Expected project period: September 2023-August 2025



Call for Applications for the DaCCoTA Clinical Research Opportunities Program

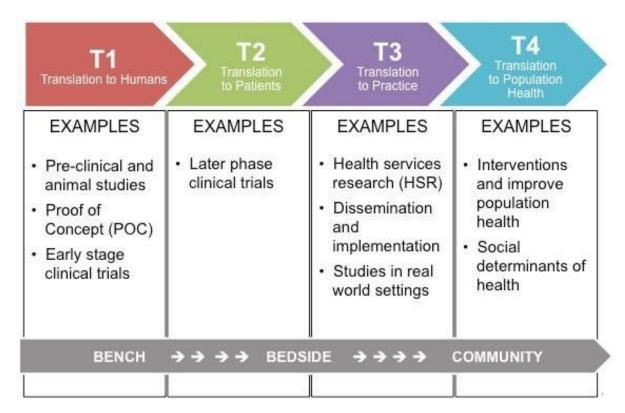
Update: The Professional Development Core of the Dakota Cancer Collaborative on Translational Activity (DaCCoTA) sponsored by the NIH/NIGMS was given approval to expand the scope of its clinical and translational research (CTR) investigations from only cancer to any health-related translational research.

Overview

The Dakota Cancer Collaborative on Translational Activity (DaCCoTA), sponsored by the National Institutes of Health – National Institute of General Medical Sciences (NIH/NIGMS), welcomes applications for the Clinical Research Opportunities Program. This program provides up to 20% release time (up to NIH cap) for two years to community-practicing, hospital-based clinicians to participate in training activities and collaborations in health-related clinical and translational research (CTR). Applications are expected to address health-related CTR, including demographic risks and social impact.

For the purpose of the DaCCoTA Scholars Program, CTR is defined as:

- "...research (that) fosters the multidirectional integration of basic research, patient-oriented research, and population-based research, with the long-term aim of improving the health of the public."
- Rubio DM et al. Defining translational research: implications for training. Acad Med 2010; 85(3): 470-8.



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This program develops clinicians' understanding of CTR, tools for identifying unmet medical needs, and training for effective collaborations. Applicants **interested in participating that do not have an idea for a project or a collaborator, contact the Professional Development Core** (lee.baugh@usd.edu) for project development assistance.

Program Requirements

- Up to 20% time commitment to CTR training for 2 years. The duration of the award can be shortened or extended; expect the percent effort to adjust accordingly.
- Partnership in a health-related CTR project: The DaCCoTA Professional Development Core and Clinical Research Resources and Facilities Core will assist applicants in identifying current CTR projects and potential collaborations and mentors.
- Complete the curriculum for DaCCoTA Clinical Research Opportunities Program Awardees (https://med.und.edu/daccota/ files/pdfs/daccota curriculum.pdf).
- Attendance and participation in the Annual DaCCoTA Symposiums while an awardee.
- Participate in on-going consultation and update meetings with Professional Development Core.
- Provide evaluation data to support project-specific goals and overt CTR initiatives.

Clinical Scholar Eligibility

- Be a member of a DaCCoTA partnering institution. Partnering institutions can be found on the DaCCoTA Website (https://med.und.edu/daccota/).
- Currently practicing medicine or an allied health field in North or South Dakota.
- Terminal degree of MD, PhD, or equivalent (e.g. PharmD, OT, PT, NP, etc.). If there are questions about qualifications, please contact the core director Dr. Lee Baugh (Lee.Baugh@usd.edu).
- Permission from the health system or practice for release time (up to 20%).
- No current project funding (PI role) through an NIH R01 or NIH IDeA program (e.g., COBRE, INBRE, DaCCoTA, etc.).

Application Process

- Applicants must register as DaCCoTA participants in the DaCCoTA Pathfinder web portal (https://pathfinder.med.und.edu/).
- Letters of Intent should be submitted as a single PDF document to christian.buresh@usd.edu.
- Applicants <u>must</u> consult the <u>Professional Development Core</u> well in advance of application submission for assistance with project development.
- Applicants <u>must</u> also consult with the <u>Biostatistics</u>, <u>Epidemiology</u>, <u>and Research Design Core</u>;
 the <u>Community Engagement and Outreach Core</u>; and the <u>Clinical Research Resources and Facilities Core</u> prior to submitting their applications.
 - o You can contact these cores by logging into the <u>Pathfinder Portal</u> and selecting the communication tab at the top of the page.
- All proposals must have completed internal approval at their respective institutions.

Application Deadlines & Required Materials

Letters of intent (1-page maximum) are due <u>September 9th, 2022</u>. Letters of intent must include: 1). Study title 2). Study overview 3). Identifying basic science and clinical mentors.

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- Letters of Intent must be accompanied by a list of pending, current, and previous grant funding received by the applicant. Each grant should be described by title, major goals, status of support, project number, name of PD/PI, source of support, primary place of performance, project/proposal start and end date, total award amount, and person months (academic, calendar, summer) allocated per budget period
- Full applications invited from selected letters of intent are due <u>November 28th, 2022</u>, and must include the following:
 - Face page (PHS398 Form Page 1 signed by institutional signing official, PHS398 forms are available at https://grants.nih.gov/grants/funding/phs398/phs398.html) Instructions for the PHS398 forms are available at U.S. DHHS Public Health Service Grant Application (PHS 398) (nih.gov).
 - o Project Summary (PHS398 Form Page 2)
 - o Personal narrative describing research interests and the role of research or other investigative work in the applicant's practice (3-page limit)
 - During your participation as a Clinical Research Opportunities Grant awardee, you'll be asked to construct a personal learning network (PLN), which is a network of people, organizations, and publications from which you'll receive continuing support during your participation in and following your graduation from the Clinical Research Opportunities program. The Professional Development Core and the DaCCoTA believe that overall success in research is based on engagement within the interdisciplinary scientific community.
 - You'll describe your current PLN by answering the following questions:
 - If you need advice or support in your research, whom do you ask first?
 - When it comes to reading peer-reviewed literature, what are your habits e.g how often do you read? What do you read? What would you like to read more of?
 - How do you learn about developments in your field?
 - You'll describe what you'd like your PLN to become by answering the following questions:
 - In your field, whom do you wish to become better acquainted with?
 - What organizations do you wish to better acquainted with?
 - What will your engagement look like with peer-reviewed literature in the future?

After all these questions are answered, the PDC will construct a visual representation of your PLN and work with you to expand it to fit your needs to support you. Expansion will consist of alerts on conferences, meeting opportunities with experienced researchers in your field, and expanding means of engagement in your field (e.g. social media, blogging, vlogging, conferences attendance, etc.).

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- o Discussion of the type of research in which the applicant would like to partner (1-page *limit*)
- o Letter of home institutional support confirming release time allowance
- o Letter of academic partner institutional cost-share (if a cost-share is proposed)
- o Curriculum vitae
- o Letters of Collaboration and Support:
 - o Letters from the proposed mentors indicating willingness to play this role and how they will assist with the awardee's participation in the Clinical Research Opportunities Grant. The mentors should have a history of funding and not be the immediate supervisor (Division Chief, Chair, Dean, or someone you have previously published with).
 - o Letters of support from mentors' and collaborators' supervisor(s) stating that they are approved to work on the project and can dedicate their time towards it
- o Budget and budget justification (PHS398 Form Pages 4 & 5). Assistance for budgeting is available at your institution's grant office.
- o Good Clinical Practice (GCP) certification and specific plans for data and safety monitoring, if applicable.
- o Evidence for submission of Human Subjects and/or Animal Welfare, if applicable.
- o Statement of consent to have subsequent productivity tracked after application.
- Applications should be submitted as a single PDF document via the DaCCoTA Pathfinder web portal. Select the proposals tab at the top of the page and upload completed application.

Proposed Fall '22 Timeline

- RFA Release Date: August 29th, 2022
- Letter of Intent Deadline: September 9th, 2022
- Letter of Intent Acceptance/Decline: September 14th, 2022
- Begin IRB Preparation: September 14th, 2022
- Required DaCCoTA Core Meetings: October 7th, 2022
- IRB Draft Application Deadline for CRRFC Consultation: October 21st, 2022
- Internal Budget and Grant Approval: November 4th, 2022
- Application Deadline: November 28th, 2022
- Notification of Review: January 6th, 2023
- **IRB Submission:** Must be approved prior to final project submission to NIH for final review.
- Notice of Award: September-October 2023

Budget

- This program provides up to 20% release time (up to NIH cap) for two years to community practicing, hospital-based clinicians.
- Disclaimer: Scholar funding for the duration of the grant will be subject to DaCCoTA receiving grant renewal from the National Institute of General Medical Sciences of the National Institutes of Health. DaCCoTA is funded through August 31st, 2023.

Review Criteria

Applications will be reviewed by NIH according to general NIH guidelines for K01 applications (https://grants.nih.gov/grants/guide/pa-files/PA-18-369.html# Section V. Application). These criteria

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include, but are not limited to, the potential for future funding, the support of the Department/Division, the significance/novelty of the project, and the strength of the applicant and mentoring team.

Additional Information

Applicants or sponsoring institutions may address questions that arise during application development to the Professional Development Core Director Dr. Lee Baugh (<u>lee.baugh@usd.edu</u>) or the Co-director Dr. Donald Sens (<u>donald.sens@UND.edu</u>).

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