

Center for American Indian and Alaska Native Diabetes Translation Research (CAIANDTR) Pilot & Feasibility Program Request for Applications

I. Overview

The objective of the Center for American Indian and Alaska Native Diabetes Translation Research (CAIANDTR) at the University of Colorado is to support translation of diabetes-related interventions and treatments of proven efficacy into American Indian and Alaska Native (AI/AN) populations. CAIANDTR is pleased to announce availability of funding for pilot and feasibility projects consistent with this mission.

This opportunity provides one year of funding (\$25,000 in total funding) to support secondary analyses investigating important questions related to diabetes translation research in AI/AN populations. The proposed analyses may be qualitative or quantitative in nature. Eligible investigators are junior faculty who meet the National Institutes of Health (NIH) definition of Early Stage Investigator (ESI). Successful proposals will be those that hold promise of benefiting Native populations, are scientifically meritorious, and are feasible within the time and resources available. Projects should represent an early step in a line of inquiry that can continue beyond the terms of this initial investment.

II. Eligibility

Proposals will be accepted from any junior faculty member from an institution or organization in the United States that is eligible to receive research awards from the NIH. Applicants must meet the NIH definition of an ESI. According to the NIH, an ESI is an investigator who is within 10 years of completing his/her terminal degree (MD or PhD) or post-graduate clinical training and who has not previously received (as Principal Investigator) a substantial independent research award from NIH (e.g., R01). Additional information about the classification of ESI is provided at the following website: <https://grants.nih.gov/policy/early-investigators/index.htm>.

III. How to Apply

Application Requirements

Applications should describe a proposed set of secondary analyses that can answer important questions related to translation of evidence-based diabetes treatments or interventions into Native communities and should include the following sections:

1. Abstract (\leq 250 words),
2. Proposal Narrative (\leq 5 pages),
3. Mentorship Plan (\leq 1 page),
4. Project Timeline (\leq 1 page),
5. References Cited (no page limit),
6. Protection of Human Subjects and Inclusion Enrollment Report (no page limit),
7. Biosketches,
8. Budget and Budget Justification (\leq 2 pages), and
9. Letter of Support from Senior Mentor.

Proposal Narrative. The narrative should describe the study's specific aims and research strategy. In describing the research strategy, investigators should summarize their methodologic approach, highlight the significance of the proposed project for Native health and diabetes translation research, and identify the ways in which the proposed research is innovative. Applicants should describe the quality of the

research environment in which the work will be completed and highlight the unique and complementary expertise of key personnel. Clarifying how the proposed project will lead to a continuing program addressing diabetes translation research in AI/AN communities is important.

Mentorship Plan. Applicants must identify a senior mentor, who will collaborate with the Principal Investigator and provide guidance throughout the course of the project. The mentor must be an experienced researcher, with expertise relevant to the content or methods of the proposed project. In the application, the Principal Investigator should describe the mentorship plan, including the methods through which the mentor will provide guidance and the frequency of project-related contacts between the investigator and the mentor. The application should include a Letter of Support from the mentor, committing to the provision of professional guidance and routine oversight of project progress.

Project Timeline. Each application should include a table and narrative briefly outlining the timeline for major project milestones. The timeline should include at least the following tasks:

- Receipt of approval from all relevant institutional review boards (IRBs),
- Completion of study analyses, and
- Submission of manuscript to peer-reviewed journal.

Protection of Human Subjects and Inclusion Enrollment Report. Although proposed projects will involve analysis of existing data, proposals should describe risks and methods for protecting human subjects (e.g., confidentiality) and plans for obtaining approval from relevant IRBs. The following website can help investigators determine what sort of review their proposed project is likely to require:

<https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html#c5>.

Investigators should describe the data set to be used as part of the proposed secondary-analysis project, including information about measures included and the participant sample. Investigators should complete the Cumulative Inclusion Enrollment Report, which can be found at the following link:

<https://archives.nih.gov/asites/grants/04-13-2016/grants/forms/phs-inclusion-enrollment-report.htm>.

Biosketches. Biosketches are required for the Principal Investigator, senior mentor, and all key personnel. Key personnel include all individuals who will contribute in a substantive way to scientific development or execution of the proposed project (whether or not they are paid members of the project staff). Applicants should prepare biosketches using the latest NIH biosketch format:

<https://grants.nih.gov/grants/forms/biosketch.htm>.

Budget & Budget Justification. A detailed budget should be provided using PHS 398 Form Page 4 – Detailed Budget for Initial Budget Period: <https://grants.nih.gov/grants/funding/phs398/fp4.pdf>. Instructions for completing the form are available at the following NIH website:

<https://grants.nih.gov/grants/funding/phs398/phs398.pdf>.

A narrative budget justification should describe project costs using the categories identified in the PHS 398 budget form. Allowable expenses include salary support, travel to present study findings, and project-specific office supplies. Although salary support is allowable for the Principal Investigator, key personnel, and other project staff, salary support cannot be requested for the senior mentor. Other unallowable expenses include (but are not limited to) computer equipment, food, furniture, telecommunications (i.e., monthly line charges), administrative support, and professional society dues. Please contact Sarah Trimmer with budget-related questions (sarah.trimmer@ucdenver.edu).

Formatting. Applications should use Arial 11-point font, be single-spaced, and use ½ inch margins.

Application Submission

Applications should be submitted as a single PDF to Angela Brega (angela.brega@ucdenver.edu).

Investigators planning to submit an application should send a letter of intent providing the following including name, degree (and year of completion), title, institution, physical and email address, and phone number as well as an abstract (≤ 250 words) describing the proposed project.

IV. Review Process

The CAIANDTR External Scientific Advisory Committee will review applications based on the five criteria normally targeted in the review of NIH research applications. Factors considered in the review process will include the following:

- **Innovation** – Is the proposed project innovative in its hypotheses and/or methods?
- **Approach** – Are the hypotheses and the research design sound? What is the likelihood of success given the methods outlined?
- **Significance** – Does the project target an important issue related to diabetes translation in AI/AN communities? Will the results further our understanding of diabetes prevention and/or treatment among Native people? Will the results support applications for continued funding?
- **Investigators** – Is the Principal Investigator an ESI and does he/she have an experienced mentor who is committed to participating in the proposed project? Has the mentorship plan been adequately outlined? Does the investigative team as a whole have the necessary expertise and capacity to complete the proposed project?
- **Environment** – Does the research environment improve the likelihood that the proposed study will be successfully completed and have an impact on the field?

Projects selected for funding may require a second stage of review by NIH.

V. Contact Information

General Pilot & Feasibility Program Information

Angela Brega
Director, Pilot & Feasibility Program
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303-724-1470

Pilot Project Budget Information

Sarah Trimmer
Center Fiscal Administrator
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303-724-7945

VI. Key Dates

Letter of Intent	May 17, 2019
Application Due Date	June 3, 2019 by 5:00pm Mountain Time
Provisional Notification of Awards	July 8, 2019
Project Period	August 1, 2019 to July 31, 2020

Provisional notification of awards will occur on July 8th, 2018, with activation of awards pending receipt of the CAIANDTR Notice of Grant Award from NIH as well as prior approval from NIH (if applicable).

Prior to initiation of project activities, the research protocol must receive approval from the appropriate IRBs and all key personnel must provide documentation of training related to human subjects research.

Throughout the project period, the Principal Investigator will be required to submit brief monthly reports describing study progress.