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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 3 **FRIDAY, MAY 3, 2024** **CONFERENCE AGENDA**

7:30 AM - 9:00 AM	**BREAKFAST … NETWORK … WELCOME TO OUR FINAL DAY!**		
9:05 AM – 9:50 AM	**THREE I's SESSION**		
Keynote THREE I's	**BIO SMUGGLING NEW NOVEL TECHNIQUES** **FBI**		
9:55 AM – 10:55 AM	**MORNING SESSIONS**		
	CURRENT ANIMAL RIGHTS ACTIVITY, THREATS, AND TRENDS **KEVIN SWINDON** CORPORATE VP, GLOBAL SECURITY CRL	**IBC** **TBA** **MATRIDA NELI** **SENIOR COORDINATOR, COMS** **HARVARD MEDICAL SCHOOL /COMS** **COMMITTEE ON MICROBIOLOGICAL SAFETY**	**RI | RA** **HOW TO ASSESS THE RESEARCH CULTURE AT YOUR INSTITUTION** **JOSHUA MANGIN, MS** GRADUATE ASSISTANT FOR MERTEC DOCTORAL STUDENT IN THE LEADERSHIP PROGRAM UNIVERSITY OF SOUTHERN MAINE In the last few years, there has been a growing emphasis on how a research culture can influence research misconduct and noncompliance. Research culture impacts what research is being done, how the research is being conducted, and who is engaging in the research process. Assessing research culture can provide a better understanding of the behaviors, values, norms, attitudes, and expectations within the institution. This information can foster guidance on what preventive and proactive measures will be needed in order to facilitate a healthy research integrity climate. This session will inform participants of various evaluation methods that can

			assess research culture such as: interviews, focus groups, surveys/questionnaires, observation, and unobtrusive measures. The rationale, purpose, strengths and limitations of each method, as well as the ethics and regulatory elements of conducting an institutional assessment, will be discussed. At the end of the session, participants will have a better understanding and possible plan on how to assess the research culture at their institution.
11:00 AM – 11:10 AM	**BREAK**		
11:10 AM - 12:15 PM	**THREE I SESSIONS**		
	ALL I'S RESEARCH INTEGRITY & RESEARCH ADMINISTRATION INVITED! **SPOT THE ISSUES** **KATHRYN A HOLTHAUS, MS, MA** DIRECTOR OF RESEARCH SUBJECTS PROTECTION AND LABORATORY SAFETY COMPLIANCE RESEARCH OPERATIONS BRIGHAM & WOMEN'S HOSPITAL **TED MYATT, ScD** TUFTS **SUSAN N CROPP, PhD** CHEMICAL BIOLOGICAL COUNTERMEASURES UNIT/WMDD FBI HEADQUARTERS **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	**INTRODUCTION TO US EMERGENCY USE REGULATIONS** **NINA EL-BADRY** SENIOR REGULATORY ADVISOR BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY (BARDA), ADMINISTRATION FOR STRATEGIC PREPAREDNESS AND RESPONSE (ASPR), DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS) This session will provide an overview of the legal and regulatory landscape for the use of medical products during public health emergencies in the United States including key considerations, and recent regulatory developments. We will discuss what products qualify as "emergency use", and what regulatory mechanisms are available to gain access to those products, including clinical trials, Expanded Access Protocols and Emergency Use Authorization. Whether you are a healthcare professional, regulatory affairs specialist, or simply interested in the evolving landscape of emergency use, this session provides valuable insights and knowledge to navigate the complexities of US regulatory compliance in an emergency context.	*IRB, Information Security, Technology, Research Integrity, Research Administration* **INTEGRATION OF IRB AND INFORMATION SECURITY REVIEW IN A COMPREHENSIVE, EFFICIENT, OVERSIGHT MODEL** **MARTHA F JONES, MA, CIP** VICE PRESIDENT, HUMAN RESEARCH AFFAIRS MASS GENERAL BRIGHAM INCORPORATED **HEATHER CARTER** RESEARCH INFORMATION SECURITY OFFICER MASS GENERAL BRIGHAM **GALA LAFFEY, MBA** DIRECTOR OF ADMINISTRATION IN HUMAN RESEARCH AFFAIRS MASS GENERAL BRIGHAM INCORPORATED Institutional Review Boards (IRBs) are increasingly challenged to review research that involves the use of new technologies such as smart phones and watches, wearables, remote data collection tools, cloud services, virtual reality, and most recently AI. All of these may pose a risk to the privacy, confidentiality and security of participant research data and protected health information. IRBs typically do not include members that have sufficient expertise or time to thoroughly vet the use of technology or data management tools to ensure these technologies

			are not exposing the research participants or the research organization to unacceptable risk. One solution is to engage information security and technology experts through an adjacent or "ancillary" review process that provides review and consultation service to both the IRB and to researchers developing and conducting their protocols. However, there is tremendous pressure on the overall research oversight system to make review processes as efficient as possible, to prevent lengthy delays in study start up, and to prevent increased administrative burden on the researcher as well as scarce organizational resources. At Mass General Brigham the IRB has partnered with the Research Information Security Office (RISO) to develop a comprehensive matrix that maps risks associated with the use of technologies in human research studies and assigns a risk level for each technology and its potential use in research. This matrix is used to identify an appropriate mitigation approach dependent on risk to the organization. Risk mitigation includes strategies from implementation of organizational policies and researcher training for technology use posing lower risk, up to review by RISO experts who work directly with the researchers for higher risk uses. The risk matrix and mitigation approaches are developed to be flexible and adaptable as new technologies arise and make their way into the research environment. Implementation of this strategy has made better use of limited organizational resources and shown an overall decrease in review times.
12:15 PM - 1:00 PM	**LUNCH**		
1:00 PM – 2:00 PM	**AFTERNOON SESSIONS**		

	IACUC **IACUC AND NOVEL SUBMISSIONS** **CORINNA BEALE, DVM, SRS DACLAM** MGH ATTENDING VETERINARIAN DIRECTOR, MGH CENTER FOR COMPARATIVE MEDICINE INSTRUCTOR, DEPARTMENT OF SURGERY, HARVARD MEDICAL SCHOOL ADJUNCT FACULTY, TUFTS CUMMINGS SCHOOL OF VETERINARY MEDICINE How to approach submissions with new technologies, new animal models, and novel therapies. A case-based interactive session.	**HIJACKERS, HAWKERS, SCAMMERS, ET AL.: VILLAINS SABOTAGING THE INTEGRITY OF THE CONTEMPORARY SCHOLARLY PUBLISHING SYSTEM** **JULIE SIMPSON, PhD** DIRECTOR, RESEARCH INTEGRITY SERVICES AFFILIATE ASSISTANT PROFESSOR OF COLLEGE TEACHING & OF EDUCATION UNIVERSITY OF NEW HAMPSHIRE The academic publishing system and incentive structure have an enormous influence on the behavior of researchers. Many phenomena plaguing the contemporary scholarly publishing system, such as predatory journals, hijacked journals, authorship for sale, citation rings, fake peer review, and paper mills, are primarily driven by the "publish or perish" culture. When the quantity of publications and funding, impact factor, and h-indexes are prioritized over the quality and integrity of scholarly works, then some researchers will respond to the incentives and villains will pop out of the woodwork to take advantage of them. All researchers, but especially trainees and early career researchers, need to know about the scams and pitfalls waiting to take advantage of their eagerness to succeed (read "publish"). To safeguard research integrity, institutions, mentors, and research integrity educators need to help educate and protect these vulnerable individuals from themselves and others. In this session, the presenter will: 1. Identify types of bad actors at large in the contemporary scholarly publishing system and how they operate. 2. Explain the impacts of the various schemes on the integrity of the research record. 3. Discuss red flags and ways that researchers can avoid falling prey to publishing scams and con artists.	**THE ROLE OF EMOTION IN ETHICAL DECISION MAKING** **R BRUCE THOMPSON, PhD** PROFESSOR OF PSYCHOLOGY - HUMAN DEVELOPMENT UNIVERSITY OF SOUTHERN MAINE MERTEC **CAROL NEMEROFF, PhD** DEAN RENAISSANCE COLLEGE UNIVERSITY OF NEW BRUNSWICK MERTEC This workshop session will provide direct participation of attendees in research case scenario analyses that are ethically complex. The MeRTEC model, which draws insights from cognitive, social and clinical psychology will be introduced to participants as a model for describing multiple internal and external influences on ethical decision-making in everyday life, especially in high stakes situations. One key element is emotion, which skews logical processes in systematic ways. In this workshop, participants will directly engage, through live, interactive response software, with ethical case analysis and issue-spotting, based on an ongoing NSF funded evaluation study of the MeRTEC model. Accuracy of issue-spotting under different emotional conditions will be illustrated using the interactive technology. Through an in-depth debriefing, participants will gain understanding of the importance of cognitive heuristic- and bias-based reasoning, and the importance of emotional self-monitoring and corrective metacognitive strategies in addressing high-stakes ethical scenarios.

2:00 PM – 2:45 PM	**GENERAL ALL Is**		
	RI RA **NEW TRENDS IN RESEARCH MISCONDUCT REGULATIONS** **ELIZABETH J. MCEVOY** PARTNER HINCKLEY ALLEN & SNYDER **JULIANNA MALOGOLOWKIN** HINCKLEY ALLEN & SNYDER Over the past year, the topic of research misconduct has become a headline in popular news media and given rise to new, and renewed, interest in the authenticity of data from both regulators as well as the general public. In particular, in the past year, we have seen a heightened scrutiny of potential plagiarism and unprofessionalism in scholarly works as well as intensified scrutiny on the potential for erroneous data to impact entire portfolios and even impact entire scientific disciplines. In this session, we will discuss new trends in allegations of research misconduct proceedings -- from the manner in which allegations are raised through PubPeer and other public forums, the impact of Artificial Intelligence in identifying potential fabrication/falsification, to the Public Health Services' proposed changes to the regulations, the rise of plagiarism-only allegations, and finally, how law enforcement has addressed these evolving concerns and renewed commitment to protecting the public from fabricated and/or falsified data in government-sponsored projects.	**BEYOND THE NIH: THE EXPANSION OF LOCAL BIOSAFETY REGULATIONS - THE CURRENT MAP AND FUTURE TRENDS** **COREY MARTIN** FOUNDER and CEO SPOTLIGHT SOLUTIONS Due in large part to the recent COVID pandemic, there has been a noticeable uptick in community interest and scrutiny related to biotech and life science research in local municipalities. Public pressure on local Boards of Health and Public Health Departments has led to a closer look at local review processes and permitting requirements for institutions conducting biological research. This session will focus on the following four topics: 1.) A brief history of local biosafety ordinances 2.) The current landscape of biosafety regulations across the US 3.) A case study of town-by-town variation in biosafety permit requirements in the Greater Boston/Cambridge area 4.) A discussion of expected future trends and anticipated regional changes	**THE ART OF COMPLIANCE AUDITING** **KELÉ PIPER** DIRECTOR, RESEARCH COMPLIANCE OFFICE OF COMPLIANCE MASSACHUSETTS GENERAL HOSPITAL **Session Objectives** • What is an audit anyway? Knowing when and why to do an audit. • Understanding the types of audits and how to determine which type is needed. • Explore the importance of auditing along with the challenges and pitfalls of compliance auditing. **Description** Compliance auditing can be a daunting task, especially when you are not sure how to approach it. Using the right tools and right audit methodology can keep you on track and help to obtain the right information so that your institution can make the best decisions and determinations. This session will introduce different audit types and tools to achieve the best outcomes.
2:50 PM – 3:00 PM	**BREAK**		
3:00 PM – 3:45 PM			
	CHAT GBT **DIFFERENT WAYS AI IS GENERATED … BEYOND PERVASIVE** FBI HEADQUARTERS		
4:00 PM	**EVALUATIONS & CLOSING REMARKS** **SEE YOU IN 2025 IN NORTH CAROLINA**		