The Duke Clinical & Translational Science Institute (CTSI), Duke University School of Medicine (SOM), and Duke University Health System have launched a new initiative aimed at achieving equal representation in clinical research. The “Changing the Face of Clinical Research at Duke through Community Outreach and Engagement” initiative is supported by funding from The Duke Endowment (TDE).

The voucher program is a funding source designed to build capacity for research projects to maximize their impact. Teams may leverage Duke Research@Pickett services and programs to maximize the ability to increase diverse participation in clinical research, enhance community partnered research, and maximize community engagement or promote outreach activities that promotes awareness, education, and participation in clinical research among underrepresented, underserved, and under engaged populations, with particular focus on race and ethnicity. A total of $195,000 is available to support a minimum of four projects focused on community-partnered research projects with a focus on enhancing diversity of clinical research and improving community health. Funding is provided in the form of a voucher to cover services provided by the Duke Research@Pickett Service Center (staff services and/or facility use). Projects that include community-academic research partnerships are preferred. In addition to receiving the voucher, a data manager and statistician are available at no cost to help support the projects receiving a voucher.

I. Key Dates

- Application deadline: April 1, 2022
- Voucher Recipients Announced: May 13, 2022
- Funding Period Terms: Voucher funds will be available on July 1, 2022 and must be spent on or before June 30, 2024.
- Brief Quarterly Reports: Due on October 1st, January 1st, and April 1st during the funding cycle.
- Annual Reports: Due on July 1st of 2023 and 2024.

II. Priorities:
The Duke SOM is interested in the following types of research projects that have been envisioned or co-created through a collaboration between community and Duke investigative partners with a plan to achieve sustainability:

- Research that focuses on health care priorities identified in the community through community-level assessments such as the 2020 Durham County Community Health Assessment, including but not limited to diabetes, obesity or overweight, mental health, substance use, social predictors of health (e.g. violent crime, affordable housing, gentrification, public transportation improvement, physical activity infrastructure, access to care), and health programming and health education.
- Priorities identified by interdisciplinary and multisector community-level organizations such as the Latinx Advocacy Team & Interdisciplinary Network for COVID-19 (LATIN-19), the African American COVID Task Force (AACT+), Aging Well Durham, the Community Health Coalition, and other community-based organizations.
- Research that focuses on areas of disparity and health equity (Race or ethnicity, sex, sexual identity, age, disability, socioeconomic status, and geographic location) related to diabetes, asthma, cardiovascular disease/hypertension, mental health, cancer, obesity, dementia, kidney disease, and COVID-19 that show promise and are committed to developing solutions that are sustainable that are geared toward improving local health and securing follow-on support for larger investigations of implementation
- Research that includes methods to increase education, awareness, and participation in clinical research by underrepresented communities.
- Research that assesses community partnered research network models, which include clinics and community based or rooted organizations.
- Research that incorporates new or innovative approaches to recruit participants from underrepresented communities.
Preference will be given to research proposals that clearly demonstrate the following:

• A problem-based/hypothesis-driven research question. The project has a strong scientific premise, with well-constructed and clearly defined aims and approach, with the potential to advance health research and understanding of community, population health, and health disparity and equity
• A plan to co-develop and test evidence-based practices such as interventions in community settings
• The ability to mobilize community assets and strengths to test the feasibility of implementation strategies for population health improvement
• Proposed research may include a team that is comprised of both Duke faculty and community partner(s)
• An overall equity framework that also includes partnership equity (shared leadership responsibilities, distribution of research activities, and financial resources)

III. Eligibility

• Consultation with Research@Pickett required prior to submission. Send email request to ResearchatPickett_Requests@dm.duke.edu to schedule a consultation.
• Submission of mandatory application (see below for submission instructions).
• Applicants may be involved in more than one proposal, but can only serve as the project lead or lead investigator in one application during the funding cycle.
• Permanent, full-time, Duke faculty, including professional and non-tenure track; open to all levels of investigators, but early stage investigators are encouraged to apply. SOM PI eligibility requirements are located here: https://myresearchpath.duke.edu/procedure-requesting-eligibility-serve-principal-investigator. Non-faculty members must apply for PI eligibility for any externally funded project and receive approval from ORA.

IV. Application Procedures

Application - Please download and use the submission template.

A. Research statement, including research question and specific aims - no more than ½ page.
B. Brief summary of proposed research design: purpose, significance, innovation, approach - up to 2 pages. Be sure to answer the following:
   a. What is your research question?
   b. What is innovative about your research study?
   c. What is the general design of your study and how will it be carried out?
   d. Who is your community partner, what is the history of your collaboration, and how are you working together to determine roles and responsibilities?
   e. How will you ensure an equity framework within your research through the design and conduct of the research project?
   f. What is the clinical/population health impact of the proposed work?
   g. What is the potential for scalability and sustainability of the findings of the proposed work?
C. Brief description of how the voucher funding will be used – up to 1 page. Be sure to answer the following:
   a. How will this funding maximize the ability to increase diverse participation in clinical research, enhance community partnered research, and maximize community engagement or promote outreach activities that promotes awareness, education, and participation in clinical research among underrepresented, underserved, and under engaged populations, with particular focus on race and ethnicity?
   b. How will success and impact be evaluated and measured?
D. Budget Estimate for Pickett Services: Provide budget estimate based on the consultation with the Duke Research at Pickett Road core service center.
E. Timeline: provide an overall time line of the entire project. If a longer-term project, submit a sustainability plan for activity after June 30, 2024.
F. Human Subjects Protections: Institutional Review Board (IRB) approval is not required prior to submission but will be required prior to the start of research activity. Briefly describe any human subject issues. If human subjects are involved, provide a description of their involvement and characteristics, specific risks to subjects who participate, and protection against those risks. Describe the sources of materials that will be obtained from human subjects as part of their study participation. Provide assurance that the project will be reviewed and approved by the Duke IRB and comply with HIPAA.
G. NIH Biosketch for faculty Investigators and Biosketch, resume (no format), or CV (no format) for
Community Investigators and for key members of the research team, as needed (combine and upload as a single PDF) - click here for NIH Biosketch details.

H. Combine all documents into a single PDF and email to somclinicalresearch@duke.edu by midnight on Friday, April 1, 2022.

V. Budget Guidelines

Note for Duke Investigators: This program is internally funded and does not need to be routed through the Office of Research Administration.

Please note the following during budget preparation:

1. The budget period is up to 24 months beginning as early as July 1, 2022 and ending no later than June 30, 2024.
2. Vouchers funds must be budgeted for use of Duke Research at Pickett Road core services (staffing and/or facility usage) only. Contact Research@Pickett (email: ResearchatPickett_Requests@dm.duke.edu) prior to application submission for an initial discussion of services available and associated costs.
3. Funds must be used to conduct the work proposed. All charges to this voucher must adhere to requirements regarding the use of TDE funds; indirect costs are not allowed. Duke SOM reserves the right to revoke funding in the event it is determined that funds were not spent in accordance with the approved proposal.

VI. Selection Process and Review Criteria

Short applications will be reviewed by a steering committee comprised of Duke SOM faculty and staff, community members and/or community organizations, researchers, and experts in community and population health. Review criteria will include:

- Overall Impact: The likelihood of funding to increase diverse participation in clinical research, enhance community partnered research, and maximize community engagement or promote outreach activities that promotes awareness, education, and participation in clinical research among underrepresented, underserved, and under engaged populations, with particular focus on race and ethnicity.
- Significance: The novelty, uniqueness, and impact of the opportunity presented by the proposal.
- Innovation: Does the proposal challenge and seek to shift current research practices?
- Approach: The overall strategy, methods, and analyses are well reasoned and suitable to the proposed research.
- Feasibility: The feasibility of accomplishing the stated project goals within the project period
- Collaboration: Plans to advance and reinforce partnerships
- Sustainability: Potential for the project to lead to future external funding, implementation and sustainability

VII. Terms (if funded)

Duke SOM will fund the research activities per the approved project proposal. The project will begin when a Memoranda of Understanding for Research@Pickett Services is signed and the PI indicates everything is in place for the project to commence. If more than three months pass after notification of funding and the Project Lead is still not ready to start, Duke’s SOM reserves the right to retract the funding. All funds must be expended by June 30, 2024; any unexpended funds will be retained by the Duke SOM. Any costs that exceed the voucher amount will be charged back to the CRU.

The primary source of funding is The Duke Endowment and should be acknowledged on any projects that flow from this work, either directly or subsequently (follow on studies).

Requests for no-cost extensions will not be approved.

A. Approvals Required Prior to Funding Start Date

- Awardees are expected to finalize all regulatory requirements during a three-month study startup period, July 1 to Sept 30, 2022.
- Fully executed appropriate legal agreement(s) between Duke and community partners must be in place prior to the start of work on the research project, if applicable.
- Failure to submit documents in the requested timeframe may result in cancellation of funding.

B. Project Execution
Research involving human subjects must have appropriate approvals from the Duke IRB. Either an IRB approval letter or an IRB response to a “Determination Whether Research or Similar Activities Require IRB Approval” must be submitted to Duke SOM. Human subjects must be reviewed in accordance with the university’s general assurances and HIPAA. In addition, if the research involves human subjects, all personnel must have certification of training in the protection of human subjects prior to the start of the grant period.

Duke SOM staff will work closely with funded teams throughout the grant period to monitor progress and, when necessary, provide assistance.

Any PI who leaves his or her position should contact Duke SOM to discuss future plans for the project.

CONTACT INFORMATION: For additional information on this funding opportunity, please contact somclinicalresearch@duke.edu.