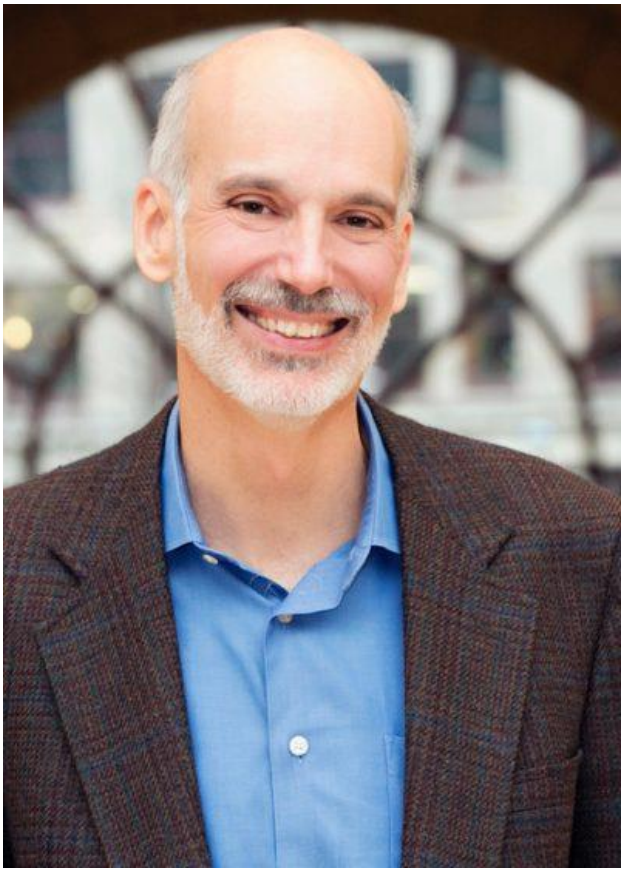
Keynote Speaker

Dr. Stephen Rosenfeld, Executive Chairperson of the Review Board at Quorum Review IRB CIP

Dr. Stephen Rosenfeld is currently the Executive Chairperson of the Review Board at Quorum Review IRB, an Independent IRB located in Seattle. Dr. Rosenfeld is a hematologist who earned his medical degree from Cornell. He trained in internal medicine at Dartmouth and completed his hematology fellowship at the National Heart, Lung, and Blood Institute of the NIH. He spent 19 years at NIH, holding positions at NHLBI and the NIH Clinical Center, doing both basic and clinical research, and finally working in medical informatics and administration. He ended his time at the NIH as the Chief Information Officer of the Clinical Center.



Dr. Rosenfeld moved from Bethesda, Maryland to Portland, Maine, where he was the CIO of MaineHealth, a large independent delivery network, before moving to Olympia, Washington as the CEO of the Western Institutional Review Board.

In addition to his medical degree, he holds a Masters in Business Administration from Georgetown. Dr. Rosenfeld received the honor of Distinguished Professor of Medicine from Daegu Catholic University Medical Center in Korea in 2013. In July 2013, he was appointed to the Secretary's Advisory Committee on Human Research Protections (SACHRP) and in 2016 he was appointed Chair of SACHRP. In 2018 he was elected to the Board of Directors of Public Responsibility in Medicine and Research (PRIM&R) and in 2019 joined the Board of Directors of the Association for the Accreditation of Human Research Protection Programs (AAHRPP).

Monday Sessions

(9:00 am – 9:30 am)

Welcome & Introductions: Who We Are!

Presented By James O'Reilly from the Massachusetts Society for Medical Research, Ross Hickey from the University of Southern Maine and William So from the Federal Bureau of Investigation

(9:30 am – 10:15 am)

Translational Research Bench to Bedside

Presented By Dr. Stephen J. Rosenfeld from Quorum Review IRB

(10:15 am – 11:00 am)

Research Compliance Headlines: Reading between the Lines CIP

Presented By Jeff Seo from Northeastern University

A light-hearted look at some of the significant headlines related to research compliance from the past year. Beyond the headlines, Jeff will explore broader implications impacting research institutions going forward. Each headline represents a story with a lesson that can be learned by the research community.

Morning Breakout Sessions (11:15 am – 12:00 pm)

OLAW

Presented by Eileen Morgan from the Office of Laboratory Animal Welfare, National Institutes of Health

What's New at the NIH Office of Science Policy – NIH Guidelines and Biosafety Oversight in the 21st Century

Presented by Kathryn Harris from the National Institutes of Health Office of Science Policy

Proposed changes to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) regarding the oversight of human gene transfer research will be presented. The presentation will also address the evolution of the Recombinant DNA Advisory Committee to focus on scientific, safety, and ethical issues associated with emerging biotechnologies, and the challenges such technologies pose for Institutional Biosafety Committee (IBC) oversight.

Risk Mitigation in Mixed SBRE / Biomedical Research CIP

Presented by Amy Ben-Arieh from The Fenway Institute & Lara Sloboda from Tufts University

Social, behavioral, and education research (SBER) encompasses a range of methodologies and tackles questions that seek to improve our understanding of human behavior, attitudes, beliefs, and interactions, as well as social and economic systems, organizations, and institutions. The primary focus of SBER is on the actions of diverse groups, including individuals and families, and regional populations and nations. Often, SBE research utilizes methods such as interviews, surveys, focus groups, observation, and/or behavioral manipulations. Census and employment data as well as records from education, social service, or healthcare programs may also be incorporated. Knowledge gained from SBE research informs the development of prevention and intervention programs and facilitates strategies in policy and practice.

Using two case studies and small group discussion, this session will focus on risk mitigation in research involving both biomedical and social science methods. The first case study to be presented examines an initiative designed to help patients with Hepatitis C (HCV) and opioid use disorder overcome reluctance to utilize group-based recovery services. Investigators will compare service utilization and outcomes of those who receive standard appointment reminders to those who receive enhanced, affirming messages and reminders. The second is an evaluation of an early intervention program to ameliorate the psychosocial effects of Chronic Traumatic Encephalopathy (CTE) in youth who play contact sports. The intervention includes teaching the students cognitive and psychosocial methods, including attention processing strategies, training for memory deficits, social behavioral guidance, and emotional training.

During this session, speakers and attendees will: review the nature of the risks, harms, and impacts associated with mixed SBER/biomedical research; explore factors likely to contribute to increased risk in research spanning both the biomedical and social/behavioral disciplines; and, discuss how to ensure sufficient protections and minimize

risks through study design.

This session is geared towards researchers, IRB members, and HRPP personnel involved in the ethical evaluation of human subjects research. Attendees should have a basic foundation in human research protections ethics and principles, including the criteria for approval and definitions from DHHS and FDA regulations. The session will make heavy use of active learning techniques, such as small group work, case studies, participant-created content, and interactive discussion.

The Canary in the Coal Mine CIP

Presented by Dan Wainstock from Harvard Medical School

Research misconduct has a narrow, federally regulated definition, related to plagiarism and the falsification/fabrication of data. However, the context in which research misconduct occurs is more complex, with a wider range of ramifications. This session will address how research misconduct represents a window into – and perhaps an opportunity to protect our institutions from – significantly broader difficulties, both at the level of individual "bad apple" (scofflaw) researchers and at the level of societal mistrust of academic research. Case studies "ripped from the headlines" will be used to illustrate and elaborate on these principles.

Afternoon Breakout Sessions (12:45 am – 1:30 pm)

IACUC (Session Title)

Presented by Marcy Brown & Eileen Morgan from the Office of Laboratory Animal Welfare, National Institutes of Health

Promoting Effective Biosafety and Biosecurity Oversight through Good Governance

Presented by Kathryn Harris from the National Institutes of Health Office of Science Policy

This presentation will discuss the importance of ensuring institutions have robust and comprehensive biosafety and biosecurity governance structures in place. Information will be provided about the activities of the Federal Experts Security Advisory Panel (FESAP) related to strengthening biosafety and biosecurity practices and oversight, as well as tools institutions can employ to enhance their biosafety and biosecurity programs.

Information Security and Privacy, the Intersection between Ethical Review, Regulatory Requirements, and Contracting CIP

Presented by Lisa Griffin from Brigham and Women's Hospital

As Information Technology becomes integrated into new areas of clinical research, and as studies become more complex with multiple sites, aspects of clinical research protocols that traditionally were strictly under the purview of the IRB may have now multiple institutional stake holders. Sponsor agreements with international sites often include regulatory requirements that differ from HIPAA and may be inconsistent with typical US data retention practices. Expectations around data ownership and licensing can be very different in the technology industry from an academic medical center. This session will discuss the experience at Brigham and Women's Hospital, in the Partners Healthcare System, integrating IRB review, with Information Security and Privacy, Contracting, and Research Compliance, to streamline project review for all institutional stakeholders, while hopefully reducing administrative burden for Investigators.

Research Data Management – Effective Options for Administrators CIP

Presented by Patti Condon from the University of New Hampshire & Julie Goldman from Harvard Medical School

In this session, Julie Goldman and Patti Condon discuss research data management as a key component of research integrity and offer effective options for addressing challenges faced by administers and researchers.

Data management involves establishing and implementing strategies for the responsible and sustainable collection, handling, sharing, re-use, secure storage, and long-term access of data. However, we face inherit challenges managing data in a digital and networked environment, for example, technological obsolescence, the quantity of data generated, data sharing and discoverability, and skills development. We are also confronted with external pressures such as mandates from federal funding agencies requiring evidence of sound data management practices and emphasizing the dissemination of data.

Through a combination of presentation, discussion, and interactive participation, this workshop addresses the various roles and opportunities of stakeholder when navigating the complex landscape of data management. At the conclusion of this session, participants will be more familiar with challenges associated with the management of data for their communities and approaches to addressing responsible conduct in data management in ways that are most meaningful and useful to the researchers they support.

Afternoon Breakout Sessions (1:30 pm – 2:15 pm)

Building Quality Assurance in Laboratory Research

Presented by Angela Birnbaum from Tulane University

Research Data Management – Effective Options for Administrators (Continued)

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(2:30 pm – 4:00 pm)

Research Integrity, Ethics and You… Using Training and Communication to Advance Your Team Research Integrity Program… CIP

Developed by Marley Thrasher from Duke University, Ross Hickey from University of Southern Maine, Marcy Brown and Angela Birnbaum from Tulane University, Michael Centola from University of Massachusetts and William So from the Federal Institute Of Investigation

Goal

Understand how to further research integrity and ethics at your organization.

Description

We are all familiar with the policies and procedures that govern the ethical conduct of research. But, why is "research integrity" so important? How does it apply directly to your role in the research enterprise? And, what can you do to promote research integrity at your institution? During this session, you'll identify best practices for enhancing research integrity and ethics to meet organizational needs and ensure compliance. Learn about the impact research integrity has on safety and security, hear from the experts about solutions for common communication challenges you face, and apply proven training techniques in your own research integrity program. Whether you're an individual contributor or a team leader, work in a research compliance office or at the FBI, this interactive session will leave you with specific, actionable ideas you can incorporate at your organization.

Learning Objectives

Upon completion of this training, you will be able to:

- Define research integrity and ethics
- Describe the importance of research integrity and ethics in research and the different roles supporting research integrity and ethics
- Identify and apply solutions to common communication challenges related to research integrity and ethics
- Apply best practices in training and development to your research integrity and ethics program
- Locate key contacts and resources

Tuesday Sessions

(8:30 am – 9:30 am)

Biosecurity Risk Assessment CIP

Presented By Gigi Kwik Gronvall from John Hopkins Bloomberg School of Public Health

Morning Breakout Sessions (9:30 am – 10:15 am)

The Process Development of Occupational Health Programs

Presented by Ted Myatt from the University of Rhode Island

The requirement of a robust research focused occupational health program can be a challenge for academic institutions that to do operate a medical school and large academic medical centers, where their occupational health programs are likely most focused on clinical care.

In this interactive session, Ted Myatt will discuss strategies to gain support of senior leadership, build a team, develop a sustainable program, and implement continual improvement processes to ensure that your program complies with requirement described in the Guide for the Care and Use of Laboratory Animals, 5th Edition, the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids, and U.S. Occupational Safety and Health Administration (OSHA) Standards.

A Year's Experience with the NIH Single IRB Review Policy – Lessons Learned!

Presented by Brenda Ruotolo from Columbia University

In January 2018 the NIH issued a policy requiring single IRB review of multicenter research and the Revised "Common Rule" (federal regulations for the protection of human subjects) will also require this, beginning in January 2020. Many industry sponsors of multicenter research have voiced their support of single IRB review and the prospect of streamlined IRB review is alluring to researchers. IRBs have been cautiously optimistic that efficiency will be increased, while being challenged to implement new procedures, forms and policies. Institutions now have more than one years' worth of experience in implementing the NIH policy. Large institutions with significant NIH funding, such as Columbia University in the City of New York, have applied the policy to many dozens of grant applications. Important lessons, such as the examples below, have been learned along the way and, while it's been a bit bumpy, roll-out of the Common Rule requirement next year will be smoother as a result.

Lesson 1: Take time to fully understand the policy, e.g., know when the policy does and does not apply, and what needs to be added to the grant application.

Lesson 2: Implement or tighten up the interface between the IRB and the pre-award office at your institution, to establish processes for incorporating newly required input into the grant application process, e.g., the decision as to whether the policy applies and guidance for the single IRB plan that is required.

Lesson 3: Establish an efficient process for determining whether the policy applies, e.g., a readily available form or electronic intake process, and a mechanism to quickly provide decisions back to the researcher.

Lesson 4: Determine whether your institution's IRB(s) can take on the role of a single reviewing IRB for some or all of the grants that your researchers are submitting, or if outsourcing the single IRB review to an independent IRB is necessary.

Lesson 5: Develop an appropriate fee schedule if your IRB will be serving as the single reviewing IRB for multiple sites.

Lesson 6: Have a process in place for researchers to notify the IRB when a notice of potential funding is received,

so necessary reliance agreements can be executed and preparation of local context documents can ensue.

And there are so many more!

Despite feeling quite prepared back in January 2018, some of the lessons we learned involved a fair amount of trial and error. As a major research institution that receives requests for reliance - either for Columbia to rely on a single IRB or for Columbia to provide the single IRB review – nearly every work day, Columbia has had to refine these processes and is happy to share our approach to managing, as expeditiously as possible, the NIH single IRB review requirement.

Social Media Recruitment

Presented by Elizabeth Buchanan from the University of Wisconsin-Stout, Wisconsin's Polytechnic University

The uses of social media in research recruitment are now well established. From SBER to biomedical to clinical trials, researchers are exploiting all sorts of social media tools to identify, recruit, and conduct studies. This session will look briefly at the historical context for social media recruitment, then turn to the extant regulatory considerations. We will review different technologies, from mobile apps to big data approaches and consider the ethical implications.

(10:35 am – 12:00pm)

CRISPR CIP

Presented by Robert Klitzman from Columbia University

New gene editing technology known as "clustered regularly interspaced short palindromic repeats" or CRISPR can alter the genes of cells, including embryos, changing the organism and its descendants, and raising critical ethical, legal, and social concerns. First discovered in 2014, scientists have rapidly used this technology in many species. In 2015, Chinese scientists began using this technology to alter human embryos. A Washington, DC, summit later that year set guidelines, with research organizations from several countries agreeing not to transfer such embryos into wombs. This technique can also alter genes in microorganisms to create superbugs. In 2016, the Pentagon listed it as a weapon of mass destruction. In 2018, a Chinese researcher stated that he had edited human embryos and transferred them into a womb, producing twin girls. He said that he had sought to prevent HIV-infected fathers from infecting their offspring, and had disabled the CCR5 gene that enables HIV to enter cells. But blocking this gene also increases risks of other viruses entering cells. Doctors can also already prevent HIV-infected fathers from infecting their offspring through sperm-washing. CRISPR can have 'off-target' effects, accidentally eliminating additional DNA, and genes may have multiple, unknown functions. He failed to seek approval from a research ethics committee, and did not conduct sufficient prior animal research. In March 2019, scientists recommended a moratorium on transfer of altered embryos into wombs, and a registry of all CRISPR trials. Questions remain, however of how long such a moratorium should last, when it should end, who should decide, based on what criteria, whether all nations and researchers will agree, and what should be done if non-compliance occurs. Questions emerge of when

CRISPR will be “safe enough” for initial research studies, and later for broader clinical use. The first human offspring may need to be followed through adulthood and the birth of their own children. A 2017 National Academy of Science report on CRISPR concluded that clinical trials should be permitted only to prevent serious disease in the “absence of reasonable alternatives,” but such an alternative already exists—Preimplantation Genetic Diagnosis (PGD). This talk will explore these critical challenges, related to ethical principles of autonomy, risks, benefits and social justice, and how these questions might best be addressed.

Afternoon Breakout Sessions (12:45 pm – 1:30 pm)

Risk Assessment in NHP

Presented by Angela Birnbaum from Tulane University

AI, Ethics, and the IRB CIP

Presented by Elizabeth Buchanan from the University of Wisconsin-Stout, Wisconsin's Polytechnic University

This session will explore the exploding use of AI across research disciplines. We will explore definitions and practical examples of AI uses in our everyday experiences and drill down to their uses and ethical implications in research. While all of us in the research community are grappling with the challenges of AI, we will review some current case examples and work together on best practices for reviewing research involving AI, which will push us to explore the parameters of human subjects research from the regulatory sense to their ethical implications.

How I Learned to Love "Well, It Depends". An Integrated Compliance Setting

Presented by Chris Mangelli from Ball State University

Do you feel lawyers do not speak the same language as you? When working with lawyers, do you feel like they create a caveat for everything? When asking a lawyer a "simple" question, do you hear the phrase "well, it depends" more than a dozen times? If yes, you are not alone.

To most lawyers, things are never black and white, but multiple shades of gray. Lawyers are trained to see things at multiple levels, to asses degrees of risk, to ask questions that may not always make sense, and to offer advice based on particular fact patterns. In many cases, this leads to conversations that are filled with "well, it depends" and caveats to cover all of the unknowns. To most non-lawyers, this leads to frustration, stress and an urge to stop asking a lawyer for help.

This presentation will help explain why this occurs, what you can do to improve your interactions with lawyers in a research compliance setting and how you can help your lawyer support you more effectively. Batteries not included.

Afternoon Breakout Sessions (1:30 pm – 2:15 pm)

IACUC Challenges: Case Studies from Real Life

Presented by Marcy Brown, Deb Frolicher from Scripps Research Institute and Eileen Morgan from the National Institutes of Health

This popular session uses a mixture of case studies, group discussion, and interactive exercises to identify best practices for resolving real-life IACUC challenges or issues. Attendees should have a working knowledge of the regulations, guidelines, and policies associated with Animal Care and Use programs.

Faculty includes IACUC Program experts as well as representatives from OLAW and the USDA. Participants will work in small and large groups to discuss challenges and case scenarios. Faculty will interact with individuals and groups to assist them in developing methods to deal with difficult situations involving the IACUC.

Situations likely to be discussed include pain/distress categories, humane endpoints, rationale for species and numbers of animals, noncompliance and investigations, difficult investigators, high risk animal models, how to implement and use veterinary verification and consultation (VVC), and training issues.

Learning Objectives

- Discuss and analyze simulated, problematic scenarios in IACUC function and responsibilities
- Formulate possibilities for resolution without conflict
- Discuss potential solutions to issues or questions while maintaining institutional compliance
- Share examples of strategies that have worked

Financial Conflict of Interest Management CIP

Presented by Yashmin Karten from the University of South Carolina

Enhancing the public good through improved health initiatives and superior economic development is the foundation of many government policies. Research universities have a responsibility to actively participate and promote these initiatives even if conflicts of interest are more likely and many times unavoidable. Conflicts of interest, therefore, may arise from ordinary and appropriate activities as a part of assigned employment duties so the existence of a conflict should not imply wrongdoing. When conflicts of interest do arise, however, they must be recognized and disclosed, then eliminated or appropriately managed. Institutions have a duty to ensure that conflicts are appropriately reviewed and acted on, to maintain public confidence in the integrity of our institutions. This session will provide a general overview and practical applications of individual and institutional conflict of interest management in research and industry interactions, relevant regulations and their implementation in an academic medical center. The session is primarily designed to benefit those new to the discipline of conflicts of interest in research and industry interactions.

The EU's General Data Protection Regulation: What Researchers Need to Know CIP

Presented by Peter Guffin from Pierce Atwood LLP

The EU's GDPR has been in effect now for almost one year. In this session we will look at this regulation's impact on scientific research involving human subjects, highlighting the similarities and differences with HIPAA's Privacy Rule and the Common Rule, as well as its interplay with national laws in the EU member states. We will focus on the issues of participant consent, the public interest (health) exception, and implementation of new procedures and practices required under the GDPR, including designation of a data protection officer, data protection impact assessments, rules regarding the reuse of personal data for research purposes, and notification and communication of personal data breach. The GDPR strengthens data protection principles applicable to personal data processing for scientific research purposes, adding requirements with respect to data integrity, confidentiality, accountability, and data protection by design and by default. It also introduces new definitions, such as "data concerning health," "genetic data," and "biometric data," expands the rights of data subjects, specifically with respect to right to rectification, to erasure, to be forgotten, to restriction of processing, to data portability and to object, and creates opportunities for the development of codes of conduct and other self-regulatory approaches.

Afternoon Breakout Sessions (2:30 pm – 3:15 pm)

IACUC Challenges: Case Studies from Real Life (Continued)

Presented by Marcy Brown, Deb Frolicher from Scripps Research Institute and Eileen Morgan from the National Institutes of Health

Biosecurity

Presented by Sonia Hunt from the Federal Bureau of Investigation

Research Integrity (Session Title)

Presented by Elizabeth McEvoy, Esq. from Barrett & Singal

Improving Research Participant's Understanding of Informed Consent

Presented by Debra Gillespie from the University of Southern Maine

One of the major ethical principles guiding research conduct with human subjects as outlined in the Belmont Report is the principle of respect, which honors individuals' right to choice. Working within this principle, investigators are required to provide a consent process to potential research subjects with sufficient knowledge and understanding of research for informed decision making. However, as much as 25-60% of research participants are unable to understand important information during the research consenting process.

Unfortunately many informed consent documents for research are lengthy, contain a lot of medical and legal jargon and are written at a reading level higher than the public is able to read and understand. In addition, the informed consent process is often seen as "bureaucratic form filling" rather than an important and necessary part of the research process requiring time, insight and communication skills. Despite 25 years of study into this area, the problem persists. This lack of comprehension may unintentionally expose research participants to potential harm.

This presentation will discuss the current state of the science from results of a rigorous systematic review of interventions empirically tested to improve research participants' understanding of informed consent and presents the results of a pilot study conducted by the author aimed at using a communication technique (teach back) to improve understanding among cardiology clinical trials participants. Unexpected findings from this study will be highlighted as well as suggestions for future interventions to be discussed.

Afternoon Breakout Sessions (3:15 pm – 4:00 pm)

IACUC Challenges: Case Studies from Real Life (Continued)

Presented by Marcy Brown, Deb Frolicher from Scripps Research Institute and Eileen Morgan from the National Institutes of Health

Biosecurity (Continued)

Presented by Sonia Hunt from the Federal Bureau of Investigation

Controlled Substances in Non-Clinical Research: Regulatory and Institutional Infrastructure

Presented by Kelé Piper from Massachusetts General Hospital and Claire Brennen from the Drug Enforcement Administration New England Field Division.

Knowledge is power. In this session, you will have the opportunity to learn about controlled substance regulations directly from the DEA and to explore strategies for complying with these regulations in the non-clinical setting. We will discuss regulation, policy, documentation, storage, ordering, checks and balances, education, and monitoring/auditing.

Conflicted Cultures of Compliance: How the Revised Federal Regulations Change the Conversation between Ethnographers and IRBs

Presented by Montana Miller from Bowling Green State University

I offer this presentation at a significant moment for the world of research compliance and its fraught relationship with qualitative fields of inquiry such as ethnography, education, anthropology, and oral history. I am a folklorist specializing in fieldwork methods and ethics, and I have long served as an IRB member at my large research university. This year, unexpected events propelled me into the position of Research Compliance Officer; suddenly I must deeply understand, clearly interpret, and reasonably enforce the regulations, just as the regulatory floor is shifting beneath our feet.

Over the past two decades I have closely observed the debates over whether and how the federal guidelines regarding the Common Rule (based on the principles laid out in the Belmont Report: respect for persons, beneficence, and justice) can or must be applied to review of studies done by scholars whose fields have traditionally policed their own ethical standards and practices. Ethnographers and oral historians have distrusted and resented IRBs which may impose unrealistic bureaucratic requirements or regulatory obstacles to the organic process of research with humans; many reviewers have little patience or understanding for a participatory, dialogic process in which the researcher adapts and improvises as needed. I have sought to help bridge the gap that unfortunately puts an institutional "culture of compliance" at odds with the ethnographers dedicated to studying "culture in context." The Revised Common Rule (effective January 21, 2019) threatens to amplify these misunderstandings, as it contains ambiguous and even paradoxical new guidelines and options for IRBs.

My presentation will clarify and illustrate (with examples relevant to qualitative researchers and compliance staff alike) the opportunities as well as potential pitfalls of the new regulations. How do we determine which research studies qualify as "research" under the Federal definition, and has that changed? What makes an ethnographic or oral history reviewable, what qualifies it as "exempt," and how are we to interpret the revised, more complex categories and meanings of "exempt" under the revised Common Rule? How must we address the slippery question of what a "reasonable" person would want to know (in order to make an informed decision) when we decide what "key information" belongs in the newly-mandated first-paragraph summary in a consent document?

In addition, I provide an overview of the human relationships of IRB culture—that is, how the mix of personalities, perspectives, and academic traditions on an IRB produces the decisions that seem frustratingly mysterious to researchers depending on the board's approval. With a trained folklorist's eye, I have observed the evolving power dynamics that develop during the back-and-forth between PI's (Principal Investigators) and IRBs; the politics at play in these debates; and the pressures placed on officials and scholars to pursue their agendas and their mandated responsibilities. I examine the interplay among these systems of ethics—the national consensus emerging from Washington's Office of Human Research Protection, the deliberations of individual IRBs across the country, the ethical codes of particular academic disciplines, and the purposes of researchers in the trenches of fieldwork.

Wednesday Sessions

(9:00 am – 9:45 am)

Research Integrity for the Three I's CIP

Presented by Fariba Houman from Boston Children's Hospital and Julie Simpson from the University of New Hampshire

Morning Breakout Sessions (9:45 am – 10:30 am)

IACUC, IBC, IRB & Biosecurity Spot the Issue©

Presented by Ted Myatt from the University of Rhode Island, Kathryn Holthaus from Bringham & Women's Hospital, Jeff Seo from Northeastern University and Will So from the Federal Bureau of Investigation

Conducting an Institutional Research Risk Assessment

Presented by Kelé Piper from Massachusetts General Hospital and Eleanor Kuszmar from Beth Israel Deaconess Medical Center

Compliance needs to evaluate and assess risk in order to successfully implement and navigate the regulatory landscape. Research in general is an inherent risk and therefore in-depth review of research risks may not always rise as a priority. Many compliance programs shy away from research feeling they don't have the expertise or knowledge of those regulations that are specific to research.

We invite you to join us for an interactive session that will demonstrate that research risk assessments are not so different from any other compliance risk assessment and you may have more tools in the toolbox than you realize. In this session, you will learn about the benefits of conducting a research risk assessment, learn the steps involved, and utilize sample tools to reinforce your understanding of applying these concepts to research.

The benefits of conducting a research risk assessment can include improving communication with your research community, opening opportunity for collaboration, building trust, and creating framework for workplan development.

Mock IRB CIP

Presented by Elizabeth Kipp from Maine Health System

Afternoon Breakout Sessions (10:45 am – 11:30 am)

What are You Afraid Of?

Presented by Christina Nascimento from Brigham & Women's Hospital

Why are some institutions hesitant to adopt acceptable methods of reducing regulatory burden? How can you get out of the self-imposed regulatory burden black hole, and adopt these practices in your program?

Overview:
For years, many IACUCs and animal care and use programs have imposed additional regulatory burden on their animal research programs, often by misinterpreting federal regulations, adopting the same regulations for all species (i.e, annual renewals), or are hesitant to adopt "new" approval options provided by OLAW (DMR, VVC). Many institutions fear that changing these practices will risk their AAALAC accreditation, loss of funding, or increase noncompliance. But how does the extra paperwork truly help animal welfare? In this session, representatives from institutions who have "taken the plunge" will share their experiences with embracing change in the IACUC landscape, methods for adoption of the practices, and have an open discussion with the attendees on barriers they face in their own programs.

Objectives:

- Review how reduction of regulatory burden practices were implemented successfully at several institutions
- Understand the key challenges for implementation, as well as reason some institutions have not adopted these practices
- Determine solutions for implementing these practices at attendees' institutions
- Brainstorm additional methods for reducing burden while increasing animal welfare

Viral Vectors in Biological Research: Biosafety Issues

Presented by Sajal Ghosh from Boston University

Viral vectors have become an essential tool for gene expression studies. Their superiority over standard transfection experiments for expression of foreign genes in host cells has been well established. At the same time development of new viral vectors that are more suitable for specific purpose are also on the rise. These technologies utilize specialized mechanisms of replication of individual viruses. It is therefore, imperative that users of these viral vectors be knowledgeable about potential hazards associated with these viruses. It is necessary that the biosafety professionals are aware of the safety issues of these vectors and remain vigilant on their safe use in the laboratories. Following topics will be covered in the talk:
Basic Research

- Brief scientific description of basic features of viral vectors (adenovirus, adeno-associated virus, retrovirus/lentivirus, herpesvirus and others) and why such vectors are advantages over traditional transfection methods for gene expression.
- Overview of different viral vectors used in molecular biology experiments along with their brief molecular characteristics will be presented.
- Discussion of the molecular features that are utilized while used as a vector. This will briefly include why use of certain vectors are advantageous over the other in a particular experiment.
- How the pathogenic potential of these vectors are modified in the vectors. Whether such modifications affect the host range of the viral vectors.

The topics will provide a clear concept of what are viral vectors, what are they used for and why people are so interested to use them.
NIH Guidelines

- Discussion on how research using viral vectors are covered by the NIH guidelines for research involving recombinant or synthetic nucleic acid molecules.
- When is an incident reportable to NIH?

This information is required in all IBC applications and this discussion will provide a rationale for what should be the choice.

Personal Protective Equipment and Disinfection

- Discussion on potential hazards in the use of viral vectors in basic research laboratories and in animal research facilities.
- What sort of precautions should be practiced while working with these vectors. What are the rationale for the PPE choice and how is it related to the pathogenic potential of these vectors (such as gene integration in host genomic DNA or immunological response to the vector, transmissibility, etc.)
- What should be the appropriate disinfection method for these vectors? What should be used for disinfection of solid or liquid wastes; 10% bleach, 70% ethanol 2% wescodyne, 5% microchem? What should dictate the choice?
- How to dispose of wastes generated from the use of viral vectors?
- How should the animal work be done with viral vectors and how animal work wastes (such as animal bedding, cages, carcasses) should be disposed of?
- Does CRISPR technology bring any additional concerns?

This section will provide answers to most common safety questions from both researchers and reviewers.

Research Compliance and Inspection

- How the research protocols involving viral vectors are reviewed?
  Role of the Institutional Biosafety Committee
  Role of Laboratory Inspectors

This section will provide information on what is reviewed in IBC applications (from compliance and personal safety perspectives).

Conducting an Institutional Research Risk Assessment (Continued)

Presented by Kelé Piper from Massachusetts General Hospital and Eleanor Kuszmar from Beth Israel Deaconess Medical Center

Compliance needs to evaluate and assess risk in order to successfully implement and navigate the regulatory landscape. Research in general is an inherent risk and therefore in-depth review of research risks may not always rise as a priority. Many compliance programs shy away from research feeling they don't have the expertise or knowledge of those regulations that are specific to research.

We invite you to join us for an interactive session that will demonstrate that research risk assessments are not so different from any other compliance risk assessment and you may have more tools in the toolbox than you realize. In this session, you will learn about the benefits of conducting a research risk assessment, learn the steps involved, and utilize sample tools to reinforce your understanding of applying these concepts to research.

The benefits of conducting a research risk assessment can include improving communication with your research community, opening opportunity for collaboration, building trust, and creating framework for workplan development.

Mock IRB (Continued) CIP

Presented by Elizabeth Kipp from Maine Health System

(11:30 am – 12:30 pm)

Carrots, Sticks or Sticks Disguised as Carrots?

Panel Discussion convened by William Harrison from the University of New England, including Carol Nemeroff from the University of Southern Maine, Karen Houseknecht from the University of New England and The Honorable Lance Walker, the United States District Court, District of Maine

This moderated panel discussion will address the role of enforcement mechanisms in regulatory compliance. Starting from the premise that there are aspirational codes (what one ought to do) and prescriptive codes (what one must do), discussants will address the question of whether regulations without actual enforcement mechanisms be anything other than aspirational?

The discussion will encompass topics like:

- institutional differences in the academic and corporate worlds including the "nothing bad has happened yet" outlook;
- behavioral change mechanisms through both extrinsic (e.g. consequences like penalties and shaming) versus intrinsic motivation (e.g. altruism, "moral compass"); and
- a view from the bench, in the form of judicial commentary on how and whether the courts can serve as an enforcement mechanism.

(1:20 pm – 2:05 pm)

Developing Your Plan… Fine Tuning Your Response

Presented by James O'Reilly from the Massachusetts Society for Medical Research

(2:10 pm – 4:00 pm)

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Panel Discussion convened by Cece Brotchie-Fine from Novartis Institutes for BioMedical Research, Inc., including Sonia Hunt and William So from the Federal Bureau of Investigati