Avera

RESEARCH INTEGRITY CONFERENCE

Creating and Promoting a Culture of Research Integrity

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THE OFFICE OF RESEARCH INTEGRITY®

Sept. 10, 2021

Hilton Garden Inn Downtown

Sioux Falls, S.D.

OUR COLLABORATORS

ACRP

AUGUSTANA UNIVERSITY

south dakota biotech
Connect. Collaborate. Innovate.

UNIVERSITY OF SOUTH DAKOTA

SOUTH DAKOTA STATE UNIVERSITY

QUIBIT
QUality, Integration, Best practices, Innovation, and Technology

Kahoot!

INSTRUCTIONS

Throughout the conference, we will be playing Kahoot! Games.

To join in the fun, you have two options:

1. Download the Kahoot! App on your phone. Join a Kahoot with a PIN provided when it is on the big screen.

2. On your mobile device browser, go to Kahoot.it. Join a Kahoot with a PIN provided when it is on the big screen.

   Note: *When using this option, it's recommended to disable or lengthen the screen timeout on your phone as you could get kicked out of the game when the screen times out.*

AGENDA

7:30–8 a.m. **Registration**

8–8:05 a.m. **Opening Remarks:** *Richard Korman, Chief Legal Officer and General Counsel, Avera Health*

8:05–8:20 a.m. **Integrity: Choosing Courage Over Comfort**
Lynn Bartholow, Executive Director of Research Compliance, Avera Health

8:20–9:20 a.m. **Identification and Ethical Reporting of Suspected Fraud or Misconduct**
Glenda Guest, CCRA, RQAP-GCP, TIACR, President, Assured Quality Consulting & Training

Summary: Attendees will be able to describe at least two methods for preventing and detecting falsification. The roles of clinical investigator, site staff, sponsors/monitors and the IRB (Institutional Review Board) role in preventing and detecting falsification and fraud will also be explained.

9:20–10:05 a.m. **What Are the Red Flags of Research Misconduct?**
John Thomas, Jr., Attorney, Duke Whistleblower Case, Hafemann, Magee & Thomas

Summary: Many research misconduct cases share common characteristics. By watching for these "red flags," researchers and administrators can identify problematic trends and address them.

10:05–10:15 a.m. **Kahoot! Game**

10:15–10:20 a.m. **Morning Break**

10:20–11:50 a.m. **Roundtable Discussions**
(Attendees can choose to attend up to four of the discussions with 20 minutes at each table. Each table will have a subject matter expert facilitating the discussion.)

TITLE	SUBJECT MATTER EXPERTS
Challenges and Pitfalls of Decentralized Clinical Trials	Seneca Harrison, Vice President, Quality Clinical Research, Omaha, Neb.
Corrective and Preventive Action (CAPAs) / Root Cause Analysis	Lynn Bartholow, Executive Director of Research Compliance, Avera, Sioux Falls, S.D.
Research Misconduct Scenarios	Kevin O'Kelley, Assistant Vice President of Research, University of South Dakota, Vermillion, S.D.
Improving the Understandability of Informed Consents	Ann Waterbury, Director of the Human Subjects Protection Program, University of South Dakota, Vermillion, S.D.
Data Integrity for Medical Devices	Aaron Harmon, Director of Quality, Inanovate, Sioux Falls, S.D.
Making the Most of Mentoring	Kevin Sackreiter, Director of the Center for the Enhancement of Teaching and Learning, South Dakota State University, Brookings,S.D.

11:50 a.m.–12:35 p.m. **Complimentary Lunch** (Kahoot! Game During Lunch)

12:35–1:20 p.m. **Best Practices for Conducting Research in Tribal Communities**
Deborah Tobacco, Clinical Research Manager, Avera Center for Community and Pediatric Research, Avera Research Institute

Jyoti Angal, Director of Clinical Research, Avera Center for Pediatrics and Community Research

Summary: Session will provide an overview of collaborative research initiatives of the Community and Pediatric Research Center. Topics discussed include strategies to build trust, recognize tribal sovereignty and acknowledge cultural context in research with Native American communities.

1:20–2:05 p.m. **The Federal Agency Perspective of Research Misconduct**
Michael Lauer, MD, Deputy Director for Extramural Research, National Institutes of Health (NIH)

2:05–2:15 p.m. **Kahoot! Game**

2:15–3:05 p.m. **Challenges of "New to Research" Staff**
Amy Lounsbury, President, Association of Clinical Research Professionals, Minnesota Chapter

Laura Menck, Director of Clinical Operations, Monteris Medical

Summary: Session will describe challenges and best practices for working with inexperienced staff.

3:05–3:15 p.m. **Afternoon Networking Break**

3:15–4:15 p.m. **Site Oversight of Decentralized Clinical Trials**
Eric Pittman, Program Director West Region, Office of Scientific Investigation, Bioresearch Monitoring, FDA

Summary: Attendees will learn about some of the points to consider when embarking on a Decentralized Clinical Trial.

4:15–5:15 p.m. **Achieving Excellence through Standards and Checklists**
Christine Senn, PhD, FACRP, CSM, CPI, Chief Implementation and Operations Officer, IACT Health

Summary: Attendees will gain an understanding of competencies, mapping competencies to your team members, and how the use of checklists can improve trial efficiency and quality.

5:15–5:45 p.m. **Final Kahoot!**
Game and Conference Assessment

5:45–7 p.m. **Social/Networking**
Mentorship Matching Event

SPEAKER BIOS

ERIC PITTMAN

Program Director West Region,
Office of Scientific Investigation, Bioresearch Monitoring,
Food and Drug Administration

Eric Pittman has the privilege of leading a large group of diverse individuals all working together to meet the Mission of the Food and Drug Administration. Pittman is stationed in Chicago, Ill.

MICHAEL LAUER, MD

Deputy Director for Extramural Research,
National Institutes of Health (NIH)

Michael Lauer, MD, serves as the principal scientific leader and advisor to the Director of the NIH on all matters relating to the substance, quality and effectiveness of the NIH Extramural Research Program and administration. He received education and training at Rensselaer Polytechnic Institute, Albany Medical College, Harvard Medical School, Harvard School of Public Health, and the NHLBI's Framingham Heart Study. He spent 14 years at Cleveland Clinic as Professor of Medicine, Epidemiology and Biostatistics. During his tenure at the Clinic, he led a internationally renowned clinical epidemiology program that applied big data from large-scale electronic health platforms to questions regarding the diagnosis and management of cardiovascular disease. From 2007 to 2015 he served as a Division Director at the National Heart, Lung, and Blood Institute (NHLBI), where he promoted efforts to leverage big data infrastructure to enable high-efficiency population and clinical research and efforts to adopt a research funding culture that reflected data-driven policy.

JOHN THOMAS, JR.,

Attorney, Hafemann, Magee & Thomas

John Thomas is a national leader in False Claims Act litigation, where whistleblowers uncover and report fraud against the government. Thomas was responsible for bringing the landmark case against Duke University for grant fraud that resulted in a $112.5 million settlement. Thomas litigates cases throughout the country involving procurement fraud, health care fraud, medical device fraud and grant fraud.

GLENDA GUEST, CCRA, RQAP-GCP, TIACR

President, Assured Quality Consulting & Training

Glenda Guest is based out of Syracuse, N.Y., and is a qualified research professional with over 20 years' experience in conducting clinical research, training and auditing. As a certified clinical research trainer with consistently high-performance scores based on attendee feedback for various venues and customized client trainings, Guest excels at audience engagement and interactivity.

CHRISTINE SENN, PHD, FACRP, CSM, CPI

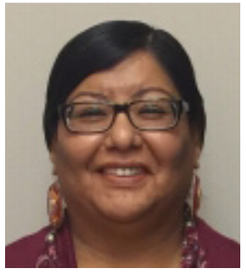
Chief Implementation and Operations Officer, IACT Health

Christine Senn is Chief Operations Officer at IACT Health in Columbus, Ga., a multi-specialty research management organization with sites throughout the southeast United States. She holds her doctorate in psychology and has master's degrees in clinical psychology and advertising/public relations. She is triple-certified by Association of Clinical Research Professionals and is proud to be among ACRP's first Fellows.

JYOTI ANGAL

Director of Clinical Research, Avera Center for Pediatrics and Community Research

Jyoti Angal provides oversight for research activities conducted at clinical sites in South Dakota. Angal was the former director of Regulatory Knowledge Core for the Collaborative Research Center for American Indian Health funded by NIHMD since 2012. The mission of the Regulatory Knowledge Core was to work with tribes in South Dakota, North Dakota and Minnesota to build tribal research infrastructure and develop policies around tribally led research oversight, including issues related to data ownership and sharing. In 2019, Angal was appointed to the Secretary of Health Human Services Advisory Committee on Human Research Protections. This committee advises the HHS secretary on conduct of research with specific focus on special populations.



DEBORAH TOBACCO

Clinical Research Manager, Avera Center for Community and Pediatric Research, Avera Research Institute

Deborah Tobacco is responsible for networking with all entities within the boundaries of the Pine Ridge Indian Reservation including the Oglala Sioux Tribe i.e. Research Review Board, Health and Human Services Committee, Indian Health Service i.e. Leadership Committee, Bright Start and WIC. Current work includes the Infant Care Practice Study that focuses on Safe Sleep Practices to improve outcomes.

AMY LOUNSBURY

President, Association of Clinical Research Professionals, Minnesota Chapter

Amy Lounsbury has over 10 years of experience managing clinical trials at a site location. Over the past six years, she has been involved in the training and management of research clinical staff. Lounsbury is currently working as a Clinical Team Manager for a clinical research organization. Lounsbury is passionate about managing successful trials to ensure accurate study data which will assist in the development of new medications and devices for the patients.

LAURA MENCK

Director of Clinical Operations, Monteris Medical

Laura Menck has been an enthusiastic clinical research professional for over 20 years with experience leading teams from site to sponsor in pharma and medical device; currently, she is the Director of Clinical Operations at Monteris Medical based in the Twin Cities. Menck has been a certified Association of Clinical Research Professionals member since 2003 and currently holds the ACRP-CCRA and PM certification.

ROUNDTABLE FACILITATORS

LYNN BARTHOLOW, CCRC

Executive Director of Research Compliance, Avera

Lynn Bartholow is an industry veteran with more than 20 years in clinical trial management, with a passion for pursuing solutions to optimize clinical trials and quality/process improvement, and share her knowledge with others.

KEVIN SACKREITER

Director of the Center for the Enhancement of Teaching and Learning, South Dakota State University

Kevin Sackreiter provides university-wide leadership for teaching and learning-focused professional development efforts for all university faculty and graduate teaching assistants at SDSU. He brings to this roundtable expertise in pedagogy, teaching-based research, faculty mentoring, and graduate teaching assistant professional development. Sackreiter recently completed training to facilitate mentoring in research with the Center for the Improvement of Mentored Experiences in Research.

SENECA HARRISON

Vice President, Quality Clinical Research

Seneca Harrison's career in clinical research began in 2008. During his time with Quality Clinical Research in Omaha, Neb., Harrison has made it his mission to diversify vital clinical studies, leading the way toward a broader and more inclusive view of clinical research. His role in bringing quality drugs to market for everyone means ensuring that drugs are developed with proper representation of each minority group. He has been able to diversify these studies with bold and creative recruitment and screening techniques.

AARON HARMON

Director of Quality, Inanovate

Aaron Harmon is a co-founder of QUIBIT, a local quality assurance professionals' network, and Director of Quality for Inanovate, Inc., in Sioux Falls, S.D. He received his doctorate in microbiology from South Dakota State University in Brookings and has over 12 years of experience in the regulated industry.

KEVIN O'KELLEY

Assistant Vice President of Research, University of South Dakota

Kevin O'Kelley is the Assistant Vice President for Research at the University of South Dakota in Vermillion, and serves as USD's Research Integrity Officer. O'Kelley managed regulatory compliance for the petrochemical industry prior to transitioning to academia in 2012. His preference is always to prevent a problem, rather than to deal with one after it arises, thus his emphasis on training and mentoring.

ANN WATERBURY

Director of the Human Subjects Protection Program, University of South Dakota

Ann Waterbury has worked in research administration at the University of South Dakota in Vermillion for 11 years, with the last five in research compliance. As Director of the Human Subjects Protection Program, she oversees the only accredited academic human research program in the state, which includes all human subject research conducted at USD as well as at two regional VA health centers.

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