National Institutes of Health (NIH) Launches SARS-CoV2 Pandemic Serosurvey and Blood Sampling Study, University of Pittsburgh Clinical and Translational Science Institute (CTSI) Plays Crucial Role

The NIH recently launched a large scale research study to test people with no confirmed history of SARS-CoV2 for antibodies to the virus, which causes COVID-19. Antibodies indicate viral exposure, and from an epidemiological perspective, understanding the number of persons with exposure will help provide insight into the impact of immunity on the spread of the virus. A better understanding of transmission, as well as knowing which communities and demographics are most affected, may in turn help with future strategies for combatting the spread of infection.

The study is being conducted by researchers at the National Institute of Allergy and Infectious Diseases (NIAID) and the National Institute of Biomedical Imaging and Bioengineering (NIBIB), with support from the National Center for Advancing Translational Sciences (NCATS) and the National Cancer Institute (NCI). The Principal Investigator, Matthew J. Memoli, MD, MS, is the Director of NIAID’s Laboratory of Infectious Diseases and Clinical Studies Unit. The study seeks 10,000 healthy participants age 18 and older from across the country who are willing to provide health information and supply a blood sample via a finger stick kit that can be used at home to draw a small amount of blood which is returned to laboratory facilities via a pre-paid package delivery service.

The NIH initially sought their own employees as participants, but as news of the study spread, it became clear that many people beyond the NIH were willing to take part. Subsequently, NIH sent a survey that received positive responses from over 375,000 potential participants indicating a willingness to be contacted about the study. Faced with this overwhelming response, the NIH turned to the University of Pittsburgh Clinical and Translational Science Institute (Pitt CTSI) and the University of Alabama at Birmingham Center for Clinical and Translational Science (UAB CCTS) for help contacting, screening, and consenting participants, and sending blood collection kits to those who are eligible. Pitt CTSI and UAB CCTS quickly mobilized call centers and developed protocols for enrolling participants. Local efforts launched May 20, and to date 3,400 calls were made to potential participants with 1,170 participants consenting to take part in the study.
Research Resources: Remote Consenting

Even before the advent of the global COVID-19 pandemic, there has been increasing interest in remote consenting procedures. Certain populations, like people living in rural areas and people with mobility issues, are more likely to be included in research if remote options are available, and the pandemic, which has placed restrictions on in-person visits, has only increased the need for remote forms of consent to enable participation in research.

In the case of minimal risk studies, some qualify for a waiver to document consent, making remote consenting easier. If the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context, a waiver may apply. A waiver may also apply if the only record linking the subject and the research study would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. An informed consent discussion still needs to take place via phone or video chat; waivers to document consent are not the same as waivers of consent. The Human Research Protection Office (HRPO) needs to make any determination regarding waivers.

For studies that do not qualify for a waiver, many researchers rely on REDCap, a secure, web-based database, as a tool to assist with remote informed consent. Informed consent documents can be created in REDCap and emailed to potential participants. Study staff then arrange a phone call or video conference in order to have a real-time informed consent dialogue before an electronic signature is obtained.

REDCap allows for signature on the informed consent document by both parties, and allows the participant and the consenting party to download a PDF of the completed informed consent document, which is also stored securely in the REDCap database. The consenting party can also document consent through signing an electronic attestation in the database or adding a note to file in the participant record. It is important that potential participants understand they should not provide an electronic signature until a thorough informed consent discussion has occurred. REDCap has instances for both University of Pittsburgh Medical Center and University of Pittsburgh users.

DocuSign represents another platform for securely sending consent for electronic signature. Like REDCap, DocuSign should be paired with a phone call or video conference to ensure a complete informed consent dialogue occurs for research purposes. DocuSign is only available to researchers with University of Pittsburgh accounts. The University of Pittsburgh’s Human Resources department is providing virtual training regarding DocuSign on June 9th.

Video conferencing with screen sharing is ideal for remote consent since both the participant and consenting party can view and discuss the document together in real time. Video platforms endorsed by the University of Pittsburgh include Zoom, Microsoft Teams, Vidyo, and Skype for Business. Please see the University of Pittsburgh Information Technology website for more information.

Funding Opportunities

Many researchers have contacted CTSI regarding potential funding opportunities for COVID-19 related research projects. A curated list of COVID-19 funding can be found on the CTSI website. The Office of Sponsored Programs also maintains a list. While the pandemic has created an urgent need for COVID-19 research, discovery in other disciplines remains ongoing and important as well. Other opportunities can be found below.

The Marian R. Stuart Grant

The American Psychological Association is offering this funding opportunity to early career psychologists investigating the connection between mental and physical health. Applications will be evaluated for originality, impact, innovation, and potential contribution to public health. More here.

Kidney Cancer, Concept Award

Unlike many grant applications, this Department of Defense funded award does not require preliminary data to support proof of concept. This funding opportunity seeks investigators with entirely novel, untested, and potentially groundbreaking concepts in kidney cancer research. Support is offered to innovative, high risk studies and not projects that represent progression of an established idea. More here.

Drug Development Program (Alzheimer’s Disease)

The Alzheimer’s Drug Discovery Foundation supports pre-clinical research in animal models that target treatment for Alzheimer’s Disease and related dementias. Both novel therapies and repurposing of approved clinical therapies used for other disease indications are appropriate for this announcement. More here.

Innovation for HIV Vaccine Discovery

The National Institute of Allergy and Infectious Diseases is sponsoring a funding opportunity for researchers with high impact proposals that investigate potential HIV vaccines. Preliminary data not required. Proposals should address an important problem or critical barrier in the field. More information here.
CTSI Updates

CTSI Coordinates COVID-19 Research Campus-Wide, Awards COVID-19 Pilot Funding and Pain Research Funding

The onset of the COVID-19 pandemic created a call to arms in the University of Pittsburgh research community, and investigators from many different departments and disciplines rose to the challenge by quickly designing protocols intended to help mitigate the crisis. Early on, CTSI was designated as the single point of contact for triaging all COVID-19 related projects.

Through a required online survey, CTSI has reviewed hundreds of COVID-19 related projects to date. All projects are sent to a leadership committee which matches investigators with collaborators planning similar research projects to eliminate redundancy and maximize efficient use of resources. All projects are offered the full support of CTSI services according to individual need. Many projects have been referred to CTSI’s Biostatistics, Epidemiology, and Research Design (BERD) group for consultation regarding statistical analysis and study design, while others have benefitted from protocol and consent development consultation with the Regulatory Knowledge and Support group.

CTSI is also supporting the battle against COVID-19 by awarding pilot funding. In April, the Office of the Provost, the Office of the Senior Vice Chancellor for Research, the DSF Charitable Foundation, and CTSI joined forces to award a total of $900,000 to 17 different research proposals addressing different aspects of the pandemic. The awardees represent a spectrum of research topics and include proposals for prevention, detection, and treatment of COVID-19 as well as bench science to better understand the underlying biological mechanisms of the virus. Learn more about these projects [here](#).

CTSI also recently selected awardees for its annual PAIN Research Challenge. The PAIN Challenge is sponsored by CTSI and the Virginia Kaufman Endowment Fund and solicits research projects that propose to ease the burden of pain, either physical or psychological. Three projects are selected each year to receive $50,000 awards. This year’s recipients include a study seeking to understand physiological, psychological, and sociological factors involved in the transition from acute to chronic pain in cancer patients, a project looking at epigenetic therapeutics for pain management, and a proposal to develop a wearable low back pain monitor to mitigate pain in patients with chronic lower back pain. To learn more about the Pain Research Challenge winners, visit the CTSI [website](#).

Regulatory Notes

Resumption of Research at the University of Pittsburgh

Senior leadership at the University of Pittsburgh has been closely monitoring public health and safety concerns associated with the COVID-19 pandemic and continuously evaluating when and how a safe resumption in campus and research activities may occur. On May 29, Senior Vice Chancellor for Research Rob A. Rutenbar announced that the first phase of on-campus research will restart on June 3. A [website](#) that will be updated in real time has been created to guide investigators in the restart process. CTSI is also closely involved and will post updates as well.

Studies in Data Analysis Only and Long Term Follow-Up required to Transition to PittPRO

The Human Research Protection Office (HRPO) now requires that all studies in data analysis only (DAO) or long term follow up (LTFU) transition to PittPRO or submit a study closure. Studies should transition at the time of continuing review, unless they have no expiration date. Studies with no expiration date should wait to hear from an HRPO representative before taking any action. Studies which only require analysis of de-identified data are strongly encouraged to consider closure.

HRPO provides detailed guidance to inform decision making for studies in DAO or LTFU, including information regarding activities that may continue after a study in DAO closes and which study activities can be conducted under a LTFU designation. They also provide step-by-step instructions for the PittPRO transition process.
Dear CTSI

Hello Readers! This space is reserved for your questions. If you have a research question you would like to see answered in print, please send it to cliftons@pitt.edu and look for answers in our next edition.

Dear CTSI,

Question: What are the IRB requirements related to moving study visits which formerly happened in person online in light of the COVID-19 pandemic and subsequent restrictions on research and in-person visits? Do we need to modify our study to transition to remote procedures? If we use video platforms, are there recommendations for those that are the most secure?

Answer: IRB requirements depend on whether or not your study is exempt and whether or not your protocol explicitly states study visits will take place in person. For exempt studies and studies that did not specify in person visits in the protocol or consent form, no modifications or exceptions are required to transition. Studies which are not exempt and specify in person visits in the protocol will need to request an exception. Modifications are not necessary.

Pitt-endorsed platforms for video conferencing include Microsoft Teams, Zoom, Vidyo, or Skype, as vendor agreements with these platforms enhance confidence in security. Zoom meetings should include a password for entry to add an extra level of protection from “Zoom bombing,” a practice in which Zoom meetings are disrupted by outsiders who sometimes display inappropriate or offensive material.

More information on changing research procedures to accommodate remote processes compliantly can be found on the HRPO website.

Upcoming Virtual Events

DocuSign Basics: Gather eSignatures and Manage Document Workflow
Presented by the University of Pittsburgh Human Resources Faculty and Staff Development Program
Tuesday, June 9, 2020 10:00 a.m. - 11:30 a.m.
More here

Introduction to Data Management
Presented by the University of Pittsburgh Health Sciences Library System
Monday, June 22, 2020 9:00 a.m.– 10:00 a.m.
More here

Getting Your Research Published
University of Pittsburgh Health Sciences Library System
Monday, July 20, 2020 12 p.m. - 1:00 p.m.
More here

Evaluating Payment to Participate in Research: Ethical and Regulatory Issues (recorded, requires sign-in, no fee)
Presented by Advarra/Forte
More here

Questions for us? We’d love to hear from you:
https://ctsi.pitt.edu/contact-us/