

Request for Applications DaCCoTA Feasibility Pilot Grant

Overview

The Dakota Cancer Collaborative on Translational Activity (DaCCoTA) Pilot Projects Program is requesting applications for **Feasibility** Pilot Grant Awards. The goal of the DaCCoTA program is to stimulate growth of expertise and engagement in cancer-related clinical and translational research (CTR) in the Dakota region encompassed by the states of North and South Dakota. The mission of the Pilot Projects Program is to provide seed funding for highly innovative projects in clinical and translational cancer 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 cancer-related hypothesis. Applications can consider the multilevel manifestations of cancer (e.g. neurological, psychiatric), demographic risks and social impact. 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 consideration of relevance for high priority cancers and vulnerable populations in North and South Dakota. 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 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 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 milestone reports, and an annual progress report that will be submitted to NIH.

Funding

A maximum budget of \$40,000 (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 on the basis of potential for immediate implementation, potential for extramural grant submission and peer-reviewed publication, readiness of the technology or process to advance to the next stage of translation, impact on clinical practice, 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.

Application process and deadlines

Letters of intent (1-page maximum) are due October 30, 2020. Letters of intent should provide a study title, a study overview, grant category targeted, and identify the clinician/non-clinician team.

Full applications will be invited from selected applicants and will be due February 1, 2021.

Awards will be announced by September 2021. Expected award period will be September 2021-August 2022.

Proposed Timeline for Pilot Grants

- **RFA Release Date:** September 15th
- **Deadline for Assistance Finding a Collaborator:** October 16
- **Letter of Intent Deadline:** October 30
- **Letter of Intent Acceptance/Decline:** November 16th
- **Required DaCCoTA Core Meetings:** December 23
- **IRB and IACUC Preparation:** March 25
- **IRB Draft Application Deadline for CRRFC Consultation:** January 8
- **Internal Budget and Grant Approval:** January 15
- **Application Deadline:** February 1st
- **Notification of Review:** March 15th
- **IRB Submission:** March 25
- **Acceptance of Revised Proposals and Materials from Applicants:** June 30th
- **Notice of Award:** September 1 -15

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 and subsequent full application should be submitted as a pdf to: Jessica.craig@und.edu.

All applicants proposing studies involving human subjects or vertebrate animals must initiate the process of obtaining IRB or IACUC 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
- 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

If the proposal involves Vertebrate Animals, IACUC approval and the Vertebrate Animal Section will also need to be submitted to NIH prior to award notice.

More information

Questions related to the **Feasibility Pilot Grant Awards** should be directed to Jessica Craig, Pilot Grant Core Coordinator: Jessica.craig@und.edu

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- 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 prior to award notice.

More information

Questions related to the **Community Engagement Pilot Grant Awards** should be directed to Jessica Craig, Pilot Grant Core Coordinator: Jessica.craig@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