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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 28, 2025** **CONFERENCE AGENDA**

7:30 AM - 9:00 AM	**BREAKFAST & NETWORK**		
9:00 AM	**WELCOME & INTRODUCTIONS** **SUZANNE W. WILKISON** | PRESIDENT NORTH CAROLINA ASSOCIATION FOR BIOMEDICAL RESEARCH (NCABR) **ROBERT DEWITT** SPECIAL AGENT IN CHARGE FBI CHARLOTTE FIELD OFFICE		
9:15 AM – 10:00 AM	**KEYNOTE ADDRESS** **THREE I's SESSION**		
Keynote **THREE I's** **NCABR** .75 CIP	**HUMANS AND MACHINES IN SCIENCE, ARE WE CONVERGING OR DIVERGING?** **MOHAMMAD HOSSEINI, MA, PHD** **ASSISTANT PROFESSOR** **FEINBERG SCHOOL OF MEDICINE, DEPARTMENT OF PREVENTIVE MEDICINE** **NORTHWESTERN UNIVERSITY**		
10:05 AM – 10:50 AM	**AM BREAKOUT SESSIONS**		
	IACUC OLAW UPDATE **VIRTUAL | Interactive** **GUIDELINES ON SIGNIFICANT CHANGE…STREAMLING PROTOCOL REVIEW, ANNUAL REPORT & CHECKLISTS** **NEERA V. GOPEE, DVM, PhD, DABT, DACLAM** ASSOCIATE DIRECTOR FOR ANIMAL WELFARE POLICY OFFICE OF LABORATORY ANIMAL WELFARE, NIH .75 CPIA	**IBC** **NIH GUIDELINES… HOW DO THEY IMPACT IBC REVIEW?** **ANTONY SCHWARTZ, PhD SM(NRCM), CBSP(ABSA)** BIOSAFETY OFFICER RESPONSIBLE OFFICIAL | DIRECTOR, BIOLOGICAL SAFETY DIVISION ADJUNCT ASSISTANT PROFESSOR DUKE SCHOOL OF MEDICINE **TED MYATT, ScD** ASSOCIATE VICE PROVOST OF RESEARCH INTEGRITY TUFTS UNIVERSITY	**IRB** **THE SINGLE IRB LANDSCAPE: WHERE WE ARE AND WHERE WE'RE GOING?** **NICHELLE COBB, PhD, CIP** SENIOR ADVISOR FOR STRATEGIC INITIATIVES AAHRPP .75 CIP

10:50 AM – 11:00 AM	**BREAK**		
11:05 AM - 12:00 PM	**BREAKOUT SESSIONS ALL I's**		
	IACUC | IBC **RNDNA & ANIMAL BIOSAFETY** **IACUC FORM, FUNCTION AND INTERACTION** **PAULNISHA D GRANGER-KOONCE, MS** RESEARCH COMPLIANCE OFFICER IACUC & IBC ADMINISTRATOR OFFICE OF RESEARCH COMPLIANCE & ETHICS DIVISION OF RESEARCH & ECONOMIC DEVELOPMENT NORTH CAROLINA A&T STATE UNIVERSITY **ROBERT NEWMAN, PhD** NATHAN F SIMMS DISTINGUISHED PROFESSOR DEPARTMENT OF BIOLOGY NORTH CAROLINA A&T STATE UNIVERSITY In a world of interdisciplinary science, compliance committees are constantly working together to ensure regulatory measures are in place to manage the safety of its participants. In this session, we will discuss the importance of the cross-talk between the IACUC and the IBC as it relates to recombinant or synthetic nucleic acid molecules (rDNA, rRNA etc.) in animal research. This includes discussing information pertinent to IACUC and IBC forms, the extent of each committee's oversight and means of communication between the committees during protocol review, facility inspection and post-approval monitoring. The speakers encourage discussion of how various institutions undergo this process. .75 CIP	**IBC** **BIOSECURITY CHALLENGES IN A TIME OF CHANGE** **SUSAN N CROPP, PHD** CHEMICAL BIOLOGICAL COUNTERMEASURES UNIT FBI HEADQUARTERS	**RI | COMPLIANCE** **INCORPORATING RESEARCH SECURITY AND EXPORT CONTROLS INTO RCR TRAINING PROGRAMS** **TORREY TRUSZKOWSKI, PhD** ASSISTANT DIRECTOR RESEARCH SECURITY AND EXPORT CONTROLS BROWN UNIVERSITY RCR programs have long been beholden to topic lists from both NIH and NSF. With the next PAPPG, NSF is expanding that topic list to include research security and export controls. In this presentation, you will be introduced to a few different successful ways of adding this content to your RCR courses, including as an eLearning component, a live presentation, and case studies. In addition, we will discuss how elements of research security training can cover other required topics. Participants will leave with concrete, straightforward ways to meet the new requirements that will keep the administrative burden on the RCR facilitators and researchers as low as possible.
12:05 PM - 1:05 PM	**LUNCH & Networking!**		

1:05 PM – 2:05 PM BIO ISAC | Cybersecurity	**UNINTENDED CONSEQUENCES, UNMET NEEDS: CYBERBIOSECURITY**		
	WHITNEY ZATZKIN **BIOECONOMY INFORMATION SHARING AND ANALYSIS CENTER** We have placed enormous demand on the bioeconomy. Are we prepared to defend it? Advancements in biomanufacturing and biotechnology drive the science we need to thrive, everything from apples to vaccines. This session reviews the current state of cyberbiosecurity defense, focusing on a handful of incidents and research from the last three years that demonstrate the connectivity between industry, systems, and threats. Following the review, we will detail what researchers, individuals, and organizations can do, starting today, about this issue through the use of cyberbiosecurity hygiene principles.		
2:10 PM – 2:55 PM	**AFTERNOON SESSIONS**		
	IS ALL GOING AS PLANNED? ENSURING PROTOCOL COMPLIANCE THROUGH POST APPROVAL MONITORING **CECE BROTCHIE-FINE, DBe, CPIA** EXECUTIVE DIRECTOR, ETHICS NOVARTIS ETHICS, RISK AND COMPLIANCE, R&D **CHRISTOPHER MANGELLI, JD, MS, M. ED, CIP** ASSISTANT VICE PROVOST FOR RESEARCH (AVPR), OFFICE OF RESEARCH BALL STATE UNIVERSITY Increasing research complexity, institutional and public pressures, and changing regulations all increase the challenges of providing ongoing study oversight to animal and human research programs. Nonetheless, institutions must still maintain oversight through its IACUC and HRPP. Post approval monitoring (PAM) programs can buttress compliance while also serving as a pathway for providing ongoing education and for forging stronger relationships with researchers. There are various approaches to PAM in both fields, but what should we do with the outcomes? While some results may provide straightforward resolutions, other outcomes	**IBC** **EXPORT CONTROL** **TBA** **COMMERCE**	**ASSOCIATIONS AMONG METCOGNITION, SELF-REGULATION AND ADVANCED ETHICAL REASONING IN STEM STUDENTS** **ROBERT BRUCE THOMPSON, MA, PhD** PROFESSOR OF PSYCHOLOGY - HUMAN DEVELOPMENT DIRECTOR, MAINE REGULATORY TRAINING & ETHICS CENTER (MERTEC) **ROSS HICKEY, JD** ASSISTANT PROVOST FOR RESEARCH INTEGRITY AT THE UNIVERSITY OF SOUTHERN MAINE (USM) **CAROL NEMEROFF, PhD** DEAN AND PROFESSOR UNIVERSITY OF NEW BRUNSWICK PRINCIPAL, AT THE MAINE REGULATORY TRAINING AND ETHICS CENTER (MERTEC) This presentation reports on Phase 1 of an NSF funded study (NSF 22-526) investigating a facet of research ethics not often addressed in RCR/ethics literature: Researchers' individual capacity for metacognitive reasoning and its role in evaluating tiers of ethical decision-making and misconduct. Many ethics and RCR trainings incorporate aspects of metacognition (mindfulness, self-

	may be complex, illustrate need for programmatic change, or involve internal and external reporting. This session will include a high-level summary of PAM, followed by a more in-depth review & discussion of the “what to do” question facilitated through vignettes of PAM outcomes. .75 CPIA		reflection), but a critical premise that requires exploration is that differences in baseline metacognition may predict important levels of moral cognition (Kohlberg, 1976) known to correlate with ethical resilience. The Study: Sixty undergraduate STEM students completed a battery of self-report assessments exploring socio-demographics: gender, ethnicity, age, family educational and occupational background. Participants completed two self-regulation instruments: the Applied Mindfulness Process Scale (AMPS); and the Behavior Rating Inventory of Executive Function (BREIF-A). Both assess individuals' ability to regulate emotions, remain mindful and self-reflective when stressed or pressured. However, an important difference is that the BRIEF-A is a clinical diagnostic tool to identify dysfunction (emotion/behavioral dysregulation) due to poor executive functioning; whereas the AMPS is a measure that captures individuals' capacity for active mindfulness and deliberate efforts to self-regulate. Our primary outcome variables were adapted from the Engineering and Science Issues Test (ESIT). Participants evaluated multi-tiered, ethically complex case scenarios involving misconduct designed to map onto Kohlberg's (1976) developmental levels of ethical reasoning: preconventional (simplistic, extrinsic); conventional (reputation and social standing); and finally, post-conventional (intrinsic, values-based). Comparison Groups: no background in ethics training; CITI training; students in conventional ethics courses, but no CITI training. Results: Our socio-demographic variables did not correlate with ethical reasoning. Participants with CITI training, as expected, trended

			non-significantly towards post-conventional levels of ethical reasoning. Our main hypothesis—that individuals' level of metacognitive reasoning ability would predict advanced forms of ethical analysis, was confirmed. Partial correlations, controlling for age and family SES revealed overall scores on the AMPS, and in particular, sub-scales about people's ability to objectively and critically evaluate the validity of their thought processes ("decentration") were found to correlate significantly with their capacity to identify ethical features of case scenarios at the post-conventional reasoning stage. Unexpectedly our hypothesis that executive function (BRIEF-A) would predict participants' ethical reasoning was not supported, and in some cases scores for strong ethical reasoning was associated with doing poorly on the BRIEF-A. Since the BRIEF-A is a clinical, diagnostic tool, this result raises the broader question about whether misconduct (as a facet of poor ethical reasoning) is a function of executive dysregulation or deficits in deliberate efforts at mindfulness. Summary/Conclusions: These results do support a link between metacognition and the ability to evaluate complex layers of ethical issues. However, they also suggest that design of RCR/ethics trainings may benefit from evaluation of individuals' level of self-regulation within these domains, in order maximize the impact of RCR/ethics education.
3:00 PM- 3:15 PM	**BREAK**		

3:15 PM – 4:00 PM	ALL I's – Biosecurity – Research Administration – Research Integrity	
	PHS FINAL RULE ON RESEARCH MISCONDUCT - WHAT INSTITUTIONS NEED TO KNOW **ELIZABETH J. MCEVOY** MEMBER OF THE FIRM EPSTEIN BECKER GREEN **MARYLANA SAADEH HELOU** MEMBER OF THE FIRM EPSTEIN BECKER GREEN On September 12, 2024, the U.S. Department of Health and Human Services (DHHS) issued final regulations updating for the first time since 2005 how hospitals, universities, and other institutions must respond to allegations of research misconduct (fabrication, falsification or plagiarism) in their U.S. Public Health Service (PHS)-funded research. The final regulations (PHS Final Rule), effective January 1, 2025, bring significant changes and clarifications in substantive definitions and required due process and procedures for investigating and reporting such allegations, while leaving behind some of the more controversial proposals from the DHHS notice of proposed rulemaking (NPRM) published last year. Institutions have until January 1, 2026 to comply with the PHS Final Rule but should not delay evaluating how their current research misconduct policies and practices will need to evolve to reflect the changes. Institutions and their researchers need to understand how the PHS Final Rule will affect them, and institutions must plan ahead to ensure compliance. As experienced advisors and advocates in the field of research misconduct, we will lead an interactive discussion reviewing the PHS Final Rule's key changes and clarifications and identify challenges remaining for institutions and researchers in interpreting the regulations as well as provide practical suggestions for institutions in revising their policies and practices.	**ALL THREE I's** **COMPLIANCE PROCESS FOR SAFE AND SECURE RESEARCH WITH SCHEDULE I CONTROLLED SUBSTANCES** **WILLIAM J. HEUETT, PhD** UNIT CHIEF SCHEDULE I RESEARCHER AND INTERNATIONAL CONTROL UNIT DRUG AND CHEMICAL EVALUATION SECTION DIVERSION CONTROL DIVISION DRUG ENFORCEMENT ADMINISTRATION Schedule I controlled (CI) substances (e.g., MDMA, THC, psilocybin, heroin, etc.) are those that have a high potential for abuse, no currently accepted medical use, and a lack of accepted safety for use under medical supervision. The U.S. Controlled Substances Act (CSA) requires researchers to obtain a registration from the Drug Enforcement Administration (DEA) in order to conduct scientific or medical research with controlled substances. The regulatory scheme protects research, prevents diversion, disrupts unsafe promotion of substances by traffickers, and allows for safe and secure use of CI substances in research, from basic-science applications that are critical to increasing our understanding and aiding in our decision-making to clinical investigations of potential therapeutics that may benefit our communities. This presentation will provide a summary of active research areas over time, highlighting hallucinogens, cannabis/THC, and fentanyl analogues, and other informative statistics about the CI research program. It will also highlight the role of DEA's scientific staff and investigators in the review process and examine the shared responsibilities this compliance process has with other compliance committees.
4:15 PM	**MEET, GREET and NETWORK!** **GRAB A DRINK … ENJOY A FEW HORS D'OEUVRES** **MARRIOTT COURTYARD**	