DaCCoTA
DAKOTA CANCER COLLABORATIVE
ON TRANSLATIONAL ACTIVITY

Request for Applications
AICoRN Community Engagement Pilot Grant

Overview
The Dakota Cancer Collaborative on Translational Activity (DaCCoTA) Pilot Projects Program is requesting applications for **AICoRN Community Engagement Pilot Grant Awards**. The goal of the DaCCoTA program is to stimulate growth of expertise and engagement in clinical and translational research (CTR) in the Dakota region encompassed by the states of North and South Dakota. The American Indian Collaborative Research Network (AICoRN) is a regional network of clinicians with a research focus aimed at addressing health disparities in a community-based way to addressed health needs of the underserved. The mission of the Pilot Projects Program is to provide seed funding to highly innovative projects in clinical and translational research. For general information about the DaCCoTA program, see https://med.und.edu/daccota/.

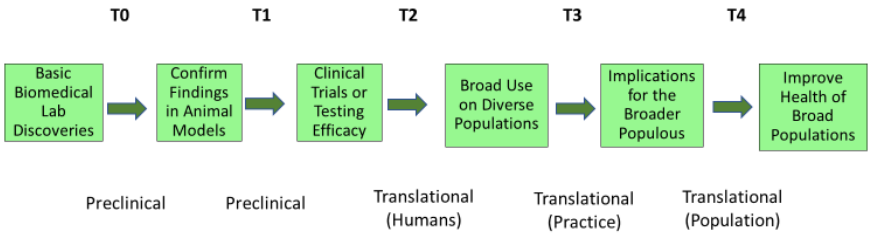
The **AICoRN Community Engagement Pilot Award** is intended for those projects addressing priority areas as determined by key stakeholder groups named as partners in AICoRN. Current partners include the UND Centers for Family Medicine in Bismarck and Minot, Monument Health, Oyate Health, Community Health Association of the Dakotas (CHAD), ND Department of Health, UND Department of Indigenous Health, the Great Plains Tribal Chairmen's Health Board.

These pilot awards are designed to provide seed funding to support activities related to the development of new or emerging partnerships with underserved, Tribal and rural populations or to perform pilot studies that will strengthen community-based relationships, relationship-based care, and potentially produce preliminary data for future competitive grant applications. Preclinical, translational and clinical research investigations will involve a provider together with a learner to address underserved, rural or American Indians who share expertise, knowledge, and skills will be considered in the following research formats:

Interdisciplinary or transdisciplinary research that includes collaborations across a range of disciplines including but not limited to medicine, mental health, psychology, nursing, physical and occupational therapy, and social work to address research from a multidisciplinary perspective that may address gaps in the fuller context of American Indian, underserved, historically marginalized and rural populations or to address underlying common root causes of poorer health outcomes. Comparative analyses of existing samples, datasets, databases and or data-mining and data curation to investigate the role interventions could play would be considered for funding. In addition, cross-cutting interdisciplinary research, studies that leverage existing funded cohorts and datasets for analyses of hypotheses related to sex and gender influence on health and disease are also of high interest. Applications will focus on **T2-T4** translational research, although T1 studies

will be considered if there is a clear plan to progress to T2-T4. See figure 1 for an overview of T0-T4 research. Successful completion of these proposals should lead to an extramural grant submission and peer-reviewed manuscript submission.

Figure 1. Continuum from Basic to Translational Research



Eligibility Criteria

Investigators having membership or affiliation with AICoRN who have applied and been accepted into the DaCCoTA Pathfinder network (https://pathfinder.med.und.edu/) are eligible to apply (instructions on website). Investigators with a Principal Investigator (PI) role from other NIH IDeA funding mechanisms are not eligible for a PI role on these awards.

All proposals must include a discussion of the relevance of the proposal to the AICoRN mission and consideration of the specific priorities described above. *Prior consultation with the DaCCoTA 1) Biostatistics, Epidemiology and Research Design, 2) Community Engagement and Outreach, and 3) Clinical Research Resources and Facilities Cores as appropriate are required*. You can contact these cores by logging into Pathfinder and selecting the communication tab at the top of the page. Demonstration of available research percentage effort for the PI/Co-I 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

Applying teams must include a collaborative clinician-non-clinician team. One member of this team must be either a Partner of AICoRN or employed at a partnering institution. Clinicians must partner with a collaborator non-clinician (epidemiologist, statistician, basic scientist, etc.). Investigators seeking appropriate partners and team members are strongly encouraged to consult with the DaCCoTA pilot core directors and/or AICoRN Director for assistance in identifying such partners. Though teams originate from the Dakotas, consultation outside of the region as is allowed, albeit unpaid.

All pilot awards must have a PI or co-I who is a clinician and a PI or co-I who demonstrates commitment to health of rural, Tribal or otherwise underserved communities of the Dakotas. The primary PI must also meet eligibility requirements for NIH funding, and be affiliated with an

academic institution (https://era.nih.gov/reg-accounts/register-commons.htm). The term clinician is inclusive of MD, DO, PA, RN, NP, OT, PT, PsyD, other health professions may be considered.

It is critical that applicants consult with appropriate DaCCoTA cores to ensure appropriate project submission. This consultation should occur between the time they submit their LOI and their full application. Preparation of all pilot awards should involve 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 AICoRN Summit/DaCCoTA symposium and provide quarterly milestone reports.

Figure 2. Contact Information

DaCCoTA Core	Director Name	Contact Information
Biostatistics, Epidemiology, and Research Design Core	Director: Gary Schwartz, PhD Co-Director: Ross Crosby, PhD	UND-CTR-BIOSTATISTICS@listserv.nodak.edu
Pilot Projects Program	Director: Holly Brown-Borg, PhD Co-Director: Sathish Venkatachalem, PhD	Holly.brown.borg@und.edu S.venkatachalem@ndsu.edu
Community Engagement and Outreach Core (CEOC)	Director: Donald Warne, MD CEOC Coordinator: Sue Thompson, MPH	Donald.warne@und.edu susan.thompson2@und.edu
Clinical Research Resources and Facilities Core	Core Coordinator: Miranda Ruiter Director: Lora Black, MPH Co-Director: Kimberly Hammer	Miranda.Ruiter@SanfordHealth.org
AICoRN	Director Allison Kelliher, MD	Allison.kelliher@und.edu

Funding

A maximum budget of $80,000 (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. Enrolling instructions via an academic institution will be necessary, contact our office if you need assistance (**Susan.thompson2@und.edu**).

Projects will be evaluated primarily on the basis of potential for immediate implementation, impact on clinical practice and health outcomes, strength of the investigative team and any collaborators, responsiveness to the RFA and the potential for extramural grant submission and peer-reviewed publication. All funded projects must have clearly established milestones. Milestone progression will be monitored by the Pilot Projects Program.

Application process and deadlines

Commented [KA1]: Per Marc- maybe you two know? Marc says "you probably should include the co-directors for Pilot projects (at NDSU) and CEOC if we have one" do you know who these folks are?

Commented [KA2]: IS this the correct/right person- per Marc this is, but I wanted to double check thanks

Commented [KA3]: Holly and Sue- is it ok to have Sue's email here vs a different contact (ie. Jamie Mitzel?) thanks

Letters of intent (1-page maximum) are due March 15, 2022. Letters of intent should provide a study title, a study overview, grant category targeted, and identify the clinician and student team. Full applications will be invited from selected applicants and will be due June 1, 2022.
Awards will be announced by October 2022. Expected award period will be October 2022-September 2023.

Proposed Timeline for Pilot Grants

- **RFA Release Date**: February 28th
- **Letter of Intent Deadline**: March 15th
- **Letter of Intent Acceptance/Decline**: March 18th
- **Begin IRB Preparation**: March 18th
- **Required DaCCoTA Core Meetings**: April 1st
- **IRB Draft Application Deadline for CRRFC Consultation**: April 18th
- **Internal Budget and Grant Approval**: May 2nd
- **Application Deadline**: May 16th
- **Notification of Review**: July 1st
- **IRB Submission**: Must be approved prior to final project submission to NIH for final review.
- **Notice of Award**: September- October

Applications must be 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 page)
  - 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 Clinical Unit Chief
- 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: Susan.thompson2@und.edu
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
   - Home Page - Pathfinder (und.edu)

Commented [KA4]: Is this appropriate Sue- or should this go to Holly or Me or what? I am SUPER BEHIND ON EMAIL AND STRUGGLE TO KEEP UP SO VOTE NOTE ME- thanks

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 (as they involve human subjects) must initiate the process of obtaining IRB approval prior to submitting their applications.

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 NIH prior to 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
  - Clinical Research Resources and Facilities Core, CEOC and or AICoRN may be necessary.
- 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 above documents, the following documents must also be submitted to NIH:

- Specific plans for data and safety monitoring.
- Good Clinical Practice (GCP) certification

More information

Questions related to the **AICoRN Community Engagement Pilot Grant Awards** should be directed to: **Susan.thompson2@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