



IACUC	
IBC	
IRB BIOSECURITY RA	
RI COMPLIANCE REGULATORY	

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

Day 2 **TUESDAY**

APRIL 29, 2025

CONFERENCE AGENDA

	BREAKFAST MEET-UPS CONFERENCE SPONSORS
9:00 AM	WELCOME TO DAY TWO!
9:05 AM- 11:00 AM	THREE I's RESEARCH INTEGRITY & ETHICS™
GENERAL SESSION	<p>RESEARCH INTEGRITY, ETHICS AND YOU© a hands-on/interactive session</p> <p>LANDSCAPE of THREATS to RESEARCH INVOLVING ALL THREE I's</p> <p>PROFFESIONAL REPUTATION MANAGEMENT AI THREATS TO HUMAN HEATHCARE LEGISLATIVE RISKS TO ALL NON COMPLIANCE ... WHO's WHAT's DRIVING THE BUS?</p> <p>SUSAN N CROPP, PhD CHEMICAL BIOLOGICAL COUNTERMEASURES UNIT/WMDD FBI HEADQUARTERS</p> <p>ETHICAL CASE STUDIES INVOLVING ALL THREE I's USE BREAKOUTS TO DISCUSS</p> <p>CECE BROTCHE-FINE, DBe MODERATOR EXECUTIVE DIRECTOR, ETHICS ETHICS, RISK AND COMPLIANCE R&D NOVARTIS</p> <p>TED MYATT, ScD MODERATOR ASSOCIATE VICE PROVOST OF RESEARCH INTEGRITY TUFTS UNIVERSITY</p>
11:00 AM -11:15 AM	REFRESHMENT BREAK

11:15 AM – 12:00 PM	ALL I's – Biosecurity – Research Administration – Research Integrity		
	<p style="text-align: center;">BUILDING RESILIENT FOUNDATIONS: HOW THE IACUC DRIVES CONTINUOUS IMPROVEMENT AND ETHICAL RESEARCH</p> <p style="text-align: center;">SALLY THOMPSON-IRITANI, DVM, PHD AVP, ANIMAL CARE, OUTREACH, & 3RS UNIVERSITY of WASHINGTON</p> <p>The Institutional Animal Care and Use Committee (IACUC) plays a pivotal role in fostering continuous improvement and refining practices in research involving animals. A powerful parallel can be drawn to the lessons learned from the collapse of the Tacoma Narrows Bridge, famously known as "Galloping Gertie." The bridge's dramatic failure in 1940 was not due to neglect but to an underestimation of critical factors like wind dynamics and structural resonance. Similarly, the IACUC serves as a safeguard against the metaphorical "collapse" of research integrity by identifying gaps, challenging assumptions, and ensuring a robust foundation for ethical practices.</p> <p>Through regular protocol reviews, post-approval monitoring, and educational outreach, the IACUC encourages investigators to anticipate potential pitfalls and implement the principles of the 3Rs (Replacement, Reduction, and Refinement). This proactive approach minimizes the risk of overlooking ethical and practical considerations in animal research. Moreover, just as engineers learned to account for aerodynamics and resonance post-Galloping Gertie, the IACUC helps the research community learn from past challenges, fostering a culture of resilience and innovation. By sharing lessons from non-compliance events, facility challenges, or animal welfare incidents, the IACUC drives improvement and builds a stronger bridge between regulatory expectations and scientific advancement. Ultimately, this continuous learning ensures that research programs are both ethically grounded and structurally sound, advancing animal welfare and scientific discovery together.</p>	<p style="text-align: center;">HAZARDOUS RESPONSE TEAMS</p> <p style="text-align: center;">FBI WMD TBA</p>	<p style="text-align: center;">TBA</p>
12:00 PM – 1:00 PM	LUNCH		

1:05 PM – 1:50 PM			
	<p style="text-align: center;">IACUC</p> <p style="text-align: center;">COLLABORATIONS AND MEMORANDUM OF UNDERSTANDING</p> <p style="text-align: center;">ANNA HAMPTON DVM, DACLAM, DACAW, CPIA</p> <p style="text-align: center;">DIRECTOR, OFFICE OF ANIMAL WELFARE ASSURANCE CHAIR, INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE IACUC ADMINISTRATIVE OFFICE DUKE UNIVERSITY</p>	<p style="text-align: center;">IBC IRB</p> <p style="text-align: center;">THE GRAY AREA BETWEEN IRBS AND IBCS IN THE REVIEW OF CLINICAL TRIALS</p> <p style="text-align: center;">GARRY COULSON, PhD, RBP DIRECTOR, REGULATORY Sabai GLOBAL</p> <p>Oversight of human gene transfer (HGT) or gene therapy clinical trials typically falls under the dual oversight umbrellas of the Institutional Biosafety Committee (IBC) and Institutional Review Board (IRB). And while these two groups are independently responsible for compliance with their own exclusive sets of rules and regulations, there may be unique situations when their respective scopes of oversight overlap with one another in a way that may potentially expose “gaps” or “gray areas” in the review process that neither party adequately addresses, or has the tools to appropriately address without the express involvement of the other party. An increasingly common example of this is in the area of biomedical clinical trial research involving novel investigational products (e.g., oncolytic viruses) that may pose potential risks not only to the research participant, but also to close contacts (“third-parties” or “bystanders”) around the participant. In this presentation, we will (i) highlight some of the potential ambiguity in ownership of the oversight responsibility for third-parties, (ii) discuss potential best practices for interactions between IRBs and IBC to comprehensively address these gray areas, and (iii) identify some operational challenges and consideration with respect to the increasing use of centralized IRBs and IBC service providers.</p>	<p style="text-align: center;">DATA MANAGEMENT and RESEARCH MISCONDUCT</p> <p style="text-align: center;">KELÉ PIPER DIRECTOR, RESEARCH COMPLIANCE OFFICE OF COMPLIANCE MASSACHUSETTS GENERAL HOSPITAL</p>
1:55 PM – 2:50 PM	GENERAL SESSION		
FBI WMD RSCH Panel	MALIGN FOREIGN RECRUITMENT PROGRAMS – IMPLEMENTATION POLICY ... TRAINING ... CERTIFICATION		

	TBA		
2:50 PM – 3:00 PM	REFRESHMENT BREAK		
3:00 PM – 4:00 PM	BREAKOUT SESSIONS		
	<p style="text-align: center;">IACUC</p> <p style="text-align: center;">LEVERAGING TECHNOLOGY to ENHANCE BIOSECURITY and ENSURE IACUC ADHERENCE in VIVARIUM OPERATIONS</p> <p style="text-align: center;">FRED BOST CEO Co-Founder LABVOICE</p> <p>Advancements in technology are transforming how vivarium operations maintain biosecurity and ensure compliance with IACUC (Institutional Animal Care and Use Committee) protocols. For example, through the use of voice-activated digital assistants, automation platforms, and integrated data systems, laboratories can significantly reduce manual entry errors, improve documentation accuracy, and minimize contamination risks. These tools enable real-time data capture, task automation, and seamless integration with existing lab & vivarium management systems, ensuring that animal welfare protocols are followed precisely and efficiently. This presentation will explore how emerging technologies not only streamline workflows but also play a vital role in maintaining biosecurity, promoting adherence to regulatory standards, and enhancing overall operational efficiency in research environments.</p>	<p style="text-align: center;">IBC IRB</p> <p style="text-align: center;">ETHICAL CONSIDERATIONS FOR CELL AND GENE THERAPY CLINICAL TRIALS</p> <p style="text-align: center;">DANIEL EISENMAN, PHD, RBP, SM(NRCM), CBSP EXECUTIVE DIRECTOR, BIOSAFETY SERVICES ADVARRO</p> <p>The presentation will provide an overview of emerging trends in gene therapy research and the associated challenges in research ethics. The following technologies will be covered: gene based vaccines, gene modified cellular therapies, gene modified microorganisms, gene therapies and gene editing. The presentation will focus on challenges including risk / benefit ratio determination, informed consent, pediatric trials, rare diseases, decentralized clinical trials and best practices for collaboration between the institutional review board and the institutional biosafety committee.</p>	<p style="text-align: center;">BIOSECURITY RA</p> <p style="text-align: center;">IS IT LIVE OR IS IT MEMOREX?</p> <p style="text-align: center;">CHRISTOPHER M. MANGELLI, JD, MS, MEd, CIP ASSISTANT VICE PROVOST FOR RESEARCH (AVPR) OFFICE OF RESEARCH BALL STATE UNIVERSITY</p> <p>It has been said anything that can be used as a tool can also be used as a weapon. In today's world, that is true on many counts. The user and the intended purpose is what defines a tool's use for good or for ill. Today's society is nearly obsessed with the AI craze, with the uses that have been coming out being both fantastic and scary. We have AI's helping with medical diagnosis, acting as translators, and even making movies and music. The use of AI in research is also a growing phenomenon where the use of AI can be a powerful tool.</p> <p>But what happens when those same tools start blurring the lines of reality. We saw innumerable examples of AI generated fake information during the last election. When people base decisions on fake or misleading information they believe is real, it is bad for all and can lead to very bad outcomes, including bad research outcomes. In this season we will explore the use of AI in research, the issues around deep-fake information, the challenges that AI generated materials can create, and some basic spotting tricks to identifying deep-fake information.</p>
SEE YOU IN THE AM FOR BREAKFAST!			