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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 **THURSDAY, MAY 2, 2024** **CONFERENCE AGENDA**

7:30 AM – 9:00 AM	**BREAKFAST | MEET-UPS | CONFERENCE SPONSORS**
9:00 AM	**WELCOME TO DAY TWO!**
9:00 AM – 11:00 AM	**THREE I's RESEARCH INTEGRITY & ETHICS™**
GENERAL SESSION	**RESEARCH INTEGRITY, ETHICS AND YOU©** **a hands-on/interactive session** **AI IMPACTING RESEARCH** **ANIMAL TO HUMAN** **SUSAN N CROPP, PhD** CHEMICAL BIOLOGICAL COUNTERMEASURES UNIT/WMDD FBI HEADQUARTERS **MINAL M. CARON** ROPES & GRAY LLP **BENJAMIN SILVERMAN, MD** SENIOR IRB CHAIR MASS GENERAL BRIGHAM, HUMAN RESEARCH AFFAIRS **CECE BROTCHIE-FINE | MODERATOR** EXECUTIVE DIRECTOR, ETHICS ETHICS, RISK AND COMPLIANCE R&D NOVARTIS **TED MYATT, ScD | MODERATOR** ASSOCIATE VICE PROVOST OF RESEARCH INTEGRITY TUFTS UNIVERSITY
11:00 AM -11:10 AM	**REFRESHMENT BREAK**

11:15 AM – 12:15 PM	ALL I's – Biosecurity – Research Administration – Research Integrity		
	THE LONG ROAD TO DRUG DISCOVERY GAME **DR CHANDRA WILLIAMS** DIRECTOR, COMPARITIVE MEDICINE PFIZER **CYNTHIA FILLIETTAZ, MBA, CPIA, LATG, CVT** IACUC ADMINISTRATOR COMPARATIVE MEDICINE PFIZER This session will provide participants with an understanding of how drugs are discovered. The Long Road to Drug Discovery Game is an engaging outreach program designed to provide an interactive and educational experience that sheds light on the complex process of drug discovery and development process. A combination of a slide presentation and a board game gives participants a glimpse into the various steps involved in getting a new medicine on the market while also experiencing the challenges and triumphs along the way. The program encourages critical thinking, teamwork, and problem-solving skills, as teams work to navigate the Drug Development path and launch their own new drug. This outreach program offers a unique opportunity to gain a general understanding of the pharmaceutical industry and the various career opportunities involved in the field. At the end of the program, participants will come away with a newfound appreciation for the complexity of developing new drugs and the significant investment in time, money, and resources that are required to make it happen.	**UNINTENTIONAL INTERNAL THREATS TO RESEARCH DATA** **KELÉ PIPER** DIRECTOR, RESEARCH COMPLIANCE OFFICE OF COMPLIANCE MASSACHUSETTS GENERAL HOSPITAL **SESSION OBJECTIVES** Assess vulnerabilities and risks to research data stemming from institutional practices and attitudes Use data incidents and breaches to improve internal controls for research data Explore and evaluate preventative measures that minimize risk of internal data incidents **SESSION DESCRIPTION** Data security is a top compliance threat facing organizations. In research, data management and security are challenging with each lab and project having unique data needs and expectations. Researchers are overwhelmed by the volume of data requirements and can inadvertently contribute to data security noncompliance, breaches and other data integrity issues. In this session, we examine ways that researchers contribute to data noncompliance, recognize hotspots and analyze ways to better help researchers comply.	**PHOOEY! WE'VE BEEN FOIA'D… NOW WHAT?** **MICHELLE SCHATZ** RESEARCH COMPLIANCE SPECIALIST HARVARD MEDICAL SCHOOL **ELEANOR KUSZMAR, MS, CHRC, CRA** DIRECTOR FOR RESEARCH COMPLIANCE OFFICE OF ACADEMIC AND RESEARCH INTEGRITY HARVARD MEDICAL SCHOOL Information requests based on information access laws are proliferating in research for many reasons. In this session, we will examine different types of information requests in research and what documents are subject to such requests. Federal, state and local laws that govern information requests will be compared and analyzed. Differences in obligations and risks for public vs private institutions will be discussed. We will demystify exemptions and provide tips on limiting exposure for sensitive research information. Attendees will review sample documents and determine which pieces of information are appropriate to redact. There will be a discussion of current information request cases and we will identify strategies to reduce risk to both institutions and individuals.
12:15 PM – 1:00 PM	**LUNCH**		

1:05 PM – 1:50 PM			
	SUPPORTING THE COMPLIANT USE OF CONTROLLED SUBSTANCES IN NON-CLINICAL RESEARCH **LAUREN PETER** BILH INTEGRITY AND COMPLIANCE Supporting the compliant use of Controlled Substances in bench or animal research requires a different set of skills and oversight mechanisms than Clinical Research. Researchers are busy, and can view certain regulations with a jaundiced eye. Lowering the threshold for them to act appropriately not only fosters good relationships with laboratories but protects the organization from potential fines. This talk will address How to collaborate with various institutional departments to offer well rounded support to research labs. How to educate registrants when staff turns over or regulations change. How to monitor compliance with limited resources. How to build relationships with regulatory agencies so that problems or questions can be easily addressed.	**LABORATORY SAFETY, COMPLIANCE, AND INTEGRITY (LABSCI) - A COMPREHENSIVE APPROACH TOWARD A CULTURE OF SAFETY** **FRANK SANGIORGI, PHD** MANAGER OF RESEARCH INTEGRITY BRANDEIS UNIVERSITY A new group, designated as LabSCI (Laboratory Safety, Compliance, and Integrity), has been assembled at Brandeis University to address the challenges unique to research administration at a smaller institution of higher education. The group's goals are to ensure that laboratory research is conducted in a safe manner, conducted according to the regulations, guidelines, and good practices adopted by relevant government agencies and leading research institutions, and that research is carried out in an ethical manner so as to foster good experiments, good data, and an overall culture of safety and integrity. LabSCI consists of individuals with expertise in IACUC, IBC, and controlled substances administration, along with extensive experience in laboratory, radiation, and laser safety. Collaborations with the IRB, EH&S, and the Foster Comparative Medicine Services to address issues concerning general laboratory safety, animal care and use, and the protection of human subjects further round out the activities of this group. LabSCI is offered here as an example of one approach to fulfill the needs of research administration and oversight at a university.	**DONE WRONG–GOTTA PAY: RESEARCH NON-COMPLIANCE AND RESEARCH** **JOHN R BAUMANN, PHD** ASSOCIATE VICE PRESIDENT FOR RESEARCH COMPLIANCE INDIANA UNIVERSITY We regularly read about how the identification of unallowable costs may lead to requirements for reimbursement federal and other sponsors of research. Less known, however, are incidents of reimbursement to sponsors due to the identification of misconduct or non-compliance in the conduct of the research. This session will provide an overview of the 'non-financial' events that may lead an organization to having to reimburse a sponsor for some or all of the claimed research expenses. More specifically, the panelists will discuss the steps leading to the identification of research non-compliance and/or misconduct (from allegation to determination) and the procedures that an institution may have to undertake to process the reimbursement.

1:55 PM – 2:50 PM	**GENERAL SESSION**		
FBI WMD	**NEW SCREENING GUIDELINES FOR DNA SYTHESIS** **Benchtop|sequencing|vetting|tracking** **JOSHUA E CANTER** WMD COORDINATOR FBI BOSTON DIVISION		
2:50 PM – 3:00 PM	**REFRESHMENT BREAK**		
3:00 PM – 4:00 PM	**BREAKOUT SESSIONS**		
	IACUC CHALLENGES: CASE STUDIES FROM REAL LIFE **MARCY BROWN, BS, MA, CMAR, CPIA** ANIMAL WELFARE AND IACUC PROGRAM SPECIALIST **DEB FROLICHER** DIRECTOR IACUC OFFICE THE SCRIPPS RESEARCH INSTITUTE **SARA TOBIAS, DVM** VETERINARY MEDICAL OFFICER USDA ANIMAL AND PLANT HEALTH INSPECTION SERVICE (APHIS)	**MORE THAN A SENTENCE, LESS THAN A GRANT PROPOSAL: WHAT IS THE APPROPRIATE LEVEL OF DETAIL FOR AN IBC PROTOCOL/PROJECT REGISTRATION?** **COREY MARTIN** FOUNDER and CEO SPOTLIGHT SOLUTIONS Quality IBC Protocols and Project Registrations are a critical aspect of the IBC process that allow for efficient and thorough assessment of the proposed research. Without sufficient information, it is impossible for the IBC to properly evaluate the risk and determine what controls should be required or recommended for the work. Conversely, when provided with too much information, it can be difficult for the IBC to sift through pages and pages of extraneous information (e.g., data acquisition and analysis methods, tables and table of background data, etc.) that don't contribute to the risk assessment. The primary challenge is that PIs generally have limited guidance for how to properly complete an IBC Protocol/Project Registration and time constraints often lead to one of two approaches: 1.) An overly simplified submission with one or a couple of vague sentences 2.) A copy and paste from a long grant proposal Both of these strategies tend to lead to many rounds of back and forth between the PI and IBC in an attempt to get the appropriate level of detail for an adequate review. This breakout session will use sample IBC Protocols and Project	**ETHICAL CONUNDRUMS OF CURRENT US FUNDING AGENCY RESEARCH SECURITY EFFORTS** **STACY PRITT, DVM, MS, MBA, CPIA, CHRC, EXCS, DACAW** ASSOCIATE VICE CHANCELLOR CHIEF RESEARCH COMPLIANCE OFFICER THE TEXAS A&M UNIVERSITY SYSTEM Research security became a focal point for US federal agencies funding academic research in 2018 when NIH started sending notifications to dozens of academic institutions about concerns involving foreign influence in research. The effort to determine the scope and extent of the foreign influence started, which started years before 2018, continues today and has culminated in the recent release of draft Research Security Program (RSP) requirements. Lost in this effort are the ethical conundrums presented by the federal government's shifting requirements, inconsistent responses by academic institutions, and the potential chilling effect that all of this has on international research collaborations. This session will breakdown the concerns US agencies have with inappropriate foreign influence in research, review how those concerns have evolved since 2018, and identify the ethical conundrums inherent to this topic. Learning Objectives: 1 - Understand the background and rationale for why US federal funding agencies are concerned with inappropriate foreign influence in research and created the current parameters of research security 2 - Review the changing landscape of research security as it impacts researchers and research institutions 3 - Identify the ethical conundrums researchers and research institutions face when evaluating proposed federal research security requirements.

		Registrations as a basis for discussing the level of detail needed for a proper IBC review and for formulating effective responses (and reference materials) to guide PIs to a constructive IBC submission.	
SEE YOU IN THE AM FOR BREAKFAST!			