



IACUC   THREE I's	
IBC	
IRB   BIOSECURITY   RA	
RI   COMPLIANCE REGULATORY	

**THREE I's: and RESEARCH INTEGRITY™: COMPLIANCE, ETHICS and BIOSECURITY ... Building Resilience**

Day 1 **MONDAY**      **APRIL 27, 2026**      **DRAFT CONFERENCE AGENDA**

	<b>VIRTUAL WHOVA NETWORKING</b>
<b>10:00 AM</b>	<b>WELCOME &amp; INTRODUCTIONS</b>  MeRTEC
<b>10:10 AM- 10:50 AM</b>	<b>KEYNOTE ADDRESS</b> <b>THREE I's SESSION</b>
<b>Keynote THREE I's</b>	<b>TBA</b>  <b>BARBARA EMILY BIERER, MD</b> PROFESSOR OF MEDICINE (PEDIATRICS), HMS MEMBER, HMS CENTER FOR BIOETHICS  <p>Barbara E. Bierer, M.D., is a hematologist-oncologist and professor of medicine at Harvard Medical School (HMS) and the Brigham and Women's Hospital (BWH). Dr. Bierer is the faculty director of the Multi-Regional Clinical Trials Center of BWH and Harvard (MRCT Center), a collaborative effort to improve the ethics, conduct, and regulatory environment of multi-site and international clinical trials. She is also the director of the Regulatory Foundations, Ethics, and Law program at the Harvard Catalyst and director of regulatory policy for SMART IRB. Dr. Bierer serves as faculty at the Center for Bioethics, HMS, and affiliate faculty at the Petrie-Flom Center for Health Law at Harvard Law School. She is a co-founder of the COVID-19 Collaboration Platform and of the non-profit Vivli, a global clinical research data-sharing platform. From 2003 to 2014, Dr. Bierer served as senior vice president of research at BWH where she founded the Brigham Research Institute and the Brigham Innovation Hub. She was previously chair of SACHRP and has served or currently serves on the board of directors of AAHRPP, PRIMR, MSH, Vivli, North Star IRB, and the Edward P. Evans Foundation. She has authored over 275 publications.</p>
<b>11:00 AM – 11:40 AM</b>	<b>REGULATORY BREAKOUT SESSIONS</b>

	<p style="text-align: center;"><b>IACUC</b></p> <p style="text-align: center;"><b>OLAW UPDATE</b></p> <p style="text-align: center;"><b>NEERA V GOPEE, DVM, PhD, DABT, DAACLAM</b> ASSOCIATE DIRECTOR FOR ANIMAL WELFARE POLICY OFFICE OF LABORATORY ANIMAL WELFARE, NIH</p>	<p style="text-align: center;"><b>IBC</b></p> <p style="text-align: center;"><b>KATHRYN HARRIS, PhD</b> SENIOR OUTREACH AND EDUCATION ANALYST OFFICE OF SCIENCE POLICY NIH</p>	<p style="text-align: center;"><b>IRB</b></p> <p style="text-align: center;"><b>REPORTING INCIDENTS IN NONEXEMPT HUMAN SUBJECTS RESEARCH: KEY REQUIREMENTS AND COMMON QUESTIONS</b></p> <p style="text-align: center;"><b>NATALIE KLEIN, PhD</b> ACTING DIRECTOR U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE FOR HUMAN RESEARCH PROTECTIONS (OHRP)</p> <p>Session Description: A seminal report on responsible research by the National Academies in 2003 identified quality improvement and compliance activities as essential functions of a human research participant protection program. This session will outline when incidents in nonexempt HHS-supported human subjects research must be reported to the Office for Human Research Protections (OHRP). Attendees will review common questions that OHRP raises during review of incident reports and learn how anticipating these questions can strengthen institutional compliance and reinforce participant protections.</p>
11:40 AM – 11:50 AM	<b>BREAK</b>		
11:50 AM - 12:30 PM	<b>BREAKOUT SESSIONS</b>		
	<p style="text-align: center;"><b>THREE I's</b></p> <p style="text-align: center;"><b>HOW DO WE TALK ABOUT WHAT WE DO?</b> <i>What is our Value?</i></p> <p style="text-align: center;"><b>MODERATOR:</b> <b>CECE BROTCHE-FINE, DBE,</b> EXECUTIVE DIRECTOR, ETHICS, NOVARTIS</p> <p style="text-align: center;"><b>SALLY THOMPSON-IRITANI, DVM, PHD</b> AVP, ANIMAL CARE, OUTREACH, &amp; 3RS UNIVERSITY OF WASHINGTON</p> <p style="text-align: center;"><b>CHRIS MANGELLI, JD</b> DIRECTOR OFFICE OF RESEARCH INTEGRITY (ORI) BALL STATE UNIVERSITY</p> <p style="text-align: center;"><b>RACHEL FRISBIE, PhD</b></p>	<p style="text-align: center;"><b>IBC   IRB</b></p> <p style="text-align: center;"><b>BRIDGING THE GAP: EFFECTIVE COLLABORATION BETWEEN IBC &amp; IRB FOR CLINICAL RESEARCH</b></p> <p style="text-align: center;"><b>RYAN SCHLIMGEN, PhD</b> IBC DIRECTOR MASS GENERAL BRIGHAM</p> <p>This session will provide an overview of how aligning biosafety oversight with human subjects protection helps clinical research meet regulatory requirements efficiently. The talk will use real-world examples to clarify when Institutional Biosafety Committee (IBC) review is required for clinical trials and when it is not, including the investigational products and activities that typically trigger IBC involvement and common scenarios where IBC review is</p>	<p style="text-align: center;"><b>RI   COMPLIANCE</b></p> <p style="text-align: center;"><b>THE GOOD BAD AND THE UGLY OF AI IN RESEARCH</b></p> <p style="text-align: center;"><b>KELÉ PIPER</b> CHIEF RESEARCH COMPLIANCE OFFICER COMPLIANCE, AUDIT &amp; BUSINESS INTEGRITY MASS GENERAL BRIGHAM</p> <p>The emergence of generative AI tools presents exciting opportunities for advancing research and innovation; however, concerns exist regarding the inherent limitations of the tools and the risks associated with their use.</p> <p>Objectives:</p> <ol style="list-style-type: none"> <li>1. The bad: Strategies to deal with the bad before</li> </ol>

	<p>COMPUTATIONAL SCIENCE EDUCATION RESEARCH MICHIGAN STATE UNIVERSITY</p>	<p>unnecessary. This clarity helps investigators and IRB teams route studies correctly from the start and reduce preventable delays. The presentation will then focus on how shared institutional oversight and governance, committee-to-committee communication, and a common electronic protocol system with dedicated ancillary review workflows support timely regulatory review. The goal is to make coordination operational and repeatable, ensuring biosafety-driven risks affecting participants and staff are translated into IRB-facing materials in a timely, consistent way that prevents missed reviews, reduces turnaround time, and strengthens review quality.</p>	<p>achieving the ugly in a research integrity program; finding the right balance for researchers</p> <ol style="list-style-type: none"> <li>2. The good: Considerations for AI tools used to enhance and improve submissions of research work; effective communication to prevent misconceptions</li> <li>3. The flat out ugly: What to do when the worst happens without going overboard with overbearing, labor-intensive fixes.</li> </ol>
<p>12:30 PM – 1:00 PM</p>	<p style="text-align: center;"><b>LUNCH &amp; Networking!</b></p>		
<p>1:00 PM – 2:00 PM</p>	<p style="text-align: center;"><b>RESEARCH COMPLIANCE, CONFLICT MANAGEMENT AND COMPASSION (3CS)</b></p> <p style="text-align: center;"><b>LLIAM HARRISON, MA JD CIP CMED</b> HURON</p> <p style="text-align: center;"><b>NIEM-TZU “REBECCA” CHEN, MS, MED, CCRP</b> RUTGERS UNIVERSITY HUMAN SUBJECTS PROTECTION SENIOR ANALYST &amp; RUTGERS CLINICALTRIALS.GOV ADMINISTRATOR</p>		
<p>COMPLIANCE</p>	<p>Research administrators and compliance professionals share a common purpose with researchers: advancing knowledge and sound science. Yet human factors—stress, burnout, and fraught interactions—often turn shared purpose into friction. This session will give attendees a taste of how approaching compliance from a perspective of compassion-informed conflict management can smooth that friction, cultivate and strengthen relationships with a shared aim of doing good, ethical research. Participants will leave with a sampling of strategies and practices to implement the 3Cs approach to reduce risk, strengthen trust, and improve adherence without sacrificing pace or quality.</p>		
<p>1:00 PM - 2:00 PM</p>	<p style="text-align: center;"><b>WHY RESEARCH OVERSIGHT AND COMPLIANCE PROGRAMS SHOULD CARE ABOUT PEER REVIEW</b></p> <p style="text-align: center;"><b>BENJAMIN C. SILVERMAN, MD, SENIOR IRB CHAIR, MASS GENERAL BRIGHAM</b></p> <p style="text-align: center;"><b>COURTNEY KARMELOTA, CHIEF OF STAFF, THE OFFICE FOR RESEARCH PROTECTIONS; EXECUTIVE DIRECTOR, ETHICAL RESEARCH AND OUTREACH; AND RESEARCH INTEGRITY OFFICER AT PENN STATE</b></p>		
<p>THREE I's</p>	<p>Peer review is a quality control mechanism in academia, where experts evaluate a research paper, scholarly work, or grant proposal before it is published or funded. It aims to ensure the scientific validity, originality, quality, and integrity of the work. While peer review remains a key component of the research process, over reliance on peer review as a mechanism for ensuring ethical, compliant, and quality research ignores its problems. Having been peer reviewers and researchers who have gone through the peer review process, the presenters will discuss the relevance of peer review for research oversight and compliance professionals, along with how the inherent flaws of the current peer review system can inadvertently enable research misconduct and noncompliance. This session will delve into how the broken peer review system directly impacts staff in research administration, including human and animal research oversight programs. In particular, the presenters will discuss how jobs that promote or monitor for research integrity and compliance have more importance than ever knowing that we cannot solely rely on peer review as a marker</p>		

	<p>of research quality, integrity, and compliance. Further, not only are HRPPs/IRBs/IACUCs and research compliance offices impacted by a broken peer review system, e.g. due to potential noncompliance or research integrity issues, but they also face some of the same challenges and can learn from these shared experiences.</p> <p>At the end of this session, participants will be able to:</p> <ol style="list-style-type: none"> <li>1. Understand what peer review is and what peer review is not and appreciate its relevance to research oversight and compliance work.</li> <li>2. Identify Limitations of Peer Review: Discuss the inherent flaws and limitations of the peer review process, particularly its potential to enable research misconduct and noncompliance.</li> <li>3. Examine the Impact of Peer Review Failures on Research Administration: Analyze how shortcomings in the peer review system affect research administrators and research oversight program staff and their roles in maintaining research integrity and compliance.</li> <li>4. Propose Solutions to Strengthen Research Integrity and Compliance: Suggest practical approaches for improving the research oversight process, emphasizing the need for more robust systems beyond peer review to ensure ethical, compliant, and high-quality research.</li> </ol>
<p><b>1:00 PM – 2:00 PM</b> <b>IACUC / COMPLIANCE</b></p>	<p><b>YOUR <i>GUIDE</i> TO ARRIVE-ING AT THE <i>GOLD</i> STANDARD: TIPS AND TRICKS FOR SUCCESS</b></p> <p><b>FERNANDO P S GUASTALDI, DDS, MSC, PHD</b> CO-PI: 360° COLLABORATIVE HUB FOR AI IN TMD RESEARCH - NIH-NIDCR IMPACT AWARD ASSISTANT PROFESSOR OF ORAL AND MAXILLOFACIAL SURGERY DIRECTOR, SKELETAL BIOLOGY RESEARCH CENTER DIVISION OF ORAL AND MAXILLOFACIAL SURGERY, DEPARTMENT OF SURGERY MASSACHUSETTS GENERAL HOSPITAL, HARVARD SCHOOL OF DENTAL MEDICINE</p> <p><b>DAWN HIDENFELTER</b> DIRECTOR OF SALES TURNER SCIENTIFIC MONITORING</p>
	<p><b>HOW EVERYONE IN THE VIVARIUM—SCIENTISTS, VETERINARY TEAMS, FACILITIES, AND ANIMAL CARE STAFF—CAN WORK TOGETHER TO BUILD A SOLID FOUNDATION FOR SUCCESSFUL GRANT AND MANUSCRIPT SUBMISSIONS.</b></p> <p>This session will focus on connecting Gold Standard guidance for funding and the ARRIVE Guidelines with the <i>Guide for the Care and Use of Laboratory Animals</i> in a way that is practical and relevant for everyone working in or alongside the vivarium. Our goal is to demonstrate how strong collaboration across roles and adhering to the guidance in each of these regulatory documents directly supports high-quality science and successful grant and manuscript submissions. Simply put, good science creates more opportunities, more funding for research programs, stronger facilities, more jobs, and better outcomes for the animals in our care. Grants, funding, and publications ultimately drive the financial and institutional support for animal care and use programs. They also influence areas we may not always think about day-to-day, such as staffing, program resources, and long-term sustainability. By highlighting how the Gold Standard, ARRIVE Guidelines and the Guide align, we hope to demonstrate how each role—from animal care staff and facilities teams to veterinarians and researchers—contributes essential data and practices that support compliance, rigor, and reproducibility.</p> <p>The presentation would provide practical tips for identifying where the necessary information already exists within animal programs and how teams can work together to ensure it supports successful submissions.</p> <p>We think this topic will resonate strongly with the audience and help reinforce the value of everyone’s role in the scientific process.</p>
<p><b>2:00PM</b></p>	<p><b>SEE YOU IN THE AM!</b></p>



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## THREE I's: and RESEARCH INTEGRITY™: COMPLIANCE, ETHICS and BIOSECURITY ... Building Resilience

Day 2 **TUESDAY**      **APRIL 28, 2026**      **DRAFT CONFERENCE AGENDA**

10:00 AM	<b>WELCOME TO DAY TWO!</b>	
10:00 AM- 11:00 AM	<b>GUIDELINES NEEDED FOR THE USE OF AI IN THE PREPARATION AND REVIEW OF IRB, IBC, AND IACUC APPLICATIONS</b>	
<b>GENERAL SESSION</b>	<p><b>DANIEL EISENMAN, PhD, RBP, SM(NRCM), CBSP, ADVARRA</b>  <b>JAMES RIDDLE, ADVARRA</b>  <b>NICHELLE COBB, PhD, AAHRPP</b>  <b>MOHAMMAD HOSEINI, PhD, NORTHWESTERN UNIVERSITY</b></p> <p>This session will present a paper submitted to the American Journal of Bioethics titled, "Guidelines needed for the use of AI in the preparation and review of IRB, IBC, and IACUC applications". Authors on the paper will serve as panelists discussing the perspectives of the IRB, IBC, IACUC and AAHRPP.</p> <p><a href="#">Full article: Guidelines needed for the use of AI in the preparation or review of IRB, IBC, and IACUC applications</a></p>	
11:00 AM – 11:10 AM	<b>BREAK</b>	
11:10 AM – 11:50 AM	<b>THREE I's</b>	
	<p><b>A FOCUS ON EDUCATION AND COLLABORATION: THE POST-APPROVAL VERIFICATION AND EDUCATION (PAVE) PROGRAM FOR IACUC, IRB, AND IBC AT THE UNIVERSITY OF TEXAS AT EL PASO</b></p> <p><b>ELAINE JOSEPH, PHD CPIA, ASSOCIATE VICE PRESIDENT, RESEARCH COMPLIANCE, REGULATORY ASSURANCES, &amp; INTEGRITY</b></p> <p><b>TURI KEIL, BSB CHRM</b> POST APPROVAL VERIFICATION AND EDUCATION ADMINISTRATOR</p> <p><b>MARYEL LOPEZ, BS</b> POST-APPROVAL VERIFICATION AND EDUCATION SR COORDINATOR UNIVERSITY OF TEXAS AT EL PASO</p> <p>Post-approval monitoring is an important component of a research compliance program that ensures investigator compliance with protocols and regulations and protects research participants and animal subjects. At the University of Texas at El</p>	<p><b>HAZARDOUS RESPONSE TEAMS   CYBER SECURITY</b> TBA</p> <p><b>FBI WMD</b></p>

	<p>Paso (UTEP) the Post-Approval Verification and Education (PAVE) program is designed to be collaborative in nature and assist researchers in maintaining compliance with their IACUC, IBC, and IRB protocols, while also providing proactive education and support to researchers and their staff.</p>		
<p>11:55 AM – 12:30 PM</p>			
	<p style="text-align: center;"><b>THREE I's</b></p> <p style="text-align: center;"><b>EXPORT CONTROL CONSIDERATIONS FOR IACUC, IBC AND IRB STAFF</b></p> <p style="text-align: center;"><b>TORREY TRUSZKOWSKI, PhD</b>  ASSISTANT DIRECTOR RESEARCH SECURITY AND INTEGRITY  EXPORT CONTROL OFFICER  CONFLICT OF INTEREST AND RESEARCH SECURITY OFFICER  RESEARCH INTEGRITY  DIVISION OF RESEARCH   BROWN UNIVERSITY</p> <p>Export controls are a set of federal laws and regulations that govern the transfer of information and items out of a country. In this session, we will discuss how these regulations apply to the work of IRB, IACUC and IBC professionals. Much of the research going on at US universities is "Fundamental Research" which is exempt from much of the US export control regulations, but this creates noncompliance risks due to the lack of knowledge. This session will provide a basis for understanding how your work can interact with export control team members at your institution and identify concerns in the research you review.</p>	<p style="text-align: center;"><b>BEYOND THE REVIEWING IRB: HOW SIRB MODELS RESHAPE INSTITUTIONAL RESPONSIBILITIES</b></p> <p style="text-align: center;"><b>MONICA KANE</b>  IRB RELIANCE ANALYST LEAD  NORTHWESTERN UNIVERSITY</p> <p>The transition to single IRB (sIRB) review has redrawn oversight boundaries within multi-site research, shifting certain responsibilities to external reviewing IRBs while leaving institutions accountable for areas such as study team training and eligibility verification, conflict of interest management, misconduct processes, and other internal compliance obligations. As oversight becomes more decentralized, unclear expectations and inconsistent communication can create operational strain, ethical concerns, and challenges for IRB and HRPP staff navigating these shared responsibilities.</p> <p>This session focuses on practical ways for IRB and HRPP professionals to clarify responsibilities, determine which oversight functions must remain local, and streamline day-to-day interactions with reviewing IRBs. Examples will highlight common pain points—including negotiating reliance terms, conducting and documenting local context review, coordinating site-specific updates, and aligning IRB operations with institutional compliance offices. Participants will explore communication models that minimize delays, identify where flexibility in reliance agreements is appropriate, and apply strategies that strengthen cross-organizational collaboration within decentralized oversight structures.</p>	
<p>12:30 PM – 1:00 PM</p>	<p><b>LUNCH</b></p>		
<p>1:00 PM – 2:00 PM</p>	<p><b>BREAKOUT SESSIONS</b></p>		
	<p style="text-align: center;"><b>IACUC</b></p> <p style="text-align: center;"><b>NAVIGATING CONFLICTS OF INTEREST: WHAT EVERY IACUC NEEDS TO KNOW</b></p>	<p style="text-align: center;"><b>THE PROMISE AND PERIL OF AI IN RESEARCH INTEGRITY</b></p> <p style="text-align: center;"><b>BLAKE TALBOT</b>  SENIOR SCIENTIFIC INVESTIGATOR  HARVARD MEDICAL SCHOOL</p>	<p style="text-align: center;"><b>RESEARCH DATA MANAGEMENT ROUND-UP: KEY DEVELOPMENTS AND WHAT TO WATCH</b></p> <p style="text-align: center;"><b>PATRICIA B CONDON, PhD</b>  ASSOCIATE PROFESSOR,  RESEARCH DATA SERVICES</p>

**SARAH N ARCHIBALD, PhD,  
MSL, MS, MDE, MA, CCEP,  
CRCMP**

ASSOCIATE VICE PROVOST,  
RESEARCH COMPLIANCE &  
REGULATORY AFFAIRS  
OFFICE OF RESEARCH &  
INNOVATION  
DREXEL UNIVERSITY

This presentation explores how conflicts of interest can arise in IACUC operations and what committees should consider when reviewing COI disclosures and management plans. We will discuss regulatory requirements, real-world examples, and best practices for ensuring impartial decision-making. Attendees will leave with actionable guidance to strengthen transparency, promote ethical review, and support institutional compliance.

Artificial intelligence is transforming how research is conducted, analyzed, and disseminated. While AI tools can enhance efficiency by drafting manuscripts and generating code, their ability to synthesize data and create realistic scientific images introduces new risks to research integrity.

This presentation examines the dual-use nature of AI in research, highlighting both legitimate applications [e.g., Large Language Models (LLMs) and AI-powered image manipulation detection] and emerging forms of misconduct including AI-fabricated data and manipulated or AI-generated images.

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LIBRARY

This session provides an overview of recent developments in the research data management and sharing landscape. It covers current funder and publisher expectations, evolving data sharing and reuse norms, and emerging risks related to sensitive data and stewardship. The discussion highlights what has changed, what to watch for, and why it matters for research integrity, compliance, and everyday research support.

**See you in the morning!**



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Day 3 **WEDNESDAY, APRIL 29, 2026**

**DRAFT CONFERENCE AGENDA**

	<b>WELCOME TO DAY 3</b>		
<b>10:00 AM - 10:45 AM</b>	<b>BREAKOUT SESSIONS</b>		
	<p style="text-align: center;"><b>IACUC</b></p> <p style="text-align: center;"><b>COMPLIANCE USE STANDARD PROCEDURE (CUSP)</b>  <b>CUSP - THE FEDERAL DEMONSTRATION PARTNERSHIP</b></p> <p style="text-align: center;"><b>PANEL</b></p> <p style="text-align: center;"><b>MICHELLE BROTT, PhD</b>          SCIENTIFIC GRANT REVIEWER          UNIVERSITY of WASHINGTON</p> <p style="text-align: center;"><b>AUBREY SCHOENLEBEN, PhD</b>          DIRECTOR, REGULATORY AFFAIRS and EXTERNAL PARTNERSHIPS          UNIVERSITY of WASHINGTON</p> <p style="text-align: center;"><b>SCOTT BURY</b>          DIRECTOR          OFFICE OF ANIMAL WELFARE ASSURANCE</p> <p style="text-align: center;">CUSP (Compliance Unit Standard Procedure) is an electronic database that offers standard procedures that can be downloaded and incorporated into animal research protocols following IACUC approval at their institution. CUSP aims to streamline the protocol writing and approval process and the presentation will provide specific examples to describe how CUSP can reduce regulatory burden and benefit researchers, administrators, veterinarians, and IACUCs.</p>	<p style="text-align: center;"><b>IRB</b></p> <p style="text-align: center;"><b>PREVENTING AND IDENTIFYING FRAUDULENT RESPONDENTS IN ONLINE SURVEY RESEARCH</b></p> <p style="text-align: center;"><b>JULIE SIMPSON, PhD</b>          DIRECTOR          RESEARCH INTEGRITY SERVICES          UNIVERSITY of NEW HAMPSHIRE</p> <p style="text-align: center;">Researchers have used the internet to conduct research for decades. More recently, however, online research has become a target for fraudulent respondents, particularly when researchers offer monetary incentives for participation in a study. This session will explore the current environment for online data collection from human participants, outline strategies for researchers and Institutional Review Boards (IRBs) to help minimize and identify fraudulent responses and protect data integrity and examine the challenges of balancing data integrity with participant welfare.</p>	<p style="text-align: center;"><b>COMPLIANCE</b></p> <p style="text-align: center;"><b>RESEARCH SECURITY: EVOLVING RISK AND REGULATION</b></p> <p style="text-align: center;"><b>MINAL MICHAEL CARON, COUNSEL</b>  <b>ROPES &amp; GRAY LLP</b></p> <p style="text-align: center;">This presentation offers a comprehensive overview of the rapidly evolving U.S. research security landscape, focusing on recent regulatory changes, enforcement actions, and compliance challenges affecting federally funded research institutions. Attendees will learn about the status of key "mandates" such as NSPM-33, the CHIPS and Science Act, and agency-specific requirements for disclosure, cybersecurity, and research security training. The session will provide practical recommendations to help research compliance and administration professionals strengthen institutional research security programs and navigate heightened federal scrutiny.</p>

	The webinar will also provide guidance on joining the platform, highlight results from an ongoing user survey, and explore future directions for the initiative.		
10:50 AM – 11:45 AM	<b>GENERAL SESSION</b>		
	<p><b>ALL I'S RESEARCH INTEGRITY &amp; RESEARCH ADMINISTRATION INVITED!</b></p> <p><b>SPOT THE ISSUES ...ETHICS CHALLENGE</b></p> <p><b>KATHRYN A HOLTHAUS, MS, MA</b> DIRECTOR OF RESEARCH SUBJECTS PROTECTION AND LABORATORY SAFETY COMPLIANCE RESEARCH OPERATIONS BRIGHAM &amp; WOMEN'S HOSPITAL</p> <p><b>TED MYATT, ScD</b> ASSOCIATE VICE PROVOST OF RESEARCH INTEGRITY TUFTS UNIVERSITY</p> <p><b>ROSS HICKEY, JD CIP CIA</b> ASSISTANT PROVOST FOR RESEARCH INTEGRITY UNIVERSITY OF SOUTHERN MAINE DIRECTOR OF THE MAINE REGULATORY ETHICS AND TRAINING CENTER (MERTEC) AT USM</p> <p><b>FBI</b></p>		
11:45 AM – 11:55 AM	<b>BREAK</b>		
11:55 AM – 12:40 PM			
	<b>IACUC</b>	<b>IBC</b>	<b>IRB</b>
	<p><b>GETTING IT RIGHT WHEN THINGS GO WRONG: A CULTURE-OF-CARE APPROACH TO NON-COMPLIANCES</b></p> <p><b>AMY KILPATRICK, BA, CVT, RLATG, CIA</b> HEAD, ANIMAL WELFARE &amp; INTEGRITY ASSURANCE CAMBRIDGE CAMBRIDGE IACUC CHAIR NOVARTIS</p> <p><b>ERICA LAFAUCE BS, LATG, CIA</b> SENIOR SPECIALIST II, ANIMAL WELFARE COMPLIANCE</p>	<p><b>SUMMARY OF THE NIH BIOSAFETY MODERNIZATION INITIATIVE</b></p> <p><b>JAMES W. KLENNER, MSC, MPH, MPA, RBP, CBSP</b> ASSOCIATE DIRECTOR, OFFICE OF RESEARCH INTEGRITY BIOSAFETY OFFICER BALL STATE UNIVERSITY</p> <p>This presentation will discuss the development of the NIH initiative to strengthen biosafety policies, practices, and oversight with an emphasis on the evolving risks related to future advancements</p>	<p><b>NAVIGATING THE ETHICAL REVIEW OF PARTICIPATORY AND COMMUNITY-ENGAGED RESEARCH</b></p> <p><b>JOSHUA MANGIN, PhD</b> RESEARCH COMPLIANCE TRAINING MANAGER, UNIVERSITY OF NEW ENGLAND</p> <p>Participatory Research (PR) and Community-Engaged Research (CEnR) models fundamentally shift the relationship between researcher and participant, moving toward equitable partnership and shared decision-</p>

	<p style="text-align: center;"><b>NOVARTIS</b></p> <p>Non-compliances are an inevitable part of work involving people—and when animals and science are involved, how we respond matters. This session will focus on handling non-compliances through a culture-of-care lens, from initial report through investigation and follow-up. We'll discuss how to maintain trust, consider context and impact, and use these events not just to identify areas for improvement, but also to reinforce what's working well. The goal is to move beyond blame and use non-compliances as opportunities to strengthen programs, teams, and outcomes.</p>	<p>in science and technology. The goal is to develop a more effective, transparent, and modern biosafety policy.</p>	<p>making. This shift creates unique ethical considerations that challenge traditional Institutional Review Board (IRB) review processes, particularly concerning power dynamics, informed consent, and data ownership. This session is designed to provide IRB members, administrators, and Human Research Protection Program (HRPP) staff with practical guidance and frameworks for the robust and responsible review of PR/CEnR protocols. This session will explore key elements such as defining PR and CEnR, discussing consent processes, and navigating complexities in data sharing and publication. The goal is to equip reviewers with the tools necessary to facilitate ethical research that respects community autonomy while adhering to regulatory standards.</p>
<p>12:45 PM – 1:15 PM</p>	<p><b>LUNCH</b></p>		
<p>1:15 PM – 2:00 PM</p>	<p><b>GENERAL SESSION</b></p>		
	<p style="text-align: center;"><b>AI INTERN YOU CANNOT FIRE: GUARDRAILS FOR USING LLMS IN IACUC AND IRB WORKFLOWS</b></p> <p style="text-align: center;"><a href="#"><u>SZCZEPAN BARAN, MS, VMD</u></a>  FOUNDER   <a href="#"><u>TECH4PETS</u></a> &amp; <a href="#"><u>BARAN CAFE</u></a>  RESEARCH ASSOCIATE   <a href="#"><u>KU LEUVEN</u></a></p> <p>IRB and IACUC offices are under the same pressure: more protocols, faster amendments, and less tolerance for inconsistency. Large language models are already in the room, even when nobody has admitted it. People paste drafts into chat tools, vendor platforms add “assistants,” and a quiet new actor starts shaping how reviewers see risk. I call it the AI intern you cannot fire: helpful, fast, and capable of inventing details with complete confidence. In this talk, I treat LLMs as decision support infrastructure, not productivity magic. I lay out guardrails that let committees use LLMs for high-value, low-authority tasks (summaries, cross-document consistency checks, amendment diffs, internal question drafting) while preventing silent drift into decision making (risk categorization, endpoint approval, or “recommended stipulations”). The core move is to define context of use before access: what task the model performs, what documents it may touch, what decisions it may influence, and where a human must verify or escalate. We will use a simple tiering model for decision impact and map each tier to minimum controls: input restrictions (PHI, proprietary sponsor content, biosafety-sensitive details), traceability (what version went in, what came out, who reviewed it), and operational safety nets. Safety nets include escalation triggers when the model flags or misses risk-relevant content, and stop-use triggers when errors repeat or behavior changes after an update. I will also show how to turn “bias” into an auditable checklist item rather than a slogan, and how to use a material-change lens so committees stop re-reviewing noise and start catching what truly changes animal welfare or participant risk.</p> <p>The goal is not to speed up review at any cost. The goal is to make review more consistent, more defensible, and easier to audit, without creating the next compliance incident.</p> <p>Audience takeaways (3 implementable items):</p>		

	<ul style="list-style-type: none"><li>• One-page LLM Context-of-Use Card you can adopt immediately (task, decision-impact tier, allowed documents, prohibited uses, human roles, escalation rules, stop-use triggers).</li><li>• Minimum “Run Log + Verification” routine (what to record every time: input version IDs, tool version, reviewer sign-off, where outputs can be stored, what must be checked before anything influences review).</li><li>• Material-change workflow for amendments that pairs LLM-generated diffs with human “materiality” classification, so IRB and IACUC focus on what changes risk, not what changes wording.</li></ul>
<b>2:00 PM</b>	<b>SEE YOU IN THE AM!</b>



IACUC   THREE I's	
IBC   IACUC	
IRB   BIOSECURITY   RA	
RI   COMPLIANCE REGULATORY	

**THREE I's: and RESEARCH INTEGRITY™: COMPLIANCE, ETHICS and BIOSECURITY ... Building Resilience**

Day 4 THURSDAY, APRIL 30, 2026

DRAFT CONFERENCE AGENDA

10:00 AM – 10:45 AM	<b>THREE I's SESSION</b>	
	<p><b>CREATING 3RS CHANGE THROUGH SCIENTIFICALLY SUPPORTED METHODS</b></p> <p><b>MEGAN LA FOLLETTE, PhD</b> EXECUTIVE DIRECTOR THE 3RS COLLABORATIVE</p> <p>This session explores how the Theory of Planned Behavior (TPB) can be used as a practical, evidence-based framework to drive meaningful 3Rs (Replacement, Reduction, and Refinement) improvements in scientific research. By examining the key components of TPB (attitudes, subjective norms, and perceived behavioral control) the session will illustrate how each factor influences decisions and behaviors around adopting 3Rs practices. Participants will learn how to use this theory to create 3Rs changes using real-world examples and strategies in action.</p>	
10:50 AM – 11:35 PM	<p><b>IACUC IBC</b></p> <p><b>RISK ASSESSMENTS FOR REVIEW OF IACUC AND ASSOCIATED IBC PROTOCOLS</b></p> <p><b>JAMES W. KLENNER, MSC, MPH, MPA, RBP, CBSP</b> ASSOCIATE DIRECTOR OFFICE OF RESEARCH INTEGRITY BIOSAFETY OFFICER BALL STATE UNIVERSITY</p> <p>Risk assessments are not always straightforward, and this presentation will describe aspects that can affect a risk assessment determination and the assignment of appropriate biocontainment. The presented examples may help participants with future reviews of hazards in IACUC and IBC submissions.</p>	<p><b>TBA</b></p> <p><b>ELIZABETH J. MCEVOY</b> MEMBER OF THE FIRM EPSTEIN BECKER GREEN</p>
11:35 AM – 11:45 AM	<b>BREAK</b>	

11:45 AM - 12:30 PM			
	<p style="text-align: center;"><b>IACUC IBC IRB</b></p> <p style="text-align: center;"><b>FROM RECRUITMENT TO RETENTION: STRENGTHENING THE REGULATORY COMMITTEE</b></p> <p style="text-align: center;"><b>IACUC</b>  <b>ANNE CLANCY, PhD</b>  DIRECTOR, OFFICE OF ANIMAL WELFARE ASSURANCE  MASS GENERAL HOSPITAL</p> <p style="text-align: center;"><b>IBC</b>  <b>RYAN SCHLIMGEN</b>  SENIOR DIRECTOR, BIOSAFETY  MGB</p> <p style="text-align: center;"><b>IRB</b>  <b>MARTHA JONES</b>  VICE PRESIDENT  HUMAN RESEARCH AFFAIRS  MGB</p> <p>This presentation will focus on the fundamental regulatory requirements for IRBs/IBCs/and IACUCs which will benefit new committee administrators and provide a refresher for the more advanced audience members. We will also review considerations and strategies for training committee members, managing conflicts and maintaining committee engagement. Bring your ideas to share with participants!</p>	<p style="text-align: center;"><b>IRB   COMPLIANCE</b></p> <p style="text-align: center;"><b>HARNESSING AI AND LLMS FOR SMARTER IRB ADMINISTRATION: PRACTICAL STRATEGIES, PITFALLS, AND PATHWAYS TO COLLABORATION</b></p> <p style="text-align: center;"><b>TOM BECHERT</b>  SENIOR DIRECTOR, HURON CONSULTING GROUP</p> <p>This session explores how Artificial Intelligence, especially Large Language Models (LLMs), can transform IRB administration and compliance. Attendees will learn practical approaches for integrating AI into IRB workflows, including investigator support, process automation, and decision-making. We'll discuss key limitations—such as bias and data privacy—and highlight the importance of process optimization and human oversight. The session emphasizes collaboration across compliance committees to reduce redundancies and improve research integrity.</p> <p>Educational Goals:  Build foundational understanding of AI and LLMS in IRB operations.  Identify practical strategies for responsible AI adoption and process improvement.  Promote interdisciplinary collaboration to enhance compliance and ethics.</p>	<p style="text-align: center;"><b>COMPLIANCE</b></p> <p style="text-align: center;"><b>LEVERAGING ANDRAGOGICAL STRATEGIES IN RESEARCH INTEGRITY COMPLIANCE EDUCATION</b></p> <p style="text-align: center;"><b>SARA FLOWERS, PhD</b>  <b>MeRTEC</b></p> <p>Mandatory training is an inevitability in many professional fields and we know both anecdotally and from research that the effectiveness of these learning sessions is questionable. Using principles from adult learning theory as well as Understanding by Design (UbD)--backwards planning--these learning experiences can be clearer, targeted, and more effective on the critical topics of research integrity compliance education. The session will cover the assumptions of adult learning, instructional planning, and alignment to the standards of training mandates.</p>
12:30 PM – 1:00 PM	<b>LUNCH</b>		

1:00 PM – 1:45 PM

**ANIMAL RESEARCH  
COMPLIANCE CAREER  
GROWTH AND THE CPIA®  
CREDENTIAL**

**CHRISTINA NASCIMENTO, MS,  
CPIA**  
IACUC MANAGER  
RESEARCH ADMINISTRATION &  
COMPLIANCE  
BRIGHAM & WOMEN'S HOSPITAL

**JENNIFER DEW, CPIA, CRA**  
IACUC DIRECTOR  
SPONSORED PROGRAMS AND  
REGULATORY COMPLIANCE  
NORTH CAROLINA STATE  
UNIVERSITY

Are you interested in growing your Animal Research Compliance career, or breaking into the IACUC field and are not sure of the next steps? There are no clear pathways or degrees for IACUC administrators to reach their maximum potential. In this session, we will review successful roads to IACUC and Animal Research Compliance careers and leadership positions. CPIA® credentials are often an important component and validates an individual's professional experience and mastery of the body of knowledge required for IACUC administrative practices. The session will also review requirements for applying for these credentials, as well as an overview of the exam process.

IBC

FBI WMD

**RI | ETHICS**

**EVALUATING THE IMPACT  
OF A METACOGNITIVE  
STEM ETHICS  
CURRICULUM**

**ROBERT BRUCE  
THOMPSON, MA, PhD  
ROSS HICKEY, JD, CIP, CPIA  
CAROL NEMEROFF, PhD**

Contemporary research on STEM ethics has firmly established that conventional approaches to ethics education and regulatory compliance, which primarily focus on rule knowledge and awareness of sanctions and penalties, is necessary but not sufficient for establishing cultures of compliance. This presentation will report on the ongoing data collection for an NSF study (NSF#22-526) exploring the efficacy of a metacognitive STEM ethics curriculum designed to increase students' ability to critically evaluate their own biases and aspects of heuristic reasoning when faced with ethically complex decisions.

Our approach uses an experimental design with control and intervention groups. The experimental intervention involves intensive training in cognitive neuroscience and psychological foundations for poor decision-making and lapses in ethical reasoning. Fictional case scenarios are used that are structured to have tiers of moral reasoning using Kohlberg's classic developmental stages.

Our assessments included instruments for self-regulation (Applied Mindfulness), executive function (BRIEF-A), and metacognitive awareness.

Ethical reasoning was evaluated using case scenarios adapted from the Engineering and Science Issues Test (ESIT) to map onto Kohlberg's developmental levels.

We also developed a new behavioral outcome measure that avoids deception, something common in psychology and highly criticized. Participants took part in the "Ethics Quiz Game," competing for money. They were informed of an honor system but made aware that they could cheat by looking at an answer key. A second behavioral measure provided an opportunity for participants to "sell out" their team member by withdrawing their earned points to cash out individual winnings, knowingly preventing their team from winning.

Initial findings demonstrated that metacognitive self-regulation significantly predicts advanced, post-conventional ethical reasoning. Our behavioral challenge yielded promising results:

**Cheating:** Almost 60% of control group participants cheated for a cash prize, compared to under 35% of students who received the Metacognitive Ethics curriculum.

**Loyalty:** None of the students who completed the Metacognitive Ethics curriculum chose to abandon their team member by cashing out their winnings, whereas over 60% of the control group did so.

This finding was paralleled by a trend showing Metacognitive Ethics students performed better than controls in identifying and devaluing ethical rationales centered on self-promotion or self-protection when evaluating fictional misconduct cases. The full, qualitative and quantitative analyses will examine the link between metacognitive skills and complex ethical evaluation.

1:50 PM – 2:30 PM	<p style="text-align: center;"><b>THREE I's General session</b></p>
	<p style="text-align: center;"><b>THE IMPACT OF EMERGING TECHNOLOGIES ON LEGAL CULPABILITY AND PROFESSIONAL ACCOUNTABILITY</b></p> <p style="text-align: center;"><b>KORY TROTT JD, MPH</b>  DIRECTOR OF RESEARCH INTEGRITY  OFFICE OF RESEARCH ADMINISTRATION  UNIVERSITY OF CHICAGO</p> <p>While integrating AI tools into data collection and analysis has the potential to reduce human error and improve efficiency, these technologies also produce complex changes in accountability for misconduct, non-compliance, and harm. This presentation will examine the impact that disruptive technologies have had on legal culpability and professional accountability in other industries to explore the possible impacts of AI on accountability in research.</p>
2:30 PM	<p style="text-align: center;"><b>EVALUATIONS &amp; CLOSING REMARKS</b>  <b>NESBR</b>  <b>SEE YOU IN 2027!</b></p>