ITHS | Institute of Translational Health Sciences
Accelerating Research. Improving Health.

Unravelling the Research Coordinator: Decipher Your Strengths & Grow Professionally

Friday, May 22nd, 10 a.m. to 4 p.m.

Seattle, WA | UW Medicine, South Lake Union, Building C

9:30 - 10:00am:	**Coffee and Check-in** *(SLU Lobby)*
10:00 - 10:30am:	**Welcome and Introduction to the Day** *(Auditorium)* Mandy Morneault and Shelley Prosise
10:30 - 11:10am:	**Managing-up: Communicating with Your PI for Mutual Success** *(Auditorium)* Robert Johnson
11:10 - 11:20am:	Break
11:20 - 12:30pm:	Morning Breakouts: **Interactive Case Studies to Refine Skills in Research Coordination**
Option 1:	**Recruitment Strategizing** *(Auditorium)* Mike Donahue with Jason Caucutt, Juan Cotto and Genecelle Delossantos
Option 2:	**Forecasting Regulatory Requirements** *(Room C-123A)* Karen Adams with Robert Johnson and Nelson Spencer
Option 3:	**Think Like an Auditor** *(Room C-123B)* Mandy Morneault with Carolyn Bea and Alana Clark
12:30 - 1:30pm:	**Networking Lunch** *(Combined rooms C-123A-B)* Catered lunch provided by Maven Meals
1:30 - 2:20pm:	Afternoon Breakouts: **Position Yourself for Growth!**
Option 1:	**Professional Development Planning: A Proactive Approach to Your Growth** *(Auditorium)* Shelley Prosise
Option 2:	**Establishing a Mentor/Mentee Relationship** *(Room C-123-A)* Michelle Doyle
Option 3:	**Research Coordinator Leadership: Growing a Research Program from the Ground Up** *(Room C-123B)* Lori Linke
2:20 - 2:30pm:	Break
2:30 - 3:30pm:	**PANEL: Where Are They Now? A Discussion with Research Coordinators about Career Progression** *(Auditorium)* Moderator: Amy Good Panelists: Reina Hibbert, Christy Hixson, Martha Horike-Pyne, Marlisa Isom
3:30 - 4:00pm:	Closing remarks *(Auditorium)* Shelley Prosise, Mandy Morneault
4:00 – 5:00pm:	Post-Conference Networking with the Speakers *(SLU Lounge)*

Session Descriptions

Managing Up: Communicating with Your PI for Mutual Success
Managing upward is a conscious approach to working with your manager toward mutual goals that are in the best interest of you, and your manager. This session will explore strategies to understand your PI's goals and preferred working style, and will discuss how to build a better working relationship with your PI through effective communication and negotiation techniques. This presentation is tailored to research coordinators to help facilitate communicating with your PI, but the concepts can be applied to working with any manager or supervisor.

Recruitment Strategizing
Meeting and exceeding recruitment goals is an opportunity for a research coordinator to stand out. In this session, participants will learn a framework for planning recruitment strategies for a variety of study populations. Participants will break into small groups to work on a case study and develop a comprehensive recruitment strategy. We will discuss strategies in a large group, and explore how the skills used in recruitment strategizing can be leveraged in other areas of RC work.

Forecasting Regulatory Requirements
Navigating the Federal and State regulations that impact human subjects research can be complex. In this session, participants will learn a framework on how to efficiently detect and plan for the regulatory requirements for a study. Participants will break into small groups to apply this framework and identify regulatory requirements to case studies. We will discuss why some regulations apply, why some do not, and when more information is needed to understand these requirements.

Think Like an Auditor
Establishing quality assurance processes in your work can ensure efficiency and compliance in a research program. In this session, participants will learn how to design quality assurance reviews of clinical research processes and problems to improve data collection process, protect data integrity, and ensure regulatory compliance. Participants will break into small groups to design a quality assurance process for various case studies. We will explore how others creatively problem solve, demonstrating their understanding of the regulations and best practices for implementing clinical research, to assess difficult situations and improve systems.

Professional Development Planning: A Proactive Approach to Your Growth
Professional development is not a one-time conversation; it is a part of your every day growth. This breakout session will explore ways you can take a proactive role in your development. Shelley Prosise will discuss how to create a professional development plan as a scaffold for your goals; how to remain open to opportunities, and other tips and strategies to position yourself for success. Whether you are looking to advance as a research coordinator, or focus on a new goal, creating a development plan will help you manage your career path.

Establishing a Mentor/Mentee Relationship
For a research coordinator working in a complex research environment, it is important to find resources to help cultivate knowledge. Michelle Doyle will discuss how formal and informal peer mentoring can help grow a research coordinator's talent and improve institutional competency. Participants will learn about the roles and attributes of both mentor and mentee, explore how these relationships are established, and how they contribute to a safe and compliant research environment.

Leadership in Research Coordination
How do you establish yourself as a leader in a growing research program? Lori Linke will talk about her experience in the Kidney Research Institute, where she helped build a research program from the ground up. This session will explore how a coordinator can find opportunities for an expanded leadership role while helping a research program be successful.

Panel: Where Are They Now? A Discussion with Research Coordinators about Career Progression
This is a moderated discussion with current and former research coordinators to explore how coordinators develop themselves within the research field. Panelists will discuss how they leverage skills from RC work to identify and pursue opportunities. This panel session will give conference participants a chance to learn from other coordinators, and reflect on how to create and pursue opportunities for their own professional growth.

Speaker Bios A-Z

Karen Adams is a Regulatory Specialist at the University of Washington, Institute of Translational Health Sciences. Karen has worked in clinical research for over 10 years and has a background in research coordination, research compliance, training and mentoring. In the Research Coordination Center, Karen consults with investigators to turn a research protocol into a thriving study. She provides start-up support to ensure studies are designed practically while meeting important ethial principles and regulatory requirements. Prior to working with ITHS, Karen was a biomedical reviewer at the UW Human Subjects Division. There, she specialized in minimal risk research, and worked to modernize the requirements of studies requiring UW IRB approval.

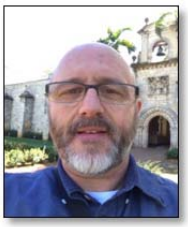
Carolyn Bea is a Research Coordinator at the University of Washington, Institute of Translational Health Sciences. Carolyn has worked in a wide range of clinical research positions for over 25 years. She has been a study coordinator for radiation therapy research protocols, and in the departments of pyschology and otolaryngology. She worked as a CRA for a monitoring company, and as a biomedical reviewer at the UW Human Subjects Division before returning to research coordination. In the ITHS Research Coordination Center, Carolyn is a walking help desk for all things clinical research support. She provides skilled research support to her investigators in areas of study start-up and general implementation.

Jason Caucutt is a Research Coordinator at the University of Washington, Institute of Translational Health Sciences. In the Research Coordination Center, Jason provides general study implementation support to investigators. Jason's specializes in recruitment, consent, and retention for diverse targeted populations including pregnant women, sexual minorities (MSM), and opioid users. Jason's background in education and sales are a credit to his successes as a coordinator partnering with research teams and participants. Prior to his work at ITHS, Jason was a lead research coordinator with the UW Cardiovascular Health Research Unit.

Alana Clark is a Research Coordinator and Regulatory Specialist at the University of Washington, Institute of Translational Health Sciences. In the Research Coordination Center, Alana manages multiple studies in the Department of Urology, and is a study monitor for three FDA Phase I IDE studies in Vascular Surgery at HMC and at the Kidney Research Institute. Alana began her research career at the University of Wisconsin Hospital in Pediatric Asthma and Allergy, and spent four years as a Senior Research Coordinator at the Veteran's Medical Research Foundation in San Diego specializing in Diabetes Research.

Juan Cotto is the Manager of Community Outreach at the Fred Hutchinson Cancer Research Center. Since 2006, Juan has partnered with Seattle's traditional communities of color to communicate the importance of participating in FHCRC research. Juan sits on the FHCRC Diversity Committee and Professional Scientific Recruitment and Retention program, which is focused on attracting and retaining diverse scientists to the center. He has also worked to establish programs aimed at increasing pathways for minority youth in scientific fields through partnerships with Seattle's Technology Access Foundation, Rainier Scholars, and the Seattle Public Schools.

Genecelle Delossantos is a Research Coordinator at the University of Washington, Institute of Translational Health Sciences. In the Research Coordination Center, she works on a wide range of studies across the UW where she provides budgeting, general implementation, and recruitment support to investigators. Prior to working with ITHS, Genecelle worked at the UW Twin Registry where she recruited twins from their registry to participate in various twin studies.



Michael Donahue is a Research Coordinator at the University of Washington, Institute of Translational Health Sciences. In the Research Coordination Center, Mike is a seasoned coordinator, and provides a wide-range of general research coordination, regulatory support, and study monitoring to investigators. Mike has travelled globally to provide research training for investigators and staff, and has become skilled in problem solving recruitment and retention issues. He has provided extensive support for clinical research programs at the UW, HMC, and the VA, including: hepatology, nephrology, surgery, oncology, otolaryngology, health services, rheumatology, and rehabilitation medicine.

Michelle Doyle, BS, RN, MA is the Director of Clinical Resources at the Institute of Translational Health Sciences. In her role, Michelle oversees and supports a dynamic group of faculty and staff who are content experts in regulatory knowledge, pre-clinical development, and bioethics consulting. She received her Master's in Health Administration from the University of Washington in 2010 and also holds a Bachelor's degree of Science in Nursing from Seattle University. Michelle has over 25 years of clinical nursing experience, including 12 years in an ICU setting and 14 years as a research nurse and lead support for the NIH K12 Roadmap Program.

Amy Good, PhD is a Research Coordinator at the University of Washington, Institute of Translational Health Sciences. In the Research Coordination Center, Amy provides research coordination and general implementation support to investigators. Amy received her PhD in Clinical Psychology with a specialization in rehabilitation and behavioral medicine. She has been involved in health-related research for 30 years.

Reina Hibbert, CCRC is a Regulatory Manager at the Seattle Cancer Care Alliance with the Phase 1 and RCC/Melanoma Programs. In her role, she provides regulatory and ethics mentoring and manages two research programs from study inception to closure. She works closely with investigators to ensure a high quality of service is provided to patients who participate in their research. Her experience spans clinical trial coordination, patient care, clinic and study start-up, systems and infrastructure implementation, regulatory compliance, ethics, protocol development, document development, and recruitment/retention of subjects. Reina previously worked at Quorum Review IRB before moving into the field of research coordination.

Christy Hixson is a Clinical Trials Assistant at Seattle Genetics. Christy currently supports the Protocol Lead in start-up for a Phase I research trial and is training for the Subject Matter Expert in all areas surrounding the path of the IND Safety Reports. Prior to working at Seattle Genetics, Christy helped establish the Regulatory Coordinator position within the Breast Oncology Group at SCCA/University of Washington. In addition to working at SCCA/UW, Christy worked at Western Institutional Review Board for five years. Starting as a Board Specialist, Christy learned about research and the reason for regulations, read and edited consent forms for various research trials, and aided the Board during their reviews.

Martha Horike-Pyne, MPH, CIP is a Senior Research Coordinator at the University of Washington Division of Medical Genetics, and the Research Manager at the Northwest Institute of Genetic Medicine. Martha focuses on consenting participants into genetic studies and manages over 40 IRB approvals for a large research program. Martha uses her interest in human subjects protections as a scientist board member for two Seattle area IRBs. This work has allowed her to gain valuable insight into the needs of investigators and the requirements of the IRB. She has considerable experience in creating template consent form language for GWAS studies and in the evaluation of existing consent forms for NIH dbGaP compliance.

Marlisa Isom, MS, CCRP is the Study Implementation Manager at the Fred Hutchinson Cancer Research Center. In the Clinical Research Support group, Marlisa manages operations, capacity, and workflow for review coordination. The study implementation team assists study teams with getting clinical trials implemented quickly and effectively by offering individual or offering comprehensive startup services. Prior to her work at FHCRC, Marlisa managed regulatory work for investigators at the University of Washington and Dana-Farber Cancer Institute. Prior to focusing her career on regulatory affairs, Marlisa worked as a clinical research coordinator in bone marrow transplant as well as psychiatric neurosciences in Boston and St. Louis.

Robert Johnson, MA is a Clinical Research Associate III at Seattle Children's Research Institute in the Center for Clinical and Translational Research. In his current work, Robert assists researchers in the coordination and monitoring of pediatric research protocols and study operations. Robert received his Master's in Biomedical Regulatory Affairs from the UW in 2011, and uses that knowledge to provide regulatory oversight, monitoring visits, and audits to investigators. Prior to his work at Seattle Children's, he was an analytical chemist and regulatory affairs specialist in the pharmaceutical industry.

Lori Linke is a Lead Clinical Research Coordinator at the University of Washington's Kidney Research Institute (KRI). In this role, Lori has helped to streamline the research endeavors of three leading nonprofit dialysis organizations. Lori works side-by-side with investigators, fellows, and clinical care providers to start-up and implement innovative research to benefit patients seeking opportunities to participate in research. Lori previously worked as a nutritionist at Northwest Kidney Centers, teaching nutrition education to those affected by kidney disease. There, she bolstered a partnership with the YMCA to provide patient access to their services free of financial barriers. Lori also worked with the Chicken Soup Brigade to found a home food delivery service for dialysis patients in need.

Mandy Morneault is the Regulatory Manager at the University of Washington, Institute of Translational Health Sciences. In the Research Coordination Center, Mandy manages staff and regulatory-based research projects. She educates and assists researchers in setting up and monitoring investigator-initiated research protocols and study operations. Prior to working with ITHS, Mandy established standards for and managed compliance review operations at the UW Human Subjects Division. There, she partnered with researchers to identify, understand, and resolve regulatory and compliance issues. Mandy previously worked in the Regulatory Affairs department at Quorum Review IRB, where she developed and managed processes for the review of protocols and patient-related materials, like consent and HIPAA documents.

Shelley Prosise is the Administrator for the University of Washington, School of Medicine Administrative Business Center. She and her staff develop tools to streamline incoming requests, track workflow, improve transparency, and enhance reporting of Pre-Award submissions, VA contracts, and Visa applications for 11 departments in the School of Medicine. Prior to working with UW Medicine, Shelley was a Research Project Manager at the Institute of Translational Health Sciences. There, Shelley assisted research faculty with implementing special projects, including a 25-site multicenter study on sudden cardiac death in NCAA Division I athletes. Shelley previously worked at Quorum Review IRB, managing IRB operations from participant safety to production of approval documents.

Nelson Spencer is a Regulatory Affairs Associate with Clinical Research Support at Fred Hutch. Nelson previously worked as a Regulatory Coordinator for the Melanoma/Renal Cell Carcinoma and Genitourinary teams at the UW. Nelson is a clinical research professional with over 12 years of experience in conducting and managing various aspects of Phase 1-3 trials. Nelson began his research career working in animal research at the University of Wisconsin. He then became a project assistant working in ophthalmology trials and moved into a role within quality assurance. After graduating from the University of Wisconsin with a degree in medical anthropology he moved to Portland and began working in quality control performing data management for an imaging company and then moved into project management which helped to land him a role as compliance project manager at Oregon Health and Science University before moving to Seattle.

Acknowledgements

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