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**	**DETECTION OF HUMANS BY BLOOD-DRINKING MOSQUITOES** **MEG A YOUNGER PHD** ASSISTANT PROFESSOR DEPARTMENT OF BIOLOGY BOSTON UNIVERSITY Meg received a BS in Neural Science in 2004 from New York University. As an undergraduate, she worked with Justin Blau at New York University on circadian rhythms in Drosophila and with David Spray at Albert Einstein College of Medicine on mammalian gap junction channels. She then earned a PhD in Neuroscience from the University of California, San Francisco in 2013, working with Graeme Davis, where she studied the homeostatic regulation of neurotransmitter release in Drosophila. She conducted her postdoctoral research with Leslie Vosshall at the Rockefeller University/HHMI where she focused on the neurobiology *Aedes aegypti* mosquitoes. Her postdoctoral work combined genetic approaches, neuroanatomy, and two-photon calcium imaging to study the mosquito sensory neurobiology that underlies two reproductive behaviors, the search for a person to bite and the selection of a site to lay eggs. Meg joined the Boston University faculty in January of 2022. She is an assistant professor in the Department of Biology and an affiliate of Department of Biomedical Engineering, the Center for Systems Neuroscience, and the Neurophotonics Center. Her lab's focus is on the neurobiology of olfaction in deadly insects. Meg was awarded the Sherrington, Charles Barbeiri, and Phi Beta Kappa Research prizes for her undergraduate research and a Genentech Fellowship for her graduate work. She was a 2014 Grass Fellow at the Marine Biological Laboratory in Woods Hole, Massachusetts. She was awarded a Leon Levy Neuroscience Fellowship in 2015, a Jane Coffin Childs Postdoctoral Fellowship in 2016, and a Kavli Neural Systems Institute Postdoctoral Fellowship in 2018. In 2022 Meg was named a Searle Scholar and a recipient of a Klingenstein-Simons Fellowship Award in Neuroscience. In 2023 she received a Smith Family Award for Excellence in Biomedical Research and she was recently named a 2024 Sloan Research Fellow. https://www.youngerlaboratory.org/

10:05 AM – 10:50 AM	**AM BREAKOUT SESSIONS**		
	IACUC **USDA UPDATE** **EILIS KARR, DVM** VETERINARY MEDICAL OFFICER USDA ANIMAL AND PLANT HEALTH INSPECTION SERVICE (APHIS)	**IBC** **IBC BEST PRACTICES AND DEALING WITH POTENTIAL CHANGES TO FEDERAL POLICY AND REGULATIONS (E.G., DURC, P3CO, BSAT) THAT IMPACT 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 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). *Describe the history of HRPPs, including what they are and why this concept came about *Identify some of the significant changes in the human research landscape *Discuss how AAHRPP standards provide a framework to ensure quality HRPPs to meet arising ethical challenges
10:50 AM – 11:00 AM	**BREAK**		
11:05 AM - 12:00 PM	**BREAKOUT SESSIONS ALL I's**		
	IACUC **DOING MORE WITH LESS. HOW CAN WE ACHIEVE COMPLIANCE WITH LESS MONEY/STAFF/TIME/ RESOURCES** **CHRISTINA NASCIMENTO, MS, CPIA** IACUC MANAGER BRIGHAM & WOMEN'S HOSPITAL	**RI RA** **NAVIGATING RESEARCH SECURITY AND CONFLICTS OF INTEREST COMPLIANCE IN 2024: STRATEGIES AND UPDATES FOR INSTITUTIONAL RECIPIENTS OF FEDERAL FUNDING** **MINAL M. CARON** ROPES & GRAY LLP	**RI** **NAVIGATING THE DATA SHARING LANDSCAPE: RESEARCH INTEGRITY, RESEARCH SECURITY, AND FUNDER POLICIES** **PATRICIA CONDON, PhD** RESEARCH DATA SERVICES LIBRARIAN UNIVERSITY of NEW HAMPSHIRE

	ANNE CLANCY, PhD DIRECTOR ANIMAL WELFARE ASSURANCE MASSACHUSETTS GENERAL HOSPITAL Are you faced with the same challenges you always had, or maybe more, but have less time in your day? Are you reseachers complainging 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? 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 discussion and brainstorm ways to get all the work done when you have limited resources. This session will review: • Ways to reduce self-imposed burden • Improving efficiancies in our IACUC programs • Sharing of practices to achieve compliance with less resources • Open discussion with idea-sharing between presenters and audience members	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) 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	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, 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.

		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.	
12:00 PM – 1:00 PM	**LUNCH & Networking!**		
1:05 PM – 1:50 PM	**AFTERNOON SESSIONS**		
	PROACTION AND REACTION: CRISIS RESPONSE IN NONHUMAN PRIMATE RESEARCH – BEST PRACTICES AND LESSONS LEARNED **JIM O'REILLY** PRESIDENT MSMR, Inc **ELEANOR KUSZMAR, MS, CHRC, CRA** DIRECTOR FOR RESEARCH COMPLIANCE OFFICE OF ACADEMIC AND RESEARCH INTEGRITY HARVARD MEDICAL SCHOOL **JIM NEWMAN** DIRECTOR OF STRATEGIC COMMUNICATIONS FOR AMERICANS FOR MEDICAL PROGRESS 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	**WESLEY R JOHNSON, PHD** **MICROBIOLOGIST** **CHEMICAL AND BIOLOGICAL CONTROLS** **BUREAU OF INDUSTRY AND SECURITY**	**BEYOND THE REGULATIONS – EFFECTIVE STRATEGIES FOR MANAGING RESEARCH COMPLIANCE COMMITTEES** **STACY PRITT, DVM, MS, MBA, CPIA, CHRC, EXCS, DACAW** ASSOCIATE VICE CHANCELLOR CHIEF RESEARCH COMPLIANCE OFFICER THE TEXAS A&M UNIVERSITY SYSTEM **CECE BROTCHIE-FINE** EXECUTIVE DIRECTOR, ETHICS ETHICS, RISK AND COMPLIANCE R&D NOVARTIS 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

	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 impede necessary, animal-based research.		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.
1:55 PM – 2:40 PM	**AFTERNOON SESSIONS**		
	CONTINUED…	**RISK ASSESSMENT\ CASE STUDIES** **FBI PANEL**	**CONTINUED…**
2:45 PM- 2:55 PM	**BREAK**		
3:00 PM – 4:00 PM	**ALL I's – Biosecurity – Research Administration – Research Integrity**		
	WORKING TOGETHER: IBCS AND IACUCS **KATHRYN A HOLTHAUS, MS, MA** DIRECTOR OF RESEARCH SUBJECTS PROTECTION AND LABORATORY SAFETY COMPLIANCE RESEARCH OPERATIONS BWH **RYAN SCHLIMGEN, PhD** IBC DIRECTOR MGB	**THE ETHICS BEHIND RESEARCH WITH INDIGEOUS COMMUNITIES** **JOSHUA MANGIN, MS** GRADUATE ASSISTANT FOR MERTEC DOCTORAL STUDENT IN THE LEADERSHIP PROGRAM UNIVERSITY OF SOUTHERN MAINE **NICHELLE COBB | AAHRRP | Moderator** 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	**OVERSIGHT OF RESEARCH INVOLVING ARTIFICIAL INTELLIGENCE (AI)** **BENJAMIN SILVERMAN, MD** SENIOR IRB CHAIR AT MASS GENERAL BRIGHAM, HUMAN RESEARCH AFFAIRS 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

		relationships throughout the research process.	criteria for approval to human 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.
4:05 PM	**MEET, GREET and NETWORK! GRAB A DRINK … ENJOY A FEW HORS D'OEUVRES**		