IACUC	
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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 2 **TUESDAY APRIL 25, 2023** **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** We will start with an historic overview of xenotransplantation that leads to the recent in-patient trials – a "how did we get here" style presentation – A panel that will include various stakeholders e.g. veterinarian, animal caretakers, PIs for both the animal and human sides, a bioethicist will discuss the implications of xenotransplantation in the future, both positive and negative. This session highlights the intersection between all committees and Biosecurity. **CECE BROTCHIE-FINE, BS, MA, MS, CPIA** AD / HEAD AWC CAMBRIDGE NIBR CA IACUC CHAIR & ANIMAL WELFARE OFFICER GLOBAL SCI OPERATIONS / CFO NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH, INC. **TED MYATT, ScD** ASSOCIATE VICE PRESIDENT FOR RESEARCH ADMINISTRATION OFFICE OF SPONSORED PROJECTS | OFFICE OF RESEARCH INTEGRITY UNIVERSITY OF RHODE ISLAND **STUART JOHNSTON KNECHTLE, MD** WILLIAM R. KENAN, JR. DISTINGUISHED PROFESSOR PROFESSOR OF SURGERY ADJUNCT PROFESSOR IN THE DEPARTMENT OF MEDICINE MEMBER IN THE DUKE CLINICAL RESEARCH INSTITUTE DUKE UNIVERSITY SCHOOL OF MEDICINE **MARC I. LORBER, MD** SR. VICE PRESIDENT AND CHIEF MEDICAL OFFICER PRODUCT DEVELOPMENT UNITED THERAPEUTICS CORPORATION LUNG BIOTECHNOLOGY PBC

	DAVID RESNIK, JD, PhD BIOETHICIST, NIEHS, NIH **FRANCIS J SUN, DVM, DACLAM, MBA** ASSISTANT PROFESSOR, DEPARTMENT OF PATHOLOGY ASSOCIATE DIRECTOR, CHIEF OF CLINICAL SERVICES FOR USDA COVERED SPECIES DIVISION OF LABORATORY ANIMAL RESOURCES DUKE UNIVERSITY SCHOOL OF MEDICINE **REBECCA L WALKER, PhD** PROFESSOR UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL DEPARTMENT OF SOCIAL MEDICINE DEPARTMENT OF PHILOSOPHY CENTER FOR BIOETHICS **SUSAN N CROPP, PhD** CHEMICAL BIOLOGICAL COUNTERMEASURES UNIT/WMDD FBI HEADQUARTERS		
11:00 AM -11:10 AM	**BREAK**		
11:15 AM – 12:00 PM	**BREAKOUT SESSIONS**		
	IACUC **CASE STUDY: A SOPHISTICATED MODERN ANIMAL ACTIVIST CAMPAIGN** **ELEANOR KUSZMAR, MS, CHRC, CRA** ASSOCIATE DIRECTOR FOR RESEARCH COMPLIANCE OFFICE OF ACADEMIC AND RESEARCH INTEGRITY HARVARD MEDICAL SCHOOL Through the lens of preparing and implementing institutional and researcher responses, we will talk through a recent animal activist campaign, as well as examine strategies and methods used by activists in accomplishing their goals. Discussion and opportunity to share experiences at other institutions as well.	**FBI | WMD** **TBA** **SUSAN N CROPP, PhD** CHEMICAL BIOLOGICAL COUNTERMEASURES UNIT/WMDD FBI HEADQUARTERS	**HARASSMENT AND HOSTILITY IN RESEARCH: HOW TO NAVIGATE CLAIMS OF SEXUAL HARASSMENT AND HOSTILE WORK ENVIRONMENT IN A FEDERALLY-FUNDED ENVIRONMENT.** **ELIZABETH J. MCEVOY** PARTNER HINCKLEY ALLEN We will be focusing on how to address allegations of hostile work environment/sexual harassment in federally-funded trials and laboratory research.
12:00 PM – 12:45 PM	**LUNCH**		

12:50 PM - 1:50 PM		
	IACUC IBC **USING "EXTERNAL ASSESSMENT" AS A QUALITY CONTROL/QUALITY ASSURANCE TOOL IN BSL3/ABSL3 TRAINING** **ANDREA VOGEL, PHD** SAFETY AND HEALTH SPECIALIST, ALTERNATE RESPONSIBLE OFFICIAL DUKE UNIVERSITY HEALTH SYSTEM High containment research (BSL-3 and ABSL-3) at Duke University occurs under extensive oversight that ensures compliance with biosafety and biosecurity best practices, guidelines and regulations. Training for personnel to work safely in the laboratory and/or animal care areas of the high containment facility is a multi-step process that starts with a boot-camp, where participants receive a lecture on the principles and practices of a high containment laboratory work, tour of the facility, hands-on experience donning and doffing personal protective equipment and assignment to a mentor for experiential learning. This mentored training can last anywhere from 1-6 months depending on the previous experience of the individual being mentored and the competency they have shown during the training. Once mentoring is finished, an internal assessment by the facility safety team is completed and a request for an external assessment by the Duke Safety Office is requested. The external assessment serves as a way to reinforce and evaluate worker competency and overall training program. In this talk, details about the components of the training, mentoring, internal and external assessments and highlight how this method of using the external assessment as a quality assurance/quality control tool has helped ensure safe worker performance under various circumstances. Additionally, various standardized tools and reports used to evaluate and document the worker's competency based on specific tasks will be reviewed..	**RI** **USING THE FEDERAL SENTENCING GUIDELINES AS A FRAMEWORK FOR YOUR RESEARCH INTEGRITY OFFICE** **ROSS HICKEY, JD, CIP, CPIA** ASSISTANT PROVOST FOR RESEARCH INTEGRITY UNIVERSITY OF SOUTHERN MAINE According to Chapter 8 of the Federal Sentencing Guidelines, one method for an organization to mitigate possible punishment for criminal liability is by demonstrating the existence of an "effective compliance and ethics program." Chapter 8 provides an outline of the specific elements constituting such a program. These elements provide a helpful framework for Compliance Programs in any field, including research integrity. This session will walk the attendees through each of these elements, as well as provide specific examples of how they would work in a research integrity program. The guidelines are a very practical tool to assess how effective your program is in building an ethical culture in your organization.
1:55 PM – 2:55 PM	**GENERAL SESSION**	
	TBA **BIOSECURITY**	
2:55 PM – 3:10 PM	**BREAK**	

3:15 PM – 4:00 PM			
	IACUC IBC **IBC COMMITTEE TRAINING PROGRAM: HOW TO MAXIMIZE COMMITTEE OVERSIGHT AND REVIEW** **ANGELA C BIRNBAUM** DIRECTOR OF BIOSAFETY TULANE UNIVERSITY	**IRB** **ONLINE RESEARCH: IT'S VIRTUALLY SAFE** **MALLORY BALL, PHD, MPH, CIP** WESTERN CAROLINA UNIVERSITY **UNDI HOFFLER, PhD** DIRECTOR OF RESEARCH COMPLIANCE & TECHNOLOGY TRANSFER NORTH CAROLINA CENTRAL UNIVERSITY With the rise of online research, many institutions are facing tough questions about safeguarding information, protecting participants, data use/privacy permissions. Social media groups, online survey platforms, and other virtual data collecting methods may require a different approach than traditional survey design and execution. How can IRBs prevent problems in a virtual environment before they occur? When is data considered private and when is it considered part of the public domain? Based on the current research, and hands-on expertise of the speakers, this presentation allows for the sharing of best practices, lessons learned, and new perspectives on survey methods and approaches in order to mitigate risk for participants and bystanders in online research studies	**RI | RA** **NSF/NIH RCR CHANGES BUT WERE AFRAID TO ASK!** **CHRISTOPHER M. MANGELLI, JD, MS, M ED, CIP** DIRECTOR, OFFICE OF RESEARCH INTEGRITY (ORI) BALL STATE UNIVERSITY Topic to include a landscape survey of all the recent changes proposed by NSF/NIH relating to RCR: The expanded topics, the data sharing requirements, the expansion of people requiring the training...etc.