



Funding Opportunity

Call for Pilot and Feasibility Grant Applications Focused on Diabetes and Obesity and the Reduction of Health Disparities in the Southeast United States

A. Key Dates

Letter of Intent (Required; see below): March 15, 2020

Application Due: April 1, 2020 @ 11:59 PM (local time of applicant)

Start Date: May 1, 2020

B. Funding Opportunity Description

Purpose. This Funding Opportunity Announcement solicits Pilot and Feasibility (P&F) proposals that focus on innovative ways to prevent or reduce the burden of diabetes and obesity particularly among high-risk populations and high-burden communities in the Southeastern United States. For this announcement, this includes Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee.

Background. The Vanderbilt Diabetes Research and Training Center (DRTC; DK20593) and the Vanderbilt Center for Diabetes Translation Research (CDTR; DK092986) seek to encourage, enable, and empower investigators from institutions throughout the Southeast to address the disease burden of diabetes and obesity. To address these challenges, this initiative seeks to engage new researchers, create new collaborations, inspire trainees, and promote interactions across institutions and NIH-supported or NIDDK-supported centers (e.g., Diabetes Research Centers, Centers for Diabetes Translation Research, Minority Serving Institutions Program, etc.). P&F investigators will be part of the Southeast Regional P&F Program, an effort to foster collaborative, interdisciplinary research across the Southeastern United States. These funds are available in response to NOT-OD-19-070 ("Availability of Funds for Revision Applications for Research Centers with a Focus in Chronic Disease and the Reduction of Health Disparities").

Research Opportunities and Scope. This announcement solicits research proposals aimed at discovering, applying, and translating scientific knowledge about diabetes, obesity, and metabolism in order to reduce the burden of disease from diabetes and obesity in the Southeastern United States. P&F proposals should focus on chronic diseases like diabetes and obesity with a focus on prevention and reduction of disease burden and improvement in the quality of care. P&F grants will provide support for studies that allow an investigator to develop preliminary data sufficient to prepare an application for independent research support through long-term granting mechanisms.

NOT-OD-19-070 suggests these types of efforts:

- “Preventive and/or treatment interventions that:
 - Act on upstream factors in the pathogenesis pathway such that the intervention may be reasonably anticipated to have significant downstream effects on multiple chronic high burden conditions and diseases; and/or
 - Are reasonably anticipated to have broad efficacy by exerting a myriad of effects on multiple chronic high burden conditions and diseases
 - Act at the individual, clinic, and/or community level(s), including natural experiments
- Strategies to prevent and/or treat multiple chronic high-burden diseases (i.e., two or more diseases that cluster in individual patients; and that present high burden on quality of life and on public health). This could include either individual or community-level interventions (such as strategies targeting patient self-management, or social determinants of health, respectively) in the context of multiple chronic diseases.
- Addressing health disparities in regions with a high prevalence of multiple chronic high-burden diseases.”

Some examples of studies that fit within the scope of this P&F program are:

1. Pilot studies of preventive and/or treatment interventions for diabetes or obesity.
2. Studies that assess health disparities in relation to risk for diabetes, diabetes-related, or obesity-related outcomes.
3. Studies that leverage existing cohorts in the Southeastern United States or national cohorts and datasets with substantial samples of people from the Southeastern United States.
4. Studies that leverage existing cohorts – for example, the Southern Community Cohort Study (SCCS), the Stakeholders, Technology, and Research Clinical Research Network (STAR CRN), or other well-established cohorts or datasets of people residing in the Southeastern United States.
 - a. The SCCS (<https://www.southerncommunitystudy.org/>) is an ongoing prospective observational study following 85,000 adults age 40-79 recruited across 12 southeastern states primarily from federally qualified community health centers (CHCs). The cohort was chosen to have a majority (66%) representation of African Americans, and because of the CHC recruitment comprised a population with both blacks and whites of similarly low income. Key advantages of the SCCS include its extensive characterization of study participants from personal interviews at entry and an extensive Biospecimen Repository with DNA banked for about 90%, blood components stored for nearly 40,000, saliva/mouth rinse samples for 39,000, and urines for 24,000. Follow up is carried out via linkages with the National Death Index and Social Security Administration mortality registers, state cancer registries, and Centers for Medicare and Medicaid Services claims databases and via periodic direct contact with surviving participants. Investigators have used the SCCS for etiologic and outcomes related to diabetes and P&F research projects could address behavioral risk factors, genomic and molecular biomarkers as contributors to risk, complications and mortality and other long-term outcomes among patients with diabetes. Such research might focus on whether and how these factors differ between blacks and whites, leading to improved strategies for disparities reduction. Questions about the SCCS should be directed to Dr. William Blot <william.j.blot@vumc.org>.
 - b. The STAR CRN (<https://starcrn.org/>) is part of a national network funded by PCORI to provide support for patient centered outcomes research (PCORnet). The STAR CRN is centered in the Southern United States and includes: (1) Vanderbilt University Medical Center (VUMC), (2) the Vanderbilt Health Affiliated Network

- (VHAN), (3) Meharry Medical College (MMC), (4) Duke University Health System, (5) University of North Carolina at Chapel Hill, (6) Wake Forest Baptist Health, (7) Health Sciences of South Carolina, and (8) Mayo Clinic. These systems comprise scores of academic medical centers, community hospitals, primary practices, and specialty clinics that encompasses over 12 million patients nationally. The populations cared for by STAR sites are diverse in age, race, ethnicity and urban/rural status. The objective of the CRN is to support projects in comparative effectiveness research, pragmatic clinical trials, and other key research areas. This network can provide access to a broad array of clinical data, patients, providers, and systems to address an array of research questions. Questions about engaging the STAR CRN should be directed to Megan Cook, megan.m.cook.1@vumc.org.
5. Studies that use the existing core facilities in the NIDDK-funded Diabetes Research Centers at Vanderbilt University Medical Center (<https://www.vumc.org/diabetescenter/DRTC>; <https://www.vumc.org/cdtr>), University of Alabama at Birmingham (<https://www.uab.edu/shp/drc/>) , or Emory University (<http://diabetes.emory.edu/research/GDTRC.html>) .

Other aspects of the Southeast Regional P&F Program. This program will match investigators with mentors, especially if a suitable mentor is not present at the investigator's institution. Collaboration between institutions is encouraged as is a partnership or collaboration with teaching-intensive and/or less research-intensive institutions.

During year two, the P&F program will bring together P&F-funded investigators in a Collaborative Research Symposium with these goals: 1) provide an opportunity for each funded investigator and other attendees to discuss innovative and collaborative approaches to reduce the burden of diabetes and obesity; 2) build collaborations between participating investigators and institutions, including those with NIDDK-funded center programs and teaching intensive institutions (e.g., Minority Serving Institutions Program); 3) engage students and trainees in the research and in research discussions; and 4) develop mechanisms to sustain the impact of the research.

Each P&F investigator's mentors, as well as researchers and trainees across the Southeast working in related areas will attend this Symposium. Attendees will also include trainees and non-P&F researchers in order to expand opportunities for networking, innovation, and potential transdisciplinary collaborations. In addition to the Symposium, P&F-funded investigators are expected to participate in conference calls every other month to discuss research projects and collaborations.

How is the Southeast Regional P&F Program different from existing P&F programs at institutions? The major differences include: 1) investigators at any faculty level are eligible (not just new investigators); 2) focus on the Southeast; 3) encouragement of collaboration between institutions; 4) primary research efforts may leverage or utilize existing repositories or networks such as the SCCS or STAR CRN for secondary analysis projects or those using mixed-methods approaches; and 5) attendance and participation in the Collaborative Research Symposium.

C. Award Information

Anticipated Number of Awards: 5-7

Award Budget: \$50,000-\$75,000/year

Award Project Period: 2 years; the second year of funding is contingent on progress as detailed in a research summary near the end of year one. The Oversight Committee will evaluate this information and make a recommendation about the second year of funding.

D. Eligibility Information

Eligible Organizations (per NIH guidelines)

- a. Higher Education Institutions
 - i. Public/State Controlled Institutions of Higher Education
 - ii. Private Institutions of Higher Education
- b. Applications from these Higher Education Institutions are encouraged
 - i. Hispanic-serving Institutions
 - ii. Historically Black Colleges and Universities (HBCUs)
 - iii. Tribally Controlled Colleges and Universities (TCCUs)
 - iv. Alaska Native and Native Hawaiian Serving Institutions
 - v. Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Eligible investigators. Investigators must have a faculty appointment (Instructor or above) and must fit within NIH Guidelines for eligibility. P&F grants are intended to provide support for studies that allow an investigator to develop preliminary data sufficient to prepare an application for independent research support through long-term granting mechanisms. P&F support can be sought by any investigator, new or established. Preference will be given to investigators in the Southeastern region of the United States, which includes Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee.

Some examples of individuals who are eligible for research P&F funding are:

1. A study proposed by a new investigator with an interest in a career in research in diabetes or obesity before he/she has developed sufficient data to obtain independent grant support.
2. A study proposed by an established investigator who has experience in other areas and who wants to test ideas related to diabetes or obesity.
3. A study by an established investigator in diabetes or obesity who wants to pursue a question in a substantially different area from his/her current research field or brings new technologies to the area of research
4. A study between clinical and basic investigators (new or established) to test a question of translational relevance to diabetes or obesity.

E. Submission Guidelines

Letter of Intent is required and due on March 15, 2020. Please submit letter of intent here: [Southeast Regional P&F Program Letter of Intent](#)

If the link above does not work, try copying the link below into your web browser:
<https://redcap.vanderbilt.edu/surveys/?s=PCYY9J7LHW>

Applications are due on April 1, 2020 (11:59 PM, local time). Please combine all sections listed below into a single pdf and submit online at this link: [Southeast Regional P&F Program Application Submission](#)

If the link above does not work, try copying the link below into your web browser:
<https://redcap.vanderbilt.edu/surveys/?s=AWETW7D8YR>

The application should be submitted on the NIH form PHS 398, which can be obtained from the website: <https://grants.nih.gov/grants/funding/phs398/phs398.html>

Required pages:

- Face page
- Abstract
- Key personnel
- Biosketch(es)
- Resources
- Research description (five-page limit)
- Literature cited pages (no page limit)
- Letters of collaboration or support (if applicable)
- Administrative page that states:
 - 1) Direct costs requested/year (maximum of \$50,000-\$75,000/year) and whether 1 or 2 years of funding is requested. No detailed budget pages are needed until an award is made.
 - 2) Two suggested reviewers who are not members of the applicant's department or a collaborator.

For questions about eligibility or scope of work, please contact Dr. Sarah Jaser, sarah.jaser@vumc.org. For questions about the grant submission process, please contact Ms. Jessica Kimber (615-875-6072; jessica.kimber@vumc.org).

F. Review criteria. Proposed P&F studies should propose a testable hypothesis and clearly delineate the question being asked, detail procedures to be followed, and discuss how the data will be analyzed and lead to future studies, new research ideas, or new research funding. For junior investigators, additional considerations will include how this award will impact the applicant's career and the potential of the applicant to compete for independent research funding in the future.

Other review considerations:

- Attract new ideas and engage investigators across the Southeast
- Focus on programs or initiatives that can be quickly and effectively implemented within the two-year timeline
- Emphasize efforts that will have an amplifying effect ("multiplier"). The program seeks new ideas, investigators, and collaborations that would have the greatest impact, especially beyond the two-year period of funding.
- Involvement of trainees or collaboration between institutions is encouraged.
- Partnership or collaboration with teaching-intensive and/or less research-intensive institutions is encouraged.