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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 **CECE BROTCHIE-FINE, BS, MA, MS, CPIA | MODERATOR** AD / HEAD AWC CAMBRIDGE NIBR CA IACUC CHAIR & ANIMAL WELFARE OFFICER GLOBAL SCI OPERATIONS / CFO NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH, INC. **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			
	I NEED TO SPEAK TO YOUR MANAGER … THE ADDED VALUE OF INCLUDING YOUR GMA PROJECT MANAGERS TO THE CONVERSATION **AMY TITELBAUM** PROJECT MANAGER - GMAP COLONY MANAGEMENT PFIZER Colony or project managers are often relied upon to ensure that just the right animals are provided for study - that genotypes are correct, ages are within range, and genders are accurate. But often, these individuals have such large breadth of experience and knowledge that they can and should be a resource for so much more. While overall research goals are often the top priority, many other aspects of colony management may be overlooked and not taken into consideration. The role of the GMA Project manager (PM) can impact the 3 R's - ensuring that breeding is not in excess while still achieving cohort goals, that only purpose driven breeding occurs. The PM can aid in reducing excess spending by proposing alternative breed schemes or aid in the search and selection of models which do not require additional licensing fees nor carry bioexcluded agents. The PM can inform veterinary staff of expected phenotypes that may require additional oversight, thereby supporting animal welfare. The PM can dictate expected timelines from model sourcing through to project completion and maintain histories that can be essential to clinical drug development. They use their knowledge and experience to propose	**TBA**	**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

	modifications to cohort goals in order to inhibit delays so that researchers can achieve target goals. The list of ways these professionals can improve the management of GMA colonies is nearly endless. The role of the PM is to allow the researchers to focus on their work, while the PM keeps the project within controlled/limited budgets, ensures potential phenotypic health concerns can be appropriately overseen, and implement every aspect of the 3 R's within their responsibilities. The more often they are included in all aspects of project development and communication, the greater the opportunity to refine all processed associated with GMA Colony Management.		
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	**TBA**	**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

SEE YOU IN THE AM FOR BREAKFAST!