½ DAY SESSIONS

DISASTER PLANNING: "WHAT DO WE DO NOW? PROACTIVE PREPARATION FOR DISASTER RESPONSE AMONG THE 3Is"

Session Coordinator: **CECE BROTCHIE-FINE, BS, MA, CPIA**
Manager, Animal Welfare Compliance and IACUC Chair
Novartis Institutes for BioMedical Research, Cambridge MA

Session Description: The goal for this session is to introduce attendees to a toolbox of disaster response options for IACUC, IBC and IRB emergency scenarios and for attendees to directly apply that knowledge in a scenario where standard operations at an institution are interrupted with cascading impact on all three committees.

Learning Objectives:

- Presentations by national experts in the fields of veterinary medicine, IACUC, IBC and IRB management, media relations and the FBI provide attendees with knowledge of response options when disaster strikes
- Experiential problem solving in small groups through scenario learning:
  - Initial disaster 'hits' the institution and one committee will be called upon to respond
  - As the initial committee is drafting a response, additional effects of the disaster will enroll subsequent committees in daisy-chain fashion
  - By the end of the disaster scenario, all three committees will be working together to respond, address specific and institution-wide problems, and all committees will be required to interact with each other to resolve normal operations
  - Enable attendees to draft response plans for their institutional committees

IRB	**CHARLOTTE H. COLEY, MACT, CIP, Training Coordinator, Office of Human Research Ethics/IRB** **University of North Carolina, Chapel Hill**
Veterinarian	**RON E BANKS, DVM, ACLAM, ACVPM, CPIA**
FBI	**STEPHANIE M. VIEGAS** **WILL SO, PhD, Policy & Program Specialist, Biological Countermeasures Unit** **Weapons of Mass Destruction Directorate**
Media	**LISA NEWBERN, Chief, Public Affairs, Emory University, Yerkes National Primate Research Center**
IACUC	**MARCY BROWN, BS, MA, CMAR, CPIA**
IBC	**ANGIE BIRNBAUM, Tulane University**

ABC's for IACUCs & IBCs: FRAMEWORKS FOR COMPLIANCE™

An MSMR training program designed and developed for the IACUCs and IBCs. Those who will profit most from this training program are IACUC and IBC administrators and staff, committee members (including non-affiliated members), research administrators, compliance staff, occupational health and safety staff, vivarium staff and attending veterinarians.

ABC's for IACUCs & IBCs: FRAMEWORKS FOR COMPLIANCE™ gives a detailed overview of the laws, regulations and policies that govern the work of these two important oversight committees. Presentations are intermingled with pertinent team exercises and sample protocols. This program is designed to help meet the requirement stated in the Guide for the Care and Use of Laboratory Animals 8th edition, 2011, that states "All personnel involved with the care and use of animals must be adequately educated, trained, and/or qualified in basic principles of laboratory animal science to help ensure high-quality science and animal well-being". It will also address USDA/APHIS/AC Policy 15.

Both the IACUC and the IBC are committed to ensure the protection of the research staff, the animal husbandry staff, veterinarians and all others involved in research or who may have contact with or exposure to biohazardous agents. Those completing the program will:

- Have a clear overview of the laws, regulations, and policies that govern the humane care and use of laboratory animals
- Learn about the NIH OBA, the contents of the NIH Guidelines for Research Involving Recombinant DNA Molecules, and the history of IBCs and develop an understanding of the range of responsibilities that IBCs have under the NIH Guidelines
- Examine the relationship of IBCs and IACUCs in terms of their respective roles and responsibilities
- Discuss obstacles and other issues that both committees experience in meeting their ongoing research efforts and objectives
- Review the key components of an integrated program through case studies and protocol review;
- Engage in discussion with colleagues to share ideas about best practices, resources, innovative approaches, and collaborations.

BARBARA GARIBALDI, DVM, DACLAM
Director of the Animal Research Facility
Beth Israel Deaconess Medical Center
Instructor, Department of Medicine, Harvard Medical School, Boston, MA.

KATHRYN A. HOLTHAUS, MS, MA
Director of Research Subjects Protection and Laboratory Safety Compliance
Research Administration and Compliance
Brigham and Women's Hospital

KAREN KRUEGER, DVM, DACLAM
Director, Animal Resources, Boston Children's Hospital
Chair, MSMR Program Committee

DAVID GOLDBERG, MS
Associate Director, Research Operations
Boston Children's Hospital

TED MYATT, SCD
Director of Research Integrity
University of Rhode Island

PRIM&R'S SPECIMENS, SERVERS, AND SITUATIONS: ETHICAL CONSIDERATIONS IN PROTOCOL DESIGN, CONDUCT, AND REVIEW

GEORGE GASPARIS
President
The Peer Consulting Group, LLC

This intensive half-day program is designed for research professionals who understand the basic principles governing human subjects research, but want to deepen their knowledge of core regulatory and ethical issues, and learn practical strategies for

effective design, conduct, and review of research with human subjects. The program begins with a brief overview of the criteria for review applicable to federally funded human subjects research, including an examination of the recently proposed changes to the Common Rule. Three interactive modules on research with biological specimens, unanticipated problems and adverse events, and internet research will round out the program. The course is designed for all members of an institution's human research protections program, including institutional review board members and staff, investigators and research staff, and institutional officials.

FULL TWO DAY CONFERENCE

DAY ONE

"OLAW UPDATE, PHS POLICY AND ASSURANCE EXPECTATIONS"

EILEEN MORGAN
Director, Division of Assurances
Office of Laboratory Animal Welfare, NIH

Learning Objectives for Research Involving Animals:

- Describe essential elements of the PHS Policy and OLAW's oversight responsibility
- Define the impact of the MOU between NIH/OLAW and the NSF to institutions
- Identify the qualifications of the nonscientist IACUC member
- Identify the qualifications of the nonaffiliated IACUC member
- Define the components of the Vertebrate Animal Section

Session description:

The session on "OLAW Update, PHS Policy and Assurance Expectations," will describe the key elements of the PHS Policy and OLAW's oversight responsibility, and will specify the details of the impact of the recent MOU between NIH/OLAW and the NSF to both PHS and NSF funded institutions. It will depict recent updates to OLAW guidance regarding the definitions of the membership roles of the IACUC and also explain recent simplifications to the Vertebrate Animal Section in NIH grant applications and the impact for completion and review of the updated document.

COMMON RULE REVISIONS

DANIEL NELSON
Director
Human Research Protocol Office (HRPO)
National Health and Environmental Effects Research Laboratory (NHEERL)
U.S. Environmental Protection Agency (EPA)

DESCRIPTION: On September 8, 2015, the U.S. Department of Health and Human Services and fifteen other agencies issued a Notice of Proposed Rulemaking (NPRM) to revise the "Common Rule" regulations that govern research involving human subjects. If adopted, these would be the first substantive changes since 1981, altering requirements and procedures for informed consent, use of biospecimens, multisite trials, and review of human subjects research. This session will preview proposed changes and discuss what they mean for researchers, IRBs and their institutions.

OBJECTIVES:

- To describe the federal rulemaking process and reasons for modernizing the Common Rule regulations
- To outline the major changes that have been proposed to the Common Rule
- To discuss the potential impact of revised regulations on institutions, IRBs and researchers

TRENDS IN RESEARCH MISCONDUCT CASES: ANTICIPATING AND MITIGATING RISKS

JEFF M. SEO, J.D., LL.M.
EXECUTIVE DIRECTOR
Office for Academic and Research Integrity
Harvard Medical School

DESCRIPTION: This session takes a look at current trends and environmental factors that contribute to questionable research practices and deceptive behavior, and attempts to provide attendees with practical strategies that can be applied to mitigate risk in this growing area of reputational, financial and institutional vulnerability.

Learning Objectives:

- Identify at-risk and vulnerable populations within your institution;
- Design effective, targeted strategies to mitigate areas of risk;
- Ensure institutional policies are designed to streamline a complex and often costly process;
- Anticipate and navigate sensitive issues in the investigative process

ANIMAL TRANSPORT-THE GREY AREA

ANGELA C BIRNBAUM
Director of Biosafety
Tulane University

This session will provide a summary of animal transport according to the Guidelines for Humane Transportation of Research Animals. A detailed regulatory overview will be provided, along with potential biosecurity issues that could be encountered during a transport activity. The session will focus on the movement of infected animals, and cover the roles of institutional oversight. A special informational focus will be provided on the Department of Transportation special permitting requirements to move infected animals, along with the steps needed to obtain a special permit.

Objectives:

- By the end of the session, participants will understand the complex matrix of regulatory oversight involved in the transportation of research animals
- Participants will be able to apply an institutional oversight process to a transport activity
- Participants will be able to draft a DOT special permit for movement of research animals that are infected with pathogens

WHEN INTERESTS CONFLICT – CONFLICTS OF INTEREST IN RESEARCH

WESLEY G. BYERLY, PHARM.D.
Associate Vice President for Research
University of Connecticut Health Center

This session will use a case-based format to review the issues surrounding conflicts of interest in research. The session will focus on the regulatory requirements and the application of those requirements to decisions required in evaluating potential conflicts of interest in research.

Learning Objectives

- Compare and contrast the regulatory requirements of the NIH, NSF and FDA
- Identify what interests should be considered
- Assess when an interest represents a potential or actual conflict of interest
- List potential management strategies when a conflict of interest is identified

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BEST PRACTICES AMONG THE THREE I's … SHARING, INTEGRATION AND OVERLAPPING … STREAMLING THE PROCESSES AND REDUCING REGULATORY BURDEN…

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

DEBRA L. HUNT, DRPH, CBSP
Director, Biological Safety Division
Occupational and Environmental Safety Office
Assistant Professor, Duke University

JODY POWER, MS, MBA, CIP
Executive Director
Institutional Review Board
Duke University Health System

While the responsibilities of IACUCs, IRBs, and IBCs may vary by institution, these three oversight committees are key to a successful and collaborative compliance program. This session will begin with a brief overview of the composition, structure, functions and responsibilities of each of the committees and how they can work together to promote a culture of collaboration. Faculty will provide ideas for sharing, integration and overlap of the three committees in areas such as coordination of protocol review, shared practices and processes, reducing self-imposed regulatory burden and streamlining processes. The session will conclude with interactive case study scenarios.

DAY 2

SPOT THE ISSUES

TED MYATT, ScD
Director of Research Integrity
Division of Research and Economic Development
University of Rhode Island

SABUNE WINKLER, JD
Director of Regulatory Affairs Operations
Harvard Clinical and Translational Science Center

KATHRYN A HOLTHAUS, MS, MA
Director of Research Subjects Protection and Laboratory Safety Compliance
Research Administration and Compliance
Brigham and Women's Hospital

CHARLES CABRAL Jr, MSc
Special Agent, WMD Coordinator
FBI, Boston

"A" is for "Animal protocol", "Z" is for "Zebra fish" and I" is for IRB, IACUC, IBC and FBI"! If only spotting the contract and compliance issues were as easy as A, B C! Issue-spotting skills are critical. Using a fact pattern, this session will be interactive and focus on 3 I's obvious issues, but also help you identify those underlying, less obvious issues. This session will help attendees recognize the legal, regulatory and contractual issues presented by the fact pattern. Identifying and scrutinizing the important facts to help attendees efficiently choose the best course of action to facilitate as well as promote compliance with federal, state, enforcement and institutional guidelines, as well as, support investigators and institutional officials. Attendees will have fun spotting legal, regulatory and business issues, as well as discussing best practices for navigating them, what to watch out for, whom to notify, how to get help, when to alert institutional authorities and so on.

Learning Objectives:

- Differentiate between regulatory, legal and business decisions and understand why the distinction is important
- Develop the ability to identify obvious and hidden issues

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

1.5 hour training for Three I's and Biosecurity Conference, Chapel Hill, NC

MARLEY THRASHER
Manager, Training 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 90-minute "boot camp," 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

SOCIAL MEDIA, PARTICIPANT RECRUITMENT, AND BEHAVIORAL STUDIES: CRAIGSLIST AND BEYOND

ELIZABETH A. BUCHANAN, PH.D.
Interim Director
Research Services
University of Wisconsin-Stout

This session will describe various approaches to participant recruitment occurring through social media networks and tools. While many recruitment sites seem straightforward, for instance, Psychological Research on the Net, researchers engaging in behavioral studies can face various challenges when recruiting participants through spaces such as Facebook or Twitter. Beyond more oft-cited concerns with subject verifiability, other concerns are emerging, including the nature of recruitment and group harms, research bystanders, and data velocity and variability and their impact on participants.

Objectives:

- Review various social media sites and tools that are used for participant recruitment
- Describe recent cases of behavioral research and the roles social media played in participant recruitment
- Discuss strategies for effective and compliant strategies for participant recruitment and ways in which an IRB can appropriately review social media recruitment plans

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ETHICAL REVIEW AND OVERSIGHT OF NANOTECHNOLOGY STUDIES INVOLVING HUMAN SUBJECTS

DAVID B. RESNIK, JD, PHD
BIOETHICIST AND IRB CHAIR
National Institute for Environmental Health Sciences
National Institutes of Health

Description: This session will describe some types of nanotechnology studies involving human subjects and the ethical and oversight issues related to this research, including: risk minimization, risk/benefit assessment, risks to third parties, informed consent, and potential interactions between IRBs, IACUCs, and IBCs.

Objectives:

- To describe some types of nanotechnology research involving human subjects;
- To understand the ethical and oversight issues related to nanotechnology research involving humans subjects.

TITLE: IMPORT AND EXPORT OF BIOLOGICAL MATERIALS SESSION

KIMBERLY ORR DVM, PHD
Microbiologist, Chemical Biological Controls Division
Bureau of Industry and Security
Department of Commerce

VON MCCLEE, MS
Chief, Programs Services Branch
Division of Select Agents and Toxins
Centers for Disease Control and Prevention

DEBORAH L. DUFFICY, DVM, MPH, DACVPM
Senior Staff Officer, Organisms and Vectors
Agriculture Select Agent Services (AgSAS)

National Import Export Services
USDA, APHIS, Veterinary Services

DANIEL VICK
Export Compliance Administrator
NC State University

The past few years of growing concerns over the secure and safe transfer of biological and other hazardous materials has prompted agencies to intensify their effort to ensure that personnel and the public are safe. Quite often, the process has become too complex that not having appropriately trained and knowledgeable personnel who are responsible could result into non-regulatory compliance, citations, fines and even loss of important materials.

This session is designed to provide participants the opportunity to directly learn from the subject matter experts in the field and get a first-hand view of the regulatory processes that are involved. Experts from the US Department of Commerce (DOC), Department of Agriculture-Animal and Plant Health Inspection Service (APHIS), and the Department of Health and Human Service-Centers for Disease Control and Prevention (CDC) Import Permit Program will provide different presentations followed by a hands-on workshop session. Participants will get a chance to role-play, immerse themselves in specifically designed scenarios, apply what they have learned and make decisions. Participants will also get the chance to analyze each scenario outcome with the experts and discuss the decisions that were taken

At the end of this session participants will gain:

- A working knowledge of the regulations, permitting, and terminology covering local, national and international shipping and receiving of biological materials
- will learn to apply these regulations to various common situations to understand the steps required to prevent problems and ensure the smooth transfer of these materials
- documents and handouts that may be easily tailored to a shipping program in an institution or entity;
- and an understanding of elements of a robust shipping, import and export program that may be applied to their own entity