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Changing Landscapes in Research

the NWABR Annual IRB Conference

NWABR
Northwest Association for Biomedical Research

JULY 25, 2024

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As one of the top five pediatric research centers in the nation, we bring together the best minds in pediatric research to set new standards of pediatric care and find new cures for childhood diseases. Our goal is that every patient at Seattle Children's has the opportunity to participate in, or benefit from, our groundbreaking research.

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The University of Washington, or "Udub," is a public research university in Seattle, WA. As the state's flagship university, it serves more than 92,000 students a year and confers greater than 12,000 bachelors, masters, doctoral, and profressional degrees annually. UW has campuses in Seattle, Tacoma, and Bothell, as well as a world-class academic medical center.

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Emergency Information, Pre-Arranged Meals, Special Requests.
Check with the main registration table for onsite solutions.

MESSAGE FROM THE BOARD

Aaron Putzke, PhD,
is a Professor and Researcher, in the Department of Biology at Whitworth University

Dear Participants,

I would like to welcome you to the annual Northwest Association for Biomedical Research Conference (NWABR) IRB Conference. This year, our theme is "Changing Landscapes in Research." We want to acknowledge all of the speakers from leading academic, medical centers, and IRBs across the country for working with us to present this program.

At NWABR, our mission is to promote the public's trust in biomedical research and its ethical conduct. This conference is an important component of NWABR's strategy. Today we connect stakeholders from nonprofit, private, and public entities who are concerned with ensuring that clinical research is designed and carried out in an ethical manner. We hope to promote shared knowledge, peer engagement, and a high-quality culture of research ethics with this conference.

I also want to acknowledge Seattle Children's Research Institute, Advarra, WCG, and the University of Washington who have also been immensely helpful in both planning and supporting this conference. The NWABR Planning Committee and our speakers have also worked hard to bring you informative, engaging, and provocative presentations.

I would like to thank NWABR staff and volunteers, the presenting partners, and the Planning Committee. In addition, I thank our corporate sponsors and vendors for their support and generosity through their presence and their generous contributions and donations.

Lastly, we are honored that you have chosen to participate in this exciting conference. We hope that you will have a constructive learning experience that will positively impact your research practice.

Aaron Putzke
Board President, NWABR

TIME	SESSION INFORMATION	SESSION OBJECTIVES
8:00 - 8:15	**Opening Remarks** Melissa Tribelhorn, MPA, Executive Director, *NWABR* Emily Guthrie, Co-Chair, *University of Washington* Julie Ozier, Co-Chair, *Advarra* Kelly Lawrence, Co-Chair, *Seattle Children's Research Institute* Bert Wilkins, Co-Chair, *WCG IRB*	
8:15 - 9:15	**Morning Keynote:** **IRB Quality and Effectiveness:** **The Pursuit of Reasonableness** Holly Fernandez Lynch, JD, MBE, *University of Pennsylvania* Holly A. Taylor, PhD, MPH, *Department of Bioethics, Clinical Center,* *National Institutes of Health*	Responding to decades of discussion about the need to develop meaningful measures of IRB and HRPP quality and effectiveness, most recently reflected in the 2023 GAO report, the co-chairs of the Consortium to Advance Effective Research Ethics Oversight (www.AEREO.org) will describe a new conceptual model focused on "IRB reasonableness." This model looks beyond regulatory compliance and efficiency to substantive pillars of quality, including stakeholder engagement, expertise, deliberation, and precedent, intended to advance the ethical goals of participant protection and research facilitation. We will share how the model of IRB reasonableness and pillars of quality guide AEREO's conceptual, empirical, and quality improvement efforts. **Objectives:** 1. Understand IRB reasonableness as a conceptual model 2. Describe AEREOs four substantive pillars of quality 3. Provide community feedback on whether IRB reasonableness and these pillars of quality capture what matters for IRB effectiveness
9:15 - 9:30	Break	
9:30-10:30	**Panel: Diversity as a Regulatory Theme** Jason Malone, MA, CIP, *University of Washington* Bessie A. Young, MD, MPH, *University of Washington* Meghan Scott, BA, *Fred Hutchinson Research Center* Laurie Price, JD, *Seattle Children's Research Institute*	How institutions can support greater diversity in their clinical trials, based on experiences with the WA State DCT bill.
10:30 - 10:45	Break	

SESSION DETAILS

TIME	SESSION INFORMATION	SESSION OBJECTIVES
10:45 - 11:45	**Software as Medical Device (SaMD)** Jaimee Heffner, PhD, *Fred Hutchinson Cancer Center* Lynn M. Rose, PhD, *UW School of Pharmacy* UW Institute of Translational *Health Sciences*	Define SaMD Products; discuss available paths to market for SaMD products; identify regulatory requirements for SaMD products under 'enforcement discretion.'
11:45 - 1:00	Lunch	
1:00 - 1:50	**My Health My Data** Tracy Lightfoot, CIA, CHPC, CHC, ADAC, *MultiCare Health System*	Examine the impact of the My Health My Data Act.
1:50 - 2:50	**Afternoon Keynote:** **Protect your research and your patients—AI Governance for Biomedical Research Environments** Bill Reid, MS, *Google*	An engaging look at emerging principles and practices of governing the use of AI in life sciences.
2:50 - 3:10	Break	
3:10 - 4:00	**What to Expect When You're Expecting: Challenges of Psychedelic Research Amidst a Social Movement** Laura Jackson, BSc, *WCG IRB* Lindsay Helm, PA-C Nathan Sackett, MD, MS, *University of Washington*	We will explore expectancy as a confounding variable; study design challenges in psychedelic trials such as true informed consent, placebo/nocebo controls, and tiered support models; and our ethical imperative as researchers, particularly within the context of a social movement.
4:00 - 4:50	**A Pragmatic Approach to Artificial Intelligence Governance: Protecting Data and Finding Value** Christopher J. Kelly, MD, MS, MSMI, MSDS, FAMIA, *MultiCare Health System*	1. Understand the different components of AI Governance, and one healthcare system's approach to ensuring safety and finding value in AI investments. 2. Understand how this governance approach can be used to evaluate the clinical implementation of DAX CoPilot.
4:50 - 5:00	**Closing Remarks** Melissa Tribelhorn, MPA, Executive Director, *NWABR*	

HOLLY FERNANDEZ LYNCH, JD, MBE

Associate Professor of Medical Ethics and Law

University of Pennsylvania

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Holly Fernandez Lynch, JD, MBE, is Associate Professor of Medical Ethics and Law at the University of Pennsylvania (effectively July 1, 2024). She pursues conceptual and empirical scholarship regarding clinical research ethics and regulation, access to investigational medicines, and FDA pharmaceutical policy, especially approaches to drug development and early approval pathways for diseases with unmet treatment needs. She is co-founder and co-chair of the Consortium to Advance Effective Research Ethics Oversight (www.AEREO.org), a collaborative endeavor to define, measure, and improve the quality and effectiveness of institutional review boards and human research protection programs. She is a board member of Public Responsibility in Medicine & Research (PRIM&R) and board president-elect of the American Society for Law, Medicine, and Ethics. She served as a member of the Secretary's Advisory Committee on Human Research Protection (SACHRP) from 2014-2019. Professor Fernandez Lynch has previously worked as an attorney in private practice, a bioethicist serving NIH's Division of AIDS, a senior analyst with President Obama's Commission for the Study of Bioethical Issues, and executive director of Harvard Law School's bioethics and health law research program. She earned graduate degrees in law and bioethics at the University of Pennsylvania.

JAIMEE HEFFNER, PHD

Fred Hutchinson Research Center

Dr. Jaimee Heffner is a clinical psychologist who researches tobacco-cessation interventions for populations who experience health disparities, including people with mental health conditions, low-income veterans, and sexual and gender minorities. Much of her work focuses on new behavioral treatments such as acceptance and commitment therapy and behavioral activation. She develops methods to deliver these interventions — such as websites, smartphone apps and other forms of technology — to improve the accessibility of treatment for all tobacco users. Her research interests also include implementation of tobacco-cessation interventions in the novel setting of lung cancer screening.

LINDSAY HELM, PA-C

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Lindsay has been working in psychedelic clinical trials for the past two years as both a study therapist and sub-investigator. She is also a psychiatric clinician with a focus on ketamine assisted therapy.

LAURA JACKSON, BSC

IRB Board Member & Expedited Reviewer

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Laura Jackson is a social and behavioral research scientist, currently serving as a Board member and Expedited Reviewer for WCG IRB. Prior to her role with WCG, Laura co-founded a non-profit research literacy training organization for university students and has worked in clinical research, specializing in conducting psychedelic medicine and neurocognition studies. She has served as a psychedelic therapy facilitator for major depressive disorder (MDD) and psilocybin research and developed the study design and facilitator training for psychedelic medicine Investigator-Initiated Trials (IITs).

CHRISTOPHER J. KELLY, MD, MS, MSMI, MSDS, FAMIA

Associate Chief Medical Information Officer for Data & Analytics

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Chris Kelly is a pediatric ophthalmologist and the ACMIO for Data and Analytics at MultiCare Health System. He currently leads the Epic Cogito Analytics team at MultiCare. By way of background, he has an MD from Harvard Medical School, and Master's degrees in Biology from the University of Chicago and in Medical Informatics as well as Data Science from Northwestern University. He is halfway through a certificate in Machine Learning through the University of Washington. He is currently leading the implementation of several clinical AI projects at MultiCare.

TRACY LIGHTFOOT, CIA, CHPC, CHC, ADAC

Director, Privacy and Civil Rights/ Chief Privacy Officer

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Tracy Lightfoot joined MultiCare in 2022 as Director, Privacy and Civil Rights. Lightfoot has over fifteen years' healthcare experience. Prior to MultiCare she served as Senior Manager, Compliance and Privacy at Fred Hutchinson Cancer Center, Program Manager, Auditing and Monitoring at Seattle Children's Hospital, and Proactive Privacy Program Manager at Providence Health Systems. Lightfoot holds a Bachelor's Degree in Business Administration from Washington State University. Lightfoot is a member of the Health Care Compliance Association and is certified in healthcare privacy (CHPC) and certified in healthcare compliance (CHC). Lightfoot also holds the Americans with Disability Act Certification (ADAC) through the ADA Coordinator Training Certification

SPEAKERS

Program and a CIA (certified internal auditor) through the Institute of Internal Auditors.

JASON MALONE, MA, CIP

Director, Human Subjects Division

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Jason Malone is the Director for the Human Subjects Division at the University of Washington (UW), which manages the four Institutional Review Boards (IRBs) that review and oversee UW human subjects research. Prior to serving as Director Jason was the Assistant Director for Regulatory Affairs, administering the IRB compliance and post-approval monitoring programs. Jason spent nine years as the Clinical Compliance Officer for the UW Institute of Translational Health Sciences where he ran the compliance programs for the pediatric and adult Clinical Research Centers as well as the Data and Safety Monitoring program. Before his career at the UW, Jason spent six years at Quorum Review IRB (now Advarra) where he was responsible at various times for overseeing their nationwide site monitoring program, IRB Administration, Regulatory Compliance, and Customer Relations. Jason has a master's degree from the UW in Public Administration, and a Certificate in Global Health.

LAURIE PRICE, JD

Senior Director,
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Seattle Children's Research Institute

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Laurie worked in criminal and civil litigation for a number of years prior to joining Seattle Children's in 2005. She has worked with the Office of Institutional Assurances (OIA) since 2006. Laurie is Senior Director of the OIA, which includes supporting the Institutional Review Board.

BILL REID, MS

Office of the Chief Information Security Officer

Google

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Bill Reid is part of Google's Office of the Chief Information Security Officer (CISO) to advise Google Cloud's Health and Life Sciences customers on ways to achieve their business goals while adopting a high security bar.

He most recently was CISO and VP for National Resilience, a bio-manufacturing company, where he established and ran the Security (Physical, IT, and OT), Privacy, and Compliance organizations.

Before Resilience, Bill was the CISO for Amazon Care, a telehealth and in-person care organization established by AWS. He built the security and privacy team as part of the launch of the service. Also at AWS, Bill led the AWS Security Solution Architecture team, working with the company's enterprise customers, and co-led the global security community of practice.

Earlier, Bill held various CISO roles at healthcare technology and medical device companies. He was also at Microsoft, where he ran a Microsoft Consulting Services payer and provider practice, was part of the Trustworthy Computing initiative, and was Director of Product Management for Microsoft Health Solutions Group, working on products like HealthVault and a joint development project with the Mayo Clinic. He began his career in healthcare administration at Group Health Cooperative (now Kaiser) where he served in a number of clinical and financial management roles.

Bill is past American College of Healthcare Executives (ACHE) Regent for Washington State, and past President of the Washington Chapter. He has been a 20+ year mentor and lecturer to the University of Washington Masters in Health Administration (MHA) program.

Bill holds a Masters of Science from Tufts University, and a BA from the University of Pennsylvania. He also completed post-graduate work in healthcare ethics at the University of Washington Medical School.

LYNN M. ROSE, PHD

Associate Professor, Affiliate

UW School of Pharmacy
UW Institute of Translational Health Sciences

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Lynn Rose is an Associate Professor (affiliate) in the UW School of Pharmacy and the UW Institute of Translational Health Sciences, where she advises academic investigators on regulatory strategies for product development. She previously held academic positions at Seattle Children's Research Institute and the Benaroya Research Institute. While working in the biotechnology industry, she had the opportunity to oversee nonclinical, clinical, and regulatory programs and departments. This experience included participation on multiple drug development teams, two of which resulted in marketed products for the treatment of cystic fibrosis and two for hemostasis. Rose has expertise in biopharmaceutical product development, including clinical study designs, and identification of regulatory strategies for new medical products. Her research experience is in the field of immunology, with an emphasis on autoimmunity, infectious disease, and immuno-oncology. Rose earned her doctorate in immunology from the University of Geneva, Switzerland.

NATHAN SACKETT, MD, MS

Director, Center for Novel Therapeutics in Addiction Psychiatry and Acting Assistant Professor, Department of Psychiatry and Behavioral Sciences, UW Medicine

University of Washington

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Nathan Sackett is a clinician, researcher and lecturer focusing on the use of emerging treatments, including psychedelics, to target substance use disorders. Clinically, Nathan sees patients in a busy academic outpatient clinic focusing on addiction care. He is the founding director of the Center for Novel Therapeutics in Addiction Psychiatry (NTAP) which focuses on developing studies from bench to bedside. NTAP currently has a range is projects, from qualitative to RCT using psilocybin, ibogaine and other emerging compounds.

MEGHAN SCOTT, BA

Director, Institutional Review Office

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Meghan Scott is the Director of the Institutional Review Office at the Fred Hutchinson Cancer Center (Fred Hutch) and has worked with IRBs since 2004. Meghan joined Fred Hutch in June 2016 where she has oversight of the AAHRPP accredited Human Subject Protection Program and the AAALAC accredited Animal Care and Use Program. Previously, Meghan worked at a leading independent IRB, Advarra (formerly Quorum Review IRB), where she led several operational teams throughout her 12-year tenure. Meghan received her BA in Business with a minor in Psychology from the University of Puget Sound.

HOLLY A. TAYLOR, PHD, MPH

Research Bioethicist

Department of Bioethics, Clinical Center, National Institutes of Health

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Holly A. Taylor, PhD, MPH, is a member of the faculty of the department of bioethics at the Clinical Center of the National Institutes of Health. She is a nationally recognized expert on the review and oversight of human subject research and on research ethics consultation. She co-leads two national collaboratives dedicated to advancing knowledge and practice in these areas: the Consortium to Advance Effective Research Ethics Oversight **(www.AEREO.org)** and the Clinical Research Ethics Consultation Collaborative **(www.iths.org/CRECC)**. Previously, she was an associate professor in the department of health policy and management at the Johns Hopkins Bloomberg School of Public Health and core faculty at the Johns Hopkins Berman Institute of Bioethics. Dr. Taylor conducts quantitative and qualitative research in the field of research ethics, including informed consent for research participation and subject selection, as well as the review and oversight of research and research ethics consultation. She also has longstanding interests in public health ethics issues related to infectious disease and has published on HIV, pandemic preparedness, Ebola, and Covid-19. She also has served on multiple institutional review boards and data monitoring committees.

MELISSA TRIBELHORN, MPA

CEO/Executive Director

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NWABR's new Executive Director Melissa Tribelhorn has dedicated her career to advocating for educational and healthcare programs that benefit patients and families, no matter their diagnosis, socioeconomic factors, or background. From her early work with HIV prevention education in sub-Saharan Africa to her most recent role as the CEO for NW Parkinson's Foundation, Melissa has always worked in and adjacent to the biomedical research space. She is excited to be part of NWABR's work to strengthen the biomedical research community and promote the public's trust in biomedical research. Melissa holds a Master of Public Administration from Seattle University and lives in Seattle with her incredibly active preschooler.

BESSIE A. YOUNG, MD, MPH

Vice Dean for Equity, Diversity, and Inclusion and Medical Director, Office of Health Care Equity, UW Medicine, Professor of Medicine, Division of Nephrology, Department of Medicine

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Dr. Young is the Vice Dean for Equity, Diversity & Inclusion and Medical Director of the UW Medicine Office of Health Care Equity at the University of Washington. She was recently awarded the 2023 Paul Beeson Award from the Washington Physicians for Social Responsibility. The award honors activists in healthcare who have made a substantial contribution to peace, justice, and health in Washington state. Dr. Young has been practicing medicine with the University of Washington since 1987.