

THE THREE I's & BIOSECURITY™: Creating Connections, Sharing Solutions & Building Strategies...

THE RENAISSANCE HOTEL DOWNTOWN

5 Avenue of the Arts

Providence, RI 02903

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MSMR
SUPPORTING BIOMEDICAL SCIENCES
IN NEW ENGLAND



Half-day Pre-program

WEDNESDAY, April 19, 2017

12:00 PM - 5:00 PM

Option 1: UNDERSTANDING THE AREAS OF COMPLIANCE INTERSECTION: A GUIDE TO UNDERSTANDING AREAS OF COMPLIANCE BEYOND THE IACUC AND IBC

BEETHOVEN ROOM

KERI G GODIN, MS

Director, Office of Research Integrity
Brown University

KATHRYN MELLOUK

Associate Vice President
Research Compliance
Boston University

1. Understand the major regulations and guidance governing research involving human subjects, animals, and biological safety. Understand when review are required by multiple committees.
2. Identify strategies to effectively manage committees and best practices for coordination of review and oversight for research requires review from multiple committees.
3. Develop an understanding of federal grants management policy, including requirements for review and oversight of research involving recombinant DNA (rDNA), human subjects, and animal subjects.
4. Discuss other compliance issues, such as export controls, financial conflicts of interest, and research misconduct and their potential relation to research reviewed by the three I's (e.g., IRB, IACUC, IBC).

An understanding of the range of research compliance areas and the regulations and guidance that underpin these areas can be beneficial to compliance professionals. For example, research typically

encountered by animal welfare professionals and IACUCs may also require Institutional Biosafety Committee (IBC) or Institutional Review Board (IRB) review and oversight. In order to develop strategies on dealing with these areas of overlap, it is helpful to have a solid understanding of IRB, IACUC, and IBC regulations and guidance. This knowledge can be used to develop best practices at your institution and in turn, reduce the regulatory burden on investigators. Additionally, comprehension of the regulations and guidance governing research involving human subjects and animal subjects, export controls, financial conflicts of interest will expand a course participant's area of expertise, potentially leading to new opportunities within an institution's overall research compliance structure.

The course will be taught with a mixture of didactic lecture, case studies and interactive exercises.

Option 2: THE MAGIC OF ENGAGEMENT: FOCUS ON THE LEARNER AND BUILD EFFECTIVE TRAINING PROGRAMS

MOZART ROOM

MARLEY THRASHER

Assistant Director, Education and Communications
North Carolina State University

Description:

How can you build a training program that not only meets organizational needs and ensures compliance, but also provides a compelling experience for your learners? What do learners need to truly engage in training and retain and apply content after they leave?

In this ½ day "WORKSHOP," you'll identify best practices for creating an effective training program that meets organizational and learner needs – and helps assure compliance. Learn how to assess training needs, identify and implement appropriate training methods, develop content with the learner in mind and evaluate outcomes. This interactive session will include case studies, small-group discussions, self-reflection and feedback on specific challenges participants face.

Learning Objectives:

After attending this session, you can:

- Develop a training strategy that aligns with organizational mission and goals
- Assess needs to identify if training is the right solution
- Understand the needs of an adult learner
- Design a training program to ensure specific goals are accomplished
- Apply a framework to evaluate new and current training solutions
- Identify appropriate training modes and methods
- Locate tools and resources you can use back home

Option 3: IACUC = Implementing Assurance Compliance Understanding and Confidence –

A NUTS AND BOLTS APPROACH TO IACUCS AND ANIMAL CARE AND USE PROGRAMS®

HAYDN ROOM

MARCY BROWN, BS, MA, CPIA
PRIM&R CPIA Council Vice-chair
AAALAC, Intl ad hoc Specialist

DEB FROLICHER, BS, CPIA
Director, IACUC Office
The Scripps Research Institute

IACUC Nuts and Bolts® is a half-day course that provides attendees with knowledge and information of the key elements of the IACUC relationship to an institution's animal care and use program. After attending this course, attendees will understand: the key elements of an effective IACUC program, the primary functions of the IACUC including protocol review, how to conduct semiannual inspections and program review, how to review animal welfare concerns, and the reporting responsibilities of the IACUC. In addition, faculty will describe the IACUC's role in overseeing post approval monitoring and the institution's training program for animal users.

This program is designed for IACUC members, IACUC administrators and support staff, institutional officials, and training and compliance personnel.

12:00-12:15 PM	Introduction
12:15-12:45 PM	Animal Care Programs and the IACUC – An Overview <ul style="list-style-type: none">* Key Elements of an Effective Program* Key Players: Their Roles & Responsibilities
12:45–1:30 PM	Functions of an IACUC: Protocol Processing <ul style="list-style-type: none">* Requirements for Review* FCR, DMR, and VVC
1:30-2:15 PM	Functions of an IACUC: Semiannual Program Evaluation and Facility Inspections <ul style="list-style-type: none">* Staying on top of semiannual inspections* Review methods* Review documentation
2:15-2:30 PM	Break
2:30-3:00 PM	Functions of an IACUC: Role in Overseeing the Training Program
3:00-3:30 PM	Functions of an IACUC: Role in Postapproval Monitoring PAM Methods Making the most of what you already do!

3:30-4:00 PM	Functions of an IACUC: Investigating Concerns and Noncompliance <ul style="list-style-type: none">* Sources of Concerns* Approaches to Investigations* Suspensions
4:00-4:30 PM	Functions of an IACUC: Reporting Responsibilities <ul style="list-style-type: none">* Reports to the Institutional Official* Reports to External Agencies
4:30-5:00 PM	Q & A
5:00 PM	Program concludes

The 2-day Conference Program is below



IACUC	SYMPHONY A
IBC	MOZART ROOM
IRB	BEETHOVEN ROOM
GENERAL	SYMPHONY A

THE THREE I's & BIOSECURITY™: Creating Connections, Sharing Solutions & Building Strategies...

Day 1 THURSDAY, April 20, 2017 CONFERENCE AGENDA

7:00 am	REGISTRATION and BREAKFAST	
8:00 am	WELCOME & INTRODUCTION ALAN DITTRICH, PhD, PRESIDENT, MSMR EDWARD YOU, SUPERVISORY SPECIAL AGENT, FBI	
8:05 am – 8:55 am	THREE I's SESSION	
Keynote		BENCH-TO-BEDSIDE TRANSLATIONAL VACCINE DEVELOPMENT DAN BAROUCH, MD, PhD Professor of Medicine Harvard Medical School Ragon Institute of MGH, MIT, and Harvard Director, Center for Virology and Vaccine Research Beth Israel Deaconess Medical Center
9:00 am – 10:30 am	THREE I's SESSION	
MEDIA/ panel - TBA		BIOSECURITY AND EFFECTIVELY COMMUNICATING VIA SOCIAL MEDIA LISA NEWBERN Chief, Public Affairs Emory University, Yerkes National Primate Research Center DEBRA SPEERT, PhD Director of Communications FASEB AMANDA DETTMER, PhD Speaking of Research FBI

10:35am – 10:50 am		BREAK		
10:55 am – 11:40 am		REGULATORY AM SESSIONS		
		OLAW UPDATE EILEEN MORGAN Director, Division of Assurances Office of Laboratory Animal Welfare, NIH	USG POLICIES FOR DURC OVERSIGHT AND GOF RESEARCH KATHRYN HARRIS PhD, RBP <i>(contractor)</i> Senior Outreach and Education Specialist National Institutes of Health Office of Science Policy	COMMON RULE REVISIONS JEFFREY M. COHEN, PH.D., CIP Senior Advisor HRP Consulting Group, A Division of BRANY CHERYL SAVINI, CIP Senior Vice President HRP Consulting Group
11:45 am – 12:30 pm		THREE I's SESSION		
		RESEARCH MISCONDUCT CASES: ANTICIPATING AND MITIGATING RISKS ROSS HICKEY, J.D., CIP, CPIA Assistant Provost for Research Integrity Director Maine Regulatory Training and Ethics Center		
12:30 pm – 1:15 pm		LUNCH IN SYMPHONY B		
1:20 pm – 2:35 pm		SPECIAL TOPIC SESSIONS!		
		IACUC - IBC ANIMAL TRANSPORT: THE GREY AREA ANGELA C BIRNBAUM Director of Biosafety Tulane University	IBC DUAL USE UNCHARTED WATERS: ENSURING RESPONSIBLE RESEARCH ON THE FRONTIER D. BEN GORDON, PhD Director MIT-Broad Foundry for Synthetic Biology	IRB KEEPING IT COMPLIANT IN CLINICALTRIALS.GOV KELÉ PIPER, MS, CIP, CHRC Director, Research Compliance Beth Israel Deaconess Medical Center
2:40 pm – 3:00 pm		REFRESHMENT BREAK		


3:00 pm – 5:00 pm	THREE I's SESSION	
		<p>BEST PRACTICES AMONG THE THREE I's ... SHARING, INTEGRATION AND OVERLAPPING ... STREAMLING THE PROCESSES AND REDUCING BURDEN...</p> <p>MARCY BROWN, BS, MA, CPIA PRIM&R CPIA Council Vice-chair AAALAC, Intl ad hoc Specialist</p> <p>ANGELA C BIRNBAUM Director of Biosafety Tulane University</p> <p>JODY POWER, MS, MBA, CIP Executive Director Institutional Review Board Duke University Health System</p>
5:00 pm – 6:30 pm		<p>SYMPHONY FOYER</p> <p>MEET & GREET WELCOME RECEPTION with CASH BAR!</p>

Day 2 Agenda is below

Day 2 FRIDAY, APRIL 21, 2017 CONFERENCE AGENDA

7:00 am	REGISTRATION BREAKFAST		
8:00 am	WELCOME TO DAY TWO!		
NEW!	AM SPECIAL TOPICS		
8:05 am – 8:25 am	<p>IACUC – IBC</p> <p>GAP ANALYSIS AND RELATIONSHIP BUILDING</p> <p>ANGELA C BIRNBAUM Director of Biosafety</p> <p>DANA BURNS Assistant Director of Biosafety</p> <p>SEAN FITZGERALD Senior Biosafety Officer Tulane University</p>	<p>IACUC - IBC</p> <p>USING THE BIORISK MANAGEMENT AMP MODEL (ASSESSMENT, MITIGATION, PERFORMANCE) TO EVALUATE AUTHORIZED ACCESS</p> <p>LOUANN C. BURNETT, MS, CBSP International Biological and Chemical Threat Reduction Sandia National Laboratories</p>	<p>IRB</p> <p>REGULATORY OVERSIGHT and CRISPR</p> <p>P. PEARL O'ROURKE, MD</p> <p>Director Human Research Affairs</p> <p>Partners HealthCare</p>
	AM BREAKOUT SESSIONS		
8:30 am – 9:15 am	<p>IACUC – IBC</p> <p>GAP ANALYSIS AND RELATIONSHIP BUILDING</p> <p><i>Continued!</i></p>	<p>IACUC - IBC</p> <p>USING THE BIORISK MANAGEMENT AMP MODEL (ASSESSMENT, MITIGATION, PERFORMANCE) TO EVALUATE AUTHORIZED ACCESS</p> <p><i>continued ...</i></p>	<p>IRB</p> <p>REGULATORY OVERSIGHT and CRISPR</p> <p><i>continued ...</i></p>
9:20 am -9:35 am	AM BREAK		

9:40 am – 10:40 am	AM BREAKOUT SESSIONS		
	<p>IACUC CHALLENGES: CASE STUDIES FROM REAL LIFE</p> <p>MARCY BROWN, BS, MA, CMAR, CPIA Animal Welfare & IACUC Program Specialist PRIM&R CPIA Council Chair AAALAC, Intl ad hoc Specialist</p> <p>DEB FROLICHER, BS, CPIA Director, IACUC Office The Scripps Research Institute</p> <p>EILEEN MORGAN Director, Division of Assurances OLAW</p> <p>WILLIAM STOKES, DVM, DACLAM, DACAW, BCES, FATS Assistant Director, Animal Welfare Operations USDA, APHIS, Animal Care</p>	<p>THREE I's</p> <p>EXPORT CONTROLS INVOLVING BIOLOGICALS</p> <p>JEFF M. SEO, JD, LLM Assistant Vice Provost for Research Compliance Northeastern University</p>	<p>IRB</p> <p>BIG DATA</p> <p>ELIZABETH A. BUCHANAN, PH.D. Interim Director Office of Research and Sponsored Programs University of Wisconsin-Stout</p>
10:45 am – 11:30 am			
	<p>IACUC CHALLENGES <i>CONTINUED</i></p>	<p>THREE I's</p> <p>SPOT THE ISSUES!</p>	

		<p>KATHRYN A HOLTHAUS, MS, MA Director of Research Subjects Protection and Laboratory Safety Compliance Research Administration and Compliance Brigham and Women's Hospital</p> <p>KATHRYN HARRIS PhD, RBP (contractor) Senior Outreach and Education Specialist National Institutes of Health Office of Science Policy</p> <p>JEFF M. SEO, JD, LLM Assistant Vice Provost for Research Compliance Northeastern University</p> <p>FBI</p>	
11:35 am – 12:20 pm		BREAKOUT SESSIONS	
	<p>IACUC CHALLENGES <i>CONTINUED</i></p>	<p>IACUC, IBC & IRB EMERGING PATHOGENS & DISEASE</p> <p>PAULA AUSTIN Task Force Officer Albuquerque Division FBI, WMD</p>	<p>IRB INFORMED CONSENT: IMPROVING THE PROCESS AND INTERPRETING THE PRINCIPLES IN THE REVISED REGULATIONS</p> <p>ELIZABETH BANKERT Director, Committee for the Protection of Human Subjects Dartmouth College</p> 
12:25 pm – 1:15 pm		LUNCH	
1:20 pm – 3:00 pm		PM BREAKOUT SESSIONS	
<p>Moderators CECE BROTCHE-FINE NIBR</p> <p>Will So, PhD FBI, WMD</p>		<p>DISASTER PLANNING!</p> <p>Biosecurity Theme: Active threats; classified research; insider threat training; cyber security</p> <p>KEITH ASTROFSKY, DVM Independent Consultant</p> <p>LYNELL DUPEPE, BS, RLATG, CMAR Associate Director, Department of Comparative Medicine TULANE UNIVERSITY</p> <p>ELIZABETH A. BUCHANAN, PHD Interim Director</p>	

		<p>Office of Research and Sponsored Programs University of Wisconsin-Stout</p> <p>CAROLYN STAHL, RS, CBSP Senior Officer MIT</p> <p>RONNELL HIGGINS Chief, Yale Police Yale University</p> <p>ALAN DITTRICH, PHD President MSMR, Inc</p> <p>PAULA AUSTIN Task Force Officer Albuquerque Division FBI, WMD</p>
3:00 pm – 3:10 pm		REFRESHMENT BREAK
3:15 pm – 5:00 pm		<i>CONTINUED ...</i>
		DISASTER PLANNING!
GENERAL SESSION		Closing Remarks EVALUATIONS