IACUC	
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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 **WEDNESDAY APRIL 26, 2023** **CONFERENCE AGENDA**

7:30 AM – 9:00 AM	**GRAB Breakfast & YOUR FAVORITE AM BEVERAGE … NETWORK|SPONSORS!**		
9:00 AM	**WELCOME TO OUR FINAL DAY!**		
9:05 AM – 9:50 AM	**THREE I's SESSION**		
	INVESTIGATING THE FUNCTIONS OF VIRAL PROTEINS IN SARS-COV-2 PATHOGENESIS **MOHSAN SAEED, PhD** ASSISTANT PROFESSOR, BIOCHEMISTRY BOSTON UNIVERSITY CHOBANIAN AND AVEDISIAN SCHOOL OF MEDICINE INVESTIGATOR, NATIONAL EMERGING INFECTIOUS DISEASES LABORATORIES (NEIDL)		
9:55 AM – 10:55 AM	**MORNING BREAKOUTS**		
	IACUC **USDA UPDATE** **DR KRISTIN NAPOLI** SUPERVISORY ANIMAL CARE SPECIALIST USDA	**IBC** **SIGNING CONTAINMENT LEVELS TO GENETICALLY MODIFIED PLANTS AND PLANT PATHOGENS IN RESEARCH** **DEBORAH HOWARD** EXPERT, GLOBAL EHS BIOLOGICAL MATERIALS MANAGER BASF Plant research is the backbone of both genetically modified, disease resistance and breeding of both academic and biotechnology research. Currently there are no published resources to help Biosafety Managers and Institutional Biosafety Committees assign containment levels to genetically modified plants and plant pathogens in the R&D pipeline. This session will provide guidance in determining containment	**ALL Is| Biosecurity | RI | RA** **COMPLEXITIES OF RESEARCH DATA SHARING IN THE AGE OF NSPM-33** **KELÉ PIPER, DIRECTOR** RESEARCH COMPLIANCE, MASSACHUSETTS GENERAL HOSPITAL **LINDSEY L SPANGLER, JD** ASSOCIATE DEAN, RESEARCH INTEGRITY DUKE UNIVERSITY With the issuance of NSPM-33 Implementation Guidance in January 2022, federal funding agencies and research institutions have been working to increase their research security. As part of this effort, changes in policies and processes related to data sharing have been put into place to comply with the new and expected requirements of NSPM-33. These changes are in addition to the

		levels in plant research. Interactive exercises to determine containment levels will be used.	existing requirements such as HIPAA, GDPR, etc. This presentation will provide background on NSPM-33 and processes institutions have implemented to secure access to research data and systems by departing researchers and external collaborators.
10:55 AM – 11:05 AM	**REFRESH …**		
11:05 AM – 12:15 PM	**BREAKOUTS**		
	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** ASSOCIATE VICE PRESIDENT FOR RESEARCH ADMINISTRATION OFFICE OF SPONSORED PROJECTS | OFFICE OF RESEARCH INTEGRITY UNIVERSITY OF RHODE ISLAND **SUSAN N CROPP, PhD** CHEMICAL BIOLOGICAL COUNTERMEASURES UNIT/WMDD FBI HEADQUARTERS **CHRISTOPHER M. MANGELLI, JD, MS, M ED, CIP** DIRECTOR, OFFICE OF RESEARCH INTEGRITY (ORI) BALL STATE UNIVERSITY		**IACUC, IBC, RA & RI** **ESSENTIALS OF INSTITUTIONAL CONFLICT OF INTEREST** **STACY PRITT, DVM, MS, MBA, CPIA, CHRC, ECOP (EAR), DACAW** Associate Vice President, Research Support & Regulatory Management Assistant Professor, Psychiatry (Ethics Division) University of Texas Southwestern Medical Center While not required by any federal regulation, institutional conflict of interest (ICOI) programs and committees are seen as a way to mitigate human subjects risk in research and avoid reputational harm. Even though the creation and maintenance of such programs is typically viewed as optional, many institutions support robust ICOI committees, in particular academic medical centers and institutions with very large human research programs. In this session, we will explore the history behind the concept of COI, along with how some of the common elements of ICOI programs developed. There will also be a discussion of best practices as well as current directions and challenges. Finally, audience participation will be garnered through the review of thought-provoking scenarios.
12:15 PM- 1:00 PM	**LUNCH**		

1:05 PM – 1:50 PM	**THREE I's**		
	FBI | TBA		
1:55 PM – 2:40 PM	**BREAKOUTS**		
	IACUC IBC BIOSECURITY **DIPHTHERIA TOXIN POLICY: A STRATIFIED RISK ASSESSMENT APPROACH TO ENSURING WORKER SAFETY WITH A COMMONLY USED MOLECULAR BIOLOGY TOOL** **MARY BROCK** SAFETY & HEALTH SPECIALIST DUKE UNIVERSITY Diphtheria toxin (DT) is an important tool in laboratory and animal research. DT can be used to target specific cells in transgenic mice engineered to express DT receptors on the surface. High concentrations of DT are necessary for this process and it presents a great risk to the workers performing these tasks, especially when using sharps to inject DT into mice. Humans are very susceptible to DT. Based on studies in mice, the estimated human LD50 is less than 100 ng/kg by IM injection. After a potential needle stick exposure, a thorough risk assessment was implemented to study the risks for those who handle DT. After extensive collaboration with physicians from Duke Employee Occupational Health and Wellness (EOHW) and a review of existing references, we stratified the control strategies into high-risk and standard-risk research activities, with the highest risk involving work with needles and high concentrations of DT. These activities and necessary requirements were clearly defined in the Duke Diphtheria Toxin Policy. A designation in the Safety Management System (SMS) tracks the users and provides automatic annual	**IBC IRB** **SUITABILITY AND PERSONNEL RELIABILITY: KEEPING AN EYE** **ANGELA C BIRNBAUM** DIRECTOR OF BIOSAFETY TULANE UNIVERSITY	**COMPLIANCE** **EFFORT, EFFORT EVERYWHERE: MANAGING FACULTY EFFORT COMMITMENTS IN A CHANGING WORLD** **ELEANOR KUSZMAR, MS, CHRC, CRA** ASSOCIATE DIRECTOR FOR RESEARCH COMPLIANCE OFFICE OF ACADEMIC AND RESEARCH INTEGRITY HARVARD MEDICAL SCHOOL

	email reminders for compliance with the ongoing health requirements. Since implementing the policy, 39 Principal Investigators and over 80 sub-researchers have been enrolled under this policy. Personnel are added to this policy through a review of institutional animal care and use protocols, laboratory safety evaluations, and institutional biosafety committee recombinant DNA/viral vector registrations. Lessons learned and challenges in the implementation and maintenance of the requirements, such as lab worker turnover or changes in assigned duties, updates to the SMS designations, maintaining changes to SOPs and animal protocols, will be discussed.		
2:45 PM – 2:55 PM	**BREAK**		
3:00 PM – 3:45 PM	**THREE I's SESSION**		
	ACTIVISM EXTREMISM **FBI WMD| BioSecurity**		
3:50 PM – 4:00 PM	**EVALUATIONS & CLOSING REMARKS** **SEE YOU MAY 2024 at THE SHERATON PORTSMOUTH, NH!**		