CTSI

Coordinator Connect



Issue 10. Winter 2020

In this issue:

- The Health Disparities Research Institute
- Research Resources: Magee Obstetric Maternal & Infant Database (MOMI)
- Funding Opportunities
- CTSI News: Cookies and Conversation
- Regulatory Notes ClinicalTrials.gov changes
- Dear CTSI: When do I need a Confidential Disclosure Agreement?
- Upcoming Events

The National Institute on Minority Health and Health Disparities (NIMHD) Sponsors Upcoming Health Disparities Research Institute (HDRI)

In recent years, the research community has become increasingly invested in inclusion - ensuring that people who have traditionally been underrepresented in biomedical research have equal opportunity to participate in studies and reap the health benefits of scientific discoveries. The NIMHD is responsible for planning, reviewing, coordinating, and evaluating minority health and health disparities research conducted by National Institutes of Health (NIH) Institutes and Centers. It also promotes diversity in the biomedical workforce. Consistent with this mission, in August of 2020, NIMHD will offer a competitive opportunity for early stage investigators to participate in the Health Disparities Research Institute (HDRI).

The Institute offers lectures on health disparities in research and minority health, group discussion, and seminars focusing on the origin of health inequities and intervention and implementation research. The HDRI also offers participants the opportunity to interact with National Institutes of Health scientific staff with expertise in health equity research. Staff will provide consultation on the process of developing a research idea into a grant application and conduct mock grant reviews.

In order to qualify, applicants must be considered early stage investigators, meaning they have completed their terminal degree or post graduate clinical training within the last ten years. Applications are limited to those who plan to submit a K or R grant proposal in the next 12 months. Additional educational requirements also apply and can be found on the announcement <u>website</u>. Applications will be accepted until March 9; HDRI will be held from August 3 - 7, 2020 at the NIH campus in Bethesda, Maryland.

Research Resources: The Magee Obstetric Maternal & Infant (MOMI) Database and Biobank

The Magee Obstetric Maternal & Infant (MOMI) Database and Biobank is a resource for the study of normal and abnormal pregnancy. Together the MOMI Database and Biobank collect and distribute obstetric biological samples and provide linked, annotated clinical information. MOMI is a core resource of the Magee-Womens Research Institute, is affiliated with the University of Pittsburgh Medical Center, and is supported by the University of Pittsburgh Clinical and Translational Science Institute.

The MOMI Database is comprised of all Magee deliveries from January 1995 to the present. It is populated in real time and includes data from medical record systems for all mother-infant pairs delivered at Magee. MOMI contains over 300 variables for over 200,000 deliveries. The MOMI Biobank, launched in 2017, partners with women receiving care at Magee-Womens Hospital who provide specimens and information throughout pregnancy and at birth. Twenty percent of women delivering at Magee participate in the MOMI Biobank with over 2,000 women enrolling each year. A unique, web-based inventory system accurately links biological samples from the MOMI Biobank to annotated clinical data from the MOMI Database to fulfill research requests.

MOMI data and specimens have been utilized by researchers working toward discoveries in the fields of OB/GYN, internal medicine, nursing, psychiatry, psychology, and pediatrics, and by investigators affiliated with the Pittsburgh Cancer Institute, the Pittsburgh Girls Study, and The Pittsburgh Study. MOMI staff have completed requests for summary statistics, clinical datasets for study cohorts, and cohort identification, along with specimen requests for banked samples and prospective collection of samples not already in the MOMI Biobank. Researchers have used MOMI staff to aid in study recruitment through targeted mailings and study referrals. For a small fee, MOMI recruiters can work with investigators to refer and enroll women in a variety of studies.

The MOMI Database and Biobank is under the direction of Dr. Janet Catov, Associate Professor of OB/GYN. The Medical Director and chair of the Ethics Committee of the MOMI Biobank is Dr. Arun Jeyabalan, Associate Professor of OB/GYN, Division Chief, Maternal Fetal Medicine.

To inquire about a Data or Specimen Request or for more information about MOMI, please contact Danielle Sharbaugh at (412) 641-1934 or at sharbaughd2@upmc.edu.



Funding Opportunities

The Pain Research Challenge

The University of Pittsburgh Clinical and Translational Science Institute (CTSI) sponsors this funding opportunity to support research that proposes ideas and solutions associated with alleviating both physiological and physical pain. Research solutions can address the dynamics of pain, causes and alleviation of pain, and treatment to prevent or mitigate pain. More here.

Discovery of Biomarkers, Biomarker Signatures, and Endpoints for Pain

As part of the Helping to End Addiction Long-Term (HEAL) Initiative, The National Institutes of Health seeks researchers investigating the biomarkers, biomarker signatures, and endpoints for pain indications. Ultimately discoveries in these areas may provide tools for the development of non-opioid therapeutics for the treatment of pain. More here.

Alexander Gralnick Research Investigator Prize

The American Psychological Foundation sponsors this prize to support outstanding research and mentoring accomplishments in the realm of research on serious mental illness. The prize aims to facilitate research by doctoral-level researchers studying illnesses including but not limited to schizophrenia, bipolar disorder, and delusional disorder. More html

Translational Research in Pediatric and Obstetric Pharmacology Therapeutics

The National Institutes of Health seeks investigators seeking to fill the gaps in knowledge in terms of information guiding safe and effective drug therapy in pediatric and obstetric patients, who have historically often been excluded from research due to ethical concerns. This funding supports pharmacological studies examining drug response among children at various developmental stages and in women during pregnancy and lactation. More information here.

B*Cured 2020 Research Investigator Grant

B*Cured funds innovative brain cancer research and invites investigators to apply tor the 2020 Research Investigator Award. Clinical and translational projects with significant clinical promise will be considered. Appropriate applicants include clinical doctors and research scientists whose primary focus is brain cancer. More here.

CTSI Updates

Cookies and Conversation Launches

There has been a growing movement to make research more inclusive and representative of communities who have traditionally been underrepresented in biomedical research. CTSI is committed to inclusion, and recently launched a quarterly event, Cookies and Conversation, to bring together persons with disabilities, researchers, advocates, providers, and caregivers to discuss how disparities affect persons with disabilities and learn more about barriers to equitable research participation.

Event facilitator RaNaja Kennedy notes that opportunities for persons with disabilities to communicate their needs to researchers are lacking: "Providers and patients do not get to communicate with bench side researchers, which is ironic, because how does the researcher know what the potential participants need for them to engineer or research?"

During the inaugural event, held in October 2019, the group identified barriers to participation, like transportation, weather, and cost barriers. Weather can be especially challenging for persons with disabilities because some assistive technology does not function well in inclement weather. Larger emotional issues are sometimes at play as well, with one participant observing that "Some persons with disabilities may feel like a lab rat or a guinea pig because they been hospitalized many times in their life, which caused them to be poked and prodded throughout their life." CTSI hopes to disseminate information gathered at these events to the research community so that the barriers are better understood and can be addressed.

The event also gave Kennedy an opportunity to make people in the disability community aware of the <u>Dan Miller Disability and Mental Health Summit</u>, which will be held in March 2020. The Summit is hosted by Representative Dan Miller and presents a large number of resources for persons with disabilities.

Cookies and Conversation will be held quarterly. If you are interested in attending or want more information, please contact RaNaja Kennedy at RCK30@pitt.edu.





Clinical Trials.gov

Regulatory Notes

ClinicalTrials.gov - Procedural Changes

As of January 2020, ClinicalTrials.gov has new procedures for posting results information submitted by investigators for applicable clinical trials (ACTs). Previously, the U.S. National Library of Medicine did not post results until a quality control review was complete and any identified issues were addressed by the research team. Now results will be posted within 30 days of submission regardless of whether or not issues are identified and it will be noted in the publicly available record that the quality control process is incomplete.

These procedures apply to studies that meet the definition of an <u>ACT</u>, have a study start date that is on or after January 18, 2017, and first submitted results information beginning in January 2020. Investigators should take all measures necessary to ensure results are accurate and consistent upon first submission to be compliant with best practices and to avoid having a record publicly identified as incomplete.

The University of Pittsburgh Office of Research Protections offers assistance with any ClinicalTrials.gov related questions at CTgov@pitt.edu. Staff at ClinicalTrials.gov also provide free assistance via conference call. To contact them for assistance:

- Log in to the <u>ClinicalTrias.gov Protocol Registration</u> and <u>Results System</u> (PRS)
- 2. Go to the "Contact ClinicalTrials.gov PRS" link in the top right corner of the home page.
- 3. Include the ClinicalTrials.gov ID (NCT number) In the message and request a one-on-one consultation.

Additionally, the Office of Research Protections periodically offers presentations on ClinicalTrial.gov and other topics relevant to the research community. Check their website for upcoming trainings.

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: When do I need a confidential disclosure agreement (CDA)?

Answer: You should use a CDA anytime confidential information that should not be disclosed to third parties is being exchanged. Use a one way CDA when only one party is disclosing confidential information and the other party is simply receiving the information. A mutual or two-way CDA should be executed when both parties are exchanging confidential information. CDAs protect potentially proprietary information, as when the protocols being shared might lead to patentable inventions or other products with the potential for commercialization; investigators often share such information when they are seeking collaborators.

CDAs that involve discussions related to research are reviewed by the Office of Sponsored Programs; agreements related to research **and** licensing/commercialization or licensing and commercialization only are reviewed by the Innovation Institute. Occasionally CDAs are needed for interactions regarding the purchasing of equipment and services, and these are reviewed by Purchasing Services.

Investigators are not empowered to provide institutional sign off on CDAs; these requests route through MyRA to the appropriate reviewing office based on the nature of the information exchanged. More information can be found on the website for the Office of Sponsored Programs.

Upcoming Events

Data Security Best Practices for Researchers

Presented by the Office of Research Protections and the Pitt Computing Services and Systems Development (CSSD)

Thursday, February 13, 2020 12 p.m. - 1:00 p.m. More here

How to Partner With and Recruit in Schools

Presented by the University of Pittsburgh Clinical and Translational Science Institute (Responsible Conduct of Research Series)

Wednesday, February 19, 2020 12 p.m. - 1:00 p.m. More here.

ACRP 2020 (Annual National Meeting)

Presented by the Association of Clinical Research Professionals

Friday, May 1 - Monday, May 4, 2020 More <u>here</u>

Questions for us? We'd love to hear from you:

https://ctsi.pitt.edu/contact-us/

