFC Consultation (if applicable):** March 4th
- **Internal Budget and Grant Approval:** March 4th
- **Application** Deadline: March 11th
- **Notification of Review:** March 25th
- **IRB Submission (if applicable):** April/May, dependent on Institution
- **Notice of Award:** August

Applications must use Arial 11-point font with 0.5-inch margins and must use PHS 398 forms https://grants.nih.gov/grants/funding/phs398/phs398.html

- Form Page 1: Face Page
- Form Page 1-continued: Additional form for Co-PI or Co-I
- Form Page 2: Summary, Relevance, Project/Performance Sites, Senior/Key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells
- Form Page 4: Detailed Budget for Initial Budget Period
- Research Plan (use Continuation Format Page)
    - Response to review if resubmission (0.5 pages)
    - Specific Aims (1 page)
    - Significance section (0.5 page)
    - Innovation section (0.5 page)
    - Research strategy (maximum of 5 pages)

- Biographical Sketches (use https://grants.nih.gov/grants/forms/biosketch.htm)
- References cited (use Continuation Format Page)
- Letters of support from the Department Head or other Supervisor
- Checklist Form Page
- Statement verifying IRB application submission (Use Continuation Format Page)
- Human Subjects Overview Form (see below)

The letter of intent should be submitted to: Mark.Williamson.2@und.edu. The subsequent full application should be submitted as a PDF to Pathfinder (see step by step instructions below):

1) Go to Pathfinder website and register/login (https://pathfinder.med.und.edu/)
2) Once you have registered/logged in, select Proposals on the top menu.
3) Select Submit a Proposal
4) Fill out Proposal Contact Information and Proposal Information
5) Under Proposal Information, click on the green box that says file, select your PDF file and then click the green box on the bottom right that says Submit Proposal.

All applicants proposing studies involving human subjects or vertebrate animals must initiate the process of obtaining IRB or IACUC approval before submitting their applications.

All proposals recommended by the review panel will require prior approval by NIH before initiation. If the proposed study involves human subjects, the following documents will need to be submitted to NIH before award notice:

- Written protocol addressing the risks and protections for human subjects, in accordance with the NIH's Instructions for NIH's Instructions for Preparing the Human Subjects Section of the Research Plan
- Institutional Review Board (IRB) approval
- Human Subjects education certification
- Create Inclusion Data Record (IDR) and enter inclusion data in Inclusion Management System (IMS)

If the proposed project involves clinical trials, in addition to the above documents, the following documents must also be submitted to NIH:

- Specific plans for data and safety monitoring.
- Good Clinical Practice (GCP) certification If the proposal involves Vertebrate Animals, IACUC approval and the Vertebrate Animal Section will also need to be submitted to NIH before award notice.

More information

Questions related to the **TREE Pilot Grant Awards** should be directed to Mark Williamson, BERDC Core Coordinator: Mark.Williamson.2@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