

**Clarifying the Ethics and Oversight of Chimeric Research**

For decades, researchers have inserted different types of human cells into nonhuman animals at various stages of development to advance our understanding of human biological processes and identify new investigational therapies. For almost as long as scientists have conducted this kind of research, there has been debate about whether it should take place and, if it does, how best to respond to the ethical and policy issues it raises. Particular public, academic, and policy attention has focused on those studies—often terms “chimera” research—that involve the transfer of human stem cells (or their direct derivatives) into nonhuman embryos or animals. These studies have raised questions about whether the moral status of the nonhuman animals is altered by the insertion of human stem cells, whether it is morally appropriate to cross species boundaries in this way, and whether chimeric studies should be subject to additional prohibitions or oversight. In the United States and several other countries, national bioethics advisory committees or other advisory bodies have published reports that address some of these ethical and policy questions, with most reports including guidance and/or recommendations about whether and under what conditions human-nonhuman chimeric research (hereafter chimeric research) should be conducted. The guidelines differ in important ways; however, their ethical bases are sometimes unclear. In addition, oversight approaches are fragmented, and specific rules or guidelines can be difficult for researchers and oversight committees to operationalize. In this session, speakers will provide an overview of the conceptual, ethical, and regulatory issues raised by chimeric research.



**Learning Objectives:**

- Review the key ethical issues raised in academic and public debate
- Explore perspectives of scientists and oversight professionals using illustrative case studies
- Identify challenges for IRB, IACUC, and ESCRO personnel and workshop ways to improve governance and oversight

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; IBC Directors; IBC Administrators, Manager and Staff; IBC Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Compliance Personnel; Clinical Research Staff; Researchers and Research Staff

**Ethical Considerations for Conducting Research During Uncertain Times: A Focus on Pharma**

The recent events of the global pandemic, military conflict in eastern Europe, and the increasing frequency of climatic, natural disasters have brought into sharp relief the importance of continuity planning and crisis management plans across a range of sectors. In particular, the biopharmaceutical industry has been keenly aware of these impacts on patients and those individuals participating in clinical research in impacted regions. This workshop will take a deep dive into topic areas that have been placed under pressure or arisen as potential solutions the past three years by these events: conduct of clinical trials; innovation in the conduct of research; and science/health literacy and combatting misinformation. Attendees will be given the opportunity to engage in small and large group discussion focusing on ethical considerations when conducting research during uncertain, chaotic times.



**Learning Objectives:**

- Develop an understanding of the ethical considerations that affect biopharmaceutical industry decision making for clinical research during periods of disruption
- Understand the global research landscape and efforts to incorporate innovative approaches to trials across distinct regions and inconsistent regulatory environments, mixing science, politics, and social justice across areas of disruption
- Gain experience in applying these learnings to relevant cases and to identify questions and best practices for managing this ethically complex space

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Researchers and Research Staff

**ICON LEGEND**

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Workshop Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

**Quality Assurance/Quality Improvement (QA/QI) in Human Subjects Research**

This workshop will provide attendees with the core concepts and fundamental knowledge needed to establish a sound and successful QA/QI function for human subjects research oversight, taking into consideration institution type, size, and budgetary constraints. This workshop is ideal for those new to the field or those interested in evaluating and improving upon their existing QA/QI program/function. Workshop content, ranging from introductory concepts such as the key components of a successful QA/QI program, to more complex and advanced topics such as emerging issues affecting QA/QI implementation, will be shared in a variety of formats, including lecture and interactive discussion.



**Learning Objectives:**

- Understand the distinction between QA and QI concepts, and related activities
- Describe the key components of a successful QA/QI program
- Discuss strategies for flexing an auditing program, including consideration of partial/focused audits; in-person, hybrid, and/or remote audits, and application of a risk-based approach
- Create connection and share best practices with others in the field on key issues impacting QA/QI programs/staff

**Target Audience:** QA/QI Professionals

**Introduction to the IACUC**

Introduction to the IACUC is a basic-level educational program covering the fundamentals of IACUC principles and operations for new IACUC members, early career IACUC administrators, and investigators. This program reviews the history of animal welfare regulations and oversight and accrediting bodies; the roles and responsibilities of the IACUC and staff members; training IACUC staff, IACUC members, and research staff; protocol review; post-approval; and how to work with others outside of the IACUC. *This workshop was pre-recorded and will be available to view on-demand.*



**Learning Objectives:**

- Briefly chronicle the history of animal welfare regulations, research oversight and accrediting bodies
- Specify the roles, responsibilities, and training topics for researchers, IACUC members and IACUC staff
- Describe the protocol review and post-approval monitoring processes
- Identify effective ways to work with stakeholders outside of the IACUC

**Target Audience:** ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; Researchers and Research Staff

**Introduction to the IRB: Ethics and Regulation**

This workshop offers an introduction to the terminology, principles, and ethical and regulatory fundamentals of IRB review for new IRB members, early career IRB administrators, and investigators. The program includes an overview of practical applications of the core ethical principles to IRB work and an orientation to the regulations and available resources. This workshop will allow those new to the field to build a foundation in the effective review of human subjects research. *This workshop was pre-recorded and will be available to view on-demand.*



**Learning Objectives:**

- Outline the federal regulatory framework governing IRBs
- Describe basic requirements for IRB review of human subjects research
- Illustrate the ethical framework that undergirds human subjects protections

**Target Audience:** HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Researchers and Research Staff

Afternoon Workshops, 2:30-5:30 PM ET

**Applying the FDA Framework in Conducting IRB Review**

IRB review of FDA-regulated research requires the interpretation and application of regulatory standards that are different from, and often in addition to, those of the Common Rule. Effective review requires the ability to identify studies that are FDA-regulated, an understanding of how diverse products become test articles, and knowledge of investigational new drug (IND)/investigational device exemption (IDE) requirements. This workshop will provide participants with a stepwise process and framework to identify and apply these unique regulatory requirements to IRB review and the oversight of FDA-regulated research.



**Learning Objectives:**

- Examine when an activity falls under FDA regulations
- Outline a step-by-step framework for applying FDA regulations in clinical investigations

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Compliance Personnel; Clinical Research Staff; Researchers and Research Staff

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**Lead From Anywhere: Strategies for Oversight Professionals**

Leaders come from all areas of an organization and are not necessarily at the top of the organizational structure. Most professionals, at some point in their careers, need to manage a supervisor, peers, or subordinates. Effective leadership is essential for those in the oversight community and is key for ensuring ethical oversight and compliance regardless of whether you are affiliated with the IRB, IACUC, IBC, or another area. Interacting with staff at all levels requires different approaches and skills. These include effectively engaging peers and managing teams and developing your own leadership style with your staff. These skills cross office, role, and organizational boundaries, and identify strategies and approaches that maximize leadership abilities that will benefit any professional. This session expands on PR IM&R's May 2021 webinar, "Leading Up, Down, and Across Your Organization."



**Learning Objectives:**

- Introduce leadership strategies that are effective regardless of the role you fill in your organization
- Learn and discuss leadership styles; new skills and approaches; and best practices for implementing these skills in a variety of situations and settings

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Researchers and Research Staff

**Crash Course in Ethical Frameworks and How to Use Them**

Even with a good grasp of how to ensure a research activity complies with prevailing rules and regulations, the gap between compliance and what is ethical may be a source of confusion or anxiety. This workshop will equip attendees with tools to understand and describe ethically relevant features of a project or a situation, to propose and defend ethical courses of action, and to communicate clearly about ethical concerns. Speakers and attendees will practice applying these tools to case studies, and attendees will come away with good, ethical decision-making strategies and useful vocabulary, enabling attendees to go beyond "what do the rules say" and engage with "what would it be ethical to do in this situation?"



**Learning Objectives:**

- Review frameworks for evaluating the ethical dimensions of an action, including how the frameworks may lead to different judgments about what is ethical in a particular situation
- Practice applying ethical frameworks to case studies, recognizing the ways that ethical decision-making is similar to tackling a design problem, which is unlikely to have one "best" solution
- Learn how to use ethical concepts and vocabulary to defend a course of action, to challenge a course of action, and to ask questions about a proposed course of action

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Researchers and Research Staff

**Daily PAM Without the SPAM: Building an Ideal Postapproval Monitoring (PAM) Program Without Excess Burden**

During this workshop, attendees will review successful PAM practices from IACUC programs of various types and sizes. A focus will be placed on implementing PAM strategies that will be successful in the various attendees' programs, instead of a one-size-fits-all approach or incorporating laborious tasks into an already overworked program. Attendees will work together in teams to design an ideal PAM program, and review these ideas as a group. Participation by attendees is key for a successful session and learning experience.



**Learning Objectives:**

- Learn how to incorporate PAM into everyday work
- Review what styles of PAM may or may not work with your program
- Discuss examples of noncompliance and brainstorm ways that PAM could have prevented them
- Share best practices for PAM across institutions

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs

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**Exploring Hot Topics in Social, Behavioral, and Educational Research (SBER)**

This workshop will examine issues of concern to HRPPs that review SBER protocols. Intermediate/general-level didactic presentations will alternate with case discussion, focusing on the practical (and realistic) application of ethical and regulatory concepts and principles. The workshop will include real-world examples of research proposals for attendees to review and discuss, and speakers will explore the application of the regulations and ethical principles of research to online research and the use of social media (including the use of deception and incomplete disclosure for online research); the classification of research as exempt vs. expedited; and the inclusion of vulnerable populations in SBER. Attendees will have ample opportunity for discussion and sharing of best practices.



**Learning Objectives:**

- Understand and describe concepts related to topics such as online research, the use of social media, deception, and incomplete disclosure, and their regulatory or legal basis
- Identify how the concepts apply in research studies that your IRB reviews
- Evaluate best practices for minimizing risk to participants in SBER related to these concepts

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Researchers and Research Staff

Afternoon Workshops, 2:30-5:30 PM ET

**Institutional Official (IO) Discussion: Navigating Ethical and Regulatory Challenges While Accelerating Research**

The role of the IO is complex and has broad responsibility for supporting and protecting the research environment, including understanding and maintaining compliance with the federal regulations for the protection of human subjects, vertebrate animals, conflicts of interest/commitment, and research security. The programs under the auspices of the IO must proactively anticipate and support research needs to protect research participants, funding, researchers, and the institution's reputation. The IO must ensure that the institution has a robust integrated infrastructure with appropriate resources. In this dynamic session, speakers will put a broad set of issues on the table for discussion, including: integrating your HRPP and animal care and use program with other compliance programs (e.g., conflicts of interest, certificates of confidentiality, export control, sponsored programs, etc.); single IRB facilitation; supporting a virtual IRB/IACUC and workforce; promoting external evaluations (peer review) of your program; supporting internal quality assurance; assessing the value and risk of investigator-initiated studies; leadership cultivation within the office and on the IRB and IACUC; promoting diversity, equity, and inclusion within the office and on the IRB and IACUC; and exploring recent noncompliance/issues of HRPP and animal care and use programs. This session is intended to be dynamic and rapid paced, in order to cover topics that IOs are currently faced with or should be anticipating.



**Learning Objectives:**

- Explore how to cultivate and support the research enterprise in a changing environment
- Assess the intersections of the various components of research administration, while gaining an appreciation for internal and external assessment
- Reflect on recent regulatory changes and challenges of implementing robust research oversight activities and associated infrastructure

**Target Audience:** Research Program Leadership and Institutional Officials; HRPP/IRB Directors; ACU/IACUC Directors

**The IRB and Diversity, Equity, Inclusion, and Justice (DEIJ): Lead? Follow? Or Get Out of the Way? Exploring the Role of the IRB in DEIJ Efforts**

IRBs have always been charged with addressing issues of equity, justice, and access, but there is an increased need for IRBs and institutions to not only expand their roles, but be more integrated in and, in some cases, lead change at their organizations. This workshop will provide perspectives and a case study approach to explore how the IRB review function and oversight responsibilities can facilitate DEIJ initiatives, the role the IRB can play in different organizational structures, and the key elements to consider in developing and implementing a DEIJ workplan. Topics will include: (1) the role of the IRB in DEIJ initiatives including whether and how it should be expanded; (2) How the IRB should work with other institutional DEIJ initiatives and how to conduct a landscape analysis; (3) How to initiate, develop and implement a DEIJ workplan; (4) the role the IRB plays in community engagement and community representation; (5) How the IRB can use a DEIJ lens to evaluate protocols; (6) the key operational and infrastructure components needed to support an infrastructure for research conduct consistent with DEIJ best practices. Attendees will have an opportunity to explore developing a workplan template for their organization and learning from others what has worked or failed at their respective organizations.



**Learning Objectives:**

- Explore how the IRB review function and oversight responsibilities can facilitate DEIJ initiatives
- Discuss the role the IRB can play in different organizational structures
- Describe the key elements to consider in developing and implementing a DEIJ workplan

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Compliance Personnel; Clinical Research Staff; Researchers and Research Staff

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**When Change Is Constant: Balancing Regulatory, Workload, Safety, and Workplace Changes During the Pandemic and Beyond**

This interactive workshop will feature a review of regulatory, workload, safety, and workplace changes that occurred during the COVID-19 pandemic and how IACUCs and laboratory animal programs rose to the challenges to continue operating and contribute to vital medical research. Looking beyond the pandemic, speakers will focus on how these changes will endure and transform laboratory animal programs. Attendees will learn how IACUCs incorporated existing and new flexibilities to creatively streamline processes in animal research oversight. Facility and animal care changes to address changing workload and staffing demands, in the face of changing safety protocols, will be reviewed.



**Learning Objectives:**

- Review regulatory, workload, safety, and workplace changes that occurred during the COVID-19 pandemic
- Discuss how these changes will endure and transform laboratory animal programs
- Consider how flexibility to creatively streamline processes in animal research oversight can address changing facility and animal care workload and staffing demands in the face of changing safety protocols

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; Compliance Personnel, Laboratory Animal and Veterinary Staff

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10:00-10:15AM ET

Welcome Remarks from PRIM&R's Executive Director

Elisa A. Hurley, PhD, PRIM&R



10:15-11:30 AM ET

**Opening General Session: The Evolution of Ethics and Compliance in IACUC and IRB Oversight**

Compliance oversight is constantly evolving and there is an underlying role of ethical concerns that often drive changes in laws and regulations. The focus of this general session will be to discuss the evolution of compliance and its relation to ethical considerations in the areas of IRB and IACUC oversight. There will also be a presentation of other co-evolving regulatory bodies and how they impact decision-making. Finally, there will be discussion about how/when/where ethical oversight and discussion can take place within institutions to ensure the challenges that need to be considered are properly addressed.



Learning objectives:

- Review the history of the regulations of animal welfare and human subjects protections and the impetuses behind their development
- Explore the roles and responsibilities of the IRB and IACUC including purview and oversight expectations
- Using case scenarios, delineate the complementary roles of ethics and compliance in animal welfare and human subjects research identifying the what, how, and when of both types of analyses

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; IBC Directors; IBC Administrators, Manager and Staff; IBC Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Legal Counsel; QA/QI Professionals; Public Relations Professionals; Compliance Personnel; Laboratory Animal and Veterinary Staff; Educators/Trainers; Clinical Research Staff; Researchers and Research Staff

11:30-11:45 AM ET: Break

Concurrent Breakout Sessions, 11:45 AM-12:45 PM ET

**A1: Bringing the IRB to the People, and the People to the IRB**

*Track(s): Advancing Equity and Justice in Research; Communication With the Public; Flexibility and Innovation in Research Oversight Processes; HRPP/IRB Administration/Management and Process; IRB Chairs*

HRPPs/IRBs are innovating to increase outreach, engagement, and collaboration with their local communities in many ways: increasing the number and diversity of IRB members; sponsoring events that inform communities about IRBs and research oversight; conducting surveys of research participants; and forming relationships with community advisory boards, community organizations, and other groups to obtain input on policies, practices, and individual studies. This session will present preliminary data from three mixed methods studies on IRB engagement of non-scientist and non-affiliated members, eliciting participant perspectives as indicators of HRPP quality, and inclusion of participant perspectives in research ethics oversight activities. Speakers will then describe the institutional experience in this arena and discuss how community engagement can ultimately improve the quality and effectiveness of HRPPs.



**Learning Objectives:**

- Identify the benefits of reaching out to and engaging with the local community of potential research participants and research partners
- Describe strategies for engaging with the local community and identifying/overcoming barriers to stakeholder participation
- Using the example of a Community Engagement Steering Committee, describe how to identify key stakeholders and institutional commitments required; review strategies for recruitment, onboarding, education, and retention of members; and how to assess meaningful engagement and evaluate impact

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Diversity, Equity, Inclusion, and Justice; Educators/Trainers

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**A2: Ethical Considerations in Studies Involving Usual Care Arms**

Track(s): *Emerging Challenges and Breaking Issues*

There have been a number of [recent high-profile cases](#) where studies have been criticized for not including usual care arms. This raises deep questions related to ethical dimensions of study design and intersects with important issues, including vulnerability.



**Learning Objectives:**

- Consider the pros and cons of including "non-protocolized" populations in trials
- Discuss the challenges of defining "usual care" and the implications of adopting different definitions
- Identify implications for IRBs in evaluating risks, given that standard care is not as "standardized" as one might think

**Target Audience:** HRPP/IRB Directors; IRB Members, Chairs, and Vice Chairs; Compliance Personnel; Clinical Research Staff; Researchers and Research Staff

**A3: Incorporating Investigator Education into Postapproval Compliance Activities**

Track(s): *QA/QI and Postapproval Monitoring; Education, Qualifications, and Training; Flexibility and Innovation in Research Oversight Processes*

This session will discuss practical strategies for incorporating education into postapproval monitoring (PAM) activities. Monitoring is often viewed by the research community as a potentially punitive activity. However, reframing it as an educational endeavor about necessary research practices will increase knowledge and skills in conducting compliant, high quality, ethically sound human subjects research. Taking the extra steps to provide education during monitoring activities builds relationships with the research community and strengthens the overall research compliance by the research community. The presenters will share specific tools and techniques that audience members may incorporate into their own monitoring programs or as a part of study related activities.



**Learning Objectives:**

- Identify strategies for incorporating education into PAM activities (e.g., risk-based, remote, in-person, internal) including routine monitoring and auditing
- Provide practical strategies for educational approaches that organizations may adopt as part of their own programs
- Discuss incentives for encouraging investigator and study staff participation/engagement

**Target Audience:** HRPP/IRB Administrators, Managers, and Staff; QA/QI Professionals; Compliance Personnel; Educators/Trainers

**A4: Categorical Conundrum: What Is the Tipping Point for Non-Exempt SBER Needing Convened Review**

Track(s): *Social, Behavioral, and Educational Research*

What is the tipping point for a behavioral study to move from expedited review to full board review outside of simply not meeting an expedited category, which is rare in behavioral research? When does the idea of what is minimal risk come into question such that a group of people would need to discuss it at a meeting? SBER usually meets the exempt and expedited categories, thus not qualifying as greater than minimal risk. This session will explore when SBER crosses the threshold for a full board discussion and what factors may contribute to that decision.



**Learning Objectives:**

- Explore whether there are times when a minimal risk social behavioral study technically meets the requirements for an expedited category, but would be more appropriate for a convened board discussion
- Examine how topics such as suicide, illegal and illicit drugs, criminal activity, immigration status, etc., are handled regarding full board or expedited review, and whether a Certificate of Confidentiality plays a role in the decision
- Consider the extent to which certain populations influence the decision to bring a study for full board consideration

**Target Audience:** HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs

**A5: A Case Study Exploring the Ethical Considerations for Pediatric Clinical Trials.**

Track(s): *FDA Regulated Research; Populations Requiring Additional Protections*

FDA's regulations for human subjects protections for children, the Additional Safeguards for Children in Clinical Investigations (21 CFR 50, subpart D), must be considered when children are enrolled in a clinical trial. This session will provide an overview of FDA's current policy related to the interpretation and application of Subpart D in pediatric clinical trials, a case example, and a panel discussion.



**Learning Objectives:**

- Describe FDA's policy related to key concepts related to the enrollment of children in clinical trials in 21 CFR 50, Subpart D, including "prospect of direct benefit," the meanings of "minimal risk" and "minor increase over minimal risk," and "component analysis"
- Evaluate a clinical trial protocol to determine if a trial may be allowed to proceed under 21 CFR 50.51, 50.52, or 50.53

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Compliance Personnel; Clinical Research Staff; Researchers and Research Staff

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### A6: A Dialogue With NIH OLAW

Track(s): *A Dialogue With the Feds*

NIH OLAW provides guidance and interpretation of the PHS Policy on Humane Care and Use of Laboratory Animals, supports educational programs, and monitors compliance with the PHS Policy by assured institutions and PHS funding components to ensure the humane care and use of animals in PHS-supported research, testing, and training. This session will provide an opportunity to hear from NIH OLAW staff on programmatic updates and to ask questions.



**Learning Objectives:**

- Hear from NIH OLAW representatives about evolving initiatives, issues, and guidance
- Participate in an open discussion about issues relevant to NIH OLAW stakeholders
- Ask questions of NIH OLAW representatives

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Legal Counsel; QA/QI Professionals; Compliance Personnel; Laboratory Animal and Veterinary Staff; Educators/Trainers; Clinical Research Staff; Researchers and Research Staff

### A7: Experimental Design as a 3Rs Imperative

Track(s): *Animal Well-Being and the 3Rs; IACUC Protocol Review*

**Brianna Gaskill, Novartis--SF; Gary Borkowski, AAALAC**

*Backups: Gaylen Edwards; Teri Oday, Novartis biostatistics; Adrian Smith; Robyn Lee-Stubbs, Chair/Statistician, Army Medical Research Institute of Chemical Defense; Heather Sidener, DVM OHSU*

*Declined: Sarah Nusser, Iowa State University; Regina Nuzzo, Gallaudet University*

AAALAC International recently released a FAQ document clarifying the IACUC's responsibility to review study design in support of reproducibility. This session will help IACUCs and investigators understand what they should be looking for in study design and statistics when assessing animal use protocols. Evolved study designs and how they can be considered a 3Rs method to reduce the number of animals needed while answering more scientific questions, will also be discussed.



**Learning Objectives:**

- Discuss different experimental design options
- Review reproducibility and translation of animal studies
- Explore the pitfalls, power, and practices including the review of online tools

**Target Audience:** ACU/IACUC Directors; IACUC Members, Chairs, and Vice Chairs; Compliance Personnel; Laboratory Animal and Veterinary Staff; Clinical Research Staff; Researchers and Research Staff

### A8: Flexibility and Innovation in Semiannual Inspections

Track(s): *Flexibility and Innovation in Research Oversight Processes; ACU Program Management*

The PHS Policy requires the IACUC to review the animal program and inspect the facilities once every six months using *The Guide* as the basis of evaluation. How does one design a semiannual inspection that meets the needs of their institution/corporation? Have institutions made permanent changes to the process based on the pandemic? This session will review these topics plus consider how successful adjustments have been made to meet the requirements and the needs of facilities.



**Learning Objectives:**

- Discuss creative approaches to semiannual inspections, ensuring the key elements of the program are evaluated
- Explore challenges that necessitated the reassessment and change of current processes
- Elaborate on the process evaluation and implementation of new processes, as well as challenges to implementation
- Share useful and practical tools or strategies for semiannual inspections to ensure ongoing compliance with regulatory requirements for semiannual inspections

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff

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**A9: Formalizing Community Bridges for Research Ethics and Trust**

Track(s): *Advancing Equity and Justice in Research; Communication With the Public; Emerging Challenges and Breaking Issues*

Because public engagement about research is important to maintaining trust and transparency between research institutions and the public, it is imperative that research professionals engage in two-way conversations about research with the general public. Doing this in a structured and ongoing way will allow for research professionals to learn about the communities they serve in ways that will impact the research being reviewed and conducted by their institutions. It also allows the public to learn about how research is considered and operationalized, so members of the public can provide feedback on, not only the research, but the research review process and priorities. Speakers will discuss how they engage communities. In Utah, for example, as a lead-in to the PRIM&R Annual Conference in Salt Lake City, a Utah-specific conference is being hosted to discuss research ethics and the needs and perspectives of the Utah's different communities. This conference involves both public leaders and research ethics professionals as speakers and attendees. This method for bi-directional exchange of information is likely to be a model that can be used at other locations. The goal of this session at PRIM&R is to discuss formal mechanisms such as this one in Utah, that allow for public participation in research.



**Learning Objectives:**

- Consider the value of formalized, bi-directional exchanges with the public about research ethics
- Explore different methods for formalizing bi-directional communication between the public and research ethics professionals
- Learn about the experience and perspectives of Utah-based public leaders who participated in a conference on research ethics prior to the PRIM&R Annual Conference

**Target Audience:** ACU/IACUC Directors, ACU/IACUC Administrators, Managers, and Staff, IACUC Members, Chairs, and Vice Chairs, HRPP/IRB Directors, HRPP/IRB Administrators, Managers, and Staff, IRB Members, Chairs, and Vice Chairs, IBC Directors, IBC Administrators, Manager and Staff, IBC Members, Chairs, and Vice Chairs, Research Program Leadership and Institutional Officials, Public Relations Professionals, Compliance Personnel, Laboratory Animal and Veterinary Staff, Educators/Trainers, Clinical Research Staff, Researchers and Research Staff, Diversity, Equity, Inclusion, and Justice

**A10: Leading With Respect, Communication, and Collaboration at All Levels of the Research Enterprise**

Track(s): *Leadership Skills Development; Research Oversight Leaders and Institutional Officials*

It is the responsibility of institutional leadership to create a culture and foundation of regulatory support, compliance, ethics—one that respects and enhances the work being done by research oversight programs. In addition, in a time when the workforce is challenged by burnout, remote work, and resignation/staffing shortages, it is imperative that leaders understand the importance of demonstrating respect, using appropriate communication, and fostering collaboration at all levels of the research program and institution. During this session, speakers will discuss how to work toward these goals, and will review how executive intelligence, coaching, and key leadership traits can contribute to building effective leaders.



**Learning Objectives:**

- Recognize how effective leadership within the research enterprise encompasses respect, communication, and collaboration at all levels within the institution
- Define executive intelligence and its link to success as a leader
- Identify effective leadership traits for executive leaders within the research enterprise

**Target Audience:** Research Program Leadership and Institutional Officials

**A11: A Dialogue With the Department of Veterans Affairs (VA): A Federal Agency's Challenges and Solutions in Working with External IRBs to Facilitate Implementation of the Cooperative Research Provisions**

Track(s): *A Dialogue With the Feds*

This session will be led by representatives from the VA.



**Learning Objectives:**

- Identify unique requirements specific to a federal agency that are barriers to VA's reliance on external IRBs and VA's solutions to eliminate the barriers
- Describe common questions and answers from VA Facilities and external IRBs (e.g., university, commercial (independent), and other federal agency IRBs) on IRB review issues and processes when VA Facilities rely on external IRBs
- Identify national and local quality improvement mechanisms VA uses to oversee the Agency's use of external IRBs

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Legal Counsel; QA/QI Professionals; Compliance Personnel; Educators/Trainers; Clinical Research Staff; Researchers and Research Staff

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Vendor Insight Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

### A12: Navigating Data and Specimen Sharing for Transnational Research

Track(s): *Transnational Research Collaborations; Research Involving Data and Biospecimens*

Transnational research collaborations increasingly include plans to share data and biospecimens across research sites. Researchers interested in sharing data and biospecimens globally must be aware of applicable data/biospecimen sharing requirements and incorporate mechanisms to address these requirements in their research plans. Likewise, IRBs must be prepared to review projects involving global data/biospecimen sharing and assist researchers in navigating applicable consent, data privacy and security and material transfer requirements.



**Learning Objectives:**

- Provide HRPPs, IRBs, and global researchers practical tools in identifying, interpreting, and applying data/biospecimen sharing requirements in the design and review of transnational research
- Share best practices for consent, data privacy and security in global research to facilitate this data/biospecimen sharing

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Compliance Personnel; Researchers and Research Staff; Clinical Research Staff

### A13: When Employees Are Research Participants: Ethical Considerations and Perspectives of Academia, Government, and Private Industry

Track(s): *Emerging Challenges and Breaking Issues; Pharma/Biotech Perspectives; Populations Requiring Additional Protections*

Although human subjects research typically excludes employees of an organization from serving as research participants (due to concerns about vulnerability and bias), it is possible for research to involve employees ethically as long as appropriate protections are in place. This session will examine the ethical considerations when employees of an institution serve as research participants. Speakers will represent a variety of settings (e.g., universities, government, private industry) and will provide recommendations for the ethical design, conduct, and review of research when it involves employees. Time will be saved at the end for questions. Attendees should have a familiarity with the ethical review of human subjects research, as well as the design and conduct of human subjects research, before attending this session.



**Learning Objectives:**

- Discuss the ethical issues raised when employees serve as research participants
- Consider the conditions under which different institutional settings may permit research involving employees
- Expand knowledge of how research involving employees is designed, conducted, and reviewed in other settings

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Legal Counsel; Compliance Personnel; Clinical Research Staff; Researchers and Research Staff

### A14: FDA and the Center for Biologics Evaluation and Research's (CBER) Regulation of Biological Products, Including Regenerative Medicine Therapies

Track(s): *FDA Regulated Research*

This session will introduce the audience to how different types of biological products are regulated by FDA CBER. The presentation will include a discussion of FDA's regulatory framework for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps), including when you need an investigational new device. The session will also cover the marketing of unapproved regenerative medicine therapies for which studies have not been done to demonstrate safety and effectiveness. The session will include an IRB representative who will discuss how an IRB might analyze regenerative medicine therapy submissions.



**Learning Objectives:**

- Review FDA CBER's regulation of biological products
- Discuss FDA CBER's HCT/P regulatory framework
- Identify different aspects of the role of an IRB in analyzing regenerative medicine therapy submissions

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Compliance Personnel; Clinical Research Staff; Researchers and Research Staff

### A15: Inspiring Innovation: The Seven Habits of Highly Effective and Flexible HRPPs

Track(s): *Flexibility and Innovation in Research Oversight Processes; HRPP/IRB Administration/Management and Process*

HRPPs are more than IRBs and include a range of responsibilities to meet the goal of protecting human subjects. However, getting components of HRPPs to work together and communicate well can be a bit like herding cats. Session speakers will share their experiences in creating and maintaining well-connected HRPPs that work together to provide robust protection of research participants. Session speakers will also highlight where better-connected components create flexibility for the HRPP.



**Learning Objectives:**

- Identify the key components of HRPPs and their roles
- Consider how to inspire and lead change within HRPPs/IRBs
- Discuss strategies, including the use of electronic systems, that promote effective information flow amongst HRPP components
- Share lessons learned in creating an effective and flexible HRPP

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Vendor Insight Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

**A16: An Update From AAALAC International**

Track(s): *A Dialogue With the Feds*

AAALAC International is a voluntary accrediting organization that enhances the quality of research, teaching, and testing by promoting humane, responsible animal care and use. It provides advice and independent assessments to participating institutions and accredits those that meet or exceed applicable standards. This session will provide an opportunity to hear from AAALAC International staff on programmatic updates and to ask questions.



**Learning Objectives:**

- Review the process of achieving or maintaining AAALAC accreditation
- Discuss AAALAC's approach to cutting edge issues in animal care and use
- Outline the most frequent identified findings during site visits
- Ask questions of AAALAC International representatives

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Compliance Personnel; QA/QI Professionals; Laboratory Animal and Veterinary Staff; Researchers and Research Staff

**A17: New and Evolving Considerations for Disaster Planning**

Track(s): *ACU Program Management; IACUC Administration/Management and Process*

Is it time to dust off and reconsider your disaster plan? Does it go far enough to protect your overall program and not just your animals in time of natural disasters? While the USDA's contingency planning rule now lays out specific areas to cover, programs should determine if there are other programmatic areas to consider as part of business continuity planning and ability to maintain operations. Even if an institution does not maintain regulated species, having an agile, accurate, and accessible plan can be a lifeline. Join this session to think beyond the standard considerations and into the bigger picture of response and reestablishing operations in light of a disaster.



**Learning Objectives:**

- Understand what could impact an institution beyond the "standard" considerations of natural disasters (e.g., cyber attack, smoke from wildfires, breach of facilities)
- Consider how to respond to disasters (e.g., what are the risks, who has the knowledge, who are the stakeholders, who are the responders, what communication actions/timelines are needed, who should be part of this chain)
- Expand thinking beyond the vivarium (i.e., does your IACUC know how to operate in the face of a disaster, should your plan include digital access considerations, how should you implement such a plan)

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Compliance Personnel; Laboratory Animal and Veterinary Staff; Clinical Research Staff; Researchers and Research Staff

**A18: How Ethical Review Occurs in Industry**

Track(s): *Pharma/Biotech Perspectives*

Private companies, such as pharmaceutical companies and Contract Research Organizations, fund their own research and do not receive US government funding, and the ethical and compliance review of animal studies and programs are done exclusively within the company. Further, if the site does not have a USDA registration, and there are no additional requirements by state or local regulations, the company may not legally be required to have an IACUC or to perform ethical review of their studies. However, because there is a strong commitment to animal welfare, building trust with society, and the quality of in-vivo research, most private companies voluntarily pursue AAALAC accreditation, which requires all the same processes and practices as an institution that receives public funds (i.e., adhering to *The Guide*). Therefore, there is a robust process in place to ensure IACUC review and compliance assurances in industry. In non-US settings, external review is often still required even if they do not receive public funding. Examples of each will be discussed.



**Learning Objectives:**

- Gain an understanding of how private companies ensure high standards of animal welfare
- Discuss various scenarios involving funding sources and species that impact regulatory oversight of in-vivo research at private companies
- Contrast and compare US and International examples of privately funded research with animals

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; Compliance Personnel; Laboratory Animal and Veterinary Staff; Clinical Research Staff; Researchers and Research Staff

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Workshop Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

**A19: Is Your Institution Ready to Handle Open Record and FOIA Requests?**

Track(s): *Shared Oversight Challenges; Legal Considerations in Research Oversight*

An institution should be ready to respond to FOIA requests and there are many aspects to consider. This session will provide an overview of open records and FOIA laws and regulations and discuss methods to deal with requests for animal care and use records.



**Learning Objectives:**

- Review the use and abuse of open records and FOIA laws in obtaining information about research programs
- Demonstrate the importance of having plans in place before open records/FOIA requests are received, including consideration of the type of information included in meeting minutes, accreditation program descriptions, etc.
- Discuss internal (e.g., IRB, IACUC, IO, FOIA Office, legal counsel) and external (e.g., regulatory and accreditation agencies, media outreach) communication strategies when open records/FOIA requests are received

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; Research Program Leadership and Institutional Officials; Legal Counsel; Public Relations Professionals

**A20: Creating Expectations for Equity and Justice in Research Protocols**

Track(s): *Advancing Equity and Justice in Research; Research Oversight Leaders and Institutional Officials*

This session will consider "whose job is it?" to create expectations and accountability for equity and justice within the research program. Should the "mandate" come from institutional leadership, the investigator, and/or from the oversight committees? What is the role of each of these parties and how can they work together to achieve progress?



**Learning Objectives:**

- Identify ways to make protocols just and equitable, including creating appropriate recruitment plans and engagement with the community on design
- Discuss the resources needed to create an ongoing infrastructure and faculty/staff education program on the communities they serve to enhance community engagement
- Examine the role leadership in ensuring appropriate committee representation and empowering/uplifting staff voices within the institution
- Explore how institutional leadership can inform and drive changes to research design and agenda

**Target Audience:** Research Program Leadership and Institutional Officials; ACU/IACUC Directors; HRPP/IRB Directors; IBC Directors; Researchers and Research Staff

**12:45-1:30 PM: Mid-Day Break**

**12:45-1:30 PM: Sponsored Presentation from Cayuse: The Power of Configurable, Flexible, and Integrated Compliance Solutions**

Track(s): *Flexibility and Innovation in Research Oversight Processes; Education; Shared Oversight Challenges*

Organizations need to rethink how they can empower their investigators and positively impact the full research lifecycle by leveraging modern and evolving technology. You need a faster process for compliance review: an easier way to identify risks, monitor progress, and preserve integrity without impeding science. A centralized place to collect all necessary information, approvals, and supporting documents before deadlines. Cayuse's research compliance software will help you adhere to regulations and increase collaboration and transparency to reduce administrative burden. We stay ahead of the latest regulatory changes and make sure Cayuse products help you adhere to them.



**Learning Objectives:**

- Review the benefits of a centralized risk management suite
- Identify ways the Cayuse Research Suite can simplify processes, allowing your team to break down silos and reduce administrative burden
- Recognize how Cayuse empowers institutions to stay ahead of regulatory changes with the use of smart form technology

**Target Audience:** ACU/IACUC Directors; HRPP/IRB Directors; IBC Directors; HRPP/IRB Administrators, Managers, and Staff; ACU/IACUC Administrators, Managers, and Staff; IBC Administrators, Managers, and Staff; Compliance Personnel

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Workshop Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

**B1: May I Borrow a Tissue? Secondary Use of Biological Samples**

Track(s): *Pharma/Biotech Perspectives; Research Involving Data and Biospecimens*

The use of de-identified biological samples is a key element for treatment and diagnostic development. However, issues remain around consent and secondary use of such tissues. These issues will become even more salient as the sophistication of methodologies and technologies for re-identification of tissues grows. This session will discuss current issues in the use of biological samples in clinical research, including consent (what is in it, what should be in it), de-identification and re-identification considerations, and ethical issues surrounding secondary use of tissues.



**Learning Objectives:**

- Discuss what should be in the consent and protocol and what to do if the consent is silent
- Review what bioethics considerations de-identification/anonymization do and do not address
- Share and discuss best practices for managing secondary use

**Target Audiences:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Legal Counsel; Clinical Research Staff; Researchers and Research Staff; Research Program Leadership and Institutional Officials

**B2: Recruiting, Training, and Retaining IRB Chairs**

Track(s): *IRB Chairs*

This session will explore what IRB chairs believe they need to know, and what HRPPs believe chairs need to know in order to perform their responsibilities. Topics include how to identify individuals to serve in the role, how the role is defined and by whom, the limits of chair authority, and the ways in which chairs may bring unique qualifications in collaborating/negotiating with investigators, faculty, institutional leadership, and other stakeholders.



**Learning Objectives**

- Discuss how to better understand the role and obligations of an IRB chair
- Consider how to manage workload, competing obligations, balance, pay considerations, etc.
- Explore how to gain the knowledge and skills associated with the role of IRB chair, including how to stay current with the regulations and evolving ethical norms
- Learn how HRPPs/IRBs can support the work of the IRB chair and vice versa

**Target Audience:** IRB Members, Chairs, and Vice Chairs

**B3: "Perfect" Study Submissions: Approaches to Improving IRB Submissions for a Better Review Process**

Track(s): *QA/QI and Postapproval Monitoring; Flexibility and Innovation in Research Oversight Processes; Education, Qualifications, and Training*

The quality of an IRB submission significantly affects the review process, both in terms of its length and how smoothly it goes. This session will explore different methods for improving IRB applications before sending them for IRB review, such as training research teams on how to prepare better protocols and IRB applications, and the role of IRB operations and compliance staff before the submission is provided to IRB reviewers. When IRB staff are involved in assessing submissions, how do they determine when it is worthwhile to work with the study team to "perfect" the submission before IRB review?



**Learning Objectives:**

- Identify the challenges posed to the IRB review process due to poor quality submissions
- Explore different methods used to improve the quality of IRB submissions, such as those that focus on study team efforts and those that leverage IRB staff expertise
- Discuss the pros and cons of different strategies to improve IRB submission quality

**Target Audience:** HRPP/IRB Administrators, Managers, and Staff; Compliance Personnel; QA/QI Professionals

**B4: Beyond Subpart C: Understanding Prisoner Vulnerability, the Role of Prisoner Representatives, and Best Practices for Just and Comprehensive IRB Review**

Track(s): *Populations Requiring Additional Protections; Advancing Equity and Justice in Research*

In this session, speakers will discuss the intricacies of Subpart C. Through examples, speakers will look at context-specific variables that contribute to or compound prisoner vulnerability, and it will consider the regulatory definition of prisoner, who it covers and when, and ways for IRB reviewers to fill the gaps. Speakers and attendees will think through the fundamentals of what makes a good (not simply compliant) IRB prisoner representative, and outline best practices for engaging with the representative to mitigate prisoner vulnerability for research participation. Attendees should have a basic understanding of ethical and regulatory considerations for research involving prisoners before attending this session.



**Learning Objectives:**

- Identify the variety of institutional factors that can contribute to prisoner vulnerability
- Pinpoint the gaps to protection in Subpart C, and describe strategies to address them
- Understand what makes a strong prisoner representative on the IRB, and how to best leverage that role

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Clinical Research Staff; Researchers and Research Staff; Compliance Personnel; Diversity, Equity, Inclusion, and Justice

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Vendor Insight Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

**B5: A Dialogue With USDA, APHIS, Animal Care**

Track(s): *A Dialogue With the Feds*

Congress has entrusted APHIS with the stewardship of animals covered under the Animal Welfare Act and Horse Protection Act, and APHIS continues to uphold that trust, giving protection to millions of animals nationwide. APHIS provides leadership for determining standards of humane care and treatment of animals, implements those standards, and achieves compliance through inspection, education, cooperative efforts, and enforcement. This session will provide an opportunity to hear from USDA staff on programmatic updates and to ask questions



**Learning Objectives:**

- Hear from USDA, APHIS, Animal Care representatives about evolving initiatives, issues, and guidance
- Participate in an open discussion about issues relevant to USDA, APHIS, Animal Care stakeholders
- Ask questions of USDA, APHIS, Animal Care representatives

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Legal Counsel; QA/QI Professionals; Compliance Personnel; Laboratory Animal and Veterinary Staff; Educators/Trainers; Clinical Research Staff; Researchers and Research Staff

**B6: Challenges and Strategies for Adequate Staffing in Animal Care and Use Programs**

Track(s): *ACU Program Management; Emerging Challenges and Breaking Issues; Leadership Skills Development; Small Research Programs*

The pandemic has created staffing challenges in multiple industries, and the animal care and use program is not exempt. Staffing shortages within the program has led to increased burnout of existing staff due to having to wear multiple hats, supervisory and professional staff performing technician tasks, and fewer CROs available to assist with laboratory work. Staffing shortages also create risk for the program regarding noncompliance, perceived adverse animal welfare by outside groups, and conflicts of interest. With no relief in sight, how do animal care and use programs monitor staffing levels, if at all? How does leadership determine which animal support tasks are more critical than others in the face of staffing shortfalls, if such an exercise is deemed necessary? How do we take care of existing staff? What is the role of education and cross training within programs to assist with promotion and growth? How do programs consider individuals from non-traditional backgrounds as potential candidates for roles? These and other related topics will be discussed.



**Learning Objectives:**

- Consider how staffing shortages negatively impact the animal care and use program and how to advocate for resources from leadership
- Explore ways to support existing staff to prevent burnout and increased compassion fatigue
- Discuss recruitment and retention strategies to broaden the network of potential candidates (e.g., cross training, promoting roles to those with non-traditional backgrounds)

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; Research Program Leadership and Institutional Officials; Laboratory Animal and Veterinary Staff

**B7: The Need for Transparency as the Public and Legislators Weigh Legal Challenges to the Future of Research With Animals**

Track(s): *Pharma/Biotech Perspectives*

Individual pharmaceutical and biotech companies, as well cross industry organizations like the Institutional Officials Consortium and Interpharma, have taken steps to increase transparency to the public about why and how they work with animals needed for the development of new therapies for human and animal patients. Advocacy partners can also serve as key partners to understand where and how to best lean into transparency and provide education to the public and legislators. Speakers will share success stories and practical tips.



**Learning Objectives:**

- Explore recent examples of animal rights sponsored legislative proposals that can or have impacted the ability to conduct in-vivo research
- Discuss the importance of the in-vivo research voice and expertise in influencing public discourse and legal challenges to in-vivo research
- Learn about successful proactive and reactive approaches to informing the public and legislators about companies' commitment to animal welfare and the continued need and value of research with animals

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Legal Counsel; Compliance Personnel; Laboratory Animal and Veterinary Staff; Clinical Research Staff; Researchers and Research Staff; Public Relations Professionals

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Workshop Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

**B8: Addressing Implicit, Unconscious, and Conscious Biases: Leadership, Investigators, and Ethics Boards Throughout the Lifecycle of Research Initiatives**

Track(s): *Advancing Equity and Justice*

The lifecycle of research initiatives can be impacted by biases and so, awareness and strategies (and courage) can help you, as a leader, contribute to a more inclusive world and make our work/research activities more intentional and deliberate. This session will help attendees explore their identities to consider their unconscious biases, reexamine ways that inherent bias impacts decisions and actions, and consider strategies to avoid bias traps. The presenters will provide diverse perspectives on the key areas of unconscious, conscious, and implicit bias that impact equity in the research enterprise. This will be done through group illustrative case studies. Additionally, the session will provide practical recommendations on how to ask the questions necessary to unpack their own bias, identify bias within institutional processes, identify and address gender bias and western/colonial dominant culture bias in the USA, and address bias in the design and conduct of research.



**Learning Objectives:**

- Identify your own internal biases and recognize implicit bias within leadership and compliance committees
- Apply anti-bias strategies across the lifecycle of work through analysis and evaluation of case studies
- Identify what leaders need to know within themselves to have an unbiased impact on the lifecycle of research activities
- Review common bias traps, and identify innovative ways to approach work practices, recognizing internal, anti- and unconscious bias, social justice, and current social issues

**Target Audience:** ACU/IACUC Directors, ACU/IACUC Administrators, Managers, and Staff, IACUC Members, Chairs, and Vice Chairs, HRPP/IRB Directors, HRPP/IRB Administrators, Managers, and Staff, IRB Members, Chairs, and Vice Chairs, IBC Directors, IBC Administrators, Manager and Staff, IBC Members, Chairs, and Vice Chairs, Research Program Leadership and Institutional Officials, Diversity, Equity, Inclusion, and Justice, Compliance Personnel, Laboratory Animal and Veterinary Staff, Clinical Research Staff, Researchers and Research Staff

**B9: Let's Get Digital: Challenges and Best Practices With Implementation of Remote Monitoring Practices**

Tracks(s): *QA/QI and Postapproval Monitoring; Flexibility and Innovation in Research Oversight Processes*

"Remote monitoring" has been a buzz phrase used almost as frequently as "risk-based monitoring." However, what does it look like to transition postapproval monitoring (PAM) programs from in-person to remote monitoring? This session will share experiences from monitoring programs at large and small institutions that transitioned to remote monitoring. Presenters will share experiences and best practices for connecting with the research community while implementing and conducting a variety of remote monitoring activities.



**Learning Objectives:**

- Identify tools and resources available to assist PAM programs in transitioning to remote activities
- Provide best practices and lessons learned from remote PAM
- Share practical strategies for educational approaches that organizations may adopt as part of implementing their own remote monitoring programs

**Target Audience:** HRPP/IRB Administrators, Manager and Staff; ACU/IACUC Administrators, Manager and Staff; QA/QI Professionals; Compliance Personnel

**B10: What You Don't Know Can Hurt You: Using Metrics to Evaluate Research Administrative Activities**

Track(s): *Research Oversight Leaders and Institutional Officials*

There is an abundance of information, data, metrics, etc., that may be available and/or useful to institutional leadership to assist them with the leadership of the research mission. But, is there too much information? Or, less useful or even useless information? What is important for institutional leadership to know? From a leadership perspective, important questions require exploration, including: 1) What metrics are important?; 2) how are the baseline metrics established?; 3) who collects the information for reporting?; 4) who receives the information and how are they used to affect change?; and 5) how do you catalyze internal and/or external evaluation activities to assess program effectiveness? This session will explore the data/metrics institutional leadership may use to determine resource allocation, set expectations, predict future needs, and measure processes and progress of our research administration and compliance activities.



**Learning Objectives:**

- Explore the metrics institutional leadership might use to carry out the research program's mission
- Consider how such data can be used to both measure effectiveness of the research program and determine future priorities

**Target Audience:** Research Program Leadership and Institutional Officials; ACU/IACUC Directors; HRPP/IRB Directors; IBC Directors

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Workshop Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

### B11: An Update From AAHRPP

Track(s): *A Dialogue With the Feds*

Join us to discuss and learn about AAHRPP accreditation. AAHRPP, founded by PRIM&R and six other research-focused organizations in 2001, is an international nonprofit organization that accredits high quality HRPPs. AAHRPP provides peer-based, collaborative, collegial and educationally based evaluations of HRPPs based on applicable standards and elements. This session is designed to answer questions about accreditation for organizations considering AAHRPP accreditation and those that are already AAHRPP accredited.



**Learning Objectives:**

- Review the process of achieving or maintaining AAHRPP accreditation
- Discuss AAHRPP's approach to cutting edge issues in the human research enterprise
- Become familiar with AAHRPP staff and web resources available to all wishing to maintain or achieve a robust system of human research protections

**Target Audience:** HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Legal Counsel; QA/QI Professionals; Compliance Personnel; Educators/Trainers; Clinical Research Staff; Researchers and Research Staff

### B12: International Data Privacy Regulations: An Overview of the Regulatory Landscape and Tools for Implementing a Review Process

Track(s): *Legal Considerations in Research Oversight; Research Involving Data and Biospecimens*

The data privacy protection regulatory landscape is rapidly evolving. Failure to comply with privacy regulations can present risk to researchers and their institutions. In this session, speakers will review US and international data privacy regulations, discuss the data privacy review processes implemented at two different institutions, and the impacts on various organizational components and their involvement in the implementation of the review process.



**Learning Objectives:**

- Learn about evolving data privacy regulations
- Understand how data privacy regulations may impact your research
- Gain knowledge regarding institutional review processes to help ensure compliance with applicable data privacy regulations

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; Research Program Leadership and Institutional Officials; IRB Members, Chairs, and Vice Chairs; Legal Counsel; Researchers and Research Staff; Compliance Personnel

### B13: Apparently, Looks Do Matter: Visualizing IRB Data Differently

Track(s): *HRPP/IRB Administration/Management and Process; Education, Qualifications, and Training*

Presenting research, operational, or individual productivity data are all requirements from institutional leadership, research communities, office staff, and clients. But, if there is too much information to comprehend, the data can be unclear to consumers. This session will explore how to assess data presentations and visualize data differently to support a better understanding of the concepts being reported.



**Learning Objectives:**

- Discuss the concepts of data visualization
- Assess the presentation of operational data
- Consider new ways of presenting data so it is more impactful for those consuming it

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Manager and Staff; Educators/Trainers

### B14: How to Evaluate Terms of Service and Privacy Policies of Mobile Technologies

Track(s): *Research Conducted in the Digital World; Legal Considerations in Research Oversight*

Mobile technologies are increasingly used in research, and some of the ethical risks posed by these technologies are embedded in dense and arcane Terms of Service and Privacy Policies. Attendees should be familiar with the regulations and processes governing the ethical review and oversight of human subjects research that use mobile technologies before attending this session.



**Learning Objectives:**

- Discuss the risks most commonly embedded in Terms of Service and Privacy Policies
- Consider how to identify these risks within Terms of Service and Privacy Policies
- Share strategies for mitigating the challenges posed by these risks, which are in the scope of the IRB
- Learn how to conduct a review of the Terms of Service and Privacy Policies for mobile health and non-health-related technologies and how that approach may change HIPAA covered entities and non-covered entities

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Compliance Personnel; Clinical Research Staff; Researchers and Research Staff; Legal Counsel

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Workshop Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

**B15: Continuing Review as a QA/QI Opportunity**

Track(s): QA/QI and Postapproval Monitoring; Flexibility and Innovation in Research Oversight Processes

Although many aspects of continuing review are common among HRPPs, some aspects are not. For example, when continuing review is required for a study, some HRPPs audit items like consent documents and HIPAA authorizations at the time of continuing review while others don't. When continuing review is not required for a research study or research is ceded to an external IRB, some institutions still require an annual check-in and others don't. This session will consider how continuing review can be used as a QA/QI opportunity, the level of auditing that should be done and the implications for staffing, timelines, noncompliance findings, etc.



**Learning Objectives:**

- Consider approaches to using continuing review as a way of ensuring study team compliance with IRB determinations (whether an internal or external IRB)
- Discuss when and how variations on the continuing review model might be applied to minimal risk research and research reviewed by an external IRB to help an institution maintain oversight of its research portfolio
- Explore how continuing review QA/QI approaches can be scaled based on HRPP resources

**Target Audience:** HRPP/IRB Administrators, Managers, and Staff; Compliance Personnel; QA/QI Professionals

**B16: Conducting Ethical Transnational Research in Times of Conflict**

Track(s): Transnational Research Collaborations

Times of global conflict may generate important research questions. It is critical that IRBs are equipped to review research that may take place during times of conflict as this research is often time sensitive and may have immediate impact for policy or relief efforts.



**Learning Objectives:**

- Share experiences from researchers who have conducted research during times of conflict including practical strategies research teams might adopt to minimize risk to participants and study team members
- Highlight best practices for IRBs, HRPPs, and researchers in planning, conducting, and reviewing global research conducted during times of conflict
- Discuss opportunities to better equip these groups when time, distance and resources may present challenges

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Compliance Personnel; Researchers and Research Staff; Clinical Research Staff

**B17: Developing Safe Spaces, Including Online Environments, that Allow for Continuous Improvements of Animal Care and Use Programs**

Track(s): Advancing Equity and Justice in Research; ACU Program Management

Open and regular communications between management, co-workers, and regulators remains crucial to ensuring the continuous improvement of animal care and use programs. These communications also help ensure new standards are regularly adopted. In addition, a diversity of voices in the program is important so all stakeholders have a voice. Positive and productive communication is critical for fostering a cohesive animal care and use program and a culture of compliance.



**Learning Objectives:**

- Learn how to develop and maintain an environment that values diversity of perspectives, ensures everyone has a voice that's listened to, and that fosters positive and productive communication
- Share communication tools that have been used by organizations to successfully keep the lines of communication open, ensuring everyone has a voice
- Explore the challenges of some forms of communications (e.g., when communications are not confidential and therefore may hamper open communications), and share possible solutions

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Laboratory Animal and Veterinary Staff

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Vendor Insight Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

**B18: Conducting and Reviewing 3Rs Literature Searches for Animal Use Protocol**

Track(s): *Animal Well-Being and the 3Rs; IACUC Protocol Review*

Thoughtfully conducted and reviewed literature searches that address animal alternatives and the 3Rs (Refinement, Replacement, and Reduction) have the potential to help researchers advance their science while improving animal welfare. You can help maximize the impact of these searches conducted at your institution by understanding which online 3Rs resources are most appropriate to use, how to construct a search strategy to find relevant 3Rs citations, and which questions to ask during the review process.



**Learning Objectives:**

- Name a number of freely available online 3Rs resources
- Describe how to construct a literature search and list some suggested keywords to use
- Discuss how the use of the ARRIVE 2.0 guidelines by researchers would impact research and animal welfare
- Understand the role of a librarian or information specialist in supporting the IACUC and researchers at your institution
- Identify potential “red flags” in the literature searches included in a protocol submitted for review

**Target Audience:** ACU/IACUC Directors; IACUC Members, Chairs, and Vice Chairs; Laboratory Animal and Veterinary Staff; Researchers and Research Staff

**B19: Inconsistencies in Review and Regulatory Creep: Is it a Problem?**

Track(s): *Shared Oversight Challenges*

Differing organizational standards and inconsistent review processes cause anxiety and confusion for researchers. These occur between organizations, but also within the same committee when they review similar protocols. By design, these are local committees, reflecting the culture and individual experiences, but, often, there’s an underlying expectation that there is always a single “right” conclusion they should be landing on in each case. What is the role of trust in the review process? How do you document the “why”? How do we communicate with researchers?



**Learning Objectives:**

- Explore strategies for achieving consistency and what can be done to ensure ethical review, protection of subjects, and a standardized and fair process
- Discuss how committees support the decisions they make in gray areas
- Consider communication approaches for explaining ethical reasoning to investigators

**Target Audience:** ACU/IACUC Directors, ACU/IACUC Administrators, Managers, and Staff, IACUC Members, Chairs, and Vice Chairs, HRPP/IRB Directors, HRPP/IRB Administrators, Managers, and Staff, IRB Members, Chairs, and Vice Chairs, IBC Directors, IBC Administrators, Manager and Staff, IBC Members, Chairs, and Vice Chairs

**B20: Best Practices for Communicating QA/QI Findings to External Groups**

Track(s): *QA/QI and Postapproval Monitoring*

QA/QI happens within committees, but there is not necessarily a universal method for communicating findings to researchers, committees, or departments when appropriate. What strategies can be used for communicating that improvement is an expectation, not an undue burden (and not just in the context of updates in regulations)? What information should be shared and in what way? What are the federal/sponsored reporting requirements and timeframes? When should we include other committees, department chairs, and/or institutional leadership? Using case scenarios, attendees will have the opportunity to hear about and share best practices on communicating findings.



**Learning Objectives:**

- Discuss how to establish program goals and/or a rubric for handling findings (e.g., noncompliance vs. educate and correct)
- Consider ways to deliver findings back to researchers, committees, and/or departments, and when that information should be delivered
- Explore how to establish rapport with the research community, and the downfalls of poor communication

**Target Audience:** ACU/IACUC Administrators, Managers, and Staff, HRPP/IRB Administrators, Managers, and Staff, IBC Administrators, Manager and Staff, QA/QI Professionals

2:30-3:00 PM: Break

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Workshop Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

### A New Hope: IRB Jedi Unite—Exploring Regulations, Guidance, and Institutional Policies

Track(s): IRB Basics; Flexibility and Innovation in Research Oversight Processes

It is a period of uncertainty. Although institutions have adapted, ambiguity persists in the galaxy. IRB Jedi continue to safeguard research integrity, remaining fluent and flexible in their response to the ever-changing landscape. In this networking session, we'll examine the importance of understanding where regulations end, where guidance begins (i.e., OHRP, SACHRP, etc.), the acknowledgement of institutional policies, and the challenges of this intersection. Through an open Q&A format moderated by the speakers, we'll discuss application of the regulations and practical strategies for "it depends" scenarios. These strategies can serve as a foundation to adopt approaches taking in account your institution's size, staff resources, and/or research community's portfolio. Moderators will have hot topics at the ready, but attendees are encouraged to come with questions in mind to drive the discussion.



**Learning Objectives:**

- Differentiate between the regulations, guidance, and institutional policies
- Discuss opportunities and challenges of exploring guidance
- Share creative solutions while staying compliant and being consistent

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Compliance Personnel

### HRPP/IRB Management 101: Real-World Discussions Regarding How to Effectively Run a HRPP/IRB Office

Track(s): Leadership Skills Development; HRPP/IRB Administration Management

Join HRPP and IRB directors for a candid discussion regarding how to tackle the most difficult management challenges. While most individuals assuming a leadership role overseeing a HRPP/IRB have sufficient regulatory expertise, many HRPP and IRB directors are new to operational and strategic management. This session will discuss core HRPP/IRB leadership responsibilities such as staffing, performance management, organizational structure, budgeting, forecasting, establishing IRB review fees, overseeing the assessment of HRPP/IRB compliance, quality, efficiency and effectiveness, and advocating for resources. Specific strategies for tackling these management responsibilities, including the use of publicly available peer metrics and local organizational data, will be discussed. Speakers will share their real-world experiences and the solutions they developed to address various management challenges.



**Learning Objectives:**

- Understand critical management responsibilities for running a HRPP/IRB office
- Identify strategies HRPP/IRB directors can adopt to effectively fulfill these responsibilities
- Through case examples, highlight real-world experiences of HRPP/IRB directors and identify solutions for specific management challenges

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff

### Everything You Wanted to Know About the CPIA Credential

Track(s): IACUC Administration/Management and Process

During this session, a member of the CPIA Council and a recently certified individual will discuss the CPIA exam, eligibility guidelines, and exam preparation techniques. This session is geared toward individuals who are responsible for IACUC administrative functions and who will be eligible to take the certification exam in the next one to two years.



**Learning Objectives:**

- Describe the CPIA program and its value
- Discuss example preparation techniques and what to expect on exam day
- Share first-hand advice from a recently certified individual

**Target Audience:** ACU/IACUC Directors, ACU/IACUC Administrators, Managers, and Staff

### Evaluating the Committee: Strategies for Conducting QA and QI of Our Ethics Committees

Track(s): QA/QI and Postapproval Monitoring

Most often we think of QA and postapproval monitoring (PAM) as monitoring of the investigator and research conduct. Yet, it is also important to evaluate the quality, effectiveness, and efficiency of our compliance committees. This session will provide examples of QA/QI strategies for assessing our committees by setting goals, establishing metrics, and implementing improvement plans.



**Learning Objectives:**

- Discuss the balance between compliance and efficiency
- Describe the process for setting QA/QI goals, identifying metrics to measure outcomes, and implementing improvement plans
- Identify examples of committee performance ripe for assessment and strategies for conducting the evaluation

**Target Audience:** ACU/IACUC Directors, ACU/IACUC Administrators, Managers, and Staff, HRPP/IRB Directors, HRPP/IRB Administrators, Managers, and Staff

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Workshop Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

**The Role of Institutional Leadership: A Case Study Analysis**

*Christina Brennan, Northwell Health—SF; Mariette Marsh, University of Arizona*

*Declined: Jon Reuter, University of Colorado Boulder*

Using case studies, this session will take a deep dive into some of the ordinary and extraordinary challenges institutional leadership may face and be required to address. Examples of topics include, but are not limited to: conflict of interest and commitment, safety events, organ research, animal cadavers transplanted into humans, deciding in what areas to or not to invest funds for research equipment, and retention of researchers.



**Learning Objectives:**

- Identify and discuss the range of issues that may come before the institutional leadership
- Share approaches to address these and other issues facing institutional leadership

**Target Audience:** Research Program Leadership and Institutional Officials

**Build Your Network and Advance Your Career With PRIM&R Membership**

This recorded presentation provides an overview of PRIM&R's membership community and the exclusive benefits available to members, with a focus on networking and professional development opportunities.



**Target Audience:** ACU/IACUC Administrators, Managers, and Staff; ACU/IACUC Directors; Clinical Research Staff; Compliance Personnel; Educators/Trainers; HRPP/IRB Administrators, Managers, and Staff; HRPP/IRB Directors; IACUC Members, Chairs, and Vice Chairs; IBC Administrators, Managers, and Staff; IBC Directors; IBC Members, Chairs, and Vice Chairs; IRB Members, Chairs, and Vice Chairs; Laboratory Animal and Veterinary Staff; Legal Counsel; Public Relations Professionals; QA/QI Professionals; Research Program Leadership and Institutional Officials; Researchers and Research Staff

**5:00-6:00 PM ET: Happy Hour by Sponsored by Advarra: Trivia and Networking**

This is not your typical networking event! Bring your preferred happy hour beverage, and enjoy your favorite tunes with other industry professionals across the country for an entertaining trivia game. *Thank you to Advarra for sponsoring this Happy Hour event!*



PRIMR22 Day 2: Tuesday, December 13

**10:00-10:15 AM ET: PRIM&R Service Award Presentation: *Clement A. Adebamowo, BM, ChB, ScD, FWACS, FACS, Professor, University of Maryland School of Medicine***



Concurrent Plenary Sessions, 10:15-11:30 AM ET

**Plenary I: When Research Context Changes—Politics, Legislation, the Culture Wars impact on Independent Ethics Oversight**

*Track(s): Advancing Equity and Justice in Research; Legal Considerations in Research Oversight; Emerging Challenges and Breaking Issues*

Good science requires the thoughtful analysis of all the variables that can impact an outcome, and the ability to consider all possible solutions. What happens when we are no longer permitted to explicitly consider key variables or have to completely reframe a topic of study due to the political winds? Research focused on systemic inequality and health disparities is now in a precarious position. Recent legislation on topics ranging from teaching about racism, teaching about sexual orientation and gender identity, limiting or outlawing abortion, and limiting or outlawing gender affirming care are having a direct impact on how educators and doctors work, and on what researchers can study. This panel will consider what this changing legal and cultural landscape may mean for research, and look at what is happening with funded and IRB-approved studies that may not be able to continue, and how to best prepare HRPPs, leadership, and staff for inquiries into active research.



**Learning Objectives:**

- Consider the impact of legislation on the research, health, outcomes, and more
- Hear about the experience of navigating a study that was paused by administration due to external pressures
- Share best practices for HRPPs in addressing transformative legislation, and techniques for preparing for interference in research

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Legal Counsel; Public Relations Professionals; Compliance Personnel; Clinical Research Staff; Researchers and Research Staff

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Workshop Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

**Plenary II: Caring for Our People, Caring for Our Animals—Supporting Compassion Fatigue Resiliency**

Track(s): ACU Program Management; Emerging Challenges and Breaking Issues

Working with research animals can lead to compassion fatigue due to challenging work such as euthanizing animals, animal pain/distress, difficulty publicly discussing work, and feeling undervalued by society. However, compassion fatigue resiliency can be promoted through general awareness, self-care, work/life balance, staff connections, culture of care, and the 3Rs. This compassion fatigue also extends beyond the facility walls and can impact IACUC members and others who are not direct animal handlers. This panel will address compassion fatigue in the lab animal setting, how compassion satisfaction can help personnel to thrive, and what resources are available and could be implemented in your setting.



**Learning Objectives:**

- Learn about compassion fatigue and the factors unique to the animal care and use field that lead to it
- Explore the concept of “compassion satisfaction” and discover ways to promote resiliency on an individual and institution levels
- Discover how compassion fatigue resiliency fits into justice, equity, diversity, and inclusion, and how your institution can benefit from addressing compassion fatigue resiliency in your program

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Public Relations Professionals; Compliance Personnel; Laboratory Animal and Veterinary Staff; Clinical Research Staff; Researchers and Research Staff

**Plenary III: Lost in Translation**

Track(s): Emerging Challenges and Breaking Issues; Shared Oversight Challenges

Why do most drugs and other basic science findings fail to translate into human outcomes? Can changes in animal research help resolve this problem? This session will explore animal models and translatability to human diseases and conditions through the lens of study design, physiology, toxicity studies, reverse translation, and reproducibility. Session attendees will explore how animal and human subject researchers and oversight committees can learn about what doesn't work, how past failures have led to successes, and how to work together to produce better research outcomes.



**Learning Objectives:**

- Discuss the failure of translatability in current animal to human research, and when failures led to successes
- Identify the issues in research design that lead to poor translatability
- Explore mitigation strategies to improve future animal to human research

**Target Audience:** ACU/IACUC Directors, ACU/IACUC Administrators, Managers, and Staff, HRPP/IRB Directors, HRPP/IRB Administrators, Managers, and Staff, Research Program Leadership and Institutional Officials, Researchers and Research Staff

**Plenary IV: Balancing Reputational Harm and Academic Freedom**

Track(s): Research Oversight Leaders and Institutional Officials; Emerging Challenges and Breaking Issues

Resources are always limited and research has risks. Additionally, the needs and goals of individual researchers and research units may sometimes not align with the needs and goals of the institution. As such, how are decisions made about what research should or should not be supported by the institution? Who makes the determination about what research cannot occur (e.g., studies that include limited participant pools balanced against competing studies trying to recruit, studies that are perceived negatively by some constituents or the public, etc.)? How are resources and competing needs prioritized against the backdrop of an institution's research goals? Panelists will explore these issues and more.



**Learning Objectives:**

- Consider the risks and benefits in conducting research
- Identify the key stakeholders in determining risk
- Share approaches to influence and strategically enhance research while balancing academic freedom

**Target Audience:** Research Program Leadership and Institutional Officials

11:30-11:45 AM ET: Break

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Workshop Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

### C1: A Dialogue With OHRP

Track(s): *A Dialogue With the Feds*

This session will be led by representatives from OHRP. Attendees are encouraged to come with questions of interest to all.

**Learning Objectives:**

- Hear from OHRP representatives about evolving initiatives, issues, and guidance
- Ask questions of OHRP representatives

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Legal Counsel; QA/QI Professionals; Compliance Personnel; Educators/Trainers; Clinical Research Staff; Researchers and Research Staff



### C2: Building Your Toolbox: Strategies for Educating and Training Adult Learners

Track(s): *Education, Qualifications, and Training*

A key responsibility of HRPP/IRB administrators is education and training of IRB members and staff, and the research community. However, many of us do not have a background in education or training, and our target audience, adult learners, require special consideration in terms of reach. This session will provide those who conduct education and training with tools to effectively reach their different constituencies and examples of how they can be applied.

**Learning Objectives:**

- Describe the principles of adult learning and why they matter
- Explore how training and education differ, and how considerations may differ by audience
- Learn how to apply adult learning principles when developing effective education and training

**Target Audience:** Educators/Trainers



### C3: "Investigational Device Exemptions (IDE) and Bioresearch Monitoring (BIMO) Inspection for Medical Device Clinical Investigations

Track(s): *FDA Regulated Research*

Generally speaking, IDE regulations apply to clinical investigations of medical devices designed to determine their safety and effectiveness. What if the healthcare provider wants to use a legally marketed device? Are the requirements the same for diagnostic devices? This session will provide an overview of the IDE regulations, including applicability of the IDE regulations. In addition, it will cover the role of sponsors and investigators in device research and how BIMO inspections contribute to enter for Devices and Radiological Health's (CDRH) review process.

**Learning Objectives:**

- Discuss the applicability of the IDE regulations, including significant risk vs. non-significant risk determinations
- Review the basics of CDRH's regulation of sponsors and investigators in clinical investigations of medical devices
- Consider the role of BIMO inspections in the review of medical devices

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Compliance Personnel; Clinical Research Staff; Researchers and Research Staff



### C4: The Workplace Shift: New Realities, Future Uncertainty, and Meeting Staff Needs in a Post-Pandemic World

Track(s): *Leadership Skills Development; HRPP/IRB Administration/Management and Process*

The COVID-19 pandemic created a whole new world of IRB professionals working remotely and has led to staff burnout and shortages. Staff and management must be transparent and flexible if evolving staff needs are to be met and valuable staff will be retained. New strategies for recruiting staff must be explored, including cross-training employees, considering individuals from non-traditional backgrounds, and more.

**Learning Objectives:**

- Explore the challenges that have occurred as a result of the pandemic (e.g., remote work, staff burnout, staffing shortages)
- Share ways to keep staff engaged and positive while organizations manage hybrid offices and staffing shortages
- Consider best practices for retention, recruitment and hiring, onboarding, and performance evaluations

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff



ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Workshop Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

### C5: The Use of Social Media in Research: The Good, the Bad, and the Ugly

Track(s): Social, Behavioral, and Educational Research; Research Conducted in the Digital World; Emerging Challenges and Breaking Issues

Social media are pervasive and fully integrated into the lives of many individuals. Accordingly, they are excellent tools for researchers, not only in terms of recruiting and communicating with participants, but also as a rich source of data. That said, social media is a collective term for a range of online tools that are constantly evolving, making it tricky for IRBs and researchers to stay on top of the issues related to human subjects protections. Further, much of the public may not fully understand who can see the information they post and how that information may be used by researchers. Speakers will explore topics such as what is human subjects data on social media, legal or contractual issues, private-public continuum considerations, recruitment and informed consent issues (including around the use of social media by participants), data identifiability, and risk assessment.



#### Learning Objectives:

- Review the types of social media, how they can be used in research, and the different human subjects protections issues each raise
- Understand the implications for researchers who use social media in their research, including who are the media users and for what have media users consented
- Identify what IRBs need to consider when reviewing studies that involve the use of social media, including what is the IRB's purview and whether researchers have increased risk to social media users
- Consider how participants use social media during the course of the study
- Explore what the use of social media data in research means for the future

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Compliance Personnel; Researchers and Research Staff

### C6: IACUC Oversight and Evaluation of an Effective Institutional Training Program

Track(s): Education, Qualifications, and Training; IACUC Administration/Management and Process

The Guide requires IACUC oversight of training and that the IACUC evaluate the effectiveness of the training program. This session will explore how to evaluate effectiveness, including what kind of data is needed, and at what intervals evaluation should occur.



#### Learning Objectives:

- Identify the goals of a training program evaluation, including what should be accounted for (e.g., noncompliance, near misses, etc.), and how to include all members of the animal care and use program
- Share different types of evaluation strategies
- Describe what type of data can be used to support a training program evaluation, who should review it (e.g., IACUC staff, IACUC members, institutional leadership, others?), and how it might be useful to affect change when needed
- Explore training intervals (i.e., retraining) and ways to implement increased training with acceptance and success
- Differentiate between evaluation of ongoing training schedules (progressive knowledge and skills) and re-training for corrective action cases.

**Target Audience:** ACU/IACUC Administrators, Managers, and Staff; Educators/Trainers

### C7: Effectively Identify, Track, and Report Departures: Meeting OLAW and USDA Requirements

Track(s): IACUC Administration/Management and Process

This session will actively engage the audience in a discussion on departures from OLAW and USDA Requirements. Before attending this session, attendees should have familiarity with exceptions from regulations and IACUC office management.



#### Learning Objectives:

- Discuss the definition of "departure" based on the PHS Policy and Animal Welfare Act and Regulations
- Review OLAW's and USDA's reporting requirements for departures
- Evaluate case studies and scenarios surrounding departure reporting
- Outline ways to track departures for reporting purposes

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff

#### ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Workshop Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

**C8: Keeping the Peace: Conflict Resolution Strategies for IACUC Chairs**

Track(s): IACUC Chairs

For many institutions, the IACUC chair is often perceived as the leader of the entire animal care and use program. In that role, the IACUC chair is required to balance programmatic oversight with research productivity with animals, and this balancing act often requires a unique set of skills to detect and prevent issues before they fester into full-blown problems. Many of these problems deal with conflict—either among members of the IACUC, the IACUC and investigators, investigators on the IACUC with other investigators, or even among different committees themselves (e.g., the IBC and IACUC, etc.). This session will use scenarios to explore strategies for coping with conflict resolution.



**Learning Objectives:**

- Discuss IACUC leadership challenges for resolving conflict within the IACUC
- Identify opportunities for promoting collegiality between the IACUC and investigators, IACUC members, and/or members from other committees
- Share techniques for deescalating and decompressing from stressful and/or frustrating situations

Target Audience: IACUC Members, Chairs, and Vice Chairs

**C9: Take Advantage of Your "Small Pond": Cultivating Community Between Researchers and Compliance Committees**

Track(s): Small Research Programs

Small research programs may provide unexpected opportunities to foster better integration of compliance committees into research communities. This session will explore ways to un-silo the IACUC and the IRB from the research groups, as well as potential advantages of having trainees learn about the ethical regulations as they are learning how to do research.



**Learning Objectives:**

- Identify opportunities afforded by a small research program to foster regular communication between researchers, research students, and compliance committees
- Share strategies for small research programs to integrate training about ethical regulations and compliance committees into the coursework or training given to science students or research trainees
- Understand the features of compliance committee resident mentoring programs, and the individual and institutional benefits such programs can produce

Target Audience: ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IBC Directors; IBC Administrators, Manager and Staff

**C10: Managing Your Research Program's Risk Tolerance**

Track(s): Research Oversight Leaders and Institutional Officials

Advancing research while balancing the need for ethical oversight of research includes identifying and understanding risk. Once risks are understood, then it must be determined if they are acceptable or not within the research enterprise based on an institution's risk appetite. In this session, experienced research leaders will provide a framework for how they determine the risk environment for their institution, establish tolerance levels for specific research projects, and implement risk mitigation strategies through policies, processes, and communication. Common risk management strategies, such as risk aversion, risk acceptance, and risk transfer, will be addressed along with the need for environmental scanning to identify new and emerging risks to the research enterprise.



**Learning Objectives:**

- Discuss how to assess institutional risk appetite and develop mechanisms to proactively identify and manage studies that require additional risk review
- Explore how to perform risk and benefit analysis (developing a risk framework)
- Identify key stakeholders for decision making and dissemination (developing a risk assessment process)

Target Audience: Research Program Leadership and Institutional Officials

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Vendor Insight Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

### C11: An Update From ORI: Misconduct in Clinical, Translational, and Animal Research: Protocol Violations, Research Misconduct, or Both?

Tracks(s): A Dialogue With the Feds

This session will provide insight into institutions' and ORI's responses to allegations of research misconduct in human research subjects, translational research, and animal research. Attendees will learn about the institutions' and ORI's requirements in response to allegations of research misconduct in accordance with the federal regulations, and what constitutes research misconduct versus unacceptable research practices.



**Learning Objectives:**

- Provide insight into the institutions' and ORI's implementation of the US Public Health Service regulations at 42 CFR Part 93, to address allegations of research misconduct
- Discuss institutions' and ORI's work to ensure institutional compliance with the federal regulations
- Share strategies and case studies to address procedural challenges at the institutional level, when investigating allegations of research misconduct in human subjects and unacceptable research practices with animals

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Legal Counsel; QA/QI Professionals; Compliance Personnel; Educators/Trainers; Clinical Research Staff; Researchers and Research Staff

### C12: Enhancing Inclusion in a Time of Division

Tracks(s): Advancing Equity and Justice in Research; Emerging Research Challenges and Breaking Issues; Populations Requiring Additional Protections

Despite the growing recognition of the importance of broad inclusion and engagement of a range of people in research, there continues to be recognition and concern about how the marginalization of important groups in society and a generally divisive political landscape impact attitudes toward research and certain research participants. As HRPP and research ethics professionals, how do we effectively promote practices that engender trust and facilitate inclusion of groups that have been excluded or marginalized? Many efforts to address these issues in the past have been rooted in and focused on the informed consent process and building in additional protections for research. However, significant tensions can exist between a culture of protection, which can be inadvertently paternalistic, and a culture of inclusion. This session will explore how to balance protection vs. inclusion approaches to promote inclusion and engagement of a range of populations in research, enhance inclusion and trust during divisive times, and build programs to assist researchers in recognizing the importance of diversity, equity, and inclusion for research and how to conduct community outreach/engagement.



**Learning Objectives:**

- Review the factors contributing to lack of inclusion and trust in research
- Discuss the tension between inclusion and protections
- Consider approaches for enhancing inclusion in divisive times, including building programs to assist researchers in community outreach/engagement to increase diversity and inclusion in research

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Researchers and Research Staff; Diversity, Equity, Inclusion, and Justice; Research Program Leadership and Institutional Officials; Clinical Research Staff

### C13: Bridging the Gap: Gene Therapy Research From the Perspectives of IRBs and Patient Advocates

Tracks(s): Emerging Research Challenges and Breaking Issues; Research Involving Data and Biospecimens

Gene therapy research is emerging at a fast and exciting pace. Oversight of this research faces many unique challenges from the perspectives of IRB review (e.g., inherent conflicts of interest, complex consent forms, unique risk considerations, unique withdrawal considerations, etc.). In addition, it is a field where much of the patient population are knowledgeable, invested, and often desperate, making it important to bring IRBs and gene therapy patient populations together to ensure responsiveness to each other's needs and to ensure the research that is approved is both ethical and appropriate. This session will bring these two groups together to discuss ways to best approach gene therapy research review on these key topics.



**Learning Objectives:**

- Consider the unique aspects of gene therapy research that pose challenges and questions for IRBs that are experienced at reviewing it
- Explore the perspective of patients or parents with experience with these trials
- Share productive ways to improve IRB oversight and participant experience, both for IRBs experienced with gene therapy research review and those who are not

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Compliance Personnel; Clinical Research Staff; Researchers and Research Staff

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Workshop Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

**C14: IRB Guidance on Data-Sharing in the Social Sciences: Evidence of a Shift**

Track(s): *Emerging Research Challenges and Breaking Issues; Research Involving Data and Biospecimens*

This session will present the results of an empirical investigation of the language used in general guidelines and consent script templates from IRBs at 50 major research universities in the United States, which documented an observable shift in attention to this topic from IRBs in the past five years, and discuss recommendations for consent language and general data management advice that individual IRBs might consider adopting in their own guidance revisions. In the social sciences, a tension persists between two scholarly imperatives advanced by federal funding organizations, disciplinary associations, and publishers alike: the longstanding mandate to treat research participants with respect and to minimize the potential risks of participating in research, and the newer expectations of providing access to the results of that research, including data generated through interaction with human participants. While IRBs tend to focus on the first concern, their decisions and practices, especially the guidance they offer researchers, directly impact research transparency possibilities. With more examples of appropriate data-sharing (enabled by informed consent scripts directly asking for data-sharing agreement and socio-technical innovations professional repositories offer) on hand, IRB personnel can continue to expand these possibilities and assist in reducing the tension described above.



**Learning Objectives:**

- Review current data sharing expectations and changing research norms on that topic
- Explore the evidence of a major shift toward discussing data-sharing possibilities, options and necessary restrictions in IRB guidance
- Discuss models for guidance details and consent scripts explicit about data sharing that assures human participant protection and allows data publication and re-use in appropriate ways

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Researchers and Research Staff

**C15: Innovations in the Oversight of Research Data**

Track(s): *Flexibility and Innovation in Research Oversight Processes; Research Involving Data and Biospecimens*

Increasingly, organizations are faced with complex questions regarding the responsible use of data for research purposes. Governance of data use may need to extend beyond the IRB, particularly since many research uses of data may not qualify as human subjects research. This session will highlight various models for research data oversight including how oversight committees may interact with research and the IRB. Models explored may include: organizational data oversight committees, patient/participant oversight committees, and data archive services to control/manage requests for published data subject to mandatory data sharing requirements.



**Learning Objectives:**

- Review various models for research data oversight
- Explore how these oversight entities may interact with the HRPP/IRB

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Compliance Personnel; Clinical Research Staff; Researchers and Research Staff

**C16: Effective Change Management Processes in an IACUC Office**

Track(s): *Education, Qualifications, and Training; ACU Program Management*

Effective change management within an animal care and use program may benefit from professional support, and it may also be done "in-house" with existing staff and the support of programmatic and organizational leadership. IACUC staff can strategically formulate a change in their program with the right tools and conversations. Throughout the change process, meaningful information must be collected which can then translate into sustainable and effective change within an animal care and use program. This can be a positive way to grow professional relationships and build a foundation of communication and trust within the organization's animal research program.



**Learning Objectives:**

- Understand the steps in developing a strong strategy that emphasizes engagement of individuals impacted by change
- Discover ways to develop clear and strong advocacy for changes within the IACUC, staff, and business processes
- Share ways to prepare the organization to fully realize the benefits of organizational change management
- Consider how changes within a program impact staffing, committee membership, IACUC protocol review.

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; Educators/Trainers

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Workshop Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

**C17: The Periodic Trends Assessment of Changes Over the Lifespan of Living Documents: Reflection on edits to Policies/Standard Operating Procedures (SOP)**

*Tracks: Flexibility and Innovation in Research Oversight Processes*

Periodic trends assessment is looking at changes/revisions to documents (policies/SOPs) that are made to address acute issues. This session will examine the broader impact of these changes for all compliance programs; in particular, downstream effects such as how changes impact associate policies/SOPs and efficiency for both investigators and compliance programs.



**Learning Objectives:**

- Determine the cost-benefit analysis of ad-hoc policy/SOP changes
- Explore options for creating routine process evaluations as they relate to policy/SOP changes
- Identify strategies to increase communication across the institution

**Target Audiences:** ACU/IACUC Administrators, Manager and Staff; HRPP/IRB Administrators, Manager and Staff; IBC Administrators, Manager and Staff

**C18: Collaborating to Advance the 3Rs in North America and Beyond: Highlighting the North American 3Rs Collaborative (NA3RsC) 3Rs Certificate Course, Refined Mouse Handling, and Environmental Health Monitoring**

*Track(s): Animal Well-Being and the 3Rs*

The NA3RsC is a non-profit organization whose mission is to advance science, innovation, and research animal welfare through collaborative 3Rs initiatives. The organization’s strategy is to identify and promote 3Rs techniques that have strong evidence, big impact, and real-world practicality. During this session, attendees will learn about current initiatives focused on key 3Rs techniques with a focus on replacement of live sentinel rodents with environmental health, refined handling of mice via tunnels, and creation of a 3Rs certification course.



**Learning Objectives:**

- Understand the breadth and scope of NA3RsC and its available resources
- Discover what the NA3RsC 3Rs Certificate covers and how to access it
- Discuss the evidence, impact, and practical implementation of the 3Rs techniques of refined mouse handling and environmental health monitoring

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Laboratory Animal and Veterinary Staff; Educators/Trainers

**C19: “One Health” and Veterinary Research With Human Health Goals**

*Track(s): Emerging Challenges and Breaking Issues; Shared Oversight Challenges*

Research spanning from animals to humans and back can face unique ethical and logistical issues. Projects investigating aging, pain management, diabetes, and cancer in pets can have the dual purpose of improving treatments for animals and, down the road, improving treatments for humans. Sometimes, these studies involve both humans and animals, and fall under the purview of both IACUCs and IRBs. How do these committees work together with researchers in these circumstances? In other cases, studies in veterinary research with eventual potential for human health impact involve humans as animal “owners” or guardians, but not as research subjects. In these cases, too, oversight that is designed around laboratory animal use may seem inappropriate when it comes to research involving companion animals. How do researchers and oversight committees manage risk mitigation and balancing benefits, informed consent, and the potential for therapeutic misconception? This session will review some examples of “one health” and veterinary research with human health goals in an attempt to highlight where problems may occur in this type of research, and how some researchers and review committees have successfully managed these problems.



**Learning Objectives:**

- Explore the variety of projects that fall in the realm of “one health” and veterinary research with human health goals
- Consider the intricacies and potential ethical issues that arise when research projects involve companion animals or both humans and animals as research subjects
- Share strategies for making sure these types of projects are thoughtfully designed and ethically sound throughout the life of a project

**Target Audience:** ACU/IACUC Directors, IACUC Members, Chairs, and Vice Chairs, HRPP/IRB Directors, IRB Members, Chairs, and Vice Chairs, Research Program Leadership and Institutional Officials, Compliance Personnel, Laboratory Animal and Veterinary Staff, Clinical Research Staff, Researchers and Research Staff

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Workshop Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

**C20: "What Is Safety?"**

Track(s): *Emerging Challenges and Breaking Issues; Research Oversight Leaders and Institutional Officials*

Everyone has the right to be and feel safe, and it is the responsibility of everyone in the institution to provide a safe environment. Safety is also critical for the responsible conduct of research. How does institutional leadership engage and inform people appropriately? How do they manage the oversight of safety, including when safety issues occur within different programs? These issues and more will be discussed during this session.



**Learning Objectives:**

- Define all elements of safety from an institutional perspective
- Demonstrate how all elements of safety are a core value to an institution
- Review institutional roles and responsibilities in promoting a culture of safety
- Share approaches for implementing a culture of safety (e.g., creating a Safety Taskforce for your institution)

**Target Audience:** Research Program Leadership and Institutional Officials; ACU/IACUC Directors; HRPP/IRB Directors; IBC Directors

**12:45-1:30 PM: Mid-Day Break**

**12:45-1:30 PM: Sponsored Presentation from Advarra: The Secret to Single IRB (sIRB) Reliance Success**

Tracks(s): *HRPP/IRB Administration/Management and Process; Flexibility and Innovation in Research Oversight Processes*

With the FDA's September NPRM publication, the research community will likely soon have additional sIRB reliance requirements to navigate for multisite research. sIRB mandates are nothing new; OHRP and NIH have had them for years, and industry sponsors have long encouraged sites to rely on a single IRB. sIRB mandates are not always easy to comply with. Policies may need revising, additional trainings may be necessary, new working relationships may need navigating, and agreements need to be executed—it can be a lot. But, some institutions seem to be handling sIRB requirements just fine. What is their secret? Find out in this session, as longtime IRB professionals share the sIRB techniques and approaches that have proven successful for many organizations.



**Learning Objectives:**

- Identify ways existing policies can be modified to accommodate sIRB requirements
- Describe how certain policies can hinder sIRB efficiencies and approaches to removing such obstacles
- Recognize roles team members can play in ensuring sIRB compliance

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs

Concurrent Plenary Sessions, 1:30-2:45 PM ET

**Plenary V: Progress in Defining and Evaluating HRPP/IRB Quality and Effectiveness**

Track(s): *HRPP/IRB Administration/Management and Process; Flexibility and Innovation in Research Oversight Processes; IRB Chairs; QA/QI and Postapproval Monitoring; Research Oversight Leaders and Institutional Officials*

The Consortium to Advance Effective Research Ethics Oversight (AEREO) was founded in 2018 with a mission to articulate what it means for IRBs/HRPPs to "work," identify meaningful measures of IRB/HRPP quality and effectiveness, evaluate how well IRB/HRPPs are working now, and pursue evidence-based ways to help them work better. This panel will open with a description of AEREO's goals, progress made to date, plans for the future, and an invitation to join the Consortium's work. It will then take a deeper look at several key projects: (1) identifying barriers to empirical research with IRBs/HRPPs and outlining possible solutions to encourage participation and engagement; (2) describing the results of interviews with HRPP/IRB stakeholders, directors, and accredited organizations about how to define and evaluate quality and effectiveness, and the identified need to focus on participant protection outcomes and develop a standard for IRB reasonableness; and (3) understanding investigator perspectives on the ways that HRPPs/IRBs add value to the research enterprise, to promote further attention to these areas as possible measures of quality and effectiveness.



**Learning Objectives:**

- Explain the difference between HRPP/IRB quality and effectiveness in contrast to efficiency and compliance
- Identify the challenges to meaningfully evaluate HRPP/IRB quality and effectiveness, including barriers to conducting empirical research in this space
- Describe promising future approaches to evaluating HRPP/IRB quality and effectiveness, including attention to IRB deliberation, participant protection, and investigator perspectives on added value

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; QA/QI Professionals

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Workshop Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

**Plenary VI: How to Balance Experimental Refinements With Scientific Justification**

Track(s): IACUC Protocol Review; Animal Well-Being and the 3Rs

Panelists will discuss their experience and perspective on how to develop and incorporate emerging refinement technologies and approaches while maintaining scientific goals and reproducibility. Topics will include an introduction on refinements, how to leverage data to evolve practices, and creative ways to encourage the use of emerging practices and approaches to facilitate high quality research and animal welfare.



**Learning Objectives:**

- Discuss the regulatory guidance on incorporating alternatives, perceived barriers, benefits, and strategies for implementation for PIs and IACUCs
- Discuss current research practical applications, different ways of conducting a harm-benefit analysis, and examples from scientific literature of refinement benefits for welfare and scientific validity
- Discuss the challenges and solutions to implementing emerging refinement approaches through case studies

**Target Audience:** ACU/IACUC Directors; IACUC Members, Chairs, and Vice Chairs; Compliance Personnel; Laboratory Animal and Veterinary Staff; Clinical Research Staff; Researchers and Research Staff

**Plenary VII: How Research Environments Influence the Ability of the People in Them to Behave Ethically**

Track(s): Advancing Equity and Justice, Shared Oversight Challenges

We often position ethical research as a matter of the choices and actions of individuals, but what choices and actions are thinkable to individuals can depend a lot on the environments they are in. This session will draw on social science studies of research environments, considering the impacts of hierarchies, myths of meritocracy, and gender and racial imbalances, among other factors, on the behaviors of people within those environments.



**Learning Objectives:**

- Discuss the features of research environments that impact the behaviors of people in them
- Consider how features of research environments can impact the people in them differently due to factors like race, gender, career stage, etc.
- Explore measures that could be implemented at different scales (from research group to research organization to scientific discipline) to foster more ethical behavior

**Target Audience:** ACU/IACUC Directors, ACU/IACUC Administrators, Managers, and Staff, IACUC Members, Chairs, and Vice Chairs, HRPP/IRB Directors, HRPP/IRB Administrators, Managers, and Staff, IRB Members, Chairs, and Vice Chairs, IBC Directors, IBC Administrators, Manager and Staff, IBC Members, Chairs, and Vice Chairs, Research Program Leadership and Institutional Officials, Legal Counsel, Compliance Personnel, Laboratory Animal and Veterinary Staff, Clinical Research Staff, Researchers and Research Staff, Diversity, Equity, Inclusion, and Justice

**Plenary VIII: Conducting Research: The Institutional Official (IO) as the Conductor**

Track(s): Research Oversight Leaders and Institutional Officials

When we imagine an orchestra conductor, we may picture someone in fancy clothes standing with their back to the audience while addressing the musicians with arm, hand, head, and body motions. However, this is just the tip of the conductor's iceberg. There are, rather, myriad activities, visions, steps, decisions, adjustments, competing priorities, and egos that must be directed, managed, determined, or resolved before the conductor steps on the stage to lead anywhere from 15 to 100 musicians in the production of an integrated sound. While not a perfect analogy, so too with the IO and their collaboration with the research community. An institution's research productivity is at least in part due to the IO's 'conducting of the institution's research enterprise, so disparate components can perform as an integrated research community, their vision: management of competing priorities and interests, balancing the wants of researchers and the research community at large, building and supporting infrastructure, etc. In this session, a panel of IOs (or their designees) will share and reflect upon their experiences 'conducting' their institution's orchestra of researchers.



**Learning Objectives:**

- Share strategies for bringing together disparate and maybe competing components into an integrated whole—or at least narrowing the dis-integration
- Identify the critical engagements in which the IO must lead, be a part of, and stay far away from (i.e., what is the proper and most effective involvement for the IO)
- Consider how resource allocation and the establishment of priorities both contributes to and flows such an integration

Target Audience: Research Program Leadership and Institutional Officials

2:45-3:00 PM ET: Break

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Workshop Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

### When You're the New Kid in Town: Taking Over as an HRPP/IRB Leader

Track(s): Leadership Skills Development; HRPP/IRB Administration/Management and Process

Whether it's a promotion at your current institution, or a move to a new institution, taking on a new HRPP/IRB leadership role brings with it a set of challenges. Those first few weeks and months can set the tone for your tenure, and also for how your HRPP/IRB will mesh with the other research stakeholders at your institution. Learn tips and tricks for making this transition from speakers who, not long ago, found themselves newly leading an HRPP or IRB, and hear from colleagues about what they want new HRPP/IRB leaders to know. Attendees should be familiar with the breadth of HRPPs and how various HRPP components, including IRBs, interact before attending this session.



#### Learning Objectives:

- Explore how to get established in a new organization, or in becoming a new leader of people who used to be your peers (whether you're replacing a respected, effective leader or were hired to make significant course changes)
- Learn approaches for identifying problem areas in the HRPP/IRB and how to make changes
- Share strategies and advice for when first starting, or that you'd want an incoming HRPP/IRB leader to know

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff

### SBER Network Discussion: Faculty Mentorship in Human Research Protections

Track(s): Social, Behavioral, and Educational Research

Join the [SBER Network](#) as we discuss faculty mentorship in human research protections. This discussion will include topics such as: what responsibility do HRPPs have for student researchers, how can HRPPs engage faculty to mentor students in the conduct of their research, and what are reasonable expectations for HRPPs to have of faculty mentors. The session will also include comments from the SBER Network Faculty Mentorship in Human Research Protections initiative.



#### Learning objectives:

- Discuss faculty mentorship in HRPPs
- Consider the nuance and challenges of engaging faculty mentors in HRPP mission
- Share strategies for improving faculty mentorship of student research

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Researchers and Research Staff

### Insights into Key Recommendations from the Secretary's Advisory Committee on Human Research Protections (SACHRP)

Track(s): A Dialogue With the Feds

During this session, speakers from SACHRP will discuss the relevant issues, rationale, and final recommendations included in three key documents recently sent to the Secretary of Health and Human Services. Attendees should review these recommendations before attending this session: (1) [A New Interpretation of the "Engaged in Research" Standard](#); (2) [Recommendations on the OHRP Draft Guidance for Use of Single Institutional Review Board for Cooperative Research](#); and (3) [New Challenges in Interactions among Sponsors, Clinical Trial Sites, and Study Subjects](#).



#### Learning Objectives:

- Consider the ethical basis underlying case scenarios leading to engagement determinations
- Identify complexities in single IRB review regarding knowledge of local context concerns
- Understand how ambiguity over a sponsor or investigator's role can compromise the integrity of study data or implicate privacy concerns.

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Legal Counsel; QA/QI Professionals; Compliance Personnel; Educators/Trainers; Clinical Research Staff; Researchers and Research Staff

### Hitting the Mark: Best Practices for IACUC Administrators

Track(s): IACUC Administration/Management and Process

During the session, speakers will facilitate a discussion among participants on the responsibilities typically assigned to IACUC administrators/coordinators, including, but not limited to: training of new administrative staff, preparation and management of IACUC-related documents, training and continuing education ideas for IACUC members and the research community, and postapproval monitoring strategies. This session will also allow for networking around different scenarios that have challenged IACUC administrators. Attendees should be familiar with IACUC administrative duties, but this session is geared toward individuals who have less than two years' experience in their role.



#### Learning Objectives:

- Compare and contrast the different ways IACUC administrators had to adjust their support and role for their animal care and use program in recent years (i.e., since the pandemic)
- Discuss best practices for navigating difficult conversations and getting buy in regarding programmatic changes (e.g., new online protocol system, new policy being implemented, change in protocol review procedure based on sponsor/funding, etc.)
- Review and advise various methods of performing protocol review and semiannual inspections based on different regulatory oversight
- Provide strategies for training new IACUC administrative staff
- Share strategies in conducting postapproval monitoring (PAM activities)

**Target Audience:** ACU/IACUC Administrators, Managers, and Staff

#### ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Vendor Insight Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

**IACUC Chairs Networking Session: Let's Discuss IACUC Chair Challenges and Solutions!**

Track(s): IACUC Chairs

An IACUC chair must forge collaborative relationships with the administrator, attending vet, IACUC members, and investigators to maintain regulatory compliance and implement best practices. However, balancing the art of building positive relationships and the science of maintaining programmatic oversight can be a daunting task and, oftentimes, the IACUC chair feels alone on a proverbial island while trying to navigate myriad challenges on their own. This networking session will provide an opportunity for IACUC chairs to discuss topics of importance to their role, ask questions, share strategies/approaches/best practices, and develop a network that can provide support beyond the meeting.



**Learning Objectives:**

- Consider the IACUC chair's role in balancing responsible decision-making and IACUC overreach
- Review the challenges of reviewing internally funded animal care and use programs compared with externally funded projects
- Discuss challenges that arose during the pandemic that has disrupted and/or improved the function of the IACUC
- Explore ways to keep IACUC members engaged and appreciated and strategies for recruiting new members
- Share strategies for recruiting and mentoring a new member assuming the role of IACUC chair

**Target Audience:** IACUC Members, Chairs, and Vice Chairs

**PRIMR22 Poster Presentation Program: Outstanding Work in Human Subjects Protections**

Track(s): Informed Consent; Education, Qualifications, and Training; Flexibility and Innovation in Research Oversight Processes

Join the authors of this year's outstanding posters in the Human Subjects Research category for a discussion on their work. Posters will be available to attendees via the Virtual Poster Gallery starting on November 29. The following work will be presented:



- "Assessing Investigators' Skills to Obtain Informed Consent" by Katherine W. Todman, LCSW-C, National Institute of Mental Health (NIMH); Carol Squires, LCSW, NIMH; Julie Brintnall-Karabelas, LCSW-C, NIMH; Sandra Bonifant, MS, CIP, National Institute of Neurological Disorders and Stroke; Meghna Krishnamurthy, NIMH; Madeline V. Seeley-Hacker, NIMH; Maryland Pao, MD, NIMH
- "Incorporating the Patient Voice into Clinical Research Policies and Processes" by Deborah Mittman, MPS; Keren Dunn, CIP; Jessica Spotts, CIP; Gordon Olacsi, CIP, Cedars-Sinai Medical Center
- "It's Like You Need the Participants, but You're Not Willing to Invest in Them": Exploring Stakeholders' Perceptions of Incentives in the US HIV Research Enterprise" by Karah Greene, BA, University of South Florida; Karine Dube, PhD, UNC-Chapel Hill; Andrea Polonijo, PhD, University of California, Merced; Jerome Galea, PhD, University of South Florida; Brandon Brown, PhD, University of California, Riverside
- "Toward Universal Return of Study Findings to Research Participants" by Brian S. Mittman, PhD, Kaiser Permanente Department of Research and Evaluation; Deborah Mittman, MPS, Cedars-Sinai Medical Center; Armida X. Ayala, PhD, MHA, Kaiser Permanente Southern California-Hawaii

**Target Audience(s):** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Compliance Personnel; Educators/Trainers; Clinical Research Staff; Researchers and Research Staff

**PRIM&R's Online Courses—EROC and AROC**

PRIM&R offers engaging, interactive online courses that equip IRB and IACUC members for their roles through the demonstration of the ethical principles and regulatory frameworks that govern their day-to-day work. In this session, you will receive an overview of the courses' many features.



**Learning Objectives:**

- Interactive content. Come and see how learners can explore selected topics in depth and move through course content at their own pace. Interactivity includes drag-and-drop and matching activities, progress checks, mini-case studies, and more.
- Simulated IRB and IACUC Discussions. Observe principles in practice by watching the simulated IRB and IACUC in action. See how each member's expertise, background, and perspective contributes to the ethical review of research as they apply principles and regulations during their meetings.
- Case Studies. See how learners can apply their new knowledge to realistic scenarios, learn best practices for reviewing research protocols, and check their understanding of each unit's learning objectives with in-depth case studies paired with questions.
- Assessment, Certificate of Completion, and Credit. Learners who successfully complete either course's final assessment will receive a certificate of completion for that course as well as earn continuing education (CE) credit.

**Target Audience:** ACU/IACUC Administrators, Managers, and Staff; ACU/IACUC Directors; Clinical Research Staff; Compliance Personnel; Educators/Trainers; HRPP/IRB Administrators, Managers, and Staff; HRPP/IRB Directors; IACUC Members, Chairs, and Vice Chairs; IBC Administrators, Managers, and Staff; IBC Directors; IBC Members, Chairs, and Vice Chairs; IRB Members, Chairs, and Vice Chairs; Laboratory Animal and Veterinary Staff; Legal Counsel; Public Relations Professionals; QA/QI Professionals; Research Program Leadership and Institutional Officials; Researchers and Research Staff

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Vendor Insight Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

10:00-10:15AM ET: Welcome from the Chair of PRIM&R's Board of Directors

F. Claire Hankenson, DVM, MS, DACLAM, University of Pennsylvania



10:15-11:30 AM ET: Welcome and General Session: Deciphering the Code, Interpreting, and Responding to Misinformation

We're swimming in a world of misinformation that often cannot be countered effectively by conventional messaging used to communicate research findings. Many who disseminate misinformation are aware of the "sleights of hand" they perform to influence thinking. Spotting and correcting misinformation can seem like a lost cause, but the consequences of not trying have serious consequences for human health, as recently played out during the COVID-19 pandemic. Research institutions and government agencies should proactively consider how they can communicate important scientific findings or health recommendations to build trust and help the public distinguish between truth and fiction. This panel will explore what misinformation is and how to identify it, why humans are susceptible to certain communication techniques, how misinformation about research can play out, and what strategies can be used to combat falsehoods and make science-based messages more persuasive.



Learning Objectives:

- Review the features that make an audience regard a piece of information as credible or not credible
- Examine the ways these features are used to propagate misinformation about research and to undermine trust in research
- Consider appropriate and effective strategies that can be used to counter misinformation and to make science-based messages more persuasive to their target audiences

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; IBC Directors; IBC Administrators, Manager and Staff; IBC Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Legal Counsel; Public Relations Professionals; Compliance Personnel; Laboratory Animal and Veterinary Staff; Educators/Trainers; Clinical Research Staff; Researchers and Research Staff

11:30-11:45 AM ET: Break

Concurrent Breakout Sessions, 11:45 AM-12:45 PM ET

D1: A Dialogue With FDA

Track(s): A Dialogue With the Feds

This session will be an open forum led by a panel of FDA representatives, and who will provide brief updates on FDA activities within their Center/Office. The session will then be open for audience questions. Attendees are encouraged to come with questions of interest to all.



Learning Objectives:

- Hear from FDA representatives about new and evolving issues, initiatives, regulations, and guidance
- Ask questions about evolving issues and initiatives at the FDA

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Legal Counsel; QA/QI Professionals; Compliance Personnel; Educators/Trainers; Clinical Research Staff; Researchers and Research Staff

D2: Equitable Inclusion and Local Community Context in Multi-Site Research

Track(s): Advancing Equity and Justice in Research; Emerging Research Challenges and Breaking Issues; HRPP/IRB Administration/Management and Process

Multi-site trials offer the opportunity to include adequate numbers of subjects from a range of populations, and findings with greater relevance to more people. While the 2018 requirements for single IRBs position the single IRB to have a comprehensive perspective on the overall population recruited for the trial, the membership may not be knowledgeable about the issues most relevant to each participant community. This session will address strategies for facilitating community competence of the single IRB and consider when the distinctive features of a community may indicate the need for additional review or an exception to single IRB review.



Learning Objectives:

- Understand the scope of the challenge multiple community contexts within multisite trials can represent for sIRBs
- Describe key mechanisms through which the single IRB can obtain additional information about multiple community contexts and how to best share with IRB membership
- Become familiar with the ethical issues associated with the regulatory requirements for equitable selection of subjects and safeguards for addressing situational vulnerabilities of subjects

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Researchers and Research Staff; Diversity, Equity, Inclusion, and Justice

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Workshop Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

**D3: Communication in Minimal Risk Research Using Waiver of Consent**

Track(s): *Emerging Challenges and Breaking Issues; Informed Consent; Communication With the Public*

There has been substantial discussion about the extent to which clinical trials comparing standard of care treatments, for example, constitute minimal risk and about the need for and role of informed consent. Significantly less attention has been paid to efforts at communication (independent of consent) when studies are considered to be minimal risk. This session will explore the function of communication and review available data on patients' expectations and concerns.



**Learning Objectives:**

- Characterize the emerging empirical data on patients' and the public's view on this topic
- Discuss what is owed to people in fostering trust, including how we should communicate with them

**Target Audience:** HRPP/IRB Directors; IRB Members, Chairs, and Vice Chairs; Compliance Personnel; Clinical Research Staff; Researchers and Research Staff; HRPP/IRB Administrators, Managers, and Staff

**D4: When Institutional Research and Corporate Worlds Collide: The Impact of Corporate Collaborations in Data Research**

Track(s): *Research Involving Data and Biospecimens; Emerging Challenges and Breaking Issues; Flexibility and Innovation in Research Oversight Processes; Research Conducted in the Digital World*

There is a growing trend for research institutions to collaborate with corporations. These collaborations benefit the institutions and corporations by providing access to data they may not previously have had. But, to what extent do they benefit society and the individuals whose data is being used? Sharing personally identifiable data across organizations to facilitate research can face significant legal, ethical, and political challenges. Most states do not have comprehensive privacy laws, therefore investigators and IRBs must trust that companies did their due diligence and obtained their data in an ethical manner and have permissions and safeguards in place for sharing of data. Privacy concerns and potential participant harms exist about the collection and sharing of personally identifiable data. Proposed policy solutions have ranged from requiring informed consent from every individual to opt-out provisions to complete de-identification of all data used for research. This session will discuss the challenges and solutions various institutions and organizations face in order to conduct collaborative data research in an ethical and lawful manner.



**Learning Objectives:**

- Consider how the corporate/institutional data-sharing initiatives are evolving
- Discuss policy solutions for the sharing of corporate and institutional data and what information should (or should not) be in the contract or data use agreements
- Review examples of complex agreements and which compliance units should be involved
- Outline examples of privacy concerns and consider the ethical and legal parameters and discuss potential IRB recommendations

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Compliance Personnel; Clinical Research Staff; Researchers and Research Staff; Legal Counsel; Research Program Leadership and Institutional Officials; Public Relations Professionals

**CANCELLED: D5: Developing and Sustaining Tribal IRB Infrastructure: Lessons Learned from the Collaborative Research Center for American Indian Health (CRCAIH) Initiatives**

Track(s): *Small Research Programs; Advancing Equity and Justice in Research; Populations Requiring Additional Protections*

Tribal IRBs play an important role in protecting the rights and safety of Native American populations. While tribal IRBs are a critical tool for exercising tribal sovereignty through research oversight, developing and sustaining a tribal IRB requires consistent resources. In this session, speakers will present their experience in developing tribal IRBs through the CRCAIH and provide effective strategies for the long-term sustainability of the IRBs.



**Learning Objectives:**

- Review the history and scope of the CRCAIH
- Provide an overview of Tribal regulatory processes and development of tribal IRB
- Consider strategies for continued tribal engagement and sustainability of the IRB office

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Researchers and Research Staff; Research Program Leadership and Institutional Officials; Diversity, Equity, Inclusion, and Justice

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Vendor Insight Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

**D6: Nonhuman Primate Sourcing Challenges: Implications for Animal Welfare**

Track(s): *Animal Well-Being and the 3Rs; ACU Program Management; Emerging Challenges and Breaking Issues*

The landscape for nonhuman primate sourcing has drastically changed over the last two years and continues to evolve. The welfare of the animals can be significantly impacted by sourcing dynamics. This session will address recent challenges, implications for welfare, and best practices for next steps we can take as a field.



**Learning Objectives:**

- Discuss the implications for nonhuman primate health and welfare
- Explore the animal rights groups' impact on international transportation to import nonhuman primates
- Consider US and international perspectives on captive bred vs. wild caught nonhuman primates

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Laboratory Animal and Veterinary Staff; Clinical Research Staff; Researchers and Research Staff

**D7: Meeting the Challenges of IACUC Administration: Case Studies in Handling Complex Protocol Issues/Situations**

Track(s): *IACUC Administration/Management and Process; IACUC Protocol Review*

Many IACUC administrators, members, and staff struggle with protocol questions and what the IACUC should consider in reviewing protocols. During this session, speakers and attendees will work through case studies on protocol review issues and discuss possible ways to handle these complex situations. Before attending this session, attendees should have a sound working knowledge of the IACUC and the regulations that provide guidance. Important to the session are well-versed IACUC administrators who can share their experiences with protocol challenges.



**Learning Objectives:**

- Discuss and analyze simulated, problematic scenarios on IACUC protocol reviews
- Share potential solutions to problems with protocols while maintaining compliance

**Target Audience:** ACU/IACUC Administrators, Managers, and Staff

**D8: Postapproval Monitoring (PAM) for Wildlife Studies and Field Research**

Track(s): *QA/QI and Postapproval Monitoring; Oversight of Non-Typical Species and Situations; Small Research Programs*

Some institutions conduct PAM for nontypical species and wildlife studies based on annual reviews or annual progress reports. What are the strategies? Is a three-year check in done before an institution is ready to renew? Is there an annual check in? Is there a request for documentation related to wildlife studies? Should you visit in areas where wildlife or field research is conducted?



**Learning Objectives:**

- Explore strategies for performing PAM without the need for in-person audits or practices
- Discuss when in-person audits or procedures are needed for appropriate oversight of wildlife studies or studies with atypical species
- Share best practices for using administrative procedures or reviews for your PAM program

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; QA/QI Professionals

**D9: Some Things Are Not So Different: The Intersection of IRB, IACUC, IBC, and ESCRO**

Track(s): *Shared Oversight Challenges; Flexibility and Innovation in Research Oversight Processes*

Federal and state oversight agencies have different requirements that underlie compliance committees and institutional policies. So, then, how does an institution coordinate these units to ensure compliance is achieved and research isn't hindered? Finding ways for compliance units to cooperate and facilitate health, safety, cutting edge research, the rights and welfare of subjects, and changing regulations is an evolving process. In this session, speakers will focus on programs that support cross-over collaboration between ethics review boards to reduce the overall administrative burden. The session will begin with talks about the similarities and regulatory overlap in IRB, IACUC, IBC, and ESCRO. Then, speakers will explore infrastructural restrictions and discuss how to establish a pathway of communication so researchers can have access to common resources (e.g., CITI training access, common forms of development with grants administration, information dissemination practices).



**Learning Objectives:**

- Discuss common regulatory concerns among IRB, IACUC, IBC, and ESCRO to enhance research compliance effectiveness
- Review common infrastructural problems among the review entities
- Understand how the "culture" of the unit shapes their work and perspective on the research enterprise

**Target Audience:** ACU/IACUC Directors; HRPP/IRB Directors; IBC Directors; Research Program Leadership and Institutional Officials; Compliance Personnel

ICON LEGEND

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Deep Dive Series	Thought Leader Series	Networking Series	Workshop Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

**D10: Supporting Workforce Diversity**

Track(s): *Advancing Equity and Justice; Research Oversight Leaders and Institutional Officials*

The research workforce is a critical component in creating an environment that supports and drives diversity and equity in research. This session will address key equity considerations in creating and maintaining a diverse workforce that values the diverse perspectives, thoughts, experiences, and skills needed to drive research excellence. Topics will include creating strong pipelines for varied research roles for staff; faculty, promotion, tenure and salaries; and working with other parts of the organization (e.g., Human Resources).



**Learning Objectives:**

- Discuss how institutional leadership can engage with Human Resources and faculty leadership to create a supportive structure and community for research staff and faculty
- Identify initiatives and engagement within the community and externally to create pipelines for future researchers
- Share approaches to recruiting and retaining research faculty and staff (e.g., research funding, training, staff support, educational opportunities, mentorship)

**Target Audience:** Research Program Leadership and Institutional Officials; ACU/IACUC Directors; HRPP/IRB Directors; BC Directors; Researchers and Research Staff

**D11: Conducting an Effective IRB Review of Artificial Intelligence (AI) Human Subjects Research (HSR) (*The Non-Clinical Edition*)**

Track(s): *Research Involving Data and Biospecimens; Research Conducted in the Digital World*

Social Behavioral and Education Research (SBER) involving AI/Machine Learning (ML) applications has received less attention than its counterpart, clinically based research involving AI/ML. This may be because the Common Rule currently does not have an established regulatory framework for HSR involving AI/ML, while clinical studies have general regulatory guidance that does cover this technology broadly. As a result, and because SBER studies involving AI/ML can be nuanced, conducting an effective IRB review and making decisions in SBER studies that involve AI/ML is often more challenging. This session will walk the audience through the current regulatory frameworks under the Common Rule using a targeted approach: Relying on the AI HSR checklist to review non-clinical AI HSR; using case studies to help work your way through several typical non-clinical AI applications; making AI HSR and exempt determinations; and discussing various consent options in non-clinical AI HSR, such as group consent. Click to read, [Conducting an Effective IRB Review of Artificial Intelligence \(AI\) Human Subjects Research \(HSR\) \(The Non-Clinical Edition\)](#).



**Learning Objectives:**

- Establish a working definition of AI and ML
- Learn to apply the Common Rule definitions in AI HSR to case-study examples
- Gain a working knowledge of how to use the AI HSR IRB Reviewer Checklist and HSR/Exempt Determination Decision Trees

**Target Audiences:** HRPP/IRB Directors; Research Program Leadership and Institutional Officials; IRB Members, Chairs, and Vice Chairs

**D12: Small Research Program and Your First Clinical Trial: Now What?!**

Track(s): *Small Research Programs; Social, Behavioral, and Educational Research*

Small to mid-size IRBs or predominantly SBER IRBs can encounter challenges and constraints when faced with that first clinical trial. Hear from institutional experts on how to set up the basic framework needed for reviewing this type of research, including creating opportunities within the current policies to remain compliant, reduce risk, and establish monitoring for clinical research



**Learning Objectives:**

- Discuss the basic requirements for reviewing a clinical trial
- Share strategies and tools for the monitoring and oversight of your first clinical trial
- Consider benefits of ceding review to an external IRB or using IRB experts

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Manager and Staff; IRB Members, Chairs, and Vice Chairs; Compliance Personnel; Clinical Research Staff

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Vendor Insight Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

**D13: IRB Process Improvements: Collaborative Methods With Institutional Clinical Research Liaisons**

Track(s): Education, Qualifications, and Training; Flexibility and Innovation in Research Oversight Processes; HRPP/IRB Administration/Management and Process

This session will focus on the value added by engaging institutional partners in HRPP process improvements. For example, an IRB might partner with a clinical trials office that focuses on improving education and resources for clinical researchers to engage and train researchers. Such relationships can enable specialized clinical research services tailored to optimize research productivity, streamline operations, and increase opportunities to develop "train the trainer" services (all of which are essential resources and benefits to the research community).



**Learning Objectives:**

- Review the benefits of collaborative education efforts with the IRB and other elements of a HRPP
- Share practical ways to approach partnerships between IRBs and other components of the HRPP to improve education and resources for clinical researchers
- Explore the benefits and challenges of establishing partnerships between IRBs and other HRPP efforts to improve education related to clinical research

**Target Audience:** HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Educators/Trainers; Clinical Research Staff; Researchers and Research Staff

**D14: When The @#&% Hits the Fan: When HRPP Noncompliance and Research Misconduct Occur Together**

Track(s): HRPP/IRB Administration/Management and Process; Legal Considerations in Research Oversight

Research misconduct (e.g., fabrication, falsification, and plagiarism) is never good, but it becomes exponentially bad when it takes place within the context of or overlaps with noncompliance in human subjects research. This session will explore the processes for and unique challenges of HRPP's collaboration with Research Integrity/Misconduct Offices to identify, manage, and resolve research misconduct allegations.



**Learning Objectives:**

- Identify and discuss challenges of identification and processing of research misconduct allegations in human subjects research
- Discuss best practices—policy and process—for HRPP's collaboration with research misconduct offices to address research misconduct allegations
- Share a case study in research misconduct that involves human subjects research

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Legal Counsel; Compliance Personnel; Clinical Research Staff; Researchers and Research Staff

**D15: In the Eyes of the Consenter: The Informed Consent Process From the Perspective of People Who Obtain Consent**

Track(s): Informed Consent

A survey of people who regularly obtain informed consent from research participants was conducted to gain a better understanding of their opinions, understanding, and confidence of the process of obtaining informed consent, as well as the informed consent document and their training around the consent process. This session will highlight the descriptive results, as well as the themes that emerged from challenges and concerns with the process to rewarding experiences. The remaining time will be used to discuss how HRPP staff can improve the consent process for the person obtaining consent based on this unique perspective.



**Learning Objectives:**

- Learn about the descriptive results of a survey conducted with people who obtain informed consent from research participants about their opinions on the consent process and document
- Describe the perceived challenges, concerns, and suggestions that people who obtain consent from research participants have
- Explore ways to combat challenges and concerns, and learn from successful experiences to provide actionable ideas to people who obtain informed consent at their institutions

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Clinical Research Staff; Researchers and Research Staff

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Workshop Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

**D16: Leading and Lagging Indicators of Quality**

Track(s): Flexibility and Innovation in Research Oversight Processes; ACU Program Management; IACUC Administration/Management and Process

Leading and lagging indicators have been identified as best practices in business. This session is an opportunity to review the concepts behind these indicators and learn how they can be applied to track behaviors, prevent noncompliance, and improve animal program operations.



**Learning Objectives:**

- Learn what is meant by leading and lagging indicators
- Identify some common indicators relevant to animal care and use programs
- Explore options for using leading and lagging indicators to improve animal program quality

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; HRPP Leadership and Institutional Officials; Compliance, Regulatory, and QA/QI Professionals; Compliance Personnel; Laboratory Animal and Veterinary Staff; HRPP Educators; Researchers and Research Staff

**D17: Fish and Wildlife Protocol Reviews: Research vs. Management**

Track(s): Oversight of Non-Typical Animals and Situations; ACU Management; Flexibility and Innovation in the Research Oversight Process; IACUC Protocol Review

Field procedures used in managing free-ranging wildlife are often very similar to those used during wildlife research projects. Yet, historically, wildlife management activities have not involved IACUC oversight. Recently, the comparisons between fish and wildlife research and management activities are becoming more relevant, in part, due to scientific journal ethical requirements. This session will discuss how IACUCs should consider this issue.



**Learning Objectives:**

- Provide an overview of common management procedures used in free-ranging fish and wildlife populations
- Discuss the similarities and differences between wildlife research and management
- Present a decision-making model to clarify research vs. management activities for the IACUC review process

**Target Audience:** ACU/IACUC Directors; IACUC Members, Chairs, and Vice Chairs; Researchers and Research Staff; Laboratory Animal and Veterinary Staff

**D18: Educating Researchers Involved in Collaborative Research**

Track(s): Flexibility and Innovation in Research Oversight Processes; Education, Qualifications, and Training

While research compliance administrators may be aware of the responsibilities of institutions engaged in collaborative research, researchers may not. Responsibilities for the relying and overseeing institutions do not end with the execution of a collaborative agreement. This session will focus on best practices for educating researchers on their responsibilities when engaged in collaborative work.



**Learning Objectives:**

- Outline researcher responsibilities for both the relying and overseeing institutions
- Discuss challenges and risks associated with limited education and communication during collaborative work
- Provide strategies for effectively educating researchers on their shared responsibilities (e.g., communication, reporting, etc.)

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IBC Directors; IBC Administrators, Manager and Staff; Educators/Trainers; Researchers and Research Staff

**D19: It's Not You, It's Us: Dealing With the Difficult IRB/IACUC/IBC**

Track(s): QA/QI and Postapproval Monitoring; Shared Oversight Challenges

Assessing our own programs to identify areas for improvement that may be rooted in long-standing policy, culture, or difficult personalities can present significant leadership challenges. In this session, speakers will discuss their experiences in dealing with "difficult" IRB/IACUC/IBC chairs, members, and/or staff, and/or committees. The focus will be on identifying areas of such difficulties, assessing to what extent their root cause lies in policy, process, or personnel, and exploring efforts by IRB/IACUC/IBC leaders to eliminate, reduce, and minimize such difficulties.



**Learning Objectives:**

- Identify where an IRB/IACUC/IBC can be problematic in terms of policy, processes, culture, and operations
- Explore root causes of problematic IRB/IACUC/IBC behavior: culture, organization, personnel
- Consider processes for addressing problematic IRB/IACUC/IBC behavior

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; IBC Directors; IBC Administrators, Manager and Staff; IBC Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; QA/QI Professionals; Compliance Personnel; Educators/Trainers

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Workshop Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

**12:45-1:30 PM: Sponsored Presentation from Huron: Improving Efficiency and Effectiveness for HRPPs and Beyond**

Track(s): HRPP/IRB Administration/Management and Process; Flexibility and Innovation in Research Oversight Processes

Maintaining compliant, efficient, an effective human research programs requires active management and constant focus. It requires effective coordination and communication between IRB leadership and the various other compliance and administrative functions within the institution. And, challenges outside the IRB's direct control may complicate efforts to maintain a high performing HRPP. As the research landscape continuously evolves, HRPP leaders need to proactively monitor and reexamine current processes, tools, and approaches, and explore new opportunities to optimize both HRPP and broader institutional approaches to managing human research while remaining compliant. Huron will use this session to provide a recap of some of the thematic challenges to HRPP operations we are seeing across the research administration landscape in 2022.



**Learning Objectives:**

- Huron's perspectives on some of the most common IRB challenges clients have faced in 2022
- Solutions aimed at addressing these common challenges
- Looking beyond the IRB office to common challenges in other administrative functions that may impact the overall HRPP

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs

**Concurrent Breakout Sessions, 1:30-2:30 PM ET**

**E1: Innovations in Recruiting Research Participants**

Track(s): Flexibility and Innovation in Research Oversight Processes

With research increasingly moving to remote modalities, we need innovative mechanisms to introduce research options to participants. This session will highlight innovations in research recruitment and the oversight of novel recruitment mechanisms. Examples will include digital marketing campaigns, direct to patient targeted recruitment through MyChart and text messaging as advertising, and participant registries.



**Learning Objectives:**

- Share best practices in implementing novel recruitment methods to reach participants
- Explore the considerations for IRBs, researchers, and organizations in adopting these strategies
- Consider when additional oversight mechanisms may be needed to support implementation of these novel recruitment mechanisms

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Compliance Personnel; Clinical Research Staff; Researchers and Research Staff

**E2: Bottlenecks to Bridges: Defining and Implementing Your HRPP Vision and the Importance of HRPP Leadership**

Track(s): HRPP/IRB Administration/Management and Process; Leadership Development Skills

Join experienced HRPP leaders and institutional leadership for a session focused on defining and implementing a vision for human research protections at your organization. Gain insight into how to identify workflow and communication bottlenecks across HRPP units and how the institutional leadership and HRPP leaders are key for establishing effective strategies to improve overall HRPP performance and quality. Speakers will review models for HRPP leadership that can complement and support the institutional leadership. Additionally, speakers will address strategies for creating a unified workflow and communication strategy across all HRPP units (including committees and units ancillary to the IRB).



**Learning Objectives:**

- Review the importance of institutional leadership in setting and implementing an HRPP vision
- Identify strategies for operating as institutional leadership, including varied HRPP leadership models that may help support the role
- Discuss how to identify potential bottlenecks across HRPP units
- Share best practices for creating solid, practical, and achievable workflow and communication plans for HRPPs

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; Research Program Leadership and Institutional Officials

ICON LEGEND

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Deep Dive Series	Thought Leader Series	Networking Series	Vendor Insight Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

**E3: “Do Not Take if You Are Pregnant”: Demystifying the Inclusion of Pregnant Participants in Research**

Track(s): Populations Requiring Additional Protections

Subpart B places additional restrictions on trials that include pregnant people, and there has been systematic and widespread exclusion of pregnant people from non-obstetric trials. The past several years have clearly demonstrated that this has led to a dangerous information gap. Doctors are placed in a position of prescribing (or not) without sufficient data, and many pregnant people feel unable to assess the risks of deciding to take needed medications and vaccines.



**Learning Objectives:**

- Review the history and rationale for protection
- Investigate two dimensions of the ethical conundrum: 1) the primacy of autonomy for adults with decisional capacity vs. the categorical vulnerability and limitations placed upon “pregnant women”; and 2) the emphasis on justice, and the exclusion of otherwise eligible prospective participants due to pregnancy
- Consider what equal and fair inclusion would look like
- Discover areas of flexibility within Part B that can be leveraged to increase opportunities for pregnant participants to join studies, common misconceptions, and how to provide guidance for investigators

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Clinical Research Staff; Researchers and Research Staff; Compliance Personnel; Diversity, Equity, Inclusion, and Justice

**E4: Equity Beyond Selection: Applying Principles of Justice After Recruitment**

Track(s): Social, Behavioral, and Educational Research; Advancing Equity and Justice in Research

Our collective instruments need a tremendous amount work. These instruments may have been validated, but haven't been validated in the communities where they're in use. As such, there are questions about the value of the data. This session will explore the IRB's responsibility in attending to diversity, equity, and inclusion (the Justice principle), beyond enrollment, in instruments, study procedures, and communications.



**Learning Objectives:**

- Explore the rationale for reframing the Justice principle beyond recruitment to include diversity, equity, and inclusion in instruments and study procedures
- Consider the implications of applying diversity, equity, and inclusion in instruments and study procedures

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Researchers and Research Staff

**E5: Training IRBs for the Review of Transnational Research**

Track(s): Transnational Research Collaborations; Education, Qualifications, Training

IRBs often struggle in understanding their responsibility in the review of transnational research. How might they approach the review? How do they appropriately consider the review of the in-country IRB? What impact should those determinations have on their review? This session will highlight approaches to training IRB members in their review responsibilities when reviewing transnational research.



**Learning Objectives:**

- Provide practical tips, training tools, and reviewer forms that can be used to facilitate the review of global research projects
- Share training resources for IRB members to orient them to their review responsibilities for the review of global research and how these may differ based on funding
- Discuss how to maximize on current global events to proactively educate members and prepare them for what to reasonably expect

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Compliance Personnel; Researchers and Research Staff; Clinical Research Staff

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
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CIP Credit	CPIA Credit	Call for Session Proposal	

**E6: Fostering Collaborative Relationships with IACUCs, Attending Veterinarians (AVs), and Investigators**

Track(s): ACU Program Management; Communication With the Public; Flexibility and Innovation in Research Oversight Processes; Education, Qualifications, Training

This session will provide an overview of how IACUCs and AVs work with investigators to support their needs while maintaining optimal animal welfare. Participants will gain a deeper understanding of the strategies IACUCs and AVs use to facilitate researchers' goals particularly with respect to husbandry practices, experimental design, environmental factors, and choice of animal model. Strengthening communication between these entities is essential for improving research rigor, translatability, and overall public trust in animal research.



**Learning Objectives:**

- Discuss how IACUCs and AVs assist investigators with their needs, including challenges and opportunities associated with various animal models and husbandry practices
- Share strategies and best practices to strengthen communication between researchers (including early-stage investigators), IACUCs, and AVs
- Explore strategies for designing an onboarding process for new investigators, including methodologies used to assist investigators in better developing animal protocols
- Review Federation of American Societies for Experimental Biology and other advocacy resources that enable animal research stakeholders to communicate the value of animal research and the oversight mechanisms in place to ensure human and animal safety

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Public Relations Professionals; Compliance Personnel; Laboratory Animal and Veterinary Staff; Educators/Trainers; Clinical Research Staff; Researchers and Research Staff

**E7: Veterinary Mentoring for Wildlife Research and Field Procedures**

Track(s): Oversight of Non-Typical Animals and Situations; ACU Program Management; Education, Qualifications, Training

Often veterinary procedures are conducted by non-veterinary scientists in fish and wildlife research and field work. Planning for these procedures requires training by and consultation with a veterinarian with appropriate expertise. In this session, speakers will review the common field procedures being conducted, the importance of considering the 3Rs, and discuss the value of the working relationship between the veterinarian and their wildlife research scientist.



**Learning Objectives:**

- Provide an overview of the topics discussed during the veterinary consultation with the principal investigator for fish and wildlife research protocols
- Discuss how to do a review of medical management and monitoring of wildlife species during field procedures
- Review invasive procedures and aseptic technique in wildlife species conducted in the laboratory vs. in the field

**Target Audience:** IACUC Members, Chairs, and Vice Chairs; Laboratory Animal and Veterinary Staff; Researchers and Research Staff

**E8: The Patients are Waiting! Balancing the Pressure of Getting New Therapies to Clinical Trial**

Track(s): Pharma/Biotech Perspectives; Flexibility and Innovation in Research Oversight Processes

This session will explore how to balance the pressures of getting new therapies to clinical trial while ensuring robust study design and providing the best animal welfare possible. Examples of the ways IACUCs and scientists/clinician scientists have found to facilitate agile review and study start times while ensuring high quality pre-clinical studies will be discussed.



**Learning Objectives:**

- Explore the unique pressures in pre-clinical studies as a critical step before new therapies can progress to clinical trials
- Discuss case studies that provide examples of what is at risk if pre-clinical studies are rushed or delayed
- Learn ways to facilitate agile but comprehensive review of pre-clinical studies to support the appropriate transition to clinical trials

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Legal Counsel; Compliance Personnel; Laboratory Animal and Veterinary Staff; Clinical Research Staff; Researchers and Research Staff

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Workshop Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

### E9: Doing More With Less: Managing Infrastructure and Staffing Resources

Track(s): Shared Oversight Challenges; Emerging Challenges and Breaking Issues

Infrastructure and staffing resources sometimes fall behind research initiatives and expanding grant portfolios. Increased employee turnover leaves vacancies and contributes to loss of institutional knowledge, putting constraints on existing resources. This session will explore how operations can be scaled to provide continued support for research, how to recruit, retain, and promote from within, and how to recognize when you need more people and how to make the case to leadership.



**Learning Objectives:**

- Discuss what makes people stay at or leave jobs (in regard to the current working environment)
- Review how we ethically structure our research environments, and the impact of using a structure that does more with less (i.e., impact on people, research, etc.)
- Consider how the aforementioned factors impact how we recruit/retain staff (e.g., hiring practices, job descriptions, interviews, etc.)

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IBC Directors; IBC Administrators, Manager and Staff; Research Program Leadership and Institutional Officials

### E10: What's Coming Down the Line that Institutional Leadership Needs to Know?

Track(s): Emerging Challenges and Breaking Issues; Research Oversight Leaders and Institutional Officials

Institutional leadership needs to keep current with the evolving federal funding landscape and its implications for research. Federal government agencies continue to focus response efforts around the COVID-19 pandemic, and these efforts mean balancing strategic initiatives and new fiscal priorities.



**Learning Objectives:**

- Discuss the national strategy, policy, and budget reports of federal funding agencies
- Consider the rise of the private sector funding with the changing funding landscape
- Review ethics and transparency within research programs and funding that several funding agencies have addressed

**Target Audience:** Research Program Leadership and Institutional Officials

### E11: An Update From DoD

Track(s): A Dialogue With the Feds

This session will describe how the DoD HRPP evolved from the 1940's through current innovations during Operation Warp Speed in its crusade against COVID-19. This session will also include how the current DoD HRPP and its Component Offices for Human Research Protections engage with internal and external investigators and other research protections personnel. For follow-up questions to the session, [email the DoD Office for Human Research Protections](#).



**Learning Objectives:**

- Review the history of the DoD HRPP alongside how federal regulations governing research participant protections were developed
- Understand how the DoD research program directs non-military science and technologies
- Learn how to engage DoD HRPPs for the purposes of prospective research

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Legal Counsel; QA/QI Professionals; Compliance Personnel; Educators/Trainers; Clinical Research Staff; Researchers and Research Staff

### E12: The Return of Data: Meeting Black Folx Where They Are While Explaining the Research and the Importance of Returning the Results to Them

Track(s): Advancing Equity and Justice in Research; Research with Data and Biospecimens; Communication With The Public

More and more research initiatives and funding agencies are asking researchers to focus on social justice and equity. Even more so, researchers are being asked to improve equity by considering inclusivity and enrolling or recruiting race or ethnic minorities/participants. Researchers and ethics professionals have a moral obligation to learn and understand the medical experimentation history from colonial times to the present (Washington, H. A. (2006). Medical apartheid: The dark history of medical experimentation on Black Americans from colonial times to the present. New York: Doubleday.). What we do with this information during the consent process and during recruitment is critical to slowly building back trust with participants while focusing on equity and justice. This session will allow for conversation on the potential for exploitation.



**Learning Objectives:**

- Expand awareness of medical experimentation beyond Tuskegee and known historical injustices
- Learn and listen to representative presenters explain more about why medical research is not trusted in the US
- Establish ground rules for working with the Black community and explain the obligation for returning results in a manner that is useful to the community

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Compliance Personnel; Clinical Research Staff; Researchers and Research Staff

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Vendor Insight Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

**E13: Rigor Rules! How IRBs Assess Sound Research Design**

Track(s): IRB Basics; Flexibility and Innovation in Research Oversight Processes

The Common Rule 111 criteria requires minimizing research risk through the use of sound research design and, similarly, NIH has placed rigor and reproducibility at the forefront of its goals for ensuring scientific merit. However, there are no clear and consistent guidelines as to how IRBs should review studies to assess research quality and rigor. This session, by way of a case-based approach, will discuss key indicators of study rigor and present them within a framework to standardize the IRB review process.



**Learning Objectives:**

- Recognize the Common Rule criteria and NIH requirements for addressing research rigor
- Understand common basic study designs, the significance of clearly iterated purposes, and how purpose dictates the outcome measures for the study
- Identify other indicators of research quality and rigor inherent in different study designs, and learn how to incorporate a rigor assessment framework into standard IRB practice for protocol review

**Target Audience:** HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Researchers and Research Staff

**E14: The Protection of Non-Subjects From Research Harm**

Track(s): Legal Considerations in Research Oversight

This session will explore to what extent IRBs should identify and consider risks to non-subjects during the process of review and approval of research involving human subjects.



**Learning Objectives:**

- Explore regulatory and ethical considerations regarding the protection of non-subjects
- Discuss scope of IRB review related to risk to non-subjects and institutional oversight mechanisms for the review of studies with potential risks to non-subjects
- Review case studies that may involve risks to non-subjects

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs

**E15: The IRB Role and Practical Tools for IRB Review of Research Proposals Involving Artificial Intelligence (AI)**

Track(s): Research Conducted in the Digital World; Emerging Challenges and Breaking Issues; Flexibility and Innovation in Research Oversight Processes; Research Involving Data and Biospecimens

AI models, and Machine Learning (ML) in particular, are excellent tools that can be used by a learning healthcare system to immediately impact healthcare delivery and patient outcomes. To achieve high impact, researchers must be able to effectively communicate to ethics professionals the essential components of the specific system, so that IRBs (and IACUCS when such algorithms are used in animal research) can accurately calculate the risk/benefit profile of the model, and thus document their criteria for approval. However, this task is daunting at best, and often what is offered by way of system description is beyond the scope of most IRB members' expertise. There is some guidance from federal agencies, but additional discussion is necessary to identify true risk and possible benefit of such models so that the field can assess appropriate review pathways for AI and ML-centered research. Through in-depth discussion and case study review, this presentation will offer tools to identify AI/ML models used in research and their risks and benefits, and present practical strategies for regulatory review so that such research is implemented with the highest of ethical standards and the precision of good science. Case studies will be discussed to allow attendees to use materials later for training IRB members.



**Learning Objectives:**

- Discuss various AI models and technologies that employ them
- Examine strategies to use when reviewing protocols with AI and ML components
- Identify risks and concerns regarding privacy and confidentiality
- Gain an understanding of US, EU and other international AI ethics standards that apply to IRB review

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Compliance Personnel; Clinical Research Staff; Researchers and Research Staff

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Workshop Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

**E16: IACUC Basics for the Use of Wildlife and Non-Typical Species in Research and Education**

Track(s): Oversight of Non-Typical Animals and Situations; IACUC Basics

During this session, speakers will discuss basic information that IACUCs need to address during the review of studies using wildlife or non-typical species (e.g., wildlife, naturally occurring disease in animal models, cephalopods, marine species, field studies). Discussion topics will include animal numbers, pharmaceuticals, occupational health and safety, euthanasia, nontarget species, and potential problems encountered in the field. Proposed AWA Standards for Birds will also be included.



**Learning Objectives:**

- Discuss and describe the expectations for IACUC review
- Address pharmaceuticals for pain relief, occupational health, and euthanasia
- Review the new USDA, APHIS Animal Care Policy on Research Involving Free-living Wild Species in Their Natural Habitat

**Target Audience:** IACUC Members, Chairs, and Vice Chairs

**E17: Keeping Them in the Fold: Creating Collaborative External Relationships**

Track(s): Pharma/Biotech Perspectives; ACU Program Management

No program has unlimited bandwidth to perform or host due diligence within a third-party collaboration. This session will explore collaborations from the perspective of both the institution conducting the due diligence and the institution being assessed. In addition, speakers will discuss why/what is the value of conducting due diligence, and share tips on how to do it collaboratively for mutual benefit of the institutions, the animals, and the study.



**Learning Objectives:**

- Discuss what is due diligence, and learn about the various components of a due diligence program and process
- Explore the value of conducting and receiving due diligence when engaging in an external collaboration
- Discuss how to start and maintain an open dialogue between the sponsor and host institution to facilitate a strong collaboration

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Legal Counsel; Compliance Personnel; Laboratory Animal and Veterinary Staff; Clinical Research Staff; Researchers and Research Staff

**E18: Researcher Rehab**

Track(s): Education, Qualifications, and Training; QA/QI and Postapproval Monitoring; Shared Oversight Challenges

IACUCs and IRBs are tasked with ensuring adherence to the approval of experimental protocols. Most organizations use an honor system, but not-for-cause and for-cause audits are necessary to demonstrate a comprehensive program. Researchers who repeatedly have problems staying in compliance or following the rules present challenges for oversight committees and have the potential to jeopardize the reputation of an entire program. This session will discuss strategies for successfully working with investigators who have had ongoing noncompliance or other problems to get them back on track.

**Learning Objectives:**

- Consider how to identify the root of the problem that is leading to ongoing compliance problems
- Explore strategies for successful interventions and providing ongoing oversight while also building stronger relationships with the research team
- Describe the benefits of keeping institutional leadership informed and discuss channels for escalating the concern to support other interventions

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; IBC Directors; IBC Administrators, Manager and Staff; IBC Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; QA/QI Professionals; Compliance Personnel; Educators/Trainers

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Workshop Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

**E19: Incentives and Strategies to Encourage Robust Committee Member Engagement**

Track(s): Shared Oversight Challenges

Committee member engagement and honest conversation are the cornerstones of effective ethical reviews. Competing priorities and safety concerns sometimes disengage participation. Proactive intervention and goal setting should include convenient training tools and expectations, and ensuring people can meet those obligations to ensure maximal attendance, robust conversation, and timely and thoughtful reviews. Term limits and periodic reviews offer opportunities to explore feedback and concerns, and generate strategies to maintain peak involvement.



**Learning Objectives:**

- Share effective onboarding strategies for new committee members
- Explore how to track and assess member contributions
- Consider approaches for assisting committee members that are not meeting established participation requirements

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff

**E20: Investing in People: Facilitating Engagement and Professional Development**

Track(s): Leadership Skills Development; Research Oversight Leaders and Institutional Officials

To recruit and retain the right staff, and in a challenged labor market, investing in people is critical. The professionals working within research programs are vital to advancing research ethics and should be provided with continual opportunities for professional development and growth to match the ever-increasing demands for ethical and compliant research. In this session, speakers will discuss how to foster professional development for staff and leaders through identifying discreet development opportunities (e.g., conferences, credentialing, etc.), encouraging staff engagement, communicating the importance of professional development to senior leaders, securing resources, and becoming life-long learners. For those wishing to personally advance in their career, there will be a discussion about developing executive level leadership skills. All discussion will focus on the goal of creating career pathways and work environments that provide for fulfilling careers in research oversight.



**Learning Objectives:**

- Explore the imperative for creating an inclusive, equitable, and supportive environment for professional development within the workplace, including staff engagement and securing resources
- Identify discreet opportunities for professional development for research oversight professionals (e.g., conferences, credentialing, networking, etc.)
- Learn how to take advantage of professional development opportunities to advance your own career

**Target Audience:** Research Program Leadership and Institutional Officials

2:30-3:00 PM ET: Break

Concurrent Networking Sessions, 3:00-4:00 PM ET

**IRB Closet Clean-Out: Keep, Toss, TBD (to be determined)**

Track(s): Flexibility and Innovation in Research Oversight Processes; HRPP/IRB Administration/Management and Process

HRPP professionals are living in interesting times: the 2018 Common Rule, 21<sup>st</sup> Century Cures Act, GDPR, and the pandemic are among the challenges that forced HRPPs to take on new, creative, and at times uncomfortable processes. What successes have you seen, lessons learned, and unforeseen obstacles experienced? In this networking session, we'll be swapping strategies and sharing attempts made in response to the ever-changing research landscape.



**Learning Objectives:**

- Share strategies used by HRPPs in response to the recent regulatory and circumstantial changes
- Network with other HRPP professionals to discuss creative approaches utilized
- Assess which processes are worth keeping, should be tossed, or need further consideration

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Workshop Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CIPA Credit	Call for Session Proposal	

**Everyone Is Doing it, But Are We Doing it Well? Evaluating Your Role as a Single IRB (sIRB)**

Track(s): Flexibility and Innovation in Research Oversight Processes; HRPP/IRB Administration/Management and Process

In this session, speakers will take a critical look at the world of sIRB and discuss what is involved, what works, and what doesn't. Reliance professionals will share insights and tools to evaluate how their institution is doing when serving as a sIRB. This session will also serve as an opportunity for institutions to educate and share progress and limitations faced by sIRBs and continue building the community of IRB Reliance professionals.



**Learning Objectives:**

- Learn how to measure effectiveness and efficiency when your institution is serving as a sIRB
- Discuss methods to identify strengths and weaknesses
- Meet and exchange contact information with sIRB professionals from various institutions for future inquiries/questions/reference

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs

**What's Your 4<sup>th</sup> R?**

Track(s): Animal Well-Being and the 3Rs

While the concept of the 4<sup>th</sup> R was introduced in the early 2000s, many different "Rs" have been suggested: responsibility, reproducibility, rehoming, respect, etc. Some organizations are even celebrating a 4<sup>th</sup> R with an award. This session will discuss if there's a need to go beyond the 3Rs and if so, which 4<sup>th</sup> R should be prioritized?



**Learning Objectives:**

- Discuss whether the 3Rs are enough
- Review various potential 4<sup>th</sup> Rs
- Explore where do we go from here

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; Laboratory Animal and Veterinary Staff; Clinical Research Staff; Researchers and Research Staff

**Leadership in Action: Real-life Scenarios and Solutions**

Track(s): Leadership Skills Development

Join this session for a snapshot of five successful leadership styles in action. Seasoned leaders will present on a leadership-related topic using a real-life experience. They will describe the actions taken, highlight leadership skills required for a successful outcome, and present key take home points. Time for questions will be reserved at the end.



**Learning Objectives:**

- Review situations where effective leadership is necessary to successful outcomes (e.g., conflict resolution, communication challenges, team development, etc.; topics to be determined)
- Identify specific leadership skills that contribute to successful resolution of real-life situations
- Learn how to cultivate leadership skills in yourself and others

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff

**"A Little Help Here?" Finding Support and Community for Compliance Committees at Small Research Programs**

Track(s): Small Research Programs

For those overseeing ethical compliance at small research programs, finding guidance and support may require looking beyond the institution. Besides regulatory bodies, who can you turn to for ideas about how to make your compliance committees successful? How do you create circumstances where you don't need to figure out solutions to all the problems yourself? How do you advocate for resources? This session will include strategies for cultivating community with IACUC and IRB staff at other small research programs and for building equitable partnerships with IACUC and IRB staff at bigger (and better-resourced) programs.



**Learning Objectives:**

- Share typical challenges for compliance professionals and compliance committees in small research programs, and identify which of these could be addressed by cultivating community beyond that program
- Identify strategies for finding and working productively with compliance committee members and compliance professionals at other small research programs
- Consider the pros and cons of cultivating relationships with compliance committees and compliance professionals at larger institutions
- Understand the range of options for implementing and sustaining relationships and community beyond your small research program (including listservs, consortia, etc.)

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IBC Directors; IBC Administrators, Manager and Staff

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Vendor Insight Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

**PRIMR22 Poster Presentation Program: Outstanding Work in Animal Care and Use**

Track(s): IACUC Administration/Management and Process; ACU Program Management; QA/QI and Postapproval Monitoring

Join the authors of this year's outstanding posters in the Animal Care and Use category for a discussion on their work. Posters will be available to attendees via the Virtual Poster Gallery starting on November 29. The following work will be presented:



- "IACUC Post-Approval Monitoring Metrics: Collection and Lessons Being Learned" by John Woollard, MSc; Tobin Emrich, DVM; Rachel Sarabia, DVM, PhD; Jeffery Schmoll, MBA, Mayo Clinic
- "Research Electronic Data Capture as a Tool for IACUC Programmatic Improvements" by Kelsey Horvath, PhD; Ajay Sagar, CPIA; Keren Dunn, CIP, Cedars Sinai Medical Center

**Target Audience(s):** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; Laboratory Animal and Veterinary Staff; QA/QI Professionals

PRIMR22 Day 4: Thursday, December 15

10:00-10:15 AM ET: PRIM&R Service Award Presentation: *John H. Parrish, DVM, PhD, ACLAM, LSSBB, Attending and University Veterinarian, Clemson University*



Concurrent Plenary Sessions, 10:15-11:30 AM ET

**Plenary IX: Decentralized Clinical Trials (DCTs): Considerations of and for IRB review**

Track(s): Emerging Research Challenges and Breaking Issues; Flexibility and Innovation in Research Oversight Processes; HRPP/IRB Administration/Management and Process; Pharma/Biotech Perspectives

DCTs may increase enrollment both by lessening the burden of participation and by increasing the geographical footprint of recruitment (including both underserved urban and rural areas), although barriers to implementation exist. Among these barriers is the relative lack of familiarity with the ethical issues presented by DCTs, particularly given their wide variation in study design, conduct, and scope that, in turn, present difficulties for IRB review and approval. These issues include electronic informed consent, tele- and/or video-medicine and home health visits, investigational drug delivery, remote monitoring, digital data collection, data transfer, data sharing, privacy, confidentiality, participant data literacy and access, and others. The recommendations for IRB review by a multi-disciplinary group of clinical trial stakeholders (e.g., IRB professionals, academia, technology companies, patients, pharmaceutical sponsors) will be presented and discussed.



**Learning Objectives:**

- Identify DCT ethical and regulatory challenges of importance to the IRB
- Share information about DCTs to be included in the submission for IRB review
- Provide a summary of points-to-consider for IRB review

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Compliance Personnel; Clinical Research Staff; Researchers and Research Staff

**Plenary X: Exploring the Future of *The Guide for the Care and Use of Laboratory Animals***

Track(s): Emerging Research Challenges and Breaking Issues; Flexibility and Innovation in Research Oversight Processes; IACUC Administration/Management and Process; IACUC Protocol Review; ACU Program Management

*The Guide for the Care and Use of Laboratory Animals* is a key document utilized by the animal research community, and it was in 2011. The Institute for Laboratory Animal Resources (ILAR) is considering methods and timelines to revise *The Guide* again, as well as exploring potential new formats to keep it updated more easily. The Veterinary Consortium for Research Animal Care and Welfare (VCRACW) conducted a survey of its members with the goals of generating objective data and providing analysis that would identify priorities for updating *The Guide* (the survey was created utilizing REDCap, data was collected from March 22-June 1, 2022, and 179 surveys were completed). This plenary session will review the data from the survey, which provide valuable guidance on priorities for the revision and can be utilized to supplement discussions around additional areas for improvement and new topic, and will also take a broader look at *The Guide* and potential revisions from the scientific community's perspective.



**Learning Objectives:**

- Hear from a representative of the ILAR Committee on potential revisions to, timelines, and format of *The Guide*
- Review the VCRACW survey results and its implications for revising *The Guide*
- Consider the scientific community's perspective on revision to *The Guide*

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; Laboratory Animal and Veterinary Staff; QA/QI Professionals

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Workshop Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

**Plenary XI: Entrepreneurialism and Research Institutions: Considerations for Successful Partnerships**

Track(s): *Conflicts of Interest; Emerging Challenges and Breaking Issues; Research Oversight Leaders and Institutional Officials; Legal Considerations in Research Oversight; Shared Oversight Challenges*  
 Declined: Megan Molteni, STAT reporter (will be at a summit); Damian Garde, STAT reporter ( 8/26, 8/30 no response); Bryn Rees, University of Colorado Boulder 9/9, 9/15 (no response)



The generation of patents and public/private partnerships are on the rise across the research enterprise as researchers and institutions increasingly see the potential for entrepreneurship to accelerate scientific findings. These potentially profit-creating situations can be well managed if approached thoughtfully with an eye toward all phases of a project's lifecycle. When not approached thoughtfully, they can cause huge headaches for administrators and researchers, and can even become the next media scandal. This session will review types of partnerships, identify areas of potential friction in the creation, growth, and maintenance of these partnerships, and provide examples of successes and failures.

**Learning Objectives:**

- Convey why public/private partnerships for development of animal models, algorithms, drugs, and pervasive data collection in public health studies may be necessary, and where there are likely to be points of friction in these partnerships
- Discuss the institutional conflicts of interest (COI) that may arise with these partnerships, how COIs might affect the research review process and community perceptions of the research, and how techniques like community engagement in the planning and execution of these projects may mitigate the institutional COI
- Explore how institutions can evolve these partnerships, ensuring research compliance as projects grow or fluctuate over time

**Target Audience:** Research Program Leadership and Institutional Officials; Legal Counsel; Public Relations Professionals; Compliance Personnel; Researchers and Research Staff; ACU/IACUC Directors@@@HRPP/IRB Directors; IBC Directors

**Plenary XII: Finding Value and Purpose: Why We Do What We Do**

Track(s): *Research Oversight Leaders and Institutional Officials*

The role of institutional leadership is more than compliance and it has tremendous impact on the research program and organizational culture. How does institutional leadership identify research stakeholders and work across their constituencies to promote a culture that values integrity, safety, compliance, and excellent research outcomes?



**Learning Objectives:**

- Determine who are the stakeholders and constituencies institutional leadership must work with, and how to prioritize engagement
- Consider the impact of institutional leadership on the overall research program
- Discuss which metrics matter and for what purpose (e.g., integrity, safety, compliance, and research outcomes)

**Target Audience:** Research Program Leadership and Institutional Officials

11:30-11:45 AM ET: Break

**F1: A Dialogue With NIH**

Track(s): *A Dialogue With the Feds*

This session will be led by a representative from the NIH, and will include discussion of NIH's work.



**Learning Objectives:**

- Hear from a representative of the NIH Office of Science Policy about activities that are pertinent to clinical research policy and the protection of participants in research
- Ask questions about new and ongoing initiatives at the NIH

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Legal Counsel; QA/QI Professionals; Compliance Personnel; Educators/Trainers; Clinical Research Staff; Researchers and Research Staff

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Workshop Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

**F2: Developing a System of IRB Precedent: Value, Approaches, and Challenges**

Track(s): IRB Chairs; Flexibility and Innovation in Research Oversight Processes; HRPP/IRB Administration/Management and Process

IRBs often rely on institutional memory in making decisions about challenging protocols, but a more systematic approach to developing and accessing IRB "precedents" can offer important benefits in terms of consistency, predictability, transparency, efficiency, and overall HRPP/IRB quality. However, creating a system of precedent requires an approach to summarizing IRB decisions and indexing them in a way that they can meaningfully inform future work; this can be challenging within an individual IRB and even more so across IRBs. In this session, speakers will make the case for using IRB precedent, describe an IRB chair's individual efforts to rely on prior decisions, explain a recent pilot study testing different approaches to retrospectively crafting IRB decision summaries, outline a current pilot study aiming to develop IRB decision summaries at the point decisions are made, and explore the future work needed to overcome barriers to incorporating IRB precedent into practice as a way to facilitate quality improvement.



**Learning Objectives:**

- Describe the value that a system of IRB precedent could offer in terms of clear justifications for IRB decisions, consistency, efficiency, and quality
- Explore different approaches to developing IRB decision summaries that could serve as the backbone of a system of IRB precedent
- Identify challenges to implementing a system of precedent within and across IRBs

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs

**F3: Compensation: How Much Inducement Is Due?**

Track(s): Pharma/Biotech Perspectives; Populations Requiring Additional Protections; Advancing Equity and Justice in Research

Paying research participants in exchange for their participation is a common practice. Yet, there is confusion and disagreement regarding exactly what can be paid and how much is appropriate. There is general alignment among the research community that participants should be reimbursed for direct expenses incurred so they are not made worse off financially from their trial participation. Beyond this, the lines are fuzzy between what is fair and just compensation or incentives, and what could be considered undue inducement. This session will explore the ethical considerations between reimbursement, compensation, and incentives for trial participation, what constitutes undue inducement, and the pros and cons of different mechanisms for providing payments. In addition, there will be discussion of the role of the IRB in discharging risks of undue inducement.



**Learning Objectives:**

- Identify considerations for determining the amount of payments to research participants (e.g., when the recipient of the payment is not the research participant or the acceptability of payments for assuming risk)
- Consider the pros and cons of different payment mechanisms (e.g., gift cards vs cash) and timing of payments
- Discuss the degree to which IRB review eliminates the possibility of undue inducement

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Legal Counsel; Clinical Research Staff; Researchers and Research Staff

**F4: Risky Business: The Basics of Evaluating Research Risk**

Track(s): IRB Basics

One of the more challenging parts of learning the ropes of IRB review is evaluating the risks of a study. To really grasp the risks of a study a reviewer needs to be able to parse research risks from risks of daily life or even routine procedures, evaluate the probability of the risk, including mitigation strategies, and consider the magnitude of the risks. In this session, speakers will explore a methodical approach to risk evaluation through case studies to help participants master the key steps to evaluating risks and documenting their risk assessments. Participants will practice applying this knowledge to a series of illustrative case studies based on real research protocols.



**Learning Objectives:**

- Define risk as it relates to human subjects research, including risk to individual participants as well as community and social risks
- Learn how to distinguish the magnitude of the risk from the probability of the risk, and understand how risk mitigation strategies may impact probability but not magnitude of risks
- Consider how to distinguish relative risks versus standard risk when applying the "minimal risk" definition

**Target Audience:** IRB Members, Chairs, and Vice Chairs; Clinical Research Staff; Researchers and Research Staff

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Vendor Insight Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

**F5: Big Data and Novel Technology: Considerations for Privacy and Participant Rights**

*Track(s): Research Involving Data and Biospecimens; Emerging Challenges and Breaking Issues; Research Conducted in the Digital World*

As technology advances, there is increased usage of apps, website data, and Artificial Intelligence (AI) in research. Big data amplifies risks to privacy, fairness, equality, and due process. As we continue to access more data to obtain modern conveniences, the information collected and for what purposes becomes more ambiguous and less transparent. As data sets continue to transfer hands for various research purposes a person's control over that data decreases. This session will look at how ethics and laws are used to define appropriate uses of big data and novel technologies in research.

Additionally, this session will help IRBs weigh the benefits of collecting and processing data against associated risks and build a systematic framework for reviewing these studies.

**Learning Objectives:**

- Discuss the regulatory framework on big data, including building a systematic framework for reviewing these studies, ethical considerations, and how well the Common Rule fits the regulatory needs of big health data research
- Review AI and big data, including US laws, when IRBs can or should require consent for AI data-only research, and the use of facial recognition
- Outline HRPP/IRB considerations, including assessing the risks vs. benefits of collecting and processing large-scale data collection, ways in which participants can be given more control over their data, educating researchers on how to minimize data breaches, and educating participants
- Explore practical considerations, including when to consider the IRB for an ethics review (even when it doesn't fit into a research category), and who to engage in these conversations during the review process

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Compliance Personnel; Clinical Research Staff; Researchers and Research Staff; Legal Counsel; Research Program Leadership and Institutional Officials



**F6: Communicating With and Educating the Public About IACUCs and Their Efforts to Ensure Animal Welfare in Research Settings**

*Track(s): Communication With the Public; Emerging Challenges and Breaking Issues*

The importance of communicating with the public about animal models in research is well known. However, the role of the IACUC in the research process is not well understood by the general public. In addition, the communications roles for key IACUC Members—specifically, the IACUC chair and attending veterinarian—are often not well defined. This session will examine the critical role the IACUC can fulfill in enhancing public understanding and trust of animal-based research.

**Learning Objectives:**

- Identify the risks currently faced/declining public support for biomedical research, and outline the benefits of expanded public education around the value of science and research
- Discuss the IACUC's role in openness and communication both within their institution and externally
- Share strategies for how members of the IACUC, especially the chair and attending veterinarian, can engage with the communications office in their institution, and identify the benefits of open communication to these parties
- Review approaches for increasing public knowledge of the IACUC's role and how it fits into the much broader and comprehensive research oversight system

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Public Relations Professionals; Compliance Personnel; Laboratory Animal and Veterinary Staff; Researchers and Research Staff



**F7: Flexibility and Innovation in Postapproval Monitoring (PAM): Many Parts, What Counts?**

*Track(s): Flexibility and Innovation in Research Oversight Processes; ACU Program Management; QA/QI and Postapproval Monitoring*

This session will describe innovations IACUC postapproval monitors are implementing in preparing for audits (in-person, virtual, collaborative), as well as to optimize monitoring and mitigate shared challenges. Speakers will share strategies used for adapting communications and materials for collaborative compliance auditing, discuss innovations being used in postapproval monitoring, and identify lessons learned.

**Learning Objectives:**

- Describe the adaptation and modification process in collaborative compliance for animal protocols
- Identify the strategies used for adapting communications and materials for virtual compliance auditing (including when audits are virtual)
- Analyze the takeaways for potential application in other compliance programs

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; QA/QI Professionals; Compliance Personnel



ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Workshop Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

**F8: Flexibility and Innovation in Protocol Review: What's the Right Process for Your Institution?**

Track(s): Flexibility and Innovation in Research Oversight Processes; IACUC Protocol Review

During this session, attendees will review different techniques for protocol review (e.g., robust pre-review, robust full committee review (FMR), designated member review (DMR), Veterinary Verification and Consultation (VVC), etc.). What are the advantages and disadvantages of the different techniques and how does one decide what is suitable for their program?



**Learning Objectives:**

- Evaluate the process of protocol review and areas for more intensive review: pre-review or during all committee review
- Discuss options for review depending on the size, complexity, and focus of your program
- Share how the IACUC can ensure robust discussions surrounding DMR and FCR with expert input to ensure compliance regulatory, funding and accrediting agencies
- Explore how to properly train IACUC members for the role they play in the protocol review process

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs

**F9: The Lifespan of a Research Protocol: The Journey From Research Using Animals to Research Involving Humans**

Track(s): FDA Regulated Research

Research may move from the laboratory to human subjects or from animal models to human subjects. Animal-to-human research/clinical trials is neither a one-way street nor is it a straight line/sequential; there might be many back and forths. What clinicians see in practice may end up back in the animal research realm to better understand underlying mechanisms so as to develop preventions and cures. Is the information from the animal research limited in time in its applicability? Are there reasons to revisit research in animals at different stages when it is used in humans or triggered by certain events. Is the characterization of an adverse event different for the two species? Should it be? And, how do we define the relevance of adverse events in animals to adverse events in humans?



**Learning Objectives:**

- Review how research in animals informs further research on the same agent in humans
- Consider how adverse events in animals translates specifically to adverse events in humans
- Learn how to identify when previous research on animals may need to be revisited in light of events occurring as the research in humans progresses

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; IBC Directors; IBC Administrators, Manager and Staff; IBC Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Public Relations Professionals; Educators/Trainers; Diversity, Equity, Inclusion, and Justice; QA/QI Professionals

**F10: To Share or Not to Share? Academic Freedom, Fundamental Research Exemptions, Open Data, and Foreign Influence**

Track(s): Research Oversight Leaders and Institutional Officials; Emerging Challenges and Breaking Issues; Legal Considerations in Research Oversight

Navigating the mandate for transparency, public access, and open data while also complying with other mandates to restrict access (e.g., data-sharing laws, export controls, HIPAA, GDPR, CMMC, NIST800-171, NSPM33, etc.) requires expertise and resources. Data curation and sequestration are essential as we develop infrastructure to appropriately share and restrict access. The speaker's discussion will address, both individually and collectively, data-sharing, navigating mandates, resource constraints, privacy concerns, and export controls.



**Learning Objectives:**

- Identify tools to support data sharing and data sequestration
- Explore resources to support training on when to share and when to embargo and influence institutional culture
- Discuss how to develop, resource, and implement a research data policy and a data stewardship plan

**Target Audience:** Research Program Leadership and Institutional Officials; ACU/IACUC Directors; HRPP/IRB Directors; IBC Directors; Researchers and Research Staff

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Workshop Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

**F11: A Dialogue With the Department of Energy (DOE): Addressing Implicit Bias in Human Subject Research—A Roundtable Style Discussion With Members of the DOE Implicit Bias Task Force**

Track(s): *A Dialogue With the Feds*

The DOE Human Subjects Protection Program launched efforts to proactively identify and address the potential for bias during IRB review. A DOE Implicit Bias Task Force was established in November 2021 to engage in open discussions and dialogue about implicit bias, evaluate specific documents within the Human Subjects Protection Program’s toolkit to ensure implicit bias is managed, and to consider how to ensure diversity and inclusion in its Board composition.



**Learning objectives**

- To provide a brief overview of: The DOE and the DOE Human Subjects Protection Program; and DOE’s diversity, equity, inclusion, and accessibility (DEIA) goals and activities.
- To describe the DOE Human Subjects Protection Program’s initiatives to better understand and incorporate DEIA considerations into all phases of human subjects research design, review and conduct, through the establishment of an Implicit Bias Task Force.

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Legal Counsel; QA/QI Professionals; Compliance Personnel; Educators/Trainers; Clinical Research Staff; Researchers and Research Staff

**F12: The Return of Genetic Information**

Track(s): *Pharma/Biotech Perspectives; Research Involving Data and Biospecimens*

Genetic information is increasingly being generated in research. As technology and our understanding of diseases evolve, more findings are becoming actionable and of great interest. This can lead to questions about what a researcher should do when they discover a genetic finding in a patient. Under what circumstances do they have an obligation to tell the patient? What if the patient doesn’t want to know? What about potentially impacted family members? When should genetic counseling be provided? Is there an obligation to review findings when new markers are validated?



**Learning Objectives:**

- Consider what makes genetic information special from an ethical perspective
- Identify considerations for return of genetic information (including as more become significant and actionable after the fact)
- Discuss considerations related to how to return genetic information and to whom

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Legal Counsel; Clinical Research Staff; Researchers and Research Staff; Research Program Leadership and Institutional Officials

**F13: Creating a Quality HRPP Reliance Program**

Track(s): *Small Research Programs; HRPP/IRB Administration/Management and Process; Flexibility and Innovation in Research Oversight Processes*

With the revised Common Rule, the requirement for designating a single IRB has required IRBs to restructure internal processes to fulfill the new mandate. This session will explore how an IRB office can create an IRB Office Reliance Team with the function of reviewing reliance requests, in a timely manner, to ensure institutional and compliance considerations are reflected.



**Learning Objectives:**

- Discuss how to develop a quality system for reliance and single IRB within the HRPP
- Gain resources and strategies to design and implement an efficient assessment process for reliance requests
- Review how to establish effective communication plans with study teams and outside organizations

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Workshop Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

**F14: Reviewing Exercise Science Research at Primarily SBER Institutions**

Track(s): Social, Behavioral, and Educational Research

This session will offer IRB administrators, chairs, and members a comprehensive review of issues related to reviewing exercise science research in primarily SBER institutions. This session will describe key ethical and regulatory issues related to exercise performance, sports nutrition, and related interventions, and differentiate these issues from similar questions encountered in SBER. Best practices for IRB applications, review processes, risk minimization, data and safety monitoring, informed consent documents, and postapproval monitoring (PAM) will be provided through case study discussions.



**Learning Objectives:**

- Describe key ethical and regulatory distinctives of exercise science research relative to SBER
- Review best practices for the review, approval, and documentation of interventions unique to exercise science research
- Identify practical solutions for effective review of exercise science research in the SBER environment through enhancements to IRB applications, review processes, informed consent materials, PAM, and related human subjects protections

**Target Audience:** HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Researchers and Research Staff

**F15: Research with Minors: Balancing Autonomy and Protection**

Track(s): Social, Behavioral, and Educational Research; Populations Requiring Additional Protections

This session will describe the importance of, and strategies for, balancing autonomy and protection when conducting research with minors. The pros and cons of paternalism when conducting research with children and minor adolescents will be presented along with relevant models for maximizing protection while respecting autonomy, particularly for research participants who are emerging into adulthood. The intersection of age and other risk categories (e.g., homelessness, LGBTQIA+) will be discussed.



**Learning Objectives:**

- Discuss the pros and cons of paternalism when conducting research with children and minor adolescents
- Describe relevant models for thinking about how best to maximize protection while respecting autonomy
- Review strategies for balancing protection and autonomy when conducting research with minors

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Educators/Trainers; Researchers and Research Staff

**F16: Zebrafish Welfare**

Track(s): Animal Well-Being and the 3Rs; Oversight of Non-Typical Species and Situations

With the growth of zebrafish models in biomedical research and our understanding of their cognitive abilities, there has been enhanced recognition for the need to promote and adopt practices that support zebrafish welfare. Recent areas of advancement include recognition and minimization of pain and distress, method refinements and value of environmental enrichments.



**Learning Objectives:**

- Review the current understanding of zebrafish welfare needs
- Discuss new and emerging methods that recognize and alleviate pain and distress
- Consider novel refinements and the value of environmental enrichments to zebrafish

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; Laboratory Animal and Veterinary Staff; Clinical Research Staff; Researchers and Research Staff

**F17: Postapproval Monitoring (PAM) in the Context of Small Research Programs**

Track(s): Small Research Programs; QA/QI and Postapproval Monitoring

This session will focus on the challenges faced by small research programs in implementing and conducting a successful PAM program, including practical strategies and flexibilities for building and developing an effective program, leveraging semiannual facility visits and program review.



**Learning Objectives:**

- Learn how to leverage your PAM program to identify areas for burden reduction and continuous improvement
- Share strategies for creating buy-in and participation for changes that reduce burden and increase efficiency
- Discuss how to build on past successes to create a culture of continuous improvement

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; QA/QI Professionals

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Workshop Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

**F18: Situational Vulnerability and Power Dynamics in the Research Sphere**

Track(s): *Advancing Equity and Justice; Shared Oversight Challenges*

Vulnerability relates to the ability to understand, protect, and advocate for one's own interests. This ability can vary based on social, economic, or cultural context, subjecting many people to risk in different ways across the research sphere. How do relational power and imbalanced power dynamics affect situationally-vulnerable individuals in the research context and what strategies can be used to effectively mitigate these? Potentially vulnerable group dynamics exist between scientists and non-scientists members of an oversight committee, study organizers and subjects, principal investigators and research staff, principal investigators and the Institutional requirements for advancement, and more.



**Learning Objectives:**

- Review case study examples related to power dynamics and situational vulnerability (e.g., conducting research in the classroom/workplace/lab, physicians or therapists recruiting clients/patients for research studies, whistleblower and research misconduct reporting, etc.)
- Recognize other ways in which power and privilege impact the research oversight enterprise (e.g., community member and/or non-scientist dynamics within HRPP/IRB and IACUC committees)
- Explore how principal investigator influence/pressure can be used to fulfill obligations

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; HRPP/IRB Directors; IRB Administrators, Manager and Staff; IRB Members, Chairs, and Vice Chairs; Researchers and Research Staff; Diversity, Equity, Inclusion, and Justice

**F19: Planning a Quality Assessment for Your Oversight Committee? Let's Create an Intentional Lens to Justice and Equity for Student and Faculty Researchers**

Track(s): *Advancing Equity and Justice; Shared Oversight Challenges*

As an organization works on the uncomfortable and difficult work of challenging systemic racism within their institution, including policies and procedures, there are discussions that should occur at multiple levels with committee administrators, vice presidents for research, or veterinarians/committee members who also serve as leaders within their department or run their own lab. There is a significant need for oversight bodies in higher education to acknowledge their role in anti-racism efforts. Addressing structural racism within institutional bodies regulating research may lead to more equitable research allowing for broader knowledge and access among historically excluded groups. This session will address how institutional leaders can develop a lens to justice and equity issues when creating quality assessment methodologies.



**Learning Objectives:**

- Establish a justice and equity framework for quality assessments
- Review institutional data related to gatekeeping, easing the burden, and creating inclusion
- Identify metrics that can be useful to measure programmatic progress, and consider benchmarks that can help organizations know when they are (or are not) on the right track in fighting racism and inequities within their research programs
- Learn how to initiate discussion with peers, including partnering with other committee administrators for a cohesive and sustainable impact
- Share ideas using the guidance provided to fine tune diversity, equity, and inclusion discussions at your organization

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; IBC Directors; IBC Administrators, Manager and Staff; IBC Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Compliance Personnel

**12:45-1:30 PM: Mid-Day Break**

**12:45-1:30 PM: Sponsored Presentation from Insight: Turbocharge Your IACUC Research Administration**

Insight has revolutionized the way we do IACUC work. This system was designed by IACUCs for IACUCs, to optimize researcher time with an integrated system and streamlined processes. Insight easily allows for data capturing and reporting, dramatically improving postapproval monitoring, business performance, staffing needs, and improved targeted communications. IACUC protocol review processing is now a breeze. The system-generated reminders and alerts for protocol renewals due or trainings that will expire, system-generated letters, meeting agendas, and minutes all reduce the need for back-and-forth emails. All the administrative work now is automated within this one-stop-shopping solution, saving hours of time and significant office resources. Insight also makes meeting management painless by calculating meeting quorum, catching member conflicts, and supporting full committee review, designated member review, and veterinary verification consultation review procedures. IACUC members love it because the system is so easy to navigate.



**Learning Objectives:**

- Learn how Insight can fast track IACUC research programs and advance research results faster
- Hear how principal investigators and the IACUC can save time and resources from submission to approval by providing direct communications and achieve results faster
- Understand how audits can be painless with Insight's capabilities with on-demand reporting on any data points

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Workshop Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

**Plenary XIII: What Can We Learn From Participant Experiences of Informed Consent Processes?**

*Track(s): Informed Consent; Emerging Research Challenges and Breaking Issues; Flexibility and Innovation in Research Oversight Processes; IRB Basics*

This session will present empirical data about informed consent from the potential participant perspective. This perspective has the potential to challenge many of the assumptions of the research ethics field, such as what constitutes respect, when the decision to participate is made, what information is used and useful and from whom, and what people pay attention to and ignore in the process and why. Empirical studies that explore this area will be presented. Data from studies involving participants belonging to underserved groups will be highlighted.



**Learning Objectives:**

- Challenge assumptions about how the informed consent process is received by potential participants
- Learn about empirical data that indicates the aspects of the process that are valuable or problematic
- Strategize ways to improve informed consent processes, particularly for underserved groups, in light of these data

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Educators/Trainers; Researchers and Research Staff; Diversity, Equity, Inclusion, and Justice

**Plenary XIV: Welcome to Compliance Unit Standard Procedure (CUSP): An Opportunity to Address Administrative Burden at the Institutional Level and Beyond**

*Track(s): IACUC Administration/Management and Process; IACUC Protocol Review; ACU Program Management; Flexibility and Innovation in Research Oversight Processes*

It's here! The CUSP Sharing Site is an online repository where institutions can share standard procedures used in animal care protocols with the broader animal welfare compliance community, offering an opportunity to address administrative burden at the institutional level and with other institutions across the country. This burden reducing initiative is being developed under the auspices of a partnership with the Federal Demonstration Project and the NIH OLAW. During this panel, attendees will learn when and how their institution can join CUSP, discuss strategies for how their institution can utilize this tool, and participate in a demonstration of the site.



**Learning Objectives:**

- Provide updates on the release, implementation, and future goals of the CUSP Project
- Discuss best practices on how to implement and utilize CUSP at your institution
- Share a live demonstration of the CUSP website with audience participation

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional; Compliance Personnel; Researchers and Research Staff

**Plenary XV: Public Trust Is Key to the Future of Biomedical Research**

*Track(s): Communication With the Public; Shared Oversight Challenges*

Public trust underpins the work of both IACUC and IRB committees, and provides the ethical framework under which research is allowed in relation to both clinical (human) and pre-clinical (animal) trials. Traditionally, IRBs and IACUCs have not had to think about how what they do and how they do it impacts public trust. However, growing challenges to the work of these committees is now starting to directly impact research (e.g., struggling to find community representatives; being subject to more stringent oversight; being caught in the cross-hairs of a debate about the appropriate role of science in the current highly polarized world, etc.). Overall, biomedical research is becoming more complex, difficult, and generally slower. There are efforts to improve trust in research, and this session will discuss several initiatives that are working to improve trust in relation to pre-clinical research through improved openness about this work and partnering with communities to undertake research.



**Learning Objectives:**

- Highlight the importance of public engagement and diversity in research in terms of both building trust and support
- Share several examples in both animal and human research where engagement has led to improved trust and diversity
- Allow time for a dialogue with attendees to allow discussion of issues raised and other examples where trust, support and diversity have been improved

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; IBC Directors; IBC Administrators, Manager and Staff; IBC Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Legal Counsel; Public Relations Professionals; Compliance Personnel; Laboratory Animal and Veterinary Staff; Clinical Research Staff; Researchers and Research Staff

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Workshop Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

**Plenary XVI: Institutional Official as JEDI Master**

Track(s): *Advancing Equity and Justice in Research; Research Oversight Leaders and Institutional Officials*

In the literary and cinematic franchise Star Wars, the Jedi Master was the highest formal rank obtainable by a member of the Jedi Order and reserved for those with not just skill, but devotion to the Force. More importantly, the Jedi Master was required to understand that the Force was powerful, but also needed balance in order to do good in the universe. For this session, the acronym "JEDI" stands for Justice, Equity, Diversity, and Inclusion, but the need for balance is still applicable. Historically, race was used to establish superiority (e.g., Nazi Germany) or to extinguish autonomy with deception (e.g., Untreated Syphilis in the Negro Male). In our current work, JEDI is an essential set of principles that must guide our work moving forward with institutional leadership setting the tone. This panel will examine the ways in which institutional leadership creates the environment and sets the expectations for effective application of the JEDI climate.



**Learning Objectives:**

- Define JEDI
- Examine the current state and explore how an evolved discussion moves us into the desired future state
- Describe our robust current emphasis on JEDI, and its historical and future significance
- Explain, in practical terms, how institutional leadership operationalizes JEDI within the organization and research enterprise

**Target Audience:** Research Program Leadership and Institutional Officials; ACU/IACUC Directors; HRPP/IRB Directors; IBC Directors

2:45-3:00 PM ET: Break

Concurrent Networking Sessions, 3:00-4:00 PM ET

**Mad Science on Trial: The Real Ethical Problems With Fictional Scientists**

Track(s): *IRB Basics*

Peter Venkman electrocuting college student volunteers and flirting with others. Catherine Halsey abducting and indoctrinating children for the SPARTAN-II program. Emmett Brown making deals with plutonium-stealing terrorists to fund his research. Antics like these are tons of fun to watch and read about, but what would happen if fictional scientists like these had their methods examined by a real ethics review board? Join our panel of ethics and pop-culture experts as they do a deep dive into some of the most famous (and infamous) scientists from movies, games, and comics. The panel will review the ethicality of research methods, address potential complaints, and discuss what kind of penalties these scientists would face in the real world.



**Learning Objectives:**

- Explores fundamental concepts in human subjects protections, including: The Belmont principles, assessment and minimization of risk, informed consent, data and safety monitoring, privacy and confidentiality protections, and IRB meeting dynamics
- Using a simulated IRB panel deliberation format, review case studies from popular culture and demonstrate how key ethical principles are applied in the IRB protocol review process
- Apply ethical principles and regulatory frameworks for IRB review

**Target Audience:** HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Researchers and Research Staff; Educators/Trainers

**The Certified IRB Professional (CIP®) Credential Presentation**

Track(s): *HRPP/IRB Administration/Management and Process*

During this session, members of the CIP Council will discuss the CIP exam, eligibility guidelines, and exam preparation techniques. This session is geared toward individuals who are responsible for HRPP/IRB administrative functions and who will be eligible to take the certification exam in the next one to two years.



**Learning Objectives:**

- Discuss the CIP program and its value
- Review exam eligibility guidelines
- Walk through the exam content outline
- Discuss exam delivery options
- Go over exam preparation techniques and what to expect on exam day

**Target Audience:** HRPP/IRB Administrators, Managers, and Staff

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Workshop Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	

**IRB Chairs Forum: A Structured Networking Event**

Track(s): IRB Chairs

This session will provide IRB chairs an opportunity to share ideas and best practices with one another based on a range of criteria (e.g., SBER vs. Biomedical, small IRB vs. large IRB).



**Learning Objectives:**

- Review and discuss contemporary issues related to human subjects protections that are commonly faced by IRB chairs, and that may not have clear guidance in the federal regulations
- Explore best practices, policies and procedures, forms, and methods that aid in resolving difficult issues presented by investigators and research study staff
- Discuss real-world situations and problems attendees face with a focus on coming up with a few possible and concrete solutions

**Target Audience:** IRB Members, Chairs, and Vice Chairs

**Institute for Laboratory Animal Research (ILAR) Wildlife Workshop: Highlights and Review**

Track(s): Oversight of Non-Typical Animals and Situations

In February of 2022, the National Academy of Sciences sponsored a workshop (“Discussing and Understanding Animal Welfare Challenges in Research and Education on Wildlife, Non-Model Species and Biodiversity—A Workshop”), which drew directly from the expertise of numerous veterinarians and biologists alike in the hopes of further clarifying and developing a greater understanding of welfare oversight and compliance as it pertains to free-range species (i.e., wildlife). This networking session will provide a recap of the workshop (to reiterate the theme, purpose, and central points), offer continued discussion, and provide any updates.



**Learning Objectives:**

- Reiterate the purpose and key points of the workshop as a refresher or for those unable to attend
- Provide an open discussion of/answer questions concerning the key points and objectives of the workshop
- Share any updates from the workshop (e.g., products/progress resultant to the event)

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; Laboratory Animal and Veterinary Staff

**BYO (Building Your Own) Circle of Influence and Professional Network to Empower Yourself and Others in the HRPP and IACUC World**

Track(s): Leadership Development Skills

In our profession of research administration, where traditional career paths are not always applicable, professional satisfaction and growth often involves cultivating a professional network. This session provides insights on how to build your own professional network in human and animal research administration and considerations for tailoring a network that fits your interests. Building a professional network successfully can help you feel empowered, energized, and more confident in your career, which ultimately supports the mission to ensure ethical conduct of research. The presenters will provide creative approaches to professional networks and models for success in key areas of professional development.



**Learning Objectives**

- Explore creative approaches to professional networking and accessing the universe of resources available.
- Understand how networking can lead to growth and professional development and improve your flexibility
- Implement networking techniques to energize and empower yourself and others

**Target Audience:** ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; IBC Directors; IBC Administrators, Manager and Staff; IBC Members, Chairs, and Vice Chairs; QA/QI Professionals; Compliance Personnel; Laboratory Animal and Veterinary Staff; Clinical Research Staff; Researchers and Research Staff

ICON LEGEND

Humans Subjects Research	IACUC/Animal Care and Use	Crossover	Institutional Leadership
Deep Dive Series	Thought Leader Series	Networking Series	Vendor Insight Series
Livestreamed Session	On-demand	Pre-Registration Required	Additional Fee
CIP Credit	CPIA Credit	Call for Session Proposal	