Center for American Indian and Alaska Native Diabetes Translation Research (CAIANDTR)

Pilot & Feasibility Program – 2024 Request for Applications

OVERVIEW

The **Center for American Indian and Alaska Native Diabetes Translation Research (CAIANDTR)** seeks to translate research of proven efficacy into clinical and community settings, with the goal of improving the prevention and treatment of diabetes in Native populations. The CAIANDTR Pilot & Feasibility Program is pleased to announce the availability of funding to support research consistent with this mission.

The **Pilot & Feasibility Program** provides support for investigators committed to conducting translational research related to diabetes in **American Indian, Alaska Native, Native Hawaiian, and/or Other Pacific Islander** (AI/AN/NH/PI) populations. During this 18-month research and training program, funded investigators will:

1. complete and publish a **secondary analysis** relevant to diabetes in AI/AN/NH/PI populations (**Months 1-12**) and
2. develop a **grant application** seeking larger-scale funding for their research efforts (**Months 13-18**).

Successful applications will be those that hold promise of benefiting Native people, are scientifically meritorious, are feasible within the time and resources available, and represent an early step in an innovative line of inquiry that can continue beyond this initial investment. CAIANDTR funding cannot be used to supplement funded research already in progress.

ELIGIBILITY

Applications will be accepted from investigators affiliated with any institution in the United States that is **eligible to receive research awards from the National Institutes of Health** (NIH), including universities, Tribal organizations, and Tribal Epidemiology Centers. Investigators are eligible to apply if they **meet the NIH definition of a new investigator or are established investigators new to the field of diabetes translation research.** A new investigator is an investigator who has not previously received a substantial independent research award from NIH as Principal Investigator (e.g., R01). Information about new investigators is provided on the NIH website: https://grants.nih.gov/policy/early-stage/index.htm

HOW TO APPLY

The application process involves 2 steps:

Step 1. Submit the CAIANDTR Pilot & Feasibility Program Interest Form

Investigators planning to apply to the Pilot & Feasibility Program should submit a completed **CAIANDTR Pilot & Feasibility Program Interest Form**. The form helps program staff to anticipate the number of applications that will be received, identify reviewers with appropriate expertise, and reach out to interested investigators with guidance on application development. Please use the following link to access the Interest Form.

https://ucdenver.co1.qualtrics.com/jfe/form/SV_01HHePQrHUTdwDI

Step 2. Submit Complete Application

Applications should describe a proposed secondary analysis that can answer important questions related to the translation of diabetes-related treatments or interventions into AI/AN/NH/PI populations. We are open to projects examining a wide range of topics, so long as they are innovative and hold promise for improving the diabetes-related health of Native people. Applications should include the following sections:

- Title Page (include project title as well as PI's name, degree (discipline), title, and affiliation)
- 250-word Abstract
- Proposal Narrative
    - Specific Aims (1 page)
    - Research Strategy (4 pages)
- Career & Research Plans (≤ 1 page)
- Mentorship Plan (≤ 1 page) & Letter of Support from Senior Mentor
- Project Timeline (≤ 1 page)
- References Cited (no page limit)
- Protection of Human Subjects & Cumulative Inclusion Enrollment Report (no page limit)
- Biosketches for Principal Investigator & Key Personnel (including Senior Mentor)
- Detailed Budget & Budget Justification
- Institutional Facilities & Administrative (F&A) Rate Agreement

Proposal Narrative. The narrative should describe the study's specific aims and research strategy. Investigators should provide an overview of the data set to be used in the proposed secondary analysis,* summarize the methodologic approach, highlight the significance of the proposed project for Native health and diabetes translation research, and identify how 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 the key personnel.

> **We have compiled a list of data sets that have been used by CAIANDTR Pilot Grant Awardees, as well as other data sets that may include data relevant to diabetes in Native populations. This list is not exhaustive and is just meant to provide examples of data sets for secondary analysis projects. Applicants may use one of the data sets listed here but are not required to.*

Career & Research Plans. Applicants should describe their career aspirations and summarize plans for a future research program addressing diabetes-related outcomes in Native populations. Investigators should clarify how the proposed secondary analysis project will serve as an important steppingstone to reaching their larger research goals.

Mentorship Plan & Letter of Support. Applicants must identify a Senior Mentor to work with on the project. The Senior 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 summarize the mentorship plan, describing the means through which mentorship will be provided and the frequency of project-related contacts between the applicant and the Mentor. The application should include a Letter of Support from the Senior Mentor, committing to the provision of guidance and oversight of 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,
- Submission of a manuscript to a peer-reviewed journal, and
- Submission of a grant application to a funding agency.

Protection of Human Subjects & Cumulative 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. IRBs that will have oversight over the project should be identified. 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 identify and describe the data set to be used as part of the proposed secondary analysis project, including information about measures included, the participant sample, and the process of obtaining permission to use the data. Investigators should complete the **Cumulative Inclusion Enrollment Report**, which can be found at the following link:
https://grants.nih.gov/grants/funding/phs398/CumulativeInclusionEnrollmentReport.pdf.

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 the scientific development or execution of the project (whether or not they are paid members of the staff). Applicants should prepare biosketches using the latest NIH biosketch format: https://grants.nih.gov/grants/forms/biosketch.htm.

Detailed Budget & Institutional F&A Agreement. Applicants should provide a detailed budget that covers the full 18-month project period and includes both phases of the program:

- **Project Phase 1** (Months 1-12): Secondary Analysis Project and
- **Project Phase 2** (Months 13-18): Grant-development Training.

Budgets should be prepared using PHS 398 Form Page 4 – Detailed Budget for Initial Budget Period: https://grants.nih.gov/grants/funding/phs398/fp4.pdf. The budget should not exceed $37,500 in direct costs for the 18-month project period. For applicants from the University of Colorado, indirect costs are not allowed and should not be calculated into the budget. For applicants outside the University of Colorado, indirect costs are allowable and should be accounted for in the budget, using the applicant's institutional F&A rate. If an external applicant can obtain institutional approval for an 8% training indirect cost rate or a full waiver of indirect costs, the difference can be converted to direct costs, thus allowing an increase in the project's Scope of Work. Please contact Dr. Brega to discuss this option before submission of an application (angela.brega@cuanschutz.edu).

A copy of the institution's **F&A Agreement** should be included in the application.

Budget Justification. A 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 research 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) rent, computer equipment, food, furniture, telecommunications (i.e., monthly line charges), administrative support, and professional society dues.

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

Application Submission. Applications should be submitted via email as a single PDF document to Dr. Brega, Director of the Pilot & Feasibility Program (angela.brega@cuanschutz.edu).

APPLICATION GUIDANCE

We encourage applicants to contact Dr. Brega with questions and to obtain guidance on the development of their applications.

Angela Brega, PhD
Director, Pilot & Feasibility Program
angela.brega@cuanschutz.edu

REVIEW PROCESS

Applications will be reviewed by investigators with expertise in the content area addressed and/or the methods described in the proposed project. Reviewers will evaluate applications based on the 5 criteria normally used in the review of NIH grants. Factors considered in the review process 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 address an important issue related to diabetes translation in AI/AN/NH/PI populations? Will the results further our understanding of diabetes prevention and/or treatment among Native people? Will the project provide preliminary data that can support a successful application for larger-scale research funding?
- **Investigators** – Is the Principal Investigator an ESI and does he/she have an experienced Senior Mentor who is committed to participating in the project? Is the mentorship plan adequately described? Does the investigative team have the expertise needed 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?

Following the review process, Pilot & Feasibility Program staff will ask applicants with competitive scores to prepare a formal written response addressing the reviewers' critiques. Applicants need not revise the application itself. Funding decisions will consider the application, the original review, and the applicant's formal response to the reviewers' concerns.

APPLICATION & REVIEW TIMELINE

- Call for Applications Opens — April 15, 2024
- Interest Form Due — August 8, 2024
- Application Due — August 22, 2024
- Review Critiques Sent to Applicant — September 20, 2024
- Written Response to Review Due — October 4, 2024
- Notification of Award — November 1, 2024
- Project Period — December 1, 2024 – May 31, 2026

EXPECTATIONS & PROJECT MONITORING

Major expectations for investigators funded through the CAIANDTR Pilot & Feasibility Program include:

- Publication of ≥ 1 peer-reviewed journal article based on the proposed secondary analysis and
- Submission of a grant application seeking funding to support continued research efforts.

Throughout the project, investigators are expected to attend and complete all required milestones and planned program activities, including:

- Regular mentoring meetings with Senior Mentor,
- Planned education and training activities, and
- Annual Pilot & Feasibility Program Awardee Meeting.

To ensure that CAIANDTR Pilot & Feasibility Program staff can monitor study progress and that projects comply with the Center's Human Subjects Research Oversight Plan, funded investigators will be required to:

- Develop a project timeline that includes specific milestones (e.g., completion of study analyses),
- Provide documentation of continuous IRB approval,
- Submit final Cumulative Inclusion Enrollment data,
- Submit a Data Safety Monitoring Plan (if the project is not exempt from human subjects review),
- Submit a Manuscript Proposal & Analysis Plan,
- Submit a Grant Application Plan, and
- Submit brief monthly reports describing study progress.

Annually, investigators will be asked to provide updated CVs and complete a brief survey outlining their accomplishments during the project year (e.g., publications, presentations, grant applications, honors). Because some outcomes of pilot funding will not be immediate, program staff will request this information annually during all remaining years of the parent grant (2021-2026).