Announcement: Pilot Awards for Clinical Translational Studies

The missions of the Georgetown-Howard University Center for Clinical and Translational Science (GHUCCTS) and the national Clinical Translational Science Award (CTSA) program highlight promotion of interdisciplinary research that translates basic research findings into clinical applications and clinical research into community practice and improves the process of research. It is also our goal to implement research that will benefit underserved populations, including disadvantaged minorities, people with disabilities, and older adults.

Application Due Date: April 12th, 2022
Applications Submissions are on-line: Link to PTCS Application

Pilot Translational and Clinical Studies (PTCS) Funding Priorities

The following topics reflect the priorities of the National CTSA program and of our hub (GHUCCTS):

A. Investigations of environmental determinants of health, particularly those involving clinical and/or public health databases and geospatial mapping, that have the potential to point toward solutions through surveillance or policy.

B. Innovative community engagement methods and technologies including research aimed at engaging minority, vulnerable, or other underserved and /or understudied populations;

C. Research that expands a translational research focus across the lifespan, including to pediatric and/or geriatric populations;

D. Research to address health disparities and the significant burden of conditions that disproportionately affect rural, minority, and other understudied and/or underserved populations. This includes research to better understand and address:

    •   the impact of structural racism and discrimination on minority health, e.g., the impact of policies and/or distribution of resources on health outcomes;

    •   and/or the impact of discrimination on health and health-related biomarkers.

E. **Pre-pilot award for team building** – Up to $10,000 to support the development of new inter or trans-disciplinary research teams that will address problems using scientific approaches beyond the capacity of the individual investigators. Funds may be used for administrative support, communication technology, transportation, and initial data collection, and must be justified in the budget. While these applications will use the same general format as our

established pilot award application, the content should emphasize the expertise and activity of the applicants and where these domains could integrate and synergize, proposed process for team building, and anticipated milestones. These awards, if productive, may lead to further pilot funding and/or submission of NIH or other grant applications.

    a. **Please note that this is considered a separate funding opportunity**. One investigator may submit to both opportunities, but it is expected that there will be separate applications submitted for each. (One application for general pilot & one application for pre-award team building)

Eligibility

Applicants must have a full-time faculty appointment at one of the GHUCCTS institutions (Howard, Georgetown, DCVA, Medstar, ORNL). Each application should identify a Contact PI who will be responsible for coordinating and submitting the application. Research teams can include collaborators who are not GHUCCTS affiliated.

Funding Opportunity Description

- **Award Amount**: up to $40,000 (includes Institutional cost share 50/50) and/or $10,000 for team building pilot
- **Duration**: Funds must be spent by March 31st, 2023, due to the restrictions on CTSA funding, no-cost extensions cannot be approved
- A **50% cost-share** with the applicant institution **is required**. (For HU and GU this has already been negotiated with your institution, for MHRI please make sure to your Scientific Center Administrator.)

GHUCCTS Resources for Project/Proposal Development

The GHUCCTS is offering free consultation services, which may be helpful to you in your proposal development. Topic areas for advice include, but are not limited to: protocol development, regulatory support, study design, biostatistics, feasibility assessment, recruitment plan, community engaged research best practices, integration of culturally and linguistically competent approaches, inclusion of diverse populations, etc. Utilization of GHUCCTS consultation services will be viewed favorably by the review committee. Please utilize the links below for more information:

- GHUCCTS Programs & Resources
- Bio-statistical Support Services
- Biomedical Informatics
- Clinical Research Units: HU & GU
- Community Engagement Services Contact: Florencia.Gonzalez@Howard.edu
- Recruitment Services

Requirements for Applications: Applications that do not comply with these guidelines will not be considered for review.

Abstract (250-word limit) To enable community representative review, <u>we require that abstracts be written so as to be understood by a lay audience; to not include, or clearly define, technical terms; and to address relevance to public/community health</u>.

Narrative
- A limit of four (4) pages, consecutively numbered at the bottom of each page
- Contact PI's name at the top of each page
- Single spaced,
- 11-point font, minimum
- 0.5-inch margins

Description of Aims, Background and Clinical and Translational Impact, Supporting Preliminary Studies, Design and Methods. If the study involves human subjects the description of human subject considerations is not subject to this page limit. References do not count towards 4-page limit.

Biosketches Current NIH biographic sketch for each investigator and/or mentor.

Budget Guidelines (Apply to both the General Pilot Award and the Pre-Pilot Award)

<u>Budget</u>: Funding will be provided for items essential to the conduct of the project. The budget should identify budget details and total by using **NIH budget page (PHS 398 Form Page 4).** *A separate budget and subcontract are needed for each participating institution.*

<u>Budget Justification</u>: Budget justifications should include the roles and responsibilities of all personnel (paid and unpaid) and details on the purpose of all requested non-personnel costs. Please utilize the template located in the application.

- **Allowable Costs**: Laboratory supplies, participant costs, consultants, research support personnel (salary/wages & fringe benefits), use of institutional/core and GHUCCTS services, travel necessary to perform research.
- **Unallowable Costs:** PI salary support or faculty collaborators, durable equipment > $5,000/unit, office supplies, meals or travel for conferences, publication or presentation costs, professional education or training, indirect costs.

Budgets **should not** include **indirect/F&A costs**.

Departmental and GHUCCTS Executive Approval

Before submitting a PTCS grant application, the PI and any Co-PI that will be requiring institutional cost share is required to obtain approval for submission from his/her departmental chair or division chief and the GHUCCTS executive at their institution, with assurance that appropriate time and resources will be made available to successful applicants. A form is provided in the application packet. GHUCCTS executive contacts are as follows:

Howard Executive: Dr. Thomas Mellman (tmellman@howard.edu)

Georgetown Executive: Dr. Joseph Verbalis ([verbalis@georgetown.edu)](mailto:verbalis@georgetown.edu)
DCVA Executive: Dr. Marc Blackman (Marc.Blackman@va.gov)
MedStar Executive: Dr. Neil Weissman (Neil.J.Weissman@Medstar.net)
ORNL: Dr. Blair Christian (ChristianJB@ORNL.gov)

IRB/IACUC & Human Subjects

Consistent with NIH policies, IRB or IACUC approval or exemption, as well as conflict of interest review will be required prior to transmission of funds and project implementation.

Although Institutional Review Board and/or Institutional Animal Care & Use Committee approval are not required prior to application submission, we strongly encourage preparation of regulatory documents as soon as possible. If human subjects are to be involved in the proposed project, provide a description of their involvement, specific risks to subjects who participate, and protection against those risks. Describe any sources of materials that will be obtained from human subjects as part of their participation. Provide assurance that the project will be reviewed and approved by the IRB.

N.B. All pilot studies to be conducted at the DC VAMC also require approval by the DC VAMC's Research & Development (R&D) Committee.

Applications will not be considered complete without all components.

How to Apply

Applications Submissions are on-line: [Link to PTCS Application](#)

Online Application:

- The application and forms will open on **February 16th, 2022**
- The completed application and signed forms (institutional support forms) are due by **April 12th, 2022.**

Applications **MUST** be submitted using the templates provided in the application (i.e. NIH budget page (PHS 398Form Page 4) and Budget justification template**)** Copies of the application templates can be downloaded through the application portal.

Review Criteria and Process

Applications will be peer reviewed and evaluated based on the following criteria:

- Relevance to the above priority themes/categories

- Use of an interdisciplinary approach. (Consider going outside of your institution if required expertise is more readily available at other GHUCCTS institutions (Georgetown University, Howard University, MedStar, DC Veterans Administration Medical Center, and Oak Ridge National Laboratory) or other CTSA hubs.

- Promising direction for future extramural funding Clearly describes how proposed aims will provide opportunities for future externally funded applications, including but not limited to NCATS initiatives.

- <u>Collaborations between junior and senior investigators.</u> For experienced investigators, participation of junior investigator/trainees; for junior investigators, adequate/appropriate mentoring and consultation.
- <u>Approach</u> Will the proposed methods achieve the aims?
- <u>Significance</u> If successful will the project move the field forward? Does the proposed project answer an important translational research question?
- <u>Innovation</u> Could apply to the approach, technology or its application to a novel focus.

New requirements for funded pilot grants:

GHUCCTS is funded through a CTSA grant from NIH's National Center for Advancing Translational Sciences (NCATS). NCATS has instituted a new policy requiring the review and approval of all GHUCCTS pilot grants involving human subjects research prior to GHUCCTS funds being utilized. Therefore, if your proposal is funded and involves research with human subjects, GHUCCTS will require additional documentation to send to NCATS. NCATS expects to complete their review in less than 30 days. The NCATS review can occur concurrently with the IRB review; however, final NCATS approval is contingent upon IRB approval

Contact:

Requests for information, including clarification about GHUCCTS resources available for pilot studies and questions about the preparation and submission of applications, can be obtained from the GHUCCTS PTCS administrator: Eddie Bauer (**Edward.Bauer1@howard.edu; 202-865-4272**)