

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.*

For Zoom links and calendar invites, please contact Charlotte Hovland at
cphovland@gwu.edu
or
gwsmsresearch@gwu.edu

Session 1. Thurs NOV 17, 12-2 pm (virtual)

Principal Investigator Responsibilities (10 slide max; 15 min ea speaker)

- 12:00-12:15** Industry-sponsored or investigator-initiated studies: **Henry Kaminski**
- 12:15-12:30** Investigators rely on trained clinical research staff: **Aileen Chang**
- 12:30-12:45** Investigators need to recognize conflicts: **Laura Sigman**
- 12:45-12:50** Break

Protocol & Study Frameworks (10 slide max; 15 min ea speaker)

- 12:50-1:05** Cohort discovery & databases: **Hiroki Morizono**
- 1:05-1:20** Protocol Builder/ OnCore: **Richard Lush**
- 1:20-1:35** Investigational drug pharmacy-do-able: **Dorinne Mettle-Amuah**
- 1:35-140** Break

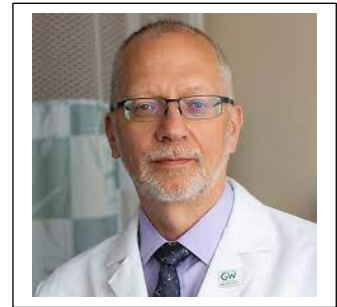
- 1:40-2:00 Breakouts:** "How To Get Started as an Investigator in an Externally Sponsored Study"
Radwa Aly, Richard Lush, GW
Jurran Wilson, Patrick O'Keefe, CNH

DETAILED AGENDA

PRINCIPAL INVESTIGATOR RESPONSIBILITIES Add photos

12:00-12:15 Industry-sponsored or investigator-initiated studies, single/ multi-site: Henry Kaminski, MD · hkaminski@mfa.gwu.edu

Dr. Kaminski is Chair of the Department of Neurology and Rehabilitation Medicine at GW. He has performed basic, clinical and translational research in myasthenia gravis for 30 years. He was part of the executive committee of the NIH-funded, multi-national, randomized trial, which demonstrated the efficacy of thymectomy for myasthenia gravis. As PI of the NIH Rare Disease Clinical Research Network (MGNet), he along with collaborators at GWU and across the nation, he is working to identify biomarkers and improve clinical trial performance



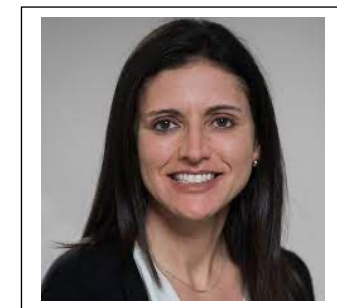
12:15-12:30 Investigators rely on trained clinical research staff: Aileen Chang MD MSPH · chang@email.gwu.edu

Dr. Chang is Associate Professor of Medicine at GW. Dr. Chang is a clinical translational researcher focused on identification and testing of therapies for viral illness including the dengue, chikungunya, Zika and Covid-19. Her international experience managing vector borne disease lead her interest in how social and political determinants affect health.



12:30-12:45 Investigators need to recognize conflicts: Laura Sigman MD · LSigman@childrensnational.org

Dr. Sigman is Children's National Hospital. She is a physician and attorney experienced in guiding companies and institutions through complex problems involving medical, legal, and regulatory issues. She is also Associate Medical Director, Children's National Emergency Department at Doctor's Community Hospital, Director of Legal and Policy Coordination for Emergency Medicine; Medical and Regulatory Affairs Contractor and Advisor, Sika Health; Medical and Legal Contractor and Advisor, Product Developer Medical and Legal Contractor and Advisor, Product Developer Alpha Medical.



12:45-12:50 BREAK

PROTOCOL & STUDY FRAMEWORKS

12:50-1:05 Cohort discovery & databases: Hiroki Morizono PhD · hmorizono@childrensnational.org

Dr. Morizono is a researcher in the [Center for Genetic Medicine](#) and Director of Biomedical Informatics at CNH. [His research](#) focuses on applications of high-performance informatic and computational methods to visualize and understand human health and disease across a range of biomedical disciplines. This includes bioinformatic analysis of gene regulation, modeling protein structure and stability as a function of mutation, creation of databases incorporating the electronic

health record and implementing tools to perform data analysis at large scales.



1:05-1:20 Protocol Builder/ OnCore: Richard Lush, PhD



· rmlush3@email.gwu.edu

Dr. Lush is Director of the [Clinical Trials Office at the GW Cancer Center](#). He has extensive experience in drug development and the study of the clinical pharmacology of agents used the treatment of cancer. He has extensive experience in finance, management, regulatory affairs, project management, process improvement and clinical research operations.

1:20-1:35 Investigational drug pharmacy-do-able: Dorinne Mettle-Amuah, Pharm D, BCPS

· dmamuah@mfa.gwu.edu

Dorinne Mettle-Amuah, PharmD, BCPS is a clinical pharmacist who specializes in clinical trial protocol development and investigational drug service operations. Originally from Hyattsville Maryland, Dr. Mettle-Amuah received her Bachelors in Biochemistry from the University of Maryland College Park. She received her Doctor of Pharmacy degree from the University of Maryland Baltimore and went on to complete a PGY1 Pharmacy Practice Residency at Sibley Memorial Hospital – Johns Hopkins Medicine. In her previous roles, her practice has focused on behavioral pharmacology clinical research and oncology clinical research. At present, she oversees all pharmacy-related logistics for the 97 clinical trials currently active at The GW Medical Faculty Associates and GWU Hospital. Dr. Mettle-Amuah is committed to improving the lives of patients enrolled in clinical trials by optimizing the drug dispensation process for clinical trials to ensure a seamless workflow.



1:35-2:00 BREAK

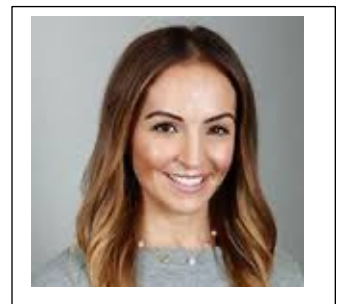
1:40- 2:00 Breakouts: Institutional solutions to challenges

“How To Get Started as an Investigator in an Externally Sponsored Study”

Breakout Questions:

1. Who are the stakeholders you need to connect with as you plan and carry out your study?
2. What documents or forms do you need to complete and when?
3. What are the relevant processes that you need to be aware of at your institution?

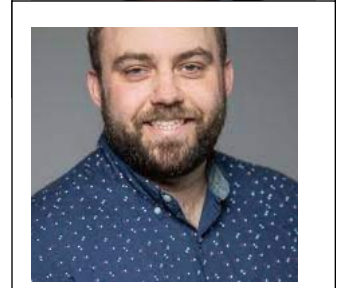
[Radwa Aly MSc](#) · raly@mfa.gwu.edu has over 14 years of extensive experience in clinical research, especially in behavioral health and neurosciences. She is Senior Director of [Clinical Research Operations](#). She is currently pursuing a PhD in Translational Health Sciences at the George Washington University School of Medicine and Health Sciences.



Jurran Wilson, CCRP · JuWilson@childrensnational.org has nearly 15 years of extensive clinical research program management experience from his involvement in more than 135 clinical trials in over 25 therapeutic areas. His primary focus is developing synergistic relationships among research stakeholders, applying data-driven and real-world evidence-based methodologies to solve research challenges, and identifying and overcoming barriers to patient enrollment. He currently serves as the [Clinical and Translational Research Program Lead](#) at Children’s National.



Patrick O’Keefe, · pokeefe@childrensnational.org Administrative Director, [CTSI-CN](#). Patrick began his career at the American Medical Association supporting the policy-making bodies representing the interests of Residents, Fellows, and LGBT



physicians. Since then he has spent a decade in research administration, starting with managing junior faculty and predoctoral student training programs at the University of Washington before joining the CTSI-CN as administrative lead for Workforce Development and KL2, and eventually taking over as Administrative Director in early 2021.

Resources for Session 1:

Faculty and staff are encouraged to complete free Association of Clinical Research Professionals training ([learn more here](#)), including essential training in Intro Clin Trials; GCP for Exp. Professional; Investigator Responsibilities, Theory to Practice: Operationalize your clinical study protocol.

Additional information is available in the Introduction to Principles & Practice of Clinical Research via the NIH ([learn more, here](#)), including lectures on FDA Product regulation (Joneckis); Legal issues (Kennedy); Intro Clinical Study Design (Johnson), or Study participant selection (Stoney).