IACUC	
IBC	
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 1 **MONDAY APRIL 24, 2023** **CONFERENCE AGENDA**

7:30 AM - 9:00 AM	**BREAKFAST … NETWORK … CONFERENCE SPONSOR BOOTHS**
9:00 AM	**WELCOME & INTRODUCTIONS** **SUZANNE WILKISON** PRESIDENT NCABR TBA CHARLOTTE FIELD OFFICE FBI
9:15 AM – 10:00 AM	**THREE I's SESSION**
Keynote **THREE I's**	**MODERN MOLECULAR TOOLS TO UNDERSTAND BRAIN FUNCTION** **SIMON GREGORY, PHD** PROFESSOR IN NEUROSURGERY VICE CHAIR FOR RESEARCH IN THE DEPARTMENT OF NEUROLOGY PROFESSOR IN MOLECULAR GENETICS AND MICROBIOLOGY PROFESSOR IN NEUROLOGY MEMBER OF THE DUKE CANCER INSTITUTE MEMBER OF DUKE MOLECULAR PHYSIOLOGY INSTITUTE Dr. Gregory is a tenured Professor and Director of the Brain Tumor Omics Program (BTOP) in the Duke Department of Neurosurgery, the Vice Chair of Research in the Department of Neurology, and Director of the Molecular Genomics Core at the Duke Molecular Physiology Institute (DMPI). As a neurogenomicist, Dr. Gregory applies his experience gained from leading the sequencing of chromosome 1 for the Human Genome Project to elucidating the mechanisms underlying multi-factorial diseases using genetic, genomic, and epigenetic approaches. Dr. Gregory's primary areas of research involve understanding the molecular processes associated with disease development and progression in brain tumors and Alzheimer's disease, novel drug induced white matter injury repair in multiple sclerosis, and social and behavioral response to oxytocin treatment animal models of autism. He is broadly regarded across Duke as a leader in the development of novel single cell and spatial molecular technologies towards understanding the pathogenic mechanisms of disease development. Dr. Gregory is also the Section Chair of Genomics and Epigenetics at the DMPI and Director of the Duke Center of Autoimmunity and MS in the Department of Neurology.

10:05 AM – 10:50 AM	**REGULATORY SESSIONS**		
	IACUC **OLAW UPDATE** **NEERA GOPEE, DVM, PHD, DABT, DACLAM** ASSOCIATE DIRECTOR ANIMAL WELFARE POLICY OFFICE OF LABORATORY ANIMAL WELFARE NATIONAL INSTITUTES OF HEALTH Don't miss out on the opportunity to learn about OLAW's initiatives to reduce administrative burden in response to the 21st Century Cures Act, trends in 2022 compliance reporting and so much more!	**IBC** **APHIS | TBA**	**IRB** **MAINTAINING A ROBUST HUMAN RESEARCH PROTECTION PROGRAM IN A SINGLE IRB WORLD** **NICHELLE COBB, PHD** SENIOR ADVISOR FOR STRATEGIC INITIATIVES ASSOCIATION FOR THE ACCREDITATION OF HUMAN RESEARCH PROTECTION PROGRAMS (AAHRPP) Since the implementation of the National Institutes of Health (NIH) policy and revised Common Rule requirements, institutions have been grappling with adapting to single IRB review for multi-site research. With the expectation that the Food and Drug Administration (FDA) will soon adopt a single IRB requirement, more institutions will need to comply with single IRB requirements for the first time or face a significant expansion of research that will require the use of a single IRB. In many cases, using external IRBs requires institutions to adopt new approaches to ensure appropriate oversight of research under their purview because their finely tuned human research protection programs (HRPPs) have been disrupted by the removal of a traditional compliance gatekeeper, the local IRB. Further, institutions must help researchers navigate a new world that involves working with many IRBs that differ in processes and policies from each other as well as those of a study team's local institution. This session will: 1. Explore the impact of single IRB on research teams, relying institutions, and reviewing IRBs 2. Provide examples of compliance challenges single IRB can present 3. Identify key approaches institutions should consider adopting to ensure they maintain effective HRPPs when a significant portion of their research is overseen by external IRBs
10:50 AM – 11:00 AM	**BREAK**		

11:05 AM - 11:50 AM	**BREAKOUT SESSIONS**	
	THREE I's Session **CREATING A COMMITTEE, WHAT HAS WORKED FOR YOU?** **ANNA HAMPTON, DVM, DACLAM, DACAW, CPIA** DIRECTOR, OFFICE OF ANIMAL WELFARE ASSURANCE CHAIR, INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE DUKE UNIVERSITY Join this brainstorming session to discuss Committee member requirements, recruitment, and retention. There will be a focus on successful strategies to form and maintain a well-balanced Committee.	**RESEARCH INTEGRITY | ADMINISTRATION** **WHAT DO WE MEAN WHEN WE SAY "CONFLICT OF COMMITMENT?"** **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 prominent within the federal regulations, federal funding agencies have ramped up their use of the term "conflict of commitment" when it comes to ensuring research security. However, that term has historically been used with very different connotations that continue to this day. This session will take a historical view of conflict of commitment, going back to the 1960s, to evaluate how the term originated and its utilization changed. Contemporary uses of the term, especially those related to inappropriate foreign influence in research, will then be discussed in details with the goal of establishing best practices for identifying conflicts in commitment in research.
11:55 AM – 12:40 PM	**LUNCH BREAK**	

12:45 PM – 1:30 PM	**AFTERNOON 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 **NEERA GOPEE, DVM, PhD** DIRECTOR DIVISION OF POLICY AND EDUCATION OFFICE OF LABORATORY ANIMAL WELFARE NATIONAL INSTITUTES OF HEALTH **DR KRISTIN NAPOLI** SUPERVISORY ANIMAL CARE SPECIALIST USDA	**IBC IRB** **GROWTH OF GENE THERAPY AND FDA GUIDANCE DOCUMENTS PERTINENT TO IBC REVIEW** **DANIEL EISENMAN, PhD, RBP, SM(NRCM), CBSP** EXECUTIVE DIRECTOR BIOSAFETY SERVICES ADVARRA – ADVANCING CLINICAL RESEARCH This session will cover: 1) Growth and current challenges within the field of gene therapy. 2) FDA guidance documents for gene therapy pertinent to IBC review. 3) Challenges Investigators may face when preparing to submit INDs for gene therapy products. This presentation will draw from two peer reviewed articles (attached) as well as the following webinar: A Guide for Successful Cell and Gene Therapy Research https://info.advarra.com/cell-and-gene-therapy-wbnr-od.html	**ADDRESSING INAPPROPRIATE FOREIGN INFLUENCE** **JOHN R. BAUMANN, PhD** ASSOCIATE VICE PRESIDENT FOR RESEARCH COMPLIANCE, INDIANA UNIVERSITY The latest compliance area to present itself to the research communality is that of 'foreign influence'. Whether from the NIH, the FBI, the Office of Science and Technology Policy or countless other agencies, the message is clear: be concerned about foreign influence. But, what is less clear is everything else – including how to integrate these efforts to reduce 'foreign influence' into the culture, practice and administration of research. In this session, panelists will address such topics as: • What is meant by 'foreign influence'? • Institutional responses to this concern – especially in light of the lack of clear regulations or even guidelines • Institutional attempts to protect against 'foreign influence' but, at the same time, continue to encourage and support international research collaborations.
1:35 PM – 2:20 PM			
	IACUC CHALLENGES: CASE STUDIES FROM REAL LIFE *continued …*	**BIOSECURITY | THREE I's** FBI WMD HEADQUARTERS ANIMAL – HUMAN SUSAN CROPP **RISK ASSESSMENT | TABLETOP Exercises**	
2:20 PM – 2:30 PM	**BREAK**		

2:30 PM – 3:15 PM			
	COMPLIANCE **DID SOMEONE SAY DIVERSION? WHAT TO DO WHEN CONTROLLED SUBSTANCES GO MISSING** **KELÉ PIPER** DIRECTOR, RESEARCH COMPLIANCE OFFICE OF COMPLIANCE MASSACHUSETTS GENERAL HOSPITAL When diversion occurs… • Don't panic! We will talk about where to start and what to do first. Each situation may be different, but let's discuss how to review the situation and determining next steps that would be core to any diversion. • After the first 24 hours...now what? The initial reports have been filed. The bleed has been stopped. Now the deep dive into the investigation to include interviews, audits, reports, and any immediate actions that need to be taken. • The aftermath, what happens with the dust settles? Implementing corrective actions, working with regulators, finding ways to proactively detect diversion, and education/training.	**CONTINUED …** **BIOSECURITY** **FBI HEADQUARTERS**
3:20 PM – 4:05 PM	**AFTERNOON SESSIONS**		
	IACUC IBC **COMMUNICATING SCIENCE TO THE PUBLIC** **LISA NEWBERN** CHIEF, PUBLIC AFFAIRS EMORY UNIVERSITY YERKES NATIONAL PRIMATE RESEARCH CENTER	**IBC RA** **BIOSAFETY CONSIDERATIONS FOR WORKING WITH GENETICALLY MODIFIED ARTHROPODS** **JANET GRIFFITHS** INSECTARY MANAGER BASF, NC New technologies are important for both agricultural and human health arthropod pests. Arthropods are becoming resistant to pesticides; pesticides have negative impacts on the environment; and many countries are restricting the use of highly hazardous pesticides. The use of genetic modification to both plants and arthropods is becoming an increasingly more ideal option to control pests and keep people safe and fed. This session will review the basics of genetic modification to arthropods,	**RI** **RI, RA** **WHEN THE @#&% HITS THE FAN: WHEN NONCOMPLIANCE AND RESEARCH MISCONDUCT OCCUR TOGETHER** **JOHN R. BAUMANN, PhD** ASSOCIATE VICE PRESIDENT FOR RESEARCH COMPLIANCE, INDIANA UNIVERSITY Research misconduct (Fabrication, Falsification and Plagiarism) is never good. But it becomes exponentially bad when it takes place within the context of or overlaps with non-compliance. The aim of this session is to explore the processes for and unique challenges of all compliance offices collaboration with

		provide some real-world examples, and discuss the biosafety considerations before and while working with GM arthropods. This will include what to discuss with your biosafety officer, required permits, Arthropod Containment Levels (ACL), as well as lab and field assay considerations.	Research Integrity/Misconduct Offices to identify, manage and resolve research misconduct allegations involving research.
4:15 PM	**NETWORKING … Meet, greet and network with all attendees and speakers.**		