



DENVER | NOVEMBER 16-18

2026 | PRIM&R

ANNUAL CONFERENCE

PRIMR26 Preconference Workshops: Monday, November 16

7:00 AM-5:00 PM MT

Registration Open

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

WS1: Biomedical IRB Review: Core Concepts and Common Challenges

Description: Biomedical IRB review involves more than understanding regulations—it requires applying them consistently in real-world situations. This workshop provides a strong foundation in key concepts while focusing on how they play out in everyday IRB practice.

Attendees will explore common areas where IRBs and investigators often struggle, including interpreting FDA regulations, distinguishing quality improvement (QI) from human subjects research (HSR), reviewing less familiar study designs such as pragmatic trials and implementation research, and evaluating corrective action plans for noncompliance. Through practical examples and discussion, the session will highlight approaches to improving collaboration, increasing efficiency, and reducing burden while maintaining a clear focus on protecting human subjects.

Learning Objectives:

- Identify and apply key FDA regulatory concepts relevant to biomedical IRB review
- Distinguish QI activities from HSR using regulatory criteria and practical examples
- Recognize common challenges in reviewing pragmatic trials and implementation research
- Evaluate corrective action plans for noncompliance for appropriateness and completeness

**WS2: Challenging Consent Decisions in Practice: Impracticability and Capacity in Real-World IRB Review**

Description: Determining when informed consent can be waived and determining when an individual's capacity to consent is limited—are both challenging and inconsistent areas of IRB review. While the Common Rule provides criteria for waivers and emphasizes protections for individuals with diminished autonomy, it offers limited practical guidance on how to interpret concepts like impracticability or how to assess and support decision-making capacity in real-world research contexts. These are distinct regulatory and ethical questions, governed by different criteria and requiring different analysis, but both are frequently misapplied or oversimplified in practice and both are especially pronounced, where remote methodologies, data-driven designs, and inclusion of diverse populations complicate traditional approaches to consent.

This interactive workshop addresses two complex consent determinations IRBs face: waivers of informed consent based on impracticability and assessments of decision-making capacity. Each topic is examined on its own terms, with its own regulatory framework and case-based deliberations, so that participants come away with a clear understanding of what distinguishes these determinations from one another as well as the practical skill to make each one well. Through applied frameworks and case-based deliberations, attendees will examine how to make defensible waiver determinations, move beyond rigid cognitive checklists toward more inclusive capacity approaches, and navigate the tension between protection and access. Participants will leave with practical tools to support consistent, ethically grounded decision-making across both types of complex consent scenarios.

Learning Objectives:

- Apply regulatory criteria and ethical frameworks to evaluate when waiver of informed consent is justified based on impracticability
- Assess approaches to evaluating and supporting decision-making capacity beyond traditional cognitive screening methods
- Analyze complex scenarios involving impracticability and capacity considerations
- Develop clear, defensible rationales for IRB determinations related to consent waivers and capacity limitations

**WS3: Grey Zone Reviews: When the Regulations Don't Give You the Answer**

Description: IRB and HRPP professionals routinely encounter protocols that fall into regulatory grey zones—situations where the Common Rule, FDA regulations, and guidance documents offer limited clarity or leave room for interpretation. In these moments, reviewers must move beyond checklists and rely on ethical reasoning, institutional context, and professional judgment to reach defensible decisions. Yet many programs lack shared frameworks or consistent approaches for navigating this ambiguity, leading to variability in determinations, internal disagreement, and uncertainty in documentation.

This interactive workshop equips attendees with practical tools to approach these “no right answer” scenarios with greater confidence and consistency. Through case-based deliberations, participants will explore how to interpret regulatory silence, apply ethical principles in complex contexts, balance precedent with innovation, and clearly document and defend IRB determinations. Attendees will leave with structured approaches they can immediately apply within their own IRBs and HRPPs to strengthen decision-making in the most challenging reviews.

Learning Objectives:

- Apply ethical reasoning frameworks to IRB review scenarios where regulations are unclear or silent
- Differentiate when to rely on regulatory guidance, institutional precedent, or professional judgment in complex determinations
- Develop clear, consistent approaches for documenting and defending IRB decisions in ambiguous cases
- Evaluate strategies for promoting alignment and reducing variability across IRB reviewers and committees



11:30 AM-1:00 PM MT

Lunch

WS4: Leading Through Uncertainty: Strategic Decision-Making for Institutional Officials

Description: The role of the Institutional Official (IO) is no longer just about oversight—it is about navigating high-stakes decisions in an increasingly complex and shifting research landscape. From evolving regulations and funding uncertainty to emerging technologies and heightened scrutiny, IOs are being asked to balance risk, efficiency, and institutional priorities in real time. At the same time, IOs play a critical role in setting the tone and culture for research ethics and compliance—shaping how expectations are communicated, how decisions are made, and how accountability is reinforced across the institution.

This workshop moves beyond theory to focus on how IOs make defensible, strategic decisions when there is no clear answer. Through practical frameworks and scenario-based discussions drawn from real-world challenges—such as AI integration in research, funding disruptions, compliance gray areas, and institutional risk tolerance—attendees will explore how to assess risk, align stakeholders, strengthen research infrastructure, and foster a culture of ethical responsibility without slowing innovation.

Learning Objectives:

- Analyze current regulatory, funding, and policy shifts to identify emerging institutional risks and pressure points
- Apply decision-making frameworks to realistic scenarios involving compliance ambiguity, operational constraints, and competing priorities
- Evaluate institutional infrastructure and governance approaches to strengthen performance without overburdening staff or systems
- Assess strategies for establishing and reinforcing a culture of research ethics and compliance at the institutional level



WS5: Old Rules, New Science: Reviewing Emerging Technologies Under FDA Regulations

Description: Biomedical research is rapidly evolving, with innovations such as artificial intelligence, machine learning-enabled diagnostics, digital health tools, and Software as a Medical Device (SaMD) challenging traditional regulatory frameworks. While FDA regulations provide a foundation for human subject protections, they were not designed with these technologies in mind. As a result, IRBs and HRPPs are increasingly asked to review studies where risk, data flows, and intervention boundaries are difficult to define, and where existing categories do not neatly apply.

This interactive workshop equips attendees with practical strategies for applying established FDA regulatory requirements to emerging technologies in a consistent and defensible manner. Through real-world case scenarios and guided discussion, participants will explore how to assess risk, evaluate consent and data considerations, and navigate uncertainty when regulatory guidance is limited or evolving. Attendees will leave with frameworks and tools to support high-quality, forward-looking review of innovative biomedical research while maintaining compliance and participant protections.

Learning Objectives:

- Apply FDA regulatory requirements (21 CFR 50 and 56) to research involving emerging technologies such as AI/ML and digital health tools
- Evaluate risk and benefit considerations when traditional regulatory categories do not clearly apply
- Analyze challenges related to consent, data use, and participant protections in technology-driven studies
- Develop defensible IRB determinations for innovative biomedical research in the absence of clear or updated guidance



WS6: Minimal Risk, Maximum Complexity: Advanced Review of SBER in the Digital Age

Description: Research that appears to qualify as minimal risk is increasingly among the most complex protocols IRBs must evaluate. In the digital age, SBER often involves passive data collection, large-scale datasets, AI-enabled tools, and third-party platforms—introducing nuanced risks related to privacy, autonomy, and group harms that challenge traditional regulatory frameworks.

This advanced workshop equips experienced IRB professionals with practical tools to assess and document minimal risk determinations in these contexts. Grounded in the Common Rule and, where applicable, FDA regulations, attendees will apply structured frameworks to real-world cases, strengthening consistency, defensibility, and ethical rigor in IRB review of complex SBER.

Learning Objectives:

- Apply regulatory definitions of minimal risk to complex SBER protocols involving digital tools, AI, and large-scale data environments
- Evaluate informational, psychological, and group harms that may not be captured in traditional risk assessments
- Determine the appropriate level of IRB review, including when expedited review is or is not appropriate
- Use structured frameworks to support consistent and well-documented IRB decision-making





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PRIMR26 IACUC Day One: Monday, November 16, 2026

7:00 AM-5:00 PM MT Registration Open

7:30-8:15 AM MT N01: IACUC First Time Attendee Coffee

Descriptor: Join other first time IACUC/ACU attendees to connect before PRIMR26 begins! Coffee and tea only will be served.



8:30-10:00 AM MT Welcome Remarks from PRIMR26 IACUC Planning Committee Co-Chairs, Executive Director
Opening Session Keynote Presentation: Breaking Silos for Science: NAMs, Animal Models, and Openness



10:00-10:30 AM MT Break

PRIMR26 IACUC Day One Breakout/Networking Session A Series, 10:30-11:30 AM MT

A01: Mastering the Transition: Tips and Tricks for Switching to a New IACUC Application System

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

Descriptor: Upgrading to a new IACUC application system is a daunting and challenging task. From outreach to the research community to training all users, the process requires substantial preparation and change management. Many lessons are learned during the process, and it is essential to address challenges while incorporating user feedback to identify successes and opportunities for improvement. This session will walk through how to develop and implement a structured training program for all user groups transitioning to a new IACUC Application system, explore methods for collecting and applying user feedback to improve the application and workflow, and highlight impactful ways to provide user resources and communicate system changes, with a focus on researcher engagement, resistance management, and clear end-user communication.

Learning Objectives:

- Design and implement a comprehensive systems training program across all user groups, incorporating feedback mechanisms to continuously improve the application and workflow
- Develop and deploy effective user resources, including town halls, help documents, and video demos, to support adoption and ongoing engagement
- Learn how to communicate system changes strategically, with an emphasis on researcher engagement, resistance management, and clear end-user messaging



A02: IACUC SOS! Evaluating Difficult Protocols by Optimizing Your Review Toolkit

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

Descriptor: Evaluating certain protocols can be challenging. This session aims to streamline and improve the quality of IACUC review by optimizing a review toolkit (e.g., ad hocs, pilot studies, etc.). Speakers will also discuss how to streamline development, review, and updates to local performance standards and SOPs.

Learning Objectives:

- Discuss challenging IACUC protocols (e.g., research where animal impacts are poorly characterized; research that involves creative technologies and engineering, and testing these innovative medical devices in animals; protocols where the risk/benefit analysis produces unclear results, and those involving an organization concerns with perception or risk)
- Review resources and approaches the IACUC can use to effectively evaluate and monitor these activities, such as the use of ad hocs, pilot projects, performance standards, and SOPs and institutional policies
- Develop strategies to streamline the use of these approaches and promote buy-in from investigators and key stakeholders



A03: Doing More With What You Have: Building Culture of Care Through Community and Commitment

Track(s): Pharma/Biotech Perspectives, ACU/IACUC Program Management and Administration, Animal Well-Being and the 3Rs, Enhancing Collaboration and Inclusion in IACUC/ACU Programs

Descriptor: Institutions continue working to strengthen a Culture of Care within animal programs, even when resources or institutional support are limited. This session highlights practical, community-driven strategies for defining your program's vision, identifying allies, recognizing welfare advancements, and celebrating staff contributions in meaningful, sustainable ways. Speakers from diverse roles will share adaptable approaches for integrating positive reinforcement into daily operations to enhance morale, retention, and animal welfare across programs of any size. By reframing Culture of Care as a dynamic, shared responsibility, attendees will leave with tangible ideas for cultivating supportive, trust-building practices within their own programs, regardless of institutional resources.

Learning Objectives:

- Define Culture of Care and identify key institutional partners, exploring practical strategies for recognizing animal welfare advancements and staff contributions
- Compare approaches for integrating positive reinforcement and celebration into everyday operations
- Apply at least one actionable idea to strengthen Culture of Care efforts at your institution, moving from concept to practice



A04: Post-Approval Monitoring (PAM): Building and Implementing a Formal Program**Track(s): QA/QI and Postapproval Monitoring, ACU/IACUC Program Management and Administration**

Descriptor: Post-approval monitoring (PAM) encompasses a broad range of activities designed to promote ongoing compliance, animal welfare, and protocol adherence beyond the IACUC's required review functions. While many PAM-related activities occur through routine administrative, veterinary, husbandry, and facility oversight processes, institutions often determine that a more structured and formalized PAM program is needed. This session will explore the essential components of a PAM program, including program goals, scope of activities, monitoring processes, documentation practices, communication pathways, and criteria for reporting findings to the IACUC. Presenters will discuss practical strategies for developing and refining a PAM program across a variety of institutional settings, including smaller programs with limited resources and no dedicated PAM staff. Attendees will leave with actionable approaches for establishing or strengthening a PAM program that supports institutional compliance and continuous improvement.

Learning Objectives:

- Explore different PAM methodologies including formal versus informal approaches and observational versus administrative methods
- Evaluate the key components of an effective PAM program
- Identify practical strategies for implementing and sustaining a PAM program, including resource-conscious approaches for smaller institutions

**A05: Building and Sustaining an Effective IACUC: Recruitment, Training, and Engagement****Track(s): Career Development and Training, Enhancing Collaboration and Inclusion in IACUC/ACU, Programs****ACU/IACUC Program Management and Administration**

Descriptor: Successful IACUC oversight depends on a well-trained, diverse, and actively engaged committee. Regulatory frameworks such as The Guide, PHS Policy, and the Animal Welfare Act and Regulations all emphasize the importance of member training and qualification. Yet many institutions struggle with consistent onboarding, continuing education, and long-term member engagement. Over time, members embedded in the animal program may grow accustomed to established practices, while nonscientific and community members may feel disconnected from the scientific and regulatory dimensions of their role. This session will address the full lifecycle of committee membership, from recruiting diverse candidates and building effective training programs, to recognizing disengagement and implementing strategies that sustain meaningful participation across all member types.

Learning Objectives:

- Describe effective onboarding and continuing education programs that support recruitment and retention of a qualified, diverse committee
- Recognize indicators of declining engagement and apply strategies that promote meaningful participation among scientific, nonscientific, and community members
- Explain how well-trained, engaged, and diverse committees strengthen IACUC functions, including protocol review, facility inspections, and overall animal care oversight



11:30-1:15 PM MT

Lunch

PRIMR26 IACUC Day One Networking Block, 12:15-1:15 PM MT

12:15-1:15 PM MT

N02: Lunch and Learn: Building Better Communication Templates: Enhancing User Experience in Electronic Protocol Systems**Track(s): IACUC Review, ACU/IACUC Program Management and Administration, Enhancing Collaboration and Inclusion in IACUC/ACU Programs**

Descriptor: Utilizing an ePMS (electronic protocol management system) is meant to make routine functions more efficient, automatic, time saving, and compliant. Establishing consistent communication models helps to ensure good science and compliance. Automated language though may not "meet the mark", thereby wasting time and making some functions harder when additional explanatory messages/emails are needed. Communications triggered by ePMS workflows affect a broad network of stakeholders, including the IACUC office, committee members and chairs, research staff, and partner groups such as the IBC and safety office. As systems evolve, there is an ongoing opportunity to evaluate how communication templates can better support clarity, efficiency, and collaboration. This interactive session invites attendees to share experiences, challenges, and successful approaches to building communication templates that serve to reduce administrative burden and improve accuracy in communications.

Learning Objectives:

- Identify template features, including conditional logic, forced formatting, and data validation, to improve accuracy, flexibility, and compliance with regulatory requirements
- Evaluate ePMS design practices that reduce administrative burden and improve document turnaround time, while avoiding common protocol template pitfalls
- Determine when and how communication documents should be updated to reflect future needs, system changes, or regulatory expectations



12:15-1:15 PM MT

N03: On the CUSP: From Shared Procedures to Shared Progress

Descriptor: The Compliance Unit Standard Procedures (CUSP) Sharing Site was created to reduce administrative burden, improve consistency, and support the development of high-quality animal research protocols through shared institutional resources. Over the past two years, CUSP has grown into a national collaborative platform connecting institutions through shared procedures and best practices.

This interactive session will provide an overview of the current state of CUSP, including platform growth, user trends, and practical examples of how institutions are using shared content to support their programs. The session will also explore how collaborative tools like CUSP fit into broader efforts to strengthen animal care and use programs, support the 3Rs (Replacement, Reduction, and Refinement), and advance conversations around New Approach Methodologies (NAMs).

Learning Objectives:

- Increase awareness and participation in the CUSP Sharing Site by demonstrating how collaborative resource sharing can support and strengthen animal care and use programs
- Gather community feedback to help inform long-term planning and future direction of CUSP
- Connect CUSP to broader national conversations surrounding the 3Rs, NAMs, and future opportunities for cross-institutional collaboration and funding initiatives



12:15-1:15 PM MT

N04: Reserved for late-breaking



12:15-1:15 PM MT

N05: Lunch and Learn: Navigating Compliance: Real-World IACUC Scenarios

Descriptor: Join us for a gripping exploration into the world of research ethics, where real-life dilemmas and compliance challenges unfold behind the scenes of IACUC offices. This session will guide attendees through complex scenarios faced by IACUC chairs and staff, offering insights and strategies for navigating the murky waters of ethical decision-making.

Learning Objectives:

- Explore real-life scenarios highlighting ethical dilemmas faced by IACUC chairs and staff
- Discuss strategies employed by IACUC chairs and staff to address and mitigate ethical concerns while upholding animal welfare standards



12:15-12:40 PM

2026 PRIM&R Conference Poster Presentation—AI-Assisted NIH Grant-Protocol Congruency Screening: A Pilot Implementation

Join us to hear from one of this year's outstanding poster abstract authors about their important and timely work. During this timeslot, our poster author will present their poster and attendees will have the ability to comment and ask questions.



PRIMR26 IACUC Day One Plenaries, 1:30-2:45 PM MT

1:30-2:45 PM MT

Plenary Session I: Institutional Readiness for New Approach Methodologies (NAMs): Leadership, Governance, and Practical Strategies

Track(s): *Animal Well-Being and the 3Rs, IACUC Review, ACU/IACUC Program Management and Administration, Emerging Research Challenges and Breaking Issues*

Descriptor: As New Approach Methodologies (NAMs) continue to gain momentum across the research enterprise, institutions must consider how to effectively evaluate, support, and integrate these approaches within existing research and oversight programs. This plenary panel will explore the evolving roles of IACUCs, Institutional Administrators, investigators, veterinarians, and other stakeholders in fostering institutional readiness for NAM adoption. Panelists will discuss governance frameworks, fit-for-purpose evaluation, validation considerations, workforce development, resource allocation, and strategies for balancing scientific rigor, animal welfare, and operational realities. Attendees will gain practical insights into preparing their institutions for the responsible and evidence-based implementation of NAMs while navigating emerging scientific, regulatory, and organizational expectations.

Learning Objectives:

- Examine the roles of institutional leaders, IACUCs, and research teams in supporting the evaluation and adoption of NAMs
- Identify scientific, operational, regulatory, and cultural factors that influence institutional readiness for NAM implementation
- Evaluate frameworks and strategies for assessing the suitability, validity, and potential impacts of NAMs on research quality, animal welfare, and oversight programs



1:30-2:45 PM MT

Plenary Session II: Beyond Mice, Beyond the Vivarium: Expanding Oversight for Evolving Research Programs

Track(s): *Oversight of Non-Typical Animals and Situations, ACU/IACUC Program Management and Administration, IACUC Review, QA/QI and Postapproval Monitoring, Animal Well-Being and the 3Rs*

Descriptor: Most animal research programs are built around traditional laboratory species housed in controlled vivarium environments, but evolving scientific needs increasingly require institutions to oversee research involving non-traditional species, field studies, zoological settings, agricultural environments, and other specialized contexts. As programs expand beyond conventional models, institutions must adapt their oversight approaches while maintaining high standards for animal welfare, personnel safety, scientific rigor, and regulatory compliance. This plenary panel will explore lessons learned from institutions that have navigated these challenges, examining how IACUC processes, stakeholder responsibilities, training programs, and operational frameworks evolve when standard vivarium assumptions no longer apply. Panelists will discuss practical strategies for planning, risk assessment, and oversight, as well as the role of external agencies, professional organizations, and institutional guidance in supporting ethical and effective research programs across diverse settings.

Learning Objectives:

- Examine the institutional, operational, and oversight considerations associated with expanding animal research programs beyond traditional laboratory species and vivarium environments
- Evaluate how IACUC processes, stakeholder roles, training requirements, and risk management approaches may need to adapt for non-traditional species and research settings
- Identify practical frameworks, guidance resources, and external partnerships that support effective oversight of animal research conducted in field, zoological, agricultural, and other specialized environments



2:45-3:15 PM MT

Break

PRIMR26 IACUC Day One Breakout/Networking Session B Series, 3:15 PM-4:15 PM MT

B01: What Would You Do? Using Scenarios to Strengthen Animal Care and Use Training

Track(s): *Career Development and Training, ACU/IACUC Program Management and Administration*

Descriptor: Scenario-based learning is an effective way to build critical thinking, reinforce regulatory knowledge, and engage animal care and use program personnel in meaningful discussion. While many training resources are readily available, institutions often face unique challenges that require more targeted educational approaches. This session will explore how to develop institution-specific scenarios that address recurring compliance issues, knowledge gaps, and emerging concerns. Drawing on educational methods used in healthcare training, attendees will learn how to translate real-world animal care and use situations into engaging learning exercises with clear objectives and assessment strategies. Through interactive activities, attendees will gain practical tools for creating and implementing scenarios that strengthen training, support continuous improvement, and promote ethical decision-making across the animal care and use program.

Learning Objectives:

- Identify institutional challenges and knowledge gaps that can be addressed through scenario-based learning
- Develop effective animal care and use scenarios with learning objectives and assessment questions
- Evaluate the benefits and limitations of scenario-based training for different animal care and use program stakeholders



B02: Living with a Citation: Responding and Moving Forward**Track(s): ACU/IACUC Program Management and Administration, IACUC Review**

Descriptor: Regulatory agency citations can disrupt research programs and shake institutional trust. This session will identify the types of and levels of citations you can receive from agencies like USDA, FDA, or OLAW and provide practical guidance for responding effectively. Speakers will highlight the importance of engaging key stakeholders such as institutional leadership, compliance offices, researchers, veterinary and animal care staff, communications teams, and external partners in the development of corrective action and communication plans. Attendees will explore strategies for rebuilding stakeholder confidence and implementing sustainable changes to prevent future noncompliance. Real-world examples will illustrate lessons learned and best practices for inclusive, transparent response efforts.

Learning Objectives:

- Learn how to develop and implement a corrective action plan following a regulatory citation – with a focus on long-term, cross-functional sustainable solutions
- Review real-world examples of strategies that demonstrate how organizations have rebuilt trust and credibility following a regulatory citation
- Identify tools and practices to build a sustainable culture of compliance and proactive oversight

**B03: The Role of the IACUC in Facilitating Scientific Rigor and Responsible Conduct of Research****Track(s): Animal Well-Being and the 3Rs, ACU/IACUC Program Management and Administration**

Descriptor: While IACUCs do not evaluate scientific merit, protocol review provides an important opportunity to ensure that proposed animal activities support humane, ethical, and responsible research. By carefully assessing protocol elements that influence both animal welfare and study quality, IACUCs help institutions meet regulatory requirements while fostering rigor, reproducibility, and public confidence in animal research. This session will explore practical approaches to reviewing challenging aspects of animal use protocols, including areas where animal welfare considerations intersect with scientific design. Through case examples and discussion, speakers and attendees will share strategies for conducting efficient, consistent protocol reviews that promote humane animal care and use while supporting responsible research.

Learning Objectives:

- Identify protocol elements that are particularly challenging to review and discuss practical approaches for evaluating them during IACUC review
- Apply the principles of Replacement, Reduction, and Refinement (the 3Rs) to strengthen protocol review and promote humane animal care and use
- Describe how effective IACUC review supports regulatory compliance, responsible research practices, and public confidence in animal research

**B04: Balancing the Bureaucracies: Communication and Collaboration Across Animal Research Programs and Oversight Structures****Track(s): Enhancing Collaboration and Inclusion in IACUC/ACU Programs, ACU/IACUC Program Management and Administration, IACUC Review**

Descriptor: Communication challenges in animal research occur at multiple levels, from day-to-day interactions among investigators, veterinarians, and animal care personnel to coordination among oversight committees, institutional offices, sponsors, and regulators. While these systems are intended to support animal welfare, research integrity, and regulatory compliance, differing priorities, responsibilities, and perspectives can create misunderstandings, duplication of effort, and operational inefficiencies. Through case scenarios and candid discussion from multiple stakeholder viewpoints, this session will examine common communication barriers across animal research programs and explore practical strategies for building trust, improving collaboration, and fostering more effective and transparent research environments.

Learning Objectives:

- Identify common communication barriers among animal research stakeholders and their potential impacts on animal welfare and research activities
- Examine areas of overlap, tension, and misalignment across oversight functions and institutional processes
- Apply strategies to promote collaboration, shared accountability, and effective communication within animal research programs

**B05: Operationalizing Alternatives Searches: A Human-Governed AI Approach to Strengthening Research Oversight****Track(s): Emerging Research Challenges and Breaking Issues, ACU/IACUC Program Management and Administration, IACUC Review**

Descriptor: Alternatives searches are a core component of animal research oversight, yet investigators and IACUCs often face challenges with inconsistent documentation, varying interpretations of requirements, and review inefficiencies. This session explores a human-governed, AI-assisted approach to operationalizing existing alternatives search guidance to support researchers, enhance documentation quality, and improve regulatory consistency. Discussion will focus on governance safeguards, ethical considerations, and alignment with established oversight frameworks, emphasizing the role of AI as a support tool rather than a replacement for researcher or IACUC judgment.

Learning Objectives:

- Identify common challenges associated with alternatives searches and documentation review
- Describe how human-governed, AI-assisted workflows can support consistency, transparency, and accountability in alternatives documentation
- Evaluate governance considerations and ethical boundaries for integrating AI into research oversight processes

**4:30-5:30 PM MT****Office Hours**

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

Only the following organizations are participating in this timeslot:

- AAALAC
- AAHRPP
- National Center for Advancing Translational Sciences (NCATS)
- The Office of Research Integrity (ORI)

4:15-5:15 PM ET**Registration Open for Early Check-in**

Attending the conference on November 17-18? Skip the morning rush! Check in early the evening of November 16 and get your badge before the conference begins. Attendees who complete early check-in will have access to the November 16 reception and be provided a free drink ticket!

4:30-5:45 PM MT**PRIMR26 Nov 16 Reception**



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PRIMR26 IACUC Day 2: Tuesday, November 17

7:00 AM-5:00 PM MT Registration Open

7:15-8:00 AM MT Office Hours

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

Only the following organizations are participating in this timeslot:

- AAHRPP
- The Office of Research Integrity (ORI)

PRIMR26 IACUC Day Two Session C Series, 8:00-9:00 AM MT

C01: Semiannual Inspections: Strategies for Efficiency and Effectiveness

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

Descriptor: Semiannual facility inspections are an important component of every animal care and use program. This session moves beyond inspection fundamentals to examine how programs can refine their processes for greater efficiency and effectiveness. Speakers will share approaches to semiannual inspection planning and execution, including designing program-specific checklists; using electronic tools to schedule, track, and document inspections and findings; and reducing administrative burden throughout the process. Attendees will have opportunities to exchange practical strategies with speakers and peers, comparing how inspections are managed across institutions and how programs address frequently encountered challenges. Attendees should come prepared to discuss their own inspection practices and persistent challenges.

Learning Objectives:

- Explore innovative approaches to planning and conducting semiannual facility inspections, including program-specific checklists and electronic tools for scheduling, tracking, and documenting inspections and findings
- Discuss strategies for reporting deficiencies, developing action plans, and tracking corrective actions through resolution while reducing administrative burden
- Exchange practical strategies for addressing common inspection challenges, including scheduling conflicts, inconsistent findings, and follow-up on deficiencies, and identify approaches that can be applied within attendees' own programs



C02: Sustaining Effective Post-Approval Monitoring Programs

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

Descriptor: Once a formal Post-Approval Monitoring (PAM) program is established, maintaining its effectiveness can be just as challenging as implementing it. Decentralized facilities, limited staffing, competing priorities, multiple regulatory requirements, and complex organizational structures can all affect a program's ability to provide meaningful oversight while supporting research activities. This session will explore common challenges encountered by established PAM programs and discuss practical strategies for maintaining efficiency, fostering productive relationships with stakeholders, and reducing opportunities for noncompliance. Through case-based discussions, attendees will examine approaches for adapting PAM activities to evolving institutional needs while continuing to support animal welfare, research quality, and regulatory compliance.

Learning Objectives:

- Identify common operational and organizational challenges that affect the efficiency and effectiveness of established PAM programs
- Evaluate approaches for addressing PAM challenges while supporting compliance, animal welfare, research quality, and stakeholder engagement
- Apply lessons learned from case studies to strengthen PAM processes, communication, and oversight within their own institutions



C03: Optimizing the Designated Member Review Process: Strategies for Efficiency and Effectiveness

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

Descriptor: The designated member review (DMR) process is the primary mechanism used by many IACUCs to review and approve animal use protocols and amendments. While DMR can improve efficiency, institutions often face challenges related to reviewer workload, consistency, timeliness, and regulatory compliance. This session will explore evidence-informed approaches for strengthening DMR programs, including reviewer selection and training, expansion of reviewer pools, use of veterinary verification and consultation (VVC), administrative pre-review practices, and other process improvement strategies. Attendees will be invited to share their institutional experiences and lessons learned, creating an interactive discussion focused on practical approaches to enhancing both efficiency and review quality.

Learning Objectives:

- Examine regulatory requirements and institutional considerations that support an effective DMR process
- Evaluate the benefits and challenges of different DMR models, including reviewer pool expansion and reviewer training approaches
- Identify practical strategies and tools to improve DMR efficiency, consistency, and compliance



C04: Closing Training Gaps: Standardizing Technical Training and Documentation in IACUC Programs

Track(s): ACU/IACUC Program Management and Administration, Career Development and Training, Animal Well-Being and the 3Rs

Descriptor: Ensuring that personnel are appropriately trained and competent to perform animal-related procedures is a critical component of an effective animal care and use program. Yet many institutions face challenges in consistently documenting peer-to-peer training, assessing competency, and maintaining training records that withstand regulatory and accreditation scrutiny. This session will explore practical approaches for developing standardized technical training programs and documentation processes that support animal welfare, research quality, and regulatory compliance. Speakers will discuss common training and documentation gaps, strategies for building curricula based on program needs, and methods for evaluating training effectiveness over time. Attendees will also have the opportunity to exchange ideas and lessons learned from their own institutions.

Learning Objectives:

- Identify common technical training and documentation gaps that may affect compliance, animal welfare, and research quality
- Apply strategies for developing standardized training curricula and documentation processes that support competency and consistency
- Evaluate approaches for assessing and continuously improving technical training programs within animal care and use programs



C05: Wildlife Studies and Field Project Review: One Size Does Not Fit All

Track(s): Oversight of Non-Typical Animals and Situations, ACU/IACUC Program Management and Administration, IACUC Review, Animal Well-Being and the 3Rs

Descriptor: 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 institutions and agencies that work almost exclusively with wildlife will discuss their specific approach to the evaluation of wildlife field projects in order to meet regulatory requirements, fulfill the mission of their institution/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
- Evaluate specialized field-research scenarios that may require MOUs or federal notifications, including inter-institutional collaborations, foreign partnerships, USDA-regulated field animals, and the use of controlled substances



9:00-9:15 AM MT

Break

PRIMR26 IACUC Day Two Session D Series, 9:15-10:15 AM MT

D01: Advances in Non-Animal Testing Methods: The 3Rs and In-Vitro Innovations

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

Descriptor: This session will examine recent advancements in non-animal testing methods through the lens of the 3Rs—Replacement, Reduction, and Refinement. Speakers and attendees will explore innovative approaches such as in-vitro models, organ-on-a-chip technologies, 3D cell cultures, and computational tools, with a focus on their growing role in drug development and regulatory acceptance within the pharmaceutical and biotechnology sectors.

Learning Objectives:

- Explain the principles of the 3Rs and their relevance to preclinical research
- Explore emerging non-animal testing methods, including organ-on-a-chip, 3D cell cultures, computational models, and high-throughput screening
- Analyze the regulatory acceptance and validation of non-animal methods in drug development



D02: AAALAC Accreditation in Practice: Implications for Biotech, Pharma, and Academia

Track(s): Pharma/Biotech Perspectives, ACU/IACUC Program Management and Administration, IACUC Review

Descriptor: AAALAC International accreditation is widely recognized as a benchmark for high-quality animal care and use programs, yet institutions often have questions about how accreditation standards are applied across diverse research environments. As research programs become increasingly complex and global, accreditation reviews must consider a broad range of scientific, regulatory, and species-specific standards relevant to an institution's activities and geographic location. This session will examine AAALAC's accreditation framework and discuss how applicable standards are used in practice to evaluate animal care and use programs. Speakers will explore the impact of accreditation on animal welfare, research quality, regulatory compliance, and organizational reputation, while highlighting similarities and differences in accreditation experiences across biotech, pharmaceutical, and academic settings.

Learning Objectives:

- Describe the purpose of AAALAC International accreditation and how applicable standards are used to evaluate animal care and use programs
- Compare the benefits, challenges, and operational considerations of accreditation across biotech, pharmaceutical, and academic research settings
- Evaluate the impact of accreditation on animal welfare, research quality, regulatory compliance, and organizational credibility



D03: When Things Go Wrong: Managing Noncompliance and Adverse Events

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

Descriptor: Noncompliance and adverse events are inevitable challenges in animal research programs, but how institutions assess, investigate, document, and respond to these events can significantly influence program effectiveness and regulatory compliance. This session will examine the IACUC's role in evaluating reported events, distinguishing between minor and significant concerns, determining when reporting is required, and identifying opportunities for corrective and preventive action. Speakers will discuss approaches for tracking and trending events, developing institutional adverse event assessment and management plans, and fostering a culture of transparency and continuous improvement. Attendees are encouraged to share their own institutional approaches for collegial discussion and practical feedback.

Learning Objectives:

- Distinguish between noncompliance and adverse events and determine when further investigation or reporting may be warranted
- Evaluate trends and recurring issues to identify opportunities for program improvement and risk reduction
- Develop strategies for assessing, documenting, and managing events in a manner that supports compliance, transparency, and continuous improvement



D04: Science of Pain and Distress

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

Descriptor: This session will discuss how the science of pain, stress, and distress has evolved in recent decades, including application of new findings to scientific methods and laboratory animal welfare, as well as the potential risks of anthropomorphism. How are pain, stress, and distress defined, conceptualized, measured, and validated in nonhuman animals? What are the broader implications of this research for fields such as comparative psychology, animal welfare, and beyond? While these experiences can sometimes have adaptive or protective functions, evolving definitions and understandings present both opportunities and challenges. This session will provide a forum to explore how shifting scientific perspectives influence research practices, laboratory animal care, and the responsibilities of IACUCs during protocol review and oversight.

Learning Objectives:

- Discuss how the science of pain, stress, and distress has evolved in recent decades
- Explain how current scientific understanding of pain and distress can inform IACUC protocol review and the evaluation of daily practices involving animal care and welfare
- Describe approaches to categorizing pain, including timeframes, post-procedure reassessment, documentation, and justification—especially in cases of disagreement or emerging scientific evidence



D05: Making It Personal: Using Storytelling to Build Understanding and Support for Research
Track(s): Communication With the Public, Emerging Research Challenges and Breaking Issues



Descriptor: Public understanding of research is shaped not only by data and evidence, but also by personal stories, relationships, and meaningful conversations. As researchers and research advocates seek to build trust and support for animal-based research, effective communication has become increasingly important. This session will explore how storytelling can help convey the purpose, impact, and value of research in ways that resonate with diverse audiences. Speakers will also discuss principles of constructive dialogue, including active listening, empathy, and responding to questions or concerns with respect and clarity. Through practical examples and communication strategies, attendees will learn how to engage family members, colleagues, community members, and other stakeholders in productive conversations about animal research and its role in advancing science and health.

Learning Objectives:

- Apply storytelling techniques to communicate the purpose, impact, and value of animal-based research to non-expert audiences
- Use principles of constructive dialogue, including active listening and empathy, to foster trust and productive conversations about research
- Evaluate communication strategies for addressing questions, concerns, and misconceptions about animal research in personal and community settings

10:30-11:15 AM MT

Office Hours

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

Only the following organizations are participating in this timeslot:

- AAALAC
- Department of Veterans Affairs (VA)
- USDA/APHIS/Animal Care
- The Office of Research Integrity (ORI)

10:30-11:15 AM MT

N07: Info Session: Everything You Wanted to Know About the CPIA Credential

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

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

Learning Objectives:

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



10:30-11:15 AM MT

N07: Info Session: Everything You Wanted to Know About the CPIA Credential

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

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Learning Objectives:

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



11:00 AM-12:15 PM MT

Lunch

2:00-3:30 PM MT

CU Anschutz Animal Research Facility Tour

University of CU Anschutz is offering a post-conference tour on **November 17 from 2:00-3:30 PM MT**. Before registering for this tour, review the important notes below as there are **specific requirements for participation**.



Important note: Attendees are responsible for their own travel to and from CU Anschutz (*One way, this is roughly a 45-minute Uber/car ride OR 1 hour train ride to facility from Colorado Convention Center*).

This post-conference offering will include a tour of CU Anschutz's animal research facilities, which will include a variety of animal rooms and areas throughout the facility. PRIM&R has food kiosks available for lunch, which will conclude around 12:15 PM MT. Attendees may then travel to the CU Anschutz Animal Research Facility and meet CU Anschutz staff prior to the tour, which is scheduled to begin at 2:00 PM MT. Attendees are responsible for their own travel to and from CU Anschutz. **Instructions for the tour will be provided in September via email by CU Anschutz staff.**

Important program notes:

This program requires **pre-registration and the cost to attend is \$10. Attendance is limited**; capacity is 40 people. A waitlist will be created if more than 40 register.

This offering involves walking; **attendees will be on their feet** for approximately 90 minutes.

If you cannot make the tour once you have registered, please let PRIM&R and the coordinators at CU Anschutz know so that they may offer the tour to a person on the waitlist.

CU Anschutz will manage all logistics and tour-related details.

All tour registration fees are final. No refunds will be issued for cancellations or no-shows.



2026 | PRIM&R ANNUAL CONFERENCE

PRIMR26 HSR/IO Day One: Tuesday, November 17

7:00 AM-5:00 PM MT

Registration Open

7:15-8:15 AM MT

Office Hours

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

Only the following organizations are participating in this timeslot:

- AAHRPP
- The Office of Research Integrity (ORI)

7:45-8:30 AM MT

N06: HSR/IO First Time Attendee Coffee

Descriptor: Join other first time HSR/IO attendees to connect before PRIMR26 begins! Coffee and tea only will be served.

8:45-10:15 AM MT

**Welcome Remarks (HSR/IO Co-Chairs & ED)
Opening Keynote Session**



10:15-10:45 AM MT

Break in Exhibit Hall

PRIMR26 HSR/IO Day One Session E Series, 10:45 AM-12:00 PM MT

E01: PLENARY: Risk Reimagined: Do IRBs Have a Responsibility to Consider Long-Term Harms?

Track(s): *Emerging Research Challenges and Breaking Issues, Research Involving Data and New Technologies, IRB Operations and Management, Navigating Ethical Challenges*

Descriptor: IRB risk assessment has traditionally focused on immediate risks to individual research attendees, while federal regulations generally exclude consideration of long-term societal harms. Yet modern research involving large-scale data aggregation, artificial intelligence, digital technologies, and secondary data use increasingly raises concerns about downstream impacts that may emerge years later and affect individuals, communities, or populations. This plenary will explore whether IRBs have an ethical responsibility to consider long-term harms beyond current regulatory requirements and whether existing oversight frameworks remain adequate for today's research environment. Through discussion of topics such as data reuse, algorithmic bias, stigmatization, and group harm, panelists will examine how institutions can thoughtfully address emerging risks while maintaining proportionality, transparency, and appropriate regulatory boundaries.

Learning Objectives:

- Distinguish between traditional regulatory risk assessments and long-term or downstream harms in modern research
- Examine ethical arguments regarding whether IRBs should consider risks beyond those explicitly addressed in current regulations
- Identify practical strategies for acknowledging emerging long-term risks within existing IRB review frameworks



E02: Two Pathways, One Mission: Navigating FDA Expanded Access for Investigational Drugs and Medical Devices

Track(s): *FDA Regulated Research, IRB Operations and Management*

Descriptor: FDA expanded access pathways provide important mechanisms for patients with serious or life-threatening conditions to access investigational drugs and medical devices outside of clinical trials, yet the regulatory requirements and review processes for each pathway differ in important ways. This session will provide a practical comparison of expanded access processes for drugs versus devices, including when each pathway may be appropriate, applicable FDA requirements, and distinctions between emergency and non-emergency use as well as single-patient and larger population requests. Attendees will also explore common IRB operational and compliance considerations, along with practical approaches and tools to support efficient and compliant review of expanded access submissions.

Learning Objectives:

- Compare FDA expanded access pathways and regulatory requirements for investigational drugs versus medical devices
- Distinguish between expanded access considerations for different patient populations and levels of urgency, including single-patient, larger population, emergency, and non-emergency use
- Identify key IRB operational and compliance considerations related to expanded access submissions, including review pathways, documentation, and oversight responsibilities



E03: From Best Practice to Standard Practice: Returning Summary Research Results to Participants

Track(s): *Pharma/Biotech Perspectives, Communication With the Public*

Descriptor: Returning summary research results is increasingly recognized as an important way to demonstrate respect, transparency, and accountability to research participants. Yet despite broad support for the practice, many organizations continue to face operational, cultural, and resource-related barriers to implementation. This interactive session will explore emerging frameworks developed by research institutions and organizations, including NIH, to support the routine return of aggregate study results to participants. Speakers will highlight key elements of successful implementation approaches, discuss current evidence and remaining challenges, and engage attendees in identifying practical solutions for making the return of summary results more consistent, accessible, and sustainable across research settings.

Learning Objectives:

- Describe emerging frameworks and institutional approaches for returning summary research results to participants
- Evaluate current evidence, implementation challenges, and opportunities for advancing the routine return of summary research results
- Apply practical strategies, tools, and communication approaches to share summary research results in ways that are timely, understandable, and meaningful to participants



E04: Where Does AI Belong in Research Oversight?

Track(s): Research Involving Data and New Technologies, Emerging Research Challenges and Breaking Issues, Navigating Ethical Challenges, Pharma/Biotech Perspectives, IRB Operations and Management

Descriptor: Artificial intelligence (AI) is increasingly being used to support clinical research administration and oversight activities, including participant recruitment, informed consent development, protocol review, adverse event monitoring, translation, scheduling, and data analysis. As these tools become more widely available, institutions and IRBs face important ethical, operational, and regulatory questions about their appropriate use. When should AI be used to support research administration and oversight activities, and where should human judgment remain central? How should organizations evaluate the reliability, transparency, and limitations of AI-generated outputs? Through practical examples and interactive case discussions, this session will explore current and emerging applications of AI in research administration and oversight operations while examining strategies and guardrails for responsible, ethical, and trustworthy implementation.

Learning Objectives:

- Identify current and emerging applications of AI in clinical research administration and oversight operations
- Evaluate ethical, operational, and regulatory considerations associated with the use of AI in research management and oversight activities
- Apply practical strategies and governance safeguards to support the responsible, transparent, and trustworthy use of AI in research environments



E05: The Influence of Identity and Experience on IRB Member Decision-Making

Track(s): Social, Behavioral, and Educational Research, IRB Operations and Management

Descriptor: IRBs are intentionally composed of individuals with diverse backgrounds, experiences, and perspectives, yet little is known about how these factors influence individual decision-making and committee determinations. This session will present findings from an exploratory study examining the role of personal identities, lived experiences, and cultural factors in IRB member decision-making. Using identity-mapping exercises and research case vignettes, the study explores how IRB members assess risks, benefits, and ethical considerations, as well as how their perceptions of their own identities align with observed decision-making patterns. Attendees will examine the implications of these findings for understanding variation in IRB decisions and consider how they can inform IRB member training, program evaluation, and efforts to strengthen the quality, consistency, and transparency of research oversight.

Learning Objectives:

- Examine how personal identities, experiences, and cultural factors may influence individual IRB member decision-making
- Evaluate research approaches for studying the factors that shape IRB deliberations and determinations
- Apply insights from this research to support IRB member training, quality improvement, and program evaluation efforts



E06: Research Misconduct, Questionable Research Practices, and Institutional Accountability

Track(s): Research Oversight Leaders and Institutional Officials, Shared Research Oversight Challenges, Navigating Ethical Challenges

Descriptor: Institutional Officials (IOs) play a critical role in promoting research integrity and overseeing research misconduct proceedings, yet responsibilities and boundaries among IOs, Research Integrity Officers (RIOs), Deciding Officials (DOs), and review committees are not always clearly understood. This session will examine the institutional leadership responsibilities associated with research misconduct processes under federal frameworks while also exploring the broader landscape of Questionable Research Practices (QRPs), including authorship disputes, inadequate data management, problematic publication practices, and emerging ethical considerations related to AI use in research. Attendees will gain practical strategies for distinguishing among research misconduct, research noncompliance, and QRPs, while strengthening institutional approaches to fostering a culture of research integrity and accountability.

Learning Objectives:

- Differentiate the roles and responsibilities of IOs, RIOs, DOs, and review committees in research misconduct proceedings
- Distinguish among research misconduct, research noncompliance, questionable research practices, and basic ethical considerations related to AI use in research
- Develop practical strategies for promoting a culture of research integrity and accountability within research institutions



E07: Developing the Next Generation of Leaders in Research Compliance

Track(s): Research Oversight Leaders and Institutional Officials, Career Development and Training, Shared Research Oversight Challenges

Descriptor: Strong leadership in research compliance is essential to supporting ethical, effective, and resilient research programs and enabling informed institutional oversight and decision-making. As the research environment becomes increasingly complex and highly regulated, institutions must take intentional steps to cultivate, mentor, and retain future leaders in research compliance. This session will explore practical strategies for building a sustainable leadership pipeline through mentorship, professional development, succession planning, cross-functional experience, and opportunities for emerging leaders to expand their institutional and strategic expertise. Speakers will discuss common leadership development gaps, approaches for preparing individuals for critical compliance leadership roles, and ways institutions can foster long-term organizational resilience and continuity within the research enterprise.

Learning Objectives:

- Describe strategies for developing and sustaining a leadership pipeline in research compliance
- Identify common competency and experience gaps among emerging leaders and approaches for addressing them through mentorship, professional development, and cross-functional experiences
- Apply succession planning and leadership continuity strategies to strengthen organizational resilience within the research enterprise



12:00-1:45 PM MT

Lunch - Kiosks open in Exhibit Hall

PRIMR26 HSR/IO Day One Networking Block, 12:45-1:45 PM MT

12:45-1:10 PM MT

2026 PRIM&R Conference Poster Presentation—Advancing Justice in Research: Evidence Based Strategies to Improve Representation in Participation

Join us to hear from one of this year's outstanding poster abstract authors about their important and timely work. During this timeslot, our poster author will present their poster and attendees will have the ability to comment and ask questions.



12:45 PM - 1:30 PM

Sponsored Session from WCG: Navigating Regulatory Change: Lessons and Leading Practices for Clinical Research Programs

1:20-1:45 PM MT

2026 PRIM&R Conference Poster Presentation—Next Gen Researchers: Cultivating Ethical Foundations for Future Scientists

Join us to hear from one of this year's outstanding poster abstract authors about their important and timely work. During this timeslot, our poster author will present their poster and attendees will have the ability to comment and ask questions.



1:20-1:45 PM MT

2026 PRIM&R Conference Poster Presentation—Oversight of Xenotransplantation Research by Institutional Review Boards and Institutional Biosafety Committees: A Conceptual Analysis

Join us to hear from one of this year's outstanding poster abstract authors about their important and timely work. During this timeslot, our poster author will present their poster and attendees will have the ability to comment and ask questions.



12:45-1:45 PM MT

Office Hours

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

Only the following organizations are participating in this timeslot:

- Department of Veterans Affairs (VA)
- The National Advisory Committee on Human Research Protections (NACHRP)
- Environmental Protection Agency (EPA)
- AAHRPP
- NIH Policy on Sharing Summary Level Study Results
- National Center for Advancing Translational Sciences (NCATS)
- The Office of Research Integrity (ORI)



12:45-1:45 PM MT

N08: Lunch & Learn: Lessons from the BRIDGES Study and the Future of Genomic Newborn Screening

Track(s):

Research Involving Data and New Technologies, Equity, Justice, and Protections in Research, Navigating Ethical, Challenges, Emerging Research Challenges and Breaking Issues

Descriptor: The BRIDGES Study (Building Evidence and Collaboration for GenOmics in Nationwide Newborn Screening) is the first coordinated multi-state genomic newborn screening initiative in the United States and offers important lessons for IRBs and HRPPs navigating the intersection of genomic research, public health, and emerging technologies. This lunchtime update session will provide an overview of the study's goals, progress, and early lessons learned, while exploring key considerations related to parental permission, privacy and future use of genomic data, return of results, equity and access, community engagement, and oversight of research embedded within public health systems. Attendees will gain insight into how existing human research protection frameworks can be applied to complex genomic research and the evolving challenges associated with large-scale newborn screening initiatives.



12:45-1:45 PM MT

N09: Lunch & Learn: Facilitation Skills for Effective Compliance Committees

Track(s): Career Development and Training, IRB Operations and Management

Descriptor: Ever feel like your committee meetings get hijacked by strong personalities or bogged down in endless reading of protocols no one's looked at before? Join us for an informal, interactive Lunch & Learn where we explore how effective facilitation can completely transform the oversight culture for your compliance committees. Together, we'll explore how to manage dominant voices, set constructive communication norms, and redesign agendas to prioritize ethical debate and real decision-making over routine reporting. Bring your real challenges and solutions to share in this networking session and leave with actionable, real-world techniques to diffuse conflict, keep members actively involved, and lead confident, high-impact meetings.



12:45-1:45 PM MT

N10: Lunch and Learn: Getting to Know Independent IRBs

Track(s): Single IRB, IRB Operations and Management

Descriptor: Independent IRBs play a growing role in research oversight, particularly for multi-site studies and industry-sponsored research, yet misconceptions about their processes, responsibilities, and relationship with institutions often remain. Join institutional and independent IRB leaders, members, and operations professionals for an interactive discussion on how independent IRBs function, how responsibilities are shared between reviewing IRBs and institutions, and practical strategies for building effective partnerships that support high-quality research oversight.



12:45-1:45 PM MT

N11: What It Means to Be an Institutional Official

Track(s): Research Oversight Leaders and Institutional Officials, Career Development and Training, Shared Research Oversight Challenges

Descriptor: The role of the Institutional Official (IO) has become increasingly complex as research organizations navigate evolving regulations, resource pressures, institutional risk, and changing expectations for research oversight and integrity. This session is designed for IOs across a range of institutional settings, from large academic medical centers to smaller health systems and research organizations where leaders may serve in multiple executive roles. Speakers will examine the core responsibilities that define the IO role regardless of institution size, including ethical leadership, regulatory accountability, institutional oversight, and stewardship of the research enterprise. The session will also explore practical strategies for leading through uncertainty, supporting organizational resilience, and navigating emerging challenges facing research institutions today.

Learning Objectives:

- Assess the core responsibilities and leadership functions of the Institutional Official role across diverse institutional settings
- Evaluate the IO's role in advancing ethical research conduct, institutional accountability, and research integrity
- Apply leadership frameworks for managing regulatory change, institutional risk, and organizational resilience



F01: PLENARY: The Promise and Reality of sIRB: Streamlining Review or Shifting the Work?**Track(s): IRB Operations and Management, Emerging Research Challenges and Breaking Issues, Single IRB**

Descriptor: The single IRB (sIRB) mandate was intended to streamline multisite research and reduce duplicative review, but many institutions have found that while regulatory burden may have decreased, operational complexity has increased. Study teams, HRPPs, IRB offices, and reviewing IRBs must navigate a growing network of reliance agreements, local context processes, technology platforms, and communication pathways that can shift rather than eliminate workload. This plenary will explore whether the current sIRB ecosystem is achieving its intended goals, where administrative burden continues to persist, and what opportunities exist to create more efficient, scalable, and investigator-friendly oversight models. Panelists will discuss emerging practices, technology-enabled solutions, and the potential for greater standardization while considering how institutions can balance efficiency, accountability, and participant protections in an increasingly interconnected research environment.

Learning Objectives:

- Examine how sIRB implementation has changed administrative responsibilities for study teams, IRB offices, and HRPPs
- Evaluate factors that contribute to operational burden and inefficiencies in the current sIRB landscape
- Discuss opportunities for standardization, technology, and process redesign to support more effective and sustainable oversight models

**F02: When Law Changes Risk: Emerging Privacy Challenges for Research Participants****Track(s): Emerging Research Challenges and Breaking Issues, IRB Operations and Management, Research Involving Data and New Technologies**

Descriptor: Privacy risk assessments are often based on the sensitivity of the data being collected, but what happens when the data remain the same while the legal, social, or technological environment changes around them? Information once considered low risk may take on new significance as laws evolve, data-sharing practices expand, re-identification techniques advance, and public expectations shift. Through real-world examples, this session will explore how changing contexts can alter assessments of privacy risk, confidentiality protections, informed consent, and participant welfare. Attendees will examine how IRBs, HRPPs, and researchers can evaluate emerging privacy challenges and determine when evolving circumstances warrant a fresh look at previously accepted assumptions about risk.

Learning Objectives:

- Describe how changes in legal, social, and technological environments can alter privacy and confidentiality risks in human subjects research
- Analyze scenarios in which evolving circumstances may change the potential harms associated with previously collected or newly collected research data
- Evaluate approaches for reassessing privacy protections, informed consent practices, and oversight strategies as participant risk landscapes evolve

**F03: When Participants Speak Up: Responding to Complaints in Phase I Clinical Research Units****Track(s): Pharma/Biotech Perspectives, IRB Operations and Management, QA/QI and Postapproval Monitoring**

Descriptor: Participant complaints can provide important insight into issues affecting participant welfare, informed consent, study conduct, and research site culture. In Phase I clinical research units, where participants may experience prolonged confinement, group living, and intensive interactions with research staff, complaints can serve as early indicators of concerns that extend beyond individual experiences. Using anonymized case examples, this session will explore how participant complaints can reveal both isolated issues and broader participant protection challenges. Speakers will discuss practical approaches for evaluating, documenting, investigating, and responding to complaints, as well as strategies for determining when concerns warrant IRB review, corrective action, or protocol-level changes.

Learning Objectives:

- Identify ethical, regulatory, and participant protection issues that may be revealed through participant complaints in Phase I research settings
- Differentiate individual grievances from broader concerns that may require institutional review, corrective action, or changes to study conduct
- Apply approaches for documenting, evaluating, and responding to participant complaints that support participant welfare, transparency, and regulatory compliance

**F04: When Innovation Meets Incentive: Conflict of Interest Challenges in AI, Startups, and Academic Entrepreneurship****Track(s): Emerging Research Challenges and Breaking Issues, IRB Operations and Management, Research Involving Data and New Technologies**

Descriptor: As academic investigators increasingly develop artificial intelligence (AI) tools, launch startups, hold equity in emerging companies, and partner with industry sponsors, traditional conflict of interest frameworks are being tested in new ways. This session explores how financial interests, intellectual property, leadership roles, and entrepreneurial activities can influence study design, recruitment, informed consent, and participant protections. Attendees will examine real-world scenarios and discuss how IRBs, HRPPs, and institutions can evaluate and manage conflicts while supporting innovation.

Learning Objectives:

- Describe emerging conflict of interest challenges associated with AI, academic entrepreneurship, startup ventures, and industry partnerships in human subjects research
- Analyze how financial interests, intellectual property, leadership roles, and other competing interests may affect study design, participant recruitment, informed consent, and participant protections
- Apply strategies for identifying, evaluating, and managing conflicts of interest while supporting innovation, maintaining transparency, and protecting the rights and welfare of research attendees

**F05: Beyond Traditional SBER: FDA Device Regulations for Wearables, Apps, and AI Tools****Track(s): Social, Behavioral, and Educational Research, IRB Operations and Management, FDA Regulated Research**

Descriptor: As wearable technologies, AI-enabled tools, digital health applications, and other emerging technologies become increasingly integrated into social, behavioral, and educational research (SBER), investigators, HRPPs, and IRBs are more frequently encountering FDA medical device regulations. This session will provide a practical overview of the investigational device exemption (IDE) requirements under 21 CFR 812, with a focus on identifying investigational devices in SBER studies, determining whether a study qualifies for an IDE exemption, and assessing device study risk as nonsignificant risk or significant risk. Through case-based discussions and real-world examples, speakers will examine common challenges in applying FDA requirements to SBER research, including institutional interpretations and review practices. Attendees will leave with tools and strategies for navigating device-related regulatory requirements within evolving SBER research environments.

Learning Objectives:

- Identify when technologies used in SBER research may be subject to FDA medical device regulations
- Apply IDE exemption criteria and device risk assessment principles to determine appropriate regulatory pathways for SBER studies
- Evaluate institutional policies, procedures, and review practices for compliance with FDA medical device requirements in SBER research



F06: PLENARY: From Headwinds to Horizons: Institutional Voices on What's Next for Federal Research Funding

Track(s): Research Oversight Leaders and Institutional Officials, Emerging Research Challenges and Breaking Issues, Navigating Ethical Challenges, Shared Research Oversight Challenges



Descriptor: Federal research funding is facing a period of significant uncertainty shaped by shifting national priorities, fiscal pressures, evolving expectations for accountability and impact, and changes in the federal research landscape. In this plenary, senior leaders from academic research institutions will examine what these developments mean for the future of the research enterprise and how institutions are adapting in response. Panelists will discuss emerging funding trends, institutional strategies for navigating risk and sustaining research programs, and the operational and ethical implications of changing support models, compliance expectations, infrastructure investments, and portfolio diversification efforts. Through candid institutional perspectives, this session will explore how research organizations are balancing uncertainty with long-term planning while continuing to advance rigorous, responsible, and impactful research.

Learning Objectives:

- Identify key trends and uncertainties shaping the federal research funding landscape
- Describe institutional strategies for responding to changing funding conditions and priorities
- Examine how evolving funding pressures are influencing institutional decision-making, research support models, and compliance approaches

F07: Ethics on Demand: Consultation Models Across Academia, Industry, and Healthcare

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



Descriptor: Many institutions have developed ethics and compliance consultation programs that extend beyond traditional IRB or IACUC review to support ethical decision-making throughout the research lifecycle. These programs create opportunities for researchers, institutional leaders, and compliance professionals to engage in proactive discussions about complex ethical, operational, and cultural issues related to research. This session will examine consultation models used across academia, industry, and healthcare settings and explore practical considerations for building, operationalizing, and sustaining these programs. Speakers will discuss how consultative services can support institutional risk management, research integrity, compliance education, and a stronger culture of ethical research.

Learning Objectives:

- Compare ethics and compliance consultation models across academic, industry, and healthcare settings
- Evaluate approaches to implementing, operating, and evaluating consultation programs within the research enterprise
- Identify ways consultation services can strengthen research integrity, institutional risk management, and compliance programs

3:15-3:45 PM MT

Break

PRIMR26 HSR/IO Day One Session G Series, 3:45-5:00 PM MT

G01: PLENARY: Unpacking Community Engagement: Opportunities for IRBs to get the Ethics of Research Right

Track(s): Navigating Ethical Challenges, Equity, Justice, and Protections in Research, Communication With the Public, Emerging Research Challenges and Breaking Issues



Descriptor: Community engagement is increasingly expected in research as funders, regulators, and research organizations place greater emphasis on trust, transparency, and meaningful community partnership. Yet significant questions remain about what meaningful engagement looks like, when it should influence IRB review, and whether IRBs are equipped—or even authorized—to evaluate it. As practices range from one-time consultations to long-term community partnerships, IRBs are often left navigating ethical and practical challenges without clear consensus or guidance. In this thought-leader panel, experts will examine the promises and pitfalls of community engagement, explore how engagement can illuminate concerns that traditional review processes may miss, and debate the appropriate role of IRBs in evaluating, encouraging, and responding to community input. Attendees will gain insight into emerging approaches, unresolved tensions, and opportunities to strengthen ethical research oversight while avoiding tokenistic or purely procedural approaches to engagement.

Learning Objectives:

- Differentiate models of community engagement and evaluate the distinct ethical considerations they raise for research oversight
- Analyze the opportunities, limitations, and potential risks of incorporating community perspectives into IRB review and decision-making
- Assess practical approaches for integrating community input into research oversight in ways that promote trust, respect, and meaningful engagement

G02: Artificial Intelligence and Software as a Medical Device: FDA Oversight, Ethical Considerations, and Emerging Best Practices

Track(s): FDA Regulated Research, IRB Operations and Management, Research Involving Data and New Technologies



Descriptor: Artificial intelligence (AI) and Software as a Medical Device (SaMD) are rapidly reshaping healthcare, research, and diagnostic innovation, yet many IRB members, investigators, and institutional leaders remain uncertain about how these technologies are defined, regulated, and responsibly implemented. This foundational session will introduce core concepts related to AI-driven medical software and SaMD, provide an overview of current FDA regulatory frameworks and oversight considerations, and examine key ethical and operational challenges including bias, transparency, validation, human oversight, and ongoing performance monitoring. Through practical discussion and real-world examples, attendees will gain a clearer understanding of how AI and SaMD fit within existing regulatory structures and how institutions can prepare for continued innovation in this evolving landscape.

Learning Objectives:

- Define key concepts related to AI and SaMD, including distinctions from traditional medical devices
- Describe current FDA regulatory pathways and oversight considerations for SaMD, including machine learning-enabled and adaptive technologies
- Identify ethical, operational, and institutional challenges associated with AI in healthcare and research, including bias, validation, data quality, transparency, and human oversight

G03: Justice Across Geography: Advancing Rural Inclusion in Research

Track(s): *Equity, Justice, and Protections in Research, Communication With the Public, Navigating Ethical Challenges*

Descriptor: Rural communities experience higher rates of chronic disease and significant health disparities, yet often face limited opportunities to participate in research due to geographic distance, workforce shortages, limited broadband access, transportation challenges, and lower availability of research infrastructure. As decentralized research, digital health technologies, and innovative recruitment approaches expand, institutions have new opportunities—and new responsibilities—to ensure rural populations are not left behind. Using the Belmont principle of justice as a framework, this session will examine the ethical implications of rural underrepresentation, explore barriers that limit access to research participation, and discuss practical strategies for designing studies, recruitment efforts, and oversight practices that promote more equitable access to research opportunities across diverse rural communities.

Learning Objectives:

- Explain why rural inclusion in research is an ethical imperative grounded in the Belmont principle of justice and the goal of equitable access to research opportunities
- Analyze geographic, structural, technological, and trust-related factors that contribute to the underrepresentation of rural populations in research
- Evaluate practical approaches institutions, investigators, and HRPPs can use to improve rural access, representation, and participation in research



G04: Opt-In or Required? Ethical and Operational Challenges in Future Use of De-Identified Data in Multi-Site Research

Track(s): *Research Involving Data and New Technologies, Navigating Ethical Challenges, Single IRB, Pharma/Biotech Perspectives, IRB Operations and Management, Emerging Research Challenges and Breaking Issues*

Descriptor: As expectations for data sharing and secondary research continue to expand, institutions and IRBs are increasingly faced with difficult questions about whether attendees in studies offering the prospect of direct benefit should be required to agree to the future storage and use of their de-identified research data for unrelated research. While NIH guidance generally supports allowing individuals to choose whether their data are stored and shared for future use, implementing this approach can create significant ethical, regulatory, and operational challenges, particularly in multi-site studies operating under a single IRB. Differences in institutional policies, consent language expectations, and interpretations of participant choice can complicate site activation, study coordination, and consistent application of data sharing practices across collaborating institutions. This session will examine the ethical tensions and practical realities surrounding opt-in, opt-out, and required approaches to future use of de-identified data, using real-world examples to explore how institutions and IRBs can navigate these increasingly common challenges.

Learning Objectives:

- Describe ethical and regulatory considerations related to the future storage and use of de-identified research data in studies offering the prospect of direct benefit
- Evaluate practical and operational challenges associated with opt-in, opt-out, and required approaches to future use of de-identified data in multi-site research
- Identify how differing institutional policies and interpretations can affect implementation of data sharing practices in studies overseen by a single IRB



G05: Beyond the Signature: Enhancing Respect for Persons Through AI-Assisted Informed Consent

Track(s): *Equity, Justice, and Protections in Research, Communication With the Public, Research Involving Data and New Technologies, Navigating Ethical Challenges*

Descriptor: Traditional consent forms—whether paper-based or electronic—often prioritize documentation over participant understanding. This session will explore how emerging AI tools, including Large Language Models (LLMs) and conversational agents, may support more participant-centered informed consent by translating complex research information into clearer, more personalized, and more accessible communication. Attendees will examine how AI-assisted approaches could enhance comprehension, appreciation, and engagement through plain language, multimedia, and real-time feedback, while also considering the ethical, regulatory, and oversight challenges these technologies introduce for HRPPs and IRBs.

Learning Objectives:

- Identify ethical and practical limitations of traditional informed consent approaches in supporting meaningful participant comprehension and autonomy
- Evaluate the potential role of LLMs and conversational AI tools in creating more personalized, accessible, and participant-centered consent processes
- Assess regulatory, ethical, and oversight considerations related to AI-assisted consent, including privacy, bias, transparency, and the continuing role of HRPPs/IRBs in human oversight



G06: What in the World Is Going On? Navigating Global Changes in Research Policy and Ethics

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

Descriptor: Research institutions operate in an increasingly interconnected global environment shaped by international collaborations, cross-border data sharing, evolving ethical standards, and changing regulatory expectations. This session will highlight significant recent and emerging international laws, policies, and guidance affecting the research enterprise, including updates to the Declaration of Helsinki, Declaration of Taipei, ICH guidance, EU regulations, and other global frameworks. Speakers will discuss practical approaches for monitoring international developments, assessing their relevance to institutional operations, and translating global policy changes into effective institutional strategies.

Learning Objectives:

- Identify key international laws, policies, and guidance shaping the research enterprise
- Describe practical approaches for monitoring and assessing global regulatory and policy developments
- Evaluate the operational, ethical, and compliance implications of emerging international requirements



G07: The Truth About Suspension: From Pause to Restart

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

Descriptor: Suspending research activities is one of the most serious corrective actions an institution can face and may have significant consequences for participants, investigators, institutional reputation, and the research enterprise. This session will explore how institutions respond when major compliance or oversight concerns require a research pause or suspension, including issues involving human subjects research, animal research, conflicts of interest, or financial compliance. Through case-based discussion, speakers will examine institutional decision-making, communication strategies, corrective and preventive action planning, and considerations for safely and compliantly resuming research activities while reducing future risk.

Learning Objectives:

- Assess circumstances that may warrant research suspension and the resulting institutional risks
- Discuss institutional decision-making and communication strategies during research pauses and suspensions
- Apply corrective and preventive action planning strategies to support compliant research recovery and reduce future risk



5:00-6:00 PM MT

Office Hours

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

Only the following organizations are participating in this timeslot:

- AAHRPP
- National Center for Advancing Translational Sciences (NCATS)
- The Office of Research Integrity (ORI)

5:00-6:15 PM MT

PRIMER26 Nov 17 Reception

5:15-6:00 PM MT

Sponsored Session from Advarra: Where AI Belongs: Defining Ethical Boundaries in Human Subjects Review

Descriptor: Artificial intelligence (AI) tools may support several institutional review board (IRB) activities, but not every function is appropriate for delegation. This session explores how IRBs can weigh potential efficiency gains against the need for human deliberation, define boundaries for responsible use, and consider the implications for trust in ethical oversight.

Learning Objectives:

- Examine the principles that can guide decisions about which IRB review functions AI may appropriately support.
- Analyze which ethical judgments should remain subject to human deliberation rather than computational delegation.
- Assess how responsible AI adoption may affect trust in ethical oversight.



2026 | PRIM&R ANNUAL CONFERENCE

PRIMR26 HSR/IO Day Two: Wednesday, November 18

7:00-10:30 AM MT

Registration Open

7:15-8:15 AM MT

Office Hours

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

Only the following organizations are participating in this timeslot:

- AAHRPP
- The Office of Research Integrity (ORI)

7:15-8:00 AM MT

N12: Info Session: Everything You Wanted to Know About the CIP Credential

Descriptor: During this session, a member of the CIP® Council will discuss the CIP® exam, eligibility guidelines, and exam preparation techniques. This session is geared toward individuals who are responsible for HRPP/IRB administrative functions and who will be eligible to take the certification exam in the next one to two years.

Learning Objectives:

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



7:15-8:00 AM MT

N13: 'Rise, Shine & Align: Building Your Research Oversight Network

Track(s): Career Development and Training

Descriptor: Powerful professional networks aren't built on business card swaps, they're built on shared experiences and opportunities for connection. Grab a cup of coffee in the Exhibit Hall and start your conference day connected with a structured, interactive session designed for the research oversight community. Through facilitated conversation and dynamic networking activities, you'll connect with colleagues from a variety of institutional settings, career stages, and areas of expertise to discuss the real challenges we face and explore the benefits of building meaningful peer relationships. Whether you're looking for a sounding board to advance your compliance programs, a mentor for career growth, or just great conversation, this session ensures you'll walk away with actionable ideas, new connections, and networking strategies to support both individual and organizational success.



7:15-8:00 AM MT

N14: Coffee and Connect: Exploring the Compliance Paradox

Track(s): Navigating Ethical Challenges

Descriptor: Research oversight professionals often navigate tensions between compliance and ethics, regulations and real-world practice, consistency and flexibility, and institutional responsibilities and individual judgment. Grab a cup of coffee in the Exhibit Hall and join colleagues for an informal conversation inspired by Compliance Paradox, a novel by research oversight leader Dr. Molly Klote, exploring the complexities and contradictions that shape human research protections. Dr. Klote will share insights from her experiences across federal oversight, healthcare, and research institutions, followed by a discussion of how these themes resonate with attendees' own work. Whether you have read the book or are simply interested in the realities of research oversight, you'll leave with new perspectives and meaningful connections.



8:15-10:00 AM MT

Welcome Remarks from Board of Director Chair Closing Keynote



10:00-10:30 AM MT

Break in the Exhibit Hall

PRIMR26 HSR/IO Day Two Session H Series, 10:30-11:45 AM MT

H01: PLENARY: Closing the Gaps: NIH's Fresh Look at Strengthening Certificates of Confidentiality Protections

Track(s): Equity, Justice, and Protections in Research, Communication With the Public, Emerging Research Challenges and Breaking Issues, Navigating Ethical Challenges

Descriptor: Certificates of Confidentiality (CoCs) are widely relied upon to protect sensitive research information, yet misunderstandings about their scope, applicability, and limitations can leave important gaps in participant protections. This plenary will examine the history, purpose, and practical application of CoCs, including how they differ from other privacy and confidentiality frameworks commonly used in research oversight. Panelists explore emerging considerations for strengthening CoC protections across the research lifecycle, including questions related to longitudinal studies, secondary data use, and activities occurring outside traditional funding periods. The session will highlight evolving policy considerations for both NIH-funded and non-NIH-funded research and discuss how stronger confidentiality protections may support participant trust and ethical research practices.

Learning Objectives:

- Explain the history, purpose, and applicability of CoCs and identify common misconceptions about their protections
- Differentiate CoC protections from other research privacy and confidentiality frameworks
- Analyze potential gaps in CoC protections across the research lifecycle, including longitudinal, and secondary use
- Evaluate emerging NIH policy considerations aimed at strengthening confidentiality protections and participant trust in research



H02: More than Skin Deep: When Studies of Cosmetics, Supplements, and Other Non-traditional Products Need an IND or IDE

Track(s): FDA Regulated Research, IRB Operations and Management, Pharma/Biotech Perspectives

Descriptor: What's in a claim? When determining whether research falls under FDA Investigational New Drug (IND) or Investigational Device Exemption (IDE) regulations, the answer is often: everything. Using FDA consumer updates, warning letters, and real-world experiences from the speakers, this engaging and practical session will explore how products marketed for seemingly non-medical purposes — including cosmetics, dietary supplements, wellness products, and other non-traditional test articles — may nevertheless be regulated as drugs or devices based on their intended use and claims. Through memorable case studies and interactive discussion, attendees will learn to recognize disease and structure/function claims, identify protocol elements that may trigger FDA oversight, and better assess when research involving non-traditional products may require IND or IDE considerations.

Learning Objectives:

- Apply FDA drug and device definitions to research involving non-traditional or “edge case” products, including cosmetics, supplements, and wellness products
- Identify study objectives, endpoints, claims, and protocol language that may trigger IND and/or IDE regulatory requirements
- Communicate FDA regulatory considerations to investigators and determine when consultation with FDA or institutional experts may be appropriate



H03: Local Context 2.0: The Most Misunderstood Concept in sIRB Review

Track(s): IRB Operations and Management, Single IRB

Descriptor: More than five years into the sIRB era, “local context” remains one of the most debated—and inconsistently applied—aspects of reliance review. What information truly matters? Who decides? When does local context become institutional preference? And how much is enough? Differences in how reviewing IRBs and relying institutions interpret and operationalize local context can lead to duplicate reviews, study delays, strained relationships, and uncertainty about roles and responsibilities.

Through interactive case studies and audience discussion, this session will explore where local context processes commonly break down, why these challenges persist, and how institutions are developing more effective approaches to information sharing, decision-making, and reliance governance. Attendees will leave with practical strategies for reducing friction, aligning expectations, and building local context processes that add value rather than administrative burden.

Learning Objectives:

- Define the purpose and key components of local context review in the sIRB environment
- Compare approaches to collecting, evaluating, and applying local context information across reviewing IRBs and relying institutions
- Apply strategies to improve communication, alignment, and reliance workflows between reviewing IRBs and relying institutions



H04: Navigating Complexity in SBE Research: Peer Perspectives and Networking

Track(s): Social, Behavioral, and Educational Research, IRB Operations and Management

Descriptor: Complex social, behavioral, and educational (SBE) research often presents unique ethical, regulatory, and operational challenges that do not have straightforward solutions. This facilitated networking session will bring together professionals from a variety of institutions to discuss three challenging SBE research scenarios: research with children in school settings, research involving reproductive rights organizations, and international research conducted with global collaborators. Through small-group discussions and peer exchange, attendees will share experiences, compare approaches to risk assessment and oversight, and explore how different organizations address similar challenges. The session is designed to foster meaningful connections, encourage the exchange of practical insights, and build a community of professionals navigating complex SBE research issues.

Learning Objectives:

- Exchange perspectives on ethical, regulatory, and operational challenges encountered in complex SBE research
- Discuss approaches used by different institutions to assess and minimize risks in diverse SBE research settings
- Build professional connections and identify opportunities for ongoing collaboration and knowledge sharing



H05: Signals in the Noise: Turning IRB/HRPP Pain Points into Early Warning Trends and Action

Track(s): Career Development and Training, IRB Operations and Management, QA/QI and Postapproval Monitoring

Descriptor: Routine oversight frustrations—such as low-quality submissions, unclear consent language, and inconsistent interpretations—can serve as early indicators of emerging regulatory and operational challenges. This session will present a leadership framework for Institutional Officials and oversight leaders to systematically identify, assess, and respond to these recurring pain points. Attendees will explore practical approaches for prioritizing issues, building cross-functional collaborations among HRPP/IRB, QA/QI, investigators, and community partners, and implementing measurable actions such as policy updates, workflow improvements, and targeted consultations. Attendees will leave with tools and strategies for developing an early warning system that strengthens review quality, trust, and overall program performance.

Learning Objectives:

- Apply a governance framework for identifying and evaluating recurring oversight pain points as indicators of emerging regulatory and operational trends
- Develop strategies for building cross-functional collaborations among oversight leaders, HRPP/IRB, QA/QI, investigators, and community partners to support timely and proportionate responses
- Identify key metrics, review processes, and implementation strategies for establishing and sustaining an early warning system that supports continuous program improvement



H06: Resilient Leadership: Leading Through Regulatory Change in Uncertain Times

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

Descriptor: Research institutions are navigating a period of rapid regulatory change, evolving oversight expectations, resource pressures, and growing operational complexity. Institutional leaders must respond to emerging challenges while maintaining ethical standards, regulatory compliance, research continuity, and organizational resilience. This session will examine key issues reshaping the research landscape, including changing FDA oversight approaches, indirect cost pressures, research security expectations, and evolving scientific and animal research models. Speakers will discuss practical leadership strategies for anticipating change, managing uncertainty, supporting teams during periods of disruption, and sustaining responsible and productive research programs in dynamic environments.

Learning Objectives:

- Identify emerging regulatory and policy trends affecting research oversight and institutional operations
- Evaluate leadership challenges arising from uncertainty, resource pressures, and evolving oversight expectations
- Discuss leadership and change-management strategies to sustain research integrity, productivity, and organizational resilience during periods of change



H07: PLENARY: From Research Resource to Commercial Asset: Rethinking Data Stewardship in the Age of AI

Track(s): Research Oversight Leaders and Institutional Officials, Research Involving Data and New Technologies, Navigating Ethical Challenges

Descriptor: Artificial intelligence is transforming the value of research data, creating new opportunities for discovery, innovation, and commercialization. As academic institutions, healthcare systems, and private companies increasingly leverage research data to develop AI-enabled tools and products, longstanding assumptions about consent, stewardship, ownership, benefit sharing, and participant expectations are being challenged. When research data become commercial assets, what obligations do institutions owe to the individuals whose data made those innovations possible? This session will examine the ethical, legal, and societal implications of AI-driven data use and explore how research institutions can balance innovation, public trust, and responsible stewardship in an evolving research landscape.

Learning Objectives:

- Examine how AI-driven commercialization is reshaping the use, value, and stewardship of research data
- Evaluate ethical challenges related to participant expectations, consent, ownership, benefit sharing, and trust when research data are used to develop commercial AI products
- Discuss emerging approaches for balancing innovation, collaboration, and responsible stewardship of research data in the age of AI



11:45 AM-1:30 PM MT

Lunch - Kiosks open in Exhibit Hall

PRIMR26 HSR/IO Day Two Networking Block, 12:30-1:30 PM MT

12:30-12:55 PM MT

2026 PRIM&R Conference Poster Presentation—Implementing Lean Six Sigma for Continuous Improvement in an IRB: A Case Study of the Continuing Review Process

Join us to hear from one of this year's outstanding poster abstract authors about their important and timely work. During this timeslot, our poster author will present their poster and attendees will have the ability to comment and ask questions.



1:05-1:30 PM MT

2026 PRIM&R Conference Poster Presentation—Invisible Insights: Bringing Hidden IVDs Back into Focus

Join us to hear from one of this year's outstanding poster abstract authors about their important and timely work. During this timeslot, our poster author will present their poster and attendees will have the ability to comment and ask questions.



12:30-1:30 PM MT

N15: Lunch & Learn: A Competency-Based Curriculum and Career Ladder for IRB Professionals

Track(s): Career Development and Training

Descriptor: Recruiting, developing, and retaining skilled IRB professionals remains a challenge for many HRPPs. This Lunch & Learn session will explore how competency-based education and structured career ladders can support workforce development from onboarding through advanced practice. Speakers will present a competency-based curriculum and career ladder model designed to support professional growth, skill development, and advancement within IRB and HRPP offices. Attendees will learn practical approaches for defining competencies, creating professional development pathways, evaluating progress, and supporting long-term career growth. The session will also explore how structured workforce development initiatives can promote staff engagement, consistency, succession planning, and organizational resilience while strengthening the overall quality of research oversight.



12:30-1:30 PM MT

Office Hours

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

Only the following organizations are participating in this timeslot:

- The National Advisory Committee on Human Research Protections (NACHRP)
- Environmental Protection Agency (EPA)
- NIH Policy on Sharing Summary Level Study Results
- National Center for Advancing Translational Sciences (NCATS)
- The Office of Research Integrity (ORI)
- OHRP



12:30-1:30 PM MT

N17: SBER Network Session - 10th Anniversary!



12:30-1:30 PM MT

N18: An Update from AAHRPP, Inc

Descriptor: Learn about the latest news and happenings from AAHRPP during this interactive session. AAHRPP staff members will update attendees on new additions to the accreditation application, annual reporting documentation, Standards and Elements, website resources and the online accreditation management system (OAMS). They will also discuss the educational opportunities and resources available to accredited and not-yet-accredited organizations alike.



Please visit the AAHRPP onsite booth during the conference and sign up to meet with AAHRPP staff members during their office hours throughout the conference.

I01: PLENARY: Against AI Exceptionalism: Rethinking HRPP and IRB Oversight of AI Research

Track(s): *Research Involving Data and New Technologies, Emerging Research Challenges and Breaking Issues, Navigating Ethical Challenges*

Descriptor: As artificial intelligence (AI) becomes increasingly embedded in healthcare and research, HRPPs and IRBs have devoted growing attention to how AI studies should be reviewed and overseen. In many cases, however, AI research has come to be treated as uniquely risky, resulting in heightened scrutiny, prolonged deliberation, and inconsistent oversight approaches that may not align with the actual level of risk involved. This thought-provoking plenary challenges the assumption that AI research is categorically more dangerous than other forms of human subjects research and examines how hype, fear, unfamiliarity, and misunderstanding can shape oversight practices. Through real-world examples and case discussions, speakers will explore how AI exceptionalism manifests within HRPP and IRB review processes, the unintended consequences it may create for researchers and institutions, and why existing ethical and regulatory frameworks are often more adaptable than assumed. Attendees will leave with practical strategies for approaching AI research oversight in ways that are proportionate, evidence-based, ethically grounded, and consistent with core human subjects protection principles.

Learning Objectives:

- Recognize how AI exceptionalism can emerge within HRPP and IRB review processes and identify factors that contribute to disproportionate oversight approaches
- Evaluate the ethical, operational, and institutional consequences of treating AI research as uniquely dangerous compared to other forms of human subjects research
- Apply practical strategies for reviewing AI research using existing ethical principles, regulatory frameworks, and proportionate risk-based oversight approaches

**I02: A Dialogue with the Department of Veteran Affairs (VA)**

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

Learning Objectives:

- Hear from VA ORD representatives about evolving initiatives, issues, and guidance
- Ask questions of VA ORD representatives
- Participate in an open discussion on topics raised at the session.

**I03: Rethinking Vulnerability in the Modern Research Environment**

Track(s): *Equity, Justice, and Protections in Research, Emerging Research Challenges and Breaking Issues, IRB Operations and Management, Social, Behavioral, and Educational Research, Navigating Ethical Challenges*

Descriptor: The concept of vulnerability has long guided human research protections, but evolving research methods, changing social contexts, and growing emphasis on inclusion are challenging traditional approaches to identifying and protecting vulnerable populations. This session will explore ethical and regulatory issues involving participants who may face increased risks in research due to underlying vulnerabilities. Through case examples and practical discussion, attendees will examine how IRBs and HRPPs can balance appropriate safeguards with equitable access to research opportunities while protecting the rights and welfare of research participants.

Learning Objectives:

- Describe emerging ethical and regulatory challenges associated with research involving vulnerable populations
- Analyze how factors such as social, economic, cognitive, and situational circumstances may influence vulnerability and research risk
- Apply strategies for balancing participant protections, equitable inclusion, and appropriate safeguards when reviewing research involving special populations

**I04: Participant Protection in Decentralized Clinical Trials: Navigating Burden, Equity, and Risk**

Track(s): *Pharma/Biotech Perspectives, Emerging Research Challenges and Breaking Issues, Research Involving Data and New Technologies, Equity, Justice, and Protections in Research, Navigating Ethical Challenges*

Descriptor: Decentralized clinical trials (DCTs) can expand access to research, but they may also shift responsibilities and burdens from research teams to participants. Differences in digital literacy, technology access, study-related responsibilities, and the collection of sensitive information can create challenges that affect participant equity, safety, and engagement. This session will examine key participant protection considerations in decentralized research, including barriers related to digital access, approaches to fair compensation for participant time and effort, and ethical management of sensitive questionnaires such as suicidality assessments. Speakers will discuss practical strategies and oversight considerations that can help IRBs and research teams design DCTs that are both accessible and responsive to participant needs.

Learning Objectives:

- Evaluate how digital literacy, technology access, and study design may affect participant equity and engagement in decentralized clinical trials
- Assess compensation approaches that appropriately recognize participant burden while supporting fairness and avoiding undue influence
- Apply ethical and operational strategies for collecting and responding to sensitive participant-reported information in decentralized research environments

**I05: Tackling Consent Process Challenges Through Quality Improvement (how can we make informed consent better for everyone?)**

Track(s): *QA/QI and Postapproval Monitoring, Research Involving Data and New Technologies, Social, Behavioral, and Educational Research, Career Development and Training*

Descriptor: Effective consent processes require ongoing evaluation and improvement as research methods, technologies, and regulatory expectations continue to evolve. This session will examine process improvement strategies for consent in biomedical research, social, behavioral, and educational research (SBER), and electronic consent environments. Speakers will explore common challenges related to consent materials, readability, documentation, privacy protection, technology use, attendee comprehension and information retention, while highlighting practical approaches for strengthening consent processes across diverse research settings. Through real-world examples and operational perspectives, attendees will gain strategies for promoting informed decision-making, supporting regulatory compliance, and enhancing human research protections.

Learning Objectives:

- Demonstrate, through interactive case studies, consent process considerations and human research protection challenges across biomedical research, SBER, and electronic consent environments
- Discuss the operational and other considerations involved in implementing and overseeing of electronic consent methodologies, and the factors that may make the use of electronic informed consent beneficial (or not) within the context of a specific study
- Identify process improvement strategies to enhance consent material's comprehension, human research protections across diverse research settings, and IRB and HRPP understanding of the realities of conducting research



I06: Data Without Borders: Data Sharing and Institutional Oversight

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

Descriptor: Data sharing plays a central role in advancing scientific discovery, transparency, and collaboration, but evolving legal, ethical, technical, and regulatory expectations have made responsible data stewardship increasingly complex. Institutions must navigate expanding requirements related to data management and sharing plans, public access mandates, cybersecurity, research security, and international collaborations while balancing commitments to open science with obligations to protect sensitive data, research attendees, intellectual property, and national security interests. This session will examine the growing intersection of data sharing, research security, and institutional oversight, with a focus on governance frameworks, operational challenges, compliance responsibilities, and practical strategies for managing institutional risk in an increasingly interconnected research environment.

Learning Objectives:

- Examine evolving federal requirements and expectations related to research data management, sharing, and public access
- Discuss legal, ethical, operational, cybersecurity, and research security considerations associated with data sharing and international collaborations
- Apply governance and oversight strategies to support responsible data stewardship and institutional risk management.



I07: From Metrics to Meaningful Change: Elevating Research Compliance Quality

Track(s): *Research Oversight Leaders and Institutional Officials, QA/QI and Postapproval Monitoring, Shared Research Oversight Challenges*

Descriptor: The monitoring of metrics is often considered the gold standard for measuring quality within a compliance program. Quantitative indicators such as volume, turnaround times, and throughput provide valuable insight into operational efficiency and can help identify bottlenecks or resource gaps. However, these measures alone offer only a partial view of program performance. A robust quality improvement program should systematically identify non-value-added tasks that consume resources without meaningfully enhancing research compliance, enabling their elimination and the reallocation of effort toward higher-impact priorities that support the ethical conduct of research. This session will explore a broader set of quality improvement measures that provide a more holistic view of the research compliance program.

Learning Objectives:

- Identify different ways to evaluate quality, consistency, and impact of compliance activities to promote ethical conduct of research
- Determine strategies to gather stakeholder feedback to reduce nonvalue added tasks and identify trends in compliance observations
- Apply data driven insights to drive change through continuous quality improvement



3:00-3:30 PM MT

Break in the Exhibit Hall

PRIMR26 HSR/IO Day Two Session J Series, 3:30-4:45 PM MT

J01: PLENARY: The End of Anonymity? Ethical Considerations for Patient Identification in Clinical Research

Track(s): *Navigating Ethical Challenges, Pharma/Biotech Perspectives, Research Involving Data and New, Technologies, Emerging Research Challenges and Breaking Issues, IRB Operations and Management*

Descriptor: Advances in data analytics, artificial intelligence, and computing power are challenging long-standing assumptions about anonymity in clinical research. As the ability to identify or re-identify individuals from datasets continues to grow, researchers, institutions, sponsors, and oversight bodies must confront difficult questions about privacy, consent, transparency, and trust. At the same time, identification capabilities may create new opportunities to improve research, support precision medicine, enhance participant engagement, and reconnect individuals with clinically relevant information. In this thought-leader panel, experts from academia and industry will examine the ethical implications of an increasingly identifiable research landscape and explore how the research community can responsibly balance potential benefits with risks to individuals and communities. Through real-world examples and emerging governance approaches, panelists will discuss what responsible use of patient identification capabilities may look like in the future of clinical research.

Learning Objectives:

- Analyze how advances in analytics and artificial intelligence are reshaping assumptions about anonymity, identifiability, and privacy in clinical research
- Evaluate ethical, governance, and trust considerations associated with the use of patient identification and re-identification capabilities
- Assess emerging approaches for balancing potential research and clinical benefits with risks to privacy, autonomy, and public trust



J02: Remote Evaluation of Capacity to Consent to Research

Track(s): *Equity, Justice, and Protections in Research, Social, Behavioral, and Educational Research, Navigating Ethical Challenges, Research Involving Data and New Technologies*

Descriptor: As remotely conducted research—including biobanks, registries, and online survey studies—continues to expand, institutions and oversight professionals must reconsider how consent capacity is evaluated when there is little or no direct interaction with prospective subjects. Traditional consent capacity assessments often rely heavily on cognitive testing approaches that may unintentionally exclude individuals or overlook important contextual factors. This session will explore the ethical goals and limitations of consent capacity assessment in remote research settings and discuss practical, participant-centered approaches to supporting informed consent and assent without face-to-face interaction.

Learning Objectives:

- Examine the ethical assumptions and unintended consequences associated with traditional consent capacity assessments
- Evaluate the goals and limitations of evaluating capacity to consent in remote research settings
- Identify practical approaches for supporting informed consent and assent in remotely conducted research without direct personal interaction



J03: Where Should AI Oversight Live? Comparing Governance Models for Human Research

Track(s): Navigating Ethical Challenges, Emerging Research Challenges and Breaking Issues, IRB Operations and Management, Research Involving Data and New Technologies



Descriptor: As artificial intelligence technologies become increasingly embedded in human subjects research, institutions are developing new approaches to evaluating AI-related risks, governance, and oversight. One emerging model relies on dedicated Artificial Intelligence Review Committees (AIRC) that conduct specialized reviews before IRB consideration, while another integrates AI expertise, review tools, and risk assessment directly into existing IRB processes. Using real-world examples and a point-counterpoint format, this session will compare the strengths, limitations, and implementation considerations associated with each approach. Speakers will examine how these models address issues such as reviewer expertise, consistency, efficiency, transparency, and coordination with exempt, expedited, and convened IRB review. Attendees will gain practical insights to help determine which oversight structure—or combination of structures—may be most appropriate for their institution.

Learning Objectives:

- Compare the structure, scope, and operational workflows of dedicated Artificial Intelligence Review Committee and IRB-integrated AI oversight models
- Evaluate the advantages, limitations, and implementation considerations associated with different approaches to AI oversight in human subjects research
- Apply AI review frameworks, tools, and governance strategies to strengthen oversight processes within their own institutions

J04: Whose Decision Is It? Navigating Conflict, Authority, and Local Context in the sIRB Era

Track(s): IRB Operations and Management, Single IRB



Descriptor: What happens when a reviewing IRB and a relying institution see the same study differently? In today's sIRB environment, disagreements can emerge over local context, consent language, recruitment approaches, risk determinations, participant protections, and institutional requirements. These conflicts often arise at critical moments and can create frustration, delays, and uncertainty about how to move forward. Through real-world case studies and audience discussion, this session will explore where disagreements most commonly occur, why they happen, and what effective organizations do to resolve them. Speakers will share practical approaches for communication, escalation, negotiation, and reliance governance that help preserve collaborative relationships while ensuring appropriate oversight and participant protections. Attendees will leave with strategies for navigating difficult conversations, aligning expectations, and managing conflict when consensus proves elusive.

Learning Objectives:

- Identify common sources of disagreement between reviewing IRBs and relying institutions in single IRB arrangements
- Evaluate approaches for resolving differences related to local context, consent requirements, risk determinations, and institutional policies
- Apply strategies for communication, escalation, and reliance governance that support effective conflict resolution and collaborative oversight

J05: Beyond Checklists: Empathic Oversight and Risk-Based Post-Approval Monitoring

Track(s): QA/QI and Postapproval Monitoring, Navigating Ethical Challenges



Descriptor: Post-approval monitoring is often viewed primarily as a compliance function, yet it also offers an opportunity to strengthen research quality, support study teams, and enhance protections for research participants. This session introduces the concept of "empathic oversight", an approach that integrates risk-based monitoring with an understanding of the operational and human factors that influence research conduct. Drawing on the ethical principles of the Belmont Report, ICH-GCP E6(R3), FDA Patient-Focused Drug Development initiatives, and emerging evidence on empathy in oversight and healthcare settings, speakers will explore how organizations can use post-approval monitoring to identify meaningful risks, foster continuous improvement, and promote a culture of accountability and trust.

Learning Objectives:

- Understand what empathic, risk-based oversight entails, and how one includes these principles in an institution's monitoring program(s) (in other words, "why this methodology?")
- Determine how to "make the case" for an official oversight program built on the principles of empathic and risk-based monitoring through an interactive case study
- Differentiate between types of oversight activities and understand how an empathic and risk-based model can be deployed in each
- Describe methods and approaches to build investigator trust in an institution's compliance oversight program

J06: Guidance, Notices, and More! Navigating Federal Policy Change

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



Descriptor: Research organizations must continually monitor and respond to proposed policy changes, agency notices, and new federal guidance that can affect operations, compliance, and strategic planning. This session will explore practical approaches for evaluating emerging federal developments, assessing institutional impact, engaging key stakeholders, and determining when public comment, strategic planning, or operational action is warranted. Using recent examples from across the research enterprise, speakers will provide frameworks and tools to support institutional readiness and effective policy response.

Learning Objectives:

- Differentiate among proposed policy changes, agency notices, and finalized federal guidance and assess their institutional significance
- Describe strategies for evaluating organizational impact, engaging stakeholders, and prioritizing institutional responses
- Apply practical frameworks for determining when public comment, strategic planning, or operational action is needed

J07: The Architecture of Trust: Leadership and Research Culture

Track(s): Research Oversight Leaders and Institutional Officials, Shared Research Oversight Challenges, Career Development and Training



Descriptor: Research culture shapes how decisions are made, how concerns are raised, and how institutions uphold ethical conduct, scientific integrity, and accountability. Leaders play a critical role in intentionally building environments that support responsible research and align with institutional values and mission. This session will explore how organizations can assess, define, and strengthen their research culture across diverse institutional settings. Through practical examples and case studies, speakers will discuss strategies for identifying cultural strengths and gaps, fostering trust and accountability, and implementing initiatives that promote a healthy and sustainable research environment.

Learning Objectives:

- Assess key elements of a healthy and effective research culture
- Evaluate approaches to measuring institutional research culture and identifying opportunities for improvement
- Apply leadership strategies to strengthen trust, accountability, and ethical research practices across the research enterprise