Icon	Label	*Description*
	CIP Credit	Session is eligible for CIP credit.
	CPIA Credit	Session is eligible for CPIA credit.
	Call for Session Proposal	Session is from the Call for Session Proposals.
	Livestreaming	Session will be livestreamed in real time and captured for on-demand viewing.
	Live Session Recorded	Session is being held in person and will be recorded for on-demand viewing.
	On-Demand	Session is recorded in advance and offered for on-demand viewing.
	Pre-Registration Required	Session requires pre-registration to attend.
	Additional Fee	Session is an additional fee.
	Humans Subjects Research Content	Human Subjects Research Content
	IACUC/Animal Care and Use Content	IACUC/ACU Content
	Crossover Content	Crossover Content
	Institutional Leadership Content	Institutional Leadership Content
	Deep Dive Series	Deep Dive Series; learn more about session formats.
	Learning Lab Series	Learning Lab Series; learn more about session formats.
	Networking Series	Networking Series; learn more about session formats.
	Thought Leader Series	Thought Leader Series; learn more about session formats.
	Vendor Insight Series	Vendor Insight Series; learn more about session formats.
	Workshop Series	Workshop Series; learn more about session formats.

PRIM&R Annual Conference
November 17-20
Seattle, Washington
Celebrating 50 Years of PRIM&R

PRIMR24 Preconference Workshop: Sunday, November 17

7:00 AM-5:00 PM ET **Registration Open**

Full Day Preconference Workshops, 8:30 AM-4:15 PM PT

Ethical and Regulatory Oversight of National and Transnational Social Science Research

Session description: The 2018 revisions to the Common Rule widened the category of exempted studies with particular relevance for the social sciences, providing greater flexibility and lessening the burden of ethical review (see, e.g. Riley and Akbar 2017). However, the complex challenges of ensuring ethical conduct in the social sciences remain. This workshop is designed for ethics administrators reviewing research projects in the social sciences so they can ask: how can we implement ethical review in the social sciences in a way that efficiently and effectively supports ethical research? The workshop will start with a brief introduction to the social sciences and the particular role they play in academic research, and then focus on three key areas which raise ethical questions, from both practical and procedural perspectives: (1) research on elites and powerful actors; (2) research with and on vulnerable people and populations; and (3) observational, inductive, and open-ended research. Speakers will use a series of real-world cases to work through these areas, exploring additional challenging dimensions to the research including working internationally and on sensitive topics. In each case, speakers will draw on existing scholarship.

Learning Objectives:

- Understand ethical regulation of the social sciences in historical and international perspectives
- Analyze key debates on ethical review in the social sciences, including an understanding of best practices
- Become familiar with resources to guide feedback and decision-making on difficult cases

Navigating Stormy IACUC Waters: Tackling Complex Protocols and Difficult Conversations

Session description: This interactive workshop consists of two distinct sessions: (1) Mock IACUC–Attendees will have the opportunity to role play IACUC deliberations of a series of research protocols. In advance of the workshop, attendees will be assigned specific roles on the IACUC (e.g., scientist, community/unaffiliated member, veterinarian, IACUC administrator) and be asked to prepare a review of a specific protocol. During the workshop, other attendees will also be allowed to participate in the "IACUC meeting," which will be moderated by the workshop facilitators. (2) Strategies for Leveraging Resources and Tactful Communications–In the course of the regular workday of ensuring that the research conducted at their institution is in compliance with prevailing regulations and policies, IACUC staff often encounter difficult situations (or personalities) that might call for especially tactful communications and/or leveraging of resources and additional support. In advance of the workshop, attendees will be invited to submit a description of a difficult situation that they had to navigate. All cases will be anonymized and presented at the workshop so attendees can discuss and benefit from each other's knowledge and experiences.

Learning Objectives:

- Describe the different roles and responsibilities within the IACUC
- Apply skills in reviewing and evaluating research protocols
- Identify and discuss strategies for navigating challenging situations within compliance review

Morning Half Day Preconference Workshops, 8:30-11:45 AM PT

Are We and They Doing It Right? Building an Effective Monitoring Program for Ongoing Oversight of Regulatory Compliance

Session description: Research and research oversight are complicated. The challenges of providing ongoing oversight to human/nonhuman animal protocols and HRPP/IACUC approvals have continually grown because of the increasing complexity of the research, institutional and public pressures, and changing regulations. What has not changed, however, is the institution's responsibility to maintain oversight through its HRPP Weand animal care and use program. Implementing a program of QA/QI can fill a compliance gap while also serving as a pathway for providing ongoing education for researchers and HRPP/IACUC staff. Such a program of QA/QI would have two dimensions: a postapproval monitoring (PAM) program that provides ongoing study oversight and a program of monitoring HRPP/IACUC determinations and documentation. Through interactive presentations and discussion, speakers will address different avenues for developing and implementing ongoing study oversight through a PAM program and how to use PAM visit results as part of an ongoing programmatic evaluation; and how to integrate monitoring of HRPP and IACUC determinations and documentation into a broader PAM program.

Learning Objectives:

- Articulate the principles on which PAM programs are founded and identify objectives of robust QA/QI programs
- Describe different models of conducting PAM
- Identify approaches to deciding who, what, when, and how to monitor
- Discuss how PAM and HRPP/IACUC monitoring results can be used when evaluating the overall animal care and use program and HRPP

Immersive Technologies and Human Subjects Protections

Session description: Immersive technologies are a potent research tool. Virtual reality, wearable sensors, and spatial computing take the study of human behavior to an arena that is not bound by typical norms. In addition, containment of participant data is no longer as simple as storage on a secured hard drive, design of a safe experiment must take into account psychological effects of embodiment, and, in some scenarios, data cannot be reasonably de-identified. Consequently, data management practices and psychological safety need to be updated in the review process. This workshop will inform participants of the risks associated with immersive technologies and provide guidance on safeguards to support productive human subjects research in this field.

Learning Objectives:

- Identify the risks associated with using immersive technologies in human subjects research
- Understand the challenges of data containment and de-identification when using immersive technologies
- Learn how to apply updated data management practices and psychological safety measures in the review process for studies involving immersive technologies
- Develop safeguards to support productive and ethical human subjects research using immersive technologies

Leadership Development: Pathways to Career Growth for Senior Research Oversight Personnel

Session description: This workshop is designed to help senior HRPP/IRB and IACUC professionals prepare for leadership roles in compliance. Through case studies, didactic presentations, and interactive exercises, attendees will gain insight into the challenges and opportunities of leadership roles in research compliance, as well as strategies for developing the knowledge, skills, and abilities needed to succeed. Workshop hosts will present real-life case studies and facilitate discussions on key topics such as ethical challenges, regulatory compliance, stakeholder management, decision-making, and effective leadership practices. Attendees will also have the opportunity to practice their interviewing skills and receive feedback and coaching from workshop hosts. This workshop is ideal for HRPP/IRB and IACUC professionals looking to advance their careers.

Learning Objectives:

- Discuss the challenges and opportunities of leadership roles in research compliance
- Share strategies for developing the knowledge, skills, and abilities needed to succeed
- Apply best practices and insights gained from the workshop to effectively prepare for leadership roles in compliance

11:45 AM-1:00 PM PT **Lunch Break.** Lunch on your own.

Afternoon Half Day Preconference Workshops, 1:00-4:15 PM PT

Compliance Issues

Session Descriptor: Guided by three different sets of research regulations, the co-occurrence of research misconduct (e.g., fabrication, falsification, and plagiarism), noncompliance in human subjects research, and noncompliance in nonhuman animal models research poses a complicated process of review and compliance for institutions and researchers. When investigators are active in both human and nonhuman animal research, with the potential for misconduct and/or noncompliance to span across their work, the challenges of oversight are complex. Yet, by the very nature of misconduct and deviations in human and nonhuman animal research, these overlapping problems are not uncommon. Building from a PRIMR23 plenary, this workshop will provide practical guidance on the processes for and unique challenges of collaboration between research integrity/misconduct offices, HRPPs/IRBs, and IACUCs to identify, manage, and resolve allegations of co-occurring research misconduct and noncompliance. In particular, the workshop will lead audience members through the examination and investigation of a case examples in which cross-committee compliance issues have occurred, by simulating a mock committee review with the speakers (and the audience via live polling) serving as representatives from each committee. By walking through the management of the case step by step, the workshop will provide action items and standard operating procedures that attendees can take home and implement based on their unique research oversight roles (e.g., successful approaches to cross committee education and checklists to help each committee understand their reporting obligations to the others). The audience will learn how parallel investigations occur between the committees during the course of an investigation, with special attention paid to the expectations and limitations of privacy and cross-committee reporting. Moreover, the audience will understand how they can be prepared to handle these complex and challenging cross-committee compliance problems before they arise!

Learning Objectives:

- Analyze a step-by-step mock review of a case example involving noncompliance and research misconduct that requires collaborative evaluation between the research integrity/misconduct office, HRPPs/IRB, and IACUC
- Understand the different regulations and processes involved in the handling of research misconduct allegations and HRPP and IACUC noncompliance
- Share best practice (policy and process), with a focus on communication, confidentiality, standard operating procedures, and checklists for collaboration between HRPPs, IACUCs, and research misconduct offices to address allegations of co-occur

Building a Quality Assurance (QA) Program for Compliance

Session Descriptor: Research compliance programs often struggle to find balance between providing quality reviews that best leverage institutional resources without impacting turnaround time. Best practices to identify and address compliance areas relevant to research also vary depending on institutional type, size, and overall compliance program structure. With an ever-increasing "gatekeeper" role placed on HRPPs, it can be challenging to ensure research compliance activities are best informed by relevant institutional components and conducted with adherence to regulatory, institutional, and administrative requirements. This workshop will showcase QA in research and how it can be implemented.

Learning Objectives:

- Learn how to design an effective QA Program
- Explore tools that support an effective QA Program
- Discuss how to scale your QA Program to fit your needs and best support the HRPP mission of compliance

The Role of the Institutional Official in Facilitating Ethical and Compliant Research

Session description: 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: assessing and balancing the relative benefits and risks of all research, including research with both humans and laboratory animals; recruiting, developing, and retaining talent; promoting diversity, equity, and inclusion within the office and on committees; integrating compliance and support infrastructure; managing unfunded mandates; and assessing programs and maintaining accreditation. This session is intended to be interactive and rapid paced, in order to cover topics that IOs are currently faced with or should be anticipating and to provide an opportunity to develop networks.

Learning Objectives:

- Identify key challenges currently faced by IOs and anticipate future issues relevant to their roles
- Strategize effective methods and approaches for addressing common and emerging issues in their work, such as ethical considerations in research, talent development, diversity, equity, inclusion, and the management of unfunded mandates
- Establish professional connections with other IOs, fostering a collaborative environment for the exchange of ideas, best practices, and solutions to shared challenges

4:15-5:30 PM ET **Workshops Networking Reception in Exhibit Hall**

4:15-5:30 PM ET **Meet and Greet With the Supporters and Exhibitors**

4:15-5:30 PM ET **View the PRIMR24 Poster Abstracts**

4:15-5:30 PM PT **Federal Agency Office Hours**

During this time, representatives from federal agencies, the accrediting bodies, and/or the CIP and CPIA Councils will be available to answer attendee questions, engage in dialogue, and/or direct attendees to additional resources. Attendees are encouraged to come prepared with questions, which will be taken on a first come basis. To participate, go to the Exhibit Hall and locate the Office Hours table(s) for the agencies participating in this timeslot. **Only the following organizations are participating in this timeslot**:

* AAHRPP, Inc.
* FDA
* OHRP
* CIP Council
* CPIA Council

PRIM&R Annual Conference
November 17-20
Seattle, Washington
Celebrating 50 Years of PRIM&R

PRIMR24: Monday, November 18

7:00 AM-5:00 PM PT **Registration Open**

7:00 AM-8:15 AM PT **Federal Agency Office Hours**

During this time, representatives from federal agencies, the accrediting bodies, and/or the CIP and CPIA Councils will be available to answer attendee questions, engage in dialogue, and/or direct attendees to additional resources. Attendees are encouraged to come prepared with questions, which will be taken on a first come basis. To participate, go to the Exhibit Hall and locate the Office Hours table(s) for the agencies participating in this timeslot. **Only the following organizations are participating in this timeslot**:

* AAHRPP, Inc.
* OHRP
* CIP Council
* CPIA Council
* NIJ

PRIMR24 Networking Block, 7:15 AM-8:15 AM PT

N01: Everything You Wanted to Know about the CIP Credential

Track(s): HRPP/IRB Management and Administration

During this session, a member of the CIP Council and a CIP who recently earned their credential 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
•Examine exam delivery options, and go over exam preparation techniques and what to expect on exam day

Target Audience(s): HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; QA/QI Professionals

N02: IACUC Morning Coffee

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

Join your IACUC colleagues to connect before PRIMR24 begins! Coffee and tea only will be served.

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

N03: Everything You Wanted to Know about the CPIA Credential

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

During this session, a member of the CPIA Council and a CPIA who recently earned their credential 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:

•Discuss the CPIA program and its value
•Review exam eligibility guidelines
•Walk through the exam content outline
•Examine exam delivery options, and go over exam preparation techniques and what to expect on exam day

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

N04: IOs Ins and Outs

Track(s): Research Oversight Leaders and Institutional Officials; Shared Research Oversight Challenges

Are you new to being an Institutional Official? Or do you have interest or aspirations to become an IO? Do you know much about one aspect of the role and have curiosities about other areas of responsibilities, or about how to navigate the politics of leadership? Have you ever scratched your head and wondered what the Institutional Official was thinking when they made "that" decision? This session is designed to provide a broad and basic overview of the role and focus of the Institutional Official. It has been designed to be interactive and challenge the audience on their current perceptions of the role, mechanisms of influence, and how success is measured and achieved. Plenty of time will be available for an open dialogue (Q&A) with existing Institutional Officials.

Learning Objectives:

•Provide basic components and responsibilities of the Institutional Official
•Discuss the focus of IOs, their mechanism of engagement, and source of information
•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 f
•Find solutions to challenges that participants are experiencing at their own institutions by receiving answers from IOs with experiences that are robust and who have the capability to brainstorm solutions for many situations

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

8:30-9:00 AM PT — **Co-Chairs Welcome and ED Remarks**

9:00-10:00 AM PT — **Opening General Session: More Cure, Less Side Effects: A Potential Role for Preclinical Studies**

Track(s): Emerging Research Challenges and Breaking Issues; IACUC Review; IRB Review; Pharma/Biotech

Preclinical animal studies often fail at predicting the most common adverse events reported by human subjects in Phase 1 clinical trials: headache, nausea, dizziness, fatigue, somnolence, and pain. Patients, particularly in oncology, often suffer severe side effects, including rash, pain, and fever, in hopes of a cure. How can we do better in preclinical studies to predict and minimize these adverse clinical signs?

Target Audience(s): IRB Members, Chairs, and Vice Chairs; Diversity, Equity, Inclusion, and Justice; Clinical Research Staff; HRPP/IRB Administrators, Managers, and Staff; Compliance Personnel; Research Program Leadership and Institutional Officials; Researchers and Research Staff; HRPP/IRB Directors; ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs

10:00-10:30 AM PT — **Beverage Break in the Exhibit Hall**

PRIMR24 Content Block A, 10:30-11:45 AM PT

HSR

A1: Reimagining Informed Consent Processes to Support Informed, Values-Concordant Decisions

Track(s): Informed Consent

One key goal of the informed consent process is to support potential research participants in making informed, values-concordant decisions about participation, yet empirical evidence suggests that, in practice, the processes of consent and decision-making may be misaligned. This session will explore how to reimagine informed consent to better support potential participants through the decision-making process. Presenters will discuss strategies and share practical examples of efforts to promote inclusive and participant-centered consent approaches, including optimizing the key information section of the consent document, incorporating multimedia support, and providing a relationship-based framework for researcher-participant engagement throughout the consent process.

Learning Objectives:

•Describe strategies to develop informed consent processes that promote informed, values concordant decisions
•Discuss how the key information section can be employed to support decision-making
•Recognize how relationship-based communication can promote deliberation during the informed consent process

Target Audience(s): HRPP/IRB Directors; Members, Chairs, and Vice Chairs; Clinical Research Staff; Researchers and Research Staff

A2: How Do You Actually Review a Protocol Involving Artificial Intelligence (AI)?

Track(s): Emerging Research Challenges and Breaking Issues; IRB Review; Research Involving Data and New Technologies

Much attention has been paid to the ethical issues posed by the use of AI in humans subjects research. Yet, most sessions raise more questions than answers and, at the end of the day, HRPP/IRB staff and reviewers are left to roll up their sleeves and review these protocols desks fast and furiously. How should HRPPs adapt their approaches and policies and train their staff to best review these protocols? How does an IRB reviewer actually review a protocol involving AI when the technology changes nearly every week? This session will provide practical guidance to IRBs and oversight bodies on how to review research involving AI, including how to determine if human subjects research definitions apply, how to assess FDA device regulations, and how to apply the federal regulatory criteria for approval to human research studies involving AI. Additionally, the session will examine special ethical considerations raised by research involving AI, including privacy and data ownership concerns related to the use of large, unconsented datasets, return of individual research results, and algorithmic bias. Finally, the session will discuss the scope and limitations of IRB review, and how oversight bodies must work together to effectively review research involving AI. For example, regulations restrict the IRB's consideration of future risks, yet AI algorithms raise exactly those concerns related to future risks posed by algorithmic bias and potential dual use.

Learning Objectives:

•Understand the unique ethical questions posed by the use of AI in human subjects research
•Gain practical tools and tips for IRB review of research protocols involving generative AI
•Identify ways HRPPs can adapt policies, procedures, training, and oversight structure to be best equipped to review research protocols involving AI and to keep up with the ever evolving technology

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

A3: Why "It Depends": General Considerations for IRBs and HRPPs When Reviewing Research Using FDA-Regulated Products

Track(s): FDA Regulated Research; IRB Review; Pharma/Biotech

For IRBs that do not routinely review FDA-regulated research, determining if and how a particular study involving a medical product is "FDA-regulated" can be challenging given Agency regulations and requirements for such research. As often noted by FDA, such determinations depend on multiple factors, so it is not often possible to determine whether a certain type of research is regulated by FDA without considering study specifics. However, there are a series of questions that IRBs and investigators may consider to help them determine whether FDA regulations apply and if FDA consultation is needed. In this session, representatives from the FDA will provide an overview of the regulations and guidances that may be useful to investigators developing and IRBs reviewing research of an FDA-regulated product.

Learning Objectives:

•Understand the FDA regulations and guidances associated with FDA oversight of clinical research
•Describe different regulatory considerations that might help facilitate determinations about whether FDA oversight is needed, and provide study examples
•Identify resources and contacts to engage with FDA about the applicability of FDA regulations for research studies

Target Audience(s): IRB Members, Chairs, and Vice Chairs; HRPP/IRB Administrators, Managers, and Staff

A4: Advancing Gender Inclusivity in Research: Overcoming Political and Regulatory Challenges in Participant Materials

Track(s): Advancing Equity and Justice; Education, Qualifications, and Training

In the rapidly evolving landscape of research ethics, the imperative for gender-inclusive language in participant-facing materials has never been more critical. This session aims to address this pressing issue basedon empirical evidence and pragmatic guidance. This learning lab will delve into the complexities and nuances of integrating gender-inclusive language within the regulatory framework. We will show and demonstrate how to take existing documents at your institution and 'workshop' them to include gender-inclusive language that can overcome these barriers while maintaining compliance and respect for persons.

Learning Objectives:

•Review empirical results of a national survey of IRB Chairs, Directors, and Institutional Officials regarding gender-inclusive language in participant facing materials

•Explore and discuss the importance of gender-inclusive language and its impact on participant engagement, and the ethical implications in research settings, based on case studies and recent research findings

•BYO documents or template language, such as consent forms, recruitment flyers, or phone scripts, so that we can "workshop" them together to include gender-inclusive language

Target Audience(s): Educators/Trainers; Researchers and Research Staff; Diversity, Equity, Inclusion, and Justice

A5: A Dialogue with the NIH

Track(s): A Dialogue with the Feds

This session will review the latest updates from the NIH Office of Science Policy (OSP). The updates may be related to issues around clinical research, scientific data sharing, technology transfer, and other topics that OSP works on.

Learning Objectives:

•Learn the latest information about science policy at NIH

•Discuss future directions of potential policy activities

•Obtain more details about current and ongoing initiatives.

Target Audience(s): 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

A6: Great "Private" Expectations: What Is Publicly Available Private Information?

Track(s): Social, Behavioral, and Educational Research; Research Involving Data and New Technologies; IRB Review

In an era of advancing technology and evolving expectations surrounding personal information, the research community faces new and complex ethical challenges. However, within the research oversight world, there has been confusion regarding the idea of private, identifiable information that is, at the same time, available to the public. How can this be? If it's available to the public, is it not by definition public data and not private? Furthermore, given the IRB's dual role in both regulatory and ethical review of research, determining whether it is ethical to use such data for research purposes can be challenging. This session will breakdown the types of data that exempt category 4(i) was intended for, help explain the confusion, and provide an ethical framework for its review.

Learning Objectives:

•Consider the types of private information that are publicly available and the ethical considerations for its use (i.e., are there additional community risks that need to be assessed?)

•Develop knowledge and understanding of what publicly available databases/datasets may look like that contain private information (i.e., how can it be considered private if the public can access it?)

•Explore the key ethical considerations in establishing a framework for ethical review of research using such data

Target Audience(s): Compliance Personnel; HRPP/IRB DirectorsHRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Legal Counsel; Researchers and Research Staff

A7: Understanding the Fine Print: Navigating Biospecimen and Data Restrictions from Legal Agreements

Track(s): Legal Considerations in Research Oversight; Research Involving Data and New Technologies; Pharma/Biotech Perspectives

Beyond government regulations, complying with legal contracts when handling biospecimens and data is a matter of ethical and professional responsibility. Therefore, it is essential to respect the rights and interests of the donors, as well as the obligations and expectations of the collaborators, when collecting, storing, sharing, and using biospecimens and data. Legal contracts can help establish clear and transparent terms and conditions for these activities. When investigators use biospecimens and data from biobanks or other sources, they may encounter hidden limitations that affect their research. These limitations may arise from the legal agreements, such as material or data transfer agreements (MTA or DTA), that govern the access and use of biospecimens and data.

Learning Objectives:

•Learn the fundamentals of legal agreements such as licenses, MTAs and DTAs, and other contracts associated with biospecimens and data

•Identify common challenges encountered in contractual arrangements involving biospecimens and data such as usage restrictions

•Explore operational strategies to adhere to these agreements effectively

Target Audience(s): Researchers and Research Staff; Compliance Personnel; Legal Counsel; Research Program Leadership and Institutional Officials; Clinical Research Staff; HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff

A8: What is the Role of Regret and Apology in Protecting the Human Participants of Clinical Trials?

Track(s): HRPP/IRB Management and Administration; Pharma/Biotech Perspectives; IRB Review

PRIM&R has frequently presented clinical trial participants who tell their own stories of participation. Most stories were return of results of successful trials. Few presenters described their stories and desires for return of results of an unsuccessful trial. In this analogues session, panelists examine the historical context and current importance of sharing the results of unsuccessful or negative projects. Their stories cover the major types of such communication: investigator's regret, institutional statement, corporate responsibility, and apology. Regret communications are typically extended by the investigator. Institutional communication is usually framed to minimize litigation. Corporate communication may be by a member of the profession or group that conducted the research. Personal apology is rare but may be crucial for enhancing trust in -- and the trustworthiness of – clinical research. The session will allow time for stories, desires, and suggestions from the audience.

Learning Objectives:

•Apply "return of research results," e.g. the status of their (successful) research results, to participants in an analogues situation, when the research project was unsuccessful
•Describe the four types of returning negative results: regret, institutional, corporate, and apology
•Analyze the possible roles of HRPP to assist researchers who return negative results of a trial

Target Audience(s): HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Public Relations Professionals;

A9: Shift Your Focus: Transforming an HRPP Into a Collegial and Efficient Partner of the Research Community

Track(s): HRPP/IRB Management and Administration

This session will focus on strategies used at different academic health center HRPPs that will help change the perception researchers may have of IRBs. The HRPP leaders from four fast-paced, cutting edge, and competitive institutions will share techniques that can be implemented at institutions of any size, regardless of resources or budget, to alleviate the burden on IRB staff and researchers through collaborative relationships. During this session, speakers will demonstrate how to utilize various techniques including metrics, customer service principles, unique resources, and concise communications to shift the perception of the IRB away from a stodgy, regulatory body towards a respected ally. Speakers will also discuss how a partnership across the HRPPs of their institutions has helped standardize these programs and in effect further enhanced the collegiality with researchers across sites.

Learning Objectives:

•Understand how to use metrics in a meaningful way that can set expectations and improve transparency
•Learn how to build customer service principles and user-friendly resources for your customer (i.e., the researchers)
•Develop a public relations strategy to build trust between your IRB and the research community

Target Audience(s): HRPP/IRB Directors; Public Relations Professionals; HRPP/IRB Administrators, Managers, and Staff; Researchers and Research Staff; Research Program Leadership and Institutional Officials

A10: Decentralized Clinical Trials (DCTs) and the Community Dimension: Advantages and Challenges

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

The DCT model for human subjects research is considered an innovative means to improve enrollment and enrich the diversity of research participants. However, it is unclear how IRBs will be able to assess the community values and interests when individual participants are enrolled from distant and disparate locations. This session seeks to explore the domains that should be considered by IRB members as they assess the values and interests of the various communities from which research participants are drawn.

Learning Objectives:

•Learn how DCTs are poised to improve diversity, equity, and inclusion in human subjects research
•Explore what challenges of DCTs are used to maximize diversity in the design and implementation of recruitment strategies
•Explore the ethical and social factors IRBs and their community members should consider to respect the values and interest of all participants recruited to and enrolled in DCTs

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

IACUC

A11: Global Perspectives on the Ethics, Principles, and Regulations Guiding Research Involving Nonhuman Animals

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

Science is a global endeavor, but there are different standards across the world. This session will explore how regulations for nonhuman animals are applied in different countries around the world and how they compare to US regulations, with the aim of exploring how to foster global collaborations with confidence. Speakers will consider how to create a set of foundational principles that supports scientific discoveries through the use of nonhuman animals in research and that guides assessment of the work. Furthermore, speakers will address the different belief systems people around the world have about nonhuman animals (as they are viewed outside of research) and how those beliefs affect how and what types of nonhuman animals are used for research.

Learning Objectives:

•Gain a comprehensive understanding of ethical considerations and regulations surrounding research involving nonhuman animals and how they are imposed globally
•Consider how different belief systems about nonhuman animals (as they are viewed outside of research) can impact how and what types of nonhuman animals are used for research
•Explore how to foster global collaborations and create a set of foundational principles that supports scientific discoveries through the use of nonhuman animals in research and that guides assessment of the work

Target Audience(s): ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; Compliance Personnel; IACUC Members, Chairs, and Vice Chairs; Researchers and Research Staff

A12: Welfare Considerations for Cephalopods

Track(s): Oversight of Non-Typical Animals and Situations; Animal Well-Being and the 3Rs

The use of cephalopods in research is a growing field. Europeans have already enacted guidance, and NIH OLAW is proposing guidance for their humane use. In this session, an overview of research uses and welfare considerations for cephalopods will be discussed, along with the areas in which IACUCs should focus their reviews of cephalopod research proposals.

Learning Objectives:

- Identify unique attributes of cephalopods and common research uses
- Discuss welfare considerations relative to cephalopods
- Provide IACUC members with tools to effectively review areas of concern in cephalopod research proposals

Target Audience(s): ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; Laboratory Animal and Veterinary Staff; Researchers and Research Staff

A13: IACUC SOS! Evaluating Difficult Protocols By Optimizing Your Review Toolkit

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

Evaluating certain protocols can be challenging. This session aims to streamline and improve the quality of IACUC review by optimizing a review toolkit (e.g., ad hocs, pilot studies, etc.). Speakers will also discuss how to handle funded protocols that don't align with institutional goals, and how to streamline development, review, and updates to local performance standards and SOPs.

Learning Objectives:

- Discuss challenging IACUC protocols (e.g., those where animal impacts are poorly characterized, those where there is limited expertise with the procedures and/or species, those where the risk/benefit analysis produces unclear results, and those where there are institutional concerns with perception or risk)
- Review resources and approaches the IACUC can use to effectively evaluate, and monitor these activities (e.g., use of ad hocs, pilot projects, development/use of performance standards, and development/evaluation of SOPs and institutional policies)
- Develop strategies to streamline use of these approaches and promote buy-in from investigators and institutional leadership

Target Audience(s): ACU/IACUC Administrators, Managers, and Staff; Compliance Personnel; IACUC Members, Chairs, and Vice Chairs

A14: A Dialogue with AAALAC

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(s): ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; QA/QI Professionals; Compliance Personnel

A15: Openness about Animal Research: Why and How to Share What We Do

Track(s): Communication With the Public

The prevalence of misinformation about research involving nonhuman animals, combined with the lack of access to honest and reliable resources, undermines and threatens this important work. This session will take a broad look at why it's important to be open about the use of nonhuman animals in research, what openness might look like, and how to take the first step.

Learning Objectives:

- Review the current landscape around openness about nonhuman animal research, including the US Animal Research Openness Initiative
- Understand why openness about nonhuman animal research is important, including the positive impacts on morale, public support, and administrative burden
- Discuss strategies to increase openness at the institutional level and get buy-in from leadership

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

Crossover

A16: PI Responsibility & Accountability Versus Effectiveness of Institutional Compliance and Ethics Review: What Will Really Make a Difference in How We Conduct Research?

Track(s): Shared Research Oversight Challenges; Research Oversight Leaders and Institutional Officials; IRB Review; IACUC Review

The recent focus on measuring the effectiveness of our institutional review committees and research administrative activities continues to ignore the most critical factor in the conduct and trust in research - PI responsibility, accountability, and training. Understanding the preparation, focus, and best mechanisms of engagement of researchers at our institutions is needed to maximize the outcomes that are desired. This session will discuss whether an alternative focus on and assessment of the PI role in conducting the research will be more effective in creating an ethical and compliant research culture and improve trust and engagement in the research enterprise.

Learning Objectives:

•Discuss how to prepare for creating PI accountability, work with PIs on research priorities, and create institutional incentives to carry out research for PIs

•Evaluate the role of the oversight committees versus the PI in effecting the ethical conduct of research and participant protections

•Explore the key factors in the research lifecycle that can strengthen ethical, compliant, and trustworthy research

Target Audience(s): ACU/IACUC Directors; IACUC Members, Chairs, and Vice Chairs; IBC Directors; IBC Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; HRPP/IRB Directors; IRB Members, Chairs, and Vice Chairs; Compliance Personnel; QA/QI Professionals; Researchers and Research Staff

A17: Consciously Uncoupling? When Institutions and Investigators Separate (amicably, or sometimes not so much)

Track(s): Shared Research Oversight Challenges; HRPP/IRB Management and Administration; ACU/IACUC Program Management and Administration; Research Oversight Leaders and Institutional Officials

While institutions often experience faculty members coming and going, there are additional considerations when there is an active research portfolio, including managing data. This session will explore challenges that can arise when the institution and faculty member divorce and are not in one accord regarding how to move forward. This includes grant funding, how to move forward with active research, and communication barriers that can present themselves during the separation. We will examine case studies related to each participating institution.

Learning Objectives:

•Identify barriers for both the compliance program and the committee when the communication between parties ceases

•Describe key recommendations and considerations for how to move forward when there are active participants

•Discuss how data and sample considerations can impact all involved parties

Target Audience(s): HRPP/IRB Directors; IRB Administrators, Manager and Staff; IRB Members, Chairs, and Vice Chairs; Legal Counsel; Compliance Personnel; ACU/IACUC Administrators, Manager and Staff; IACUC Members, Chairs, and Vice Chairs; IBC Administrators, Managers, and Staff; IBC Members, Chairs, and Vice Chairs

A18: The Cost to Having a Revolving Door: PI Onboarding & Exit Planning

Track(s): Education, Qualifications, and Training; HRPP/IRB Management and Administration; ACU/IACUC Program Management and Administration; Shared Research Oversight Challenges; Research Oversight Leaders and Institutional Officials

This session delves into the preventative side of research compliance to engage investigators as they close out a relationship with one institution and begin their journey at a new institution. Experienced compliance leaders know this is a critical gap in many programs. Presenters will describe steps that can be taken to aid in planning and improve PI understanding of expectations earlier in the exit and onboarding process. They will also provide examples of a proactive approach with new investigators. Presenters will share their journey in achieving compliance.

Learning Objectives:

•Identify key PI onboarding topics and the importance of timing

•Create a plan that conforms to the institutional workflow and leadership expectations

•Discuss the potential risks of not having a process

Target Audience(s): ACU/IACUC Directors; HRPP/IRB Directors; IBC Directors; Leadership and Institutional Officials

Institutional Leadership

A19: New Regulations and Federal Policy Updates: Get Up to Speed!

Track(s): Shared Research Oversight Challenges; Research Oversight Leaders and Institutional Officials

Institutional leadership needs to stay up-to-date with evolving research trends, as well as upcoming changes to the federal regulatory landscape and implications for research. In this session, speakers will explore three key changes: FDA's single IRB mandate, NIH Office of Science Policy (OSP) Guidelines, and the Department of Justice's (DOJ) False Claims Act enforcement. These changes will have implications for institutional leadership and their institutions. This dynamic session will provide an opportunity to engage with session speakers and peers, and is preparatory for the "Planning for Ethical and Regulatory Changes in Research Programs" session.

Learning Objectives:

•Understand the basic elements of the changes from the FDA's single IRB mandate, NIH OSP Guidelines, and the DOJ's False Claims Act

•Share practical tips and best practices for applying appropriate and necessary changes

•Discuss with peers planning and implementation activities occurring at institutions

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

A20: How Institutional Leaders Can Promote COI Program Effectiveness

Track(s): Education, Qualifications, and Training; Shared Research Oversight; Legal Considerations in Research Oversight

Everyone is familiar with the concept of COI in research, but what does that mean for institutional leaders responsible for COI program effectiveness? This session will explore how institutional leaders can best support their COI programs to create a culture that encourages timely and accurate disclosures, along with transparency, while at the same time eliminating, minimizing, and managing conflicts in a way that does not diminish an institution's research competitiveness, but, rather, enhances an institution's reputation.

Learning Objectives:

•Identify the main functional components of COI programs including policy development, training, disclosure processes, conflict identification, management strategies and monitoring, and funding agency reporting
•Learn how to optimize functional components to support research innovation while managing financial COIs in research
•Explore how to destigmatize discussions on COIs to encourage openness and transparency within research ethics

Target Audience(s): Educators/Trainers; Research Program Leadership and Institutional Officials

11:45 AM-1:30 PM PT **Lunch Break.** Lunch on your own (kiosks open in exhibit hall).

PRIMR24 Networking Block, 12:30 PM-1:30 PM PT

N05: When You're the New Kid in Town: Taking Over as an HRPP/IRB Leader

Track(s): HRPP/IRB Management and Administration; IRB Review

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(s): HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs

N06: REACH, the Research Ethics Action Collaborative for HRPPs, for Justice

Track(s): Advancing Equity and Justice; Emerging Challenges and Breaking Issues

We introduce the Research Ethics Action Collaborative for HRPPs (REACH), an initiative spearheaded by the MRCT Center, AAHRPP, PRIM&R, and Mass General Brigham. This effort aims to curate, align, and disseminate tools to advance inclusion and accessibility in clinical research tailored for Institutional Review Boards (IRBs), Human Research Protection Programs (HRPPs), and the broader community. The session will introduce a comprehensive suite of resources for members of the clinical trial ecosystem to use, adopt, and improve to help ensure equity and justice in biomedical and sociobehavioral research.

Learning Objectives:

•Identify ethical and operational challenges to diverse inclusion in clinical trials
•Review freely available tools and resources to promote inclusion in clinical trials
•Articulate the compelling case for change and the business case to leadership

Target Audience(s): HRPP/IRB Directors; IRB Administrators, Manager and Staff; IRB Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Compliance Personnel

N07: Rodents and Birds and Cephalopods…Oh My!: Shared Procedures for All Species in CUSP

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

The Compliance Use Standard Procedure (CUSP) Sharing site is an online repository of standard research methodologies and procedures supported by the NIH and the Federal Demonstration Partnership as a burden-reducing initiative of the 21st Century Cures Act. CUSP is free to users and contains easy-to-access information about research procedures for lab animals, field studies, and non-typical species including cephalopods. Participants should join this session to learn how to incorporate resources accessed through the site into their institutional animal protocols, thereby saving time and disseminating best practices.

Learning Objectives:

•Learn about the CUSP Sharing Site and how this innovative knowledge resource can benefit them and the greater research community
•Explore opportunities for researchers using atypical (e.g., bats, marsupials, and cephalopods) and more common species to share procedures in areas of husbandry, veterinary care, enrichment, handling techniques, and experimental techniques that promote good animal welfare
•Participate in a guided demonstration of the CUSP Sharing Site, with audience participation, offering direct exposure to the site

Target Audience(s): ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs and Vice Chairs; Lab Animal and Veterinary Staff; Researchers and Research Staff

N08: Planning for Ethical and Regulatory Changes in Human and Non-human Animal Research Programs

Track(s): Shared Research Oversight Challenges; Research Oversight Leaders and Institutional Officials

This session is a networking session for those that attended the breakout session titled, "New Regulations and Federal Policy Updates." Several changes, some of them significant, have recently occurred or are planned within the next few years for human and non-human animal research oversight, and the adjacent oversight areas of research misconduct and research involving biohazards/select agents. Since many research oversight programs require a significant infrastructure, institutional leaders need to know how they can best plan for what's coming. In this session, institutional leaders, including institutional officials, will discuss how they are keeping abreast of the rapid changes to research oversight and how they are contemplating changes within their institution's research enterprise infrastructure.

Learning Objectives:

•Learn how to keep informed about pending changes to the regulatory landscape
•Identify what kind of planning is needed to effectively handle changes in human and non-human animal research oversight processes
•Explore differences in planning between academic medical centers, R1/R2 institutions, and non-academic organizations
•Discuss the impacts of these changes on staffing, financial resources, software systems, researcher communication and training, and policy development/maintenance

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

12:30 PM-1:30 PM PT **Federal Agency Office Hours**

During this time, representatives from federal agencies, the accrediting bodies, and/or the CIP and CPIA Councils will be available to answer attendee questions, engage in dialogue, and/or direct attendees to additional resources. Attendees are encouraged to come prepared with questions, which will be taken on a first come basis. To participate, go to the Exhibit Hall and locate the Office Hours table(s) for the agencies participating in this timeslot. **Only the following organizations are participating in this timeslot**:

* AAHRPP, Inc.
* DOE
* FDA
* OHRP
* CIP Council
* CPIA Council

12:30 PM-1:30 PM PT **Meet and Greet With the Supporters and Exhibitors**

12:30 PM-1:30 PM PT **View the PRIMR24 Poster Abstracts**

12:30 PM-1:30 PM PT **Affiliate Events: Rodents and birds and cephalopods…Oh My!: Shared procedures for all species in CUSP**

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

The Compliance Use Standard Procedure (CUSP) Sharing site is an online repository of standard research methodologies and procedures supported by the NIH and the Federal Demonstration Partnership as a burden-reducing initiative of the 21st Century Cures Act. CUSP is free to users and contains easy-to-access information about research procedures for lab animals, field studies, and non-typical species including cephalopods. Participants should join this session to learn how to incorporate resources accessed through the site into their institutional animal protocols, thereby saving time and disseminating best practices.

Learning Objectives:

•Learn about the CUSP Sharing Site and how this innovative knowledge resource can benefit them and the greater research community
•Explore opportunities for researchers using atypical (e.g., bats, marsupials, and cephalopods) and more common species to share procedures in areas of husbandry, veterinary care, enrichment, handling techniques, and experimental techniques that promote good animal welfare
•Participate in a guided demonstration of the CUSP Sharing Site, with audience participation, offering direct exposure to the site

Target Audience(s): ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs and Vice Chairs; Lab Animal and Veterinary Staff; Researchers and Research Staff

12:45 PM-1:30 PM PT **Vendor Insight Series: Sponsored Presentation from WCG**

PRIMR24 Content Block B , 1:45-3:00 PM PT

HSR

B1: Ethical Considerations With Healthy Research Participants: Current Perspectives From the Field
Track(s): IRB Review; Advancing Equity and Justice

The ethical considerations of research with healthy volunteers are distinct from research with patients in several ways. Unlike research with patients, where participants are often motivated by the prospect of direct benefit, healthy participants are usually motivated by either altruism or compensation. In addition, while there is a well-acknowledged lack of representation of minorities and underserved populations in clinical trials, many healthy volunteer trial participants are significantly composed of minority and underserved populations. A comprehensive consensus on the ethics of payment, maximum risk level, and potential exploitation of healthy volunteers remains elusive. This session features a conversation between experts in bioethics and research participants in two types of trials (Challenge Trials and Phase I Trials). Drawing on existing literature, personal experiences, and writing produced in tandem with other healthy participants, this conversation will open up dialogue about what the status quo gets right and wrong about the ethics of research with healthy volunteers, especially through the lenses of economic and racial justice. Particular attention will be given to the tensions between protection, justice, and autonomy in research oversight and the role of participant perspectives in shaping IRB decisions.

Learning Objectives:
•Describe ongoing debates regarding ethical issues surrounding healthy volunteers
•Understand how healthy volunteers view study participation, risk, and exploitation and how those view may differ from those of an IRB
•Suggest how to move forward to have a consistent and ethical approach to healthy volunteers in research

Target Audience(s): Researchers and Research Staff; HRPP/IRB Directors; IRB Members, Chairs, and Vice Chairs; Clinical Research Staff

B2: Cybersecurity and Research Integrity: Can We Be Trusted to Keep Research Information Safe?
Track(s): Emerging Research Challenges and Breaking Issues; Research Involving Data and New Technologies

Almost all research, not just the studies that are clearly related to digital health, faces the risk of research data being compromised, stolen, damaged, diverted, etc. To reduce these risks, some sort of cybersecurity review of the hardware, software, and processes involved should be done. This is usually beyond the direct expertise of the IRB and needs close cooperation with IT security experts. This session will investigate existing guidelines, current approaches, and alternative solutions.

Learning Objectives:
•Identify major sources of security vulnerability to data during collection storage and distribution
•Explore best practices in reviewing research proposals to locate and mitigate data security vulnerabilities
•Understand how to leverage existing institutional resources and infrastructure to achieve the goal of more secure research data

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

B3: Assessing Capacity to Consent for Research Participation: When and How Do You Actually Do It?
Track(s): Populations Requiring Additional Protections; Informed Consent; Advancing Equity and Justice; IRB Review; Social, Behavioral, and Educational Research

People with disabilities, including those with impaired decision-making capacity, have the right to equal access and opportunity to consider participation in clinical research. The Common Rule identifies individuals with impaired decision-making capacity as being "vulnerable to coercion or undue influence" and specifies the expectation of "additional safeguards to protect the rights and welfare" of these participants (45 CFR 46.111). Researchers and IRBs often rely on assessments for capacity to consent to research participation as the required additional safeguard provided to these participants. Yet, capacity assessments for research participation are highly variable and fraught with problems, including implicit and explicit bias, unfamiliarity regarding the capacity of people with cognitive disabilities, and a failure to provide necessary accommodations, among others. This session will present case examples to illustrate the varying ways in which capacity to consent for participation can be incorporated in research.

Learning Objectives:
•Understand when capacity assessments for research participation can serve as an additional safeguard for participants with impaired decision-making capacity
•Learn the ways in which capacity assessments for research participation can be implemented in clinical research and understand how different types of studies require different types of assessments
•Identify the problems that often exist with capacity assessments and understand potential solutions to these problems

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

B4: Ethical Implications and Practical Application of Broad Consent
Track(s): Pharma/Biotech Perspectives; Informed Consent; Research Involving Data and New Technologies; IRB Review

Broad consent allows researchers to conduct research on identifiable data/biospecimens without study specific consent or having to request a waiver of informed consent. This reduces administrative burden on researchers sharing data and specimens and for using these materials in future research. This session will explore the benefits and ethical implications of broad consent as well as the operational challenges that institutions face when implementing it.

Learning Objectives:
- Identify the operational infrastructure needed to implement broad consent at an institution
- Articulate ethical concerns associated with broad consent
- Obtain a working understanding of three models that can be used to facilitate broad consent

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

B5: A Dialogue with the Department of Energy (DOE)
Track(s): A Dialogue with the Feds

Led by representatives from the DOE Human Subjects Protection Program, this session is designed to inform attendees about the DOE HSPP, DOE specific requirements, and major initiatives. Attendees are encouraged to come with questions of interest to all.
- Learn about the DOE Human Subjects Protection Program and DOE specific requirements
- Gain insight on evolving initiatives and key guidance
- Provide an opportunity to engage in conversation with the DOE HSPP Managers and address questions of interest for all

Target Audience(s): 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

B6: Are You Leaving Money on the Table? Ensuring IRB Fees Are Accounted for in a Single IRB (sIRB) World
Track(s): Single IRB; HRPP/IRB Management and Administration

With the implementation of sIRB regulations, IRBs may not always know how to ensure the associated IRB fees are accounted for, including identifying if the development of fee schedules when serving as the IRB of record is the appropriate route. This session will go through the life cycle of research when an IRB serves as a sIRB and also when ceding review, and explore fees that should and can be recouped for overall HRPP operations.

Learning Objectives:
- Identify methods to ensure IRB fees are appropriately calibrated and billed for industry and IRB of record
- Discover key recommendations when exploring fee schedule development
- Discuss additional tools that can be utilized for billing IRB fees

Target Audience(s): HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; Compliance Personnel

B7: Key Information in Informed Consent: Ethical Principles, Policy, and Practice
Track(s): FDA Regulated Research; Informed Consent

In response to the growing length and complexity of informed consent documents, the revised Common Rule added two provisions that require informed consent to begin with key information about the research which is to be presented in a clear and concise manner, and that informed consent as a whole be presented in a way that facilitates understanding of the reasons why someone might or might not want to participate in research. FDA issued a proposed rule to adopt identical language to harmonize with these provisions. In March 2024, FDA and OHRP published joint draft guidance discussing suggested approaches to presenting key information and facilitating understanding in the informed consent, including oral, written, and electronic consent. The guidance also recommends approaches for informed consent documents that may improve comprehension. This session will provide an overview of the ethical principles and policy goals that led to the inclusion of the new provisions about informed consent, including key information. It will also address proposed approaches to key information and consent changes as described in draft guidance and discuss opportunities and challenges to reviewing key information and enhanced consent materials.

Learning Objectives:
- Understand how the key information provision helps support respect for persons
- Describe the FDA and OHRP draft guidance on the presentation of key information and recommendations for the content, organization, and presentation of informed consent
- Identify considerations for presenting key information and enhancements to aid understanding in informed consent

Target Audience(s): Clinical Research Staff; Researchers and Research Staff; IRB Members, Chairs, and Vice Chairs

B8: Empowering the Participant Voice: Using Research Participant Experience Data to Address Research Disparities and Enhance Quality
Track(s): QA/QI and Postapproval Monitoring; Advancing Equity and Justice

Although safeguarding research participants is a fundamental role of HRPPs, the research participant experience is rarely assessed systematically and remains an area with limited study. Empowering the Participant Voice is a collaborative project that created an infrastructure to streamline the collection of actionable research participant feedback and a framework for benchmarking within and between institutions over time to improve research. This session will explore this initiative and engage the audience in discussing its potential value to HRPPs and institutions in fulfilling their mission.

Learning Objectives:
- Discuss the significance of participant perspectives to the mission of HRPPs
- Provide an overview of and lessons learned from a decade-long effort to assess research participant experiences through a validated Research Participant Perception Survey
- Describe the various implementation approaches and impacts of the survey across diverse institutions

Target Audience(s): Compliance Personnel; Researchers and Research Staff; Clinical Research Staff; HRPP/IRB Administrators, Managers, and Staff; HRPP/IRB Directors; QA/QI Professionals; Diversity, Equity, Inclusion, and Justice

B9: When SBER Meets the Definition of a Clinical Trial, Then What?

Track(s): Social, Behavioral, and Educational Research; IRB Review

Some social-behavioral controlled trials may meet the NIH definition of a clinical trial. For example, the use of a mobile app to provide a mindfulness intervention and measure the change in behavior over time in relation to stress reduction. This session will cover when SBER crosses over into the clinical research space.

Learning Objectives:

- Learn the definition of a clinical trial in relation to SBER
- Identify what additional information needs to be considered by the IRB, for example, FDA regulations and/or ClinicalTrials.gov registration
- Understand how funding plays into decisions and how it can possibly change the review paths

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

B10: Advancing Justice, Equity, and Trustworthiness Through Community Engaged Research (CEnR): What HRPPs/IRBs Need to Know

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

CEnR is a powerful approach to advancing justice and equity in research and can also improve the trustworthiness of institutions. By making community agencies and members equal partners in the research team, CEnR has the potential to improve human research protections, but also presents new considerations for IRB review related to the engagement of different kinds of collaborators (e.g., unique conflicts of interest/commitment, specific threats to participant voluntariness or confidentiality, and the need for tailored human research protections training). Ultimately, benefits of community engagement far outweigh the challenges, and HRPPs/IRBs have an important role in advancing the practice of CEnR.

Learning Objectives:

- Describe how CEnR can advance justice, equity, and trustworthiness in research
- Discuss some of the unique challenges CEnR poses for HRPP/IRB review
- Share resources for reviewing and supporting CEnR

Target Audience(s): HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Educators/Trainers; Clinical Research Staff; Researchers and Research Staff; Diversity, Equity, Inclusion, and Justice

IACUC

B11: What Comparative Psychology Can Tell Us About Laboratory Animal Care and Behavioral Management

Track(s): Animal Well-Being and the 3Rs; ACU/IACUC Program Management and Administration

In this session, comparative psychologists with expertise studying different nonhuman animals that are commonly involved in biomedical and behavioral research, will share how laboratory animal care has evolved with continued advancements in knowledge about animals' social, behavior, physiological, and cognitive functioning. Speaker will discuss how reliance on comparative psychology research in regard to advancing laboratory animal care can lead to continuous improvement. Speakers will also strategies to improve and expand evidence-based standards for laboratory animals.

Learning Objectives:

- Consider how reliance on comparative psychology research can assist with the continuous improvement of laboratory animal care
- Discuss how and why it is important to rely on comparative psychology research in regard to advancing laboratory animal care
- Explore strategies to improve and expand evidence-based standards for laboratory animals

Target Audience(s): ACU/IACUC Administrators, Managers, and Staff; Compliance Personnel; Educators/Trainers; IACUC Members, Chairs, and Vice Chairs; Laboratory Animal and Veterinary Staff

B12 (IACUC): The First 48 Hours: What to Do Right Away When Things Go Wrong

Track(s): Communication With the Public

In nearly every crisis situation, an organization's initial actions during the first few hours and days of an emerging event will greatly impact their ability to "weather the storm." This session will offer guidance and provide attendees with concrete ideas on what steps should be taken if/when organization faces a major issue such as a anti-animal research group infiltration, allegations by former staff, a significantly negative USDA inspection or OLAW report, unexpected or preventable nonhuman animal deaths, or a challenging incident such as a nonhuman animal escape.

Learning Objectives:

- Explore strategies and best practices on how to respond effectively in an emerging crisis situation
- Highlight the key roles of head veterinarians, animal care staff, and compliance staff during these events
- Provide guidance on establishing partnerships and creating necessary materials preemptively to effectively manage crisis situations
- Analyze case examples of successful crisis management strategies

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

B13 (IACUC): A Dialogue with 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(s): ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; QA/QI Professionals; Compliance Personnel

B14 (IACUC): Reproducibility and the IACUC
Track(s): IACUC Review; Animal Well-Being and the 3Rs; IACUC Basics

This session will discuss key aspects of experimental design that should be considered for all study proposals and that can help improve reproducibility. Fundamentals include: appropriate sample size justification and incorporation of randomization and masking (aka blinding). Speakers will identify key criteria and red flags the IACUC can look for in a protocol, provide sample questions the IACUC can ask researchers if key information is missing, and describe currently available resources to assist in the design of statistically valid and reliable experiments.

Learning Objectives:
•Understand the basics of sample size determination with and without a power calculation
•Understand what information about randomization and masking (aka blinding) might be seen in a protocol
•Identify resources that can help IACUCs and researchers improve experimental design

Target Audience(s): ACU/IACUC Directors; Researchers and Research Staff; Compliance Personnel; IACUC Members, Chairs, and Vice Chairs

B15 (IACUC): Building a Professional Network in the Animal Care and Use Community
Track(s): ACU/IACUC Program Management and Administration; Education, Qualifications, and Training

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 nonhuman 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
•Explore other non-traditional roles such as 3Rs, Culture of Care, and animal welfare oversight

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

Crossover

B16: Rulemakers and Gatekeepers: Demystifying the Federal Regulations Journey
Track(s): Legal Considerations in Research; Research Oversight Leaders and Institutional Officials; Shared Research Oversight Challenges; IRB Fundamentals; IACUC Fundamentals

This presentation offers an exploration of the intricate journey through the federal regulations process. Delving into the complexities, it unveils the key players, stages, and challenges involved specific to research regulations. Attendees will gain a comprehensive understanding of how rules are made, altered, and enforced at the federal level, shedding light on the regulatory landscape's inner working.

Learning Objectives:
•Understand the key stages of the federal regulations process. Attendees will gain a comprehension of the steps involved
•Identify the pivotal players in the regulatory landscape. Explore the roles of various entities, including regulatory agencies, stakeholders, and the public/institutions
•Learn about common hurdles within the process and develop insights into compliance strategies

Target Audience(s): ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; Compliance Personnel; Educators/Trainers; IACUC Members, Chairs, and Vice Chairs; IBC Directors; IBC Administrators, Managers, and Staff; IBC Members, Chairs, and Vice Chairs; HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs

B17: Effectively Managing the Use of Controlled Substances in Research
Track(s): Education, Qualifications, and Training; HRPP/IRB Management and Administration; ACU/IACUC Program Management and Administration; Shared Research Oversight Challenges; Research Oversight Leaders and Institutional Officials; Legal Considerations in Research Oversight; Pharma/Biotech Perspectives

Controlled substances are frequently used in animal research and increasingly becoming more common in human subjects research. Even though drug registrations are held by investigators, institutions can be held to account when problems occur. Implementing institutional policies, procedures, and monitoring can help ensure investigators are using and managing controlled substances in compliance with federal regulations. This session will provide insight into requirements for use of controlled substances in research and share institutional approaches to providing oversight.

Learning Objectives:
•Identify federal regulations governing use of controlled substances in research settings
•Define policies and procedures for use of controlled substances that can help ensure compliance with federal requirements
•Develop resources for investigators to help them navigate this complex regulatory environment

Target Audience(s): ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; HRPP/IRB Directors; IRB Administrators, Manager and Staff; HRPP Leadership and Institutional Officials; Legal Counsel; Compliance Personnel; QA/QI Professionals; Researchers and Research Staff

B18: Cross Training and Successful Transfer of Knowledge

Track(s): Shared Research Oversight Challenges; Education, Qualifications, and Training; ACU/IACUC Program Management and Administration; HRPP/IRB Management and Administration

There are constant staffing changes and subsequent losses of institutional knowledge across research administration, most especially in research compliance. This session will discuss strategies for cross training and developing systems for effective transfer of knowledge.

Learning Objectives:

•Explore considerations for effective cross training of staff across compliance areas
•Discuss the development and enhancement of SOPs and other ways to standardize processes among compliance areas
•Learn ways to manage transitions and maintain staff levels and staff morale

Target Audience(s): Research Program Leadership and Institutional Officials; Educators/Trainers; Compliance Personnel; HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IBC Directors; IBC Administrators, Managers, and Staff; ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff

Institutional Leadership

B19: Institutional Approaches to Research Security Programs

Track(s): ACU/IACUC Program Management and Administration; HRPP/IRB Management and Administration; Research Oversight Leaders and Institutional Officials; Shared Research Oversight Challenges

This session will provide an overview of the federal requirements for an integrated research security program, as currently articulated in NSPM-33 and the CHIPS and Science Act, as well as resulting sponsor requirements. Speakers will also share approaches to assessing institutional readiness and measures to build awareness and educate investigators, and consider specific initiatives being implemented as part of a broad research security framework.

Learning Objectives:

•Identify research security program components and compliance required by NSPM-33 and CHIPS Act
•Consider options for assessing institutional readiness and generating ongoing awareness among the research community
•Explore institutional approaches to defining a broad research security framework and building a robust, responsive program

Target Audience(s): ACU/IACUC Administrators, Managers, and Staff; ACU/IACUC Directors; Compliance Personnel; HRPP/IRB Administrators, Managers, and Staff; HRPP/IRB Directors; IBC Administrators, Managers, and Staff; IBC Directors; Legal Counsel; Research Program Leadership and Institutional Officials

B20: Leaders of International Research: Navigating Research Regulations and Promoting Ethical Practices

Track(s): Research Oversight Leaders and Institutional Officials; Shared Research Oversight Challenges

Whether they are U.S.-based or abroad, research programs face challenges such as securing funding amidst fierce competition, ensuring regulatory compliance for ethical research, recruiting and retaining talented personnel, maintaining infrastructure and resources, fostering collaboration, new technologies, and data sharing and security. As the landscape of scientific research evolves with advances in areas such as artificial intelligence, institutions must develop innovative approaches to oversight. More than ever, research programs must have effective leadership, strategic planning, and collaboration among researchers, administrators, and external stakeholders to sustain and advance research initiatives. This session will share best practices, implemented both here and abroad, to promote ethical research practices while promoting excellence in research.

Learning Objectives:

•Explore challenges faced by research programs in the current regulatory framework, both nationally and internationally
•Foster dialogue to explore innovative approaches to address emerging challenges, inclusive of discussing the workforce stability, establishing processes, and managing your existing infrastructure
•Share best practices to navigate the complexities of the regulatory landscape more effectively and foster a culture of innovation and responsible research conduct

Target Audience(s): ACU/IACUC Administrators, Managers, and Staff; ACU/IACUC Directors; Compliance Personnel; HRPP/IRB Administrators, Managers, and Staff; HRPP/IRB Directors; IBC Administrators, Managers, and Staff; IBC Directors; Legal Counsel; Research Program Leadership and Institutional Officials

3:00-3:30 PM PT **Break w/ food and drinks**

PRIMR24 Content Block C , 3:30-4:45 PM PT

HSR

C1: Taking Stock of the Research Ethics Oversight Ecosystem: Healthy Developments, Overgrowth, and Audit Culture

Track(s): QA/QI and Postapproval Monitoring; Emerging Research Challenges and Breaking Issues

The goal of this session is to consider how the ecosystem of research ethics oversight has grown (and perhaps overgrown) over the past 50 years, via a proliferation of approaches toward professionalism, accreditation, and efficiency that must balance the tension between appropriate maturation of the system and problematic tendencies toward "audit culture" in which the system loses sight of central goals. The session will begin with a "back to basics" historical reminder of why IRBs were developed and what problems they were intended to solve, followed by a brief discussion of recent governmental findings regarding quality and quality assessment. Speakers will then engage in an environmental assessment of the current IRB ecosystem, including the development of many programs and expectations that exceed regulatory requirements. Which of these developments represent true quality improvements and which might reflect "over-proliferation," considering what is necessary to reasonably protect research participants, current costs and burdens, and risks of over-bureaucratization and professional self-interest? Speakers will close with a discussion of what the ideal research ethics oversight ecosystem might look like and possible alternate approaches to its future.

Learning Objectives:

•Review the historical goals and objectives of IRBs and how those have changed over time
•Consider the current IRB ecosystem with a focus on mechanisms that promote "audit culture"
•Explore alternative approaches to return to the basics of high-quality, effective research ethics oversight

Target Audience(s): IRB Members, Chairs, and Vice Chairs; Compliance Personnel; Clinical Research Staff; Researchers and Research Staff; HRPP/IRB Administrators, Managers, and Staff; HRPP/IRB Directors; Research Program Leadership and Institutional Officials; QA/QI Professionals

C2: A Dialogue with SACHRP

Track(s): A Dialogue with the Feds

This session will explore the recommendations approved by SACHRP in 2024, including considerations for the participation of LGBTQI subjects in HHS conducted or supported research.

Learning Objectives:

•Understand the development and legal authority of SACHRP's recommendations
•Discuss key recommendations from 2024
•Learn when SACHRP will be soliciting new members

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

C3: Postapproval Monitoring (PAM) in a Single IRB (sIRB) World: FDA Edition

Track(s): Single IRB; QA/QI and Postapproval Monitoring; FDA Regulated Research

The introduction of the various sIRB mandates (e.g., NIH, Common Rule, and potentially FDA) has created new complexities for what were once routine research administrative activities, such as PAM. As institutions continue to navigate PAM for studies subject to the various sIRB mandates, a new mandate from the FDA would further complicate this function for studies not currently subject to sIRB mandates. Some such variables, which would impact this critical function in the protection of human subjects, that may be unique to the FDA mandate include monitoring for industry-funded studies vs. small minimally- or unfunded investigator-initiated trials, differences in monitoring between funded and unfunded research, monitoring investigator-held Investigational New Drugs and Investigational Device Exemptions across multiple institutions, monitoring studies subject to the exception from informed consent provisions and community consultation/public disclosure.

Learning Objectives:

•Learn the basics of the FDA sIRB mandate under the Notice of Proposed Rule Making and the applicable FDA regulations for clinical trial monitoring
•Explore the responsibilities and common practices for PAM when engaged in studies subject to sIRB mandates (both as reviewing and relying institutions)Explore the responsibilities and common practices for PAM when engaged in studies subject to sIRB mandates (both as reviewing and relying institutions)Explore the responsibilities and common practices for PAM when engaged in studies subject to sIRB mandates (both as reviewing and relying institutions)
•Understand the impact of sIRB mandates on PAM monitoring for FDA-regulated studies

Target Audience(s): HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Compliance Personnel; QA/QI Professionals

C4: What's That You're Wearing? Human Research Protections and Wearable Devices

Track(s): Research Involving Data and New Technologies; Emerging Research Challenges and Breaking Issues; IRB Review; Social, Behavioral, and Educational Research

With wearable devices, researchers can noninvasively collect massive amounts of data around the clock. From fitness trackers to smart clothing, from surveillance to sousveillance, wearables are at the intersection of big data, artificial intelligence, and digital health technologies.

Learning Objectives:

•Learn about the current wearables landscape, and what wearable devices can add to research and healthcar
•Explore what IRBs should consider when reviewing wearables research
•Use case studies about wearables to address how human research protections considerations were addressed

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

C5: IRBs Greatest Challenges for Youth-Centered Research
Track(s): Populations Requiring Additional Protections; IRB Review; Social, Behavioral, and Educational Research

During this session, speakers will discuss the challenges in youth-centered research including how to (1) assure the benefits outweigh risks; (2) appropriately recognize the concerns of guardians/parents without unduly restricting the conduct of important research; (3) obtain guardian/parent permission, especially in settings with low socioeconomic status; (4) review studies of adolescents with mental or physical disabilities; and (5) assure voluntary, autonomous recruitment and assent of adolescents. In addition, speakers will address the ways IRBs can support researchers who focus on youth including how to make participant-facing language simple, how to include standards and mores of families in research materials, and how to address the requirements and ethical concerns of research involving adolescents. The session will conclude with youth-centered sample text, reviewer checklists, and other tools for IRB reviewers and researchers.

Learning Objectives:
•Learn about the greatest challenges for IRBs conducting youth-centered research reviews
•Explore the ways IRBs can support researchers who focus on youth
•Discover youth-centered sample text, reviewer checklists, and other tools for IRB reviewers and researchers

C6: Medical Devices: A Beginner's Guide to Understanding the Basics of FDA Regulation and How to Apply it to a Study
Track(s): FDA Regulated Research; IRB Fundamentals; IRB Review

IRBs have an important role in reviewing and approving the use of investigational medical devices, as well as ensuring investigators comply with all applicable regulations for these devices. Despite the available resources, understanding FDA regulations regarding investigational medical devices often feels overwhelming and complex for IRB reviewers and HRPP staff, and can be a source of frustration for researchers. This session will introduce basic terminology pertaining to FDA regulations and walk through the different decision pathways for Investigative Device Exemptions (IDEs) as well as describe the responsibilities of the IRB determined by the review pathway.

Learning Objectives:
•Discover the basics of FDA regulation, including what is a 'Device', 'Clinical Investigation', and 'Human Participant'?
•Discuss the decisional pathways and options for medical devices and considerations to be taken when venturing down the pathways
•Explore case studies in order to apply what is learned towards real-world scenarios paired with general Q/A

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

C7: This Coffee Is HOT! Burning Topics in the SBER Space (Needle)
Track(s): Social, Behavioral, and Educational Research; HRPP/IRB Management and Administration; IRB Review

In this networking session, speakers and attendees will examine how we are handling questions of the day. Through an open Q&A format moderated by the speakers, attendees will discuss the application of the regulations, guidance, and local policies in ways that will provide strategies for how an institution can adapt its policies taking into account the institution's size, staff resources, and/or research community's portfolio. Moderators will have some hot topics at the ready if needed, but attendees are encouraged to come with questions in mind to drive the discussion and interact with peers.

Learning Objectives:
•Discuss opportunities and challenges in the current SBER landscape
•Share creative solutions while staying compliant and being consistent
•Network with other SBER colleagues

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

C8: Help! I Don't Understand: Making the Consent Process and Form Meaningful Through Health Literacy and Adult Learning Theory
Track(s): Informed Consent; Advancing Equity and Justice; Social, Behavioral, and Educational Research

A recurring theme in all the human subjects research regulations is that there be a consent process that is a meaningful interaction between the research team and their participants. How the process is handled and what information is presented in the form to participants often varies with different degrees of comprehension. This session will explore the integration of adult learning theory principles into informed consent procedures for human research projects. Speakers will propose an alternate method to address the Belmont Report's ethical principles of Respect for Persons and Justice by addressing the barriers that exist for many people and communities preventing them from participating in research and closing the health inequality gaps.

Learning Objectives:
•Assess current practices and identify opportunities to improve the clarity, readability, and accessibility of informed consent documents
•Develop strategies for incorporating health literacy principles into the language and format of informed consent materials, ensuring comprehension and informed decision-making among diverse participant groups
•Provide recommendations for training researchers on effective communication strategies, ensuring the ethical conduct of studies by fostering participant comprehension and informed decision-making

Target Audience(s): HRPP/IRB Directors; IRB Members, Chairs, and Vice Chairs; Diversity, Equity, Inclusion, and Justice; Researchers and Research Staff; Clinical Research Staff

C9: From Researcher to Sponsor Investigator: How to Work With Your Broader HRPP to Develop and Deploy Safe, Effective, and Ethical Artificial Intelligence (AI)

Track(s): HRPP/IRB Management and Administration; Emerging Research Challenges and Breaking Issues; Research Involving Data and New Technologies

The role of a research healthcare organization is changing. These institutions have traditionally been in the research space of innovation where industry would then take their ideas and commercialize the product. AI and Machine Learning (ML) are introducing a new paradigm in which research healthcare organizations are becoming the manufacturers while maintaining their leading role in research. Is your HRPP ready to take on this new responsibility? While the protection of human subjects who participate in AI/ML research is a paramount concern, the safety, effectiveness, and ethical deployment of that end product is entirely dependent upon how the AI/ML research is conducted. IRB efforts alone are not sufficient to address the complex and dynamic challenges posed by AI/ML. Therefore, as researchers begin to adopt a sponsor-investigator role, a holistic and collaborative approach that leverages the expertise and resources of the entire HRPP is needed. This session will introduce considerations for institutions to utilize their current resources, community, and broader HRPP in coming together in this collective effort to accelerate translation of healthcare software into clinical practice by developing and deploying safe, effective, and ethical AI in healthcare, starting with the IRB. Attendees are encouraged to bring their own documents for cross-institutional learning and collaboration. Session findings and outcomes will bed disseminated after the conference.

Learning Objectives:

•Explain the challenges and opportunities for healthcare institutions developing and deploying their own healthcare software (AI/ML SaMD)

•Learn how to develop a standardized framework that is aligned to regulatory expectations for ensuring quality, safety, ethics, and innovation of AI healthcare software from research to deployment

•Identify the key individuals and their roles that HRPPs/IRBs need to work with in developing and implementing an oversight program for AI healthcare software from research to deployment

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

C10: Updates to the Declaration of Helsinki

Track(s): Pharma/Biotech Perspectives

The Declaration of Helsinki from the World Medical Association (WMA) is a foundational document for human research ethics. The first version was adopted in 1964, and has been amended seven times through 2013. The principles described within the document have been embedded as an expectation for research conduct in ICH Good Clinical Practice Guidelines and International Committee of Medical Journal Editors (ICMJE) Publication Recommendations, as well as at many institutions. At the WMA Council meeting in April 2022, a workgroup was established to begin another revision. This session will provide an overview of the changes to the document and associated rationale.

Learning Objectives:

•Learn the history of the Declaration of Helsinki

•Explore timing and the process for updates

•Examine what has changed and the potential impact for research

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

IACUC

C11: The Historical Impact of Politics on Scientific Research With Nonhuman Animals

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

For decades, politics has permeated both science and medicine, and was recently thrust into the forefront during the early days of the COVID-19 Pandemic and with the Supreme Court's decision to overturn Roe v Wade. It's often presumed that a Republican led government leads to fiscal restraint for social programs (including healthcare and education) and budgetary expansion for the US Military. Whereas a Democratic led government is associated with increased funding for social programs and a downsized military. Conservatives were previously not swayed by anti-animal research arguments while more liberal lawmakers were. And, until recently, the funding of research was often viewed as a bipartisan issue. But, are those presumptions really the current reality or mere myths? Have standard positions shifted and become less predictable? This session will explore how funding for medicine and basic research, including studies designed to use nonhuman animals, has fluctuated over the last half-century and explore the influential role of politics on research.

Learning Objectives:

•Describe how politics has altered funding opportunities for nonhuman animal research over the last 50 years

•Identify politically-charged topics that alter basic research and medicine

•Discuss strategies to preemptively prepare for potential political landmines that could disrupt specific areas of research and/or restrict using specific animal models (e.g., nonhuman primates like macaques or chimps) needed to achieve modern medical breakthroughs to improve human health

Target Audience(s): ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; Compliance Personnel; IACUC Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; Researchers and Research Staff

C12 (IACUC): Driving Postapproval Monitoring (PAM) Program Priorities by Harnessing Existing Data
Track(s): QA/QI and Postapproval Monitoring; ACU/IACUC Program Management and Administration
This session will provide creative ways to leverage existing data such as noncompliance reports, health information of animals, etc. to identify areas of weaknesses and correct them.
Learning Objectives:
•Evaluate available data and what information can be garnered/extrapolated from them
•Consider how to develop and implement of a program based on the selected data
•Review alternative approaches to PAM activities (e.g., leveraging existing processes to collect PAM data)
•Explore how to measure the effectiveness of the program and how to build PAM documentation (what is required in regards to Record Retention policies, and what is beneficial to keep, but not necessarily required, in ongoing analysis of an institution's PAM program)

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

C13 (IACUC): A Dialogue with USDA
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 nonhuman animals nationwide. APHIS provides leadership for determining standards of humane care and treatment of nonhuma 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(s): ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; QA/QI Professionals; Compliance Personnel

C14 (IACUC): What Needs to Change in Nonhuman Primate (NHP) Housing and Why
Track(s): Pharma/Biotech Perspectives; Animal Well-Being and the 3Rs
Since the first iteration from turkey cages, many advancements have been made in NHP housing. But, are the minimum legal requirements for NHP housing in the US meeting welfare needs? Speakers will review the latest data that informs what NHPs benefit from in their housing environment, how this can impact the studies on which the animals are enrolled, and how programs are enabled or challenged in evolving to meet our growing understanding of these species.
Learning Objectives:
•Understand what aspects of NHP housing matters to the animals' well-being
•Learn about the impact of minimal and refined NHP housing on research data
•Define what goals and steps should be taken to generate change

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

C15 (IACUC): Exploring NAMs and Complement-ARIE: Insights for IACUCs
Track(s): Emerging Challenges and Breaking Issues; IACUC Review; ACU/IACUC Program Management and Administration; Animal Well-Being and the 3Rs
Join us for a comprehensive discussion on NAMs and their relevance to nonhuman animal research. This session will delve into the definition of NAMs and provide valuable insights into what IACUCs need to know about them. Additionally, speakers will introduce Complement-ARIE to further explore the integration of alternative methodologies in research practices.
Learning Objectives:
•Define NAMs and assess the current state of development and validation of NAMs
•Consider the challenges and benefits associated with integrating such methodologies into nonhuman animal based research
•Discuss how to best educate the next generation of scientists about NAMs
•Introduce Complement-ARIE and learn about new approach methodologies and the NIH Common Fund Project

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

C16: Bridging Preclinical to Clinical Research With Artificial Intelligence (AI) and Digital Biomarkers: Current Landscape, Vision, and the Collaborative Path Toward Improved Translation

Track(s): Emerging Challenges and Breaking Issues; Pharma/Biotech Perspectives; Animal Well-being and the 3Rs; Research Involving New Data and Technologies

Advances in sensor technologies, wearable devices, computer vision, and AI- informed digital measures are providing an opportunity to improve nonclinical to clinical translation in both directions. Better insights into the onset and progression of human diseases better inform animal modeling approaches. Digital biomarkers facilitate continual measurements of patients at home and animals within home cage environments. This session will rationalize that digital biomarkers offer holistic, dynamic, and actionable insights into disease modeling and drug assessment, enabling improved translatability, accelerated throughput, heightened utility, and increased reproducibility. In the preclinical research environment, such technologies also enable less human interaction and disruption to the animal and improved detection of health/welfare events and earlier intervention.

Learning Objectives:

•Learn how clinical digitalization is providing a better understanding of the onset and progression of human disease, how digital biomarkers in animal studies can support the conduct of more data rich, humane, and informative animal studies
•Discuss approaches to validation and building confidence in the analytical rigor and clinical relevance of digital measures for both animal studies and human patients
•Explore the ethical considerations of digital health and the application of digital technologies in preclinical and clinical research

Target Audience(s): ACU/IACUC Directors; ACU/IACUC Administrators, Manager and Staff; IACUC Members, Chairs, and Vice Chairs; HRPP/IRB Directors; IRB Administrators, Manager 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; QA/QI Professionals; Laboratory Animal and Veterinary Staff; Researchers and Research Staff; Clinical Research Staff

C17: Nurturing True Inclusion: Moving Beyond Tokenism to Actual Inclusion

Track(s): Advancing Equity and Justice in Research; Education, Qualifications, and Training; Shared Research Oversight Challenges

Tokenism is a performative practice of hiring a small number of historically excluded folx to fulfill a quota, thereby checking the diversity box giving the appearance of equity in the workplace. It ignores the structural elements and challenges that individuals face. Relevant to researchers, human and animal research programs perpetrating tokenism may promote stereotypes, encourage microaggressions and stifle honest efforts of diversity, equity, inclusion, justice, and belonging. Venturing beyond the bounds of tokenism can lead to a broader range of thoughts, ideas, opinions which can lead to sustainable better solutions and greater access to research communities and shared resources within and between organizations.

Learning Objectives:

•Explore the nuanced difference between genuine inclusion and tokenism in the research environment and the committees that oversee their work
•Discuss how to implement appropriate peer-to-peer mentoring by committee members, which can help foster increased engagement in an IRB/IACUC, as well as improve mentoring of students by that faculty
•Discover how the detrimental effects of tokenism impact research teams, IRBs, and IACUCs, and learn practical solutions and strategies for fostering genuine inclusion within research teams, IRBs, and IACUCs as well as fostering inclusive mentoring processes

Target Audience(s): ACU/IACUC Directors; ACU/IACUC Administrators, Manager and Staff; IACUC Members, Chairs, and Vice Chairs; HRPP/IRB Directors; IRB Administrators, Manager and Staff; IRB Members, Chairs, and Vice Chairs; IBC Administrators, Manager and Staff; Research Program Leadership and Institutional Officials; Researchers and Research Staff

C18: Committee Meeting Navigation for Those in the Room

Track(s): IRB Review; IACUC Review; Shared Research Oversight Challenges

This session will provide oversight committee chairs, board members, and administrators an opportunity to share ideas and best practices with meeting design and management. Speakers will organize the discussion around various topics of interest to the audience, including: using virtual meetings; engaging members; holding space for differing perspectives; and utilizing different roles to keep the conversation on topic and moving. With any luck, these tips will help ensure your meetings are a venue for getting the work done thoroughly, collegially, and efficiently.

Learning Objectives:

•Explore best practices to developing a "game plan" or strategy for compliance meetings to ensure they are engaging yet efficient
•Share strategies for navigating the meeting in the moment (e.g., how to set the ground rules, keep discussions on track, document votes, address disagreements)
•Elicit a variety of different approaches and strategies that can be used in different contexts

Target Audience(s): IACUC Members, Chairs, and Vice Chairs; IBC Members, Chairs, and Vice Chairs; IRB Members, Chairs, and Vice Chairs

C19: What You Don't Know Can Hurt You: Using Metrics to Evaluate Research Administrative Activities
Track(s): ACU/IACUC Program Management and Administration; HRPP/IRB Management and Administration; Research Oversight Leaders and Institutional Officials; Shared Research Oversight Challenges

There is an abundance of information, data, metrics, etc., that may be available and/or useful for institutional leadership to assist them with the leadership of the research mission. But, is there too much information? Or, is there 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(s): ACU/IACUC Administrators, Managers, and Staff; ACU/IACUC Directors; Compliance Personnel; HRPP/IRB Administrators, Managers, and Staff; HRPP/IRB Directors; IBC Administrators, Managers, and Staff; IBC Directors; Legal Counsel; Research Program Leadership and Institutional Officials

C20: Research Integrity Management in the New Public Arena
Track(s): ACU/IACUC Program Management and Administration; HRPP/IRB Management and Administration; Research Oversight Leaders and Institutional Officials; Shared Research Oversight Challenges

Research integrity has now moved into the public arena with community sleuths combing through publications using advanced technical capabilities to identify potential research integrity issues. They are selectively targeting leading scientists and leadership figures, providing their findings to the press instead of to the academic research integrity process. What are the new challenges with this shift and how are institutions handling the public and internal challenges?
Learning Objectives:
•Identify the key players involved when an institution is confronted with allegations in the public arena
•Explore how and when institutions respond when the rules have changed
•Discuss how to ensure the integrity of the process when institutions are limited in what they can state publicly

Target Audience(s): ACU/IACUC Administrators, Managers, and Staff; ACU/IACUC Directors; Compliance Personnel; HRPP/IRB Administrators, Managers, and Staff; HRPP/IRB Directors; IBC Administrators, Managers, and Staff; IBC Directors; Legal Counsel; Research Program Leadership and Institutional Officials

4:45-6:00 PM ET **Welcome Reception & 50th Anniversary in the Exhibit Hall**

4:45-6:00 PM ET **Meet and Greet With the Supporters and Exhibitors**

4:45-6:00 PM ET **View the PRIMR24 Poster Abstracts**


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PRIM&R Annual Conference
November 17-20
Seattle, Washington
Celebrating 50 Years of PRIM&R
2024

PRIMR24: Tuesday, November 19

7:00 AM-5:00 PM PT

Registration Open

7:00 AM-8:15 AM PT

Federal Agency Office Hours

During this time, representatives from federal agencies, the accrediting bodies, and/or the CIP and CPIA Councils will be available to answer attendee questions, engage in dialogue, and/or direct attendees to additional resources. Attendees are encouraged to come prepared with questions, which will be taken on a first come basis. To participate, go to the Exhibit Hall and locate the Office Hours table(s) for the agencies participating in this timeslot. **Only the following organizations are participating in this timeslot**:

* AAHRPP, Inc.
* FDA
* OHRP
* CIP Council
* CPIA Council
* NIJ

8:30-9:00 AM PT

Board Remarks & Award Presentation(s)

9:00-10:00 AM PT

Opening General Session: The Next Frontier: Space Exploration Research

Track(s): Emerging Research Challenges and Breaking Issues

Space is all over the news with almost daily reports of sending humans into orbit and preparing to send humans to the moon and even Mars. Research is critical to ensuring the physical and mental wellbeing of humans who go into space both when they leave the planet and return home. Further, putting humans in space, whether through government or private efforts, presents a rare opportunity to glean information that can improve human health on Earth. This session will briefly examine where space research has been and where it is going and then focus on what we can learn in space that will inform science and medicine on Earth and some of the unique ethical challenges it presents because of where the research occurs and its potential subjects.

Target Audience(s): IRB Members, Chairs, and Vice Chairs; Diversity, Equity, Inclusion, and Justice; Clinical Research Staff; HRPP/IRB Administrators, Managers, and Staff; Compliance Personnel; Research Program Leadership and Institutional Officials; Researchers and Research Staff; HRPP/IRB Directors; ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs

10:00-10:30 AM PT

Beverage Break in the Exhibit Hall

PRIMR24 Networking Block, 7:15 AM-8:15 AM PT

N09: Single IRB (sIRB) Networking Jam Session

Track(s): Single IRB

Hey there, IRB rockstars! Get ready to rock and roll at this networking session, where the spotlight is on sIRB implementation. Picture this: a laid-back jam session where professionals come together to riff on their experiences, jamming out on the challenges and triumphs of sIRB review. Guided by sIRB peers, this session promises to hit all the high notes of engaging conversation and collaboration. We'll crank up the volume on practical strategies for implementing sIRB, sharing tips and tricks to help you hit the right chords in your research endeavors. Whether you're shredding through mountains of paperwork or fine-tuning your process, this session is your chance to rock out with like-minded professionals and steal the show. So, grab your lunch, grab a seat, and let's tune in to the rhythm of sIRB with the energy and enthusiasm of virtuosos. Reliance doesn't have to be a solo act – together, we'll make sweet music and set the stage for success! This session is for seasoned performers or tuning your instruments for the first time.

Target Audience(s): Compliance Personnel; HRPP/IRB Administrators, Managers, and Staff; HRPP/IRB Directors

N10: How It Works: A Peek Inside the IACUC in Industry

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

If you are in academia, but ever wondered what nonhuman animal research oversight is like in industry, this session will review some of the key differences and similarities between the two spaces. Come with curiosity and stay for a conversation to have your questions answered.

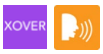
Learning Objectives:

• Review regulatory similarities and differences between academia and industry
• Discuss differences in the culture and structure between an industry role versus an academic role
• Ask questions about or get insight into what it is like to make the switch from academia and industry and how to go about exploring this career option

Target Audience(s): ACU/IACUC Administrators, Managers, and Staff; ACU/IACUC Directors; Compliance Personnel

N11: 50 Years of PRIM&R: Pioneers, the Present, and the Path Forward

Track(s): ACU/IACUC Program Management and Administration; HRPP/IRB Management and Administration; Research Oversight Leaders and Institutional Officials; Shared Research Oversight Challenges



Join us for a celebratory networking session marking the 50th anniversary of PRIM&R. This special roundtable discussion will feature a panel of esteemed experts who have paved the way in ethical research practices. Participants will have the unique opportunity to engage directly with pioneers in the field, gaining insights from their extensive experiences and discussing the evolution and future of research ethics. This session aims to foster a deeper understanding of past challenges and achievements, equipping the next generation with wisdom and guidance for ethical dilemmas in the contemporary context.

• Examine the historical context and foundational understanding that helped shape the field
• Gain insights from the panelists experiences and personal reflections
• Identify future trends and priorities, including considerations of technological advancements, cultural shifts, and global perspectives

Target Audience(s): ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; Compliance Personnel; Educators/Trainers; IACUC Members, Chairs, and Vice Chairs; IBC Directors; IBC Administrators, Managers, and Staff; IBC Members, Chairs, and Vice Chairs; HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs

PRIMR24 Content Block D, 10:30-11:45 AM PT

HSR

D1: Responsibility Does Not End With Death: Establishing Systems for Ethical Decedent Research

Track(s): Legal Considerations in Research Oversight; Emerging Research Challenges and Breaking Issues; IRB Review

The Common Rule offers a framework for protecting human subjects who are living individuals, but these protections do not extend to decedents. Recent investigative journalism has shined a light on the consequences of lacking regulations. Proposed bipartisan legislation, Consensual Donation, and the Research Integrity Act would help address these gaps. In this session, speakers will discuss historical ethical violations in decedent research, and share ideas about what individual institutions can do in the absence of federal regulations in order to ensure ethical treatment of this unique category of research participant and to uphold public trust.

Learning Objectives:

•Learn about ethical violations that have occurred with decedent research
•Understand the current laws and regulations that do/do not relate to decedent research
•Consider how to support ethical research with decedents

Target Audience(s): HRPP/IRB Directors; Research Program Leadership and Institnutioal Officials; Legal Counsel; Public Relations Professionals; Researchers and Research Staff; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs

D2: When the Feds Come to Town: What to Expect from a Federal "Site Visit"

Track(s): HRPP/IRB Management and Administration; A Dialogue With the Feds

During this session, federal officials from OHRP, FDA, and NIH will explain the process of a site visit, including what will be reviewed, what needs to be prepared, and how the process is implemented. In addition, speakers will discuss the roles and responsibilities of the IRB, the investigator, and the study team in preparing for and facilitating a federal site visit, explain the common triggers and types of federal site visits and how they differ in scope and expectations, review the key documents and records that need to be readily available and organized for a federal site visit, and share best practices for communicating with federal officials before, during, and after a site visit.

Learning Objectives:

•Describe the purpose and benefits of a federal site visit from the perspective of the site and OHRP/FDA/NIH
•Identify the key steps and best practices for preparing for a successful site visit
•Learn how to serve as a resource and partner to the study team, including how to communicate about the site visit and answer questions and concerns

Target Audience(s): HRPP/IRB Directors; IRB Members, Chairs, and Vice Chairs; Legal Counsel; Compliance Personnel; Researchers and Research Staff; Clinical Research Staff; QA/QI Professionals

D3: An Update from AAHRPP, Inc.

Track(s): A Dialogue with the Feds

Learn about the latest news and happenings from AAHRPP during this session. AAHRPP staff members will update attendees on new additions to the accreditation application, annual reporting documentation, Standards and Elements, website resources and the online accreditation management system. They will also discuss the educational opportunities and resources available to accredited and not-yet-accredited organizations alike. Also, make sure to visit the AAHRPP onsite booth during the conference and sign up to meet with AAHRPP staff members during their office hours.

Target Audience(s): 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

D4: Relationship Building to Respect Tribal Sovereignty and Improve Research Safety

Track(s): Populations Requiring Additional Protections; Advancing Equity and Justice; IRB Review; Social, Behavioral, and Educational Research

American Indian/American Native (AI/AN) Nations have diverse and unique research needs. This session will share the steps individuals and organizations can take to engage and build relationships with Indigenous partners. Relationship building is a critical step to ensuring AI/AN protections while also respecting Indigenous sovereignty.

Learning Objectives:

•Discuss the importance and centrality of sovereignty in AI/AN research
•Deepen one's understanding of Indigenous Nations today and their healthcare needs
•Identify steps in building relationships with Indigenous partners and reflect on steps one my apply in their own work

Target Audience(s): HRPP/IRB Directors; IRB Members, Chairs, and Vice Chairs; Legal Counsel; Compliance Personnel; Educators/Trainers; Clinical Research Staff; HRPP/IRB Administrators, Managers, and Staff; Research Program Leadership and Institnutioal Officials; Researchers and Research Staff

D5: Evaluating the Impact of Current and Future Single IRB (sIRB) Requirements on Local IRBs

Track(s): Single IRB; FDA Regulated Research

In the last five years, there has been extensive discussion about how the federal sIRB requirements (e.g., NIH, Common Rule) have changed the HRPP landscape. However, the focus has been on the need to rethink the local processes regarding other institutional reviews when the local IRB is not the IRB of record. Little discussion has been centered on the sIRB's impact on the workload, composition, education, and the number of the IRB committees themselves. This is an especially pressing topic in the light of the upcoming FDA sIRB requirement, which will further centralize IRB review. The goal of this session is to bring awareness around the need to evaluate and respond to the impact of current and future sIRB review requirements on local IRBs and how those evaluations tie into the need to rethink IRB member composition, number of IRBs, and member training. This interactive session will walk through examples of how small and larg research programs can plan for the impact of sIRB requirements on the composition and function of local IRB committees. Tips for strategic planning and evaluations will also be shared.

Learning Objectives:

•Review the current sIRB landscape and how the NIH and Common Rule sIRB requirements affect IRB committees (i.e., assessing number of reviews, variety of research, and project types)
•Examine the new FDA sIRB requirement and potential impact on HRPPs
•Share case examples to highlight strategies for evaluating number, composition, and training/ education of IRBs and their members

Target Audience(s): HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Research Program Leadership and Institnutioal Officials; Educators/Trainers; Compliance Personnel

D6: The Limits of Permissible Research Without Consent

Track(s): Informed Consent; IRB Review

All the major ethical codes addressing human subjects research emphasize the central importance of obtaining the voluntary informed consent of the participant prior to commencing any research activities. Nonetheless, longstanding ethics and regulations in the U.S. acknowledge that some research with human subjects is difficult or impossible to conduct with prospective consent, and that the importance of the research may outweigh this obligation under certain circumstances. Thus, there are established and evolving mechanisms that allow research to take place without obtaining consent at all, or with alterations of some elements of consent. That being said, it is important that these mechanisms are applied appropriately and conservatively to ensure that individuals are not being exploited or that consent is not waived for purposes of the convenience of the researcher. This session will review the complex regulatory requirements surrounding research without consent as it applies to different types of situations (e.g., eligibility screening, secondary research using previously collected information and/or biospecimens, cluster randomized trials, deception research, interview studies). Speakers will review what the regulations permit and require (including changes introduced with the 2018 revisions to the Common Rule), and use case-based discussion to highlight the ethical considerations where researchers may request to conduct their research without consent.

Learning Objectives:

•Review the regulatory requirements that permit a waiver or alteration of consent
•Explore pre-2018 Common Rule requirements to the 2018 Common Rule vs. the FDA regulations
•Consider when an IRB should consider granting a waiver or alteration of consent

Target Audience(s): HRPP/IRB Directors; IRB Members, Chairs, and Vice Chairs; Clinical Research Staff; Researchers and Research Staff

D7 :Reviewing Incidents of Non-Compliance: Strategies for IRB Chairs and Members

Track(s): QA/QI and Postapproval Monitoring; IRB Review; IRB Fundamentals

Incidents of noncompliance may occur in human subjects research. At many organizations, the IRB serves an important role in assessing these events and determining if any corrective actions proposed are appropriate. However, little guidance exists to help IRB members and chairs navigate these reviews and understand how to assess these events and any planned follow-up. This interactive session is designed to discuss the role of IRB members and chairs in reviewing incidents of noncompliance and making assessments of whether events may qualify as serious and/or continuing noncompliance. IRB members and chairs, and HRPP/IRB professionals that support IRB members in their reviews are encouraged to attend to share their experiences and strategies. Through interactive discussion of case examples highlighting real-world incidents of noncompliance, this session seeks to build skills in reviewing incidents of noncompliance, in reviewing (and assisting investigators in constructing) corrective action plans, in making determinations of serious and/or continuing noncompliance, and in considering whether participant notification of errors is appropriate. Attendees will also consider issues related to review of events occurring at other sites when the IRB is serving as the single IRB of record (sIRB) for multisite research.

Learning Objectives:

•Understand the roles and responsibilities of IRB members and chairs in reviewing incidents of noncompliance and making assessments of whether the events constituted serious and/or continuing noncompliance
•Identify strategies IRB members and chairs can adopt to facilitate their reviews of these events
•Discuss case examples highlighting real-world incidents of noncompliance and build skills in reviewing incidents of noncompliance

Target Audience(s): HRPP/IRB Administrators, Managers, and Staff; IBC Members, Chairs, and Vice Chairs; QA/QI Professionals;

D8: The Island of Misfit Rules: How Not-So Day-to-Day Issues Can Ruin Your Day

Track(s): Social, Behavioral, and Educational Research; HRPP/IRB Management and Administration

The Family Educational Rights and Privacy Act, Department of Justice funded research, mandatory reporting, and Title IX rules may all impact an IRB's review of a research study. There are many issues and rules HRPP staff don't see very often, maybe never, but that nonetheless require appropriate oversight and understanding. As such, this can create a blind spot for HRPP professionals. This session will explore a few of the more uncommon encounters in the ethical and regulatory environment and provide some insight on how to manage and approach them.

Learning Objectives:

•Identify and discuss the applicability of some of the more uncommon rules connected to human subjects research
•Explore how these rules and their associated issues might impact HRPPs/IRBs in the review of human subjects research
•Discuss best practices when one of these uncommon issues may require outside assistance or insight

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

D9: The Shifting Paradigm of Data Sharing: Navigating New Challenges Through a Participant-Centered Lens

Track(s): Research Involving Data and New Technologies; IRB Review; Emerging Research Challenges and Breaking Issues

Recent changes to federal guidelines set the expectation for researchers to bank study data for purposes of fostering future research. However, ethical guidelines developed before this paradigm shift do not provide clear guidance for how researchers should proceed with sharing different types of data, for example, images and other data that may be challenging to de-identify in a way that appropriately protects participants while still achieving the important goals of data sharing. This session will examine emerging ethical challenges that arise for different types of data, explore participant values and expectations about data sharing, and propose next steps for participant-centered data protections.

Learning Objectives:

•Discuss the implications of new data sharing requirements for researchers and IRBs
•Describe participant perspectives on data sharing, including unique considerations based on type of data and condition of study
•Identify opportunities to better align data sharing and consent practices with participant values

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

D10: Accessibility Basics: Making Word Documents and Videos Accessible

Track(s): Advancing Equity and Justice; Education, Qualifications, and Training; IRB Review; IRB Fundamentals; Social, Behavioral, and Educational Research

Ethical research must adhere to the principle of justice, which means that research studies (including informed consent) must be designed and conducted with accessibility in mind. Accessibility is crucial, not only because of the federal civil rights law Americans with Disabilities Act (ADA), but also to ensure that research is available to all people. This session will explain the terms and concepts associated with the ADA and accessibility, as well as provide solutions and tips for supporting accessibility in IRB review. This includes ways to make accessible documents, allow for physical accessibility of research sites, use of new and innovative tools such as AI to improve and expand access to research participation, and more.

Learning Objectives:

•Explain terms and concepts associated with the ADA and accessibility
•Learn the basics of making Word documents and videos accessible
•Provide solutions and tips for supporting accessibility in research and IRB review

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

IACUC

D11: Improving Efficiency and Effectiveness at the Intersection of IACUC and IBC Administration

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

IACUCs and research safety units (e.g., IBC, environmental health and safety) have independent and shared roles and responsibilities in the overall programmatic efficiency and effectiveness of animal care and use programs. This session will focus on developing and refining processes to improve the efficiency and effectiveness of these research compliance areas.

Learning Objectives:

•Review the regulatory and administrative oversight of IACUC and IBC programs
•Discuss operational and administrative processes and responsibilities of the various roles within the program(s) (e.g., IACUC, IBC, OHSP)
•Identify challenges inherent in these programs and share solutions (e.g., develop and refine processes) to improve the efficiency and effectiveness of these research compliance areas

Target Audience(s): ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; IBC Administrators, Managers, and Staff; IBC Directors; Compliance Personnel; Laboratory Animal and Veterinary Staff; Researchers and Research Staff; IBC Members, Chairs, and Vice Chairs

D12 (IACUC): Dealing With Conflict and Difficult Discussions: The Role of the IACUC Chair

Track(s): IACUC Review

For many institutions, the IACUC chair is often perceived as the leader of the animal care and use program. In that role, the IACUC chair is required to balance programmatic oversight with research productivity with nonhuman 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 the problems faced by IACUC chairs deal with conflict among members of the IACUC, during the IACUC meeting itself, or even among different interacting committees. This session will use scenarios to explore strategies for coping with conflict resolution in an IACUC meeting.

Learning Objectives:

•Discuss IACUC leadership challenges for resolving conflict within an IACUC meeting
•Identify opportunities for promoting collegiality and managing tensions in the meeting and beyond
•Explore how to lead without authority (i.e., how does the chair manage a committee with individuals who may be higher in the hierarchy)

Target Audience(s): IACUC Members, Chairs, and Vice Chairs

D13 (IACUC): Wildlife Animal Welfare 101: A Foundational Overview for Navigating the World of Oversight and Compliance With Free-Range Species

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

This introductory session will cover the basic tenets of the use of wildlife in research with an emphasis on the interpretation of the Animal Welfare Act and Regulations, The Guide, and the Professional Taxon-Specific Guidelines in the context of oversight and compliance.

Learning Objectives:

•Learn the basic laws and policies involved in the oversight and compliance of wildlife animal use activities in the United States
•Discuss the roles of principle investigators, attending veterinarians, and IACUCs in assessing wildlife animal use activities
•Review the unique considerations IACUCs must take into account when assessing wildlife animal use activities
•Provide brief examples and scenarios for discussion

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

D14 (IACUC): Looking Inside the Cabinets: IACUC Facility Inspections from Start to Finish
Track(s): ACU/IACUC Program Management and Administration; Education, Qualifications, and Training; IACUC Basics

IACUC facility inspections are a critical component of an animal care and use program, but a lot goes into making them efficient and effective. This session will take a high-level look at the facility inspection process from start to finish, sharing tips and strategies to help you stay in compliance, reduce administrative burden, and support a robust animal care and use program.

Learning Objectives:

•Learn the regulatory requirements that relate to performing IACUC facility inspections, documenting and reporting findings, and completing corrective actions
•Review strategies and logistics related to IACUC facility inspections, including scheduling, conducting, documenting, following-up, and reporting
•Discuss methods for training IACUC members to perform facility inspections, including new member training and continuing education

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

D15 (IACUC): Impactful Animal Welfare Refinements When Options Are Limited and the Need Is Great
Track(s): Animal Well-Being and the 3Rs; ACU/IACUC Program Management and Administration; IACUC Review

Protocols that are likely to involve pain and distress pose special challenges for IACUCS, especially when options for mitigation may be limited. This session will discuss research areas where this can be a concern, such as high containment research, disease characterization, vaccine research, sepsis studies, and oncology research. Speakers will also explore ways to improve the welfare of the study animals.

Learning Objectives:

•Discuss research areas where animal use presents special welfare challenges
•Identify practical approaches to improve welfare even in the face of environmental or study-based limitations
•Create buy-in and a roadmap for implementation

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

Crossover

D16: A Crisis Is a Crisis: Lessons Learned From Human-Based and Animal-Based Controversies and What We Can Learn From Our Colleagues Across the Hall
Track(s): Communication With the Public; ACU/IACUC Program Management and Administration ; HRPP/IRB Management and Administration; Shared Research Oversight Challenges; Research Oversight Leaders and Institutional Officials

In many organizations, the management and oversight of human-based research and animal-based research are often highly siloed. This means that when unforeseen incidents occur, response approaches - both internally and externally - can be vastly different. In reality, there is much to be learned from the successes and failures of managing both human-based and animal-based crisis situations. This session will seek to bring both parties together to discuss past successes, failures and suggest out-of-the-box collaborative solutions when controversies arise in either animal or human-focused labs.

Learning Objectives:

•Examine the similarities and differences between animal-focused crisis and human-focused crisis
•Identify some of the most powerful strategies used in human-based crisis circumstances that might also be used in animal-based crisis circumstances
•Highlight current hurdles to launching more powerful communication strategies for animal-based controversies
•Discuss methods for reducing or removing those hurdles

Target Audience(s): Research Program Leadership and Institutional Officials; Compliance Personnel; HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; Public Relations Professionals; ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff

D17: Shipping Human and Animal Biospecimens: Perspectives from the Field
Track(s): ACU/IACUC Program Management and Administration; HRPP/IRB Management and Administration; Legal Considerations in Research Oversight; Pharma/Biotech Perspectives

Trade compliance is a crucial aspect of shipping human and animal biospecimens. This session will discuss some of the export challenges and import license requirements that we face when dealing with different countries and regions. Human and animal biospecimens must adhere to valuation requirements otherwise shipments will be held at customs and senders can be fined. One of the main issues encoutered is trade sanctions with certain countries, which limit our access to biospecimens and data from certain areas. This session will share the perspectives of trade compliance experts and offer some solutions and best practices for shipping biospecimens globally.

Learning Objectives:

•Understand basics of trade compliance process (import and exports)
•Explore the challenges of shipping human and animal material (e.g. trade country sanctions)
•Discuss best practices for shipping biospecimens globally

Target Audience(s): HRPP/IRB Directors; ACU/IACUC Directors; Legal Counsel; Compliance Personnel; Clinical Research Professionals; Researchers and Research Staff

D18: Hiring , Diversity and Soft Skills: How Do We "Walk the Talk" and Get What We Need/Want From New Hires?
Track(s): Education, Qualifications, and Training; ACU/IACUC Program Management and Administration; HRPP/IRB Management and Administration

This session will discuss pragmatic topics like writing job descriptions using accessible language and how to conduct interviews that are welcoming and support new entry into a niche field of expertise. Presenters will highlight the "soft skills" to seek in potential applicants, and the tools and necessary training to keep them engaged. Finally, this session will cover how to keep new hires engaged in regulatory content through peer mentoring programs and relevant training.

Learning Objectives:
•Evaluate current hiring job posts and practices to support a diverse new workforce that does not have prior regulatory background
•Recommend interview questions to evaluate potential candidates based on their responses, and learn how to evaluate soft skills
•Discuss how to facilitate a peer mentoring program throughout the HRPP for new employees to understand the totality of the responsibility of IRB review and application

Target Audience(s): HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; Research Program Leadership and Institutional Officials; Educators/Trainers; ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IBC Directors; IBC Administrators, Managers, and Staff

Institutional Leadership

D19: Do Institutional Officials (IOs) Understand Ethics?
Track(s): ACU/IACUC Program Management and Administration; HRPP/IRB Management and Administration; Research Oversight Leaders and Institutional Officials; Shared Research Oversight Challenges

Many times, IOs achieve the position without ever receiving a formal education in ethics. That said, the IO role often involves ethical decision-making, the evaluation of the ethical decisions made by others, and policy development that incorporates ethical concepts. As such, IOs should have a basic grounding in ethics as applied to human and non-human animal research. This session will review, at a high level, the most important ethical theories and frameworks relevant to the IO role to ensure effectiveness.

Learning Objectives:
•Identify important ethical theories and frameworks relevant to the IO role
•Delineate between ethics, compliance, and integrity when it comes to research
•Review the IO role as it relates to the welfare of human and non-human animal in research
•Discuss how IOs can embark on self-learning to equip themselves for the ethical questions they will face, including identifying others within an institution that can provide contextual support for ethical decision-making

Target Audience(s): ACU/IACUC Administrators, Managers, and Staff; ACU/IACUC Directors; Compliance Personnel; HRPP/IRB Administrators, Managers, and Staff; HRPP/IRB Directors; IBC Administrators, Managers, and Staff; IBC Directors; Legal Counsel; Research Program Leadership and Institutional Officials

D20: Retaining Good Research Ethics and Oversight Staff
Track(s): ACU/IACUC Program Management and Administration; HRPP/IRB Management and Administration; Research Oversight Leaders and Institutional Officials; Shared Research Oversight Challenges

People are the key to success of the research program. How can institutional leaders establish an environment where key staff are developed, encouraged, and retained? During this session, speakers from peer institutions will discuss their experience with career ladders, training, empowerment, and other topics to support the retention of good staff. This session will also include time for an interactive discussion on the role institutional leadership has in cultivating an environment where good staff are encouraged in their work and have a desire to stay.

Learning Objectives:
•Understand the key elements of professional development for research ethics and oversight staff
•Identify career ladders and how they can be implemented
•Discuss the role institutional leadership plays in creating an environment to retain good staff and encouraging a learning workplace

Target Audience(s): ACU/IACUC Administrators, Managers, and Staff; ACU/IACUC Directors; Compliance Personnel; HRPP/IRB Administrators, Managers, and Staff; HRPP/IRB Directors; IBC Administrators, Managers, and Staff; IBC Directors; Legal Counsel; Research Program Leadership and Institutional Officials

11:45 AM-1:30 PM PT **Lunch Break.** Lunch on your own (kiosks open in exhibit hall).

12:30 PM-1:30 PM PT **Meet and Greet With the Supporters and Exhibitors**

12:30 PM-1:30 PM PT **View the PRIMR23 Poster Abstracts**

12:30 PM-1:30 PM PT **Federal Agency Office Hours**

During this time, representatives from federal agencies, the accrediting bodies, and/or the CIP and CPIA Councils will be available to answer attendee questions, engage in dialogue, and/or direct attendees to additional resources. Attendees are encouraged to come prepared with questions, which will be taken on a first come basis. To participate, go to the Exhibit Hall and locate the Office Hours table(s) for the agencies participating in this timeslot. **Only the following organizations are participating in this timeslot**:
* AAHRPP, Inc.
* DOE
* FDA
* OHRP
* CIP Council
* CPIA Council

PRIMR24 Networking Block, 12:30 PM-1:30 PM PT

N12: Quality Connections Networking: Exchange QA/QI Tips, Tools, and Tactics

Track(s): QA/QI and Postapproval Monitoring

This session is an opportunity to meet and trade QA/QI resources and discuss strategies and challenges. Use this session to make QA/QI connections and build community. No need to be shy -- our facilitators can kick start the discussion with ice breakers and discussion questions to make this networking session fun and fruitful. All size shops and skill levels are welcome!

Learning Objectives:

- Make connections with QA/QI professionals
- Build a network of colleagues from a variety of institutions
- Utilize your new network to leverage expertise, discover existing resources, and be a sounding board for your own QA/QI initiatives and challenges

Target Audience(s): QA/QI Professionals

N13: An Update from the Consortium to Advance Effective Research Ethics Oversight (AEREO): Progress in Defining and Measuring HRPP and IRB Quality and Effectiveness
Track(s): HRPP/IRB Management and Administration; IRB Review

The AEREO Consortium (www.aereo.org) is a collaborative group of volunteers working to understand what it means for HRPPs/IRBs to "work," identify meaningful measures of HRPP/IRB quality and effectiveness, evaluate how well HRPPs/IRB are working now, and pursue evidence-based ways to help them work better. This session will describe AEREO's goals, progress to date, and plans for the future, with an invitation to join the Consortium's work. We will share information about AEREO's vision for "pillars" of HRPP/IRB quality, with participant protection and facilitation of ethical research at the foundation, supported by pillars focused on expertise, deliberation, community engagement, and others. Each pillar is informed by empirical and conceptual projects, which contribute to recommendations and tools for further testing and adoption to improve quality.
•Explain the difference between HRPP/IRB quality and effectiveness in contrast to efficiency and compliance
•Identify the core pillars of HRPP/IRB quality
•Describe promising approaches to evaluating HRPP/IRB quality and effectiveness

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

N14: Wildlife Animal Welfare 101: Networking Follow-Up Session
Track(s): Oversight of Non-Typical Animals and Situations; IACUC Basics

Did you attend the breakout session titled, "Wildlife Animal Welfare 101"? Do you have new questions and/or want to continue the discussion? Do you have ideas on how to approach the issues that were discussed and/or thoughts and experiences to share? Join this networking session to connect with colleagues and speakers to continue the conversation started during the earlier session!
•Reflect on key concepts and insights gained from the "Wildlife Animal Welfare 101" session
•Discuss strategies and methods for addressing wildlife animal welfare issues
•Exchange personal and professional experiences related to wildlife animal welfare

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

N16: Thriving in the Small Program Oasis: Navigating Challenges and Cultivating Success for the Single-Person Office
Track(s): Education, Qualifications, and Training; HRPP/IRB Management and Administration

Working in single-person offices and small programs can often feel like being on a desert island, but it doesn't have to be isolating. Join us for a dynamic session that expands on the challenges faced by single-person offices and small programs and offers valuable insights on empowering compliance professionals to thrive in a small program oasis. Expand your network while we explore strategies for prioritizing processes, building collaborative relationships, and discuss practical education initiatives.
•Gain practical insights into optimizing processes
•Explore strategies for establishing and maintaining collaborative relationships
•Share practical tips for delivering educational initiatives with limited resources

Target Audience(s): ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; Compliance Personnel; Educators/Trainers; IACUC Members, Chairs, and Vice Chairs; IBC Directors; IBC Administrators, Managers, and Staff; IBC Members, Chairs, and Vice Chairs; HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs

PRIMR24 Content Block E , 1:45-3:00 PM PT

HSR

E1: Fast Forward: Update on Inclusion of Sexual and Gender Minorities in Clinical Research
Track(s): Advancing Equity and Justice

In the 2023 PRIM&R Annual Conference Plenary Session "It's About Time: Inclusion of Sexual and Gender Minorities in Clinical Research" the panel outlined barriers to LGBTQIA+ participation and/or visibility in clinical research, strategies to encourage appropriately expansive eligibility criteria, and emerging practices around sexual orientation, gender identity (SOGI), and variations in sex characteristic data collection. Equitable and diverse representation in clinical research is a rapidly evolving area and just one year can involve a broad scope of change in the regulatory environment, available guidance and tools, and practical experience through testing of novel approaches. This panel aims to provide an overview of these changes, implications for clinical trial oversight and practice, and new challenges on the road ahead.
Learning Objectives:
•Review emerging guidance from the federal level and clinical research organizations for collection of sexual orientation and gender identity (SOGI) data, and the development of interoperable data standards
•Explore new tools for LGBTQIA+ Inclusion by Design in clinical research, on topics such as inclusive language, data collection and privacy, and accountabilit
•Understand how different clinical research stakeholders, such as IRBs and sponsors, have navigated adding SOGI questions to data collection templates and surveys, and discuss lessons learned

Target Audience(s): HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Research Program Leadership and Institnutioal Officials; Legal Counsel; Clinical Research Staff; Researchers and Research Staff; Equity, Inclusion, and Justice

E2: Key Information in Informed Consent: Ethical Principles, Policy, and Practice

Track(s): FDA Regulated Research; Informed Consent

In response to the growing length and complexity of consent documents, the revised Common Rule added two provisions: that require informed consent to begin with key information about the research which is to be presented in a clear and concise manner, and that informed consent as a whole be presented in a way that facilitates understanding of the reasons why someone might or might not want to participate in research. FDA issued a proposed rule to adopt identical language to harmonize with these provisions. In March 2024, FDA and OHRP published joint draft guidance discussing suggested approaches to presenting key information and facilitating understanding in the informed consent, including oral, written, and electronic consent. This session will address proposed approaches to key information and consent changes as described in draft guidance and discuss opportunities and challenges to reviewing key information and enhanced consent materials.

Learning Objectives:

•Understand how the key information provision helps support respect for persons
•Describe the FDA and OHRP draft guidance on the presentation of key information and recommendations for the content, organization, and presentation of informed consent
•Identify considerations for presenting key information and enhancements to aid understanding in informed consent

Target Audience(s): IRB Members, Chairs, and Vice Chairs;HRPP/IRB Administrators, Managers, and Staff

E3: All Things Subpart C

Track(s): Populations Requiring Additional Protections; IRB Review; IRB Fundamentals; Social, Behavioral, and Educational Research

Prisoners who participate in research are considered a vulnerable population and are afforded additional protections under subpart C of HHS regulations, 45 CFR 46. It's critical that IRB members understand the historical and ethical basis of the regulations in order to make informed decisions around the challenges associated with including individuals who are incarcerated. For example, what are the regulatory requirements when a subject becomes a prisoner during the course of the study? Are parolees considered prisoners under Subpart C? What types of activities can and cannot be conducted inside a prison, and what requirements and expectations exist around privacy and confidentiality for people who are incarcerated? Speakers will provide an ethical, regulatory, and historical foundation in order to equip attendees to address such questions.

Learning Objectives:

•Learn how a "prisoner" is defined under Subpart C
•Investigate the requirements surrounding a prisoner representative on the IRB
•Discover if greater than minimal risk research can be conducted with prisoners as subjects

Target Audience(s): IRB Members, Chairs, and Vice Chairs; HRPP/IRB Administrators, Managers, and Staff

E4: Building Trust in Science: Enabling Frameworks for Returning Individual Research Results to Research Participants

Track(s): Emerging Research Challenges and Breaking Issues; HRPP/IRB Management and Administration; IRB Review

As the research paradigm shifts to becoming more participant-centered, calls to return research results have grown as a means to promote respect for participant autonomy, facilitate long-term engagement, and further recruitment of diverse participants in studies. However, returning results to participants is not without its challenges, including navigating a complex regulatory environment, ethical considerations, and the need for infrastructure and support. This session will explore emerging frameworks, tools, and best practices in returning individual research results, including beyond genomic data, while highlighting current gaps and opportunities.

Learning Objectives:

•Describe current tools and approaches for returning individual research results and how these activities help to build trust in science through promoting respect to participants as partners
•Examine the evidence base, gaps, and opportunities to strengthen and advance the return of research results
•Understand ways in which NIH and others are advancing work to enable frameworks for the responsible return of results from biomedical and behavioral research to participants who wish to receive their personal information

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

E5: A Dialogue with the Department of Veteran Affairs (VA)

Track(s): A Dialogue with the Feds

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

Learning Objectives:

•Describe VA research initiatives, including the Office of Research and Development's (ORD) status of its reorganization and enterprise-wide approach for supporting VA research facilities with new and upcoming initiatives
•Describe VA's role in the White House Cancer Moonshot initiative and implementation of Decentralized Clinical Trials
•Identify key issues and solutions from both ORD and the Office of Research Oversight (ORO) associated with multi-site research activities

Target Audience(s): 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

E6: Couch to QA/QI: Creating a QA/QI Program

Track(s): QA/QI and Postapproval Monitoring

Need to get your QA/QI program off the ground? Don't reinvent the wheel! Come to this session to get an introductory understanding of QA/QI. Learn more about common QA/QI hurdles and how to overcome them on the marathon of continuous quality improvement.

Learning Objectives:

•Learn how and where to access basic tools, templates, and resources
•Discover how to assess your institution's specific needs and priorities with respect to QA/QI
•Discuss how to adapt existing tools, templates, and policies to your identified institutional context
•Examine the multi-faceted nature of QA/QI programs and approaches, ranging from post-approval monitoring to proactive educational outreach

Target Audience(s): QA/QI Professionals; HRPP/IRB Administrators, Managers, and Staff; HRPP/IRB Directors

E7: Using Artificial Intelligence (AI) to Author Key Information (KI) Sections of Human Research Consent Documents

The KI section of the Informed Consent Document (ICD) is intended to provide information that would be most important to individuals contemplating participation in the study. A pilot effort involved guiding GPT4 through linguistic tasks to generate working drafts of study specific KI sections based on content in the body of the ICD and existing IRB template language. GPT4-generated KI sections were scored by research investigators and IRB review experts for factual accuracy, clarity, readability, and potential for future use by research investigators.

Learning Objectives:

•Discover the benefits of using an AI tool to develop components of human research documents
•Examine the infrastructure necessary to develop and support an AI guided process and web interface for use by researchers
•Discuss challenges to using AI tools in the human research environment

Target Audience(s): HRPP/IRB Directors; IRB Members, Chairs, and Vice Chairs

E8: Building Bridges: Towards an International Framework for Specimen Sharing (Part II)

This session aims to further the discourse initiated in a session held at PRIMR23, focusing on the utilization of biospecimens in international research. The session will expand into the complexities and challenges posed by the lack of a harmonized framework for ethical, legal, and policy considerations, which are crucial for facilitating research endeavors. An update will be provided for the status of the Seattle principles, a proposed set of guidelines designed to foster ethical and responsible international research involving biospecimens. Also, this session will take a deep dive into dissecting the conflicting regulations among various countries, particularly the differences in consent requirements that researchers and IRB staff must navigate. Speakers will discuss strategies to manage the intricate web of regulatory differences across borders.

Learning Objectives:

•Review the general challenges with international biospecimen sharing
•Learn about the differences in regulations with biospecimens
•Explore the Seattle principles and institutional policies

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

E9: Robots in Disguise: When Your Participants are More Than Meets the Eye

Track(s): Research Involving Data and New Technologies; Emerging Research Challenges and Breaking Issues; IRB Review; Social, Behavioral, and Educational Research

Bots designed to imitate human research participants can respond to online research prompts, muddy research integrity, and jeopardize human subjects recruitment. Bot-generated responses are challenging to detect if researchers do not implement design safeguards (e.g., attention checks) and over-protective research designs can impact equitable recruitment, limiting access to the study for qualified human subjects. Bot designers often target studies with participant compensation and cost research teams time and money. IRB reviewers and researchers aiming to anticipate and address bot incidents need a broad organizational plan and response. Based on lessons learned from case studies, speakers will offer strategies and resources for anticipating and responding to bots by identifying IRB and researcher (mis)steps, strategic and thoughtful safeguard moves, and interdepartmental routines for research compliance and bot prevention.

Learning Objectives:

•Discuss the IRB's roles and responsibilities in responding to a bot incident
•Present a workflow for collaborating with other HRPP staff in one's organization to address bots
•Provide best practices and tools that support research compliance staff when a bot incident occurs

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

E10: The Essentials of Onboarding and Training IRB Administrators

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

Onboarding new IRB administrators is complex and time-consuming, but it is one of the most important tasks. Many IRBs are facing staffing challenges and/or constant staffing turnover due to the increased availability of remote job opportunities. This has forced IRB offices to think about how to provide innovative training and education. This session will discuss the training plans implemented at two large academic medical center IRB offices.

Learning Objectives:

•Learn strategies for recruiting high-performing IRB administrators
•Identify the challenges with training and how to turn them into opportunities
•Share how to influence and enhance team morale and productivity

Target Audience(s): HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; Educators/Trainers

IACUC

E11: Ensuring Consistency With Both the Letter AND Spirit of Regulations at the Local Institutional Level in Nonhuman Animal Research

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

In the US regulatory system, local IACUCs are charged with the review and oversight of research with nonhuman animals, and these IACUCs interpret and implement federal, state, and local, regulations, policies, and standards. The strength of this decentralized system is that it allows for agility, flexibility, and application of performance standards to protocol review and oversight of ongoing research in a manner that facilitates both research the welfare of the nonhuman animals involved in the study. However, a decentralized system also introduces the potential for variance across (and sometimes within) (e.g., the same type of study or experimental procedure may receive different pain categorization depending on the institution). From a public perspective, variation across institutions may appear capricious and it as the potential to undermine confidence in the system for oversight of nonhuman animal research. From a researcher perspective, such variance may lead to uncertainty in research planning and implementation. From a rigor and reproducibility perspective, such variance may lead to arbitrary, non-scientifically grounded decisions about research procedures. This session will provide an opportunity for attendees to explore why the US system depends on decentralization and how variance in interpretation of core principles can be challenging from multiple perspectives.

Learning Objectives:

•Evaluate the strengths and weaknesses of a decentralized system
•Analyze the potential problems that arise from variance in interpretation and implementation of regulations and standards across different IACUCs within an institution
•Discuss the implications of this decentralized model on public perception of nonhuman animal research and confidence in research outcomes
•Share strategies to mitigate potential negative consequences of institutional variance in IACUC oversight, and that aim to enhance transparency, consistency, and accountability in nonhuman animal research

Target Audience(s): ACU/IACUC Administrators, Managers, and Staff; ACU/IACUC Directors; Compliance Personnel; IACUC Members, Chairs, and Vice Chairs; Researchers and Research Staff

E12 (IACUC): How to Manage a Noncompliance or Adverse Event

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

This session will explore how the IACUC should proceed after a report of a noncompliance or adverse event, with a particular focus on guidance from AAALAC International concerning self-reporting of adverse events. Noncompliance and unanticipated adverse events (e.g., water supply issues, lack of feed) may be individually addressed by the IACUC when they occur, but developing a system to track and assess the occurrence of such events can outline areas for improvement within the program. During this session, speakers will examine when these types of events rise to a level of concern, and will explore the responsibility of the IACUC to investigate and/or track events and when events should be reported to AAALAC International. This session will further review the need for an institutional "Adverse Event Assessment and Management Plan" and share best practices for IACUCs and institutions to communicate and self-report to AAALAC International. Attendees are invited to share their institutional plan for collegial, low stakes guidance from the speakers.

Learning Objectives:

•Define noncompliance and adverse events and understand the distinction between significant versus minor events
•Learn how the animal care and use program can evaluate trends in noncompliance and adverse events to continuously improve the program
•Review AAALAC International guidance on adverse event reporting and management
•Discuss elements of an adverse event reporting plan and explore different ways to fulfill the AAALAC International expectation for use of such a plan

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

E13 (IACUC): From Alpacas to Zebrafish: How to Select and Evaluate Environmental Enrichment

Speakers: Keely McGrew from Charles River Laboratories; Tara Martin from the University of Michigan; Anastasia Schimmel, Mgr Ani Hlth Tech & Enrichment (UCLA enrichment coordinator)

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

Environmental Enrichment is a fundamental component of nonhuman animal welfare and should enhance nonhuman animal physical and psychological well-being. Thus, enrichment plans should be selected based upon the natural behaviors they are intended to support, and plans can vary greatly especially for non-typical species. How do we identify the behavioral goal and measure if it was achieved? In this session, speakers will review environmental enrichment requirements and provide an overview of resources available to support nonhuman animal programs evaluating enrichment. This information aims to empower staff to undertake robust evaluations of environmental enrichment items and assess their impact on nonhuman animal welfare.

Learning Objectives:

•Discuss the regulatory requirements for environmental enrichment and the different enrichment methods
•Learn how to identify and define a behavioral goal for the species and select/create an enrichment plan to support the goal
•Explore how to measure whether the behavioral goal was met by the enrichment selected for the species of interest

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

E14 (IACUC): Specialized IACUC Applications for Studies in the Field

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

Traditional IACUC protocols for laboratory-based studies do not cover many areas critical to the welfare of nonhuman animals studied in the field. These protocols may be overly burdensome and frustrating for field researchers. The IACUC must review topics relevant to field research including capture, restraint, marking/identification, nonhuman animal care and euthanasia in the field, and release of nonhuman animals back into the environment. How can the IACUC effectively collaborate with field researchers to efficiently collect information required to fulfill its oversight responsibilities?

Learning Objectives:

•Identify protocol questions that are key to a thorough review of studies in the field
•Discuss opportunities to reduce burden on the IACUC and researchers for IACUC review and approval of wildlife studies
•Understand the key areas the IACUC should consider to ensuring nonhuman animal welfare in wildlife studies
•Gain insights into the operational procedures and best practices of IACUC Administrators at their respective institution

Target Audience(s): ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; Compliance Personnel; Researchers and Research Staf; ACU/IACUC Directors

E15 (IACUC): Improved Communications About Nonhuman Animal Studies: Starting on the Inside

Track(s): Communication With the Public

Many research organizations are hesitant to communicate externally about their use of nonhuman animals in research for fear that doing so will make them a primary target by opponents. As a result of this failure to communicate, internal communications about nonhuman animal research are often minimal and communications departments significantly understaffed. Therefore, one of the most powerful and low-risk improvements an organization can make is to expand internal communications and assign specialized staff for this important task. Building up these resources can benefit the institution both internally and externally. This session will explore the many benefits of expanding internal communications and provide guidance for doing so in every kind of research organization from small to large.

Learning Objectives:

•Provide guidance about improving internal communications to increase staff engagement and morale while emphasizing the importance of two-way communications (i.e., listening to employees and responding)
•Share ideas for engaging non-animal care staff and removing some of the negative stereotypes and misunderstandings about nonhuman animal studies that are commonplace in large, diverse workplaces where a significant number of staff do not have day-to-day experience with these studies
•Explore how to engage and better educate communications to help improve proactive and reactive external communications about nonhuman animal studies (so employees are better prepared to respond to questions surrounding your organization's use of nonhuman animals in research)
•Offer suggestions to small organizations that may not have specialized communications staff (i.e., this work often falls on IACUC administrators)

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

Crossover

E16: Done Wrong, Gotta Pay: Research Non-compliance and Research Misconduct and Possible Sponsor Pay-Back

Track(s): Education, Qualifications, and Training; HRPP/IRB Management and Administration; ACU/IACUC Program Management and Administration; Shared Research Oversight Challenges; Research Oversight Leaders and Institutional Officials; Legal Considerations in Research Oversight

HRPP and ACUP leaders are rarely directly concerned with the funding of research, our responsibilities generally exist and are the same whether there is external funding or not. One area where HRPP and ACUP leaders must consider funding and sponsorship, however, is in the assessment of non-compliance and/or research misconduct: incidents of reimbursement to sponsors due to the identification of noncompliance or misconduct in the conduct of the research. This session will provide an overview of and the role of HRPP/ACUP officials of the steps leading to the identification of noncompliance and/or misconduct from allegation to determination and the procedures an institution may have to consider and process possible reimbursement.

Learning Objectives:

•Identify and discuss institutional processes for the identification and assessment of research noncompliance misconduct and their relationship to research administrative community
•Examine circumstances under which research noncompliance and misconduct may require the institution to return funds to a sponsor - and explore processes that institutions have implemented for the management of this process
•Explore relevance and applicability for attendees and their institutions

Target Audience(s): ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; HRPP/IRB Directors; IRB Administrators, Manager and Staff; HRPP Leadership and Institutional Officials; Legal Counsel; Compliance Personnel; QA/QI Professionals

E17: Sex as a Biological Variable and as an Animal Welfare Variable

Track(s): IRB Review; IACUC Review; Pharma/Biotech Perspectives

This session will present an overview of sex as a biological variable. Failure of sex inclusion can impact results in both animal and human clinical research, but also introduce impacts to animal welfare, which can in turn create other confounding variables. This session will explore both scientific and welfare impacts.

Learning Objectives:

•Discuss sex as a biological variable and its implications for research, and sex as an animal welfare variable
•Understand how failing to account for sex can have primary impacts on the research in terms of hypothesis testing and secondary impacts from effects exerted through welfare impacts
•Explore best practices in terms of experimental design, animal care and use, and publication of research findings

Target Audience(s): Clinical Research Staff; Researchers and Research Staff; IACUC Members, Chairs, and Vice Chairs; IRB Members, Chairs, and Vice Chairs; Compliance Personnel

E18: What Institutional Leadership Needs to Know...From You!

Track(s): ACU/IACUC Program Management and Administration; HRPP/IRB Management and Administration; Shared Research Oversight Challenges; Research Oversight Leaders and Institutional Officials

Are you a committee administrator who needs to interface with institutional leadership and are not sure where to start? Do you have a new institutional official or leader and need to prepare them for their role? In this networking session, participants will discuss specific topics and share methods on how to inform--and not overwhelm--an institutional leader.

Learning Objectives:

•Learn what institutional leadership needs to know/be updated on and when (i.e., what is required vs. urgent vs. general awareness vs. hold-for-now)
•Consider how to communicate real or perceived risks, changes in regulations, or other matters that could have a material impact on the research program
•Explore who else in the institution can be a resource for information that institutional leadership needs to know
•Share best practices for a collaborative and collegial working relationship, especially if leadership was appointed to the position without much background on the role

Target Audience(s): ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; HRPP/IRB Directors; IRB Administrators, Manager and Staff; HRPP Leadership and Institutional Officials

Institutional Leadership

E19: Balancing Risk and Reward in Research Programs

Track(s): ACU/IACUC Program Management and Administration; HRPP/IRB Management and Administration; Research Oversight Leaders and Institutional Officials; Shared Research Oversight Challenges; Legal Considerations in Research Oversight

Achieving a balanced approach to managing risks in research programs demands a comprehensive strategy that includes assessing and mitigating risks, strategic planning, engaging stakeholders, ongoing monitoring, and fostering a culture of risk awareness and innovation, including consideration of financial risks, regulatory compliance, ethical considerations, and reputational harm. Institutional leadership should foster an environment of transparency and accountability, ensuring that all constituents are informed and involved in decision-making processes related to risk management. This session will provide a framework for assessing the risk environment and setting tolerance levels for individual research projects, and review common risk management approaches (e.g., risk avoidance, reduction, mitigation, aversion, acceptance, sharing, and retention).

Learning Objectives:

•Explore strategies for evaluating institutional risk tolerance
•Consider processes to implement that can anticipate studies necessitating further risk assessment
•Learn how to investigate procedures for conducting risk and benefit evaluations, including the establishment of a structured risk framework
•Determine essential constituents for decision-making and information dissemination, establishing a formalized risk assessment process

Target Audience(s): ACU/IACUC Administrators, Managers, and Staff; ACU/IACUC Directors; Compliance Personnel; HRPP/IRB Administrators, Managers, and Staff; HRPP/IRB Directors; IBC Administrators, Managers, and Staff; IBC Directors; Legal Counsel; Research Program Leadership and Institutional Officials

E20: Institutional Officials (IOs): Navigating the Complex Roles of IOs and the Model Best for Your Organization

Track(s): Research Oversight Leaders and Institutional Officials; Shared Research Oversight Challenges

IOs are responsible for ensuring compliance with federal, state, and institutional policies and regulations regarding human subjects research and nonhuman animal research. However, IOs often face conflicting demands and expectations from different stakeholders, such as researchers, regulators, administrators, sponsors, and the public. How can IOs balance their multiple roles and identities while maintaining their integrity and credibility? In this session, we will explore the various organizational models that IOs operate in, and discuss the challenges and opportunities they present. Speakers will also share strategies and best practices for IOs to manage their diverse responsibilities and relationships effectively. This session is intended for IOs, Research Integrity Officers, Compliance Officers, and anyone who works with or supports IOs in their institutions.

Learning Objectives:

•Describe the different organizational models that IOs serve in and the implications for the IOs' role and function
•Identify the common challenges IOs face in fulfilling their compliance and oversight duties
•Learn effective communication and negotiation skills to manage the expectations and interests of various stakeholders
•Develop a personal action plan to enhance performance and professional development as IOs

Target Audience(s): Research Program Leadership and Institutional Officials

3:00-3:30 PM PT **Break w/ food and drinks**

PRIMR24 Content Block F, 3:30-4:45 PM PT

HSR

F1: Risk Associated With Human Subjects Research: Who Are We Obligated to Protect?
Track(s): Emerging Research Challenges and Breaking Issues; IRB Review; HRPP/IRB Management and Administration

This session will explore participant, institutional, and investigator risk with research that is controversial. What is the HRPP/IRB's role and should it be influenced by institutional liability and risk? Examples may include research involving impacts of implicit bias of employees, research that involves occupational health hazards, research involving transgender youth, potential concerns about the safety of the research team, and repetitional risks or risks of being targeted.

Learning Objectives:
•Explore the HRPP/IRB's role in evaluation of risk to others and an institution
•Discover whether and how the regulations cover these issues
•Examine case studies to illustrate several examples for discussion

Target Audience(s): HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Legal Counsel; Researchers and Research Staff; Research Program Leadership and Institnutioal Officials

F2: Artificial Intelligence (AI) Days of Future's Past: Tomorrow's Research Yesterday
Track(s): Social, Behavioral, and Educational Research; HRPP/IRB Management and Administration; IRB Review; Research Involving Data and New Technologies; Emerging Research Challenges and Breaking Issues

In The Coming Wave: Technology, Power, and the Twenty First Century's Greatest Dilemma, M. Suleyman, CEO of Microsoft AI and formerly of Deepmind wrote, "The irony of general-purpose technologies is that, before long, they become invisible and we take them for granted." ChatGPT made a big mainstream splash over a year ago, and the general public's interest in AI shifted. But, is this AI phenomenon really new or is it a rapid scaling up at an exponential rate? The systems known by name were not created overnight. From helping write consent form key information sections to allowing researches to map brain waves and read the thoughts of a human being, it all happened yesterday. This session will explore how to stop playing catch-up and look forward at how IRBs and the research community at large will need to address the interwoven existence of AI in the fabric of our daily lives.

Learning Objectives:
•Explore the privacy issues AI poses when utilized in studies involving identifiable information, genetic testing, collection of brain waves, etc.
•Examine how AI cannot be addressed by policies or practices of the IRB alone, or even the HRPP
•Discuss whether AI is creating a third category or research outside of the binary biomedical vs. social/behavioral we have operated under for decades

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

F3: A Dialogue with the FDA

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(s): 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

F4: IRB Review of Research Involving Politicized Topics and Populations

This session will explore the IRB review of research that may involve increased risks to participants related to the sociopolitical environment and changes to law (e.g., reproductive health, gender-affirming care, immigration, diversity, etc.). Discussion will include the assessment of the '111' criteria, the reporting and review of significant new information, IRB reliance and local context, IRB minutes and records, and other areas of challenge and opportunity.

Learning Objectives:

•Review the application of the '111' criteria to research that involves risks related to the sociopolitical environment and changes to law

•Explore the evaluation of significant new information when risks to participants change as a result of changes in the sociopolitical environment and law

•Discuss challenges related to IRB reliance and the management of changes to local context

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

F5: The Ethical Conduct of Cell and Gene Therapy Research: Novel Challenges for Industry and the IRB

Track(s): Pharma/Biotech Perspectives; Research Involving Data and New Technologies

Cell and gene therapy presents complex challenges in trial design and implementation to ensure equitable recruitment, effective informed consent, and participant safety. The scientific and clinical novelty of each intervention, cost of treatment development, the irreversibility of the therapeutic intervention, and the required commitment by industry to long-term engagement with participants each create new standards for ethical conduct and its oversight that are distinct from other interventional trials. Fulfilling the goals of equitable and diverse enrollment introduces additional responsibilities. In this session, experts from industry and bioethics will describe the novel ethical demands of gene therapy trials in adults and in children and discuss model approaches.

Learning Objectives:

•Identify the distinct elements of cell and gene therapy trials requiring special ethical considerations

•Discuss the challenges of informed consent in cell and gene therapy in adults and in children

•Review the challenges of equitable participant recruitment and engagement in cell and gene therapy in medically underserved communities and low resource countries

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

F6: Human Subjects Research Determinations: Before and After the Fact

HRPPs are often contacted with requests for HRPP/IRB approval of a project that has already occurred. More often than not, these endeavors constitute a QA/QI undertaking or a project that fails the regulatory definition of research at its onset, with research "interest" occurring later (often when submitting findings for publication). Institutions may feel a lack of empowerment to interpret components of the regulatory definition of research where the regulations are silent (e.g., terms such as "research development" or "generalizable knowledge"). HRPPs must clearly communicate institutional policies and procedures for human subjects research determinations and local interpretation of regulatory requirements. This session will provide attendees with examples of different institutional interpretation of regulations and review pathways and helpful tips for how institutions and HRPPs can address requests for approval after a project is complete.

Learning Objectives:

•Explore methods to communicate and socialize institutional requirements for human subjects research determinations

•Review varied approaches to defining generalizable knowledge and QA/QI projects from several different HRPP representatives

•Discuss "noncompliance or not" for researchers seeking retroactive approval for projects

Target Audience(s): HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; HRPP/IRB Directors; Compliance Personnel; QA/QI Professionals; Researchers and Research Staff

F7: Adults with Developmental Disabilities and Research: Ethical, Legal, and Social Implications (ELSI) Solutions to Inclusion as Co-Researchers and Research Participants

Adults with developmental disabilities experience substantial health disparities. Enhancing research and health equity through community-engaged approaches is hindered by the absence of easily comprehensible research ethics education and inclusion strategies. Instead of prioritizing responsible inclusion based on justice, existing frameworks often rely on protections tied to perceptions of vulnerability, perpetuating enduring obstacles to these objectives. Speakers will present our new research ethics educational program for community researchers with developmental disabilities, including our multi-stakeholder engagement process and findings from our systematic review on approaches to consent/assent for adults with developmental disabilities.

Learning Objectives:

•Describe challenges to include adults with developmental disabilities as community researchers and research participants

•Explore a new resource to educate community researchers with developmental disabilities

•Discuss approaches to consent/assent with adults with developmental disabilities that integrate Belmont and Disability Rights principles

Target Audience(s): HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Educators/Trainers; Clinical Research Staff; Researchers and Research Staff; Diversity, Equity, Inclusion, and Justice

F8: Navigating Ethical and Institutional Considerations for Data and Biospecimen Sharing in the Era of Single (sIRB)

For nearly a decade, institutions and IRBs have been grappling with regulatory and policy requirements for sIRB review and increased expectations for data and biospecimen sharing. However, little guidance exists to help HRPPs/IRBs navigate the potential intersection of these regulatory and policy requirements and consider who is responsible for addressing data and specimen sharing requirements in the era of sIRB review. This interactive session will discuss the role of reviewing IRBs and relying institutions in addressing requirements for data and specimen sharing, and topics will include: funding requirements for data and specimen sharing, potential roles of the reviewing IRB and relying organization in managing these requirements, possible conflicts that may arise when institutional expectations differ from the determinations of the reviewing IRB, and recommendations for how these conflicts might be addressed.

Learning Objectives:

•Understand the unique considerations related to data and biospecimen sharing that arise within a sIRB model
•Identify roles and responsibilities of reviewing IRBs and relying institutions related to data and biospecimen sharing
•Discuss and examine potential challenges that may arise when navigating data and specimen sharing in a sIRB model and available solutions that may address those challenges

Target Audience(s): HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; Researchers and Research Staff; Research Program Leadership and Institnutioal Officials; Clinical Research Staff; IRB Members, Chairs, and Vice Chairs

F9: I Don't Remember This Being in the Training Manual: An Exploration of Challenging IRB Situations

This session will feature brief opening remarks from each panelist and then focus on an interactive session with participants about challenges of current IRB chairs/professionals and potential solutions to those challenges. We will build an ongoing email group for future discussions, providing an ideal networking event for IRB Chairs, Administrators, & IRB Members all over the country.

Learning Objectives:

•Gain a network of attendees that can continue to ask questions long after PRIM&R is completed
•Learn some of the challenges currently facing IRBs and different potential solutions to those challenges
•Explore questions and receive feedback on challenges they experience at their own institution

Target Audience(s): 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

F10: Designing an HRPP/IRB Website that Builds Trust

Track(s): HRPP/IRB Management and Administration

HRPP/IRB offices interact with research communities in various ways, with the website playing a vital role in ensuring information is readily available. Ensuring the website is cultivated in a way where information can be easily identified also assists in reducing frequently asked questions, thus minimizing the need for staff to continuously navigate those inquiries. This session will offer strategies, tips, tools, and best practices from experienced website designers to help you leverage your website to support the research community.

Learning Objectives:

•Discuss and evaluate HRPP/IRB topics and content most important or relevant for participants, potential participants, and the general public
•Explore how website architecture can support the HRPP/IRB and build trust through transparency and efficient communication, as well as offer strategies and approaches for assessing and designing online content that will help achieve the institution's goals
•Outline challenges, lessons learned, and recommendations for improvement based on experience and expertise working with IRBs, researchers, and the public

Target Audience(s): HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; Educators/Trainers

IACUC

F11: New and Evolving Considerations for Disaster Planning

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

Is it time to dust off and reconsider your disaster plan? Does it go far enough to protect the overall program and not just the animals in times 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(s): ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; Compliance Personnel; IACUC Members, Chairs, and Vice Chairs; Laboratory Animal and Veterinary Staff; Researchers and Research Staff; Research Program Leadership and Institutional Officials

F12 (IACUC): Unlocking the Potential of IACUC Members: A Comprehensive Guide to Training

Track(s): Education, Qualifications, and Training; ACU/IACUC Program Management and Administration; IACUC Basics

The Guide, the PHS Policy, and the Animal Welfare Act and Regulations present an expectation to ensure that IACUC members are provided with training opportunities to understand their work and role. Institutions often find it difficult to find the time or resources for training IACUC Members. This session will explore ideas and ways to provide an orientation for new members and opportunities for continuing education, in in an effort to build an engaged committee with members fully understanding their role.

Learning Objectives:

•Understand the reason for creating an effective training program for IACUC members

•Learn how to create an onboarding program for new members, while developing an effective continuing education program for existing members

•Explore how to unlock the benefits of effective protocol review, thorough inspection teams and in-depth meeting discussions

Target Audience(s): ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; Educators/Trainers; IACUC Members, Chairs, and Vice Chairs; Compliance Personnel

F13 (IACUC): Challenges and Opportunities in IACUC Administration at Underrepresented Minority (URM)-Serving Institutions

The session will emphasize the importance of equity and inclusion in animal research programs at URM-serving institutions. Participants will explore strategies for ensuring the representation and meaningful involvement of underrepresented populations in research design, decision-making processes, and animal care practices.

Learning Objectives:

•Explore the challenges and opportunities of IACUCs and animal care and research programs of US URM-serving institutions

•Compare and contrast experiences of researchers, IACUC members, and animal care program staff at URM-serving institutions with those at primarily white institutions (PWIs), as well as historical relationships among URM institutions with local PWI institutions

•Consider how the the work of the IACUC at an URM-serving institution encompasses programs designed to facilitate URM participation in science (e.g., summer research programs supported by NIH IDEA state initiatives)

Target Audience(s): ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; Compliance Personnel; Laboratory Animal and Veterinary Staff; Educators/Trainers; Researchers and Research Staff; Diversity, Equity, Inclusion, and Justice

F14: What Happened to ILAR and What is BAHSCR?

Track(s): A Dialogue With the Feds

The NASEM (National Academy of Science, Engineering, and Medicine) has rebranded ILAR (Institute for Laboratory Animal Research) to BAHSCR (Board on Animal Health, Science, and Conservation Research). This session will cover the transition and the path forward for BAHSCR and the Standing Committee on the Guide.

Learning Objectives:

•Review the transition of ILAR to BAHSCR

•Discuss future vision and objectives of BAHSCR

•Identify opportunities for involvement and future directions for BAHSCR

Target Audience(s): ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; QA/QI Professionals; Compliance

F15 (IACUC): Avoiding the Slippery Slope: Complimenting Semi-annual Reviews With a Program of Ongoing QA/QI Review

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

Whether an IACUC office is large or small, consisting of a team of individuals with a division of labor or just one or two people who do it all, the implementation of an ongoing program of QA/QI to supplement the semi-annual reviews can help in the identification, correction, and prevention of the slippery slope of process deviations and noncompliance. In this session, speakers will describe how they have developed and implemented such programs to identify and correct process deviations and noncompliance, as well as prevent future occurrences. Special attention will be paid to the role of the IACUC, office structure, and institutional leadership.

Learning Objectives:

•Discuss the role of proactive reviews of IACUC office processes, practices, and documentation to identify and correct process deviations and noncompliance
•Learn how challenges and approaches may vary due to various office sizes and structures
•Identify the challenges of implementing changes needed to bring the program back into compliance, while avoiding compliance over-reach

Target Audience(s): ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; QA/QI Professionals; Compliance Personnel

Crossover

F16: Conducting Research "With" and "Not On" Indigenous Populations

Track(s): Advancing Equity and Justice in Research; Education, Qualifications, and Training; Legal Considerations in Research Oversight; Shared Research Oversight Challenges

US Federal regulatory framework serve as the default for the oversight of human participants research. There can be a conflict between Western and indigenous approaches to science. When research includes American Indian and Alaska Native (AI/AN) communities, we tend to hold that same federal regulatory framework as the gold standard and the role of community requirements – or requirements of sovereign tribal nations - is treated as a secondary concern. For example, the US Federal regulations do not permit IRBs to consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) and focus on risks to individuals while the impact of the research and potential group harms may be of significant concern to AI/AN communities. This panel will take a step back from the Western-centric view and move away from competing regulatory or rules-based requirements and instead focus on the research needs, interests, and shared values guiding research efforts with AI/AN communities. In addition, the panel will explore how our shared experiences with the AI/AN community might inform the approach of researchers and research ethics professionals to build trust with other communities.

Learning Objectives:

•Understand the research needs and explore examples of current research efforts that involve the AI/AN communities
•Explore some of the challenges and successes of research collaborations that include AI/AN populations
•Identify best practices for relationship-building with an emphasis on shared values between US regulations and indigenous perspectives on research ethics
•Give advice to Identify approaches the research ethics community might adopt who review research that may involve indigenous peoples or their lands

Target Audience(s): ACU/IACUC Directors; ACU/IACUC Administrators, Manager and Staff; IACUC Members, Chairs, and Vice Chairs; HRPP/IRB Directors; IRB Administrators, Manager and Staff; IRB Members, Chairs, and Vice Chairs; IBC Administrators, Manager and Staff; Research Program Leadership and Institutional Officials; Researchers and Research Staff

F17: Trust Me, I Know What I'm Doing

At each level, research fundamentally relies on trust - public trust in the research enterprise, community trust in institutions and researchers, and equally but sometimes less discussed: trust between researchers and review committees. In this session, we'll explore the influence of trust dynamics between researchers (commonly seen as the regulated?) and review committees (seen as the regulators?) on the function and cultural ethos of HRPPs and IACUCs. Additionally we will examine how these relationships affect the overall ethical decision-making processes in research environments. We'll share helpful tips and strategies on how to build trust around shared missions of protecting research subjects (be they animal or human!), and how to navigate and possibly rebuild when trust is broken.

Learning Objectives:

•Explore and understand the dynamic of trust (and mistrust) can have the researcher-committee relationship
•Creating a culture of trust: Identify strategies to build trust between researchers and review committees (Regardless of which side you're on!)
•Identify and Address trust breaking incidents: Discuss proactive measures to prevent the breakdown of trust and responsive strategies for restoration

Target Audience(s): ACU/IACUC Directors; ACU/IACUC Administrators, Manager and Staff; IACUC Members, Chairs, and Vice Chairs; HRPP/IRB Directors; IRB Administrators, Manager and Staff; IRB Members, Chairs, and Vice Chairs; IBC Administrators, Manager and Staff; Research Program Leadership and Institutional Officials

F18: Shake It Up: An Interactive Discussion of Lessons Learned from IRB/IACUC Leaders
Speakers:
Track(s): Shared Research Oversight Challenges; Research Oversight Leaders and Institutional Officials; IRB Review; IACUC Review
Whether you're replacing a respected and effective leader or were hired to make significant programmatic changes, leadership requires institutional knowledge, strong allies, and a creative vision of the future state of the program. Learn strategies from speakers who lead IRB/IACUCs through case study analysis and collective problem solving.
Learning Objectives:
•Utilize case studies to illustrate unique challenges and strategies for success when entering the role of an IRB/IACUC leader
•Recognize ways to stay current with your organization's vision and goals by learning and respecting your institution's culture
•Identify needed resources and allies who support a stable and compliant research enterprise

Target Audience(s): ACU/IACUC Directors; ACU/IACUC Administrators, Manager and Staff; HRPP/IRB Directors; IRB Administrators, Manager and Staff; HRPP Leadership and Institutional Officials

Institutional Leadership

F19: Proposed Changes to the Public Health Policy (PHS) on Research Misconduct: Impact on the Researcher Community
Track(s): ACU/IACUC Program Management and Administration; HRPP/IRB Management and Administration; Research Oversight Leaders and Institutional Officials; Shared Research Oversight Challenges; Legal Considerations in Research Oversight
The Office of Research Integrity issued a notice of proposed rulemaking in October 2023 to update its 2005 PHS Policies on Research Misconduct. However, from the research community perspective, the proposed changes seem to reflect diminished trust in science and research/researchers. While the intention is to enhance transparency and trust, the proposed rule includes features that have the potential to undermine trust and jeopardize reputations. Successfully navigating the new regulation to maximize the positive and minimize the negative ramifications will have substantial impact on researchers, research administrators, and regulators.
Learning Objectives:
•Understand the changes to the rule
•Explore the impact on institutional policies and procedures
•Discuss strategies for successful implementation

Target Audience(s): ACU/IACUC Administrators, Managers, and Staff; ACU/IACUC Directors; Compliance Personnel; HRPP/IRB Administrators, Managers, and Staff; HRPP/IRB Directors; IBC Administrators, Managers, and Staff; IBC Directors; Legal Counsel; Research Program Leadership and Institutional Officials

F20: Developing an Emergency Preparedness Plan for an Effective Research System
Track(s): ACU/IACUC Program Management and Administration; HRPP/IRB Management and Administration;
Over the past several years, events, such as widespread hurricane damage and the COVID-19 pandemic, have demonstrated the importance of having an emergency preparedness plan for both human and non-human research programs. An emergency preparedness plan is a set of policies and procedures that aim to ensure the continuity and quality of research activities, and minimize the potential risks and disruptions caused by unforeseen events or disasters (e.g., natural hazards, public health emergencies, cyber-attacks, civil unrest, or institutional crises). This session will provide an overview of the key components and steps involved in developing and implementing an emergency preparedness plan, and will discuss best practices for and challenges around emergency preparedness in different types of research settings and scenarios.
Learning Objectives:
•Describe the purpose and scope of an emergency preparedness plan for an effective research system
•Identify the essential elements and processes of an emergency preparedness plan (e.g., risk assessment, mitigation strategies, communication plans, contingency plans, and recovery plans)
•Learn how to develop, evaluate, and update an emergency preparedness plan based on best practices and lessons learned from simulated or real emergency situations

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

PRIMR24 Networking Block, 5:00-6:00 PM PT

N16: Human Subjects Research Trivia!
Track(s): HRPP/IRB Management and Administration; IRB Review; Social, Behavioral, and Educational Research; IRB Fundamentals
This session will be a review of regulatory requirements in the form of a game. Categories include 2018 Common Rule, vulnerable subjects, informed consent, investigational drugs, and investigational devices and expanded SBER content! Attendees will be divided into teams. After a team provides the question to the answer given, the host will provide an explanation for the answer. This session experience will help attendees understand the fundamentals, as well as serve as a refresher for people with advanced knowledge. In addition, attendees will build teamwork skills while developing an answer to questions about human subject research.
Learning Objectives:
•Understand HRPP/IRB and research ethics fundamentals
•Build teamwork skills
•Have fun!

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

N17: IACUC Game Night
Join your fellow IACUC/ACU colleagues for an enjoyable evening of games! We'll have board games, card games, and more. Come unwind and have some fun after a day at the conference!

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

PRIM&R Annual Conference November 17-20 Seattle, Washington Celebrating 50 Years of PRIM&R

PRIMR24: Wednesday, November 20

7:00 AM-5:00 PM PT **Registration Open**

7:00 AM-8:15 AM PT **Federal Agency Office Hours**

During this time, representatives from federal agencies, the accrediting bodies, and/or the CIP and CPIA Councils will be available to answer attendee questions, engage in dialogue, and/or direct attendees to additional resources. Attendees are encouraged to come prepared with questions, which will be taken on a first come basis. To participate, go to the Exhibit Hall and locate the Office Hours table(s) for the agencies participating in this timeslot. **Only the following organizations are participating in this timeslot**:

* AAHRPP, Inc.
* FDA
* OHRP
* CIP Council
* CPIA Council
* NIJ

PRIMR24 Networking Block, 7:30 AM-8:30 AM PT

N18: SBER Network Discussion Session

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

Join the SBER Network as we continue the discuss on faculty mentorship in human research protections. Based on comments collected at our session last year, the SBER Network Faculty Mentorship in Human Research Protections initiative has developed a training tool for HRPPs to use with faculty mentors. This session will present the Faculty Mentorship tool and through small group discussions brainstorm challenges and opportunities for outreach to faculty.

Learning Objectives:

•Share the Faculty Mentorship tool
•Discuss strategies for outreach to faculty
•Network with SBER IRB professionals

Target Audience(s): HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs;

N19: IRB Chairs Community-Building Networking Forum

Track(s): IRB Review

This session will provide new and more seasoned IRB chairs an opportunity to network with others at similar types of IRBs, such as SBER, biomedical, small institution, single IRB, international, and commercial IRB. Facilitators will poll the audience to determine the top five categories, and then attendees will break into small groups to share experiences, ideas, and strategies about working in IRBs like their own.

Learning Objectives:

•Understand the unique experiences and challenges faced by IRB chairs at particular types of IRBs
•Share strategies and support for addressing these issues

Target Audience(s): IRB Members, Chairs, and Vice Chairs

N20: Horror Stories of an IACUC Chair

Track(s): IACUC Review

Join us for a spine-chilling journey into the realm of research ethics as we uncover the horror stories that lurk within the corridors of IACUCs. In this session, attendees will delve into the scenarios faced by those who serve as IACUC chairs and explore solutions to challenging dilemmas.

•Explore real-life scenarios highlighting ethical dilemmas faced by IACUC chairs
•Discuss strategies employed by IACUC chairs to address and mitigate ethical concerns while upholding animal welfare standards
•Describe promising approaches to evaluating HRPP/IRB quality and effectiveness

Target Audience(s): IACUC Members, Chairs, and Vice Chairs

PRIMR24 Content Block G, 8:45-10:00 AM PT

HSR

G1: Responsible Research Practices in Computing

Track(s): Research Involving Data and New Technologies; Emerging Research Challenges and Breaking Issues; IRB Review

Over the past few years, there have been calls from academia, industry, government, and civil society for researchers in computing to grapple with the societal impacts of their work. These calls go beyond the long-standing requirement to attend to the welfare of the human subjects involved in research studies; rather, these recent calls ask researchers to reflect on and attempt to address the potential negative impacts of their research findings on society more broadly. These calls have been especially common and particularly forceful when it comes to research on artificial intelligence (AI) and machine learning, with a number of leading conferences and publication venues introducing requirements or recommendations that authors include a statement in their submissions about the possible downstream harms posed by their work. While there is growing agreement that researchers, and industry researchers in particular, should do more to attend to the dangers posed by the release of their work, it is still unclear how this should be done effectively. This session, which brings together a number of key actors who have been deeply involved in this debate over the past few years, will take stock of recent efforts, identify key challenges, and develop ideas for a path forward.

Learning Objectives:

•Provide an overview of the recent, numerous, and varied developments in computer science, especially in the fields of AI and machine learning, to encourage researchers to consider and attempt to address the potential negative societal impacts of their work
•Explore these efforts to better understand their efficacy, as well as key challenges
•Consider how to improve on these efforts, how these efforts might learn from related efforts in other fields, and how such efforts might translate to other fields

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

G2: Change the Game By Working Together: Tips for Increasing HRPP/IRB and Researcher Collaboration

Track(s): IRB Review; HRPP/IRB Management and Administration; Social, Behavioral, and Educational Research

As researchers innovate and regulations change, the advancement of science is increasingly dependent on creative approaches to how regulatory work gets done. This session will focus on strategies and evidence-based tools to strengthen and expand the HRPP/IRB-researcher relationship while promoting strong scientific design and the protection of human subjects. Approaching this topic from both the HRPP/IRB and researcher perspectives will provide clear steps to improving relationships and streamlining processes.

Learning Objectives:

•Identify ways HRPPs can use flexibility in the regulations and researcher input to reorganize and re-envision the way IRB work is done

•Highlight ways research teams can build collaborative relationships with HRPP/IRB staff to encourage protective, but not burdensome, regulatory oversight in innovative research design

•Provide examples of successful collaborations between HRPP/IRB offices and research teams that have spurred institution-level change

Target Audience(s): 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

G3: 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(s): 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

G4: Expectations for the Use of Electronic Systems to Conduct Clinical Trial Activities and Considerations for IRBs: Perspectives From Regulators and Institutional Review Boards

Track(s): FDA Regulated Research; HRPP/IRB Management and Administration; Pharma/Biotech Perspectives; QA/QI and Postapproval Monitoring

FDA regulations under 21 CFR part 11 are specifically intended to help ensure that the electronic records and data are trustworthy and reliable. In addition, the appropriate use of electronic systems in clinical trials is an important component of good clinical practice (GCP). Compliance with FDA regulations and GCP quality standards provide public assurance that the rights, safety, and welfare of study participants are protected and that the clinical trial data and information are credible. In this session, FDA staff will provide an overview of part 11 regulations, including enforcement discretion related to part 11 compliance, and recently published guidances related to good clinical practice and the use of electronic systems in clinical trials. Presenters will also discuss considerations for applying risk-proportionate approaches to the management of electronic systems used in clinical trials that are relevant to IRB activities for FDA-regulated research.

Learning Objectives:

•Understand the general regulatory expectations for use of electronic systems, electronic records, and electronic signatures in clinical trials, including enforcement discretion related to part 11 compliance

•Describe technical and compliance considerations associated with part 11 and GCP quality standards for ensuring systems used in clinical trials are fit for their intended purpose

•Identify aspects of these regulatory expectations that might be relevant to IRB review of a research protocol or other IRB activities

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

G5: Navigating the Shifting Landscape: Politics and Legislation in Embryonic Research

Track(s): Legal Considerations in Research Oversight; Emerging Research Challenges and Breaking Issues; IRB Review

The regulatory framework governing human embryo and embryoid research in the US is complex and shaped by a combination of federal and state laws. Federal policies primarily dictate funding provisions, while state laws can vary significantly, ranging from outright bans to allowances under certain conditions. The varying regulations across states reflect different ethical and moral perspectives, which can be difficult for researchers to navigate. IRBs must consider a range of factors when reviewing embryonic research proposals. This session will do a deep dive on what is embryonic research, and the speakers will review the history and current landscape of this controversial research. What are key considerations for investigators and IRBs when reviewing studies involving embryonic material? Will current events impact future embryonic research?

Learning Objectives:

•Learn the history of how embryonic stem cell laws have changed over time, influenced by different presidential administrations and current regulatory landscape

•Consider key considerations for investigators and IRB staff when research involves embryonic material, including how to navigate the challenges

•Discuss the future of embryonic stem cell research

Target Audience(s): HRPP/IRB Directors; Research Program Leadership and Institnutioal Officials; Legal Counsel; Public Relations Professionals; Researchers and Research Staff; Clinical Research Staff; IRB Members, Chairs, and Vice Chairs

G6: Managing Dual/Multiple Relationships: Grappling With Identity and Interpersonal Boundaries in Human Subjects

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

While HRPPs and investigators are comfortable examining financial conflicts of interest, conflicts that stem from who we are, our relationships, and our roles or positions within a community are both harder to talk about, harder to manage, and maybe harder to identify. As our understanding of research equity becomes more nuanced, we expect more involved community participation, consultation, and partnership in all fields of human subjects research. HRPPs and IRBs now need to carefully approach the conflict and bias that can arise when investigators themselves, and the research staff they hire, not to mention the IRB members, are members of the communities to be studied. Lived-experience gives these teams crucially important perspective and credibility. It may also mean they feel pulled in different directions by conflicting behavioral norms, biases, and expectations. Identifying ways to encourage and celebrate authenticity, while avoiding pitfalls in these multiple relationships, is critical to inclusive and equitable science. Speakers will contend with this challenge, engaging with both the profound importance of representation and the ethical minefield of multiple relationships and our intersectional lives.

Learning Objectives:

•Understand what dual/multiple relationships are in the context of human subjects research and how these relationships may be helpful toward improving research equity and community partnership

•Learn how to develop a management plan for dual/multiple relationships in human subjects research and understand how this compares to how we manage dual relationships in clinical medicine

•Explore management plans through case examples (from the researcher, HRPP, and IRB perspectives, and how we might approach different scenarios)

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

G7: Exploring the Enigma of the Expedited (Category 7)

Track(s): Social, Behavioral, and Educational Research; IRB Review

Given the nature of our constantly changing human world, there is value in having flexibility with the interpretation and application of Expedited Category 7. However, with such a broad definition, it can be difficult for novice and expert reviewers alike to precisely know whether the application is appropriate to be reviewed at the expedited level, whether the research activities may be exempt from the HHS regulations, or in finding that full committee review is needed. Examination of the regulatory language in this session will provide a better understanding of what/who this category applies to and offer insight into navigating considerations for protecting the participants involved.

Learning Objectives:

•Identify common research activities that present no more than minimal risk to human subjects and involve criteria listed within Expedited Category 7

•Assess how the threshold for what is considered minimal risk can alter based on participant population(s), sensitivity of questions/procedures, informed consent considerations, and other elements necessary to ensure criteria for approval are met

•Evaluate various case studies and explore strategies for ensuring consistency in reviews and appropriate protections for subjects are in place

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

G8: Let It Go! Strategies to Prevent Over-Regulation During Local Context Review

Track(s): Single IRB; IRB Review

The regulatory shift toward the use of a single IRB has been justified by a presumed reduction in review timelines. The tendency for institutions that rely on an external IRB to wade into topics that are under the oversight of the reviewing IRB can prevent realization of these benefits. Learn how three separate institutions have incorporated strategies to prevent over-regulation during local context review.

Learning Objectives:

•Learn about review processes that can be implemented to prevent IRB staff at a relying institution from considering items that do not fall under their regulatory purview

•Explore strategies used to reduce the tendency of your relying sites to request changes to the protocol that do not fall under their regulatory purview

•Discuss structural changes that can be made to your IRB staff roles and responsibilities that can reduce over-regulation

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

G9: IBC and IRB Collaboration: Working Together for Safety and Oversight

Track(s): Shared Research Oversight Challenges; HRPP/IRB Management and Administration

As institutions increase the number of human gene therapy trials, it is important for biosafety officers and IBC administrators to understand the role of the IRB, and vice versa. With a common understanding of roles, these professionals can more thoroughly address how best to work together. IBCs and IACUCs have worked closely together for many years. However, as therapies move from pre-clinical animal studies into human trials, the IBC needs to be equally as connected with the IRB where the review dynamics, risks for participants, and overall focus of the oversight changes. In this session, speakers from local research institutions will discuss how they work collaboratively between the IBC and IRB to advance research through the start-up process and ensure ongoing safety and ethical oversight of human gene therapy trials and other research involving genetically engineered materials.

Learning Objectives:

•Define and understand the core review functions as well as the regulatory and ethical framework of IBC review

•Share practical examples for how the IBC office and/or biosafety officer can work collaboratively with the IRB office to advance study start-up and oversight

•Describe how the IBC's interaction with the IRB office is and should be different than with the IACUC office

Target Audience(s): HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; IBC Directors; IBC Administrators, Managers, and Staff; IBC Members, Chairs, and Vice Chairs; Research Program Leadership and Institnutioal Officials; Clinical Research Staff; Researchers and Research Staff

IACUC

G10: Replicability, Reproducibility, Rigor, and Red Herrings

Track(s): Emerging Challenges and Breaking Issues; Animal Well-Being and the 3Rs; IACUC Review

Critics of research with nonhuman animals often cite the presumed “replication/reproducibility crisis” as undeniable evidence that such research is pointless and should end immediately. However, it is important to note there isn’t a universally accepted definition of either of these terms. In fact, not only are these terms defined differently by different disciplines, they also vary by geographical location (e.g., US vs. Europe). Furthermore, the banding around these terms can undermine ethically sound and scientifically valid research with humans and other animals and can reflect a limited understanding of the scientific process. This session will explore the problems with conflating these terms because of how each is defined and used, and they can be used to undermine nonhuman animal research. Speakers will also describe how research programs, scientists, and publishers are adopting their own strategies to improve the transparency and replicability of research with animals.

Learning Objectives:

•Define the terms "replicability," "reproducibility", and “rigor” as they relate to scientific research, acknowledging the lack of universal definitions and variations across disciplines and locations

•Explore how differing definitions and interpretations of these terms can impact the perception of research integrity and scientific rigor in both human and nonhuman animal research

•Identify instances where the misuse or misinterpretation of replication and reproducibility concepts has led to unwarranted criticism of nonhuman animal research

•Explore strategies for effectively communicating the nuances of these terms to various groups, including the general public, policymakers, institutional leaders, and fellow scientists, to foster a more accurate understanding of research integrity

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

G11 (IACUC): Agricultural Animals in Research

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

Agricultural animals, including poultry, used for research present unique challenges for husbandry, veterinary care, and IACUC oversight. What regulations apply to these species and activities? What standards for their housing and care are applicable? How can common compliance issues be addressed and prevented?

Learning Objectives:

•Discuss special issues related to the use of agricultural animals in biomedical research

•Using case studies, identify solutions to commonly encountered problems with compliance in agricultural settings

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

G12 (IACUC): Better Together-Effective Collaboration During IACUC Protocol Review
Track(s): IACUC Review; ACU/IACUC Program Management and Administration
There are many groups involved when performing IACUC protocol review (e.g., IACUC administrators, environmental health and safety, veterinarians, etc.), not just the IACUC, which is an essential process of an animal care and use program. This session will discuss these groups and the efficiency of the reviews, as well as how IACUC administrators can greatly contribute to this process. The session will discuss strategies for collaboration, communication, and important key factors for streamlined and efficient reviews.
Learning Objectives:
•Identify common groups involved in the IACUC protocol review process and eliminate processes that are not needed (e.g., not required by regulations or policies)
•Identify what the needs are for each group and how these can be beneficial in collaborating with all parties
•Discuss strategies for how IACUC administrators may facilitate collaboration between groups and how effective communication may improve the protocol review process
•Explore how to develop training materials to aid in protocol review by these groups (e.g. live video demonstrations on key software applications for animal protocol management databases and/or manual protocol forms).

Target Audience(s): ACU/IACUC Administrators, Managers, and Staff; Compliance Personnel; IACUC Members, Chairs, and Vice Chairs; ACU/IACUC Directors

Crossover

G13: Ethical Review of Human and Animal Subjects Research Proposals
Track(s): Shared Research Oversight Challenges; Research Oversight Leaders and Institutional Officials; IRB Review; IACUC Review
Many in our field would describe the research projects with human and animal subjects conducted by our institutions as ethical or at least disagree with the characterization that they are unethical. But how and where is this ethical assessment made? When external assessments of research proposals are made, such as when grant funding is awarded, a scientific merit review is performed, but do study sections consider the ethics of the proposals they review? In some cases, there is no external body that reviews the research proposal, such as when internal funds are used. Often the IRB and IACUC are the last to review a project and may represent our best opportunity to ensure that research we conduct is indeed ethical. Opinions vary on whether IRBs and IACUCs do, should, or even can perform an ethical assessment of human and animal research proposals. Some suggest that IRBs and IACUCs should stick to their regulatory scope and that any discussion not directly supported by a regulatory requirement is out of scope. Is a review against regulatory standards enough to ensure that ethical reviews are conducted and if not, how do we ensure research gets adequate ethics review?
Learning Objectives:
•Understand the current scope of ethical review by IRBs and IACUCs, including their regulatory responsibilities and limitations
•Evaluate whether regulatory compliance alone ensures ethical research and explore potential gaps in current ethical review processes
•Explore strategies for enhancing ethical review practices and the role of external bodies

Target Audience(s): ACU/IACUC Directors; IACUC Members, Chairs, and Vice Chairs; IBC Directors; IBC Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials; IRB Directors; IRB Members, Chairs, and Vice Chairs; Compliance Personnel; QA/QI Professionals; Researchers and Research Staff

G14: No Findings, No Problem: Finding the Positives in Auditing
Track(s): IRB Fundamentals; IACUC Fundamentals; QA/QI and Postapproval Monitoring
Working with audit-resistant or "problem" researchers can result in low morale and burnout of QA/QI staff. On the other hand, "finding-free" audits also may trigger QA/QI staff to question their skills, and may prompt PIs, study teams, or institutional leadership to question the value of QA/QI work. Finding-free audits, however, are a key indicator for successful QA/QI programs and provide unique opportunities to both recognize the research community for a job well done and to create bandwidth for new QA/QI compliance activities. Speakers will share examples of how to foster audit engagement, keep up staff morale, and capitalize on "finding-free" audits to improve relations between faculty and QA/QI. Participants will also be encouraged to share their own best practices in these areas.
Learning Objectives:
•Review strategies for reducing resistance to audit selection and improving audit engagement
•Discuss the benefits of, and approaches for celebrating, finding-free audits (for investigators as well as auditors!)
•Identify methods to facilitate an increase in findings of strengths and opportunities to commend researchers on what they are doing well

Target Audience(s): Educators/Trainers; QA/QI Professionals

G15: Diversity, Equity, Inclusion, and Justice (DEIJ) and Impact on Staffing in Research Oversight Programs
Track(s): Advancing Equity and Justice in Research; Education, Qualifications, and Training; Shared Research Oversight Challenges; HRPP/IRB Management and Administration; ACU/IACUC Program Management and Administration
This session aims to provide attendees with actionable insights and practical strategies, utilizing interactive learning, to navigate DEIJ challenges within staffing. By promoting a supportive and inclusive environment, leaders can empower staff members to develop psychological safety, foster long-term job satisfaction and retention, and improve research and compliance outcomes.
Learning Objectives:
•Explore how staff members are affected by DEIJ issues and how that can impact one's ability to perform at a job that has multiple inherent stress factors
•Review workplace situations that can impact personnel, work quality (nonhuman and human subjects protection), safety, and job satisfaction
•Discuss effective communication between oversight program leaders and the research community with a focus on inclusivity and justice (e.g., safety, HRPP/IRB, IACUC, animal program management, IBC, etc.)

Target Audience(s): ACU/IACUC Directors; ACU/IACUC Administrators, Manager and Staff; HRPP/IRB Directors; IRB Administrators, Manager and Staff; IBC Administrators, Manager and Staff; Research Program Leadership and Institutional

10:00 AM-10:30 AM PT **Break in Exhibit Hall w/ drinks and food**

PRIMR24 Content Block H, 10:30 - 11:45 AM PT

HSR

H1: Regulatory and IRB Challenges in Reviewing Decentralized Clinical Trials (DCTs)
Track(s): FDA Regulated Research; HRPP/IRB Management and Administration; IRB Review

Among other Task forces in the White House Cancer Moonshot is a Work Group promoting the implementation of decentralization (including decentralized methods) in federal government and private sector clinical trials. This session will review important regulatory, educational, and operational hurdles to implementing DCTs/DCT methods along with current resources and solutions for Human Research Protection Plans (HRPP) reviewing and implementing them. Case examples from the Department of Veterans Affairs (VA) will be discussed along with the regulatory issue of engagement and FDA requirements related to Investigational New Drug clinical investigations and its draft guidance on DCTs.

Learning Objectives:
•Articulate the basic framework of a DCT
•Describe some of the benefits and potential complications of implementing a DCT or DCT methods
•Recognize DCTs/DCT methods when they are submitted and have resources for considering the regulatory and operational issues that need to be considered prior to approval and in post-approval monitoring

Target Audience(s): IRB Members, Chairs, and Vice Chairs; HRPP/IRB Administrators, Managers, and Staff

H2: Group Harm: A Toolkit for Researchers, IRBs, and Data Access Committees
Track(s): Populations Requiring Additional Protections; IRB Review; Social, Behavioral, and Educational Research

One of the primary risks of biorepository-driven research is group harm. This harm may hinge on features of self-identified communities (e.g., geography, disease, sexual orientation) or be algorithmically-defined as a result of research practice uninformed by community contexts using features known or unknown to individuals. Speakers will review a toolkit designed to support researchers' and oversight boards' systematic consideration of the wide range of community interests in research planning and execution.

Learning Objectives:
•Understand the risk of group harm posed by biorepository-driven/secondary data use research
•Contextualize this risk within existing research regulations and oversight requirements
•Critically apprise a novel toolset designed to aid in the positive consideration of group interests in biorepository-driven research

Target Audience(s): HRPP/IRB Directors; IRB Members, Chairs, and Vice Chairs; Legal Counsel; Clinical Research Staff; Researchers and Research Staff; Diversity, Equity, Inclusion, and Justice; Research Program Leadership and Institnutioal

H3: Houston, We Have Problem: Exploring Noncompliance in a Single IRB (sIRB) Universe
Track(s): Single IRB; QA/QI and Postapproval Monitoring

Handling noncompliance can be complicated enough when it happens within your galaxy, but when your researchers leave their orbit and enter the new world of sIRB the complexity can increase exponentially. This session will boldly go where many IRBs and institutions have begun to find themselves and explore their new roles and responsibilities when noncompliance happens on the sIRB frontier. Speakers will discuss how to effectively communicate with external collaborators when policies or institutional cultures collide, including key considerations when researcher or IRB noncompliance arises and how to handle that in a sIRB space. Finally, speakers will share real-life experiences about keeping institutional ships on course and avoiding difficult landings when noncompliance turbulence hits.

Learning Objectives:
•Identify the challenges noncompliance cases present in the sIRB world and how they parallel and differ from those in a local IRB review model
•Review roles and responsibilities for the review and reporting of noncompliance and what to do when disagreements arise
•Explore proactive approaches, such as how auditing and monitoring and education can be adapted to the new sIRB world to help avoid noncompliance or mitigate its impact

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

H4: Comparative Effectiveness Research (CER): When Important Research Does Not Fit the Regulatory Mold
Track(s): IRB Review; Emerging Research Challenges and Breaking Issues

Ten years after OHRP issued a determination letter that investigators of the SUPPORT study were in violation of the federal regulations on informed consent, resources and support for IRB's review and oversight of CER remains sparse. Despite draft guidance from OHRP published in 2014, IRBs struggle with identifying research procedure risks and determining the overall risk for the studies, assessing what qualifies as adequately addressing informed consent requirements, and determining the applicability of FDA regulations. With additional institutional interest in supporting evidence-based practice research, CER is increasing in frequency and IRBs must be prepared to properly review this research.

Learning Objectives:
•Define CER studies
•Examine the existing regulatory framework and identify challenges with applying regulations to CER studies
•Discuss case studies of CER where IRBs came to divergent conclusions to illustrate difficult aspects of these reviews

Target Audience(s): 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

H5: Pharma Perspectives on the Use of Social Media and Social Media Influencers in Clinical Research
Track(s): Pharma/Biotech Perspectives; Emerging Research Challenges and Breaking Issues

The use of digital and social media engagement is rapidly evolving in its application to health and life sciences. Although there are guidelines and regulations in place, the increasing use of social media and external online influencers is raising nuanced, ethical challenges within the clinical research space. This session will take a deep dive into a framework for how life sciences, ethics, and compliance professionals within research and development can build sustainable, ethical decision-making into their internal consultation and approval processes to deliver social media campaigns involving external online influencers that are responsible, transparent, and trusted.

Learning Objectives:
•Learn how biopharmaceutical companies are leveraging social media and online influencers to raise awareness of clinical research and clinical trials
•Examine the unique ethical considerations of engaging online influencers in clinical research (e.g., paying influencers "fair market value", how content can be re-used and shared, characteristics of different social media platforms)
•Understand how biopharmaceutical companies are preparing to support the responsible use of influencer-driven social media use in clinical research

Target Audience(s): Clinical Research Staff; HRPP/IRB Administrators, Managers, and Staff; HRPP/IRB Directors; Researchers and Research Staff

H6: What Are You Going To Do With My Specimens and Data? When Research Specimens and Data are Used for Commercial Profit

Track(s): Research Involving Data and New Technologies; Legal Considerations in Research Oversight; IRB Review; Pharma/Biotech Perspectives

When applicable, HHS regulations require informed consent forms to include a statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit. However, it may not be clear to many subjects/participants why commercial uses of biospecimens are essential for scientific and medical advancement, how they are used for commercial research, and why it may not be possible to share commercial profits with them. This session will discuss scenarios when research biospecimens and data may be used for commercial profit and best practices for explaining these issues to potential research subjects.

Learning Objectives:

•Identify when it is appropriate to include the additional element of consent regarding use of biospecimens for commercial profit in consent forms

•Discuss different scenarios where biospecimens may be used for commercial profit

•Examine best practices for communicating with potential research subjects on why commercial uses of biospecimens are important, how biospecimens may be used commercially and when such research could result in commercial profit, and why the sharing of any profits might not be possible

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

H7: Protecting Third Parties in Research: Whose Job Is it Anyway?

Track(s): Shared Research Oversight Challenges

Infectious disease research, gene therapy research, social and behavioral research, and many other types of research reviewed by IRBs frequently pose risks to many more people than those who directly consent to participate in it. Whether they are called "third parties," "bystanders," "close contacts," or some other name, risks to these people raise important questions for research oversight as to whose responsibility it is to inform them of these risks, and protect them. Responsibilities for third parties can be placed with institutions conducting the research, the institutions or locations where the research is conducted, with other committees like IBCs or Community Advisory Boards, or, sometimes, there is no entity with direct responsibility for protecting these individuals. This session will discuss the ways third party risks manifest in three different types of research and the challenges and gaps in existing oversight that arise when third party risks exist. Speakers will propose recommendations for IRBs for filling in these gaps with explicit assignment of responsibility or explicit communication channels between responsible entities.

Learning Objectives:

•Recognize the prevalence of third party risks in human subjects research across different domains

•Learn how protections for third parties are inconsistently applied in the research oversight process, and how this can leave these individuals without adequate protections

•Propose strategies IRBs can use to coordinate and communicate with other entities to ensure third parties are adequately protected in human subjects research

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

H8: A Dialogue With the Environmental Protection Agency (EPA)

Track(s): A Dialogue with the Feds

This session will be led by representatives from the EPA. It will include discussion of the EPA's work and attendees are encouraged to come with questions of interest to all.

Learning Objectives:

•Hear from EPA representatives about new and evolving issues, initiatives, regulations, and guidance

•Ask questions about evolving issues and initiatives at the EPA

Target Audience(s): 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

H9: Exempt Study Review: How to Find Flexibilities in the Current Regulations

Track(s): IRB Review; Social, Behavioral, and Educational Research; IRB Fundamentals

IRBs are under pressure from their researchers to review research proposals as quickly as possible while still maintaining regulatory and institutional compliance. When studies are not subject to Common Rule or FDA regulations, it may be appropriate to determine that some studies are Exempt, which would not meet the categories at 104 when commensurate protections are implemented. This session will explore various flexibilities (including an Exempt Self-Determination mechanism) employed at two biomedical/SBER campuses.

Learning Objectives:

•Understand the areas of flexibility inherent in the regulations and the concepts behind flexing the regulations for "unregulated" studies

•Discuss how an Exempt Self-Determination pathway can be implemented to reduce administrative burden while maintaining regulatory and institutional compliance

•Learn how to determine what commensurate protections may be implemented based on study characteristics when flexing the regulations for "unregulated" studies

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

IACUC

H10: Making the 3Rs More Than a Checkbox: Institutional 3Rs Programs

Track(s): *Animal Well-Being and the 3Rs; IACUC Review; ACU/IACUC Program Management and Administration*

Applying the 3Rs of animal research (replacement, reduction, refinement) is a critical, but sometimes challenging part of conducting humane experiments. Strategic institutional 3Rs programs can accelerate and bolster 3Rs implementation across all relevant stakeholders. Using case studies from diverse institutions, attendees will learn why and how to create an institutional 3Rs strategy.

Learning Objectives:

•Understand the importance of having a dedicated institutional 3Rs strategy
•Share examples of successful 3Rs programs across academia and industry
•Determine potential action steps to create or bolster 3Rs program support and their institution

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

H11: Oversight of Animal Care and Veterinary Staff Qualifications and Training

Track(s): Education, Qualifications, and Training; IACUC Basics

Research facilities must ensure that all personnel, including animal care technicians and veterinary staff, are qualified to perform their duties. What is the IACUC's role in assessing qualifications and training for animal care staff and addressing noncompliance, especially when noncompliance results in negative nonhuman animal welfare impacts?

Learning Objectives:

•Understand IACUC's role in ensuring animal care and veterinary staff are appropriately qualified and trained
•Discuss approaches to addressing noncompliance related to inadequate training of animal care and veterinary staff
•Explore how to develop a comprehensive staff training program to ensure personnel are appropriately qualified to fulfill their duties

Target Audience(s): Educators/Trainers; ACU/IACUC Administrators, Managers, and Staff; Laboratory Animal and Veterinary Staff; IACUC Members, Chairs, and Vice Chairs; ACU/IACUC Directors

H12: Adverse Events and Animal Welfare in Biotech and Academia Alike: Creating Efficiency, an Open Program, and Automated Functions of Reporting

Track(s): Pharma/Biotech Perspectives; QA/QI and Postapproval Monitoring; IACUC Review; ACU/IACUC Program Management and Administration

Adverse events and noncompliance in an animal care and use program are important to address not only for resolving the situation at hand, but to show key indicators or trends that may help to strengthen the program in the long run. This session will explore guidelines for open communication with the IACUC and scientists, define policies, and share efficient ways to streamline the information into automated reports for IACUC review.

Learning Objectives:

•Learn effective strategies for engaging the IACUC chair and veterinarian in discussions regarding protocol noncompliance, and develop skills to schedule collaborative meetings with science staff through effective coordination by the IACUC administrator/manager
•Create and develop an organized system for open communication with research staff, encouraging positive reinforcement for reporting adverse events and illustrating the impact of animal welfare concerns on research outcomes
•Develop clear and concise policies to eliminate ambiguity in reporting requirements
•Explore innovative methods to streamline the reporting process by implementing automated forms that notify the IACUC office, generating PDF documents, and adopting simplified formats for enhanced discussion during IACUC meetings

Target Audience(s): ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; Compliance Personnel; ACU/IACUC Directors

Crossover

H13: Tick-Tock! How to Not Waste Your Time While Writing Minutes!

Track(s): FDA Regulated Review; IRB Review; IRB Fundamentals; IACUC Fundamentals; IACUC Review

Documentation, documentation, documentation. The regulations define requirements for committee recordkeeping, documenting committee discussions and findings, and for communicating committee decisions. It can be a daunting and time consuming task to interpret complex conversations and capture them in succinct yet meaningful terms, and even more so if the subject matter isn't your forte! With so much pressure to get it right - and only so much time in which to do it - it can help to take a step back and refocus on strategies for efficiency! In this session, seasoned compliance professionals will provide helpful tips to make sure writing meeting minutes isn't daunting, time-consuming task, AND tips to make sure your minutes are accurate, reliable, and reader-friendly for your future self (and the scary regulatory compliance people who might one day visit your workplace).

Learning Objectives:

•Outline the basic federal requirements for records and documentation
•Explore tips for keeping track of content/note taking during the meeting
•Learn useful insights for identifying key content that should be reflected in the minutes, and how to avoid documenting the "noise" which often comes up during IRB discussions

Target Audience(s): ACU/IACUC Administrators, Manager and Staff; IACUC Members, Chairs, and Vice Chairs; IRB Administrators, Manager and Staff; IRB Members, Chairs, and Vice Chairs; IBC Administrators, Manager and Staff

H14 : Don't Reinvent the Wheel! How to Ask the Right Questions and Leverage Existing Resources to Address Critical Compliance Needs

Track(s): Education, Qualifications, and Training; Shared Research Oversight Challenges; HRPP/IRB Management and Administration; ACU/IACUC Program Management and Administration; QA/QI and Postapproval Monitoring

When we're faced with critical compliance challenges, it can be overwhelming, and it can be hard to know where to start. Join us in this session to learn how to have conversations across the compliance aisle, how to find and leverage existing resources, and how to use both to tackle your trickiest challenges. In this session, we will describe a case study in leveraging an existing database (IPEDS) to identify peer institutions in a research compliance context. We will also walk through how an Animal Care and Use Program could do a similar exercise which could be implemented during semiannual review, a stand-alone post-approval monitoring program, or other programmatic challenges that may arise. Participants will leave the session with information on existing resources, as well as a list of questions to ask themselves when engaging in the work of planning, policy development, and resource advocacy.

Learning Objectives:

•Initiate critical conversations within and between research administration groups (i.e., IACUC, IRB, IBC, Sponsored Programs, etc.)
•Identify what you want/need to know; how to gather the data, and translate data, metrics, and peer institution information for presentations and discussions with stakeholders
•Leverage existing innovations, data, and networks to answer questions and receive/advocate for resources

Target Audience(s): ACU/IACUC Directors; ACU/IACUC Administrators, Manager and Staff; HRPP/IRB Directors; IRB Administrators, Manager and Staff; IBC Administrators, Manager and Staff@@@Compliance Personnel; QA/QI Professionals

H15: Considering Yourself: Self-Care for Compliance Professionals
Track(s): Education, Qualifications, and Training; Shared Research Oversight Challenges; HRPP/IRB Management and Administratio; ACU/IACUC Program Management and Administration

Assuring our communities conduct responsible research requires a lot of thoughtful and deliberate effort. This session offers opportunities to place that same intention on supporting and renewing the energy of compliance professionals. Turning our considered attention to sharing strategies of self-care and discussions of how to attend to the stresses and exhaustions that can come while supporting others.

Learning Objectives:
•Learn about stress-reducing strategies
•Connect with peers and colleagues to build a support network
•Find ways to be compassionate with yourself

Target Audience(s): ACU/IACUC Directors; ACU/IACUC Administrators, Manager and Staff; HRPP/IRB Directors; IRB Administrators, Manager and Staff; IBC Administrators, Manager and Staff; Compliance Personnel

12:00 PM PT **Conference Ends**

12:00-5:00 PM PT **Bridging the Gap: Showcasing the University of Washington (UW) Animal Research Facilities and Program**

UW's Office of Animal Welfare (OAW) is sponsoring a post-conference offering on November 20 from 12:00-5:00 PM PT. Before registering for this offering, review the important notes below as there are specific requirements for participation.

This post-conference offering will include a tour of the UW animal research facilities*, special program highlights, and networking. Attendees will meet at the conclusion of PRIMR24 and OAW staff will accompany them by light rail to the UW Heath Sciences Building (a short walk from the station). Upon arrival, attendees will be provided with lunch and an overview of the program. Attendees will then be assembled into small groups to tour several animal research spaces* on campus, which may include facilities for primates, frogs, zebrafish, gnotobiotics, and mouse behavioral testing. Investigators will be present to describe their research and answer questions. Following the tour, there will be a session providing brief highlights of the UW's animal researcher training program, the IACUC Mock Site Visit room, the electronic protocol database system, grant/protocol congruence reviews, and the UW Dare to Care compassion fatigue program. The session will conclude with a networking Happy Hour, after which attendees will be transported back downtown or to the airport on the light rail.

**The final facility tour schedule will be provided in October.*

Important program notes:
•This program requires pre-registration and the cost to attend is $35 (includes transportation, lunch, and happy hour). Attendance is limited; capacity is 30 people.
•To visit the Primate Facility, you need to provide proof of a TB test (within the last year from Nov. 2024) and measles vaccination. If you cannot prove documentation of these, you cannot participate in parts of the animal facility tour. Once you're registered, a form will be sent.
•This offering involves walking; attendees will be on their feet for approximately 90 minutes.
•It is encouraged that attendees stay for the whole event. If you cannot make the Happy Hour event, you will be asked to let the coordinators at UW know.

Icon	Label	*Description*
	CIP Credit	Session is eligible for CIP credit.
	CPIA Credit	Session is eligible for CPIA credit.
	Call for Session Proposal	Session is from the Call for Session Proposals.
	Livestreaming	Session will be livestreamed in real time and captured for on-demand viewing.
	Live Session Recorded	Session is being held in person and will be recorded for on-demand viewing.
	On-Demand	Session is recorded in advance and offered for on-demand viewing.
	Pre-Registration Required	Session requires pre-registration to attend.
	Additional Fee	Session is an additional fee.
	Humans Subjects Research Content	Human Subjects Research Content
	IACUC/Animal Care and Use Content	IACUC/ACU Content
	Crossover Content	Crossover Content
	Institutional Leadership Content	Institutional Leadership Content
	Deep Dive Series	Deep Dive Series; learn more about session formats.
	Learning Lab Series	Learning Lab Series; learn more about session formats.
	Networking Series	Networking Series; learn more about session formats.
	Thought Leader Series	Thought Leader Series; learn more about session formats.
	Vendor Insight Series	Vendor Insight Series; learn more about session formats.
	Workshop Series	Workshop Series; learn more about session formats.