



GHUCCTS/CTSA COVID-19 Research Initiatives

As many of you know, there is a proliferation of clinical trials, basic research and data science projects targeting COVID-19 treatments, diagnostics, and pathophysiology. As of today, more than 800 COVID-19 trials are registered on clinicaltrials.gov. Many of these trials are non-randomized single-site trials that will not have the statistical power to detect meaningful differences among interventions. The national NIH-funded [CTSA](#) network consists of 60 centers of clinical and translational research excellence across the country (called CTSA "hubs") that support large multi-site clinical trials, which can be implemented and completed quickly and efficiently and have the power to generate meaningful and actionable results. Because our CTSA, the Georgetown-Howard Universities Center for Clinical and Translational Science ([GHUCCTS](#)), was recently renewed for its [third 5-year cycle](#), our hub is now eligible to participate in all national CTSA-supported networking activities and clinical trials. The purpose of this announcement is to make our investigators aware of the GHUCCTS/CTSA resources that are available and how to access information about them for COVID-19-related research.

1. GHUCCTS Pilot Projects. GHUCCTS has funding to support 6-8 pilot projects yearly with budgets of up to \$40,000 for one year per selected project. This year the priority areas for funding included "Research that addresses the transmission, course, and consequences of COVID virus infection." A total of 27 applications were received on May 4, of which 13 addressed COVID-19 research. A GHUCCTS review committee will be meeting shortly to review the applications, with award notifications expected by June 5, 2020.

2. NOSIs of the National Center for Advancing Clinical and Translational Science. Many NIH institutes have issued Notifications of Special Interest (NOSI) related to COVID-19 research. The [National Center for Advancing Clinical and Translational Science](#) (NCATS) has also issued one:

[NOT-TR-20-011](#). NCATS is particularly interested in "projects focusing on the use of informatics solutions to diagnose cases and the use of CTSA-supported core resources (e.g., advanced scientific instruments, highly-specialized facilities, and regulatory expertise) to facilitate research on COVID-19 and advance the translation of research findings into diagnostics, therapeutics, and vaccines." The funding mechanisms available include Collaborative Innovation Awards (U01 - a collaboration of investigators from 3 or more CTSA hubs, with funding up to \$750,000/year (clinical projects) or \$400,000/year (non-clinical projects) for up to 4 years) and Exploratory Collaborative Innovation Awards (R21 – a collaboration of 2 or more CTSA hubs with funding up to \$275,000 for 2 years). Due dates for both of these grants are July 10, 2020. Information about the applications can be found in the NOSI, and interested individuals should contact GHUCCTS leadership at each of our institutions to discuss their plans and eligibility (listed at the end of this announcement).

3. CTSA Trial Innovation Network. The [Trial Innovation Network](#) (TIN) is a collaborative national network of CTSA hubs that leverages the expertise and resources of the national CTSA Program to execute clinical trials better, faster, and more cost-efficiently, and to be a national laboratory to study, understand and innovate the process of conducting clinical trials. [Resources](#) available through TIN include a nationwide single IRB system, master contracting agreements, quality by design approaches, and a focus on evidence-based strategies for recruitment and patient engagement. GHUCCTS participates in the TIN in two ways:

1. Investigators who are planning a multi-site clinical trial can submit their protocol to the TIN for a consultation that can either be broad (e.g., advice about trial design, statistical analysis, data extraction from health IT systems, etc.) or focused (use of a TIN single IRB, recruitment of other sites, etc.).
2. Multi-center-trials accepted by the TIN are pushed out to CTSA hubs to rapidly assess ability and interest to participate as a site in the trial. Ability is assessed by analysis of our electronic health records to determine if the hub has enough patients who meet eligibility requirements; interest is assessed by contacting potential GHUCCTS investigators about their interest in being a site-PI for the trial.

We have recently been selected as a site for two important TIN protocols involving a randomized controlled double-blinded Phase 2 study comparing the efficacy and safety of human coronavirus immune plasma (HCIP) vs. control (SARS-CoV-2 non-immune plasma) in high-risk patients. These protocols will soon be active at both MGUH and MWHC. Information about the TIN is available at the [TIN website](#) or through our GHUCCTS TIN point of contact, [Emily Paku](#).

4. COVID-19 Collaboration Platform. The COVID-19 Collaboration Platform ([COVID-CP](#)) is a repository of randomized control trial (RCT) protocols whose PIs are open to collaborating with new teams of researchers in order to transmit high-quality evidence to clinicians quickly. The CTSA TIN has issued an Expression of Interest to all CTSA hubs to enlist our help by identifying clinical trial PIs who are interested in collaborating and sharing their protocols with the COVID-CP team, as well as identifying other interested stakeholders (i.e., clinical researchers, ethicists, health care delivery scientists) to help build the COVID-CP framework and oversight for interim aggregated statistical analyses. Although still in its infancy, the promise of the COVID-CP platform is to have PIs exchange ideas about potential clinical trials that can be run jointly at multiple sites in order both to refine the design of the study, and to increase the numbers of enrolled patients to improve the power of the study to achieve statistically significant results.

Investigators with protocols for COVID-19 clinical trials (either complete or in draft form) can submit them directly to [COVID-CP](#) for a promised quick review by the TIN before posting them for other investigators at different sites to begin discussions about potential collaborations. It will be important to inform our GHUCCTS TIN point of contact, [Emily Paku](#), about any submissions prior to sending them to COVID-CP so we can be sure they are entered into the TIN dashboard.

We anticipate additional opportunities for collaboration and participation in CTSA-sponsored clinical trials related to COVID-19 research in the near future. We will forward these directly to faculty with expertise in the protocol subject, and will also post them on the [COVID-19 section of our website](#).

You may also sign up to receive weekly updates regarding GHUCCTS events, funding opportunities and resources by emailing ghuccts@georgetown.edu. As always, GHUCCTS leadership at each of our institutions is available to discuss these and other initiatives directly with our faculty:

Georgetown University: [Joe Verbalis](#)

Howard University: [Tom Mellman](#)

MedStar Health Research Institute: [Neil Weissman](#)

Washington DC VAMC: [Marc Blackman](#)