



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 1 **WEDNESDAY, MAY 1, 2024**

CONFERENCE AGENDA

7:30 AM - 9:00 AM	BREAKFAST & NETWORK		
9:00 AM	WELCOME & INTRODUCTIONS MSMR & MeRTEC FBI		
9:15 AM - 10:00 AM	THREE I's SESSION		
Keynote THREE I's	AI RISKS WITH BIOSECURITY CHATGBT PANDEMIC HOAX RESEARCH & INTEGRITY		
10:05 AM - 10:50 AM	AM BREAKOUT SESSIONS		
	IACUC USDA UPDATE	IBC CHANGES TO DUAL USE (DURC) REQUIREMENTS AND BEST PRACTICES FOR IBCS TED MYATT, ScD ASSOCIATE VICE PROVOST OF RESEARCH INTEGRITY TUFTS UNIVERSITY	IRB WHAT MAKES A HIGH QUALITY HRPP? ELYSE SUMMERS PRESIDENT AND CEO ASSOCIATION FOR THE ACCREDITATION OF HUMAN RESEARCH PROTECTION PROGRAMS (AAHRPP) NICHELLE COBB, PHD, CIP SENIOR ADVISOR FOR STRATEGIC INITIATIVES AAHRPP

			<p>The human participants research environment is continuously changing. For example, single IRB mandates, decentralized clinical trials, and institutional and researcher conflicts of interest have particularly emphasized the need for organizations to clarify the role of the IRB versus the HRPP. These changes present new ethical challenges. This session will explore a framework that organizations can adopt to ensure they have high quality Human Research Protection Programs (HRPPs).</p> <p>*Describe the history of HRPPs, including what they are and why this concept came about</p> <p>*Identify some of the significant changes in the human research landscape</p> <p>*Discuss how AAHRPP standards provide a framework to ensure quality HRPPs to meet arising ethical challenges</p>
10:50 AM – 11:00 AM	BREAK		
11:05 AM - 11:50 AM	BREAKOUT SESSIONS		
		<p style="text-align: center;">RI RA</p> <p style="text-align: center;">NAVIGATING RESEARCH SECURITY AND CONFLICTS OF INTEREST COMPLIANCE IN 2024: STRATEGIES AND UPDATES FOR INSTITUTIONAL RECIPIENTS OF FEDERAL FUNDING</p> <p style="text-align: center;">MINAL M. CARON ROPES & GRAY LLP</p> <p>Federal government regulation and oversight regarding research security programs and conflicts of interest/conflicts of commitment management for universities, academic medical centers, and other institutional recipients of federal funding continues unabated. This presentation will address the latest developments relating to research security and conflicts of interest and conflicts of commitment. By May 2024, the Office of Science and Technology Policy (OSTP) will most likely have issued final Research Security Program Standards, and the National Science Foundation (NSF)</p>	<p style="text-align: center;">RI</p> <p style="text-align: center;">NAVIGATING THE DATA SHARING LANDSCAPE: RESEARCH INTEGRITY, RESEARCH SECURITY, AND FUNDER POLICIES</p> <p style="text-align: center;">PATRICIA CONDON, PhD RESEARCH DATA SERVICES LIBRARIAN UNIVERSITY OF NEW HAMPSHIRE</p> <p>I will discuss key factors in data sharing, emphasizing research integrity, security, and funder mandates. The data sharing landscape in the United States is evolving rapidly, marked by a growing emphasis on openness, transparency, and collaboration. Researchers are increasingly recognizing the value of sharing their data to foster scientific progress and innovation. Research funders and the federal government play a pivotal role in shaping the data sharing landscape through policies that researchers and institutions must navigate. While there is a strong push for responsible data sharing practices,</p>

will have made research security training modules available to the public and finalized common disclosure forms for use in submission of research applications. Research institutions will need to ensure that they understand and implement the final requirements so that they can make required certifications, advise faculty members of their obligations, and understand possible compliance and enforcement risks. Institutions must also consider other recent OSTP, agency, and legislative research security requirements (e.g., DOD risk assessment programs), as well as those that are “in the works” (e.g., proposed research information sharing and risk analysis organization). This session will focus on latest developments and implementation strategies for research security. This session will also include updates on a cluster of specific topics relating to federal scrutiny of conflicts of interest and commitment in research and researchers collaborating with their peers at foreign institutions. Although the US Department of Justice has ended the “China Initiative,” regulatory changes and enforcement targeting malign foreign influence continues unabated. This presentation will address NIH’s recent response to academic community consternation over NIH’s inquiries into undisclosed foreign relationships and income of NIH-funded researchers, and will provide updates on related regulatory issues, such as NASA’s increasingly strict interpretation of the Wolf Amendment, foreign gift and contract reporting under section 117 of the HEA and the CHIPS Act (including NSF requirements that will require certain disclosure relating to foreign gifts no later than July 31, 2024), and recent NIH guidance on prime awardee’s responsibilities for data generated by foreign subawardees. The presenters will provide practical guidance and provide attendees with checklists and other handouts to equip participants with tools to identify areas of risk and implementation priorities during the second half of 2024 and beyond

emphasizing the importance of integrity, security, and ethical standards, this openness is not without challenges. Safeguarding sensitive information and addressing the risks associated with research security are critical concerns. Researchers must find a balance between the call for openness and the necessity for data protection. In this presentation, I will highlight the significance of data sharing in fostering responsible and transparent research practices; discuss policies requiring data management and sharing plans for funded research; and address challenges associated with safeguarding sensitive information and mitigating risks.

12:00 PM – 1:00 PM	LUNCH & Networking!		
1:05 PM – 1:50 PM	AFTERNOON SESSIONS		
	<p>PROACTION AND REACTION: CRISIS RESPONSE IN NONHUMAN PRIMATE RESEARCH – BEST PRACTICES AND LESSONS LEARNED</p> <p>JIM O’REILLY PRESIDENT MSMR, Inc</p> <p>ELEANOR KUSZMAR, MS, CHRC, CRA DIRECTOR FOR RESEARCH COMPLIANCE OFFICE OF ACADEMIC AND RESEARCH INTEGRITY HARVARD MEDICAL SCHOOL</p> <p>JIM NEWMAN DIRECTOR OF STRATEGIC COMMUNICATIONS FOR AMERICANS FOR MEDICAL PROGRESS</p> <p>Research involving animals is frequently criticized by groups and individuals opposed to the involvement of animals in medical and scientific progress. The nation’s National Primate Research Centers and other research facilities that study animals are regularly targeted with protests, targeted outreach, facility infiltrations, records requests and legislative efforts initiated by opponents, with the goal of restricting or halting research. During this discussion session moderators with extensive experience in animal research compliance and research communications will examine this issue more deeply with participants and offer “lessons learned” based on firsthand experiences and observations of other research organizations facing animal rights campaigns. It is hoped that attendees will depart this interactive discussion armed with information to better protect their institution and staff from campaigns seeking to</p>	<p style="text-align: center;">FBI</p> <p style="text-align: center;">LAB PRESENTATION</p> <p style="text-align: center;">SUSAN N CROPP, PhD</p>	<p>BEYOND THE REGULATIONS – EFFECTIVE STRATEGIES FOR MANAGING RESEARCH COMPLIANCE COMMITTEES</p> <p>STACY PRITT, DVM, MS, MBA, CPIA, CHRC, EXCS, DACAW ASSOCIATE VICE CHANCELLOR CHIEF RESEARCH COMPLIANCE OFFICER THE TEXAS A&M UNIVERSITY SYSTEM</p> <p>CECE BROTCHE-FINE EXECUTIVE DIRECTOR, ETHICS ETHICS, RISK AND COMPLIANCE R&D NOVARTIS</p> <p>Knowing the applicable laws, regulations, and guidelines is a baseline expectation for administrative managers of research compliance committees. However, successfully managing these commitments requires additional expertise beyond technical know-how. In this session, seasoned committee leaders will discuss common skill sets, which in addition to regulatory knowledge, can substantially contribute to committee success. These elements include effective policy development and administration, non-compliance and adverse event management, member training, and communication. Combining these elements with concepts like gaining consensus, establishing and following precedent, policy implementation, and understanding your committee’s role within the organization, the speakers will describe strategies that can be immediately used to improve committee performance.</p>

	impede necessary, animal-based research.		
1:55 PM – 2:40 PM	AFTERNOON SESSIONS		
	CONTINUED...		CONTINUED...
2:45 PM- 2:55 PM	BREAK		
3:00 PM – 4:00 PM	ALL I's – Biosecurity – Research Administration – Research Integrity		
	<p>DOING MORE WITH LESS. HOW CAN WE ACHIEVE COMPLIANCE WITH LESS MONEY/STAFF/TIME/ RESOURCES</p> <p>CHRISTINA NASCIMENTO, MS, CPIA IACUC MANAGER BRIGHAM & WOMEN'S HOSPITAL</p> <p>Are you faced with the same challenges you always had, or maybe more, but have less time in your day? Are you researchers complaining that submissions are taking longer to approve, but you are down staff and up on workload? How do you get it all done and stay compliant?</p> <p>In this session, we will discuss ways to reduce self-imposed burden, meet the needs of the researcher community, and meet regulatory standards in our new norm of having less. Attendees should come ready to have an open, idea-sharing</p>	<p>THE ETHICS BEHIND RESEARCH WITH INDIGEOUS COMMUNITIES</p> <p>JOSHUA MANGIN, MS GRADUATE ASSISTANT FOR MERTEC DOCTORAL STUDENT IN THE LEADERSHIP PROGRAM UNIVERSITY OF SOUTHERN MAINE</p> <p>NICHELLE COBB AAHRRP Moderator</p> <p>The proposed session will be a moderated panel discussion on the topic of research with Indigenous communities. The panel will explore the ethics, social responsibility, and legal and regulatory aspects of conducting and working with Indigenous participants. Specific topics will include exploring the regulatory processes between IRBs and Tribal Nations, sharing the lived experience of Indigenous members experiencing research fatigue, and the importance of building and maintaining</p>	<p>OVERSIGHT OF RESEARCH INVOLVING ARTIFICIAL INTELLIGENCE (AI)</p> <p>BENJAMIN SILVERMAN, MD SENIOR IRB CHAIR AT MASS GENERAL BRIGHAM, HUMAN RESEARCH AFFAIRS</p> <p>The use of artificial intelligence (AI) in human participant research raises unique and rapidly evolving scientific, ethical, regulatory considerations that require new approaches to research oversight. This session highlights the promises and challenges posed by AI within human participant research and provides guidance to IRBs and oversight bodies on how to review research involving AI. Topics include how to determine if human subjects research definitions apply, how to assess FDA device regulations, and how to apply the federal regulatory criteria for approval to human</p>

	<p>discussion and brainstorm ways to get all the work done when you have limited resources.</p> <p>This session will review:</p> <ul style="list-style-type: none"> • Ways to reduce self-imposed burden • Improving efficiencies in our IACUC programs • Sharing of practices to achieve compliance with less resources • Open discussion with idea-sharing between presenters and audience members 	<p>relationships throughout the research process.</p>	<p>research studies involving AI. Additionally, the session will examine special ethical considerations raised by research involving AI, including privacy concerns related to the use of large, unconsented data sets, return of individual research results, and algorithmic bias. Finally, the session will discuss the scope and limitations of IRB review and how oversight bodies must work together to effectively review research involving AI. For example, regulations restrict the IRB's consideration of future risks, yet AI algorithms raise exactly those concerns related to future risks posed by algorithmic bias and potential dual use. Regulatory change should be considered, and IRBs should engage ancillary reviews such as biosecurity assessment for future dual use risks to ensure effective oversight. We hope this session will educate the research oversight community on the current capabilities and issues when AI is used in human participant research, stimulate discussion among multidisciplinary oversight bodies, and challenge the audience to consider the roles and responsibilities of IRBs, HRPPs, and research integrity and biosecurity offices, among others, in oversight of this rapidly progressing field of research.</p>
<p>4:05 PM</p>	<p align="center">MEET, GREET and NETWORK! GRAB A DRINK ... ENJOY A FEW HORS D'OEUVRES</p>		