





IACUC	
IBC	
IRB	
RA	
Bio ETHICS	
RESEARCH INTEGRITY COMPLIANCE REGULATORY THREE I'S BIOSECURITY	

THE THREE I'S (IACUC, IBC & IRB): RESEARCH INTEGRITY & BIOSECURITY™ PROMOTING RESEARCH, INTEGRITY AND COMPLIANCE BY PROVIDING TRAINING IN THE ETHICAL AND RESPONSIBLE CONDUCT OF RESEARCH

Day 1 APRIL 29, 2019

7:00 AM - 9:00 AM

CONFERENCE AGENDA

REGISTRATION and BREAKFAST

GENERAL SESSION	WELCOME & INTRODUCTION			
9:00 am	Suzanne Wilkison PRESIDENT, NCABR NORTH CAROLINA ASSOCIATION FOR BIOMEDICAL RESEARCH ON BEHALF OF			
		MSMR, NCABE	R & MeRTEC	
	SSA Gregory Kline/ASAC Charlotte CHARLOTTE FIELD OFFICE FEDERAL BUREAU OF INVESTIGATION			
9:15 AM – 10:00 AM				
GENERAL SESSION Keynote THREE I's	THE SYNCHRONY AND SYNERGY OF BRAIN RHYTHMS FLAVIO FROLICH, PHD ASSOCIATE PROFESSOR UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL NEUROSCIENCE CENTER			
10:05 AM - 10:50	AM			
The Research Administration Track is geared toward those in sponsored research administration and those new to the field of research compliance and ethics.	Research Administration IACUC/IRB/IBC 101 GENERAL RESEARCH COMPLIANCE FARIBA HOUMAN, PhD Research Compliance Officer RESEARCH ETHICS AND REGULATORY COMPLIANCE BOSTON CHILDREN'S HOSPITAL	IACUC OLAW NEERA GOPEE, DVM, PhD DIRECTOR DIVISION OF POLICY AND EDUCATION OLAW	IBC BEST PRACTICES FOR INSTITUTIONS ADAPTING TO A BOOM IN GENE THERAPY DANIEL EISENMAN, PhD, RBP DIRECTOR OF BIOSAFETY SERVICES ADVARRA	IRB THE COMMON RULE IS FINALLY REVISED WHERE DO WE GO FROM HERE? DANIEL NELSON ADJUNCT PROFESSOR OF SOCIAL MEDICINE AND PEDIATRICS FACULTY ASSOCIATE, CENTER FOR BIOETHICS UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL

10:55 AM - 11:10 AM

REFRESHMENT BREAK

11:15 AM - 12:00 PM

MORNING BREAKOUT SESSIONS

In these sessions the presenters will provide an introduction to the basic requirements of regulatory committees (IRB, IACUC, IBC) and sponsor nonfinancial compliance requirements (e.g., export control, data management, COI, Privacy) with a focus on how these requirements may impact externally funded awards.

Research Administration IACUC/IRB/IBC 101

ANIMAL WELFARE

CE CE BROTCHIE-FINE, MA, CPIA ASSOCIATE DIRECTOR & HEAD, AWC CAMBRIDGE NIBR CA IACUC CHAIR & ANIMAL WELFARE OFFICER NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH **IACUC IBC**

RISK ASSESSMENT FOR DIFFERENT ANIMAL MODELS: THE EVER-CHANGING PUZZLE

> biosafety risk assessment of different animal models

ANGELA C BIRNBAUM DIRECTOR OF BIOSAFETY TULANE UNIVERSITY IRB

USE OF AN AUTOMATED WIZARD TO PROCESS MINIMUM RISK RESEARCH

JANE A
MCCUTCHEON, DDS,
PHD
ASSOCIATE PROFESSOR
NYU

RI

THE FALSE CLAIMS
ACT'S APPLICATION
TO RESEARCH
INTEGRITY

DEREK M ADAMS
PARTNER
FELDESMAN TUCKER
LEIFER FIDELL LLP

12:00 PM - 12:45 PM

LUNCH IN THE BALLROOM

12:45 PM - 1:30 PM

AFTERNOON BREAKOUT SESSIONS

RESEARCH ADMINISTRATION IACUC/IRB/IBC 101

NONFINANCIAL COMPLIANCE

TED MYATT, ScD
ASSOCIATE VICE
PRESIDENT FOR
RESEARCH
ADMINISTRATION
UNIVERSITY OF RHODE
ISLAND

IACUC

IACUC TOOLS OF THE TRADE TO ENGAGE AND PROMOTE COMPLIANCE FOR CONTROLLED SUBSTANCES IN NON-HUMAN RESEARCH

KELÉ PIPER, MS, CIP, CHRC

DIRECTOR
RESEARCH COMPLIANCE
OFFICE OF COMPLIANCE
MASSACHUSETTS
GENERAL HOSPITAL

IACUC IBC

STANDARDIZING PRACTICES BETWEEN IACUC AND IBC TO IMPROVE/MAINTAIN QUALITY PROGRAMS

VICTOR CUEVAS

REGULATORY

COMPLIANCE MANAGER

THE JACKSON

LABORATORY

RI

OUTSIDE INFLUENCES ON RESEARCH AND ACADEMIC INTEGRITY

CHRIS MANGELLI,
JD

DIRECTOR, OFFICE OF RESEARCH INTEGRITY (ORI) BALL STATE UNIVERSITY

1:30 PM - 2:15 PM

RESEARCH ADMINISTRATION IACUC/IRB/IBC 101

BIOLOGICAL SAFETY

ANGELA C BIRNBAUM DIRECTOR OF BIOSAFETY TULANE UNIVERSITY IACUC

AT THE
INTERSECTION OF
CONFLICT OF
INTEREST & THE
IACUC: RE-EXAMINING
CONFLICTS IN ANIMAL
RESEARCH
OVERSIGHT

STACY PRITT, DVM,
MS, MBA, CPIA,
CHRC, DACAW
ASSISTANT VICE
PRESIDENT, COI & IACUC
UNIVERSITY OF TEXAS
SOUTHWESTERN MEDICAL
CENTER

IRB

TBA

REBECCA D.
ARMSTRONG, DVM,
PHD
DIRECTOR, RESEARCH

SUBJECT OR, RESEARCH
SUBJECT PROTECTION
OFFICE FOR PROTECTION
OF HUMAN SUBJECTS
OFFICE FOR ANIMAL CARE
AND USE
UC BERKELEY

RI

LYING, CHEATING AND STEALING: A PRIMER ON RESEARCH MISCONDUCT

JULIE SIMPSON,
PhD
DIRECTOR
AFFILIATE ASSISTANT
PROFESSOR OF
COLLEGE TEACHING &
OF EDUCATION
UNIVERSITY OF NEW
HAMPSHIRE

Review the foundations of ethical conduct in science;
Learn about research misconduct and federal requirements;
Review the research

	on research misconduct; Look at examples of research misconduct; Participate in case study discussions; and Learn about research misconduct resources.		
2:15 PM - 2:30 PM	REFRESHMENT BREAK		
2:30 pm - 4:00 pm	THREE I'S RESEARCH INTEGRITY & ETHICS™		
BALLROOM	RESEARCH INTEGRITY, BIOETHICS AND YOU™		
GENERAL SESSION	a hands-on/interactive session		
	Developed by MARLEY J THRASHER, M.ED DUKE UNIVERSITY		
	DOSS HICKEY ID CID CDIA		
	ROSS HICKEY, JD, CIP, CPIA ASSISTANT PROVOST FOR RESEARCH INTEGRITY		
	DIRECTOR, MAINE REGULATORY TRAINING AND ETHICS CENTER		
	MARCY BROWN, BS, MA, CMAR, CPIA		
	ANIMAL WELFARE AND IACUC PROGRAM SPECIALIST		
	ANGELICA N. MARTINS, PHD, RBP		
	INTERIM DIRECTOR OF RESEARCH COMPLIANCE RESEARCH AND ECONOMIC DEVELOPMENT		
	UNC CHARLOTTE		
	CASSANDRA MEYERS JENNIE OFSTEIN		
	IRB DIRECTOR OFFICE OF HUMAN RESEARCH ETHICS SPONSORED PROGRAMS AND		
	UNIVERSITY OF NORTH CAROLINA REGULATORY COMPLIANCE		
	AT CHAPEL HILL NORTH CAROLINA STATE UNIVERSITY		
	SA MATTHEW PERKINS/SA JOSHUA CANTER		
	WEAPONS OF MASS DESTRUCTION COORDINATORS		
	FEDERAL BUREAU OF INVESTIGATION CHARLOTTE/BOSTON FIELD OFFICES		
4:00 PM	DAY 1 EVALUATIONS		
4:00 PM	NETWORKING OPPORTUNITY!		
	MEET & GREET		
	Join your colleagues for a drink and appetizers in the registration area to unwind and share your conference experiences!		







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IBC	
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Day 2 April 30, 2020

CONFERENCE AGENDA

7:00 AM - 9:00 AM

REGISTRATION and BREAKFAST

8:30 AM

WELCOME TO DAY TWO! ROSS HICKEY, JD, CIP, CPIA

ASSISTANT PROVOST FOR RESEARCH INTEGRITY
DIRECTOR, MAINE REGULATORY TRAINING AND ETHICS CENTER (MeRTEC)

Moderator
CECE BROTCHIE-FINE, MA,
CPIA
Associate Director & Head,
AWC Cambridge
NIBR CA IACUC Chair &
Animal Welfare Officer
NOVARTIS INSTITUTES FOR
BIOMEDICAL RESEARCH

INTRODUCTION TO BIOETHICS ACROSS THE THREE Is and BIOSECURITY

ROBERT KLITZMAN, MD

PROFESSOR OF PSYCHIATRY
DIRECTOR, ONLINE AND IN-PERSON MASTERS OF BIOETHICS PROGRAM
COLUMBIA UNIVERSITY

9:50 AM - 10:35 AM

BREAKOUT SESSIONS

The pre-award folks will need to look closely at proposals to see if the activities involve collaboration with foreign colleagues/entities or if the sponsor itself is a non-US institution or entity, determine if there are any concerns, and coordinate with the compliance folks to figure out if any export control regulations are triggered. The compliance folks will need to look at conflict of interest disclosure forms from another angle when employees report relationships with foreign institutions

RESEARCH ADMINISTRATION

THE RISK OF FOREIGN INFLUENCE AND RESEARCH

ROBIN CYR
ASSOCIATE VICE
CHANCELLOR FOR
RESEARCH
UNC CHAPIL HILL

IACUC IBC

PRIMER ON BIOSECURITY REQUIREMENTS FOR SELECT AGENT RESEARCH

ANGELA C
BIRNBAUM
DIRECTOR OF
BIOSAFETY
TULANE UNIVERSITY

IRB

BRINGING YOUR IRB UP TO SPEED ON SOCIAL MEDIA RESEARCH CONTEXTS AND DILEMMAS

MONTANA MILLER, PHD

RESEARCH COMPLIANCE OFFICER & ASSOCIATE PROFESSOR BOWLING GREEN STATE UNIVERSITY

COMPLIANCE/ REGULATORY

RESEARCH RISK
ASSESSMENTS: A
TOOL TO IDENTIFY
RISK, DEVELOP A
WORKPLAN, AND
EFFECTIVELY
ALLOCATE
RESOURCES

KELÉ PIPER, MS, CIP, CHRC DIRECTOR RESEARCH COMPLIANCE OFFICE MASSACHUSETTS GENERAL HOSPITAL

10:35 AM - 10:45 AM		REFRESHMENT BREAK			
10:50 AM - 11:50 PM	GENERAL SESSION				
I HOUR SESSION	RESEARCH ADMINISTRATION	THREE Is	II	RB	RI
	GOOD FENCES MAKE GOOD NEIGHBORS: BUILDING A RELATIONSHIP BETWEEN SPONSORED PROGRAMS AND RESEARCH COMPLIANCE SHERRIE SETTLE DIRECTOR OF SPONSORED PROGRAMS AND REGULATORY COMPLIANCE SERVICES NORTH CAROLINA STATE UNIVERSITY JENNIE OFSTEIN IRB DIRECTOR SPONSORED PROGRAMS AND REGULATORY COMPLIANCE NORTH CAROLINA STATE UNIVERSITY	IACUC IBC IRB & BIOSECURITY SPOT THE ISSUES© TED MYATT, ScD ASSOCIATE VICE PRESIDENT FOR RESEARCH ADMINISTRATION UNIVERSITY OF RHODE ISLAND ELIZABETH KIPP CAMPBELL, PhD, CIP DIRECTOR OF RESEARCH COMPLIANCE MAINEHEALTH CHRIS MANGELLI, JD DIRECTOR, OFFICE OF RESEARCH INTEGRITY (ORI) BALL STATE UNIVERSITY MATTHEW MELLINI SENIOR IACUC PROTOCOL ADMINISTRATOR BRIGHAM AND WOMEN'S HOSPITAL FBI	THE COM CANNO STAND TH CASSAND C MIKE MA MS	IVIDED BY MON RULE OT ONLY , IT CAN RIVE RA MYERS, CIP FAMOROS, , CIP BERTS, CIP el Hill OHRE	NAVIGATING NORMS ANNE M CORBIN, JD, PhD JUSTICE POLICY MANAGER STATE OF VERMONT ROSS HICKEY, JD, CIP, CPIA ASSISTANT PROVOST FOR RESEARCH INTEGRITY DIRECTOR, MAINE REGULATORY TRAINING AND ETHICS CENTER
12:00 PM - 12:45 F	² M	LUNCH			
12:50 PM- 1:50 PM	AF	TERNOON BREAKC	UT SESSI	ONS	
I HOUR SESSION	SCIENCE & SOCIETY: USING YOUR VOICE AN YOUR STORY TO ADDRESS MYTHS, MAYHEM AND STRATEC MISUNDERSTANDINGS (A hands-on science communications sessio) SUZANNE WILKINSON PRESIDENT NCABR Framed as a general scien communications session. This session could have no animal people in attendar because of the important of all three I's! We will ha content for the IACUC People in the room.	JOSHUA CANTE JOSHUA CANTE FBI, Customs and Bo agents, the head of Security Program at US Attorney's O representative of the Commerce focused controls, and one or from USDA and the session is in response incidents that have at Airports with tra of biological materian important topic implications are hupting institution institution.	order Patrol the National the Boston office, a he Dept of on export two people CDC. This e to multiple taken place ensportation als. This is c because ge for both and the	HUMAN RESPROGRAM	IRB ING A HIGH QUALITY SEARCH PROTECTION (HRPP): THE AAHRPP MODEL I. SUMMERS, JD SIDENT AND CEO AAHRPP FEIGE, MSW, LCSW-C IVE VICE PRESIDENT AAHRPP

BREAK

1:50 PM - 2:05 PM

2:05 PM - 3:05 PM

This session uses a mixture of case studies, group discussion, and interactive exercises to identify best practices for resolving real-life IACUC challenges or issues. Faculty includes IACUC Program experts as well as representatives from OLAW and the USDA.

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 OLAW

MICHAEL NEAFSEY, DVM, MPH

ASSISTANT DIRECTOR OF FIELD OPERATIONS USDA APHIS - ANIMAL CARE

RISK ASSESSMENT/TCE

SA JOSHUA CANTER SA MATTHEW PERKINS

IRB / RI INFORMATION, INTEGRITY, AND IRBS (THREE IS) IN THE ERA OF SOCIAL DATA

ELIZABETH A BUCHANAN, PhD

ENDOWED CHAIR AND DIRECTOR,
CENTER FOR APPLIED ETHICS
ACTING DIRECTOR, OFFICE OF
RESEARCH AND SPONSORED
PROGRAMS
UNIVERSITY OF WISCONSIN-STOUT
WISCONSIN'S POLYTECHNIC
UNIVERSITY

JULIE F SIMPSON, PhD

DIRECTOR, RESEARCH INTEGRITY
SERVICES
AFFILIATE ASSISTANT PROFESSOR OF
COLLEGE TEACHING & OF EDUCATION
UNIVERSITY OF NEW HAMPSHIRE

3:10 PM - 3:55 PM

IACUC CHALLENGES: CASE STUDIES FROM REAL LIFE

Continued!

THREE I's

ETHICAL CONCERNS OF FOREIGN INFLUENCE

MARY BETH KOZA

TREASURER - DIVISION OF CHEMICAL HEALTH & SAFETY OF THE ACS

IRB

DATA SECURITY AND PRIVACY: A PRACTICAL APPROACH TO PROTECT CONFIDENTIALITY

LISA DESANTES

RESEARCH REVIEW SPECIALIST UNIVERSITY OF PITTSBURGH

4:00 PM

EVALUATIONS!





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Day 3 MAY 1 2020

Day 3 MAY 1, 202	20 CONFERENCE AGENDA		
7:00 AM - 9:00 AM	REGISTRATION & BREAKFAST		
	WELCOME TO OU JAMES (JIM) O'REILLY,		
9:00 AM - 10:45 AM	MORNIN	G SESSION	
MODERATORS: WILL SO SONIA HUNT	CHALLENGES OF FOREIGN INTEREST, DUE DILIGENCE, INTER AND CONFLICT OF INTEREST SPECIAL AGENT MATTHEW PERKINS, WMD Coordinator, FBI SSA Gregory Kline, Charlotte Division US Attorney's Office Representative (TBD) We will address foreign influence and cyber threat to universities, its research, and the protection of intellectual property rights from a North Carolina perspective. The panel would consist of special agents who specialize in Counterintelligence, Cyber Security, and Biosecurity. DEVELOP PROCESSES & CONTROLS CRITICAL ELEMENTS OF A PLAN INVOLVE & Communicate to ALL the plan		
10:50 AM - 11:00 AM	REFRESHMENT BREAK		
11:00 AM - 12:00 PM	BREAKOUT SESSIONS		
THREE I'S SESSIONS DEB FROLICHER DIRECTOR IACUC OFFICE THE SCRIPPS RESEARCH INSTITUTE MARCY BROWN, BS, MA, CMAR, CPIA ANIMAL WELFARE AND IACUC PROGRAM SPECIALIST	Abstract: Dependent on the nature of the stem cell research, approval may be required from the IRB, the IBC and the IACUC. In 2005, a well-known case of scientific misconduct involved stem cell research. What should be considered when your institution conducts stem cell research? DANIEL EISENMAN, PHD, RBP, SM(NRCM), CBSP JOSEPH ANDREWS, PHD, CIP, CCRP Assistant Dean Regulatory Affairs & Research Integrity Wake Forest School of Medicine	RESEARCH WITH NATIVE AMERICAN AND INDIGENOUS POPULATIONS: ETHICAL AND REGULATORY PERSPECTIVES FROM A TRIBAL IRB ADMINISTRATOR HEATHER LARSEN, MEd RESEARCH SPECIALIST/TRIBAL IRB ADMINISTRATOR	RI NAVIGATING FOREIGN INFLUENCE IN THE LAB: What Institutions Should Know about Disclosures, the 'China Initiative' and Protecting US-based Research ELIZABETH MCEVOY, Esq PARTNER BARRETT & SINGAL

12:00 PM - 12:45 PM	LUNCH			
12:50 PM - 1:35 PM	BREAKOUT SESSIONS continued			
	IACUC JEOPARDY! MARCY BROWN, BS, MA, CMAR, CPIA ANIMAL WELFARE AND IACUC PROGRAM SPECIALIST DEB FROLICHER DIRECTOR IACUC OFFICE THE SCRIPPS RESEARCH INSTITUTE	RCR AS ETHICS, NOT COMPLIANCE ROBIN TYNDALL DIRECTOR, RESEARCH PROTECTIONS APPALACHIAN STATE UNIVERSITY	THREE I'S BIOETHICS Q & A TBD CASE STUDIES ROBERT KLITZMAN, MD PROFESSOR OF PSYCHIATRY DIRECTOR, ONLINE AND IN-PERSON MASTERS OF BIOETHICS PROGRAM COLUMBIA UNIVERSITY BARBARA GARIBALDI, DVM, DACLAM DIRECTOR, ANIMAL RESEARCH FACILITY BETH ISRAEL DEACONESS MEDICAL CENTER FARIBA HOUMAN, PhD RESEARCH COMPLIANCE OFFICER RESEARCH ETHICS AND REGULATORY COMPLIANCE BOSTON CHILDREN'S HOSPITAL TODD KUIKEN, PhD SENIOR RESEARCH SCHOLAR GENETIC ENGINEERING AND SOCIETY CENTER NCSU JOSHUA CANTER FBI,WMD	
1:40 PM - 2:25 PM		BREAKOUT SESSIONS C	ontinued	
	INTEGRATING AND MANAGING START-UPS IN AN ACADEMIC INSTITUTION REBECCA D ARMSTRONG, DVM, PhD DIRECTOR, RESEARCH SUBJECT PROTECTION UC BERKELEY	THREE I'S continued BIOETHICS Q & A TBD CASE STUDIES		
2:30 PM - 2:40 PM	REFRESHMENT BREAK			
2:45 PM - 3:45 PM	FINAL SESSION for 2020!			
THREE I's SESSION	HOW INCREASED COMMUNICATIONS AND TRANSPARENCY TRANSLATE INTO IMPROVED SECURITY AND REDUCED RISK JIM NEWMAN DIRECTOR OF STRATEGIC COMMUNICATIONS AMERICANS FOR MEDICAL PROGRESS (AMP)			
3:50 PM - 4:00 PM	CLOSING REMARKS and EVALUATIONS SEE YOU NEXT YEAR in PORTSMOUTH, NH!			
	MAY 3 - 5, 2021			