

# NED 2014

Research Coordinator Networking & Education Day

## Laying the Groundwork for Research Success

Friday, April 25th, 10am-3pm

Seattle, WA | University of Washington, South Campus Center, room 316

- 9:30-10:00am:** Coffee and Check-in
- 10:00-10:50am:** Introduction to the Day and Networking Activity  
Room 316
- 10:50-11:00am:** Break
- 11:00-11:50am:** Morning Breakout Sessions
- Option 1:** **Navigating The Research Start-Up Process -What should come first?**  
Amy Deyle, RN, Research Nurse, UW ITHS  
*Navigate through the research start-up process the right way!*  
Room 303
- Option 2:** **Adverse Events- Love Them, Hate Them, but Report Them**  
Billi Tatum, RN, CCRC, Research Nurse. UWMC/HMC Regional Vascular Center  
*Learn invaluable tools to help meet adverse event reporting requirements*  
Room 354
- 12:00-1:00pm:** **Networking Lunch**  
Catered lunch provided by Maven Meals  
Room 316
- 1:00-1:50pm** Afternoon Breakout Sessions
- Option 1:** **Budget Building Basics**  
Amy Deyle, RN, Research Nurse, UW ITHS  
*Understand the basics to building a successful study budget*  
Room 303
- Option 2:** **A Review of Audit Case Studies**  
Mandy Morneault, Regulatory Manager, Compliance Analyst, UW ITHS  
*Hear about preventing high-stakes mistakes in your studies*  
Room 354
- 1:50-2:00pm:** Break

**2:00-2:50PM:**

**PANEL: Keeping Calm in Chaos – A Discussion with Multi-Site Study Project Managers,**

Room 316

Michael Donahue (Moderator), Research Coordinator, UW ITHS

Marisa Benich, Research Project Manager. VA Center of Excellence for Limb Loss Prevention & Prosthetic Engineering

Alana Clark, Research Coordinator & Regulatory Specialist, UW ITHS

Amy Gest, Research Coordinator, UW Department of Surgery, Resuscitation Outcomes Consortium

Marilynn Rothen, Clinic Manager, UW School of Dentistry, Regional Clinical Dental Research Center

*Organize regulatory files and streamline communications for complex projects*

**2:50pm-3:00pm:**

Final remarks

## Speaker Bios

### **Laura Baker MS, RN, Nurse Manager, UW ITHS**

Laura is a research nurse who recently joined the UW Institute of Translational Health Sciences, Research Coordinator Core in 2013. Prior to ITHS, Laura worked at Northwestern Medical Center on the Clinical Research Unit. While in Chicago, her passion for research inspired her to complete her Masters of Science in Clinical Research and Regulatory Administration at Northwestern. Laura has experience working on a variety of research studies ranging from circadian rhythm sleep studies to islet cell transplant studies. She is settling down in the Northwest and looks forward to furthering research here at the University of Washington.

### **Marisa Benich, Research Project Manager Seattle Institute for Biomedical and Clinical Research**

Marisa is a Research Project Manager at the Seattle Institute for Biomedical and Clinical Research (SIBCR). SIBCR is the nonprofit that supports research and education endeavors within the VA Puget Sound Health Care System. She graduated with a BS in Psychology from John Carroll University and later happily relocated to the Pacific Northwest. She has worked in government and academic clinical research for almost six years and has experience with grant preparation, budgets, designing data collection tools, and writing operations manuals. Marisa currently works with other VA and non-VA sites on interventional and observational studies in the areas of orthopaedics and rehabilitation medicine.

### **Alana Clark, Regulatory Specialist & Research Coordinator, UW ITHS**

Alana is a Research Coordinator and Regulatory Specialist at the UW Institute of Translational Health Sciences, Research Coordinator Core. Prior to ITHS, she worked as a Senior Research Coordinator at the Veteran's Medical Research Foundation in San Diego in Diabetes Research. Alana started her research career at the University of Wisconsin Hospital in Pediatric Asthma and Allergy. In her current work, Alana supports the UW Department of Sports Medicine as a Research Study Manager for a national multi-site study and is a study monitor for two FDA Phase I studies in Vascular Surgery at Harborview.

### **Amy Deyle, RN, Research Nurse, UW ITHS**

Amy is a Research Nurse at the UW Institute of Translational Health Sciences, Research Coordinator Core. She has worked as a research nurse for 17 years, starting at the Minneapolis Medical Research Foundation, working specifically with women's health research. At the University of Minnesota she continued to coordinate clinical trials in multiple different clinical areas including oncology, medical genetics, anesthesia, pulmonology, and rheumatology. In 2004 she moved to Seattle and worked for the Clinical Trials Support Office (now CRS) at Fred Hutchinson Cancer Research Center. During her last several years there, she was the lead for the study start up team and served as the research liaison between FHCRC/SCCA and Seattle Children's Hospital. In 2012, Amy moved back to Minnesota and currently works for the ITHS remotely doing study start up, data abstraction, and CRF building.

### **Michael Donahue, Regulatory Specialist & Research Coordinator, UW ITHS**

Mike is a Research Coordinator and Regulatory Specialist at the UW Institute of Translational Health Sciences, Research Coordinator Core. He has been a Research Coordinator since 1998, with a two year detour to work as an Administrator in the UW Human Subjects Division. He has worked in a number of different clinical programs, including hepatology, nephrology, surgery, oncology, otolaryngology, health services, and rehabilitation medicine. In his current work, Mike is involved in research coordination, regulatory support, monitoring, and training.

**Amy Gest, Research Coordinator, Data Coordinating Center at the UW Resuscitation Outcomes Consortium**

Amy is a Research Coordinator with UW Data Coordinating Center at the Resuscitation Outcomes Consortium. She has 15 years of experience in study coordination, regulatory compliance and international research. In her current work, Amy provides project support for clinical trials and other outcome-oriented research in the areas of cardiopulmonary arrest and severe traumatic injury.

**Mandy Morneault, Regulatory Manager & Compliance Analyst, UW ITHS**

Mandy is the Regulatory Manager at the UW Institute of Translational Health Sciences, Research Coordinator Core. Prior to working with ITHS, Mandy established standards for and managed compliance review operations at the UW Human Subjects Division. There, she worked with researchers to identify, understand, and resolve regulatory and compliance issues. Mandy previously worked for 5 years in the Regulatory Affairs department at Quorum Review IRB, developing and managing processes for the review of protocols and patient-related materials, like consent and HIPAA documents. In her current work, Mandy educates and assists researchers in setting up and monitoring investigator-initiated research protocols and study operations.

**Marilynn Rothen, Research implementation Manager, UW ITHS**

Marilynn is the Research Study Implementation Manager at the UW Institute of Translational Health Sciences, Research Coordinator Core. She also works in the School of Dentistry, where she manages the Regional Clinical Dental Research Center and has overseen research studies for over 20 years. Marilynn is also the Associate Director of the Master of Science in Oral Biology for Dental Hygiene Educators program, and sees patients in the Dental Fears Research Clinic. Her experience coordinating multi-site projects is through her work with the PRECEDENT network, at the UW and OHSU, where practice-based research was conducted in private and public dental offices. She was the lead regional coordinator for the network, involved in project design, materials development, & training offices to conduct research.

**Billi Tatum, RN, CCRC, Research Nurse, Regional Vascular Center, HMC and UWMC**

Billi is a Research Nurse at the Regional Vascular Center and works at both UWMC and HMC. Billi has been a nurse for many, *many* years working in the Critical Care and made the switch to research 11 years ago. Her research experiences are at Madigan Army Medical Center and Harborview, where she worked/works with drug and device studies in the Urology, Cardiac, Wound Care and Vascular Surgery specialties. Billi has worked with major drug and device companies and is currently working on two investigator initiated IDEs (Investigational Device Exemptions).

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