

Georgia Center for Diabetes Translation Research: Pilot and Feasibility Program

2023 Request for Pilot Grant Proposals Letter of Intent: November 1 – 30, 2022 Application Receipt: February 15, 2023

The Georgia Center for Diabetes Translation Research (GCDTR) is pleased to announce the 2023 Pilot and Feasibility Project Program. The CDTR is a collaboration of Emory University, Georgia Tech, and Morehouse School of Medicine, with funding provided by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and interinstitutional sponsors. The mission of the center is to facilitate and grow diabetes translation research at the partner institutions, within Georgia, and regionally with the overarching theme of health equity across race/ethnicity, age, sex and gender identity, geography (rural, urban), and associated comorbid conditions (e.g., cardiovascular disease, HIV, depression, cancer, cystic fibrosis, covid-19 and long-term consequences, and others).

A. FUNDING OPPORTUNITY DESCRIPTION

GCDTR is seeking pilot grant proposals in the field of diabetes translation research that advances health equity. Pilot proposals are expected to be developed to gather preliminary data to generate subsequent funding. Two levels of funding are available for applicants:

- 1. **Preliminary or formative research**: This opportunity is for exploratory, feasibility, and formative diabetes health equity studies to generate preliminary data to facilitate a subsequent submission of a research grant for external funding. Examples include, but are not limited to, qualitative field work, community-engaged research for development of research questions, instrument, or assay testing, and secondary data analyses that leverage existing databases for data science, analytics, and modeling. Budget: up to \$30,000 for one year.
- 2. **Prospective clinical or community-based studies:** This opportunity is for pilot studies addressing diabetes health equity questions using prospective approaches in clinical or community-based settings to create or strengthen preliminary data to facilitate subsequent external grant submissions. A variety of methods may be used, including social, behavioral, clinical and community concepts, evaluations of clinical or innovative interventions, and dissemination and implementation studies. Budget: up to \$50,000/year

B. GCDTR ELIGIBILITY CRITERIA

- 1. Faculty researchers from Emory University, Morehouse School of Medicine, and Georgia Institute of Technology are eligible to apply for pilot and feasibility funding provided that they fit into one of the following categories:
 - a. Early career faculty (e.g., Assistant Professor, Clinical Lecturer, Instructor) with limited current or past research support as PD/PI. Because the intent is that the project should lead to a subsequent NIH proposal, faculty should be eligible as a principal investigator for an NIH K or NIH R-level grant application at the time of submission.
 - b. Established investigators who: a) have no experience in diabetes translation research or b) are proposing









ideas that represent a clear departure from their past research and have a fully engaged junior-level Co-PI (post-doc or junior faculty).

C. PROGRAM CONSIDERATIONS

- 1. In alignment with this purpose, this Request for Pilot and Feasibility Applications is a solicitation for innovative small grant proposals. All projects should fall under the umbrella of T2 T4 translation research and address comorbidities as noted above and risk with:
 - a. Diabetes
 - **b.** Diabetes Complications
 - c. Diabetes and Long COVID/Post-COVID
 - d.Prediabetes/Metabolic Syndrome
 - e. Obesity Prevention/Treatment.

The following definitions for the stages of translation research are:

- a. **T2 Research translation to patients:** Translation and/or implementation of interventions/approaches that have clearly demonstrated efficacy into real world health care settings, communities, and populations at risk with an emphasis on reach and sustainability.
- b. **T3 Research translation to practice:** Effectiveness, cost effectiveness, and comparative effectiveness studies conducted in practice sites, ensuring the translation of results from clinical studies into clinical practice settings.
- c. **T4 Research translation to population:** Dissemination and implementation research, which identifies and resolves barriers to implementation of evidence-based guidelines into community practice.
- 2. Proposed studies should align with one or more of the GCDTR's research cores.
 - a. The **Design and Evaluation for Equity Core** focuses on:
 - Leveraging datasets to evaluate diabetes prevention and management interventions that have been implemented and whether they enhanced equity.
 - Designing effective patient-centered prevention and delivery strategies and utilizing implementation science and evaluation methods.
 - Use of methods to evaluate the economic and logistical scalability of diabetes prevention and management interventions in clinics, communities, counties, or states.
 - b. The Socioecology and Behavior Science for Equity Core provides expertise in:
 - The application of socio-ecological and behavioral sciences for equity in diabetes translation studies.
 - Community-engaged translation research and behavior change models.
 - Mixed methods designs and data collection.
 - Integration of digital technologies for measurement and data collection.
 - c. The **Technologies Advancing Translation and Equity Core** supports a regional network to:
 - Work towards reducing health care disparities in diabetes care and prevention using open, accessible
 technology approaches. Examples include but are not limited to data science, wearable technologies,
 clinical platforms for data and decision making, and interactive systems such as mobile health and social
 media.
 - Identify key gaps and share best practices in the use of diabetes care and prevention technologies.









D. FUNDING LIMITS AND BUDGETING REQUIREMENTS

- Applicants may request one year of funding with amounts up to \$30,000 direct costs for preliminary/formative projects or up to \$50,000 for prospective clinical/community projects. Budgets must be in the NIH R&R format [i.e. detailed, NOT modular].
- Funds may be requested for data collection and analysis, research lab supplies and assays, and travel directly related to the conduct of the research.
- PI, Co-PI(s), or Co-Investigators are not required to request salary but are required to have departmental approval if cost sharing effort is required.
- Funds may be requested for salaries for study staff, students, post-doctoral fellows, and other study- related personnel.
- Senior investigators are strongly discouraged from requesting salary support for themselves; however, senior investigators are encouraged to collaborate with and assist junior investigators.
- Funds may be requested for travel and activities associated with writing an NIH research grant proposal based on project findings and/or attending meetings to present project-related data. Supported travel must be completed within the project period unless permission has been granted by the GCDTR administration to extend the travel deadline.
- Do not request indirect costs. Indirect costs may be awarded later, depending on the source(s) of funding used to support the award.
- Routing for institutional approval is not required for Emory University. Routing is not required by GCDTR
 for other institutions, but applicants should consult with their institution to determine internal routing
 policies.
- Applicants should consult with departmental pre-award support for budget development.
- Investigators can apply for a no-cost extension of one year if sufficient progress is demonstrated on the project following the first year of funding.

E. REVIEW AND AWARD PROCESS

Applications will be reviewed in an NIH study section format with at least two reviewers assigned to each proposal. Preference will be given to proposals that have a likelihood of leading to subsequent funding of applications and address areas of overlap across the Center's priorities and cores of expertise (Design and Evaluation for Equity, Socioecology and Behavior Science for Equity, and Technologies Advancing Translation and Equity). Awards are subject to IRB approval/waiver. All federal and university rules and regulations regarding the administration of grants apply to awarded projects.

2023 CYCLE COMPONENTS

Letter of Intent: Studio Consultations with Core Faculty: Application Receipt: Anticipated Start:

DATE

Tuesday, November 1 – Wednesday, November 30, 2022 December 2022 – January 2023 Wednesday, February 15, 2023 Thursday, June 1, 2023

PROGRAM CONTACTS

Sandra Dunbar, PhD, RN, FAAN, FAHA, FPCNA

Pilot and Feasibility Program Director, Georgia Center for Diabetes Translation Research Professor, Associate Dean for Academic Advancement, Nell Hodgson Woodruff School of Nursing, Emory University

Arshed A Quyyumi, MD, FACC

Pilot and Feasibility Program Director, Georgia Center for Diabetes Translation Research Professor, Department of Medicine, Emory University School of Medicine







For program related questions, please contact the GCDTR Program Director, Jeff Mills jeff.mills@emory.edu

F. LETTER OF INTENT REQUIREMENTS (one page maximum)

- Descriptive title of proposed research.
- Overall aims/hypotheses of proposed research.
- Description of how the project advances the investigator's overall research plan and career trajectory.
- How is health equity being addressed in the proposed research.
- Name, e-mail address, and telephone number of the Principal Investigator and all key personnel.

G. APPLICATION REQUIREMENTS

- 1. Cover Page: Include department grants administrator contact information and signatures.
- 2. Research Plan: Use Arial 11 point font size; minimum 0.5 inch for all margins for all pages.
 - a. **Abstract**: Describe in lay language the general scope of the research and its likely impact. (200 words or less)
 - b. **Specific Aims:** State concisely the hypothesis to be tested and the specific aim(s) to be achieved during the pilot award. The aims must be reasonable to achieve during the one-year budget period of the grant. (maximum of 5 single-spaced pages for Specific Aims and Research Strategy, including tables and/or figures)
 - c. **Research Strategy:** (maximum of 5 single-spaced pages for Specific Aims and Research Strategy, including tables and/or figures)
 - i. <u>Significance:</u>
 - Explain the importance of the problem and/or how it addresses health equity in the prevention and treatment of diabetes and related conditions.
 - Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
 - Describe how the concepts, methods, technologies, treatments, services, or preventive interventions that drive this field will be changed if the proposed aims are achieved.

ii. Innovation:

- Explain how the application challenges and seeks to shift current research, clinical practice, or community-level intervention paradigms.
- Explain how health equity issues will be addressed.
- Describe any novel theoretical concepts, approaches or methodologies, instrument(s) or intervention(s) to be developed or used, and any advantage over existing methodologies, instrument(s), or intervention(s).

iii. Approach:

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately, include how the data will be collected, analyzed, and interpreted as well as any resource sharing plan as appropriate.
- Describe ways in which your research methods inform and support health equity.
- Describe how your approach will engage with relevant GCDTR research cores.
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high-risk aspects of the proposed work.









- Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.
- d. **References Cited:** Provide a bibliography of any references cited in the Research Plan. Each reference must include names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. Include only bibliographic citations. Follow scholarly practices in providing citations for source materials relied upon in preparing any section of the application.
- e. **Protection of Human Subjects** (follow NIH application guidelines): Applicants must ensure that all human subjects are protected. Reviewers will assess the potential risk to human subjects in proposed research and evaluate what protections are in place to guard against any research-related risk. Awards cannot be made until assurances are on file with GCDTR. Decision charts are presented that are helpful in thinking through relevant human subject protections issues (see: https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#3.1)
- f. Research Timeline: Gantt chart of study related activities.

3. List of Key Personnel/Other Significant Contributors:

- a. Key Personnel are individuals who contribute to the scientific development or execution of the project in a substantive, measurable way, whether or not salaries are requested. (These individuals will have effort included on the budget or will be a paid consultant.)
- b. Other Significant Contributors are individuals who have committed to contribute to the scientific development or execution of the project but are not committing any specified measurable effort to the project. Unpaid consultants/collaborators should be included if they meet this definition.
- 4. **Next Stage Funding:** Identify potential funding sources for the next stage of this project. If known, include all four of the following: 1) name of PI for external grant submission; 2) funding agency; 3) funding mechanism; and 4) anticipated date of submission.
- 5. **Detailed Budget Pages**: See section D for allowable costs.
- 6. **Budget Justification**: Provide a justification for all costs (both personnel and non-personnel). Describe the role of each individual listed on the project. Do NOT include any salary figures in the justification. For non-personnel costs, itemize the expenses and describe how they will be used to conduct this project.
- 7. **Biosketches:** Submit biosketches in the <u>NIH format</u> (version effective Jan 25, 2022) for Key Personnel and Other Significant Contributors.

8. Letters of Support:

- Letters from research sites/collaborators if they are being used for primary data collection.
- Confirmation of contributions that will be used to offset the cost of the study.







