PRIM&R
2023 PRIM&R Annual Conference
December 3–6, 2023
Washington, DC

SBER Conference
December 3, 2023
Washington, DC

PRIMR23 Preconference Workshop: Sunday, December 3

7:30 AM-5:00 PM ET **Registration Open**

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

8:30 AM-4:15 PM ET **Introduction to the IRB: Ethics and Regulation**

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

Learning Objectives:

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

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

8:30 AM-4:15 PM ET **Introduction to the IACUC**

Introduction to the IACUC is a basic-level, full-day workshop program covering the fundamentals of IACUC principles and operations for new IACUC members, early career IACUC administrators, and investigators. This program reviews the history of animal welfare regulations and oversight and accrediting bodies; the roles and responsibilities of the IACUC and staff members; training IACUC staff, IACUC members, and research staff; protocol review; postapproval; and how to work with others outside of the IACUC.

Learning Objectives:

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

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

8:30 AM-4:15 PM ET **Institutional Official (IO) Discussion: Navigating Ethical and Regulatory Challenges While Accelerating Research**

The role of the IO is complex and has broad responsibility for supporting and protecting the research environment, including understanding and maintaining compliance with the federal regulations for the protection of human subjects, vertebrate animals, conflicts of interest/commitment, and research security. The programs under the auspices of the IO must proactively anticipate and support research needs to protect research participants, funding, researchers, and the institution's reputation. The IO must ensure that the institution has a robust integrated infrastructure with appropriate resources. In this dynamic session, speakers will put a broad set of issues on the table for discussion, including: 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 dynamic 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

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

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

8:30-11:45 AM ET **Leadership Development: Pathways to Career Growth for Senior Research Oversight Personnel**

This three-hour workshop is designed to help senior 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 IRB and IACUC professionals looking to advance their careers.

Learning Objectives:

•Gain insight into the challenges and opportunities of leadership roles in research compliance
•Develop strategies for developing the knowledge, skills, and abilities needed to succeed
•Learn how to effectively prepare for leadership roles in compliance

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

8:30-11:45 AM ET **Overseeing Decentralized Clinical Trials (DCTs): Navigating Ethical and Regulatory Challenges With Single IRBs**

DCTs use a variety of modalities to facilitate research in today's digital world. The implementation of DCTs relies on the use of digital tools for recruitment, consent, monitoring (e.g., wearable devices), interventions, etc. across multiple sites. While DCTs and the use of digital tools make research more accessible to a much wider population, it also raises new ethical challenges. This three-hour session will discuss the various ethical considerations and challenges surrounding decentralized trials and single IRBs.

Learning Objectives:

•Explain the concept and background of DCTs and differentiate them from traditional clinical trials
•Identify the key ethical considerations for sponsors, investigators, and IRBs when overseeing DCTs, including the use of digital tools for recruitment, consent, and monitoring
•Discuss ethical challenges in DCTs with single IRBs and the opportunities and challenges associated with conducting these trials

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

8:30-11:45 AM ET **Mastering FDA Regulations: Strategies for Review and Oversight of Complex Research Scenarios**

This advanced-level, three-hour workshop is designed for research compliance professionals, regulatory affairs professionals, clinical research coordinators, and others involved in the study, oversight, and regulation of drugs, biologics, and devices. A prerequisite for attendance is a foundational knowledge of FDA research regulations governing human subjects protection and the conduct of clinical trials. Through interactive exercises, immersive case studies, and expert-led presentations, attendees will gain proficiency applying the FDA regulatory framework to advanced scenarios. The workshop will explore real-life examples of research with FDA-regulated products and test articles, including emerging technologies; use existing resources to support regulatory determinations; and consider ongoing oversight with an emphasis on protecting human subjects.

Learning Objectives:

•Synthesize and develop strategies and resources for navigating FDA-regulations
•Analyze and evaluate research scenarios to identify applicable regulatory requirements and requisite determinations
•Identify resources for interpreting regulations and strategies for effective communication with FDA

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

8:30-11:45 AM ET **Building an Effective Postapproval Monitoring (PAM) Program**

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

Learning Objectives:

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

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

11:45 AM-1:00 PM ET **Lunch**

Lunch will be available for those taking full-day Workshops or both a morning and half day Workshop (those taking a morning only or afternoon only Workshop are not eligible for lunch).

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

1:00-4:15 PM ET **Building Your Toolbox: Digital Learning Tools**

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

Learning Objectives:

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

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

1:00-4:15 PM ET **Designing and Implementing a Robust Responsible Conduct of Research (RCR) Education Program**

Conducting rigorous research in accordance with the fundamental values of science is key to the advancement of knowledge and of science, and in promoting the public's trust in the scientific enterprise. In the United States, a growing number of federal agencies, including National Institutes of Health, National Science Foundation, and United States Department of Agriculture National Institute of Food and Agriculture, require identified individuals (e.g., trainees, faculty) on awards RCR education. In this three-hour workshop, participants will learn about the fundamentals of an effective RCR education program, lessons learned from established programs, resources at an institution with whom to partner, and resources for teaching RCR and professional development of RCR staff.

Learning Objectives:

- Understand the foundations of RCR, federal mandates, and their history
- Explain best practices for RCR programs and lessons learned from established RCR programs
- Identify resources and professional development opportunities to support an RCR program

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

1:00-4:15 PM ET **Building Community Support for Your Animal Research Program**

Sustained campaigns of disinformation have resulted in widespread public misunderstanding of how nonhuman animal research is conducted, and the dynamic process involved in regulatory oversight of such research. In addition, faculty and staff at institutions and organizations where such research is conducted may often lack appreciation for the contributions and true nature of research with nonhuman animals. Consequently, it is essential to establish and implement preemptive communication strategies on biomedical and behavioral research with nonhuman animals, which is key to building community-wide support for institutional animal research programs. Through engaging exercises and case studies, attendees will acquire the skills needed to meet their institutions' responsibilities to support animal research programs and the researchers involved.

Learning Objectives:

- Recognize the significance of advocating for responsible research with nonhuman animals
- Identify available resources that can help institutions and organizations in developing a communication program
- Describe the key components of an effective communication program
- Share examples of best practices with communication strategies

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

4:15-5:30 PM ET **Networking Reception**

Join your colleagues in the Exhibit Hall to connect, view posters, and meet this year's Supporters and Exhibitors.

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

4:15-5:30 PM ET **View the PRIMR23 Poster Abstracts**

4:15-5:30 PM ET **Federal Agency, Accrediting Body, CIP/CPIA Council Office Hours**

During this time, representatives from federal agencies, the accrediting bodies, and the CIP/CPIA Councils will be available to answer 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. A list of agencies participating at this time is forthcoming.

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PRIMR23: Monday, December 4

7:30 AM-5:00 PM ET	**Registration Open**
8:30-8:45 AM ET	**Welcome Remarks**
8:45-10:00 AM ET	**Opening General Session: What Keeps You Up at Night: Future Frontiers in Research** What will the research landscape look like in 10-20 years? During this moderated session, a diverse panel of national experts in clinical trials and drug development, artificial intelligence, nonhuman primate research, scientific workforce development, and more will provide their perspectives on the research enterprise trajectory and what challenges that may lie ahead for the ethics and oversight community.
10:00-10:30 AM ET	**Break in the Exhibit Hall**

PRIMR23 Plenary Session Series, 10:30-11:45 AM ET

Plenary Session: Beyond Evaluating Risk: Now We Must Navigate Sociopolitical Events in Research

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

This plenary session will explore the challenges researchers and regulatory bodies face when conducting research and reviewing studies in a politically charged environment where controversial news stories and policy decisions can greatly impact research and the experience of research subjects. From the Supreme Court's decision to overturn Roe V. Wade to watchdog groups scrutinizing studies on social media to the judicial branch reexamining FDA approvals, it is clear politics and sociopolitical environments influence how research is conducted, or if it is even conducted at all on politically charged topics, as well as the risks subjects encounter participating in research. For example, the risks related to confidentiality and privacy of routine pregnancy testing in research are now higher for persons living in states with abortion bans. Research participants must be informed of these risks, researchers need to learn operational best practices for safeguarding participant information, and HRPPs/IRBs need to learn to reevaluate risks in the setting of a changing political landscape. These tasks become even more challenging in the setting of multi-site research, in which varying and conflicting state and federal laws, and associated risks of their possible violation, come into play. Beyond evaluating risks, the combination of sociopolitical events, public controversy, and understandable risk aversion by institutions, researchers, and participants limits research on areas of critical public health and social need, such as gun violence, maternal health, LGBTQIA+ health, and primary and secondary education. This session will discuss how researchers and institutions must handle these issues of public controversy and help subjects, researchers, and HRPPs/IRBs to evaluate and understand the risks of conducting and enrolling in research in the context of a changing political landscape. Speakers will provide examples and discuss the lessons learned from encountering these challenging situations, including strategies to minimize risk. Further, speakers will address the roles of research overisght professionals, and attendees of the PRIM&R annual meeting, as leaders in public responsibility in research, including if and how we are supposed to advocate for the types of research conducted and supported by our community, as well as for social justice and political change.

Learning Objectives:

•Learn how sociopolitical events impact research, including the unique challenges and obstacles to conducting certain types of research

•Explore how to evaluate and understand the risks of conducting and enrolling in research in the context of a changing political landscape

•Examine if and how the field is supposed to advocate for the types of research conducted and supported by our community, as well as for social justice and political change

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

Plenary Session: Impact of the Nonhuman Primate (NHP) Crisis on Public Health

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

Over the last decade, caving to sustained campaigns by groups opposed to nonhuman animal research, airlines ceased transportation of laboratory animals, particularly NHPs. The negative impact of this on biomedical and behavioral research was further exacerbated by recent supply chain problems, stemming from a ban on importation of these animals from China and Cambodia. The session will present diverse perspectives from early-stage investigators, academic leadership, and suppliers on how the supply chain has been impacted/shaped by legislative initiatives spearheaded by groups opposed to animal research as well as campaigns targeting NHP researchers. The perspective from the consumer side will be discussed, as the NHP crisis likely will have a long-term impact on the scientific community and mission.

Learning Objectives:

•Review the key factors contributing to the crisis in research with NHPs
•Describe the impact of the NHP crisis on the biomedical and behavioral research supply chain
•Discuss the potential long-term consequences of the NHP crisis on science and the scientific community

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

Plenary Session: Demystifying the Research Enterprise

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

This session is based on the book titled, *Demystifying the Academic Research Enterprise* , and will will provide an overview of the scope of academic research and the factors that need to be considered.

Learning Objectives:

•Identify the constituencies and components of the research enterprise
•Discuss why and where research is performed
•Explore the difference between perception and reality, and understanding the value of academic research and communicating that value

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

Plenary Session: The Ethics of Data Sharing

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

This session will focus on the ethical implications of the newly implemented NIH Data Management and Sharing Policy, including concerns regarding privacy, loss of intellectual property, scooping, and potential for misuse of shared data. Beyond the ethical implications, speakers will explore various compliance options to ensure ethical data sharing, as well as adherence to approved data management and sharing plans.

Learning Objectives:

•Review the requirements of the newly implemented NIH Data Management and Sharing Policy
•Identify the ethical issues specific to data sharing prior to peer-reviewed publications
•Explore the ethical reasons for not sharing data and how those ethical reasons compare to the acceptable justifications for not sharing data as put forth by the NIH
•Discuss various compliance options institutions could implement to ensure the sharing of research data is not only done in an ethical manner, but in a manner that is in compliance with approved data management and sharing plans

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

11:45 AM-1:00 PM ET **Lunch in the Exhibit Hall**

12:15-1:00 PM ET **Meet and Greet With the Supporters and Exhibitors**

12:15-1:00 PM ET **View the PRIMR23 Poster Abstracts**

12:15-1:00 PM ET **Federal Agency, Accrediting Body, CIP/CPIA Council Office Hours**

During this time, representatives from federal agencies, the accrediting bodies, and the CIP/CPIA Councils will be available to answer 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. A list of agencies participating at this time is forthcoming.

12:15-1:00 PM ET **Sponsored Presentation**

Join one of the PRIMR23 Supporters/Exhibitors at this time to hear a presentation on a timely topic, serivce, resource. Information is forthcoming.

PRIMR23 Breakout/Networking Session A Series, 1:00-2:00 PM ET

A1: Power Dynamics: Gearing Up to Do Research--Conducting Research With People, Not on Them

Track(s): *Advancing Equity and Justice; Communication With the Public; HRPP/IRB Administration/Management and Process; Populations Requiring Additional Protections; SBER*

The Belmont Report provides with three principles for conducting and reviewing human subjects research: Justice, Beneficence, and Respect for Persons. As we think more critically about racial justice and inclusivity, we argue that there is more that HRPP personnel, IRB members, and researchers could do beyond merely meeting regulations around ethical research with historically excluded populations. Researchers and IRBs can take lessons from community based participatory research (CPBR) and integrated knowledge translation (IKT) about the importance of acknowledging power dynamics and the collective creation of knowledge with communities and research participants. This session will take a deep dive into integrating these models into the research design and ethics review processes.

Learning Objectives:

•Consider the role of researchers and IRBs in privilege, marginalization, and equitable creation of knowledge in the research enterprise

•Learn how to apply the principles of CBPR and IKT to recruitment, community engagement, and knowledge sharing by using appropriate language and other approaches to foster more equitable research and broader acceptance by historically excluded groups

•Identify and acknowledge how power dynamics show up in the research process

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

A2: A Dialogue With SACHRP

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

This session will be led by representatives from SACHRP. 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 SACHRP 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 Personnel; Educators/Trainers; Clinical Research Staff; Researchers and Research Staff

A3: The Use of Artificial Intelligence (AI) for Informed Consent Form Development

Track(s): *Informed Consent; Emerging Research Challenges and Breaking Issues*

ChatGPT is a natural language processing tool that allows users to have human-like conversations with an AI chatbot and can be used on a variety of tasks ranging from writing papers to composing music. That said, the technolooy has also been met with some controversy. This session will explore the use of ChatGPT and other AI technologies to write consent forms and explore whether an AI application designed to get straightforward and uncluttered responses can improve the quality of consent forms and create consent forms that are more understandable to everyday people while meeting regulatory requirements.

Learning Objectives:

•Gain a basic understanding of ChatGPT

•Explore potential benefits of using AI to improve the quality of consent forms

•Consider ethical implications of using AI when writing consent forms

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

A4: Do You Really Want to Be the Single IRB (sIRB)? Navigating Institutional Risk Assessments When Requested to Serve as the sIRB for Federal Proposals

Track(s): *Single IRB; HRPP/IRB Administration/Management and Process*

Navigating regulations and institutional policies for sIRBs can be a minefield. This session will discuss the implications for serving as the sIRB for cooperative research and how developing institutionally-minded standards for reliance protects IRB and HRPP interests.

Learning Objectives:

•Review the history of regulations surrounding reliance and sIRBs, and the added responsibilities of serving one

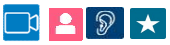
•Underscore the implications for serving as the sIRB and the risk it introduces if a given study exceeds the capabilities of an HRPP/IRB office

•Provide benchmarks that institutions can use when developing best practices for serving as the sIRB and when to pivot to ceding review to another IRB

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

A5: Finding the Path Forward: Research that Faces a Difficult Route to Approval

Track(s): *Legal Considerations in Research Oversight; Emerging Research Challenges and Breaking Issues; Flexibility and Innovation in Research Oversight Processes*



A researcher with federal funding wants to do a study involving current criminal activity of pregnant people to help society better understand what contributes to criminal behavior and to test interventions that might alleviate pressures to commit crimes. The study doesn't directly affect the fetus, but the data, if subpoenaed, could lead to criminal charges or jail time for the pregnant participants. How does that work with 45 CFR 46 subpart B? Or, a research center wants to study methods to promote the adoption of evidence-based practices by randomizing clinics to different implementation strategies – but the practices may impact patients, and it is not clear which institutions are engaged and who is considered a human subject. How does this work for assurance and informed consent requirements? A researcher wants to compare a novel intervention to a sham intervention in a greater than minimal risk study. Although the sham arm poses few risks, the overall study is greater than minimal risk. Is this possible to do if the sham arm requires deception for scientific purposes? Society could benefit from outcomes of the research if they result in a more flexible organ supply chain. Is this approvable? In our current regulatory context, some types of potentially beneficial research face a difficult path to approval. This session will identify some of these regulatory gray areas and discuss how stakeholders can come together to create a path to approval in the context of the Common Rule and other governing statutes or regulations. Come prepared for collaboration!

Learning Objectives:

•Learn about particular types of research that seem difficult to approve under the regulations

•Discuss potential existing pathways to approval for these types of research

•Consider ways that stakeholders within and outside the government could partner to address new pathways to approval for potentially beneficial research that doesn't fit tidily into current regulation

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

A6: Research with Minors: Balancing Autonomy and Protection

Track(s): *SBER; Populations Requiring Additional Protections*

This session will describe the importance of, and strategies for, balancing autonomy and protection when conducting research with minors. The pros and cons of paternalism when conducting research with children and minor adolescents will be presented along with relevant models for maximizing protection while respecting autonomy, particularly for research participants who are emerging into adulthood. The intersection of age and other risk categories (e.g., homelessness, LGBTQIA+) will also be considered.

Learning Objectives:

•Discuss the pros and cons of paternalism when conducting research with children and minor adolescents

•Describe relevant models for thinking about how best to maximize protection while respecting autonomy

•Review strategies for balancing protection and autonomy when conducting research with minors

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

A7: Confessions of a Seasoned IRB Professional: What I Thought I Knew, What I Think I Know, and What I'm Afraid I've Been Wrong About

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

Ever conflate an institutional policy with a regulatory requirement? When's the last time you insisted that the Common Rule requires Exempt research to pose less than minimal risk? Do investigators at your institution believe that OHRP will come for them in the middle of the night for letting their CITI training expire? This session will feature brave HRPP professionals willing to admit to their misconceptions, identify their blind spots, and scrutinize their long-held erroneous beliefs. It will also offer an opportunity to examine common sources of confusion and reasons for perpetuating inaccuracies and falsehoods among professionals in the field of human subjects research protections.

Learning Objectives:

•Examine what we know, question what we think we know, and accept that we may ultimately know nothing

•Reflect on when regulations end and institutional policies begin

•Review the difference between regulatory guidance, FAQs, official correspondence, SACHRP recommendations, and other communications issued by regulatory bodies

•Consider institutional approaches to human subjects protections and question when something is a regulatory must vs. an institutional should

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

A8: One Million or More Considerations for Regulatory Management of a Large Scale Multi-Site Research Program

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

Responsibility for protecting research participants goes beyond the IRB. Whether it's a national consortium, a network of local or regional researchers, or a single site study, researchers and research staff play a critical role in ensuring the safety and wellbeing of participants. Building a trusting relationship between stakeholders including the IRB, researchers, and community can enhance these efforts. In this session, speakers will explore best practices and the challenges encountered "where the rubber meets the road," including inclusivity of under-represented populations, data sharing mechanisms and future use of data, and how to address variable local context.

Learning Objectives:

•Explore best practices for collaborating with numerous internal and external stakeholders to protect research participants

•Identify and problem solve challenges associated with projects spanning multiple institutions and states, with multiple different roles

•Discuss best practices for interactions with the IRB in the context of projects involving multiple engaged and non-engaged stakeholders

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

A9: Designing and Implementing Quality Control (QC) for your Research Compliance Program

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

Research compliance programs often struggled to find a 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 session will showcase QC in research and how it can be implemented for any aspect of your program.

Learning Objectives:

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

Target Audience(s): HRPP/IRB Directors; IBC Administrators, Manager and Staff; Public Relations Professionals; Compliance Personnel; HRPP Educators

A10: Ethical Considerations in the Management of Research Data Using Tokens Session

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

The session will describe emerging data uses in synthetic data and token technologies and the ethical implications of these technologies in research protocols. The session will introduce the concept of token technology and describe token technology and its relationship to synthetic data. Speakers will discuss PHI in regard to synthetic data and if it is a HIPAA compliant method for deidentification, and will discuss the technology's impact on privacy and how it may or may not support the human subjects research regulatory framework we have now. This session will provide insight from IRBs, healthcare institutions, and pharma on questions IRBs, institutional officials, and privacy boards may have about the ethical considerations around privacy, consent, and data validity when using tokens and synthetic data in research and clinical trials.

Learning Objectives:

•Discuss ethical issues of data management technologies, including tokens and synthetic data
•Explore how new data management technologies such as tokens and synthetic data impact privacy, consent, and data validity
•Evaluate best practices for considering protocols utilizing tokens for ethical and regulatory review

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

A11: Working Hard AND Smart: How to Improve Integrity, Effectiveness, and Efficiency with a Collaborative HRPP

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

The mission of the HRPP, including the IRB, is to protect human subjects. How do we ensure that policies, processes, and workflow add value to the HRPP's mission and goal, which is to be high quality, effective, and efficient? On an operational level, this means to constantly reflect on what is or is not being done and why. This session will address these concerns by focusing on topics, including but not limited to: clearly defining the authority of the IRB, HRPP, and institution and operating accordingly; ensuring effective communication among the various components of the HRPP; taking full advantage of what the regulations permit or don't require and not imposing requirements that are not required; avoiding double or over review when relying on an external IRB; and leveraging other operational or workflow resources.

Learning Objectives:

•Understand IRB, HRPP, and institutional responsibilities related to human subjects research
•Identify potential approaches to avoid overregulation
•Explore the challenges with using the IRB as the compliance hub and how other models for distribution of institutional responsibilities can facilitate a more effective and efficient HRPP

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

A12: Let's Not Be So HHS-Centric
Track(s): *HRPP/IRB Administration/Management and Process; A Dialogue With the Feds*

The HHS (e.g. NIH, CDC) dominates our discussion and focus on how the Common Rule is applied and what regulatory guidance offices such as OHRP promulgate and enforce. This session will explore the human subjects work and protections requirements of other Common Rule departments and agencies, when they apply, how they're different from HHS, and who/where you can turn to for help.
Learning Objectives:
•Learn about the human subjects research conducted or supported by non-HHS Common Rule departments and agencies
•Explore the challenges faced by these Common Rule signatories and delve into the types of guidance and additional regulatory requirements they have in place
•Get insight into how other Common Rule departments and agencies work with OHRP
Target Audience(s): HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Compliance Personnel; Researchers and Research Staff

A13: A Dialogue with the NIH OLAW
Track(s): *A Dialogue With the Feds*

NIH OLAW provides guidance and interpretation of the PHS Policy on Humane Care and Use of Laboratory Animals, supports educational programs, and monitors compliance with the PHS Policy by assured institutions and PHS funding components to ensure the humane care and use of animals in PHS-supported research, testing, and training. This session will provide an opportunity to hear from NIH OLAW staff on programmatic updates and to ask questions.
Learning Objectives:
•Hear from NIH OLAW representatives about evolving initiatives, issues, and guidance
•Participate in an open discussion about issues relevant to NIH OLAW stakeholders
•Ask questions of NIH OLAW representatives
Target Audience(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

A14: Driving Postapproval Monitoring (PAM) Program Priorities by Harnessing Existing Data
Track(s): *QA/QI and Postapproval Monitoring; ACU Program Management; Flexibility and Innovation in Research Oversight Processes*

This session will help attendees think of creative ways to leverage existing data such as non-compliance 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
Target Audience(s): ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; Compliance Personnel; QA/QI Professionals

A15: Addressing Administrative Burden When Some Burden Might Be Beneficial
Track(s): *IACUC Protocol Review; IACUC Administration/Management and Process*

There has been much discussion in recent years about reduction of administrative burden and the advantages this can offer to animal care and use programs and personnel. However, this has also raised questions for some. How do we assess burden and what should we do when burden to some may be a key source of information for others? Does the public perception of burden reduction equate to less care for animals and less oversight? In this session, we will discuss how animal care and use programs evaluate burden in the context of a specific institution/program. Attendees will review different techniques for evaluating administrative burden, including the advantages and disadvantages of each, and how programs can use information for programmatic and process improvements.
Learning Objectives:
• Discuss options for evaluating burden depending on the size, complexity, and focus of your program
• Consider how the public perception of "burden" might impact specific programs and overall climate of animal use
• Share how the animal care and use program can make meaning of the evaluation
• Learn how to use data and information to enact program and process improvements
Target Audience(s): ACU/IACUC Administrators, Managers, and Staff; ACU/IACUC Directors

A16: An Update on the US Animal Research Openness Initiative

Track(s): *Communication With the Public*

In this session, peakers will report on the progress of the US Animal Research Openness Initiative. In particular, they will share the results of the inaugural Openness Survey and will introduce the inaugural openness exemplars.

Learning Objectives:

•Learn the background and importance of the Initiative

•Review the survey results of the inaugural Openness Survey and the importance of these findings

•Discuss "Inaugural Openness Exemplars" and consider how organizations can be potential Exemplars

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; Researchers and Research Staff; Research Program Leadership and Institutional Officials; Public Relations Professionals

A17: Nonhuman Animal Welfare Toolbox for Protocol Review

Track(s): *IACUC Protocol Review; Education, Qualifications, and Training*

What are the basic knowledge and skills IACUC members need to effectively conduct protocol review? This session will discuss how to meet regulatory requirements, promote sound science, and ensure humane nonhuman animal care and use by discussing essential but challenging components of protocol review. Speakers and attendees will learn and share ways to efficiently assess nonhuman animal welfare aspects of protocols that are difficult to assess and may overlap with scientific review.

Learning Objectives:

•Evaluate justifications for nonhuman animal use, including the chosen species, model justification, nonhuman animal numbers, and sex of the nonhuman animals

•Discuss evaluation of experimental design through the lens of nonhuman animal welfare and care, particularly the components of experimental design in relation to study aims and nonhuman animal numbers

•Determine if pain and distress is minimized, if alternatives have been adequately considered

•Explore common risk-benefit paradigms and synthesis session components into a comprehensive risk-benefit analysis that focuses on the ethics of the proposed activity by weighing the potential benefits, the soundness of the proposed study design, and potential costs to the animals

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

A18: The Use of Wildlife in Research 101

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

•Share brief examples/scenarios for discussion

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

A19: The Invisible Role of IACUC Administrators

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

During the session, speakers will provide a review of hidden and the often not recognized responsibilities typically assigned to IACUC administrators/coordinators. The session will also explore unique ways to help facilitate a meeting agenda, meeting minutes, and all aspects of the role such as regulatory oversight, postapproval monitoring (PAM), program reviews, and/or facility inspections. Attendees should be familiar with IACUC administrative duties, but this session is geared toward individuals who little to vast experience in this role.

Learning Objectives:

•Discuss the various ways IACUC administrative staff serves as the supporting role during the protocol review process (i.e., leading without authority), and how to communicate the success of the program due to the involvement of this role without sounding self-promoting (e.g., metrics, examples, successes, opportunities for improvement sharing)

•Discuss how to help the IACUC chair navigate the diversity of the IACUC during IACUC functions

•Learn how to collect adequate meeting minutes while focusing on the outcome and deliberation process to demonstrate a fully functioning and engaged committee

•Provide PAM support/review IACUC member training requirements

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

A20: FDA and Alternatives

Track(s): *Animal Well-Being and the 3Rs; A Dialogue With the Feds*

The FDA sponsors and supports a range of alternative development programs. Attendees will learn about recent achievements, current programs underway, and what is coming next for the FDA in development of validated alternatives. ***This session will be presented on-demand; there is no live interaction.***

Learning Objectives:

•Hear about the alternatives FDA is excited about in nonhuman animal research

•Learn how FDA evaluates non-animal models and decide if it is an acceptable alternative in leu of nonhuman animal studies

•Explore the process for applying for a new alternative to be considered for FDA acceptance

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; Researchers and Research Staff; Research Program Leadership and Institutional Officials

A21: Great Public Education Ideas that Deserve to Be Stolen

Track(s): *Communication With the Public; Education, Qualifications, and Training*

As the saying goes, "Imitation is the greatest form of flattery." This presentation will focus on existing research public education efforts initiated by universities and biotech organizations that have paid significant dividends when it comes to better informing the public about research involving nonhuman animals. ***This session will be presented on-demand; there is no live interaction.***

Learning Objectives:

•Hear about a variety of efforts employed by both private and public research organizations to improve public understanding about the need for health studies in animals

•Discuss how expanded communications and messaging can assist in several venues (e.g., websites, other public communications, legislative materials, etc.)

•Explore why some institutions decided to expand communications about animal studies, along with the benefits of doing so

•Consider the challenges in seeking institutional approvals for these efforts, and specific strategies to get organizational buy-in on the value of expanded communications

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

A22: Promoting a Culture of Scientific Integrity in Federal Research

Track(s): *Emerging Challenges and Breaking Issues; Flexibility and Innovation in Research Oversight Processes; Shared Research Oversight Challenges; Research Oversight Leaders and Institutional Officials; Education, Qualifications, and Training*

This session will review the scientific integrity policy development process at US federal agencies, based on the 2023 Framework for Federal Scientific Integrity Policy and Practice. Speakers will discuss a roadmap of activities, metrics, communication, training, and other federal agency-specific practices to promote scientific integrity in federal research.

Learning Objectives:

•Provide the federal definition of scientific integrity
•Identify agency-specific scientific integrity resources
•Name specific practices that promote scientific integrity in research

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

A23: A Little Help Here? Finding Support and Community for Compliance Committees at Small Research Programs

Track(s): *Shared Research Oversight Challenges; Small Research Programs*

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

Learning Objectives:

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

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

A24: Reserved for Late-Breaking session

A25: Reserved for Late-Breaking session

A26: The Institutional Official (IO): Removing the "Outlier" Cloak

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

The Institutional Official (IO) has responsibilities that differ in many ways from those of other senior officials at an institution. The Institutional Official has the dubious task of not only being charged with oversight of research activities but promoting the research culture and advancing the research agenda as well. As both a research superintendent and research advocate, the Institutional Official has to readily adapt interactions with other senior leaders and external stakeholders depending on the nature of the research activity being discussed. Enhancing collaboration and understanding among other senior leaders as well as the comprehensive research community facilitates the integration of all affected parties and discussions about the resources, operations and opportunities relative to the research programs under the purview of the IO. This talk looks the IO as the overseer, facilitator, and driver of research programs and how these diverse roles effectually promote excellence in research.

Learning Objectives:

•Advance knowledge of individuals who aspire to become IOs
•Share tools and strategies for individuals newly in this role
•Provide a forum for discussion among individuals who are currently in the IO role

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

A27: Indirect Costs: What Are the Facilities and Administrative (F&A) Costs?

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

Most research includes "indirect costs," the costs that are not specific to the research project, but that are essential to its success (e.g., buildings, electricity, and often research administration). For federal funders, institutions must submit a justification and rate that supports their F&A costs. Knowing what is included in that calculation, what should be included in the research budget, and when/how to waive the F&A, is essential for successful research. ***This session will be presented on-demand; there is no live interaction.***

Learning Objectives:

•Understand what F&A is, how it is calculated, and when it applies

•Consider the impact and applicablility of F&A waivers

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

2:00-2:15 PM ET **Break in the Exhibit Hall**

PRIMR23 Breakout/Networking Session B Series, 2:15-3:15 PM ET

B1: 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

•Insert learning objective #3

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 Personnel; Educators/Trainers; Clinical Research Staff; Researchers and Research Staff

B2: Grappling With "Classic" Research Ethics Cases: An Exercise in Humility and Course Correction

Track(s): *Advancing Equity and Justice; Communication With the Public*

This session will reframe the enduring lessons from familiar/classic ethics cases to correct some common misperceptions and oversimplifications. For example, how do we seriously consider received from Tribal leaders and bioethicists of color when we talk about ethics cases? How do we refer to them so we don't perpetuate the stigma already attached to them (e.g., referring to US Public Health Service Study instead of Tuskegee, referring to the Arizona State University case when talking about what is commonly referred to as the Havasupai case, etc.). How do we reframe the focus to those who caused the harm rather than those who were on the receiving end?

Learning Objectives:

•Consider how to "flip the script" to focus on stories of resilience and successful collaboration, to bring in positive examples of what successful collaboration and trust-building look like

•Discuss how to reframe cases not (only) as failures of informed consent, but of broader equity and justice considerations

•Learn how to be transparent about our own positionality to cases and how we've evolved in our personal understanding over time

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

B3: Progress in Defining and Evaluating HRPP/IRB Quality and Effectiveness

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

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

Learning Objectives:

•Explain the difference between HRPP/IRB quality and effectiveness in contrast to efficiency and compliance

•Identify the challenges to meaningfully evaluate HRPP/IRB quality and effectiveness, including barriers to conducting empirical research in this space

•Describe promising future approaches to evaluating HRPP/IRB quality and effectiveness, including attention to IRB deliberation, participant protection, and investigator perspectives on added value

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

B4: "Do Not Take if You Are Pregnant": Demystifying the Inclusion of Pregnant Participants in Research

Track(s): *Populations Requiring Additional Protections*

Due to hurdles throughout the clinical trial timeline, pregnant people are routinely excluded from participation. This has led to problematic knowledge gaps and making it hard to make evidence-informed decisions about medical care during pregnancy. Is it safe to continue taking anti-depressants? Is it okay to have surgery? Ethical oversight has been one such hurdle, with many sponsors and investigators finding it easier to exclude pregnant people than to navigate the intricacies of Subpart B IRB review. However, this exclusion represents an ethical dilemma that can addressed as an equitable inclusion matter. When IRBs consider the participation of pregnant people in this way, they have the opportunity to serve as levers for thoughtful inclusion.

Learning Objectives:

•Discuss common misconceptions about the participation of pregnant people in clinical trials

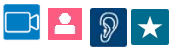
•Discover areas of flexibility within Part B that can be leveraged to increase opportunities for pregnant participants to join studies

•Review strategies for providing guidance to investigators

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

B5: Local Considerations: Navigating the Regulations, Recommendations, and Review

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



In the single IRB world, reviewing IRBs are requesting relying Institutions to document institutional, local, and state requirements relevant to an instance of research in the form of local considerations. Local considerations will help the reviewing IRB ensure that appropriate methods are in place for conducting research within the relying Institution's community. In this session, speakers will explore local context/considerations and best practice recommendations proposed by a SMART IRB Harmonization Working Group.

Learning Objectives:

•Learn about the challenges and local considerations present for the reviewing IRB, relying institutions, and study teams

•Define local considerations

•Understand the roles and responsibilities related to local considerations in a single IRB arrangement

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

B6: IRB Closet Clean-Out: Keep, Toss, TBD (to be determined)

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

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

Learning Objectives:

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

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

B7: Supporting Informed Decision Making: How IRBs Can Foster the Development of Understandable Research-Related Information

Track(s): *Communication With the Public; Education, Qualifications, and Training; Informed Consent*

The ability to understand and use health and science information (including complex information like percentages and other numeracy concepts) in clinical research is a critical component of informed decision-making and public trust in the research enterprise. Increasing awareness amongst IRBs about health literacy and the need to include relevant visuals and other aides when developing and sharing clinical research-related information, supports the creation of tailored information that meet the needs of the intended audience of potential and enrolled study participants. During this session, speakers will introduce health and science literacy considerations within the clinical research context and outline specific techniques that IRBs can use and share with investigators to present visual information that augments understanding of research studies, participation, and results.

Learning Objectives:

•Understand what health and science literacy is and its role in clinical research and effective informed consent
•Describe specific approaches to communicating complex health and scientific information (e.g. numeric info) within participant-facing materials
•Apply plain language and health literacy principles to the presentation of research-related participant-facing information

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

B8: Artificial Intelligence (AI) Is Not the Boogey Man: Simplifying the Concept of "Data" in the Context of AI to Enable Knowledge and Know-How in Review

Track(s): *Research Conducted in the Digital World; Communication With the Public; Flexibility and Innovation in Research Oversight Processes*

AI is becoming more and more prevalent in human subjects research. However, many researchers don't understand why using this technology might require extra protections and considerations. Many see AI as just a tool, like a calculator, and don't realize that the data that powers it is not neutral. This means that there are a number of ethical and regulatory considerations that need to be taken into account when using AI in research. Unfortunately, many IRBs lack the resources to fully understand AI and its implications, making it difficult for them to provide adequate oversight. This session will provide IRBs with a clear and straightforward walk through of an effective IRB review of AI in human subjects research using the current regulatory framework and standards.

Learning Objectives:

•Define the terms "data," "algorithm," and "machine learning" in the context of AI
•Review the historical background of data and how that is relevant to the issues presented in AI today
•Identify and discuss the ethical and regulatory considerations of using AI in human subject research

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

B9: Determining the Undefined: Research Development and Generalizable Knowledge

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

The terms "research development" and "generalizable knowledge" are not formally defined in HHS regulations, but both are facets of the regulatory definition of "research." This session will present multiple perspectives and interpretations of these phrases, propose a framework for assessing whether an activity constitutes research development, explore what does and does not make knowledge generalizable, and explore when QA/QI and user experience activities are in fact research activities, per the Common Rule regulatory definition.

Learning Objectives:

•Explore institutional interpretations of "research development" and "generalizable knowledge"

•Discuss novel and discipline-specific definitions of these terms and consider the challenges with shifting programmatic approaches to these concepts and definitions within specific disciplines (SBER included)

•Apply definitions of "research development" and "generalizable knowledge" to QA/QI/UX activities and demonstrate how QA/QI and user experience activities can be research activities

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

B10: Protocol Deviations, Protocol Violations, Protocol Variances, Protocol Exceptions, and Noncompliance: What Really Needs to be Reported to an IRB

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

The Common Rule and sections 21 CFR 50 and 56 of the FDA regulations only refer to serious and continuing noncompliance, but do not define any of the terms while the phrase protocol deviations only occur in FDA device regulations. Even though protocol deviations, exceptions, and violations are common parlance amongst research teams, auditors and monitors, and IRBs and HRPPs, the regulations are unclear regarding what events should be reported to an IRB, which has led to significant variation in IRB reporting requirements. Using didactic and case study approaches, participants in this session will explore the following objectives.

Learning Objectives:

•Discuss the regulatory basis of event reporting

•Explore variation in IRB requirements for event reporting, the consequences of this variation (including for single IRB arrangements), and opportunities for harmonization

•Discover which events should be reported to IRBs to promote the protection of human subjects

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

B11: How to Cultivate a Vibrant HRPP Team

Track(s): *Leadership Skills Development*

The origin stories of seasoned HRPP/IRB professionals often include tales of unexpected beginnings that just so happened to turn out well. What would it look like to stumble across or be invited into a community eager to bring in new people and new perspectives? How can we, as a community, explore new opportunities for growth and diversity? In this session, attendees will hear from seasoned HRPP/IRB professionals who can provide guidance on what they would have liked to know early-on in their careers and advice on what to consider during career progression; what makes a good HRPP/IRB professional (spoiler: it's not just about certification!); and what strategies are recommended to expand the pathways to the HRPP/IRB for members from historically marginalized communities. This session will also review different opportunities for education, mentorship (e.g., webinars, PRIM&R's Mentoring Program, etc.), and pathways for career progression (e.g., leadership, non-leadership, IRB operations, post-approval monitoring, etc.).

Learning Objectives:

•Identify the type of person (e.g., knowledge, skills, dispositions, etc.) who might make a good HRPP/IRB professional, the places from which to recruit, and the types of supports necessary to ensure their development and success

•Help new IRB/HRPP professionals build a foundation that will allow them to grow and flourish during their early careers

•Explore opportunities and pathways for advancements as an HRPP/IRB professional as the career matures

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

B12: Reseved for Late-Breaking Session

B13: FDA Remote Regulatory Assessments (RRAs): Another Tool for Regulatory Oversight

Track(s): *FDA Regulated Research*

This session will discuss how FDA uses RRAs to assess establishments and their compliance with applicable FDA requirements. The session will focus on the use of RRAs during the COVID-19 pandemic and outside of the pandemic. Relevant guidance and resource materials will be reviewed with specific dicussion on BIMO program areas where RASs have been conducted. ***This session will be presented on-demand; there is no live interaction.***

Learning Objectives:

•Describe what a RRA is comprised of, including the steps taken before, during, and after the RRA is concluded

•Explore the current draft Guidance for Industry–Conducting Remote Regulatory Assessments, Questions and Answers

•Review FY22 Bioresearch Monitoring Program Information (BIMO) Metrics and the number of alternative activities conducted in BIMO program areas

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

B14: Establishing a Culture of Care: Benefits for Science, People, and Animals

Track(s): *ACU Program Management; Animal Well-Being and the 3Rs; Communication With the Public*

A "culture of care" refers to the commitment of an entire institution to the continuous improvement of animal welfare, scientific quality, care of staff (including promoting compassion fatigue resiliency), and openness with external stakeholders. Committing to such, this goal requires dedicated effort from all staff including institutional officials, facility managements, IACUCs, laboratory animal and veterinary staff, researchers and research staff, compliance personnel, public relations professionals, and more. Establishing a culture of care is an opportunity to provide benefits to staff, research animals, and scientific conduct. This session will address why and how to begin establishing a good culture of care at your institution.

Learning Objectives:

• Learn what a culture of care is broadly and the benefits such culture can hold for personnel, animal care, and scientific quality

•Explore concrete ways to evaluate your current culture of care

•Discover practical ways to implement a culture of care at your institution

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

B15: The IACUC Experience in Underrepresented Minority (URM)-Serving Institutions

Track(s): *Advancing Equity and Justice*

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 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

B16: A Dialogue With USDA, APHIS, Animal Care
Track(s): *A Dialogue With the Feds*

Congress has entrusted APHIS with the stewardship of animals covered under the Animal Welfare Act and Horse Protection Act, and APHIS continues to uphold that trust, giving protection to millions of nonhuman animals nationwide. APHIS provides leadership for determining standards of humane care and treatment of nonhuman 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): 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

B17: Nonhuman Animal Welfare Soft Skills Toolbox
Track(s): *IACUC Protocol Review; Leadership Development Skills*

Now that you know how to effectively review protocols, how can you have productive, collegial discussions with investigators? How do you gain expertise you don't have? How do you gain buy-in you don't have? How can you address protocol issues collaboratively with investigators? This session will discuss the soft skills and strategies needed to help with this process.
Learning Objectives:
•Share approaches for building lasting and trusting relationships with investigators to promote collaboration both within and outside of the context of protocol review
•Discuss ways to promote buy-in for pilot studies, adoption of 3Rs, performance standards, and development of standardized procedures
•Describe methods to effectively encourage use of appropriate alternative methods and the 3Rs
•Apply knowledge through an illustrative scenario that integrates these techniques
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

B18: Keeping the Peace: Preventing and Addressing Conflict in the IACUC
Track(s): *IACUC Chairs*

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)
•Share techniques for deescalating and decompressing from stressful and/or frustrating situations
Target Audience(s): IACUC Members, Chairs, and Vice Chairs

B19: Everything You Wanted to Know About the CPIA Credential

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

During this session, a member of the CPIA Council and a 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
•Discuss exam delivery options, and go over exam preparation techniques and what to expect on exam day

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

B20: Wildlife Research Across Jurisdictions: Navigation of Protocol Reviews and IACUC Oversight

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

Wildlife species live in many areas across regulatory landscapes and they do not recognize jurisdictional boundaries. As such, research projects involving wildlife will cross over boundaries including county, state, federal, Tribal, and international property borders. In addition, many wildlife research projects have academic institutional involvement. During this session, speakers will discuss ways to manage protocol review and approval with subsequent joint or concurrent IACUC oversight of wildlife projects at collaborating institutions.

Learning Objectives:

•Define terminology and criteria for a concurrent review process with collaborating institutions, and federal/state/Tribal/international agencies
•Discuss ideas for how to conduct a concurrent protocol review with collaborating institutions, under varied agency oversight requirements
•Explore ways to provide appropriate protocol oversight, annual reviews, and postapproval monitoring in these situations where multiple IACUCs are involved

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; Researchers and Research Staff

B21: The Iron Fist and Velvet Glove: Expanding the Implementation of the 3Rs

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

While researchers in principle may support the expansion of the 3Rs, they are not necessarily proactive in implementing them for their own research. This is, however, a role that the animal care and use program, especially the IACUC, may and should play. This presentation offers a discussion of how the animal care and use program and IACUC may push researchers to further replace, reduce, and refine their use of animals using both the Velvet Glove (education, support, encouragement) and the Iron Fist (regulatory action) approaches. ***This session will be presented on-demand; there is no live interaction.***

Learning Objectives:

•Develop a better understanding of what is involved in the 3Rs
•Identify practices implemented by institutions in support of the 3Rs
•Identify best practices for their own institutions

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

B22: Did I Mention I'm in a Hurry? Improving Efficiency in the Animal Care and Use Program

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

This session explores opportunities to improve efficiency for various aspects of the animal program oversight system, without compromising quality or effectiveness. Topics include meeting administration, the review process, semi-annual program and facility assessments, and other facility operations. ***This session will be presented on-demand; there is no live interaction.***

Learning Objectives:

•Learn about common barriers to animal program efficiency
•Explore options to clarify and streamline routine procedures
•Review strategies to monitor progress in meeting performance goals

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

B23: Data Sharing and Management in Research

Track(s): *Research Involving Data and Biospecimens; Shared Research Oversight Challenges*

For many institutions, federal agency requirements for data sharing and management mean that existing policies and processes must be modified and researchers must be educated on how to appropriately share and manage data. This session will provide an overview of what considerations should be made when retooling programs to meet new expectations.

Learning Objectives:

•Review federal agency requirements for data sharing and management
•Explore the interface between new data sharing requirements and the risks involved with sharing human and animal research data, especially prior to publication
•Identify actions that human and animal research oversight programs can take to help mitigate the risk of data sharing

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

B24: Building Effective Mentoring Relationships

Track(s): *Leadership Skills Development; Shared Research Oversight Challenges*

This networking session will review how to build effective mentoring relationships in and outside research ethics and oversight, including how to be a mentor, how to find a mentor, types of mentoring relationships, and more. Speakers will share their experiences facilitating mentorship for career satisfaction and growth, and attendees will be encouraged to share their experiences and ask questions.

Learning Objectives:

•Define the role of a mentor, including expectations, responsibilities, and ethical considerations associated with being a mentor
•Discuss different types of mentoring relationships, such as formal, informal, peer, and cross-institutional mentoring, and their relevance in the research ethics and oversight field
•Share strategies and resources for identifying and approaching potential mentors both within and outside the institution, emphasizing the importance of diverse perspectives and expertise. Explore strategies for identifying and promoting mentees' professional development needs, including networking, collaborations, and skill enhancement
• Address common challenges encountered in mentoring relationships specific to research ethics and oversight, and provide strategies for managing conflicts, fostering inclusivity, and ensuring diversity in mentorship

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

B25: Institutional Review: What HRPPs and IACUCs Can Learn from Each Other

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

Review of institutional requirements is as important of a step in the review process as is the regulatory review of research. This session will focus on various models for conducting institutional reviews for human and nonhuman animal subjects research, commonalities, differences and what we can learn from each other to enhance these processes.

Learning Objectives:

•Examine HRPP and IACUC review processes, including both regulatory and institutional components and reviewers responsible for each major step

•Learn how ancillary reviews (e.g., safety, funding, etc.) factor into the overall review process and ways to minimize bottlenecks

•Explore how the HRPP and IACUC can work together to improve the efficiency and strength of both processes

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

B26: How Can Institutional Leadership Support Research Oversight Committee Chairs

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

This session will discuss what it is that compliance committee chairs both need and want from their institutional leadership. The session will include a discussion about IRB/IACUC/IBC chairs' resource needs in order to properly manage, train, and recruit for their review committee members. How can institutional leadership support these efforts? What does leadership need to know from chairs? What do chairs need to know about their leadership?

Learning Objectives:

•Identify strategies to present resource needs to institutional leadership in the context that addresses benefits, risks, and opportunities for growth

•Discuss how to create a blueprint for the continued success and longevity of oversight committee chairs

•Explore alternative approaches to foster communication amongst oversight committees chairs and institutional leadership regarding resources

Target Audience(s): IACUC Members, Chairs, and Vice Chairs; IBC Members, Chairs, and Vice Chairs; IRB Members, Chairs, and Vice Chairs; Research Program Leadership and Institutional Officials

B27: Building and Growing an Innovation Program

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

Growth in technology and science has led to an explosion of innovation opportunities in the academic and healthcare environment. This session will discuss how to leverage these opportunities to support strategic mission, attract talent, and build a strong innovation pipeline.

Learning Objectives:

•Identify and evaluate the role of an innovation program within an organization and the important staff roles and expertise to support the program

•Discuss how to work with various customers and how to effectively bring together the inventors, thought-leaders, entrepreneurs, and industry to achieve impactful products

•Explore how to evaluate innovative products and the potential for commercialization

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

B28: How to Support Researchers Under Attack

Track(s): *Research Oversight Leaders and Institutional Officials; Shared Oversight Challenges; Communication With the Public*

This session will discuss how to support researchers who are under attack at an institution, and address when both human and nonhuman animal researchers are targeted by anti-research groups, social media, and mainstream media. Speakers will touch on what support is needed from institutional leadership, respective committees, compliance, legal, and public relations offices to mitigate risks and impact. ***This session will be presented on-demand; there is no live interaction.***

Learning Objectives:

•Identify tactics used against researchers along with mitigation strategies
•Develop effective approaches to communicate vetted plans of action with institutional leadership
•Consider how to communicate with stakeholders pre- and post-attack on researchers

Target Audience(s): Research Program Leadership and Institutional Officials; ACU/IACUC Directors; IBC Directors; Researchers and Research Staff; Legal Counsel; Public Relations Professionals

3:15-3:45 PM ET **Break in the Exhibit Hall**

Concurrent Breakout Sessions, 3:45-4:45 PM ET

C1: Single IRB (sIRB) Coordination Models: Innovative Approaches from Four Clinical and Translational Science Award (CTSA) Programs

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

Academic IRBs serving as sIRB for multi-site research have developed several operational models and utilize key tools to adapt to this complex role. This session will outline coordination challenges faced by IRBs and study teams throughout the sIRB review process and describe operational models and essential tools employed in response to the NIH sIRB mandate, including how multiple CTSAs utilize IRB Reliance Exchange (IREx), developed by Vanderbilt, to support sIRB coordination. This includes a liaison model, study team coordination model, or a hybrid of both.

Learning Objectives:

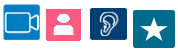
•Identify coordination challenges faced by IRBs and study teams throughout the sIRB review process and describe operational models and essential tools
•Discuss metrics and outcomes of five years of Single IRB data and share outcomes gleaned from it
•Define methods for centralizing study/reliance documentation and communication between site study teams, IRBs, HRPPs, etc., using tools like IREx and other electronic systems

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

C2: Decolonizing Science for Justice: Closing the Research Loop
Track(s): *Advancing Equity and Justice; Communication With the Public; Social, Behavioral, and Educational Research*

The call to decolonize research methods has become increasingly pressing, particularly for historically marginalized and oppressed groups, following the publication of Dr. Linda Tuhiwai Smith's seminal work, "Decolonizing Methodologies: Research and Indigenous Peoples" (2012) and the renewed focus on social justice following the murder of George Floyd in 2020. Decolonizing research methods entails re-examining and breaking down the traditional power structures in scientific knowledge creation, where the principal investigator holds control over all aspects of the project, from conceptualization to dissemination of findings. It emphasizes empowering and engaging study participants as expert contributors, who actively shape the study design, data collection, and dissemination process. This approach, however, presents challenges as it often conflicts with traditional IRB protocols. How can HRPP/IRBs professionals re-imagine work with researchers to decolonize and liberate methods? And how can researchers and HRPP/IRBs ensure that research gives rather than takes from communities?
Learning Objectives:
•Present the Mapping the Life Course of Adoption Project (MAP) as an example of a collaborative and innovative approach for researchers and HRPP/IRB professionals
•Encourage and inspire HRPP/IRB professionals to use their skills to actively involve and engage with their communities
•Highlight the potential for empowerment and research community growth when centering the experiences and perspectives of participants
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; QA/QI

C3: Ethical, Legal, and Regulatory Challenges of Conducting Research on Psychedelic Substances
Track(s): *Emerging Research Challenges and Breaking Issues*



Psychedelic drugs are gaining increased favor as potential treatments for a number of psychiatric conditions. Recent data has shown promise for the use of MDMA, psilocybin, and LSD to treat depression and trauma-based conditions, not to mention the increasingly widespread use of FDA-approved ketamine for treatment refectory depression. The FDA has designated psilocybin a "breakthrough therapy," while two states (Colorado and Oregon) and a number of cities across the US have decriminalized the use of psilocybin for therapeutic and non-therapeutic purposes. Yet, it remains illegal as a Schedule 1 substance (with "no currently accepted medical use and a high potential for abuse") under the federal Controlled Substances Act. In recent years, driven by both unmet medical needs and potential for commercialization, interest in research on psychedelic drugs has skyrocketed. Conducting research on psychedelic drugs raises unique ethical, legal, and regulatory challenges, with which HRPPs/IRBs are currently grappling. How do we appropriately inform subjects about expectations for taking such study drugs, e.g., including the possibility of profound psychedelic experience? These drugs often put participants in an altered state of consciousness and a potentially vulnerable position. Which extra safeguards must researchers consider in conducting these types of studies? How do we handle issues of therapeutic misconception, given the strong public interest in this work? How must institutions handle and store such "illegal" controlled substances? Where is it acceptable for researchers to obtain product and when do FDA regulations apply? How should HRPPs/IRBs resolve conflicting federal and state laws? What issues arise in accepting funding from a psychedelic manufacturer for research? What issues arise when conducting social-behavioral observational studies about psychedelics (i.e., when the researcher is not actively providing the drug as part of research? How are issues of equal access and bias playing out in psychedelic research? What other legal and regulatory concerns must IRBs consider?)? This session will pull together expert researchers, lawyers, ethicists, and HRPP/IRB staff to discuss the above questions and to provide a framework for IRBs to consider in reviewing these types of studies.
Learning Objectives:
•Learn the latest developments in this research space
•Understand the current regulatory framework and legal requirements for conducting research with psychedelics
•Recognize the ethical concerns in connection with such research and understand how HRPPs/IRBs should conduct their reviews to address these concerns
Target Audience(s): HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Research Leadership and Institutional Officials; Legal Counsel; Compliance Personnel; Researchers and Research Staff

C4: Exception From Informed Consent (EFIC): Overview and Common Pitfalls

Track(s): *FDA Regulated Research; Informed Consent*

EFIC requirements for emergency research at 21 CFR 50.24 provide a narrow exception to obtaining informed consent. Protocols for clinical trials conducted under EFIC have a high regulatory and ethical threshold for acceptability and also require robust community engagement, transparent public disclosure, rigorous review prior to being allowed to proceed, and thoughtful oversight.

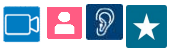
Learning Objectives:

•Describe the regulatory requirements under 21 CFR 50.24
•Identify common EFIC related deficiencies identified in submissions to FDA
•Review the commonalities of the regulations between 21 CFR 50.24 and 21 CFR 50, subpart D "Additional Safeguard for Children in Clinical Investigations"
•Discuss the unique issues, ethical considerations, and requirements in clinical trials conducted under EFIC

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

C5:An Insider's Guide to Utilizing Outside Experts: What We Didn't Know, What We Now Know, and Where We Go From Here

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



This session will be led by HRPP professionals who will provide an in-depth exploration of a a multi-phase project about the use of outside IRB experts. Attendees will also participate in a discussion where they can share their experiences using outside IRB experts.

Learning Objectives:

•Renew their understanding of the regulatory provisions for utilizing outside experts
•Reflect on the IRB's use of outside expertise to date, and assess satisfaction with current practices
•Consider any unmet needs, barriers, challenges, and/or concerns related to external consultation

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

C6: Beyond Research

Track(s): *HRPP/IRB Administration/ Management and Process; SBER*

There are several activities that fall into the gray area between human subjects research and non-human subjects research. When activities exist in these gray areas, the role of HRPPs may move beyond IRB review to facilitating institutional relationships with community partners, supporting ethical student scholarship, and navigating activities as they transition from non-human subjects research to human subjects research. This session will offer some examples of situations when HRPPs are involved in activities that are not considered research, such as case studies, QA/QI, and work with Tribal communities.

Learning Objectives:

•Discuss situations where activities are not research, but HRPP involvement may still be needed
•Explore the reasons HRPPs can be helpful in these situations
•Share examples from different institutions on their approaches to these activities

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

C7: A Dialogue With the Department of Energy (DOE)

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

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

Learning Objectives:

•Provide a brief overview of the DOE and the DOE Human Subjects Protections Program; and DOE's diversity, equity, inclusion, and accessibility (DEIA) goals and activities

•Describe the DOE Human Subjects Protections Program's initiatives to better understand and incorporate DEIA considerations into all phases of human subjects research design, review and conduct, through the establishment of an Implicit Bias Task Force

Target Audience(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 Personnel; Educators/Trainers; Clinical Research Staff; Researchers and Research Staff

C8: Incentive Structures in Research: When the Conflict Is Inside the Building

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

The research community has had endless conversations about the importance of identification and management of conflict of interest (COI). Financial and leadership conflicts show up across the spectrum, from individual investigator conflicts to complex conflicts involving transnational or entrepreneurial relationships, as well as on conference agendas with varying degrees of regularity. Nonetheless, we still have scandals regarding COI ripped from the headlines. What are we missing? Why are conflicts, financial, leadership, or other circumstances still causing so many identification and management problems at all levels of the research enterprise? What do we do when the institution itself has a conflict related to a study, a research program, or an entrepreneurial partnership? How do we think about conflict and mitigation when the IRB may benefit from approval of research? This session will explore how the research incentive structure itself causes all types of conflict, and ways we have to move forward to a less conflicted research endeavor.

Learning Objectives:

•Discuss how the research incentive structure results in COI across the research enterprise

•Identify different pathways toward identification and management of COI in situations not typically discussed (e.g., when the conflict is in the institution or reviewing IRB)

•Create a community willing to openly discuss the research incentive structure and COI (within the context of keeping the private parts private, of course!) with a goal of increasing transparency so we can create a more accountable research environment moving forward

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

C9: Strengthening Research Ethics Committees (RECs) in Francophone African Countries

Track(s): *Transnational Research Collaborations; HRPP/IRB Administration/Management and Process; IRB Chairs*

The majority of efforts to strengthen RECs across Africa have mainly been focused on English speaking African countries due to various reasons. This session will discuss and highlight various efforts and programs aimed at strengthening RECs in Francophone Africa. The session will cover additional strategies that can be adopted in taking REC operations in Francophone Africa to the next level.

Learning Objectives:

•Review challenges in the operations of RECs in Francophone African Countries

•Discuss recent and current efforts aimed at strengthening the operations of research ethics committees in Francophone African Countries

•Explore other strategies that can be adopted in the strengthening of RECs across Francophone Africa

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

C10: Are We the Same or Are We Different? Addressing Challenges Faced by HRPPs Across All Organizations

Track(s): *HRPP/IRB Administration/ Management and Process; Small Research Programs*

HRPPs come in all shapes and sizes, yet all strive to achieve the same goal: ensure the protection of human research participants. HRPPs have a big job, with the IRB being only one of the many components. Depending on the organization type, the challenges faced by HRPPs and approaches taken to overcome them may be similar or vary significantly. This presentation will bring the perspectives of the small, non-academic affiliated HRPP; the large academic affiliated HRPP; and a commercial HRPP to compare and contrast the various challenges and offer ideas to enhance HRPP management regardless of the organization type. Examples and case studies form each organization will be presented and discussed.

Learning Objectives:

•Understand the common challenges among all types of HRPPs

•Describe the unique challenges encountered by HRPPs of varying organization types

•Learn strategies for HRPP success for each organization type and working collaboratively to address common issues

Target Audience(s): HRPP/IRB Directors; IRB Administrators, Manager and Staff

C11: An Adult Lacks Capacity to Consent to Research… Now What Do I Do?

Track(s): *Informed Consent; Populations Requiring Additional Protections*

Some adult participants are unable to provide consent to research participation for themselves, leading to a set of complex decisions regarding whether it is ethical to allow that person to enroll in the study. While the regulations address the requirements for research and assent with minors, beyond requiring the use of a legally authorized representative to provide consent, there are no such regulatory requirements for adults unable to consent for themselves. Therefore, institutions and researchers are left to determine how to best balance the multitude of considerations, including whether there should be limitations on acceptable levels of research risk, designation of a proxy, whether the prospective participant can consent for some aspects of the study, and the need for assent when consent cannot be obtained. In this session, speakers will discuss these and other issues related to enrolling cognitively impaired adults in research studies, and discuss ways IRBs and researchers can ensure the ethical and meaningful participation in research of those that cannot consent for themselves.

Learning Objectives:

•Identify the ethical challenges regarding participation in research of cognitively impaired adults

•Learn best practices for reviewing research to ensure appropriate protections are in place while allowing for the meaningful participation in research of adult participants who cannot consent for themselves

•Gain practical knowledge on assessing decisional capacity and what constitutes an effective assent process for those situations in which the individual cannot provide consent

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; Compliance Personnel

C12: IRB Review of Technology Used for Virtual and Virtual/Remote Clinical Trials

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

Sponsors and investigators are increasingly incorporating mobile medical applications and other virtual trial technologies into their research (e.g., remote clinical investigations involving wearables). What questions should be posed to sponsors or researchers about these technologies? How can researchers at the institution better plan their protocols and documentation to aid IRB review? This session will explore the current regulatory landscape governing mobile health and virtual trial applications, and offer practical tips on how IRBs should approach review of research involving these virtual modalities.

Learning Objectives:

•Describe current regulations surrounding mobile health and virtual trial technology such as relevant .111 criteria (Criteria for IRB Approval), HIPAA (Privacy Rule, Security Rule, HITECH, etc.), cyber security issues, FDA Part 11, etc.

•Identify potential IRB considerations for studies involving virtual trial technologies

•Outline ways IRBs can support their researchers in preparing protocols for IRB review

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

C13: Wildlife Studies and Field Project Review: One Size Does Not Fit All

Track(s): *Oversight of Non-Typical Animals and Situations; ACU Program Management; Flexibility and Innovation in Research Oversight Processes; IACUC Administration/Management and Process*

Animal use activities involving wildlife in either field or captive settings encompass unique situations that may be challenging for IACUCs to evaluate. Attending veterinarians from multiple agencies that work almost exclusively with wildlife will discuss their agency-specific approach to the evaluation of wildlife field projects in order to meet regulatory requirements, fulfill the mission of their agency, and ultimately, ensure the welfare of the wildlife used in projects.

Learning Objectives:

•Consider how there is no "one size fits all" approach for the evaluation of wildlife studies and field projects

•Describe the unique challenges that wildlife studies and field projects present and thus be better prepared to work with principle investigators submitting proposals that involve wildlife

•Learn how to calibrate the institution's mission with regulatory requirements to develop unique processes to ensure the welfare of wildlife

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

C14: Getting the Buy-In to Do Better in Animal Care and Use Programs

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

Maybe its extended release formulation of buprenorphine or housing that facilitates vertical flight for nonhuman primates (the literature supports these refinements as valuable for nonhuman animal welfare, but they can be more expensive than staying with the current practice). How can institutional leadership help support adoption of refinements? This sessions is aimed at institutional leadership that often need to prioritize resources for programs to embrace evidence based refinements to animal housing, care, and methods.

Learning Objectives:

•Learn how to address concerns about time and money around refinements

•Explore how to enhance programs to improve nonhuman animal welfare and build trust with the public

•Consider how not investing/prioritizing costs to implement refinements can lead to lack of quality in research

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

C15: The Current State of the Use of Dogs in Research

Track(s): *Pharma/Biotech Perspectives; Communication With the Public; Emerging Research Challenges and Breaking Issues*

Where are dogs needed for research, who benefits, and where do they come from? The supply chain for dogs needed for research is, in some cases, down to a single link. In this session, speakers will explore where dogs are still critically needed for biomedical research, potential repercussions if the US loses the ability to conduct research with dogs, and what we can do as a community to influence change.

Learning Objectives:

•Learn what would happen if there suddenly were no dogs for research

•Consider how this would impact drug discovery and development for human and veterinary patients

•Explore how to share this information with patients, patient groups, legislators, and the media

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; Researchers and Research Staff; Research Program Leadership and Institutional Officials; Public Relations Professionals

C16: Career Pathways in the 3Rs and Animal Welfare

Track(s): *Animal Well-Being and the 3Rs; Leadership Development Skills*

During this session, speakers will discuss training and career opportunities in the 3Rs and nonhuman animal welfare. Attendees will hear perspectives from individuals in academia, industry, and non-profit: (1) a laboratory veterinarian boarded in animal welfare; (2) a nonprofit leader from The North American 3Rs Collaborative with an MS and PhD in animal behavior and welfare; (3) a Coordinator Animal Behavior & Welfare Management Programs; and (4) Associate Director of Animal Welfare in Industry. Speakers will explore their pathways to show how they got where they are today, and highlight additional certifications or specializations in the field.

Learning Objectives:

•Learn about four distinct career path options through academia, industry, and nonprofit in nonhuman animal welfare and the 3Rs

• Discuss available 3Rs certifications and training programs

•Hear advice on where to get started on a 3Rs career trajectory from a variety of roles including technician, administrator, investigator, and veterinarian

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; Researchers and Research Staff

C17: Reducing Barriers to Participation in Nonhuman Animal Research and Animal Care and Use Programs

Track(s): *Advancing Equity and Justice; Education, Qualifications, and Training; IACUC Administration/Management and Process; ACU Program Management*

What features of nonhuman animal-based research and teaching--and of our animal care and use programs--make them accessible or inaccessible to the people who may want to participate in them? What are specific challenges involved in reducing barriers for human participants while also protecting animal welfare and high quality data?

Learning Objectives:

•Describe the basics of accessibility in research contexts and student laboratory classes including non-human animals

•Share experiences and strategies around reducing barriers for people with disabilities or challenges (physical, mental, learning, etc.) to participate in nonhuman animal-based research or teaching activities

•Identify potential resources and allies in the work of improving the accessibility of our animal care and use programs

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; Researchers and Research Staff; Research Program Leadership and Institutional Officials; Diversity, Equity, Inclusion

C18: Challenges and Strategies for Adequate Staffing in Animal Care and Use Programs

Track(s): *Small Research Programs; ACU Program Management*

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

Learning Objectives:

•Consider how staffing shortages negatively impact the animal care and use program and how to advocate for resources from leadership

•Explore ways to support existing staff to prevent burnout and increased compassion fatigue

•Discuss recruitment and retention strategies to broaden the network of potential candidates (e.g., cross training, promoting roles to those with non-traditional backgrounds)

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

C19: Review Cycles for Documents (SOPs, Protocols, Policies): How Best to Schedule

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

Standard Operating Procedures (SOPs) and policies can improve compliance, enhance standardization, and improve the quality of animal care and use programs and scientific activities, but can add to burden to IACUC review and version control when SOPs, policies, and protocols are revised. This session will consider how to optimize the use of SOPs, policies, and protocols to minimize burden and improve research quality, and how to schedule review so that documents are updated, but on a staggered schedule so as to eliminate burden.

Learning Objectives:

•Discuss methods to optimize the review schedule while minimizing administrative burden, and assess methods to maintain version control in protocols

•Analyze how judicious use of SOPs can improve research reproducibility, consistency of practices, prevent noncompliance, and enhance training

•Consider how SOPs compliment succession planning and continuity for the animal care and use program

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

C20: Veterinary Mentoring for Wildlife Research and Field Procedures

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

Often veterinary procedures are conducted by non-veterinary scientists in fish and wildlife research and field work. Planning for these procedures requires training by and consultation with a veterinarian with appropriate expertise. In this session, speakers will review the common field procedures being conducted, the importance of considering the 3Rs, and discuss the value of the working relationship between the veterinarian and their wildlife research scientist. ***This session will be presented on-demand; there is no live interaction.***

Learning Objectives:

•Provide an overview of the topics discussed during the veterinary consultation with the principal investigator for fish and wildlife research protocols

•Discuss how to do a review of medical management and monitoring of wildlife species during field procedures

•Review invasive procedures and aseptic technique in wildlife species conducted in the laboratory vs. in the field

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

C21: Foreign Regulations That Matter to American Programs

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

Most animal care and use programs and leaders are concerned with 'our program' and compliance with *The Guide* and USDA Animal Welfare Act and Regulations, but the COVID-19 pandemic has clearly illustrated that everything is a global matter. As demonstrated by AAALAC, nonhuman animal welfare concerns are global, and for those using nonhumananimals in the US, working with foreign programs can feel, at times, difficult, due to the slight differences among different countries. This session will highlight the similarities and differences nonhuman animal welfare regulation and nonhuman animal import/export between programs in the US with other parts of the world. ***This session will be presented on-demand; there is no live interaction.***

Learning Objectives:

•Highlight similarities and differences in animal welfare regulations, predominantly in Europe and Asia

•Identify areas in which American research facilities can learn from European and Asian counterparts

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

C22: Situational Vulnerability and Power Dynamics in the Research Sphere

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

Vulnerability relates to the ability to understand, protect, and advocate for one's own interests. This ability can vary based on social, economic, or cultural context, subjecting many people to risk in different ways across the research sphere. How do relational power and imbalanced power dynamics affect situationally-vulnerable individuals in the research context and what strategies can be used to effectively mitigate these? Potentially vulnerable group dynamics exist between scientists and non-scientists members of an oversight committee, study organizers and subjects, principal investigators and research staff, principal investigators and the Institutional requirements for advancement, and more.

Learning Objectives:

•Review case study examples related to power dynamics and situational vulnerability (e.g., conducting research in the classroom/workplace/lab, physicians or therapists recruiting clients/patients for research studies, whistleblower and research misconduct reporting, etc.)
•Recognize other ways in which power and privilege impact the research oversight enterprise (e.g., community member and/or non-scientist dynamics within HRPP/IRB and IACUC committees)
•Explore how principal investigator influence/pressure can be used to fulfill obligations

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

C23: The Making of the Expert IRB/IACUC Staff

Track(s): *Education, Qualifications, and Training; Leadership Development Skills; IRB Chairs; HRPP/IRB Administration/Management and Process; IACUC Administration/ Management and Process; IACUC Chairs*

The quality of training given to new IRB/IACUC staff is mostly responsible for not only their success on the job, but also their ability to become experts quickly. Building a standardized training program is key to giving consistent high quality training. This session will discuss the steps and tools needed to ensure that HRPP and IACUC offices are training experts in a consistent and efficient way.

Learning Objectives:

•Discuss what training methods are not ideal for IRB/IACUC staff
•Explore steps and tools to create a formal training program
•Consider varying approaches for varying parts of the job

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

C24: Meeting Management for Oversight Committee Chairs

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

This session will provide oversight committee chairs an opportunity to share ideas and best practices with meeting management. Speakers will briefly share their experiences running meetings and then invite audience participation to exchange ideas and recommendations.

Learning Objectives:

•Share best practices for running a meeting in general (e.g., how to set the ground rules, keep members on track)

•Consider how to engage and train new members in real-time, give feedback, and manage difficult members

•Discuss how to best integrate community/unaffiliated/non-scientist members into meetings

•Learn approaches for communicating with investigators

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

C25: Environmental Scanning: How to Keep Up with the Changing Regulatory and Ethical Landscape

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

Success as a leader in research ethics depends largely on access to information and professional networks, both formal and informal. Having the right access to information at the right time enables leaders to proactively manage ethical and compliance related issues, rather than reactively respond to changes in the ethical landscape. This session will focus on how leaders can build a high-level network of "in-the-know" individuals, leverage staff to maximize information gathering, and manage time productively to stay on top of new and emerging trends and issues.

Learning Objectives:

•Identify the best methods for information gathering for the research ethics professional

•Discuss how to build a high-level professional network, including options for formal and informal networks

•Review how leaders can best leverage their staff and time to ensure that they are keeping current with new and emerging ethics and compliance trends and issues

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

C26: The Role of Institutional Leadership in Public Policy

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

How does institutional leadership utilize information associated with public policy updates and trends to anticipate and qualify the impact of this information on the ethical conduct of research? The session will assist institutional leadership with determining the impact of policy on research conduct as well as local research policy. In addition, the session will prepare institutional leadership for engagement and how to respond to policy information, using concrete examples of approaches/comments made on behalf of the institution in general and the research enterprise in particular.

Learning Objectives:

•Discover how institutional leadership obtains, communicates, and incorporates policy matters into their work, which are research related, occurring nationally, within their state, and locally

•Explore the role of the institutional leadership in engaging other senior-level institutional officials in thoughtful discussions that assist institutions in incorporating external policy decisions into the research enterprise

•Learn what national organizations do to engage institutional leadership in order to garner feedback and respond to governmental policies or practices

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

4:45-6:00 PM ET **Networking Reception 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 PRIMR23 Poster Abstracts**

4:45-6:00 PM ET **Federal Agency, Accrediting Body, CIP/CPIA Council Office Hours**

During this time, representatives from federal agencies, the accrediting bodies, and the CIP/CPIA Councils will be available to answer 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. A list of agencies participating at this time is forthcoming.

PRIM&R

2023 PRIM&R Annual Conference
December 3–6, 2023
Washington, DC

SBER Conference
December 3, 2023
Washington, DC

PRIMR23 Day 3: Tuesday, December 5

7:30 AM-5:00 PM ET **Registration Open**

8:30-8:45 AM ET **Welcome and PRIM&R Service Award Presentation**

8:45-9:45 AM ET **General Session Keynote Presentation**

9:45-10:15 AM ET **Break in Exhibit Hall**

PRIMR23 Plenary Session Series, 10:15–11:30 AM ET

Plenary Session: Informed Consent Perspectives from Those in the Room

Track(s): *Informed Consent*

Improving informed consent means looking beyond the form and listening to the perspectives of those in the room for the conversations. Researchers may assume that they are effectively conveying the right information to prospective participants. Conversely, prospective participants may not know what information they should be receiving at the time the consent process is taking place. Rarely, if ever, is there an opportunity for these two key parties to compare notes and learn how to improve the informed consent process. This plenary session will discuss the perspectives of research coordinators and participants on the informed consent process, as well as possible implications for practice in response to them.

Learning Objectives:

•Hear empirical results of a study regarding the perspectives of research coordinators about their consent experiences

•Review the results of an empirical study about the perspectives of participants on their consent experiences

•Explore strategies to improve the process in light of these perspectives

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

Plenary Session: Ethical Research With Animal "Pests"

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

IACUCs are tasked with looking after the welfare of vertebrate animals used in research, but do our responsibilities change when the animals are invasive species in field research? How is our understanding of our responsibility to animals shaped by our understanding of where they "belong"? And how did researchers leverage the status of the mouse as a "pest" to create a new niche for mice in our biomedical research enterprise?

Learning Objectives:

•Explore the cultural factors that shape which animals we regard as pests and which animals we view as worthy of protection

•Examine the case of the mouse as an animal whose "pest" status made it an animal whose use in biomedical research was acceptable to the broader public

•Consider situations in field research where an IACUC's understanding of how to ensure animal welfare may be challenged by the presence of vertebrate animals that are invasive species

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

Plenary Session: When Research Misconduct Worlds Collide--Navigating Cross-Committee Compliance Issues

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

Guided by two different sets of research regulations, the co-occurrence of research misconduct (e.g., fabrication, falsification, and plagiarism) and noncompliance in human subjects 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 potential for misconduct and/or noncompliance to span across their work, the challenges of oversight grow even more complex. Yet, by the very nature of misconduct and deviations in human and nonhuman animal research, these overlapping problems are not uncommon. Through a moderated discussion including interaction with the audience, this session will explore the processes for and unique challenges of collaboration between Research Integrity/Misconduct Offices, HRPPs, and IACUCs to identify, manage, and resolve allegations of co-occurring research misconduct and noncompliance.

Learning Objectives:

•Share case studies of co-occurring research misconduct and noncompliance in human and nonhuman animal research

•Review and understand the different regulations and processes involved in the handling of research misconduct allegations and HRPP and IACUC noncompliance

•Discuss best practices—policy and process, including a focus on communication, confidentiality, and standard operating procedures—for collaboration between HRPPs, IACUCs, and research misconduct offices to address allegations of co-occurring research misconduct and noncompliance

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; Research Leadership and Institutional Officials; Compliance Personnel; Clinical Research Staff; Researchers and Research Staff

Plenary Session: Research Ethics Through the Lens of Healthcare Delivery Models-- Statism, Consumerism, and Professionalism

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

Healthcare is delivered via the intersection of three models: statism (the state oversees healthcare), consumerism (consumers drive the healthcare market), and professionalism (medical professionals determine the provision of healthcare). Research ethics shares significant commonalities with these models--state oversight, consumer driven changes to what is viewed as ethical, and professional opinions that support research participant welfare for both human subjects and nonhuman animals. This session will take a deep dive into how these three models can be viewed within the context of research ethics, as well as how the state, consumers, and professionals all impact how research ethics are defined and operationalized.

Learning Objectives:

•Learn the components of statism, consumerism, and professionalism within research ethics

•Explore the advantages and disadvantages each approach brings to human subjects and nonhuman animal research oversight

•Consider how to best communicate about research ethics using a combination of these models

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

11:30 AM-1:00 PM ET **Lunch**

11:45 AM-1:00 PM ET **Plenary Session: Real Time IACUC—This Session Is In!**

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

Be sure not to miss this real-time discussion by our mock IACUC panel of a variety of issues that might arise in a real IACUC meeting. Representatives from AAALAC International, OLAW, and USDA will provide their perspective on the issues discussed by the mock IACUC. This session will be held over lunch. Attendees should get their lunch in the Exhibit Hall before proceeding to this session.

Learning Objectives:

•Learn about how IACUCs handle discussions around timely topics

•Hear from the federal agencies and accrediting body on how they would respond to regulatory/accreditation questions

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

12:15-1:00 PM ET **Meet and Greet With the Supporters and Exhibitors**

12:15-1:00 PM ET **View the PRIMR23 Poster Abstracts**

12:15-1:00 PM ET **Federal Agency, Accrediting Body, CIP/CPIA Council Office Hours**

During this time, representatives from federal agencies, the accrediting bodies, and the CIP/CPIA Councils will be available to answer 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. A list of agencies participating at this time is forthcoming.

12:15-1:00 PM ET **Sponsored Presentation**

Join one of the PRIMR23 Supporters/Exhibitors at this time to hear a presentation on a timely topic, serivce, resource. Information is forthcoming.

PRIMR23 Breakout/Networking Session D Series, 1:00-2:00 PM ET

D1: Finding Our True North: Informed Consent as the Moral Compass in the SBER Seas

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

The informed consent process is a critical guiding force in research participation. During this exploration, presenters will delve into the principles and practices that make informed consent a cornerstone of ethical research. Furthermore, we'll discuss how IRBs can encourage the informed consent process as a means to initiate a meaningful and ethical relationship with research participants.

Learning Objectives:

•Review consent over a study lifecycle in different SBER contexts (e.g., ethnographic studies, longitudinal, digital world, etc.)

•Analyze the ethical considerations and recognize the importance of establishing a respectful and trustworthy relationship with participants

•Share creative insights on how IRBs can help support researchers prioritize this principle

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

D2: Ethical and FDA Regulatory Considerations for Returning Individual Genetic Testing Results

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

Next Generation Sequencing (NGS) tests are capable of rapidly identifying or 'sequencing' large sections of a person's genome and are key advances in the clinical applications of precision medicine. Researchers can use these tests to find genetic variants that help them diagnose, treat, and understand more about human disease, but there are no best practices for the return of health-related genetic information in a research setting. This session will discuss ethical strategies and applicable FDA requirements for the genetic return of research results directly to research participants.

Learning Objectives:

•Describe the applicability and requirements of FDA device and human subjects regulations to research involving the return of health-related genetic sequencing results

•Compare and contrast different strategies that research studies have taken to return health-related genetic sequencing results to research participants

•Recognize the complexities of returning health-related genetic sequencing results to research participants

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

D3: A Tale of Two Institutions: Examining the Impact of the FDA Single (sIRB) Mandate

Track(s): *Single IRB; Emerging Research Challenges and Breaking Issues; FDA Regulated Research; HRPP/IRB Administration/Management and Process*

In Fall 2022, the FDA released a Notice of Proposed Rule-Making (NPRM) that detailed a requirement for a large proportion of multi-site studies regulated by the FDA to be reviewed and approved by a sIRB. As many of these studies will be funded by industry Sponsors, there is a consensus amongst IRB professionals that commercial IRBs will fulfill this requirement and this transition from local IRB review to reliance reviews has the potential to have a tremendous impact on IRB offices around the country. In this session, attendees will hear from institutions that will be impacted very differently: one institution will have to adapt to studies transitioning "out" and another institution which already utilizes commercial IRB services for industry-funded studies. The institutions will address enforcing HRPP (local context) requirements when serving as neither the IRB of record or Sponsor (holding the investigational new drug or investigational device exemption). Additionally, this session will include the view from an independent IRB about the potential FDA sIRB mandate will affect the IRB-review landscape.

Learning Objectives:

•Review the FDA NRPM for the sIRB mandate and identify when the sIRB requirement will apply

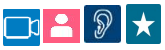
•Discuss the impact of this mandate for sites which review industry-funded studies and examine strategies to transition the work to enhance support for study teams and the institution

•Define local context requirements and the challenges of ensuring these continue to be met under this specific sIRB mandate

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

D4: Change the Game By Working Together: Tips for Increasing HRPP/IRB and Researcher Collaboration

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



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; Clinical Research Staff; Researchers and Research Staff; Compliance Personnel

D5: Accessibility by Design: Operationalizing Full Commitment to the Americans With Disabilities Act in Clinical Research Practice

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

Although people with disabilities make up the largest minority group in the United States, relatively little attention has been paid to the underrepresentation of people with disabilities in clinical research. Speakers will discuss the legal statutes that guarantee or are intended to guarantee equal opportunities for people with disabilities, experiences of people with disabilities as clinical trial researchers and participants, and the features of a new Accessibility by Design in Clinical Research Toolkit.

Learning Objectives:

•Review the fundamental international and domestic regulations and guidance that address non-discrimination of people with disabilities in clinical research

•Learn from people with disabilities about the realities of working and participating in clinical research and their foci for improvement

•Explore the new Accessibility by Design in Clinical Research Toolkit, including the key themes, recommendations, and tools

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

D6: Criminal Justice Research Studies: Navigating IRB Challenges and Considerations

Track(s): *SBER; Populations Requiring Additional Protections; HRPP/IRB Administration/Management and Process*

In recent years, the public outcry surrounding policing practices and the call for criminal justice reform has led to increased awareness and funding to study these issues. However, the diverse range of topics and study populations within criminal justice studies present unique challenges for IRBs.

This session aims to provide overview of different types of criminal justice studies, review complexities, and address strategies. Speakers will discuss when a full board review is required and what is involved when reviewing studies sponsored by the US Department of Justice.

Learning Objectives:

•Provide an overview of the types of criminal justice studies being conducted

•Discuss when to apply 45 CFR 46 Subpart C—Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners

•Identify situations requiring full board review (i.e., when studies necessitate a more comprehensive review process)

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

D7: Adding Another P to the HRPP: The Voice of the Participant in HRPPs

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

HRPPs are intended to ensure that the rights, welfare, and safety of those that participate in research are protected. However, research participants have little, if any, effective voice in how research is designed and implemented, and even less in the operation of those programs designed to protect their rights. Thus, HRPPs risk missing the mark in how they serve the intended beneficiary of their work and serving interests other than the research participant. Speakers will discuss the problems intrinsic to the current HRPP system and suggest solutions that can increase the role of the participant and enhance the ability of HRPPs to fulfil their mission.

Learning Objectives:

•Identify the key stakeholders in HRPPs and how their interests are represented

•Understand the ways in which the role of research participants in human research protections can be enhanced

•Consider the role of government and regulation in acting as a proxy for participants

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

D8: IRB Chairs Community-Building Networking Forum

Track(s): IRB Chairs

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

D9: A Dialogue With the Department of Defense (DOD)

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

This session will describe how the DOD HRPP evolved from the 1940's through current innovations during Operation Warp Speed in its crusade against COVID-19. This session will also include how the current DOD HRPP and its Component Offices for Human Research Protections engage with internal and external investigators and other research protections personnel.

Learning Objectives:

•Review the history of the DOD HRPP alongside how federal regulations governing research participant protections were developed

•Understand how the DOD research program directs non-military science and technologies

•Learn how to engage DOD HRPPs for the purposes of prospective research

Target Audience(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 Personnel; Educators/Trainers; Clinical Research Staff; Researchers and Research Staff

D10: Research or Not? Applying the Common Rule "Carve-Outs"

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

The Common Rule deems four types of activities that are not research, including scholarly and journalistic activities, public health surveillance, collection or analysis of material for criminal justice investigations, and authorized operational activities for intelligence, defense, or national security. What should HRPP professionals consider when reviewing activities that potentially fall into one of these categories?

Learning Objectives:

•Learn about the four categories of activity deemed not to be research and what this means for HRPPs

•Discuss best practices for making and documenting these determinations

•Review challenging case studies

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

D11: Translating Ethical Principles for the Responsible Use of Emerging Science and Technology Across a Global Pharmaceutical Company

Track(s): *Pharma/Biotech Perspectives; Emerging Research Challenges and Breaking Issues; Research Conducted in the Digital World*

The biopharmaceutical industry understands that their work impacts people in a fundamental way--with regard to their health and when they are at their most vulnerable. Given the rapid evolution of emerging science and technology and the speed at which legislation, regulation, and guidance governing these are developed, it is critical to have ethical decision-making frameworks that are available for use and embedded throughout the medicine lifecycle--from drug discovery and development to product distribution and patient care. This session will take a deep dive into a collaborative approach to responsible innovation and review specific case studies that demonstrate how it is evolving biomedical ethics toward a model that requires multi-stakeholder, cross-functional engagements.

Learning Objectives:

•Learn how to collaboratively develop ethical principles and frameworks for the responsible use of emerging science and technology, specifically in the areas of sharing and reusing health data as well as the responsible use of Artificial Intelligence (AI)

•Understand how the organizational approach and application of data and AI ethical principles has been foundational to responsible innovation in drug discovery, drug development, product distribution through to patient care

•Gain experience applying these principles to relevant cases and learn to identify questions and build best practices for being transparent and managing this ethically complex space together

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

D12: Leading Up: Strategies for Impacting the Oversight of Your HRPP

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

This session is designed to provide practical advice for HRPP/IRB directors and managers on how to educate and collaborate with new or existing research leadership to ensure effective oversight of an HRPP. Often HRPP/IRB directors and managers are tasked with training and educating those they report to on key functions and responsibilities of institutional leadership. This may occur as part of onboarding new leadership or as changes in an HRPP may necessitate new educational efforts. Training up is challenging, but it is critical that HRPP/IRB directors and managers ensure those with oversight responsibility have information and understanding to make important decisions impacting the HRPP. Join current HRPP/IRB directors and managers in a networking session that reviews strategies for leading up and how it can effectively create opportunities for empowerment and career growth. Themes that will be explored include onboarding new institutional leadership, collaborative HRPP change management, responding to complaints or concerns about the HRPP, strategic planning, and enabling leadership to advocate for the HRPP.

Learning Objectives:

•Understand challenges and opportunities with "leading up" and training institutional leadership about HRPP function and responsibilities

•Identify strategies to address these challenges and opportunities

•Explore short and long term solutions for "leading up" to ensure effective oversight of an HRPP through case examples highlighting real-world experiences of HRPP/IRB directors and managers

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

D13: Developing Educational and Quality Assessment Materials for IRB Protocol Submissions

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

Where do IRB administrators begin in their educational and quality assessment material development? This session will outline steps to creating a systematic educational approach that utilized online modules (Canvas), easy-to-access design software (Canva), streamlined website updates (blogs and guides), simple screengrab editing tools (Evernote/Skitch), social media considerations (Twitter), audio/video walkthrough guides, recorded webinars and workshops, fillable PDFs (with checkboxes), self-paced website tours (with URL links) and networking strategies for engaging internal and external departments to help create and broadcast IRB educational materials in accessible and user-friendly ways to the research community. ***This session will be presented on-demand; there is no live interaction.***

Learning Objectives:

•Learn how to harness user-friendly technology in an IRB office

•Share examples of design templates to build from

•Streamline educational materials on IRB topics

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

D14: A Dialogue With AAALAC International

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

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

Learning Objectives:

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

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

D15: New Animal Welfare Act Regulations for Birds and the IACUC

Track(s): *Education, Qualifications, and Training; Emerging Challenges and Breaking Issues; IACUC Protocol Review; Oversight of Non-Typical Animals and Situations IACUC; A Dialogue With the Feds*

The USDA recently promulgated regulations and standards that cover birds not bred for use in research. This session will discuss what birds and activities are now regulated under the Animal Welfare Act, what entities need licenses or registrations, and the role of IACUCs in ensuring compliance with these new regulations.

Learning Objectives:

•Review standards and regulations related to birds not bred for use in research
•Understand new requirements for licensees and registrants under the Animal Welfare Act
•Discuss new IACUC responsibilities under the regulations to ensure compliance

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

D16: FDA Modernization Act 2.0: Fact and Fiction

Track(s): *Pharma/Biotech Perspectives; Emerging Research Challenges and Breaking Issues*

In 2022, the FDA Modernization Act 2.0 was passed. The media immediately began reporting "No more animals needed for drug discovery and development!" Is this accurate? In this session, we will separate fact from fiction and examine our current and future state in regards to when and where animals will be needed when developing new medicines.

Learning Objectives:

•Learn what was changed in with the passing of the FDA Modernization Act 2.0
•Discuss where the field is with alternatives for developing and testing new drugs
•Explore where nonhuman animal models are still needed, why, and the value they bring to the scientific process

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; Researchers and Research Staff; Research Program Leadership and Institutional Officials

D17: Tips and Tricks for IACUC Chairs in the Private Sector

Track(s): *IACUC Chairs*

Due to the nature of the research conducted in the private sector (e.g., 'big pharma', contract research organizations, etc.), the IACUC at these institutions often deal with slightly different problems and scenarios than the IACUC sees in academia. This session is devoted to presenting and discussing problems and/or issues that are unique for the care and use of nonhuman animals by the private sector.

Learning Objectives:

•Identify situations unique to the private sector that cause issues for the IACUC and the IACUC chair

•Describe strategies for dealing with sensitive issues, including conflicts that are unique to an IACUC in private sector businesses that use nonhuman animals for research

•Discuss how recent regulatory changes and/or supply chain issues have affected the protocol review process and/or other IACUC functions that may need to be navigated by the IACUC chair

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

D18: The 3Rs: Who's Responsibility Is it Anyway?

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

When everyone is responsible for the 3Rs, there can be a dilution of responsibility. How should various key leaders in an animal care and use program support and advance the 3Rs individually and together? Speakers will discuss where they see their roles (Investigator, IACUC Chair, and Attending Veterinarian) having responsibilities for the 3Rs. Interdependencies will be explored through discussion.

Learning Objectives:

•Learn how each key leaders in the animal care and use program can actively engage in advancing the 3Rs

•Explore how these roles can work together to synergistically achieve more through collaboration

•Discuss how these roles can overcome inertia and resistance to change to implement 3Rs advancements

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; Researchers and Research Staff

D19: Investigators as a Resource for Animal Care and Use Innovation

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

This session will include discussion of outreach methods that build a culture of collaboration. Investing in relationships extending beyond official IACUC business can not only improve compliance and welfare, but also promote a culture of diversity, inclusion, and good animal welfare. The panelists will discuss collaborative opportunities such as employing PIs for training and as ad hoc consultants. It will also discuss ways to customize approaches to solve issues with PIs and prevent future issues by making relationships more mutually productive.

Learning Objectives:

•Develop methods for IACUCs to build positive relationships with PIs extending beyond protocol modifications and correction of noncompliances

•Discuss methods to address root causes of progammatic issues by leveraging these relationships

•Learn how to promote a culture of diversity and inclusion for personnel and good animal welfare for research animals

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

D20: Meeting the Challenges of IACUC Administration: Case Studies in Handling Complex Protocol Issues/Situations

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

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

Learning Objectives:

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

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

D21: Moving the Needle: The Marseilles Declaration--What Is it?

Track(s): *Pharma/Biotech Perspectives*

In 2022 at the Federation of European Laboratory Animal Science Associations meeting in Marseille, France, animal welfare experts from a diverse range of Pharma companies came together to discuss and define their shared animal welfare expectations and goals. From that discussion, the framework for the Marseille Declaration was crafted. Thus far, six Pharma companies have signed on, aligning their expectations for animal care and use both internally and at their third parties, globally. This voluntary collaboration provides a proactive initiative to align and advance animal welfare. ***This session will be featured on-demand; there will be no live interaction.***

Learning Objectives:

•Review the principles and goals of the Marseille Declaration
•Discuss the benefits of joining the Marseille Declaration
•Learn how to overcome hurdles to signing and getting buy-in from institutional leaders

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; Researchers and Research Staff; Research Program Leadership and Institutional Officials; Public Relations Professionals

D22: Training IACUC Members: New Member On-Boarding and Continuing Education

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

How can we best keep IACUC members engaged through training? By developing dynamic on-boarding training for new IACUC members, it can inspire their confidence to participate in committee duties from the beginning. Additionally, offering diverse continuing education opportunities can keep IACUC members informed and foster participation in active learning sessions. In this session, we will review strategies to engage new and veteran IACUC members through interactive training opportunities. ***This session will be featured on-demand; there will be no live interaction.***

Learning Objectives:

• Review training requirements for the IACUC
•Learn effective on-boarding strategies to train new IACUC members
•Discuss continuing education opportunities for IACUC members

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

D23: Chimeras, Who's responsibility Is it? IRB, IACUC, IBC, All of the Above?

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

For decades, researchers have inserted different types of human cells into nonhuman animals at various stages of development to advance understanding of human biological processes and identify new investigational therapies. For almost as long as scientists have conducted this kind of research, there has been debate about whether it should take place and, if it does, how best to respond to the ethical and policy issues it raises. Particular public, academic, and policy attention has focused on these studies—often termed “chimera” research—that involve the transfer of human stem cells (or their direct derivatives) into nonhuman embryos or animals. These studies have raised questions about whether the moral status of the nonhuman animals is altered by the insertion of human stem cells, whether it is morally appropriate to cross species boundaries in this way, and whether chimeric studies should be subject to additional prohibitions or oversight.

Learning Objectives:

•Review the key ethical issues raised in chimeric research
•Discuss the guidance and recommendations around chimeric research
•Explore who is responsible for providing oversight in chimeric research

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

D24: Public Policy Roundtable

Track(s): *Communication With the Public; Leadership Skills Development; Shared Research Oversight Challenges*

Before finalizing regulations, policies, and guidance, federal agencies issue drafts of the documents for public comment, as they seek to interpret and implement laws passed by the United States Congress. Regulators are required to not only review all the comments that they receive from the public, but they have to be transparent about how all the comments were handled. To that extent, the preamble to the final regulations or policies typically includes a detailed rationale for accepting and rejecting recommendations and suggestions received. It is incumbent on the research community to share their expertise and real-world experience in shaping public policies impacting research with humans and other animals. This networking session will focus on the research ethics and oversight community's vital role in federal policy making as it impacts research and research oversight, including the importance of engaging, how to identify what to comment on, and best practices for submitting comments.

Learning Objectives:

•Understand the federal policy making process and the mechanisms for the public to engage
•Identify ways to stay abreast of policy notices and determine items to comment on
•Learn the process and best practices for submitting regulatory comments

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

D25: Ask the Institutional Official (IO) Session

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

This is an open forum opportunity for IO's to explore hot topics or pressing cases from the audience. Sharing approaches to address these and other issues facing institutional leadership will help cultivate assessment and strategic skills to support research programs and maintain organizational culture.

Learning Objectives:

•Identify and discuss the range of issues that may come before the institutional leadership
•Share strategies for bringing together disparate and maybe competing components into an integrated whole or at least narrowing the dis-integration
•Identify the critical engagements in which the IO must lead, be a part of, and stay far away from (i.e., what is the proper and most effective involvement for the IO)
•Consider how resource allocation and the establishment of priorities both contribute to and flow such an integrationand stay far away from (i.e., what is the proper and most effective involvement for the IO)

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

D26: What's Coming Down the Line that Institutional Leadership Needs to Know?

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

Institutional leadership needs to stay up-to-date with the evolving federal funding landscape and its implications for research. Following the conclusion of the COVID-19 pandemic, federal government agencies continue to refocus their efforts, which means balancing strategic initiatives and new fiscal priorities.

Learning Objectives:

•Learn about the national strategy, policy, and budget reports from federal funding agencies that help to inform research institutions and their leadership
•Explore the rise of the private sector funding and push for public/private partnerships to move research forward
•Review associations that inform institutional leadership and the mechanisms of engagement, as well as current issues that institutional leadership should be paying attention to

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

D27: What You Don't Know Can Hurt You: Using Metrics to Evaluate Research Administrative Activities

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

There is an abundance of information, data, metrics, etc., that may be available and/or useful 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): HRPP/IRB Directors; ACU/IACUC Directors; IBC Directors; Research Program Leadership and Institutional Officials

2:00-2:30 PM ET **Break in the Exhibit Hall**

PRIMR23 Plenary Session Series, 2:30-3:45 PM ET

Plenary Session: It's About Time: Inclusion of Sexual and Gender Minorities in Clinical Research

Track(s): *Populations Requiring Additional Protections; Advancing Equity and Justice in Research; HRPP/IRB Administration/Management and Process; Pharma/Biotech Perspectives*

While the importance of representatively diverse study populations in clinical trials has been well-established, a dearth of guidance and engagement initiatives related to the inclusion of LGBTQIA+ participants in research persists. This panel will discuss key areas to consider in the development and review of study protocols, facilities, and institutional research policies to foster more equitable inclusion. The panel will discuss overt and covert barriers to LGBTQIA+ participation, strategies to encourage appropriately expansive eligibility criteria, practices around sexual orientation, sex, and gender data collection, and the importance of listening to and leveraging community feedback to understand research risk.

Learning Objectives:

•Understand the current scope of LGBTQIA+ inclusion in clinical trials and the barriers
•Identify key organizational and procedural changes to foster inclusion in clinical trials
•Be equipped with skills to respectfully communicate with all participants to foster safe environments, to protect confidentiality, and to recruit and retain participants

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

Plenary Session: Evidence-Based Environmental Enrichment and Behavioral Management

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

Environmental enrichment standards for laboratory animal species should be evidence-based, rather than based on non-scientific approaches, such as anthropomorphism and/or colloquial experience. Given the dearth of information on and understanding of the needs of many of species, other than nonhuman primates (NHPs) and marine mammals that are covered under the Animal Welfare Act (AWA), there is a pressing need for continued substantial investment in the science of enrichment and behavioral management. In this session, behavioral management experts, as well as researchers who explore the science behind changing the environmental milieu of research animals, will present their perspectives on environmental enrichment. The goal is to discuss strategies for improving and expanding the supportive evidence for environmental enrichment of research animals, while keeping the pragmatic elements (e.g., differing institutions with widely varying resources) as a key consideration.

Learning Objectives:

•Discuss the importance of evidence-based environmental enrichment standards for laboratory animals
•Describe the need for continued investment in the science of enrichment and behavioral management for species other than NHPs and marine mammals that covered by under the AWA
•Consider strategies to improve and expand the supportive evidence for environmental enrichment for laboratory animals

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

Plenary Session: The Lifespan of a Research Protocol: The Journey From Research Using Nonhuman Animals to Research Involving Humans

Track(s): *Shared Research Oversight Challenges; IACUC Protocol Review; FDA Regulated Research*

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

Learning Objectives:

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

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

Plenary Session: An Institutional Approach to Research Integrity

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

There are multiple federal initiatives to promote scientific integrity and change the culture of research. The new CHIPS Act mandate expands the requirement for responsible conduct in research (RCR) training to include faculty and other senior personnel on National Science Foundation awards; it expands the scope of such training to include mentoring training and training to raise awareness of research security risks, as well as Federal export control, disclosure, and reporting requirements.

Learning Objectives:

•Understand and discuss what specific changes the CHIPS Act made to responsible conduct of research training requirements

•Explore training tools and discuss implementation strategies

•Identify RCR tracking mechanisms to help maintain compliance and ensure accurate reporting

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

3:45-4:00 PM ET **Break in the Exhibit Hall**

PRIMR23 Breakout/Networking Session E Series, 4:00-5:00 PM ET

E1: A Dialogue With FDA

Track(s): *A Dialogue With the Feds; FDA Regulated Research*

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 Personnel; Educators/Trainers; Clinical Research Staff; Researchers and Research Staff

E2: Digital Marketing Strategies for Research Participant Recruitment: Ethical Considerations, Efficacy Assessment, and Regulatory Compliance

Track(s): *Research Conducted in the Digital World; Emerging Challenges and Breaking Issues; Social, Behavioral, and Educational Research; HRPP/IRB Administration/Management and Process*

In this session, speakers will delve into the realm of digital marketing and its crucial role in recruiting study participants. Speakers will explore the intersection of digital marketing tools and research recruitment strategies, considering their potential benefits, challenges, and ethical considerations within the context of human subjects research. In addition, speakers will lead discussions on the application of technology-driven approaches, drawing parallels to commercial entities' practices while emphasizing the unique considerations that arise in recruiting research participants, and participants will critically assess the efficacy of various digital marketing techniques, equipping study teams and IRBs with effective methods to track and evaluate their impact. Attendees will gain insights into the utilization of robust assessment frameworks and explore practical approaches for measuring the success of their recruitment endeavors. The session will conclude with a comprehensive examination of the regulatory landscape surrounding the use of digital marketing tactics in research recruitment.

Learning Objectives:

•Review the ethical considerations, benefits, and challenges of employing digital marketing strategies for recruiting research participants

•Explore how to evaluate the efficacy of digital marketing techniques and utilize assessment frameworks to measure the success of research participant recruitment efforts

•Gain awareness of the regulatory landscape and compliance requirements when utilizing digital marketing tactics in participant recruitment, ensuring adherence to ethical guidelines and protecting participants' rights and welfare

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

E3: Key Information Sections Four years In: Where Are We and Where Should We Be Going?

Track(s): *Informed Consent; IRB Basics*

As of January 2019, all consent forms for federally funded studies must have a key Information section containing elements aimed at increasing participant understanding and assisting decision-making. There has been significant uncertainty and debate in the research community over what exactly Key Information sections should include and look like, which remains relevant in light of the FDA's recent proposal to mirror the Key Information requirement for FDA-regulated research. In this session, speakers will present the results of empirical research characterizing actual Key Information sections as they are found on consent forms posted to ClinicalTrials.gov, and present recommendations on how to improve Key Information sections and best practices for writing and reviewing them.

Learning Objectives:

•Understand the regulatory requirement for Key Information sections and what the Common Rule and other regulatory documents say about the sections to date

•Review the results of empirical research characterizing Key Information sections as they are found in consent forms posted to ClinicalTrials.gov across several axes, including length, readability, and topics included

•Explore a set of empirically-informed recommendations for best practices concerning the writing and IRB review of Key Information sections

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; Compliance Personnel

E4: Leveraging Logic Tools for Not Human Subjects Research and Exemption Determinations

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

On the one hand, by its nature, exempt human subjects research carries little risk. The research community expects streamlined review process for research that carries minimal risk, and as the revised Common Rule suggests, the regulators agree with this view. This expectation for an efficient review process extends to the assessment of whether projects meet the definition of human subject research and require regulatory oversight, including IRB review. On the other hand, just because a project is determined to be exempt does not mean institutions do not have an obligation to ensure that the research meets high ethical standards. Further, the determination of whether activities constitute research involving human subjects can be difficult and incorrect determinations can increase regulatory risks. The goal of this session is to show how to streamline exemption determinations through automated tools while maintaining regulatory compliance and robust ethical standards. Speakers will look at the pros, cons, and challenges of using tools to automate the decision processes for not human subjects research and exemption determinations present, including how to ensure these tools are accurate and compliant and how they can encourage research teams to take an active role in and ownership of the review process.

Learning Objectives:

•Understand different ways of being exempt from the regulations and who can and should makes exemption determinations

•Learn about tools that institutions have deployed for not human subjects and exemption determinations

•Explore the considerations that should underpin development of automated tools and lessons learned

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

E5: Communicating With the Public: What Does the Public Have to Say?

Track(s): *Communication With the Public*

Former New York Mayor Ed Koch stood on street corners and greeted passersbys with his now famous slogan, "How'm I doin'?" This session aims to ask former and current research participants, “How’s the research community doing?” Do research participants feel heard? Has all the talk of participants as partners in research translated into an inclusive and collaborative research environment? What can researchers, IRBs, and other entities responsible for protecting the rights and welfare of research participants do to improve the experience of those participating in research?

Learning Objectives:

•Learn what the research enterprise is doing well and where it can improve its communications with the public

•Gain a more intimate understanding about the experience of research participation from current and former participants in research

•Identify and acknowledge the power dynamics between the research enterprise and research participants and explore ways of bridging this divide

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

E6: Considering Yourself: Self-Care for HRPP/IRB Professionals and Members

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

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 HRPP/IRB professionals and members. 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): Compliance Personnel; HRPP/IRB Administrators, Managers, and Staff; HRPP/IRB Directors; IRB Members, Chairs, and Vice Chairs; Researchers and Research Staff; Educators/Trainers; Compliance Personnel

E7: Whose Job Is it Anyway? The Role of the IRB in Increasing Protections of Vulnerable Populations

Track(s): *Populations Requiring Additional Protections; Advancing Equity and Justice in Research; HRPP/IRB Administration/Management and Process; SBER*

This session will utilize case studies of current research ethical failures framed by the Belmont Justice Principle. Using current regulatory guidance and regulations, attendees will be invited to discover the agency of their role in the IRB and HRPP/IRB office to change the current landscape of research participation in order to mitigate the downstream social and group harms.

Learning Objectives:

•IIllustrate how HRPPs and IRBs provide guidance beyond the regulations to protect participants
•Evaluate case studies to identify blind spots in the current regulatory landscape
•Design and develop tools that will be a starting point for your HRPP/IRB on how to consider the Belmont Justice Principle

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

E8: CARE: A Model for the Integration of Cultural Humility into Human Subjects Research

Track(s): *Advancing Equity and Justice; Populations Requiring Additional Protections; Social, Behavioral, and Educational Research; Transnational Research Collaborations*

The presentation distinguishes between cultural competence and cultural humility. The importance of cultural humility and strategies for its implementation are provided. The consequences of a lack of cultural humility are explored in the context of an actual research study gone awry.

Learning Objectives:

•Distinguish between cultural competence and cultural humility
•Explain how cultural humility can be integrated into human subjects research
•Identify strategies for the development and application of cultural humility in research

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

E9: Zen and the Art of IRB Meeting Minutes

Track(s): *IRB Basics; FDA Regulated Research; HRPP/IRB Administration/Management and Process*

Documentation, documentation, documentation. The FDA and Common Rule regulations define requirements for IRB recordkeeping, for documenting IRB discussions and findings, and for communicating IRB decisions. It can be a daunting 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, it can help to take a step back to gain focus on what's important when writing IRB meeting minutes. In this session, seasoned IRB professionals will provide helpful tips to ensure IRB meeting 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 IRB records and documentation
•Learn useful tips 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
•Understand the value of using standard formats or templates when recording and writing minutes, or if applicable, how electronic systems can play a role in writing the minutes

Target Audience(s): HRPP/IRB Administrators, Managers, and Staff

E10: Reserved for Late-Breaking Session

E11: Maintaining a Robust HRPP in a Single IRB World

Track(s): *Single IRB; HRPP/IRB Administration/Management and Process; Small Research Programs*

Since the implementation of the NIH policy and revised Common Rule requirements, institutions have been grappling with adapting to single IRB review for multi-site research. With the expectation that the FDA also will adopt a single IRB requirement, more institutions will need to comply with single IRB requirements for the first time or face a significant expansion of research that will require the use of a single IRB. In many cases, using external IRBs requires institutions to adopt new approaches to ensure appropriate oversight of research under their purview because their finely tuned HRPPs have been disrupted by the removal of a traditional compliance gatekeeper, the local IRB. Further, institutions must help researchers navigate a new world that involves working with many IRBs that differ in processes and policies from each other as well as those of a study team's local institution.

Learning Objectives:

•Explore the impact of single IRB on research teams, relying institutions, and reviewing IRBs
•Provide examples of operational and compliance challenges single IRB can present
•Identify key approaches institutions should consider adopting to ensure they maintain effective HRPPs when a significant portion of their research is overseen by external IRBs

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

E12: Leading With Respect, Communication, and Collaboration at All Levels of the Research Enterprise

Track(s): *Leadership Skills Development*

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

Learning Objectives:

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

Target Audience(s): HRPP/IRB Directors

E13: The Role of the IACUC in the Context of Wildlife Rehabilitation

Track(s): *Oversight of Non-Typical Animals and Situations; ACU Program Management*

IACUCs form the legal, ethical, moral, and professional foundation of oversight involving nonhuman animal use activities in the United States. Since the passage of the Animal Welfare Act and its Regulations (AWAR) in 1966, this has traditionally been the case for academic institutions, federal agencies, private industry, and state agencies. Concerning wildlife animal use activities, however, whether academic, federal, private, or state entities, an appropriate, consistent, comprehensive, and formally established interpretation of the role of the IACUC remains in development. Moreover, the complexities of this issue likewise extend to any potential role for an IACUC in the realm of wildlife rehabilitation. There are, however, notable benefits to the installation of an IACUC in a wildlife rehabilitation setting: 1) Wildlife rehabilitation centers often function as de facto gatekeepers of disease surveillance in free-range species, thus positioning them in excellent condition to pursue disease research; 2) Wildlife rehabilitation centers often collaborate/overlap with state, federal, and academic entities (among others) in the course of operations--a condition that often results in a sort of professional multilingualism, which has the potential to allow wildlife rehabilitation centers to function as a nexus of multi-agency collaborative efforts; and 3) Programs of veterinary care at wildlife rehabilitation centers are often unique to the demands of the discipline, and thus have the potential to greatly expand and inform nonhuman animal care and use techniques across the veterinary research field, especially concerning wildlife. Moreover, wildlife rehabilitation facilities typically engage in, as standard practice, the three main qualifying tenets of nonhuman animal welfare compliance and oversight; specifically research, teaching, and exhibition. This session will present each of these benefits as goals toward generating greater understanding and appreciation for the role of the IACUC in facilitating compliance and oversight in the context of wildlife rehabilitation.

Learning Objectives:

•Learn about the role of IACUC oversight and compliance in the context of wildlife rehabilitation, with an emphasis on disease surveillance
•Consider the role of IACUC oversight and compliance in the context of wildlife rehabilitation, with an emphasis on facilities functioning as a collaborative nexus for disparate wildlife groups
•Explore the role of IACUC oversight and compliance in the context of wildlife rehabilitation, with emphasis on the development of needs-based, adaptive nonhuman animal handling techniques

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; Researchers and Research Staff

E14: Addressing Anti-Animal Research Groups: An Examination of Emerging Tactics and Recommendations to Enhance Public Support for Nonhuman Animal Research

Track(s): *Communication With the Public; ACU Program Management; Emerging Challenges and Breaking Issues; Shared Research Oversight Challenges*

The growing opposition to biomedical research with nonhuman animals over the last decade coincides with rising pressures and expanded lobbying efforts from animal rights groups who are increasingly using policy, regulatory, and public relations tactics to achieve their goals. Recently, the Federation of American Societies for Experimental Biology (FASEB), Americans for Medical Progress (AMP), National Association for Biomedical Research (NABR), and the Foundation for Biomedical Research (FBR) published a report in February 2023 titled, "Animal Research Activism: Update and Recommendations to Promote Communication, Transparency, and Public Outreach About Animal Research," that accounts for the more modern, non-violent approaches used by anti-animal research groups to discourage public support for animal research. This session will examine the emerging tactics anti-animal research groups use and review the report's recommendations for nonhuman animal research stakeholders, including proactive strategies to minimize targeted action and enhance communication and openness about nonhuman animal research.

Learning Objectives:

•Examine the tactics used by anti-animal research groups to discourage public support for biomedical research with nonhuman animals

•Review the FASEB/AMP/NABR/FBR report recommendations and strategic advice for organizations, IACUCs, and individual investigators to minimize the risk of targeted action by anti-animal research groups

•Discuss the report's recommendations for promoting communication and effective public outreach on nonhuman animal research, including legislative strategies, policy approaches, and communication with nonscientists

Target Audience(s): ACU/IACUC Directors; ACU/IACUC Administrators, Managers, and Staff; IACUC Members, Chairs, and Vice Chairs; Research Oversight Leaders and Institutional Officials; Public Relations Professionals; Compliance Personnel; Laboratory Animal and Veterinary Staff; Researchers and Research Staff; Clinical Research Staff; Legal Counsel

E15: How to Manage a Noncompliance or Adverse Event

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

How should the IACUC proceed after a report of a noncompliance or adverse event, especially in light of more guidance from AAALAC concerning self-reporting of adverse events? Reporting unanticipated events such as water supply issues, lack of feed, and other possible scenarios may not individually result in a concern, but how can the tracking of these events outline areas for improvement? When do these types of events rise to a level of concern and when should you report this to AAALAC? Can adverse events only happen during the actual study process? When/should the IACUC investigate versus track? This session will discuss these issues, detail how to create an "Adverse Event Plan," and define best practices for IACUC and institutions to communicate and self-report to AAALAC.

Learning Objectives:

•Define major vs. minor noncompliance events (e.g., definitions, processes, reporting timeline, programmatic vs sporadic, etc.)

•Explore what should be reported to AAALAC

•Discsuss how the animal care and use program can use metrics of unanticipated events to manage change

•Learn how to create an "Adverse Event Plan"

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

E16: Building a Professional Network in the Animal Care and Use Community

Track(s): *IACUC Basics; Education, Qualifications, and Training; Leadership Skills Development; IACUC Administration/Management and Process*

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

E17: Postapproval Monitoring (PAM) in the Context of Small Research Programs

Track(s): *Small Research Programs; QA/QI and Postapproval Monitoring*

This session will focus on the challenges faced by small research programs in implementing and conducting a successful PAM program, including practical strategies and flexibilities for building and developing an effective program, leveraging semiannual facility visits and program review.

Learning Objectives:

•Learn how to leverage your PAM program to identify areas for burden reduction and continuous improvement
•Share strategies for creating buy-in and participation for changes that reduce burden and increase efficiency
•Discuss how to build on past successes to create a culture of continuous improvement

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

E18: Global Disease Surveillance: What We've Learned from COVID-19

Track(s): *Transnational Research Collaborations*

Zoonotic disease transmission is a serious concern, and with major branches of the US government still at odds about the origin of the SARS-CoV2 virus (nature or lab), what can be done on a local basis to increase the global odds of catching the next 'superbug' or deadly virus before it kills millions of nonhuman animals or humans? This session will highlight recent disease outbreaks and how nonhuman animal researchers, especially individual nonhuman animal resource programs, can contribute to monitor disease outbreak around the world.

Learning Objectives:

•Discuss recent zoonotic disease outbreaks (other than COVID-19)
•Understand how potential zoonotic diseases are monitored in wild populations and how zoonotic disease outbreaks are identified when they occur
•Explain contributions of individual animal resource programs to detecting and responding to zoonotic disease outbreaks

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

E19: Regulatory and Compliance Updates in Animal Care and Use

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

During this session, faculty will provide information on compliance updates and potential regulatory changes involving animal use in research and testing. Participants will receive an up-to-date summary of all regulations and the laws that affect their processes. There will be an opportunity for Q&A with the panelists following their series of presentations.

Learning Objectives:

•Learn about regulatory updates over the last year
•Gain insight into potential forthcoming regulatory initiatives
•Discuss and ask questions in terms of updates

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

E20: Effective Change Management Processes in an IACUC Office

Track(s): *ACU Program Management*

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

This session will be presented on-demand; there is no live interaction.

Learning Objectives:

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

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

E21: Building and Sustaining Inter-Institutional IACUC Collaborations

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

Inter-institutional collaborations are an effective strategy for developing and diversifying an institution's nonhuman animal research portfolio. Successful partnerships provide opportunities to leverage resources, expand research opportunities, innovate, improve productivity, and develop staff. This session explores the IACUC's unique responsibilities relevant to inter-institutional partnerships and collaborations that involve the animal program.

Learning Objectives:

• Learn about the benefits and challenges of inter-institutional research collaborations
• Understand the IACUC's oversight roles and responsibilities related to collaborative research
• Explore best practices to ensure a successful partnership

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

E22: Foundational Understandings on Indigenous Sovereignty, Settler-Colonialism, and Research

Track(s): *Advancing Equity and Justice; Education, Qualifications, and Training; IRB Basics; SBER*

This session introduces participants to fundamental understandings of settler-colonialism, Indigenous history in the US, and Indigenous Sovereignty today. Participants will also gain an understanding of what this history means for research oversight committees and researchers today who live and work on Indigenous homelands, and how to foster better working relationships with Indigenous nations and peoples.

Learning Objectives:

•Define settler colonialism and recognize its historic relationship with Indigenous peoples via research
•Discuss the impact and manifestation of settler-colonialism in research oversight work today
•Recognize measures research oversight committees can take to be accountable to their institution's histories and Indigenous Nations today

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

E23: Diversity, Equity, Inclusion, and Justice (DEIJ) and Impact on Staffing in Research Oversight Programs

Track(s): *ACU Program Management; Advancing Equity and Justice; HRPP/IRB Administration/Management and Process; IACUC Administration/Management and Process; IACUC Chairs; IRB Chairs; Leadership Development Skills; Shared Research Oversight Challenges*

This session aims to provide attendees with actionable insights and practical strategies to navigate DEIJ challenges within staffing. By promoting a supportive and inclusive environment, leaders can empower staff members, foster long-term job satisfaction and retention and improve animal research 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 the how issues can impact people differently, which in turn affects their ability to deliver appropriate and consistent nonhuman animal care and human subjects protections with job satisfaction (which affects retention)
•Discuss effective communication between departments that have influence (e.g., safety, HRPP/IRB, IACUC, animal program management, IBC, etc.)

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

E24: Get Your S@!* Done (and Other Helpful Tips for Managing a Remote Oversight Committee Office)

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

In a time where many HRPP/IRB/IACUC offices have gone fully or hybrid remote, it can be challenging to ensure that all routine work is done in a timely and efficient manner while still providing ongoing training and staff development. This session will provide tips and tools to help manage a remote HRPP/IRB/IACUC office.

Learning Objectives:

•Provide tips for managing HRPP/IRB/IACUC staff when leadership and/or staff are remote
•Discuss how to maintain review consistency and ongoing staff training
•Learn about use of data to measure success and inform decision making

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

E25: Building a Sustainable Data Infrastructure

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

Running a research enterprise requires an effective and efficient infrastructure to support data use and storage. Institutional leaders need information/data on successful programs and programmatic needs to plan and prepare for the future of their IT systems. This session will discuss the strategies leadership should have in place to build, sustain, and grow an appropriate infrastructure to meet the ever-changing needs of the research community.

Learning Objectives:

•Discuss the current challenges of maintaining and growing a research information environment to support various types of research, types of data, and collaboration or interactions with entities outside of the organization

•Identify various options for obtaining sustainable financial support for key infrastructure and deciding who should be responsible to pay for various systems and resources

•Understand the information and strategies needed to position your organization for not only its present-day needs, but to prepare for the continuous changes in the technology environment

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

E26: Building Effective Institutional Leadership Skills and Competencies

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

In today's rapidly evolving research landscape, strong institutional leadership is crucial for research programs to thrive. This session will explore the essential skills and competencies required for effective institutional leadership. Speakers will delve into the multifaceted roles and responsibilities of institutional leadership, examining the core competencies necessary to navigate complex challenges, drive innovation, and inspire teams towards success.

Learning Objectives:

•Identify key skills and critical competencies institutional leaders need to guide organizations towards achieving their missions and goals (e.g., strategic thinking and decision-making, effective communication, stakeholder management)

•Consider the role of leaders in setting a strong ethical framework, promoting equity and justice, and fostering a culture of integrity and accountability within institutions

•Explore the importance of emotional intelligence, adaptability, and resilience in leadership

•Learn how to cultivate self-awareness, empathy, and the ability to manage change and create positive work cultures

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

5:00-6:00 PM ET **Networking Reception in the Exhibit Hall**

5:00-6:00 PM ET **Meet and Greet With the Supporters and Exhibitors**

5:00-6:00 PM ET **View the PRIMR23 Poster Abstracts**

5:00-6:00 PM ET **Federal Agency, Accrediting Body, CIP/CPIA Council Office Hours**

During this time, representatives from federal agencies, the accrediting bodies, and the CIP/CPIA Councils will be available to answer 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. A list of agencies participating at this time is forthcoming.

PRIM&R

2023 PRIM&R Annual Conference
December 3–6, 2023
Washington, DC

SBER Conference
December 3, 2023
Washington, DC

PRIMR23 Day 4: Wednesday, December 6

7:30 AM-12:00 PM ET **Registration Open**

7:30-8:15 AM ET **Meet and Greet With the Supporters and Exhibitors**

7:30-8:15 AM ET **View the PRIMR23 Poster Abstracts**

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7:30-8:15 AM ET **Sponsored Presentation**

Join one of the PRIMR23 Supporters/Exhibitors at this time to hear a presentation on a timely topic, serivce, resource. Information is forthcoming.

PRIMR23 Plenary Session Series, 8:30-9:45 AM ET

Plenary Session: From Compliance to Embracing the Belmont Report Tenets as the Framework for the Operations of the HRPP

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

Federal regulations (e.g., Revised Common Rule, FDA, DOD, etc.) provide regulatory frameworks meant to ensure the ethical treatment of people who participate in research. Although these regulatory frameworks can be seen as extensions of the principles of the Belmont report—Respect for Person, Beneficence, and Justice—they are often applied in ways that reflect a more compliance approach. They can become check boxes that are used by HRPPs and IRBs to guarantee adherence to the literal language of the regulation or law rather than guiding principles that inform the approach to the application of the regulations. As a result, IRBs are often seen as gatekeepers that arbitrarily constrain research activities instead of ethics boards that focus on the protection of human research participants. In addition, a compliance approach can interfere with the development of a partnership between HRPPs and IRBs and the research community as they stand behind the regulations as their explanation for their decisions (e.g., 'the regulations made me do it'). By adopting a more principal based approach to the implementation of the regulations, HRPPs and IRBs can reframe the conversation with the research community, increase transparency, and cultivate a collective accountability to the review process. This shift in orientation requires organizational change that is both structural (e.g., processes that are in place) as well as human (e.g., how people understand their work).

Learning Objectives:

•Examine the difference between a compliance-based approach to human research protections and a principle-based approach

•Consider the structural implications of shifting from a compliance-based approach to a principle-based approach

•Discuss the human (psychological, emotional) implications of shifting from a compliance approach to a principle-based approach

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

Plenary Session: Ethical Considerations for Using Generative Artificial Intelligence (AI) in Human Subjects Research--Implications for IRB Regulation

Track(s): *Emerging Research Challenges and Breaking Issues; Informed Consent; Research Conducted in the Digital World*

Generative AI is a rapidly advancing technology that allows computers to learn from training data and generate "content" that are similar to those produced by humans. Chat GPT is one example that has gained increasing public recognition and use. Generative AI has the potential to revolutionize many aspects of human subjects research, from generating interview questions and protocol or consent materials, to creating synthetic data. However, the use of Generative AI in human subjects research raises a host of ethical questions that must be addressed—many we cannot even fathom because we know so little about the technology. For example, how can we ensure that a consent generated by an AI is accurate and sufficiently understandable to research participants? Should we be using AI generated content for consents? What are the potential risks and benefits of using AI-powered chatbots in health interventions? Can the Generative AI be trusted to interact independently with research subjects? How can the researcher be sure the Generative AI won't go "off the rails" like we have seen every current Generative AI do, for example, telling someone seeking mental health services to harm themselves? What safeguards can researchers put in place when they use Generative AI to interact with research participants? How can we prevent Generative AI from perpetuating bias in data analysis or in generating biased materials and recommendations for participants? Moreover, the use of Generative AI in research presents a unique challenge for IRBs tasked with regulating this research. IRBs will need to understand the capabilities and limitations of Generative AI in order to make informed decisions about the ethical implications of using this technology in research. But, where do they start to learn?

Learning Objectives:

•Explore the potential uses of Generative AI in research and the ethical considerations that arise when using this technology with human subjects

•Discuss the implications of using Generative AI for IRB regulation of research

•Consider the development of guidelines and best practices for researchers and IRBs

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; Compliance Personnel; Research Program Leadership and Institutional Officials; Researchers and Research Staff

Plenary Session: The New Age of Gene Edited Xenotransplantation

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

The use of animal organs, or xenografts, has long been viewed as a promising solution to the insufficient supply of human organs to meet the needs of an ever-growing list of individuals who could benefit from lifesaving transplants. Historically, xenotransplantation has been unsuccessful due to transplant rejection from a cycle of immune reactions to the foreign graft. Advances in gene editing have now allowed genetic engineering of animals to improve human compatibility. Combined with advances in immunosuppressive therapy and techniques for prolonged xenograft survival time, we have now seen recent groundbreaking cases of successful xenotransplantation, such as the first genetically modified pig heart transplanted into a living human in 2022 at the University of Maryland. To further understand the mechanical, molecular, and immunologic aspects of xenotransplantation, several research centers are currently performing research involving heart, kidney, and liver xenotransplantation to recently deceased donors maintained on ventilator support. The advancing progress of gene edited xenotransplantation raises ethical and regulatory concerns of relevance to HRPP, IRB, and IACUC members. Considerations for human recipients include fair and just allocation of this research and ensuring appropriate informed consent for xenotransplantation research, including the risk/benefit conundrum presented by this cutting-edge research for "desperate" patients and the potential public perceptions related to the research and recipient. Considerations for animals include revisiting the ethical dilemmas of sacrificing animals for the benefit of extending human life, with the added challenge of using gene editing in large and highly sentient animal models (e.g., pigs and baboons), who are raised specifically as donors for human recipients and research. For research on recent human decedents, institutional questions arise with regard to what oversight of this work is needed and to which regulatory body it falls, along with ethical concerns related to next-of-kin consent, substituted judgment, and the questionable role for advanced directives. Further, we might ask if improvements in the United Network for Organ sharing would invalidate the ethical basis on which the need for xenotransplantation is grounded.

Learning Objectives:

•Discuss the history and development of xenotransplantation, and the recent advances in gene editing that have led to successful xenotransplantation research in recently deceased individuals and a living human

•Consider the ethical and regulatory challenges faced by HRPPs, IRBs, IACUCs, and institutions as this research continues to grow

•Explore the institutional questions that arise with regard to what oversight of this work is needed and to which regulatory body it falls

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

Plenary Session: Conceptualizing and Assessing the Social Value of Research

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

Ethicists have engaged in discussions regarding the necessity of adequate social value to justify the potential risks and burdens imposed on its subjects, as well as the investment of public resources research involves. However, several questions arise: who bears the responsibility for assessing social value? Additionally, at what stage of the research design and review process should such assessments be made? Should oversight committees routinely evaluate the social value of a research project while they are conducting risk/benefit assessments? How should social value be conceptualized? What is the relationship of social value to a study's scientific validity? Is the "importance of the knowledge expected to result" from the research synonymous with its social value? How does thinking about social value affect selection of nonhuman animal models for preclinical work? How is social value assessed in a way that is equitable, rather than exacerbating the marginalization of certain lives and perspectives? This plenary session will delve into these questions, exploring why a clear, agreed-upon framework for assessing the social value of research (in either nonhuman animal or human subjects research space) could be beneficial. Additionally, it will examine the potential role of oversight committees in considering the social value of research.

Learning Objectives:

•Review the dimensions of social value in research and the current challenges conceptualizing and assessing social value in research

•Identify potential approaches and frameworks that can help stakeholders assess the social value of research

•Examine the influence of funding agencies, such as the NIH, in shaping research practices and promoting socially valuable research

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

9:45 AM-10:15 AM ET **Break in the Exhibit Hall**

PRIMR23 Breakout/Networking Session F Series, 10:15-11:15 AM ET

F1: A Dialogue With the NIH

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

This session will be led by a representative from the NIH, and will include discussion of NIH's work. Attendees are encouraged to come with questions of interest to all.

Learning Objectives:

•Hear from a representative of the NIH Office of Science Policy about activities that are pertinent to clinical research policy and the protection of participants in research

•Ask questions about new and ongoing initiatives at the NIH

Target Audience(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 Personnel; Educators/Trainers; Clinical Research Staff; Researchers and Research Staff

F2: Research With Substance Use Disorder (SUD) Data as Secondary Use

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

There is a diverse set of interpretations as to how 42 CFR Part 2 applies in research. Due to subjective interpretations, much collection, use, and sharing of SUD data for research appear to be in contrast with intentions. This session will discuss the federal law that protects SUD treatment records and data, as well as the challenges that are being faced in enforcing these protections. For example, when can consent be waived? The session will also provide IRBs with tools to protect the confidentiality of SUD treatment records and data used for research purposes. The speakers will discuss the federal law that protects SUD treatment records and data (42 CFR Part 2), which sets forth rules for the collection, use, and disclosure of SUD treatment records and data, including those used for research purposes, and the challenges faced in implementing this law (e.g., lack of awareness of the law among providers and researchers, the difficulty of obtaining consent from individuals for the use of their records and data), and the lack of enforcement of the law). The speakers will conclude with a discussion on how to protect the confidentiality of SUD treatment records and data. This session will help IRBs identify when Part 2 is applicable and to ensure that patient records are protected. By taking these steps, IRBs can help to protect human subjects and the trust they place in their SUD treatment facilities and healthcare institutions.

Learning Objectives:

•Define the regulations (45 CFR Part 2) and when they apply
•Explore the implications for sharing and use of SUD data
•Consider how this impacts research in this field

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

F3: Utilizing a System of IRB Precedent: Moving Toward Consistency and Transparency

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

IRBs are often criticized by investigators for a perceived inconsistency in their decisions, or for a lack of transparency regarding how decisions are made. Three separate institutions will describe their experience incorporating an IRB precedent system into their IRB practice by implementing a templated "institutional memory bank" tool to test its effectiveness at promoting consistency, providing transparency, and promoting communication with the research community. The searchable "institutional memory bank" could become an important tool as a quality metric for IRBs.

Learning Objectives:

•Describe the implementation of an IRB precedent tool, how it can foster IRB staff knowledge, how it can promote consistency among IRB panels, and its impact on communication with the research community
•Explore the use of the tool as a quality metric for IRBs and how it can be incorporated as a quality improvement project
•Identify challenges to implementing a system of IRB precedent within and across institutions

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

F4: Supported Decision-Making: From the Law to the Bedside

Track(s): *Legal Considerations in Research Oversight; Advancing Equity and Justice; Informed Consent; Populations Requiring Additional Protections*

In the US, disability rights laws (e.g., Americans with Disabilities Act and Rehabilitation Act) require federally funded medical centers to ensure people with disabilities are not discriminated against with respect to access to their services, programs, and/or benefits. This non-discrimination requirement includes a right to reasonable accommodations, if requested. Yet people with disabilities, including those with impaired decision-making capacity, are routinely excluded from participation in clinical research. Supported decision-making is a process that enables individuals with impaired decision-making ability to choose designated supporters to help them make informed choices and represents an emerging accommodation that facilitates their participation in research. This session will introduce the concept, history, and legal status of supported decision-making and will share an example of how supported decision-making has been implemented at a large academic medical center, including investigator education, documentation templates, and considerations for IRB review.

Learning Objectives:

•Understand what supported decision-making is and when it is legally required to ensure people with disabilities are not discriminated against with respect to access to clinical research

•Review the difference between supported decision-making and surrogate decision-making and how supported decision-making safeguards the autonomy of people with disabilities

•Learn how supported decision-making can be implemented at your institution

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

F5: IRB Review of FDA-regulated Research: From Comfort to Competence!

Track(s): *QA/QI and Postapproval Monitoring; FDA Regulated Research; HRPP/IRB Administration/Management and Process*

This session will cover how a frequent and familiar process for many IRBs--review of FDA-regulated research--may generate overconfidence or complacency among the IRB team (operations staff and reviewers/members), and how comfort with the routine might hinder recognition of the occasional twists and new or unique products that may be subject to FDA regulation. How do IRBs avoid common pitfalls, such as the misconception an investigational new device exempt study is not FDA regulated? How might an organization internally assess the ongoing competence of its entire IRB team? How can an organization support robust awareness, discussion, and documentation of key IRB and HRPP considerations when reviewing FDA-regulated research?

Learning Objectives:

•Describe an IRB's process for reviewing FDA-regulated research and areas for more intensive evaluation (e.g., pre-screening or during formal review)

•Recognize the necessity of periodic assessment of an IRB team's knowledge, processes, and resources related to IRB review of FDA-regulated research

•Appreciate the value of a quality assurance process and improvement initiative focused on an IRB team's review of FDA-regulated research

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

F6: What Are We Doing When We're Doing What We're Doing? Revisiting the Tenets of Biomedical Ethics and Embracing the "Ethics" in our "Applied Ethics" Field

Track(s): *IRB Basics*

Principlism is an applied ethics approach to examination of moral dilemmas that is based upon the application of certain ethical principles. This session will review the origins of Principlism, including its advancement by the authors of the Belmont Report, and offer a review of the way Principlism came to guide the field of bioethics following the publication of Principles of Biomedical Ethics by Tom Beauchamp and James Childress. The session will also draw connections between Principlism in bioethics and the rules and regulations governing federally funded or conducted research in the United States.

Learning Objectives:

•Consider the historical and philosophical underpinnings of the work of human subjects research protections

•Recognize that this work cannot be reduced to simplistic checklists that do not and cannot take account of ethical reasoning and deliberation

•Learn about the importance of cultivating a background in philosophy when doing the work of an HRPP/IRB professional

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

F7: SBER Network Discussion Session

Track(s): *SBER*

Join the SBER Network in discussing a hot topic in SBER (topic forthcoming)!

Learning Objectives: *(forthcoming)*

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

F8: Human Subjects Research Trivia

Track(s): *IRB Basics; HRPP/IRB Administration/Management and Process*

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. 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): Clinical Research Staff; Compliance Personnel; Educators/Trainers; HRPP/IRB Administrators, Managers, and Staff; HRPP/IRB Directors; IRB Members, Chairs, and Vice

F9: Are We Doing Enough? Creating a Sense of Belonging and Opportunities for HRPP Professionals

Track(s): *Advancing Equity and Justice in Research; Leadership Development Skills*

This session will provide insight into the challenges faced by ethics professionals from marginalized backgrounds, as well as strategies for creating more diversity, belonging, and opportunities for these individuals in the field of research ethics. Participants will discuss potential strategies for increasing diversity and opportunities for ethics professionals from different backgrounds, and will gain insight into how to create more inclusive and equitable career pathways.

Learning Objectives:

•Identify the challenges faced by ethics professionals from diverse backgrounds

•Discuss strategies for creating a sense of belonging and opportunities for ethics professionals from different backgrounds

•Gain insight from HR professionals into how leaders and managers can create more inclusive and equitable workplaces

Target Audience(s): Compliance Personnel; Diversity, Equity, Inclusion, and Justice; Educators/Trainers; HRPP/IRB Administrators, Managers, and Staff; HRPP/IRB Directors

F10: HRPP/IRB Management 101: Real-World Discussions Regarding How to Effectively Run a HRPP/IRB Office

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

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

Learning Objectives:

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

Target Audience(s): HRPP/IRB Directors

F11: Navigating Data and Specimen Sharing for Transnational Research

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

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

Learning Objectives:

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

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

F12: Maintaining Compliance at Any Size: How to Get the Most Bang for Your Buck!

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

Not all HRPP programs have equal resources nor share the same needs when it comes to compliance activities. Further, it is important for an HRPP to remain nimble in order to respond to its environment, which may mean adjusting its compliance activities in real-time. Speakers will provide a picture of their HRPP compliance structure, discussing their existing compliance strategies and how they may be adapted according to organizational needs and resources. Conversation will include successes, pitfalls, and recommendations; attendees will be provided with tools and guides that may be adapted as needed by a variety of types of organizations. Participants are encouraged to share their best practices and raise questions and challenges from their experience for group discussion.

Learning Objectives:

•Discuss how to assess the compliance needs of specific HRPPs and determine the most effective strategies given the resources available
•Learn how to design flexible compliance initiatives that can vary depending on an organization's portfolio of human research, investigator experience, and bandwidth of QA/QI staff, among other important variables
•Provide practical strategies and tools that may be adapted according to an organization's needs

Target Audience(s): QA/QI Professionals; Compliance Personnel

F13: Bringing the IRB to the People, and the People to the IRB
Track(s): *Advancing Equity and Justice; Communication With the Public; Flexibility and Innovation in Research Oversight Processes; HRPP/IRB Administration/Management and Process; IRB Chairs*

HRPPs/IRBs are innovating to increase outreach, engagement, and collaboration with their local communities in many ways: increasing the number and diversity of IRB members; sponsoring events that inform communities about IRBs and research oversight; conducting surveys of research participants; and forming relationships with community advisory boards, community organizations, and other groups to obtain input on policies, practices, and individual studies. This session will present preliminary data from three mixed methods studies on IRB engagement of non-scientist and non-affiliated members, eliciting participant perspectives as indicators of HRPP quality, and inclusion of participant perspectives in research ethics oversight activities. Speakers will then describe the institutional experience in this arena and discuss how community engagement can ultimately improve the quality and effectiveness of HRPPs.
Learning Objectives:
•Identify the benefits of reaching out to and engaging with the local community of potential research participants and research partners
•Describe strategies for engaging with the local community and identifying/overcoming barriers to stakeholder participation
•Explore how to identify key stakeholders and institutional commitments required; review strategies for recruitment, onboarding, education, and retention of members; and how to assess meaningful engagement and evaluate impact

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

F14: The Ethical Conduct of Cell and Gene Therapy Research: A Conversation With Industry on Inclusion, Patient Engagement, and Trustworthiness
Track(s): *Pharma/Biotech Perspectives; Advancing Equity and Justice; Emerging Research Challenges and Breaking Issues; Research Involving Data and Biospecimens*

Cell and gene therapy presents complex challenges in trial design and implementation to ensure equitable recruitment, effective informed consent, and participant safety. The 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 that are distinct from other trials. Meeting these standards in low- and middle-income countries introduces additional responsibilities. In this panel session, experts from industry and bioethics, including a gene therapy trial participant, will describe the novel ethical demands of gene therapy trials in developed and less-developed countries, 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): Clinical Research Staff; Compliance Personnel; Diversity, Equity, Inclusion, and Justice; HRPP/IRB Administrators, Managers, and Staff; HRPP/IRB Directors; IRB Members, Chairs, and Vice Chairs; Researchers and Research Staff

F15: Show Me the Money: Models for Billing for HRPP/IRB Review Fees
Track(s): *HRPP/IRB Administration/ Management and Process*

This session will cover billing of HRPP/IRB review fees. It will detail the old and current methods being used, including the pros and cons of each method.
Learning Objectives:
•Learn about different models for billing for internal and external HRPP/IRB fees
•Consider the pros and cons of different models of billing
•Review different ways of billing HRPP/IRB fees for activities not directly related to IRB review
Target Audience(s): HRPP/IRB Directors; HRPP/IRB Administrators, Managers, and Staff

F16: Mission Overlap Between IRBs and IBCs and the Institutional Implications

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

Review of research, especially research with novel technologies like gene therapy and immunotherapy, increasingly involve the use of viral vectors. These trigger protections from both IRBs, who are charged with protecting research participants, and IBCs, who are charged with protecting research personnel, the community, and the environment. While their jurisdictions are distinct, the content of their reviews can often overlap. For instance, while IBCs are responsible for third party safety from viral vectors, only IRBs have jurisdiction over the consent form which can detail safety measures required of the participants to protect those third parties. This means that communication between these committees is paramount. This session will discuss the challenges in the "gray zone" between IRBs and IBCs and how these are either addressed or exacerbated with different structural relationships. Specifically, with the increase in central IRBs and external IBCs, when these boards exist across different institutional divides, what are the implications for communication and co-review?

Learning Objectives:

•Identify the ways in which the tasks of IRBs and IBCs can overlap and the importance of cooperation to provide input necessary for each committee to fulfill its charge

•Evaluate the ways that structural relationships between IBCs and IRBs (within institutions, between institutions and centralized/external committees, and between centralized/external committees) impact their ability to communicate and cooperate

•Suggest ways in which current effective structural arrangements can be strengthened, and current problematic arrangements can be altered to facilitate the effective cooperation between IBCs and IRBs

Target Audience(s): 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 Leadership and Institutional Officials

F17: Disclosure, Trust, and Transparency: What Drives the Ethical Management of Conflicts of Interest in Research?

Track(s): *Communication With the Public; HRPP/IRB Administration/Management and Process; Shared Oversight Challenges*

Once an institution identifies a research conflict of interest, the institution must then determine how to manage or minimize the conflict. Since there are no required measures for such management, the requirements placed on the researcher involve the ethical determination as to what actions will best support trust and transparency. Often the management actions include disclosure, but other requirements must also be applied based on various ethical principles.

Learning Objectives:

•Learn how institutions draw upon research ethics to manage conflicts of interest in research

•Consider how to best leverage disclosure of financial interests and conflicts of interest to support trust and transparency in research

•Explore the other actions that can be required of researchers to ethically manage research conflicts of interest in order to support trust and transparency

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

F18: Addressing Implicit, Unconscious, and Conscious Biases: Leadership, Investigators, and Ethics Boards Throughout the Lifecycle of Research Initiatives *Room*

Track(s): *Advancing Equity and Justice in Research; Shared Oversight Challenges*

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

Learning Objectives:

•Learn how to identify internal biases and recognize implicit bias within leadership and compliance committees

•Apply anti-bias strategies across the lifecycle of work through analysis and evaluation of case studies

•Consider what leaders need to know within themselves to have an unbiased impact on the lifecycle of research activities

•Review common bias traps, and identify innovative ways to approach work practices, recognizing internal, anti- and unconscious bias, social justice, and current social issues

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

F19: One Health, One Welfare: Special Considerations for Wildlife Studies and Field Projects

Track(s): *ACU Program Management; Flexibility and Innovation in Research Oversight Processes; Oversight of Non-Typical Animals and Situations*

One Health is defined as the achievement of optimal health outcomes by recognizing the interconnection between people, animals, plants, and their shared environment. Frequently, the principles of One Health are embraced by a variety of other disciplines, including the review of animal use activities, even though the adoption of a One Health approach may not be explicitly acknowledged. The One Health approach is especially suited to the review of wildlife studies and field projects because of the unique challenges that these studies often present, thus necessitating a more holistic, multidisciplinary, collaborative review strategy that includes biosafety and occupational health and safety components.

Learning Objectives:

•Discuss the connection between nonhuman animal welfare and One Health

•Explore the unique challenges to human health and safety that wildlife studies and field projects may present

•Assess the current capabilities of IACUCs to evaluate the biosafety and occupational health and safety concerns that wildlife studies and field projects may present

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

F20: Novel and Innovative Approaches on Inter-Institutional Agreements

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

Institutions may enter into a variety of inter-institutional agreements to support research collaborations that involve the IRB, IACUC, IBC, conflict of interest, or other regulatory/ethics functions. While some templates exist for a few types of inter-institutional agreements, they may not include all facets of complex inter-institutional relationships and collaborations. In this session, speakers will explore the various types of multi-institutional relationships and collaborations that currently exist, or may develop in the future, along with novel and innovative approaches on how to construct agreements to best support ethical research in these situations.

Learning Objectives:

•Identify different types of research relationships and collaborations that institutions can engage in that may involve ethical research oversight

•Develop an understanding of existing templates for inter-institutional agreements and where there may be shortcomings with them

•Review and explore novel and innovative approaches to support emerging types of multi-institutional research relationships and collaborations

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

11:15-11:30 AM ET **Break in the Exhibit Hall**

PRIMR23 Breakout/Networking Session G Series, 11:30 AM-12:30 PM ET

G1: Look Who's Doing Research Now! What Does it Mean for Walgreens, CVS, Walmart, Etc., to Be Conducting Human Subjects Research?

Track(s): *Pharma/Biotech Perspectives; Emerging Research Challenges and Breaking Issues*

In the past two years, numerous national chains entered the clinical trials game. What does this mean? Who is conducting these studies? Where are they originating? What regulatory oversight is there? How is research being informed by the communities participating in these studies? Is this decentralization making the participant pool more diverse? What training do these researchers receive? How are participants protected? Why are these corporations now conducting HSR? Are clinical trials now a retail product? This session will explore these issues and more.

Learning Objectives:

•Discuss clinical trial diversification

•Review the challenges with conducting clinical trials

•Oversight and training of clinical trials

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

G2:The Ethics of Data Sharing in SBER

Track(s): *Emerging Research Challenges and Breaking Issues; Flexibility and Innovation in Research Oversight Processes; SBER; Research Involving Data and Biospecimens; HRPP/IRB Administration/Management and Process*

The NIH Data Management and Sharing Policy that went into effect in January 2023 has brought fresh energy to discussions of the ethics and expectations of researchers to share data. Included in these discussions are ethical issues such as informed consent, participant autonomy, as well as privacy and confidentiality considerations, and whether data sharing expectations should be the same for quantitative, qualitative, and mixed-methods research and how these expectations may influence the nature and process of collecting data.

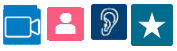
Learning Objectives:

•Discuss the ethics of data sharing, especially the NIH Data Management and Sharing Policy
•Consider different expectations given the research approach, philosophy, and/or topic
•Provide recommendations for IRB evaluation of data sharing during the review process

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

G3: Improving IRB Quality: Learning from Participants, Investigators, and Outside Experts

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



IRBs, and the HRPPs of which they are often a part, face a daunting task: they must review and oversee a wide range of studies and work closely with investigators to ensure the protection of research participants with whom the IRB may never directly interact. To succeed at this task, IRBs and HRPPs need to integrate the perspectives and insights of a variety of stakeholders and experts. In this session, we will discuss how listening to participants, investigators, and outside experts might help improve the quality of IRBs and HRPPs – and address some of the challenges and shortcomings that can arise in these approaches.

Learning Objectives:

•Identify approaches to gathering insight about participant experiences in research and how these might be used to inform IRB/HRPP practice and decision-making
•Consider how HRPPs/IRBs can learn from investigator perceptions of value in their engagement with these entities
•Understand when and how to engage with outside experts when reaching IRB decisions

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

G4: QA/QI for Non-Clinical or Minimal Risk Research

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

Many postapproval monitoring efforts focus on more than minimal risk clinical research. However, because most research monitoring efforts internal to institutions view study team audits as educational opportunities (as much or more than ensuring compliance), non-clinical researchers and investigators conducting minimal risk research may benefit from the feedback an audit can provide. This session will explore audit approaches that may benefit non-clinical researchers; tools that can be offered to assist study teams to conduct self-audits or provide check ins in the absence of formal monitoring (e.g., in the case of minimal risk research where continuing review may not occur); and how to tailor audits to be most helpful specific researcher populations, such as students, inexperienced researchers, or basic scientists.

Learning Objectives:

•Consider the benefit of auditing for non-clinical research
•Identify tools and strategies for auditing non-clinical research
•Understand the importance of varying auditing approaches to accommodate a range of researcher educational needs

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

G5: The Metrics System: Launching a Formal IRB Metrics Program

Track(s): *HRPP/IRB Administration/ Management and Process*

Data, data everywhere, but how do we make sense of it? "Time under review" is a useful metric, but it's not enough to measure IRB quality and performance. This session will describe how one IRB developed, promoted, and implemented a formal data collection program to assess performance and to provide evidence for resource requests and workflow changes.

Learning Objectives:

•Learn how to develop the questions you want your metrics data collection to answer
•Discuss potential data collection methods
•Consider how to get buy-in from staff around using a metrics program, and how to present results to the institution

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

G6: Developing and Sustaining Tribal IRB Infrastructure: Lessons Learned from the Collaborative Research Center for American Indian Health (CRCAIH) Initiatives

Track(s): *Small Research Programs; Populations Requiring Additional Protections*

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

Learning Objectives:

•Review the history and scope of CRCAIH
•Provide an overview of the tribal regulatory processes at Turtle Mountain Tribal IRB
•Consider strategies for continued tribal engagement and sustainability of the Tribal IRB office

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

G7: "Hey Guys, Let Me Tell You About This Awesome Clinical Trial!" Exploring the Role of Social Media Influencers in Clinical Trial Recruitment

Track(s): *Communication With the Public; Emerging Research Challenges and Breaking Issues; Research Conducted in the Digital World*

In an effort to increase diversity in research and recruit hard-to-reach populations, a growing number of researchers, clinical trial institutions, and sponsors are turning to social media influencers with high numbers of followers to help spread the word about clinical trials and research participation. This session will explore how engaging social media influencers to recruit for clinical research demonstrates a potential to increase access to research for traditionally under-represented populations, and will also consider the potential dangers and pitfalls associated with this approach.

Learning Objectives:

•Explore how to engage social media influencers to recruit for clinical research trials
•Consider the potential dangers and pitfalls associated with this approach

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

G8: A Dialogue With AAHRPP, Inc.

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

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

Learning Objectives:

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

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

G9: IRB Chairs Hot Topics Networking Forum

Track(s): *IRB Chairs*

This session will provide an opportunity to discuss topics faced by IRB chairs in various areas. We will start with a poll to choose the top five most popular topics, and then split into tables to discuss the topic with others who share the interest. We will switch tables at least once during the session. Topics will include: navigating conflicts of interest with the institution; mediating between researchers, staff, and board members; the role of the IRB chair (i.e., division of responsibility between the chair, IRB staff, and board members); burn out and balance; things we don't talk about (e.g., compensation, evaluation, firing members, etc.); what do you need to know to do your job well; what type of institutional support do you need and how do you get it; and evaluating members.

Learning Objectives:

•Discuss the popular issues facing IRB chairs
•Share experiences and strategies to address these issues

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

G10:Innovative Strategies to Improve Readability of Informed Consent Forms

Track(s): *Informed Consent*

Attention spans are getting shorter, health literacy is often low, and consent forms are getting longer. The mission of an HRPP/IRB is to communicate protections and ensure informed consent takes place prior to a study. Although the process is more than the form, the form is an often essential part of this process, and should support, rather than detract, from understanding. Is it time to reinvent the methods to better match the current environment and make studies more understandable and available to today's wide audiences? We know we must do better, but how? This session will focus on strategies that improving readability, facilitating understanding and supporting decision-making with the informed consent document.

Learning Objectives:

•Generate new ideas for creating effective informed consent documents in SBER and biomedical research protocols
•Leverage platforms and ideas used in other communication domains to improve understanding of informed consent documents
•Learn what the regulations allow or encourage in obtaining and documenting informed consent

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

G11: Bots as Study Participants: and Online Human Subjects Research

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

Researchers who use online platforms often aim to collect data from hundreds or even thousands of participants. Bots, programmed to complete surveys in minutes, can sabotage the online research system by posing as eligible human participants. Bot programmers have developed ways to create a normal distribution across responses or craft open-ended responses using extracted language from the survey itself to appear logical or believable. Bot-generated responses can jeopardize data quality, add undue researcher stress, delay study timelines, and potentially absorb researchers' valuable resources, especially when the study offers participant payment. The recent spike in bot programmers makes it essential for researchers to remain diligent and develop quality attention checks to identify bots, but not overburden legitimate human participants. Researchers should always consult technology experts for data security strategies particular to their research design. This panel will offer the latest strategies for online data collection, bot prevention, and data security management.

Learning Objectives:

•Discuss strategies for online data collection
•Consider Bot prevention strategies
•Explore issues around data security management

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

G12: Recent Updates from FDA Guidances on Informed Consent and IRB Review for Expanded Access Use of Investigational Drugs

Track(s): *FDA Regulated Research; Informed Consent*

In this session, FDA representatives will discuss recent updates from guidances on the regulatory requirements and timing for obtaining informed consent from patients receiving experimental treatment under different categories of expanded access. The key elements of an informed consent template, which physicians and institutions may use to model their forms for obtaining informed consent, will be shared. The discussion on IRB review for expanded access use of investigational drugs will focus on regulatory requirements, the process for requesting an FDA waiver from full board IRB review, and FDA's recommendations for IRB review procedures, including factors to be considered by the IRB during review of individual patient expanded access requests.

Learning Objectives:

•Describe the regulatory requirements for obtaining informed consent for expanded access patients
•Use the FDA template to model their institutions' expanded access informed consent forms
•Identify considerations for IRB review of expanded access informed consent forms

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

G13: Adding "A" to our Diversity Alphabet: Accessibility is Key to Diversity, Equity, and Inclusion (DEI)

Track(s): *Populations Requiring Additional Protections; Advancing Equity and Justice; Education, Qualifications, and Training; HRPP/IRB Administration/Management and Process*

Any program director, project lead, or initiative member that does not include accessibility as part of their DEI commitment may be unintentionally excluding a large part of the population or intended audience. It is important to include individuals with disabilities, along with members of racial and ethnic minorities, women, LGBTQIA+, and those from other underserved communities, in DEI initiatives. Incorporating accessibility within DEI efforts can provide concrete action items compared to some DEI initiatives that may seem ambiguous or even overwhelming. This session will cover some of the basics of creating forms, documents, and other materials that are accessible, and will discuss different aspects of accessibility such as neurodiversity, digital accessibility, and developing a disability inclusive culture.

Learning Objectives:

•Explore the role of accessibility in DEI initiatives
•Discuss various considerations when implementing accessibility including things like neurodiversity and digital accessibility
•Describe the basics of accessibility in forms, documents, and digital spaces

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

G14: Building Bridges: Towards An International Framework for Specimen Sharing

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

International specimen sharing is critical to answer important questions about complex diseases and ensure the diversity in collections necessary to develop therapies that benefit all populations. However, many challenges exist in international specimen sharing, including lack of harmonized ethical, legal, and policy frameworks regarding the secondary use of specimens, regulatory and policy challenges, and differences in cultural perspectives and practices among various regions. This session will discuss and refine a set of draft ethical principles related to biospecimen and data sharing that could help harmonize practices globally. These principles could also form the basis for advocacy for more consistency among national laws regulating the collection, retention, and research uses of human biospecimens and associated data. The ultimate goal is to develop an international framework that will facilitate global specimen sharing in an ethically and socially responsible way.

Learning Objectives:

• Understand the challenges of sharing specimens and associated data at the international level
• Consider diverse cultural/international ethical perspectives on specimen collection and use for research
• Discuss and refine draft ethical principles that could help inform the development of a globally relevant ethical framework for cross-border specimen and data sharing

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

G15: Everything You Wanted to Know about the CIP Credential

Track(s): *HRPP/IRB Administration/Management and Process*

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
•Discuss exam delivery options, and go over exam preparation techniques and what to expect on exam day

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

G16: ICH E6 Good Clinical Practice (GCP) Training: Programs--Approaches to Achieving Training Compliance Certification for Researchers

Track(s): *Education, Qualifications, and Training; HRPP/IRB Administration/Management and Process; Shared Research Oversight Challenges; Pharma/Biotech Perspectives*

This session will review various GCP training requirements. Also, diverse learning modalities will be discussed to offer certified GCP training, as required by research institutions, the NIH, or trial sponsors. The presenters will offer strategies for instruction recognizing that not all individuals come to the table with the same learning styles, background, or expertise. In addition, challenges and advantages to different training approaches will be presented.

Learning Objectives:

•Recognize the various requirements for certified GCP training
•Understand training elements necessary for certification
•Be aware of different training approaches, such as in-person, static content, or virtual/online

Target Audience(s): HRPP/IRB Directors; Research Leadership and Institutional Officials; Researchers and Research Staff; Clinical Research Staff; ACU/IACUC Directors; Educators/Trainers

G17: Quantifying Good, Bad, and Ugly Submissions to Increase Program Effectiveness

Track(s): *IACUC Protocol Review; QA/QI and Postapproval Monitoring; Shared Research Oversight Challenges; HRPP/IRB Administration/Management and Process; IACUC Administration/Management and Process*

IRB and IACUC effectiveness depends greatly on the quality of the submissions received because well written, complete protocols are faster and easier to approve. This session will discuss approaches to defining what a high quality submission looks like and for measuring quality in meaningful ways.

Learning Objectives:

•Recognize what features make a submission higher or lower quality
•Understand how to measure quality in numerical and descriptive ways
•Discuss how to use data about submission quality to effect change

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

G18: Leadership in Action: Real-life Scenarios and Solutions

Track(s): *Leadership Development Skills; Shared Research Oversight Challenges*

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

Learning Objectives:

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

Target Audience(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; Research Program Leadership and Institutional Officials

G19: Collaboration through Communication: Building Rapport with Stakeholders and Others within your Circle of Influence

Track(s): *Leadership Skills Development; Communication With the Public; IACUC Basics; Advancing Equity and Justice in Research*

In this session, attendees will explore effective approaches to communication styles helpful for building and maintaining empowering relationships with colleagues, collaborators, and the public. Attendees will receive takeaways that they can apply at work, and may use these skills to empower others and build trust within their communities when engaging in sensitive topics such as diversity, equity, inclusion, justice, and anti-nonhuman animal research sentiments. This session will be interactive, with a focus on takeaways that attendees can apply in both personal and professional settings.

Learning Objectives:

•Identify and apply effective communication styles in interactions with colleagues, collaborators, researchers, and the public to improve their relationships, achieve better results, and promote a culture of collaboration within their circle of influence

•Review the indicators of rapport, and discuss strategies necessary to build trust while navigating conflicting objectives or resistance (e.g., how to enhance negotiation skills with the goal of achieving mutually beneficial outcomes)

•Consider the value of exhibiting behavioral flexibility to direct conversations and achieve better outcomes, helping to navigate complex situations in a professional setting

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 Leadership and Institutional Officials; Compliance, Regulatory, and QA/QI Professionals; Compliance Personnel; Laboratory Animal and Veterinary Staff; HRPP Educators; Clinical Research Staff; Researchers and Research Staff; Diversity

G20: A Dialogue With the Office of Research Integrity (ORI)

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

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

Learning Objectives:

•Provide insight into the institutions' and ORI's implementation of the US Public Health Service regulations at 42 CFR Part 93, to address allegations of research misconduct

•Discuss institutions' and ORI's work to ensure institutional compliance with the federal regulations

•Share strategies and case studies to address procedural challenges at the institutional level, when investigating allegations of research misconduct in human subjects and unacceptable research practices with animals

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

12:30-1:45 PM ET **Lunch**

12:45- 1:45 PM ET **Town Hall: Is it Time to Revisit the Belmont Report?**

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

The Belmont Report, which articulates the ethical principles underlying the regulatory framework for research with human subjects in the United States, was promulgated nearly 50 years ago. Since then, the research and cultural landscape have changed significantly—from the proliferation of digital technologies and the vast quantities of data they produce, to the expansion of team and collaborative science; from evolving norms about personal privacy, social justice, and harms to communities, to the engagement of nontraditional actors, such as computer scientists, in human subjects research. While the Belmont principles are broad and flexible enough to continue to be relevant to much of the current research, research ethics scholars, oversight practitioners, and scientists have, in recent years, identified gaps in the foundations Belmont provides, along various dimensions—in terms of disciplines, technologies, participant populations, research entities, social norms, and research concepts that were not conceived at the time of the original Belmont Report. PRIM&R is spearheading a multi-stakeholder effort to examine whether it is time to revisit and update the Belmont Report and identify what such an update might include. This Town Hall, led by members of PRIM&R's Public Policy Committee, is an opportunity for the human subjects research ethics community to share with PRIM&R their perspectives on (a) if and how well the principles described in Belmont Report are still "working" for them; and (b) whether and in what ways Belmont should be updated to continue to provide a strong ethical framework contemporary research across varied disciplines. ***This session will be presented over lunch.***

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

PRIMR23 Breakout/Networking Session H Series, 1:45-2:45 PM ET

H1: Insights into IRB Student-Led Protocol Submissions

Track(s): *Education, Qualifications, and Training; SBER; HRPP/IRB Administration/Management and Process; QA/QI and Postapproval Monitoring*

Student-led research is the culmination of a student's scholarly work and contributes to partial completion of a degree's requirements. An accomplished student researcher familiarizes themselves with the expectations of systematic investigations, human subjects research, and IRB regulations. The IRB will make the final determination of the IRB review category or if the research does not involve human subjects. Some IRBs do not allow student-led research, others require the inclusion of a faculty co-investigator or faculty sponsor advising on the student project. This session will focus on the challenges and opportunities of student-led human subjects research and how IRB administrators can assess pathways forward.

Learning Objectives:

•Consider the pros/cons of student-led research

•Provide examples of training and education for students who lead research, including creating guides on how students can prepare for the IRB protocol submission process

•Consider approaches for postapproval review and monitoring

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

H2: OHRP, FDA, and the General Accountability Office (GAO) Report on IRB Oversight and Effectiveness: A Conversation With the PRIM&R Community

Track(s): *FDA Regulated Research*

In its recent report on actions needed to improve federal oversight and effectiveness of IRBs, the GAO recommended that OHRP and FDA convene stakeholders to examine approaches for measuring IRB effectiveness in protecting human subjects (Recommendation 4). In this session, OHRP and FDA will provide an overview of ongoing efforts to gather input from stakeholders regarding approaches to measure IRB effectiveness and will facilitate a group discussion regarding the general themes emerging from those interactions. This session will also serve as a forum for session attendees to provide input on approaches to examining IRB effectiveness at their individual institutions.

Learning Objectives:

•Recognize OHRP and FDA's initial efforts to solicit input from the stakeholder community regarding methods used to examine IRB effectiveness
•Identify common themes arising from OHRP/FDA stakeholder interactions to-date
•Provide input on their opinions and experiences with assessing IRB effectiveness at individual institutions

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

H3: The Speech Act of Informed Consent

Track(s): *Informed Consent*

Research ethics discussions often refer to informed consent as a decision, a process, a form, or a signature, and regulations that outline particular requirements for what informed consent must entail. All of these notions are lacking in some way. This session will approach the idea of informed consent as a kind of "speech act," that is, as something prospective subjects do with words. Speech acts are not simply true or false, but rather serve a function and are also evaluated according to standards which imply ethical commitments on the part of both prospective subjects and investigators. Understanding informed consent as a speech act helps to illuminate how subjects and investigators ought to behave.

Learning Objectives:

•Learn how and when informed consent may be viewed as a speech act
•Understand how informed consent as a speech act shapes the subject's ethical behavior
•Consider how informed consent as a speech act implies ethical commitments on the part of investigators

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

H4: Eliminating Financial Barriers to Clinical Study Participation: The Need for Industry and Academic Partnership for a Sustainable Solution

Track(s): *Pharma/Biotech Perspectives; Advancing Equity and Justice*

To advance health equity and further promote diversity and inclusion in clinical research, industry and academia need to work together to overcome many challenges. A particularly vexing issue is potential out-of-pocket costs to study participants in interventional clinical research studies who may be un- or under insured (e.g., co-pays, tests/procedures associated with standard of care). Eliminating this barrier while ensuring that ethical and regulatory imperatives are abided is complicated. This session will identify challenges and issues associated with full cost neutrality to study participants in interventional clinical research studies and explore potential solutions to resolve them ethically and compliantly.

Learning Objectives:

•Review the different ways in which financial considerations serve as barriers to participation which hamper efforts to ensure equitable subject selection
•Explore how decisions regarding site selection, eligibility requirements, and compensation and reimbursement considerations affect who can participate in clinical trials
•Discuss innovative approaches that have been implemented in clinical trials to achieve cost neutrality for participants

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

H5: Postapproval Monitoring (PAM) for Studies Overseen by a Single External IRB of Record: Challenges for Local Monitoring Programs

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

Since the Revised Common Rule, there has been an increase in the reliance on a single IRB of record for multi-centered research. With the recent issuance of the FDA NPRM, this trend will continue. Increased reliance on single IRBs for multi-centered research will undoubtedly increase burden on local PAM programs. Challenges may emerge for communication and coordination with the external IRB regarding monitoring for compliance with both the local site's and the external IRB's specific policies and requirements. There will be a need to reimagine local PAM programs and consider strategies for communication, collaboration, and resource utilization.

Learning Objectives:

•Understand the policies and requirement of external IRB of record
•Develop procedures for reporting to external IRB oversight/QA personnel
•Integrate corrective action procedures for both local and external IRB policies and requirements

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

H6: Engaging Our Community in the Mission of IRBs

Track(s): *Communication With the Public; Flexibility and Innovation in Research Oversight Processes*

To advance public health for all communities, engagement is needed by all community groups in the research, discovery, and oversight processes–from participating in research to serving on an IRB. A community member's decision to participate in research and discovery starts with building a relationship grounded in trust. In this session, speakers will share innovative and practical approaches to building sustainable community relationships. This session will provide examples from several institutions, including one who used a "Reader's Theater script" to successfully build relationships with our community. Reader's Theater is a well-established method for engaging lay community members and familiarizing them with clinical ethics committees at hospitals by "acting" out a mock clinical ethics committee meeting and was recently adapted for IRBs

Learning Objectives:

•Examine "trust" in the context of community members' involvement in research as study participants and IRB members
•Determine strategies for IRBs to provide awareness and open dialogue with community members
•Identify innovative methods used to build sustaining relationships with community members

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

H7: 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:

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

Target Audience(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 Personnel; Educators/Trainers; Clinical Research Staff; Researchers and Research Staff

H8: When You're the New Kid in Town: Taking Over as an HRPP/IRB Leader

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

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

Learning Objectives:

•Explore how to get established in a new organization, or in becoming a new leader of people who used to be your peers (whether you're replacing a respected, effective leader or were hired to make significant course changes)

•Learn approaches for identifying problem areas in the HRPP/IRB and how to make changes

•Share strategies and advice for when first starting, or that you'd want an incoming HRPP/IRB leader to know

Target Audience(s): HRPP/IRB Directors

H9: Human Subjects Protections in the US Intelligence Community (IC)

Track(s): *Communication With the Public; Emerging Challenges and Breaking Issues; Populations Requiring Additional Protections; Legal Considerations in Research Oversight*

The IC conducts and supports a range of research activities involving human subjects. IC research is typically reviewed and approved by IRBs, some of which follow the requirements of the Common Rule, while others adhere to other regulatory requirements and Executive orders. This session will explain some of the ethical and legal "guardrails" the IC uses in conducting authorized research activities, and address how the IC promote transparency and accountability in its human subjects research.

Learning Objectives:

•Provide the context of human subjects research in the intelligence community

•Discuss IC activities and the regulatory frameworks used, including compliance with the Common Rule regulatory requirements

•Explore the practice of excluding certain IC activities from the Common Rule regulatory definition of research and outline how certain Exemptions are utilized for some forms of IC research

•Identify methods of promoting transparency and accountability in their research

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

H10: Training IRBs for the Review of Transnational Research

Track(s): *Transnational Research Collaboration*

IRBs struggle in determining how they should work transnationally with peer IRBs. The appropriate "review order" is often unclear and there may be no clear pathway as to how differences in review requirements can be reconciled, leaving investigators frustrated and confused. IRBs may lack clear communication channels with other IRBs across the globe to reconcile any differences and advance the review of global research. This session will bring together IRB representatives from across the globe to work together to develop a framework for transnational IRB collaboration.

Learning Objectives:

•Provide a networking opportunity through which IRB representatives across the globe can develop a framework for global IRB collaboration

•Share strategies from organizations experienced with transnational IRB collaborations

•Discuss how a solid foundation of trust, accessibility and clear guidance can yield positive returns for a successful global research network

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

H11: When Secondary Data Use Involves an FDA Regulated Device Study

Track(s): *Research Involving Data and Biospecimens; FDA Regulated Research*

Secondary research with data can trigger FDA's investigational device regulations when a data algorithm is developed with the intention to diagnose, treat, mitigate, or prevent and/or cure a disease or condition, and therefore meets the regulatory definition of a medical device. Both investigators and IRBs may not recognize that the research involves an investigational device, and often struggle with interpreting and applying the relevant regulations. As research with machine learning and artificial intelligence (AI) increases, it is becoming even more confusing. In this session, case studies will be used to identify and apply the relevant regulatory frameworks including how to make risk determinations and how to assess AI-system risks.

Learning Objectives:

•Recognize when data algorithms used in research are investigational medical devices subject to FDA regulations

•Understand how differences in Common Rule and FDA regulations impact the need for IRB review of secondary research using data

•Learn to correctly apply the device regulations to common scenarios involving data research

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

H12: Methods for Improving Diversity, Equity, Inclusion, and Justice (DEIJ) in Research Administration and Oversight

Track(s): *Advancing Equity and Justice; HRPP/IRB Administration/Management and Process*

This conversation will provide attendees with a clearer understanding of the dimensions of the equity, diversity, and inclusion challenge for research, as illuminated by research initiated by HRPP leaders from large academic medical centers that asked the questions: Is the lack of DEI a result of the planning of the research or of the execution of the research? Do researchers need additional resources to better diversify their recruitment? If so, what resources might be useful? Presenters will then provide insight on what is being done at their institutions, what they believe can be done, and begin discussing what should be done.

Learning Objectives:

•Review the dimensions of the DEI Challenge

•Present partnership strategies used by Boston Children's Hospital in order to promote and accomplish equity, diversity, and inclusion in research, including a collaboration between the IRB and the Office of Health Equity and Inclusion, and one between the IRB and a Clinical and Translational Science Center Community Engagement Program

•Use the example of a Community Engagement Steering Committee, describe how to identify key stakeholders and institutional commitments required; review strategies for recruitment, onboarding, education, and retention of members; and how to assess meaningful engagement and evaluate impact

•Discuss strategies used to incorporate DEI activities into everyday administrative tasks and responsibilities of an HRPP

Target Audience(s): Diversity, Equity, Inclusion, and Justice; HRPP/IRB Administrators, Managers, and Staff; HRPP/IRB Directors

H13: Essentials of Ethical Research with Human Subjects at Risk for Suicide: Overview of eLearning Course and Suicide Risk Mitigation

Track(s): *Populations Requiring Additional Protections; Education, Qualifications, and Training; SBER*

Essentials of Ethical Research with Human Subjects at Risk for Suicide is an innovative, interactive, and self-paced eLearning course designed to teach researchers about the foundational aspects of safe and responsible research with people who may be at risk for suicide. Available free of charge, the course includes a scientifically informed and peer-reviewed curriculum, advice and tips from subject matter experts, animation, activities, and an experiential component to enhance skill building in suicide risk determination and response. This session will provide an overview of the eLearning course that will be made available to the public by late 2023 and will highlight several suicide risk mitigation considerations for a well-formulated, ethical, culturally sensitive, and safety-driven approach to human subjects research.

Learning Objectives:

•Define non-suicidal self-directed violence, suicidal ideation, and suicidal self-directed violence

•Recognize suicide risk indicators and warning signs commonly encountered in the context of human subjects research

•Learn how to prepare a research protocol sensitive to the needs of participants at risk for suicide, including the elements of a Suicide Risk Determination and Response Plan

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

H14: Incorporating Human Research Protections Training in the Preparation of Research Professionals

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

Training in the protection of human research participants remains a complicated practice. While the recent increase in public awareness of the conduct of clinical research has not necessarily resulted in transparency in study outcomes, the perceived treatment of human research participants and the actual treatment of these individuals is tantamount. Equipping research professionals with competencies to facilitate human research protections enhances the ethical treatment of human research participants as well as mitigates non-compliance. This session describes leading practices for knowledge, comprehension, analysis, practical application, information synthesis, and evaluation of human research protections competencies.

Learning Objectives:

•Describe avenues for developing competencies and opportunities for hands-on skills application for the protection of human research participants

•Compare and contrast practitioner preparation across universities and clinical research education organizations

•Identify strategies and analyze leading practices for evaluation of HRP skillsets

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

H15: Oversight Committee Interaction in Clinical Research Beyond the IRB

Track(s): *Flexibility and Innovation in Research Oversight Processes; FDA Regulated Research*

In this session, speakers will delve into the role and function of Data Monitoring Committees (DMCs), Data Safety Monitoring Boards (DSMBs), and Endpoint Adjudication Committees (EACs). These committees are increasing best practice to provide an independent, expert evaluation of clinical trial events and an unbiased adjudication to determine if certain clinical trial events have been met. This basic session will review what other oversight committees exist at big institutions, but for whom little is known.

Learning Objectives:

•Define the basic FDA and European Medicines Agency guidelines governing when DMCs/DSMBs and EACs should be considered for clinical trials

•Explain the role of DMCs/DSMBs and EACs and how their oversight is different than the IRB

•Describe why independence of DMCs/DSMBs and EACs from the sponsor/Clinical Research Organization is critical to eliminating the perception of bias

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; QA/QI Professionals

H16: As Compared to... What? A Data-Driven Approach to Identifying Peer Institutions in a Research Compliance Context

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

Research compliance areas almost always collect metrics on their own programs, and are tasked with developing institutional policies where there is flexibility in regulation. But, how can a compliance area know how their metrics stack up against similarly situated institutions, and how can a compliance area ensure its institutional policies are appropriate to their own context, without completely reinventing the wheel? This session will discuss a novel data-driven approach to identifying institutional peers (or aspirational peers), in order to conduct benchmarking and to assist in the development of effective policies and procedures that are appropriate to the institutional context.

Learning Objectives:

•Discuss the importance of peer-identification and benchmarking for the purposes of measuring effectiveness and efficiency in compliance programs, and for the process of developing institutional policy

•Explore the various ways institutions identify peers or aspirational peers in non-research-specific contexts, and discuss the benefits and drawbacks of each kind of approach

•Develop a model for identifying institutional peers or aspirational peers for the research compliance context specifically, using a mix of existing institutional data and supplemental survey information

Target Audience(s): ACU/IACUC Directors; HRPP/IRB Directors; IBC Directors; Research Leadership and Institutional Officials; Compliance, Regulatory, and QA/QI Professionals

H17: Balancing the Pressure of Getting New Therapies to Clinical Trial: Ensuring Robust Study Design, Nonhuman Animal Welfare, and Human Subjects Protections

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

This session will address the challenges of balancing the pressures associated with advancing new therapies to clinical trials while ensuring robust study design, optimal nonhuman animal welfare, and human subjects protections. It will explore the critical role of the IACUC and IRB in facilitating agile review processes and study start times while maintaining high-quality research. This session will highlight the potential risks of rushing or delaying pre-clinical studies and offer strategies to support the appropriate transition to clinical trials while upholding ethical standards.

Learning Objectives:

•Explore case studies that exemplify the potential consequences when pre-clinical studies are rushed or delayed, impacting both nonhuman animal welfare and human subjects

•Consider how the increased pressure of getting new therapies to market has led sponsors to explore the use of commercial IRBs verse local IRBs

•Learn what both IACUC and IRB committees can do to facilitate the transition from the pre-clinical stage to clinical trials, and how to balance agile yet comprehensive review of pre-clinical data

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

H18: Survival Guide: Techniques and Know-How for Surviving in a Single-Person Office

Track(s): *HRPP/IRB Administration/Management and Process; Small Research Programs*

People who work in single-person offices and small research programs have unique experiences that often come with feeling overwhelmed as if they were alone on a desert island. This session will address the things small programs are challenged by and provide practical tips on how to manage these issues. Topics will include, but are not limited to: relationship building, meaningful metrics, resource-reasonable education initiatives, maintaining work life balance, strategies for prioritizing when everything seems urgent, navigating faculty mentorship (particularly with poor quality student research submissions), managing committee members, and more!

Learning Objectives:

•Provide a high level overview of single-person office/small program topics

•Discuss considerations regarding relationship building, meaningful metrics, developing education initiatives,etc., that are sized for a single-person office

•Share practical tips on these topics

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

H19: Welfare as a Tenet in Research Oversight: How do We Apply Welfare To Our Work?

Track(s): *Animal Well-Being and the 3Rs; Flexibility and Innovation in Research Oversight Processes; Shared Research Oversight Challenges*

The new PRIM&R vision statement and strategic plan intentionally include the word 'welfare' as a goal for the regulatory oversight communities. This term holds a very different connotation for the nonhuman animal research verse human subjects research community. Regardless of interpretation, welfare remains critical to our work and this session will discuss how it applies to our future mission.

Learning Objectives:

•Define welfare for nonhuman animal and human subjects research

•Expand interpretations for improved research outcomes

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; Compliance Personnel; Laboratory Animal and Veterinary Staff; HRPP Educators; Clinical Research Staff; Researchers and Research Staff

H20: Virtual Training Hurdles and Solutions

Track(s): *Education, Qualifications, and Training; Shared Research Oversight Challenges*

As a result of the COVID-19 pandemic, many research organizations are increasingly reliant on online models, such as webinars and streamed videos to conduct employee training. However, it's widely accepted that these methods are not as effective as in-person training. In addition, for new employees, an opportunity for team building is lost. This session will seek to address those issues and provide case examples of solutions that research organizations have developed.

Learning Objectives:

•Discuss options for virtually training research oversight staff that are effective

•Review challenges associated with remote training and how to mitigate

•Share experiences and advice on dealing with these new technology-based challenges Consider where in-person training is needed over a virtual option

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

Icon	Label	*Description*
	CIP Credit	Session is eligieble for CIP credit.
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	Humans Subjects Research Content	Human Subjects Research Content
	IACUC/Animal Care and Use Content	IACUC/ACU Content
	Crossover Content	Crossover Content
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	Learning Lab Series	Learning Lab Series; learn more about session formats.
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