Announcement: Pilot Awards for Clinical Translational Studies

The missions of Georgetown-Howard University Center for Clinical and Translational Science (GHUCCTS) and the national Clinical Translational Science Award (CTSA) programs highlight promotion of interdisciplinary research that translates basic research findings into clinical applications and clinical research into community practice, and improving the process of research. It is also our goal to implement research that will benefit underserved populations, including minorities, people with disabilities, and older adults. Additional priorities recently indicated by the agency that administers CTSAs, the National Center for Advancing Translational Science (NCATS) (see https://ncats.nih.gov/ctsa), further emphasize interaction and collaboration of the 62 CTSA hubs spread throughout the United States (see https://ctsacentral.org).

Application Due Date: April 15, 2019 11:59PM
Applications Submissions are on-line: Link to PTCS Application

2019 Pilot Translational and Clinical Studies (PTCS) Funding Priorities

We are proposing a new core capacity in our recently submitted competitive renewal application to leverage emerging information technology to investigate environmental determinants of health. The proposed core includes collaborations with the Health Data Sciences and Urban Dynamics Institutes of Oakridge National Laboratories and the DC Department of Health. Information on contacting individuals at these institutes and their capacities can be obtained through Shannon Gopaul (Shannon.Gopaul@Howard.edu; 202-865-7260). We will be prioritizing applications that focus on this topic (environmental determinants of health). Potential to be advanced through the proposed core will be considered favorably though collaboration with our proposed partners is not required for applications at this time. Further questions can be addressed to Ms. Gopaul. Other priority topics overlap past announcements and reflect the evolving missions and priorities of GHUCCTS and NCATS.

Summary of priority topics:

- Investigations of environmental determinants of health, particularly those involving clinical and or public health data bases and geospatial mapping, and have potential to point toward solutions through surveillance or policy.

- Innovative community engagement methods and technologies including research aimed at engaging minority, vulnerable, or other understudied populations;

- Research that brings together a new type of team;

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

- Innovative approaches to the implementation of precision medicine;

- Engaging individuals with Opioid Use Disorders in research and clinical care while developing effective models of care delivered within medical settings of interest;

- Research to address health disparities and the significant burden of conditions that disproportionately affect rural, minority, and other underserved populations.

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 that 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)
- **Duration**: Funds must be spent by March 31st, 2020.
- A **50% cost-share** with the applicant institution **is required**. (In most cases this has previously been negotiated with the participating institutions.)

Requirements for Applications

Abstract (250-word limit) To enable community representative review, we are requiring that abstracts be written to be understood by a lay audience and to not include or clearly define technical terms, and for the abstracts to address relevance to public/community health. Failure to provide such an abstract could lead to return of the application without it being reviewed.

Narrative A limit of four (4) pages (single spaced, 11-point font, minimum 0.5-inch margins) for 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 limit. References do not count towards 4-page limit. Include the contact PI's name at the top of each page and consecutively number all pages in the applications at the bottom of each page

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

Budget Guidelines

Budget: 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 is needed for each participating institution and subcontract.*

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

- **Allowable Costs**: Laboratory supplies, small equipment (if deemed essential to the conduct of the project), 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, office supplies, meals or travel for conferences, 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)
DCVA Executive: Dr. Marc Blackman (Marc.Blackman@va.gov)
MedStar Executive: Dr. Neil Weissman (Neil.J.Weissman@Medstar.net)

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 is 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.

Applications will not be considered complete without all components.

How to Apply

Applications Submissions are on-line: <u>Link to PTCS Application</u>

Online Application:

- The application and forms will open on **Tuesday, March 12ᵗʰ 2019.**
- The completed application and signed forms (institutional support forms) are due by **Monday, April 15ᵗʰ, 2019 at 11:59pm.**

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

Review Criteria and Process

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

- <u>Relevance to the above priority themes/categories</u>

- <u>Use of an interdisciplinary approach</u>. (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.

- <u>Promising direction for future extramural funding</u> 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, utilization 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.

Additional Information

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 t: protocol development, study design, biostatistics, feasibility assessment, recruitment plan, community engaged research best practices, integration of culturally and linguistically competent approaches, inclusion of diverse populations, etc.   Please utilize the links below for more information:

[GHUCCTS Programs & Resources](#)

[Biostatistical Support Services](#)

[Clinical Research Units](#): HU & [GU](#)

Community Engagement Services Contact: Florencia.Gonzalez@Howard.edu

[Recruitment Services](#)

[Protocol Development](#)

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: Yejide Obisesan (**yejide.obisesan@howard.edu; 202-806-9481**)