

KL2-Special Interest Group Event

Bootcamp on Clinical Research for New Investigators

A series of four workshops on how to operationalize biologic clinical trials at GW and CNH. An emphasis on available programs, templates, and resources.
Review archived Bootcamps [here](#).

For Zoom links and calendar invites, please contact Pesh Rubinstein at
Pesha.Rubinstein@gwu.edu

or

gwsmsresearch@gwu.edu

Session 3. Thurs, JAN. 19, 12-2 PM (virtual)

Participant recruitment and retention (10-slide max; 15 minutes each speaker)

12:00-12:15 Enhancing participant diversity in Covid-19 trials **David Diemert, MD**

12:15-12:30 Control populations, Healthy Heroes **Beth Tarini, MD, MS**

12:30-12:45 Radio outreach to Latinx communities **Elmer Huerta, MD, MPH**

12:45-12:50 *Break*

IRBs and E-consent (10-slide max; 15 minutes each speaker)

12:50-1:05 E-consent and tracking **Sarah Ford-Trowell, MPH**

1:05-1:20 sIRB for multi-site research **Almarie Coleman, CIP**

1:20-1:35 Defining the institutional indemnification parts of consent **Alavy Sos, MS**

1:35-1:40 *Break*

1:40-2:00 Breakouts: Institutional Solutions to Challenges

Steps to enhance recruitment and retention? Understanding consents and building equity?

What is good monitoring? How to foster social media for communication?

GW: Sarah Ford-Trowell, MPH; Richmond Amoako, MPH; and Mila Tahai, MSPH

CNH: Kristen Breslin, MD, MPH; Almarie Coleman, CIP

DETAILED AGENDA

PARTICIPANT RECRUITMENT AND RETENTION

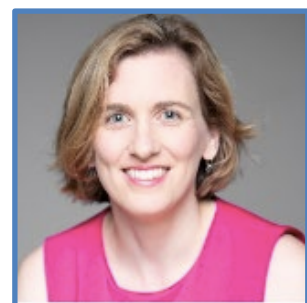
12:00-12:15 Enhancing participant diversity in Covid-19 trials:
David Diemert, MD · ddiemert@gwu.edu

Dr. David Diemert is a Professor in the Departments of Medicine (primary) and Microbiology, Immunology, and Tropical Medicine (secondary) at GW. Additionally, he is the Clinical Director of GW Vaccine Research Unit (GW VRU), which is a collaboration between the School of Medicine and Health Sciences and GW MFA. Dr. Diemert's research is focused on conducting clinical trials to develop vaccines for viral infections (COVID-19, HIV, Lassa Fever) and neglected tropical diseases (hookworm and schistosomiasis) in the United States, Brazil, and Africa.



12:15-12:30 Control populations, Healthy Heroes:
Beth Tarini, MD, MS · btarini@gwu.edu

Dr. Beth Tarini conducts health services research that focuses on optimizing the delivery of genetic services to families and children, particularly newborn screening. Dr. Tarini's research has been funded by the National Institutes of Health, HRSA, the Robert Wood Johnson Foundation and the Cystic Fibrosis Foundation. At the federal level she served as an appointed member of the Advisory Committee on Heritable Disorders in Newborns and Children, a committee which advises the Secretary of the US Department of Health and Human Services on the most appropriate application of universal newborn screening tests, technologies, policies, guidelines and standards. Dr. Tarini served as the President of the Society for Pediatric Research from 2021-2022.



12:30-12:45 Radio outreach to Latinx communities:
Elmer Huerta, MD, MPH · ehuerta@gwu.edu

Dr. Huerta is a Clinical Professor of Medicine in the Division of Hematology & Oncology and the GWU Cancer Center. In 1994, to reach underserved, urban Hispanic/Latino community in the Washington, DC, area, he founded the Cancer Preventorium at the Washington Cancer Institute/MedStar Washington Hospital Center. This low-cost prevention and screening clinic is now a part of the GWU Cancer Center. In 1998, Dr. Huerta was appointed by President Clinton as Member of the National Cancer Advisory Board. His pioneering model in cancer prevention and early detection is highlighted by the Innovation in Prevention Award that Dr. Huerta received from the US Secretary of Health and Human Services in 2004. In 2007 he became the first ever Latino elected as National President of the American Cancer Society. Dr. Huerta has developed a high degree of respect and trust from the Hispanic community at the local, national, and international level through his radio and television educational programs. He is a senior health correspondent for CNN en Espanol and heard daily nationwide and in Latin America.



12:45-12:50 BREAK
IRBs AND E-CONSENT

12:50-1:05 E-consent and tracking:

Sarah Ford-Trowell, MPH · sstocker@mfa.gwu.edu

Sarah Ford-Trowell, MPH, is the Senior Manager of Regulatory and Compliance in the George Washington Office of Clinical Research (GW OCR). She and the OCR are a resource for faculty and staff involved in clinical and translational research. The OCR is committed to providing clinical research education and ensures that operations, regulatory-compliance, and finances are properly managed.



1:05-1:20 sIRB for multi-site research:

Almarie Coleman, CIP · ascoleman@childrensnational.org

Almarie Coleman, CIP, is the Reliance Manager at Children’s National Hospital. She joined Children’s National in 2018 after serving 10 years as an IRB analyst at the University of Minnesota. She and her office review and evaluate human research activities and ensure that they are conducted according to the highest ethical standards. Committee decisions whether or not to approve studies are based on federal regulations and established ethical principles.



1:20-1:35 Defining the institutional indemnification parts of consent:

Alavy Sos, MS · asos@childrensnational.org

Alavy Sos is the Executive Director of Research Regulatory Affairs at Children’s National Hospital where he oversees research compliance operations, regulatory affairs, and efforts to support research enterprise risk management. Over the past 18 years, he served in various senior roles within human research protections, animal research compliance, quality assurance, institutional biosafety, and strategic planning to manage research risks. He is a co-author of the CITI Program, the research ethics and compliance training program that serves as the foundation for ethical animal and human research at many research institutions in the US and the world.



1:35-1:40 Break

1:40- 2:00 Breakouts: Institutional Solutions to Challenges

Breakout topics and questions:

*Steps to enhance recruitment and retention? Understanding consents and building equity?
What is good monitoring? How to foster social media for communication?*

GW: Sarah Ford-Trowell, Richmond Amoako, and Mila Tahai

Sarah Ford-Trowell, MPH, is the Senior Manager of Regulatory and Compliance in the George Washington Office of Clinical Research (GW OCR). She and the OCR are a resource for faculty and staff involved in clinical and translational research. The OCR is committed to providing clinical research education and ensures that operations, regulatory-compliance, and finances are properly managed. Email: sstocker@mfa.gwu.edu



Richmond Amoako, MPH, CPH, CIP, is an IRB Administrator with George Washington University. He is a certified IRB professional and earned his MPH at Drexel University. Email: richmond.amoako@gwu.edu

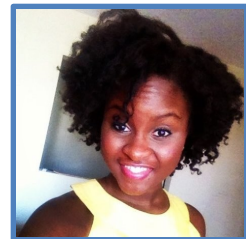


Mila Tahai, MSPH, CIP, is the Assistant Director of the Office of Human Research in the Office of the Vice Provost for Research at GWU. She is a certified IRB professional and earned her Master of Science in Public Health and Health Systems from the University of Waterloo. Email: ltahai@gwu.edu



CNH: Almarie Coleman, Kristin Breslin

Almarie Coleman, CIP, is the Reliance Manager at Children’s National Hospital. She joined Children’s National in 2018 after serving 10 years as an IRB analyst at the University of Minnesota. She and her office review and evaluate human research activities and ensure that they are conducted according to the highest ethical standards. Committee decisions whether or not to approve studies are based on federal regulations and established ethical principles. Email: ascoleman@Childrensnational.org



Kristen Breslin, MD, MPH, is a pediatric emergency medicine physician at Children's National Hospital. She earned her MD degree at Harvard Medical School and completed her pediatric emergency medicine fellowship at Children's National. She is the Research Director of the Pediatric Emergency Medicine Fellowship and Assistant Director of Research for the Division of Emergency Medicine, and Chair of the CNH Institutional Review Board. She is also a Global Health Faculty Mentor for pediatric residents at Children's. Email: kbreslin@childrensnational.org



Resources

Advarra posts useful articles about Informed Consent [here](#), including Enhancing Research Conduct Using eConsent ([blog](#), Advarra)

Association of Clinical Research Professionals (ACRP) clinical research training is available at no cost to GW, MFA and CNH participants to enhance the quality and safety of our clinical and translational research. Portals differ by institution, with GW access at <https://acrp.smhs.gwu.edu/>, and CNH website in re- development (contact Jurrans Wilson juwilson@childrensnational.org)

See recommended curriculum [here](#), as well as lectures

- “Let’s Talk Patient Recruitment: Strategies, Tools, Communication
- “Research Ready: Leveraging Technology in the New Research Landscape”
- “A Two-Step Approach to Improving Patient Recruitment”

NIH Introduction to the Principles and Practice of Clinical Research (IPPCR) course info and free registration [here](#). The full 2022-2033 syllabus is [here](#); note these lectures in particular:

IPPCR: Institutional Review Boards (Menikoff)

IPPCR: Data and Safety Monitoring Committees (Shaw)

IPPCR: Data Management & Case Report Form Development (Good)

IPPCR: Community-Based Participatory Research (Powell-Wiley)

GWU Resources

GWU Institutional Review [here](#)

Office of Clinical Research [here](#)

New Trial Startup Guidance [here](#)

REDCap Training [here](#)

REDCap template for e-consent [here](#)

Children's National Hospital Resources (sign-in may be required)

The Center for Translational Research [here](#)

CNH IRB Electronic Application Review System: [here](#)

[CNH sIRB Documents Library](#) - houses protocol and procedures

Emergency Department Request Research Support - https://is.gd/ED_Research_Support

REDCap e-consent training document for CNH (sign-in required)

https://cnhirb.huronresearchsuite.com/IRB/sd/Doc/0/27QOUGJTUS8UOKK4NGE9CLIG00/e-Consent_REDCap%20Guidance_11-17-2020.pdf

REDCap training for CNH: [Data Resources & Access | GW CTSI \(ctsicn.org\)](#).

Register for REDCap/training at [REDCap Support Request](#).

Additional Resources (NIH, FDA, ...)

Caplan A, Friesen P. Health disparities and clinical trial recruitment: Is there a duty to tweet?. *PLoS Biol.* 2017;15(3):e2002040. Published 2017 Mar 1. doi:10.1371/journal.pbio.2002040 [[Article](#)]

[CTEP protocol templates and guidelines](#)

[FDA Investigator Responsibilities](#)

[FDA Code of Federal Regulations Title 21](#)

[FDA Draft Guidance: Diversity Plans to Improve Enrollment of Participants From Underrepresented Racial and Ethnic Populations in Clinical Trials; Draft Guidance for Industry; Availability](#)

[Investigator: ICH E6 \(R2\) Good Clinical Practice](#)

FDA proposed rule on protection of trial participants and IRBs: <https://bit.ly/3rxfIT>.

FDA proposed rule on IRBs and cooperative research: <https://bit.ly/3LS7cL7>.

Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard. [Pediatric Research Informational Materials](#) targeting ages 12 – 17.

Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard. "Achieving Diversity, Inclusion, Equity In Clinical Research." <https://mrctcenter.org/diversity-in-clinical-research/>, with permission.

NIH "[SmartIRB](#)" with sIRB resources and talk forum

Sophie's Science Project <https://youtu.be/m8e0z-96QTU>

Sophie's Science Project is an engaging and lively animation video that explores the ins and outs of participating in research and outlines the informed consent process. It can be used by clinical research teams as a resource to share with study participants or shared in educational settings to educate children and families about the importance of medical research in advancing human health.