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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 **TUESDAY APRIL 25, 2023**

**CONFERENCE AGENDA**

7:30 AM – 9:00 AM	<b>BREAKFAST   MEET-UPS   CONFERENCE SPONSORS</b> <b>OLD WELL BALLROOM</b>
9:00 AM	<b>WELCOME TO DAY TWO!</b>
9:00 AM – 11:00 AM	<b>THREE I's RESEARCH INTEGRITY &amp; ETHICS™</b>
<b>GENERAL SESSION</b> <b>HILL BALLROOM</b>	<p style="text-align: center;"><b>RESEARCH INTEGRITY, ETHICS AND YOU©</b> <b>a hands-on/interactive session</b></p> <p>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 discussion will include various stakeholders (e.g., veterinarian, animal caretakers, PIs for both the animal and human sides, and bioethicists) will discuss the implications of xenotransplantation in the future, both positive and negative. This session highlights the intersection between all committees and Biosecurity.</p> <p style="text-align: center;"><b>STUART JOHNSTON KNECHTLE, MD</b> 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</p> <p style="text-align: center;"><b>MARC I. LORBER, MD</b> SR. VICE PRESIDENT AND CHIEF MEDICAL OFFICER PRODUCT DEVELOPMENT UNITED THERAPEUTICS CORPORATION LUNG BIOTECHNOLOGY PBC</p> <p style="text-align: center;"><b>DAVID RESNIK, JD, PhD</b> BIOETHICIST, NIEHS, NIH</p> <p style="text-align: center;"><b>FRANCIS J SUN, DVM, DACLAM, MBA</b> 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</p> <p style="text-align: center;"><b>REBECCA L WALKER, PhD</b> PROFESSOR UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL</p>

<p><b>2.0 CIP</b></p>	<p>DEPARTMENT OF SOCIAL MEDICINE DEPARTMENT OF PHILOSOPHY CENTER FOR BIOETHICS</p> <p><b>SUSAN N CROPP, PhD</b> CHEMICAL BIOLOGICAL COUNTERMEASURES UNIT/WMDD FBI HEADQUARTERS</p> <p><b>CECE BROTCHE-FINE, BS, MA, MS, CPIA   MODERATOR</b> AD / HEAD AWC CAMBRIDGE NIBR CA IACUC CHAIR &amp; ANIMAL WELFARE OFFICER GLOBAL SCI OPERATIONS / CFO NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH, INC.</p> <p><b>TED MYATT, ScD   MODERATOR</b> ASSOCIATE VICE PRESIDENT FOR RESEARCH ADMINISTRATION OFFICE OF SPONSORED PROJECTS   OFFICE OF RESEARCH INTEGRITY UNIVERSITY OF RHODE ISLAND</p>	
<p><b>11:00 AM -11:10 AM</b></p>	<p><b>REFRESHMENT BREAK</b></p>	
<p><b>11:15 AM – 12:00 PM</b></p>	<p><b>BREAKOUT SESSIONS</b></p>	
	<p><b>HILL BALLROOM</b></p> <p><b>CASE STUDY: A SOPHISTICATED MODERN ANIMAL ACTIVIST CAMPAIGN</b></p> <p><b>ELEANOR KUSZMAR, MS, CHRC, CRA</b> ASSOCIATE DIRECTOR FOR RESEARCH COMPLIANCE OFFICE OF ACADEMIC AND RESEARCH INTEGRITY HARVARD MEDICAL SCHOOL</p> <p>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 will be provided as well.</p> <p><b>0.75 CPIA</b></p>	<p><b>CHANCELLOR WEST</b></p> <p><b>HARASSMENT AND HOSTILITY IN RESEARCH: HOW TO NAVIGATE CLAIMS OF SEXUAL HARASSMENT AND A HOSTILE WORK ENVIRONMENT IN A FEDERALLY FUNDED ENVIRONMENT</b></p> <p><b>ELIZABETH J. MCEVOY</b> PARTNER HINCKLEY ALLEN</p> <p>We will be focusing on how to address allegations of hostile work environment/sexual harassment in federally funded trials and laboratory research.</p>
<p><b>12:00 PM – 12:45 PM</b></p>	<p><b>LUNCH</b> <b>OLD WELL BALLROOM</b></p>	
<p><b>12:50 PM - 1:50 PM</b></p>		
	<p><b>HILL BALLROOM</b></p> <p><b>IACUC IBC</b></p> <p><b>USING “EXTERNAL ASSESSMENT” AS A QUALITY CONTROL/QUALITY ASSURANCE TOOL IN BSL3/ABSL3 TRAINING</b></p> <p><b>ANDREA VOGEL, PHD</b></p>	<p><b>CHANCELLOR WEST</b></p> <p><b>RI</b></p> <p><b>USING THE FEDERAL SENTENCING GUIDELINES AS A FRAMEWORK FOR YOUR RESEARCH INTEGRITY OFFICE</b></p> <p><b>ROSS HICKEY, JD CIP CPIA</b> ASSISTANT PROVOST FOR RESEARCH INTEGRITY UNIVERSITY OF SOUTHERN MAINE</p>

	<p style="text-align: center;">SAFETY AND HEALTH SPECIALIST, ALTERNATE RESPONSIBLE OFFICIAL DUKE UNIVERSITY HEALTH SYSTEM</p> <p>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.</p>	<p style="text-align: center;">DIRECTOR OF THE MAINE REGULATORY ETHICS AND TRAINING CENTER (MERTEC) AT USM</p> <p>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.</p> <p style="text-align: center;"><b>1.0 CIP</b></p>
<p><b>1:55 PM – 2:55 PM</b></p>	<p><b>GENERAL SESSION</b></p>	
<p><b>HILL BALLROOM</b></p>	<p><b>BIOSECURITY CASE STUDIES FROM THE FBI</b></p> <p><b>SA FELIX DEL TORO SILVA</b> FBI, WMD</p> <p><b>SSA JOEL HOLMES</b> FBI,WMD</p> <p><b>SUSAN N CROPP, PhD</b> CHEMICAL BIOLOGICAL COUNTERMEASURES UNIT/WMDD FBI HEADQUARTERS</p>	
<p><b>2:55 PM – 3:10 PM</b></p>	<p><b>REFRESHMENT BREAK</b></p>	

<b>3:15 PM – 4:00 PM</b>	<b>BREAKOUT SESSIONS</b>		
	<p style="text-align: center;"><b>HILL BALLROOM</b></p> <p style="text-align: center;"><b>IACUC IBC</b></p> <p style="text-align: center;"><b>IBC COMMITTEE TRAINING PROGRAM: HOW TO MAXIMIZE COMMITTEE OVERSIGHT AND REVIEW</b></p> <p style="text-align: center;"><b>ANGELA C BIRNBAUM</b> DIRECTOR OF BIOSAFETY TULANE UNIVERSITY</p>	<p style="text-align: center;"><b>CHANCELLOR EAST</b></p> <p style="text-align: center;"><b>IRB</b></p> <p style="text-align: center;"><b>ONLINE RESEARCH: IT'S VIRTUALLY SAFE</b></p> <p style="text-align: center;"><b>MALLORY BALL, PHD, MPH, CIP</b> WESTERN CAROLINA UNIVERSITY</p> <p style="text-align: center;"><b>UNDI HOFFLER, PhD</b> DIRECTOR OF RESEARCH COMPLIANCE &amp; TECHNOLOGY TRANSFER NORTH CAROLINA CENTRAL UNIVERSITY</p> <p>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</p> <p style="text-align: center;"><b>0.75 CIP</b></p>	<p style="text-align: center;"><b>CHANCELLOR WEST</b></p> <p style="text-align: center;"><b>RI   RA</b></p> <p style="text-align: center;"><b>NAVIGATING NSF'S NEW MENTOR TRAINING REQUIREMENT: CHARTING A COURSE FORWARD FOR YOUR INSTITUTION</b></p> <p style="text-align: center;"><b>JOSHUA MANGIN, MS, LCPC-C, CCC</b> GRADUATE ASSISTANT FOR MERTEC GRADUATE MEDIA FELLOW FOR SCHOLARS STRATEGY NETWORK – MAINE DOCTORAL STUDENT IN THE LEADERSHIP PROGRAM UNIVERSITY OF SOUTHERN MAINE</p> <p>Taking into effect at the end of July 2023, the National Science Foundation will require Responsible and Ethical Conduct of Research to include training specifically on mentoring and mentorship. This session will explore the new NSF requirements and discuss and describe possible options to incorporate mentoring training and mentorship opportunities for your institution.</p>
	<b>SEE YOU IN THE AM FOR BREAKFAST!</b>		