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Three I's: Biosecurity and Research Integrity™: *Promoting the Responsible Conduct of Research, Partnership, Ethics, Best Practices and the Exploration of Current Trends*

Day 3 **WEDNESDAY, APRIL 30, 2025** **CONFERENCE AGENDA**

7:00 AM - 8:30 AM	**BREAKFAST … NETWORK … WELCOME TO OUR FINAL DAY!**
8:30 AM – 9:15 AM	**THREE I's SESSION**
	THREATS TO AGRICULTURE **SUSAN N CROPP, PhD** CHEMICAL BIOLOGICAL COUNTERMEASURES UNIT FBI HEADQUARTERS
9:20 AM – 9:50 AM	
	OPERATION OUTBREAK **KIAN SANI** OO, The BROAD INSTITUTE **CURTIS HOFFMANN** OO, The BROAD INSTITUTE
9:50 AM – 10:00 AM	**BREAK**
10:00 AM – 11:00 AM **THREE Is**	**WHEN YOU WORK WITH A JERK: UNPROFESSIONALISM AND RESEARCH INTEGRITY** **ROBIN S TYNDALL, MS** DIRECTOR, OFFICE OF RESEARCH COMPLIANCE RESEARCH INTEGRITY OFFICER CHAIR, CLEMSON UNIVERSITY COMMISSION ON ACCESSIBILITY CLEMSON UNIVERSITY The narrow federal definition of Research Misconduct--Fabrication/Falsification/Plagiarism--does not account for all sorts of other bad practices, including unprofessional conduct, which can include but is not limited to harassment, bullying, etc. This presentation and discussion will include how professional misconduct is defined, how these behaviors can be intertwined with research integrity investigations, how to prevent and report misconduct in all forms, and the federal reporting requirements for these investigations.

11:00 AM – 12:00 PM			
	IBC IRB **UNIQUE CHALLENGES POSED BY DECENTRALIZED CLINICAL TRIALS INVOLVING BIOLOGICS** **DANIEL EISENMAN, PhD, RBP, SM(NRCM), CBSP** EXECUTIVE DIRECTOR BIOSAFETY SERVICES ADVARRO Decentralized clinical trial (DCT) modalities continue to transform the way we conduct clinical research. One surprising area: studies involving genetically modified biologics. In this webinar, you'll find out what FDA says about DCTs and biologics, and what this means in practice. Dr. Daniel Eisenman provides a biosafety perspective on these types of studies, explaining the unique risks and important considerations for ensuring safe, responsible trial conduct. **Learning Objectives:** 1. Describe key ways biologics research differs from small molecule research 2. Summarize what FDA guidance says about DCTs involving biologics 3. Discuss ways to address the unique challenge of biologics in DCTs 1.00 CIP	**ALL I'S** **RESEARCH INTEGRITY & RESEARCH ADMINISTRATION INVITED!** **SPOT THE ISSUES** **ETHICS CHALLENGE** **KATHRYN A HOLTHAUS, MS, MA** DIRECTOR OF RESEARCH SUBJECTS PROTECTION AND LABORATORY SAFETY COMPLIANCE RESEARCH OPERATIONS BRIGHAM & WOMEN'S HOSPITAL **TED MYATT, ScD** ASSOCIATE VICE PROVOST OF RESEARCH INTEGRITY TUFTS UNIVERSITY **ROSS HICKEY, JD CIP CPIA** ASSISTANT PROVOST FOR RESEARCH INTEGRITY UNIVERSITY OF SOUTHERN MAINE DIRECTOR OF THE MAINE REGULATORY ETHICS AND TRAINING CENTER (MERTEC) AT USM **SUSAN N CROPP, PhD** CHEMICAL BIOLOGICAL COUNTERMEASURES UNIT FBI HEADQUARTERS
12:00 PM - 12:45 PM	**LUNCH**		
12:50 PM - 1:35 PM	**THREE I SESSIONS**		
	THREE I's **PAM OVERSIGHT FOR ALL FINDING COMMON VALUE** **PANEL** **IACUC** **DAVID LYONS, PhD** IACUC DIRECTOR RCR COORDINATOR DEPUTY RESEARCH INTEGRITY OFFICER WAKE FOREST UNIVERSITY SCHOOL OF MEDICINE AND ADVOCATE/ATRIUM HEALTH **IBC** **TED MYATT, ScD** ASSOCIATE VICE PROVOST OF RESEARCH INTEGRITY	**BETWEEN SCYLLA AND CHARYBDIS:** **WORKING WITH VULNERABLE POPULATIONS IN A CHANGING WORLD OF VULNERABILITIES** **CHRISTOPHER M. MANGELLI, JD, MS, MEd, CIP** ASSISTANT VICE PROVOST FOR RESEARCH (AVPR) OFFICE OF RESEARCH BALL STATE UNIVERSITY What do you do when the world around you is changing faster than you can keep up with? What do you do when this is happening in the research and regulatory areas we are charged	**CONFLICT MANAGEMENT SKILLS FOR RESEARCH COMPLIANCE AND INTEGRITY PROFESSIONALS** **LLIAM HARRISON, MA, JD, CIP, C.MED** EDUCATION & RESEARCH CONSULTING MANAGER HURON **CAROL NEMEROFF, PhD** DEAN AND PROFESSOR UNIVERSITY OF NEW BRUNSWICK PRINCIPAL, AT THE MAINE REGULATORY TRAINING AND ETHICS CENTER (MERTEC) **VIRTUAL SPEAKER** Building and maintaining a culture

	TUFTS UNIVERSITY **IRB** **ALAN GOBLE, PhD ACUE** RESEARCH COMPLIANCE OFFICER AND IRB COORDINATOR OFFICE OF RESEARCH COMPLIANCE AND ETHICS NORTH CAROLINA AGRICULTURAL AND TECHNICAL STATE UNIVERSITY This panel discussion will address post-approval monitoring (PAM) from the different compliance committee perspectives, focusing on commonalities as well as committee-specific strategies and challenges. This interactive session will include scenarios to promote discussion and engage session attendees to share their own strategies & challenges and highlight innovative approaches to implementing an efficient PAM program. .75 CPIA	with managing? One of the greatest challenges IRBs and research administration staff handle are the protections for vulnerable populations. The regulations define these groups and IRBs have years of experience with the traditional "solutions". So what happens when these groups, and some that are not delineated in the regulations, become more vulnerable simply because of who and what they are? This session will look at the changing nature of what it means to be "vulnerable", what IRBs can do to help protect these groups, and what we as a community can do in the future. This session will be part interactive conversation in an effort to develop some new best practices. .75 CIP	of ethical behavior in the conduct of research is more than the right thing to do – it is the foundation of responsible conduct of research, of good science and of being a good community partner. Cutting ethical corners for expedience or in pursuit of research dollars or accolades is risky. Think of your institution's name under a headline of a multi-million-dollar False Claims Act settlement, or in twelve-foot-high letters on a screen before a jury, or in a paper retraction. Chances are that this is not a situation you and your institution want to encounter. But the research enterprise is fraught with competing interests, giving rise to conflicting motivators. How can we respond to these divergent interests in a way that enhances rigor and integrity of our science while mitigating risk? One pathway to this balancing point is through the application of conflict management techniques in building an ethical culture of compliance. Whether by giving stakeholders (and rights-holders) a voice in the process, engaging cold cognition rather than responding to emotionally driven decision making, competing interests can be clearly framed and measured against institutional core values, legal and regulatory requirements, with the result that ethical conduct becomes ingrained as an institutional priority and, ultimately, a reality. Learning Objectives: 1. Recognize that conflict (distinct from conflict of interest) is not inherently a threat, and can be the basis for growth, collaboration, and the fostering of a culture of integrity and compliance. 2. Understand the difference between conflict and dispute and the role of interests versus positions in conflict.

1:40 PM – 2:25 PM			
	RESEARCH COMPLIANCE THREE I's Case Studies IACUC **SALLY THOMPSON-IRITANI, DVM, PHD** AVP, ANIMAL CARE, OUTREACH, & 3RS UNIVERSITY of WASHINGTON IRB **CHRISTOPHER M. MANGELLI, JD, MS, MEd, CIP** ASSISTANT VICE PROVOST FOR RESEARCH (AVPR) OFFICE OF RESEARCH BALL STATE UNIVERSITY IBC **JENORA T WATERMAN, PHD** DIRECTOR/CHAIR, APPLIED SCIENCE AND TECHNOLOGY PH.D. PROGRAM ASSOCIATE PROFESSOR, DEPARTMENT OF BIOLOGY COLLEGE OF SCIENCE AND TECHNOLOGY NORTH CAROLINA AGRICULTURAL AND TECHNICAL STATE UNIVERSITY .75 CIP	**IT'S NOT YOU, IT'S US: HOW COMPLIANCE OFFICES CAN BUILD EFFECTUAL RELATIONSHIPS WITH RESEARCHERS** **ROBIN S TYNDALL, MS** DIRECTOR, OFFICE OF RESEARCH COMPLIANCE RESEARCH INTEGRITY OFFICER CHAIR, CLEMSON UNIVERSITY COMMISSION ON ACCESSIBILITY CLEMSON UNIVERSITY It seems that virtually every research compliance conference has a session titled something along the lines of "dealing with the difficult researcher." What doesn't seem to exist, however, are sessions entitled: Dealing with the Difficult Research Compliance Office. In this session, we will discuss experiences in dealing with "difficult" RC offices, committees, and staff. The focus will be on identifying areas of such difficulties, assessing to what extent their root cause lies in policy, process, or personnel, and exploring efforts by RC leaders to eliminate, reduce, minimize such difficulties.	**CONFLICT MANAGEMENT SKILLS FOR RESEARCH COMPLIANCE AND INTEGRITY PROFESSIONALS** ***CONTINUED…***
2:30 PM – 2:40 PM	**BREAK**		
2:40 PM – 3:15 PM			
	THE IMPORTANCE OF BIOSURVEILLANCE **SUSAN N CROPP, PhD** CHEMICAL BIOLOGICAL COUNTERMEASURES UNIT FBI HEADQUARTERS		
	EVALUATIONS & CLOSING REMARKS **SEE YOU IN 2026!**		