CTSI Clinical and Translational Science Institute at Children's National
A PARTNERSHIP WITH THE GEORGE WASHINGTON UNIVERSITY

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.

For Zoom links and calendar invites, please contact Pesha Rubinstein at

Pesha.Rubinstein@gwu.edu
or
gwsmhsresearch@gwu.edu

Session 2. Thurs, DEC 15, 12-2 pm (virtual)

Optimizing Roles on the Study Team (10-slide max; 15 minutes each speaker)

12:00-12:15 How the strengths of CRA and the investigator tie into the audit: **Radwa Aly**

12:15-12:30 Who is part of the safety team? **Caitlin Joffe**

12:30-12:45 Optimizing stakeholder input: **Randi Streisand**

12:45-12:50 *Break*

The Clinical Trial Contract (10-slide max; 15 minutes each speaker)

12:50-1:05 Budgeting and contracts: **Melanie Bossi**

1:05-1:20 Standard of care testing vs research costs: **Stephanie Bair**

1:20-1:35 Service biostatistics: **Qing Zeng**

1:35-1:40 *Break*

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

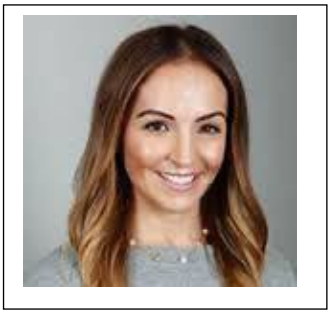
Who pays for what? Who defines standard of care?
Who do you contact if there is disagreement; who helps resolve?

- **GW: Hiromi Sanders, Melanie Bossi**
- **CNH: Bobbe Thomas**, **Stephanie Bair**

DETAILED AGENDA

OPTIMIZING ROLES ON THE STUDY TEAM

12:00-12:15 How the strengths of the CRA and investigator tie into the audit: Radwa Aly MSc · raly@mfa.gwu.edu



Radwa Aly MSc has over 14 years of extensive experience in clinical research, especially in behavioral health and neurosciences. She is GW 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.

12:15-12:30 Who is part of the safety team?
Caitlin Joffe MBA, CCRP · CJOFFE@childrensnational.org

Caitlin Joffe has over 15 years' experience working in various positions in clinical research with a focus on oncology studies, having overseen everything from quality assurance and study compliance to staffing and budgeting of multisite institutional trials. She is an experienced trainer, educating new colleagues both domestically and abroad. She joined CNH in January 2022 from the Cancer Center at Johns Hopkins and currently serves as Director of Research Quality Assurance.

12:30-12:45 Optimizing stakeholder input:
Randi Streisand PhD, CDCES · rstreis@childrensnational.org

Dr. Streisand is Division Chief, Psychology and Behavioral Health, Vice Chair, Institutional Review Board, clinical and pediatric psychologist and certified diabetes educator. She provides and supervises psychosocial services for children and families across a variety of pediatric populations including diabetes, craniofacial syndromes and urological disorders. Dr. Streisand is an active clinical researcher and runs projects funded by NIH on managing type 1 diabetes in children and adolescents.

12:45-12:50 BREAK

THE CLINICAL TRIAL CONTRACT

12:50-1:05 Budgeting and contracts: Melanie Bossi, MPA
· mbossi@mfa.gwu.edu

Melanie Bossi has over 30 years of experience in the field of biomedical and clinical research administration and has served the GW academic medical clinical enterprise for 26 years in various positions in research administration. She has focused her career specializing in pre-award management, proposal and budget development, and negotiation of contracts and legal transactions to support and advance clinical research in academic medical center and corporate settings. Ms. Bossi leads the integration of key operational services that support the GW Office of Clinical Research's (GW OCR) programs, including pre-award budget and proposal development, coverage analysis, research billing charge review, and contracting, across the SMHS federal and non-federal clinical research portfolios.

1:05-1:20 Standard of care testing vs research costs: Stephanie Bair
· sbair@childrensnational.org

Stephanie Bair is the Director of Research Finance for the Children's National Health System in Washington, DC. She has almost 20 years' experience in sponsored projects administration for various hospitals and has held several different positions ranging from pre-award to post-award and departmental as well as central offices. She enjoys training and mentoring newcomers to the research administration field.

1:20-1:35 Service biostatistics: Qing Zeng, PhD · zengq@gwu.edu

Qing Zeng, PhD, is Director**,** Biomedical Informatics Center, and Professor, Department of Clinical Research and Leadership, at the GW SMHS. Dr. Zeng has special expertise in AI, large clinical datasets, and consumer health informatics. She has published over 150 peer-reviewed articles, as well as served as the PI and Co- PI on a number of VA HSR&D, NIH and DOD-funded research projects. Dr. Zeng has joined the OCR to direct biostatistics support.

1:35-1:40 BREAK

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

Breakout questions:

Who pays for what? Who defines standard of care?
Who do you contact if there is disagreement; who helps resolve?

GW Breakout: Hiromi Sanders, Melanie Bossi

Hiromi M. Sanders PhD, JD is GW's Director of Research Integrity. She is responsible for matters related to research compliance involving animal care and use, human subjects protection, financial conflicts of interest, laboratory safety, responsible conduct of research, and export controls. She serves as deputy to the university's associate vice president for research integrity. Email: sandersh@gwu.edu

Melanie Bossi MPA has over 30 years of experience in the field of biomedical and clinical research administration and has served the GW academic medical clinical enterprise for 26 years in various positions in research administration. She has focused her career specializing in pre-award management, proposal and budget development, and negotiation of contracts and legal transactions to support and advance clinical research in academic medical center and corporate settings. Ms. Bossi leads the integration of key operational services that support the GW Office of Clinical Research's (GW OCR) programs, including pre-award budget and proposal development, coverage analysis, research billing charge review, and contracting, across the SMHS federal and non-federal clinical research portfolios. Email: mbossi@mfa.gwu.edu

CNH Breakout: Bobbe Thomas, Stephanie Bair

Ms. **Bobbe Thomas** is a Clinical Research Program Manager at Children's National Medical Center. Ms. Thomas has skills in Medical Research, Clinical Trials, Electronic Data Capture (EDC), Program Management, Leadership, Clinical Research, Good Clinical Practice (GCP). Email: tbthomas@childrensnational.org

Ms. **Stephanie Bair** is the Director of Research Finance for the Children's National Health System in Washington, DC. She has almost 20 years' experience in sponsored projects administration for various hospitals and has held several different positions ranging from pre-award to post-award and departmental as well as central offices. She enjoys training and mentoring newcomers to the research administration field. Email: sbair@childrensnational.org

Resources below:

Resources

Clinical Research Acronyms (Advarra): https://www.advarra.com/blog/clinical-research-acronyms-abbreviations-know/

The Diamond initiative offers trainings for clinical and translational research professionals (free and fee): https://www.diamondportal.org/trainings_browse

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 Jurran Wilson juwilson@childrensnational.org)

Some ACRP courses include

- "Certification and Promotion"
- "Mastering Budgeting at Your Site"
- "Evaluation Protocol Budget"
- "Master Clinical Trials agreement"
- "Fee Schedule "charge master"

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

CNH Office for the Protection of Human Subjects here

CNH Biostatistics and Research Design here

CNH IRB Electronic Application Review System: here

The Center for Translational Research here

CNH grants office website:
https://cnmc.sharepoint.com/sites/research/SitePages/GrantsContracts/GCAF.aspx

CNH Grants Office Intent to Apply form: Office of Grants and Contracts, Intent to Apply Form (childrensnational.org)

Clinical Trials Office email: CTO@childrensnational.org

GWU Resources

GWU Office of Human Research here

GWU Institutional Review here

GWU Office of Clinical Research here

Biomedical Informatics Center Request for Consultation & Assistance with Clinical Study Data

Additional Resources (NIH, FDA, ...)

CTEP protocol templates and guidelines

FDA Investigator Responsibilities

FDA Code of Federal Regulations Title 21

Investigator: ICH E6 (R2) Good Clinical Practice

NIH New and Early-Stage Investigators

NIH Introduction to the Principles and Practice of Clinical Research (IPPCR) course info and free registration here. The full 2022-2033 syllabus is here; and reprinted on the next page:

NIH Introduction to the Principles and Practice of Clinical Research Course 2022-2023

Module 1: Introduction to Clinical Research		
1	History of Clinical Research	Dr. John I. Gallin
2	Clinical Research Overview ***NEW***	Dr. Anne Zajicek & Dr. Lisa Cordes
3	Clinical Research Team ***NEW***	Various Speakers
4	FDA Product Regulation	Dr. Chris Joneckis
5	Ethical Principles in Clinical Research	Dr. Christine Grady
6	Research Ethics	Dr. Ezekiel Emanuel
7	Legal Issues in Clinical Research	Carrie Kennedy, JD

Module 2: Conceptualizing the Clinical Trial Study/Protocol		
1	Introduction to Clinical Study Design	Dr. Laura Lee Johnson
2	Information Resources for Clinical Research	Mr. Josh Duberman
3	Choosing a Research Question	Dr. John Powers, III
4	Designing Trials Efficiently	Dr. John Powers, III
5	Overview of Hypothesis Testing	Dr. Paul Wakim
6	Sample Size and Power	Dr. Laura Lee Johnson
7	Issues in Randomization	Dr. Paul Wakim
8	Measures	Dr. David Luckenbaugh
9	Quality of Life	Dr. Kevin Weinfurt
10	Study Participant Selection	Dr. Catherine Stoney
11	Considering Inclusion in Research	Dsr. Clayton, Corbett & Noursi
12	Health Disparities Research	Dr. Larissa Aviles-Santa
13	Research with Vulnerable Participants	Dr. David Wendler
14	Health Research Linked to Disasters and Other Humanitarian Crises	Dr. Larissa Aviles-Santa

Module 3: Protocol Review, Implementation & Monitoring		
1	Developing Protocols and Manuals of Operating Procedures	Dr. Wendy Weber
2	NIH Peer Review Process ***NEW***	To Be Determined
3	Technology Transfer	Dr. Bruce Goldstein
4	Institutional Review Boards - Overview	Dr. Jerry Menikoff
5	Mock IRB	Dr. Jerry Menikoff
6	Data and Safety Monitoring Committees	Dr. Pamela Shaw

Module 4: Data Quality & Results Reporting		
1	Research Misconduct: Fabrication, Falsification, & Plagiarism	Dr. James Gulley
2	Quality Management in Clinical Research	Elizabeth Ness, MS, BSN
3	Data Management & Case Report Form Development	Dr. Marge Good
4	Clinical Data Interchange Standards (CDISC)	Dr. Stephen Wilson
5	Clinical Trials Registration & Results Reporting	Dr. Deborah Zarin

Module 5: Topics of Special Interest		
1	Secondary Data/Meta-Analysis	Dr. Charles Natanson
2	Conceptual Approach to Survival Analysis	Dr. Laura Lee Johnson
3	Dissemination and Implementation Research	Dr. Catherine Stoney
4	Designing and Testing Questionnaires	Ms. Barbara Stussman
5	Pharmaceutical Development: Management of Projects	Dr. Christopher Breder
6	Community – Based Participatory Research	Dr. Tiffany M. Powell-Wiley
7	The Clinical Researcher and the Media	Mr. John Burklow
8	Using Large Datasets for Population-Based Health Research	Dr. Leighton Chan