

Ampersand

PRIMER 2025 Conference Proceedings

2025 PRIM&R Annual Conference Proceedings

Public Responsibility in Medicine and Research (PRIM&R) proudly presents the proceedings from our 2025 Annual Conference, held November 17-20, 2025, in Baltimore, Maryland.

As a leading 501(c)(3) nonprofit organization founded in 1974, PRIM&R has dedicated five decades to ensuring the highest ethical standards in research through education, professional development, and community building within the research oversight enterprise.



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PRIM&R is pleased to present descriptions and original commentary about the highest-ranked sessions from the 2025 conference in Baltimore.

To frame this exceptional content, I want to reiterate PRIM&R's vision statement:

We envision a world in which all who contribute to and benefit from research embrace ethics, welfare, inclusion and trust as central to science and medicine.

You will see how these session speakers have addressed important nuances, such as:

- Who contributes to research and how?
- Who benefits from clinical trials – individually and as a member of larger communities?
- What are the key tenets of ethics and how are they measured?
- What strategies support the welfare of subjects, patient groups, investigators, and research professionals?
- Who has the opportunity to participate in research and enjoy the fruits of scientific advancement?
- What are the obstacles?
- How can we help the public, patients, research subjects, scientists, review professionals, and regulators trust each other and trust the infrastructure that advances our body of scientific knowledge?

Our community of experts – IRB and IACUC professionals, subjects and their advocates, researchers, laboratory animal experts, regulators, policy makers, community members, ethicists, and institutional leaders – have aligned themselves with this vision. Their generous sharing of expertise and strategies benefits the entire research ethics community.

In this edition of Ampersand, you will find the conference descriptions for the top ranked sessions in the following categories: Human Subject Research (HSR), Animal Care and Use (IACUC), Crossover (applies to both HSR and IACUC), and Institutional Officials (IO). The ranking for these sessions comes from the scores and comments from audience attendance. The first nineteen sessions in this Ampersand issue are accompanied by written comments from the presenters. The other sessions are represented by the descriptions found in the conference program. Where possible, a link is included that will lead to a recording of the conference presentation.

Please enjoy these conference offerings, and I know you join me in appreciating the breadth and depth of this shared knowledge.

Gianna McMillan, D. Bioethics, MFA
2026 PRIM&R Board Chair

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Top-Ranked Sessions | Human Subjects Research

(A04) Local Context Review: Why It's Essential and How to Do It Well

Session Description

A recent article by Morain et al. (2025) on local context review in the sIRB model highlights significant challenges. The multisite research experts surveyed disagreed on the goals of local context review, what information should be gathered and considered, and whether current processes achieve their intended purpose. This variation in interpretation and practice can lead to inefficiencies and frustration in the IRB review process. This interactive session will use case examples to examine the respective roles of reviewing IRBs and relying institutions in fulfilling local context review requirements. Speakers and attendees will explore strategies for navigating differing expectations and key areas of variation, including the primary goals of local context review, the information requested and provided, and the appropriateness of current processes.

Learning Objectives

- Explain the concept of local context and its significance in the sIRB review process
- Identify the implications of varying definitions and processes in local context review
- Identify opportunities for harmonization to improve the local context review process

Speakers

- Megan Kasimatis Singleton, JD, MBE, CIP
- Nichelle Cobb, PhD, CIP

Significance

As a recent paper (Morain et al 2025) underscores, identifying and communicating local context remains a barrier to single IRB (sIRB) review. One reason why this area continues to be a challenge is that the requirement to provide reviewing IRBs with local context information is implied by but not defined within federal regulations, which has led to variation in how sIRBs and relying institutions define and implement local context review. This session explored the concept of local context and its significance in the sIRB review process, the implications of varying definitions and processes in local context review, and opportunities for harmonization to improve the local context review process. Review of local context information about a relying institution ensures the sIRB conducts an appropriate review for that site not only in terms of ethical issues and compliance with federal regulations and federal and state laws but also in considering potential community sensitivities that are a product of their unique local histories.

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Regulatory basis of local context

The need for IRBs to collect local context information is based on the interpretation of the Common Rule [45 CFR 46.107(a)] and FDA regulations [21 CFR 56.107(a)], which require IRBs to be:

- sufficiently qualified through the experience and expertise of its members (professional competence) and the diversity of its members to be sensitive to such issues as “community attitudes”.
- “able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice.”

Additionally, the terms of the Department of Health and Human Services Federalwide Assurance (FWA) implies that local context must be taken into consideration by a reviewing IRB (i.e., an IRB that reviews for another organization) and states:

- Whenever the Institution relies upon an IRB operated by another institution or organization for review of research to which the FWA applies, the Institution must ensure that this arrangement is documented by a written agreement between the Institution and the other institution or organization operating the IRB that outlines their relationship and includes a commitment that the IRB will adhere to the requirements of the Institution's FWA [emphasis ours].

Research on local context

The presenters discussed a recent paper on local context review in the context of studies subject to sIRB review requirements (Morain et al, 2025), which found that experts agreed local context review should aim to protect local participants and ensure compliance with applicable laws and institutional policies.

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Although there was alignment on the key goals of local context review, several concerns were identified related to current processes for local context review, including:

- uncertainty about which specific characteristics should be considered;
- a lack of standardized tools or processes for identifying relevant information;
- uncertainty about who should review information (e.g., IRB staff versus IRB members); and
- that staffing at many IRBs was insufficient to facilitate adequate review.

SMART IRB proposed definition of local considerations (aka local context)

Similar to the information presented in the Morain, et al article, a SMART IRB working group produced recommendations that emphasized the importance of adopting a shared understanding of what local context review is and what goals it aims to achieve. A key recommendation was for IRBs and organizations to adopt the following common definition of local context:

A *local consideration [local context]* is an aspect about the Relying Institution which could affect the reviewing IRB's determinations, including the criteria for IRB approval. Local considerations may include:

- State and local laws or Relying Institution policies relevant to the study or subject population.
- Customs, beliefs, values, or practices of a distinct subject population(s) that a Relying Institution could expect to be enrolled or included (such as records or biospecimens used for the research) in a study and that may have an impact on IRB review.
- Variations in how a study will be implemented across sites, including differences in standard of care (i.e., routine care).

The concepts of *customs, beliefs, values, and practices* cover a range of considerations that could be relevant to research, such as:

- Expectations around decision-making – whether it is done as a family, a community, or individually
- Whether oral is emphasized over written communication, which can affect how information is conveyed and understood
- The level of comfort with documents being signed, especially those that appear to be official
- Prohibitions on the use of certain technologies, which may limit transportation modes or use of any devices used in a study either as the focus of the research or to support participation in the research
 - Forms of contraception permitted by a belief system, which may affect eligibility requirements for a study or the description of birth control within a consent document
 - Use of health insurance, which can influence informed consent language

Local context process variation

The presenters noted that an additional challenge related to local context review is organizational variability in how local context review is implemented. Areas of variation include:

- Whether the reviewing IRB collects the information
- What information is collected
- When information is obtained
- How information is assessed
- Whose verifies or provides the information
- If the information is tailored to the study
- Method of communicating to the reviewing IRB

These variations matter because they can affect the accuracy and quality of IRB review, including assessment of:

- Recruitment procedures
- Approaches to informed consent and assent processes and language
- Risks
- Additional safeguards
- Privacy and confidentiality

The presenters polled session attendees to get a sense of variation in approaches to local context.

- When asked who performs local context review at their organizations, the most common response (42%) was that reliance staff conduct the review, followed by a combination of people (34%), other IRB staff (27%), researchers providing information to the reviewing IRB (9%), and the IRB chair (6%).
- When asked whether who is involved in local context review varies by type of study or what the study procedures are, 66% of attendees responded *no*, 34% *yes*, and 16% were uncertain.

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- When asked how confident they are that their organizations have a robust process to identify local context issues that should be communicated to the reviewing IRB, most attendees were somewhat or very confident (64%), some were not at all confident (28%), and a minority indicated they did not have a process (13%).

Enhancing Local Context Review: The JHM IRB Experience

As an example of how to grapple with who should perform local context review, presenters shared preliminary experience from the Johns Hopkins Medicine (JHM) HRPP to expand their local context review processes to include additional expertise, where applicable. While the JHM has a robust process for local context review that incorporates members of the reliance team, individuals with regulatory expertise and local consent form specialists, clinical expertise or other relevant community expertise has not yet been systematically incorporated in the process for initial local context review and may be important to help identify relevant local considerations. Because every application relying on an external IRB does not require additional local expertise, the JHM HRPP sought to develop a system to determine when such expertise should be included, beginning with clinical expertise. A working group developed a list of “triggers” (e.g. study factors) that might suggest additional review is needed.

The preliminary list of triggers identified to triage local context applications for additional expert review was shared and included:

- An assessment/comparison of standard(s) of care/usual care practices
- A sham arm
- Randomization
- Placebo administration
- Use of deception
- Emergency Research with a Waiver of Consent/Exception from Informed Consent (EFIC)
- Research involving particular risk areas (e.g. medical errors)
- Studies raising specific ethical or local community concerns

Results from piloting this triage process will be disseminated when available. Types of studies requiring additional expertise may vary by organization based on the organization’s research portfolio. Each organization might consider identifying key local considerations and how to flag those as part of a local context review process as well as assess how and when to incorporate additional expertise into their own local context review processes.

Discussion Case: A Comparative Effectiveness Study of the Use of Continuous Glucose Monitors for Hospitalized Patients

This case was used as an example to identify and discuss potential local context considerations during the session. We encourage readers to use their case to evaluate local context processes and whether current processes may be enhanced.

CASE DETAILS:

A researcher submits a multisite comparative effectiveness study for local context review. The study involves a comparison of two continuous glucose monitors (CGMs) for hospitalized patients, which are increasingly used to decrease fingerstick blood glucose testing. Little data are available about which glucose monitor to choose for hospitalized patients. Randomization will occur at the site level and sites randomized to utilize one of two CGMs commonly used for glucose monitoring in hospitalized patients.

The study is proposed to be conducted under a waiver of consent.

Potential local considerations/questions:

- Are both CGMs standardly used as part of routine care at the hospital? If not, is the introduction of any new CGMs “minimal risk” to the local population?
- Are there factors that typically suggest use of one GGM over the other at the site and will those be taken into consideration in the randomization plan?
- Are there any operational barriers to launching the study?

Potential local expertise needed for local context review:

- Clinical expertise to confirm whether CGMs are standard of care at the site
- Clinical expertise to evaluate whether assigned use of CGM versus finger stick could represent more than minimal risk
- Hospital operations expertise to assess feasibility/ability to operationalize the trial as planned

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Conclusion

This presentation highlights opportunities for improvement and standardization in local context review processes including who is engaged in the local context review process, what is considered as part of that review and how the outcome of that review is communicated from relying organizations to reviewing IRBs.

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B01: Through the Looking Glass: How Research Participants and IRBs See Ethics in HIV and SUD Studies

Session Description

IRBs rely on principles, regulations, and judgment to navigate ethical dilemmas, but these frameworks can overlook participants' lived experiences—especially those outside societal norms. Emerging digital health tools and restrictions on “vulnerable” participants may raise privacy and autonomy concerns IRBs don't always anticipate. This panel will explore shifting from a paternalistic model to one that respects participants as moral agents with valuable ethical insights. Through interactive discussions, attendees will learn how incorporating participant perspectives can strengthen ethical oversight, protections, and trust in research.

Learning Objectives

- Compare ethical concerns of IRB professionals and research participants in HIV and SUD studies
- Recognize how participants use personal moral reasoning to navigate research risks and benefits
- Explore strategies to incorporate participant perspectives into IRB reviews to enhance protections and trust

Speakers

- Brenda Curtis, PhD, MsPH

Significance

This topic holds critical importance for the research ethics community because it addresses a fundamental gap between institutional protection frameworks and the lived experiences of research participants. Institutional Review Boards have traditionally operated within rule-based, principle-driven systems focused on procedural compliance. In contrast, participants in HIV and substance use disorder (SUD) research often navigate ethical decision-making through contextual, relational, and socially embedded moral reasoning. This divergence carries significant implications for the effectiveness of human subjects protections.

Understanding participant perspectives is especially crucial in HIV and SUD research, where individuals face layered vulnerabilities including stigma, criminalization, structural inequality, and histories of research exploitation. When IRB assessments of risk and benefit diverge from how participants themselves conceptualize ethical concerns, several problems emerge: informed consent may emphasize risks participants find less salient while overlooking those they experience as most pressing; protective measures may unintentionally undermine dignity; recruitment and retention may suffer when procedures feel ethically misaligned with community norms; and the principle of respect for persons risks becoming procedural rather than substantive.

The presentation's emphasis on shifting from a paternalistic model to one that recognizes participants as moral agents reflects an essential evolution in research ethics. As digital health technologies, precision medicine, and community-engaged research expand, traditional oversight models face growing limitations. Incorporating participant moral reasoning into IRB deliberations can strengthen both ethical integrity and scientific rigor by aligning protections with participants' lived concerns, building authentic trust, reducing participation barriers, and fostering research partnerships rather than one-directional protection. In an era marked by emerging surveillance technologies and renewed restrictions on research with “vulnerable” populations, this shift toward ethical partnership is not optional—it is necessary.

Content

The interactive learning lab *Through the Looking Glass: How Research Participants and IRBs See Ethics in HIV and SUD Studies* provided a structured, case-based exploration of the disconnect between institutional research ethics frameworks and the moral reasoning employed by research participants. The session was designed as an interactive learning laboratory rather than a traditional lecture and was structured around two detailed case studies drawn from published research on participant perspectives. Mentimeter polling was used throughout to engage attendees in real-time reflection and to surface differences between IRB instincts and participant perspectives.

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Framing: Why Revisit Participant Perspectives Now?

The session opened by establishing the urgency of revisiting participant perspectives: “For decades, IRBs have protected participants through rules and risk categories. But studies with people who use drugs, or those living with HIV, show that participants also practice their own ethical reasoning—sometimes at odds with ours.” This framing positioned the session as an effort to expand and enrich existing IRB practices.

An opening Mentimeter warm-up asked, “What word or phrase comes to mind when you think of ‘research ethics’?” As responses populated in word-cloud format, facilitators narrated emerging patterns, noting the prominence of terms such as consent, protection, and risk, with comparatively fewer references to trust or partnership. This observation served as a transition into examining participant perspectives more closely.

The framing concluded with a visual contrast:

- IRB Lens: “Respect for persons means obtaining informed consent.”
- Participant Lens (Fisher, 2009): “Respect means not making me a spectacle.”

The session emphasized that IRB logic is often rooted in rules and principles, whereas participant reasoning is grounded in context and relationship. Attendees were asked to consider: “If both are ‘ethical,’ whose definition should guide our review?”

Case 1: Street Recruitment & Stigma

The first case drew from Oransky, Fisher, Mahadevan, and Singer’s (2009) study on recruitment of street drug users in nonintervention HIV risk research. The scenario described a community health worker approaching individuals in a city park, offering \$40, an HIV test, and a short survey, while wearing a badge identifying the research program.

Attendees were invited to consider whether their IRB would approve this method and to reflect on their initial concerns. Poll #1 asked: “What feels most ethically risky in this scenario?” with options focusing on payment, public setting, recruiter approach, or manageability through protocol safeguards. Responses revealed common IRB focal points such as coercion, privacy, and procedural adequacy.

Participant quotations from the study were then presented:

- “If somebody approached me like that, I’d be scared...might be an undercover cop.”
- “What if someone sees me talking to her—they’ll think I’m using again.”
- “I’d do it if she was respectful, explained it private-like.”

Discussion highlighted that participants conceptualized risk in social and relational terms rather than procedural ones. While IRBs may focus on consent documentation and payment thresholds, participants expressed concern about surveillance, stigma, and reputational harm. The badge intended as transparency could increase visibility and perceived risk.

The ethical insight emphasized the distinction between procedural safeguards and contextual dignity—who approaches, where, and how. The practical takeaway was to integrate participant or community advisors to vet recruitment sites and approaches, shifting from abstract risk assessment to context-informed ethical review.

Case 2: Digital Health & Data Privacy

The second case extended the discussion into digital research contexts. Drawing from Rendina and Mustanski (2018), the scenario described a relapse-prevention app collecting GPS and motion data alongside daily mood and craving surveys, with data encrypted and stored on secure servers.

Attendees were asked whether this constituted minimal risk and whether GPS tracking should be considered sensitive data. Polling revealed variation in how IRBs might classify such data. Facilitators probed assumptions underlying minimal-risk determinations and invited attendees to reflect on what would build participant trust in digital studies

Participant quotations revealed concerns centered on transparency and control:

- “I trust researchers more than app companies, but I still want to know exactly what data they collect.”

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- “It’s not that I don’t want to help—I just don’t like the idea of them knowing where I go all the time.”
- “If it’s anonymous and only for research, that’s fine—but I don’t want my info sold or sent anywhere else.”

The discussion underscored that participants equate ethics with control and visibility, not solely with technical security. The session emphasized that ethical protection does not necessarily equal perceived respect. Proposed strategies included visualizing data flows within consent materials and offering pause or opt-out controls to support ongoing agency.

Group Synthesis: How Ethics Frameworks Must Evolve

The synthesis segment shifted from analysis to application. Attendees reflected on the prompt: “What would ethical partnership look like in your IRB or research practice?”

Small-group discussions generated concrete suggestions, such as collaboratively revising consent language, incorporating community advisors into review processes, and reframing vulnerability as capability rather than deficit. Large-group sharing organized takeaways under three themes:

- Transparency: making risk and data practices visible
- Reciprocity: balancing participant contribution and researcher responsibility
- Agency: treating participants as collaborators in ethics

The synthesis reinforced that participants are not seeking less protection but partnership in defining what protection means.

Wrap-Up Poll & Takeaways

A final Mentimeter poll asked which lesson best captures how IRBs can integrate participant perspectives: moving from compliance to collaboration, redefining vulnerability as capability, building trust through transparency, or treating participants as co-interpreters of risk. The session concluded by reinforcing the central message:

“When we look through the participant’s eyes, ethics shifts from protection to partnership.”

References

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B02: Navigating the New Frontier: IRB Challenges with Complex Innovative Trial Designs

Session Description

This session will introduce why the FDA is encouraging industry to move toward complex innovative design protocols and what IRBs should know about these types of trials. Discussed will be some history of why these are becoming more frequent now and some background as to why the Bayesian statistics framework offers advantages but also some challenges. Cases will be presented to highlight areas that IRBs should consider when reviewing these types of protocols.

Learning Objectives

- Define Complex Innovative Designs (CIDs) and identify common types, such as adaptive trials and master protocols, that may be submitted for IRB review
- Articulate the primary advantages and disadvantages of CIDs from a human research protection perspective
- Analyze the unique and heightened ethical challenges that CIDs present to core IRB principles, including informed consent, benefit-risk assessment, and justice

Speakers

- Molly Klote, MD
- Kelly FitzGerald, PhD, CIP

Significance

Complex Innovative Trial Designs (CIDs) represent a significant and rapidly expanding shift in clinical research. Advances in genomics, precision medicine, data analytics, and computing power have enabled trial designs that move beyond traditional fixed randomized controlled trials (RCTs) toward adaptive, master protocol-based, and learning-oriented approaches. Regulatory agencies, including the U.S. Food and Drug Administration (FDA), have explicitly encouraged the exploration and use of such designs, particularly in oncology and rare diseases, where conventional RCTs may be infeasible, inefficient, or ethically challenging.

As the use of CIDs grows, Institutional Review Boards (IRBs) and research oversight bodies face new and heightened responsibilities. While the ethical principles underlying human subjects research, respect for persons, beneficence, and justice, remain unchanged, the context in which they are applied has become more complex. Adaptive modifications, shared control arms, Bayesian statistical methods, and platform trial structures pose challenges for informed consent, ongoing benefit-risk assessment, equitable subject selection, and mid-trial oversight. These challenges require IRBs to move beyond static protocol review toward oversight of pre-specified processes for change.

This session was important to the research community because it addressed a critical gap between evolving trial methodologies and traditional IRB review frameworks. By clarifying what CIDs are and what they are not, the session demystified these designs and emphasized that innovation in trial design does not diminish ethical rigor but requires more deliberate and informed oversight. The session equipped IRB professionals, investigators, and research administrators with practical tools and guiding questions to evaluate CIDs with confidence, ensuring robust participant protections while supporting scientifically and ethically responsible innovation in clinical research.

Content

This session, *Navigating the New Frontier: IRB Challenges with Complex Innovative Trial Designs*, provided an in-depth examination of Complex Innovative Trial Designs (CIDs) and their implications for research oversight. The presentation was designed for a mixed audience of IRB professionals, investigators, and research administrators and focused on bridging the gap between methodological innovation and ethical review. The session focused primarily on FDA-regulated clinical trials, with regulatory oversight grounded in 21 CFR Parts 50 and 56, while acknowledging that many studies are also subject to the Common Rule.

The session opened by framing the need to discuss CIDs and emphasizing that while traditional randomized controlled trials (RCTs) remain the foundation of clinical research, they are evolving to meet the demands of modern medicine. Advances in precision medicine, rare disease research, and data science have driven the development of more flexible trial designs that can learn and adapt over time.

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Importantly, the presenters underscored that RCTs are not being replaced but rather extended and modernized through innovative design approaches.

The presentation then defined CIDs and described common examples, including basket trials, platform trials, adaptive designs, seamless phase 2/3 trials, and designs that incorporate real-world data and Bayesian statistical methods. Particular attention was given to platform trials, illustrated with a visual example showing how multiple investigational treatments can be evaluated simultaneously under a single master protocol, with arms entering and exiting over time. This example highlighted both the efficiency of such designs and the increased complexity they pose for IRB oversight.

Regulatory momentum supporting CIDs was discussed, including the 2017 passage of PDUFA VI and the FDA's 2018 launch of the Complex Innovative Trial Designs Pilot Program. The session also addressed the FDA's 2020 guidance encouraging early collaboration and simulation-based validation of innovative designs. Bayesian approaches were presented as key tools in many CIDs, emphasizing probabilistic reasoning and continuous learning rather than relying on binary statistical significance thresholds.

The advantages and disadvantages of CIDs were examined from a human research protection perspective. Advantages included increased efficiency, reduced exposure to ineffective treatments, the ability to stop trials early for futility or success, and improved alignment with a learning healthcare system. Disadvantages included increased operational complexity, reliance on advanced statistical expertise, data management challenges, and heightened demands on communication and oversight.

A central theme of the session was that, despite their novelty, CIDs share the ethical and scientific foundations of traditional RCTs. Randomization, informed consent, safety monitoring, and pre-specified analysis plans remain core requirements. What distinguishes CIDs is the inclusion of pre-planned adaptations and the need for IRBs to oversee a process of change rather than a static protocol.

Specific IRB considerations for reviewing CIDs, including scientific validity, adequacy of safety monitoring and stopping rules, research site qualifications, and the availability of appropriate expertise to review complex designs, were presented. Key focus areas for IRBs were discussed in detail: informed consent, continuous benefit-risk assessment, fair subject selection and equity, data privacy and integrity, and oversight of mid-trial adaptations.

Informed consent was identified as a particularly challenging area, given the need to communicate uncertainty and potential trial modifications to participants in clear, understandable language. The session emphasized that while re-consent and protocol amendments are not new to IRBs, CIDs differ in that these changes are anticipated and pre-specified. This shift allows IRBs to review adaptation frameworks up front, promoting transparency and predictability in participant communication.

The session also examined emerging applications of CIDs beyond traditional drug and device trials, including behavioral health research. Adaptive and platform-style approaches were presented as promising tools for evaluating psychosocial interventions, with acknowledgment of challenges in outcome measurement and infrastructure.

The final portion of the session shifted to case studies, highlighting real-world IRB challenges in reviewing complex adaptive and master protocol trials. Audience engagement was strong throughout, with active participation in the discussion. Attendees asked thoughtful questions about IRB readiness, consent practices, regulatory expectations, and the ethical implications of adaptive randomization and platform trials, underscoring strong interest and practical relevance.

Overall, the presenters cautioned that, despite their promise, complex innovative trial designs are resource-intensive and operationally demanding, requiring substantial time, expertise, and infrastructure to review and oversee effectively. Not all IRBs may currently have the capacity to support these trials without additional training, access to specialized expertise, or institutional investment, underscoring the importance of thoughtful feasibility assessment before approval.

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B04: Building a Positive Post-Approval Program—Even with Limited Resources

Session Description

Faced with ongoing resource constraints, many HRPPs find it challenging to develop or enhance post-approval monitoring (PAM) programs. But it's possible! In this session, HRPP staff from four institutions at different stages of implementing PAM programs will share their experiences and provide practical guidance for others navigating similar challenges.

Learning Objectives

- Understand and list the benefits of a collaborative, relationship-based PAM program
- Identify, prioritize, and document where and how to start
- Describe strategies to build and/or maintain a PAM program with limited resources

Speakers

- Jessica Orak, BA
- Jennifer Ensley Gorshe, CIP, CHRC
- Regan Pulaski, BS, CCRP

Significance

Post Approval Monitoring (PAM) program is a vital component of an effective Human Research Protection Program (HRPP). With increasing resource constraints and growing protocol complexity, institutions need oversight models that support consistent regulatory compliance without overburdening investigators or staff. A constructive PAM framework helps ensure that studies continue to align with approved procedures, ethical standards, and participant protections.

By emphasizing collaboration, transparency, and education, a positive PAM approach reduces anxiety around monitoring, promotes early identification of issues, and encourages investigators to engage proactively with the HRPP. This shift from a punitive model to a supportive one strengthens relationships, enhances communication, and fosters a culture where compliance is viewed as a shared responsibility.

For programs with limited staffing or infrastructure, relationship-based strategies offer a scalable way to prioritize risk, streamline workflows, and focus monitoring efforts where they provide the greatest benefit. Ultimately, this topic is significant because it addresses a widespread operational challenge and presents practical, adaptable methods that can improve oversight quality, institutional resilience, and overall participant safety.

Content

The overall goal of the compliance mechanism is to bring support to investigators by reviewing best practices, answering questions, and ensuring study success! Compliance and process monitoring activities frequently induce a sense of anxiety and unease. Research compliance often consists of retrospective corrective actions. This presentation encourages a prospective, positive and collaborative compliance program – perfect for small organizations, programs with limited resources, or a fresh start to bolster an existing program! Building a positive PAM program requires intentional planning, relationship-centered strategies, and a practical understanding of institutional constraints.

Audit Selection Process

This first section gave a high-level view of how audits might be selected. Ideally an assessment of Institutional Risk Factors would be conducted by gathering input from key stakeholders at the organization and to stratify areas of concern. Prioritized areas that were discussed included: studies with high enrollment, investigator-initiated studies/sponsor-investigators, federally funded studies, studies with a drug or device, and an assessment of any newly implemented processes. An annual audit plan, consisting of both on-site study reviews and programmatic process assessments, is created based on these key areas of risk and concern.

Standard Review Format

Once an audit area has been identified, a standard process is typically followed for each audit as it comes up for review in the

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annual audit plan. Development of compliance processes that are simple, repeatable and transparent promotes streamlined and consistent oversight of research. Tools do not have to be elaborate.

In fact, simpler systems can reduce administrative burden and support consistent monitoring.

The key steps reviewed include:

- Audit Announcement Notifications: Include meetings through each step of the audit review
- Audit Program Structure and Preparation: Identify key controls to test and verify
- Data Assessment and Site-Visit: Execute test work through detailed record review
- Evaluate Potential Findings: Discuss corrective and preventive action plans
- Report Writing: Educate team on controls and self-assessments
- Management Action Plan and Closeout Meeting: Confirm remediation timelines

Case Series Scenario 1

The networking aspects of audience participation in this session were encouraged through various Case Scenarios. The first case discussion revolved around building a post-approval program, especially when a small research center expands to include additional sites with varied portfolios. There was a discussion amongst presenters and attendees in the room as to how best to roll out a post-approval monitoring program under these circumstances.

Challenges reviewed included the lack of standardization between sites, organizational resistance, incomplete infrastructure, and resource constraints. Dialogue continued at each table via small group discussions addressing potential plans, developments, strategies and structures to ensure positive and collaborative implementation of a PAM program.

Pam Stafford - University of Kentucky

In research compliance, a primary concern for monitoring audit reviews is getting eyes on the research prior to study completion. The presenters recognized Pam Stafford's concept for prospective Wellness Checks, presented at PRIM&R 2022.

Wellness Check Positive Impacts

Presenters shared benefits of a Wellness Check process, such as:

- Pro-active Review Breathes Positivity
- Effective Monitoring with Limited Resources
- Facilitate Cleaner Annual Continuing Review Process
- Premiere Virtual Review
- Scalable Implementation

The Wellness Check model pairs a remote review with early assistance to investigators. This collaboration fosters positive and collaborative relationships with investigators, enabling the identification and resolution of concerns prior to the first continuing review. So, no matter who you are or where you are from, Wellness Checks are doable for you – however you wish to scale its implementation!

Wellness Checklist Implementation

The rollout of the Wellness Check can be adjusted using a risk-based approach. Depending on your institution, a scalable approach to your specific risk areas should be focused. The Wellness Check consists of a 5-page checklist going through the main components of a study. Preparation typically involves reviewing the IRB application and approved documents to have an understanding of the study. Key sections include:

- Regulatory Documentation
- Study Documentation
- IRB Documentation
- Unanticipated Problems / Adverse Event Reporting
- Drug Dispensing Accountability
- Device/Equipment Accountability
- Record Keeping
- Subject Recruitment Procedures
- Informed Consent Process

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- Individual Subject Review

Case Series Scenario 2

The second networking discussion topic involved a hypothetical university that was plagued with understaffing and an increasingly complex portfolio of studies, which led to a deterioration of their PAM program. After a transition of university leadership, it became a priority to ensure compliance with policies and SOPs, ensure investigator adherence to all requirements, and an expectation of institutional service.

Attendees considered how priorities would be set and rolled out under this new initiative. Discussion included how policies and SOPs should be modernized, as well as how training and communication should be utilized. Finally, the vital step of Post-Approval Monitoring oversight was confirmed as a way to sustain the change.

Wellness Checklist Feedback Form and Results

Connecticut Children's implemented a Wellness Check program in 2024. Between 2024 and 2025, 41 total studies were reviewed through this new process. Researchers were surveyed to assess implementation and garner feedback. There was a 32.8% response rate consisting of 22 respondents out of 67 total investigators involved.

Investigators overwhelmingly confirmed the positive impact of the Wellness Check process. 95% reported that the information reviewed during the Wellness Check helped them better understand their regulatory obligations. Researchers also commented that they appreciated someone not familiar with their study to provide insight and that it provided reassurance that they were on the right track.

Conclusion

Compliance programs often struggle to build, create and improve their post-approval monitoring program. Especially in smaller organizations, tasks increase while support plateaus. Building a positive PAM process does not require extensive staffing or sophisticated infrastructure. By anchoring in collaboration, education, and simple tools HRPP teams can create meaningful programs that strengthen oversight while fostering trust and engagement across the institution. This scalable approach enhances research resilience through subject protections and reduction of compliance risk.



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D01: PLENARY: Continuing the Mission: Conducting Ethical Research and Good Science in the Face of Pressure

Session Description

This plenary session examined the ethical principle of **Justice** as articulated in the Belmont Report and its continued relevance to conducting scientifically rigorous and ethically sound research in a rapidly shifting policy, funding, and sociopolitical environment. Using historical context, contemporary regulatory frameworks, empirical research data, and real-world case studies, the speakers demonstrated that justice is not synonymous with political ideology or discretionary diversity initiatives, but rather a foundational requirement for valid science, public trust, and ethical research oversight.

The session addressed how pressures—including reduced federal research funding, evolving rhetoric around diversity, equity, and inclusion (DEI), and global competition—risk undermining equitable research participation. Speakers emphasized that the erosion of justice in research design and implementation compromises generalizability, measurement validity, and mechanistic understanding, ultimately harming both participants and the broader public. The discussion concluded with practical strategies for research administrators, IRBs, and institutions to sustain justice-focused practices even in a “post-DEI” environment by leveraging existing regulations, reframing inclusion as scientific necessity, and strengthening community-centered research approaches.

Learning Objectives

At the conclusion of this session, participants were able to:

- Analyze the Belmont principle of Justice in relation to DEI programs and contemporary research environments using empirical data and regulatory frameworks
- Examine real-world case studies and patient experiences that illustrate the consequences of inequity, uniformity, and exclusion in research
- Identify practical strategies research administrators and oversight bodies can use to promote Justice in research design, review, and implementation despite political, financial, and institutional pressures

Speakers

- Joshua Fedewa, MS, CIP, CHRC
- Lynnea M. Lau, MPH, MBA, CIP
- Christelle “Yvette” King, BA, CHW, CIM, CCRP

Significance

Justice is one of the three foundational ethical principles governing human subjects research, yet it is frequently misunderstood, deprioritized, or reframed as optional in contemporary research discourse. This session is significant because it clarifies that justice is not an abstract moral aspiration or a politically contingent concept, but a scientific and ethical necessity embedded in U.S. regulations, federal funding requirements, and international research standards.

The exclusion or underrepresentation of specific populations in research undermines the validity, reliability, and applicability of scientific findings. When studies fail to reflect the populations they are intended to serve, researchers risk producing incomplete or misleading evidence, missing clinically relevant biological variation, and perpetuating health disparities. Historical abuses—including the Tuskegee Syphilis Study, the exploitation of Henrietta Lacks, and the Willowbrook hepatitis studies—demonstrate the catastrophic consequences of ignoring justice, while contemporary examples illustrate how structural exclusion continues to distort the evidence base.

This topic is particularly urgent given the current climate of reduced federal research funding, challenges to DEI-related initiatives, and increasing global competition in science. These pressures threaten to reverse decades of progress in ethical oversight and inclusive research practices. By grounding justice firmly in scientific rigor, regulatory mandates, and public trust, this session provides research professionals with a defensible framework for sustaining ethical research practices regardless of shifting political narratives. The session underscores that justice is inseparable from good science and that abandoning it compromises both ethical integrity and the credibility of the research enterprise.

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Historical Foundations of Justice in Research

The session began with an overview of historical research abuses that prompted the development of modern ethical frameworks. Pre-Belmont research frequently exploited vulnerable populations, placing disproportionate burdens on marginalized communities while conferring benefits elsewhere. The Tuskegee Syphilis Study, the nonconsensual use of Henrietta Lacks' biological samples, and the Willowbrook hepatitis studies exemplify systemic failures to ensure informed consent, equitable participation, and fair distribution of research benefits. These cases were presented not as isolated incidents, but as evidence of structural injustice embedded in research practices.

The Belmont Report and Justice as a Core Ethical Principle

In response to these abuses, the Belmont Report (1979) articulated Justice alongside Respect for Persons and Beneficence as foundational principles for human subjects research. Justice requires the equitable selection of research participants and fair distribution of research risks and benefits. The speakers emphasized that this principle directly informs current regulatory requirements, including the Common Rule's mandate that IRBs ensure equitable subject selection based on research purpose, setting, and vulnerability.

Justice as a Scientific Imperative

A central theme of the session was that justice is essential for scientific rigor. Data from FDA Drug Trials Snapshots demonstrate persistent underrepresentation of Black, Asian, and other minority populations in clinical trials, despite these groups comprising a substantial portion of the U.S. population and bearing disproportionate disease burdens. Speakers highlighted that lack of representation undermines generalizability, leading to evidence that cannot be confidently applied across populations.

Examples of clinically relevant biological variation illustrated how exclusion produces tangible harms. Pharmacogenetic differences affecting drug metabolism, such as CYP2C19 variants influencing clopidogrel efficacy and HLA-B*15:02-associated risks with carbamazepine, were discussed as cases where insufficient representation delayed recognition of serious safety and efficacy concerns. Additionally, biased measurement tools—such as pulse oximeters that overestimate oxygen saturation in patients with darker skin tones—demonstrate how instruments validated in narrow populations can introduce systematic error and patient harm.

Contemporary Regulatory and Policy Frameworks

The session traced how justice has been operationalized through modern research oversight mechanisms. NIH inclusion policies require the inclusion of women and racial and ethnic minorities by default and demand scientific justification for exclusions. FDA Diversity Action Plans mandate proactive strategies to improve enrollment of underrepresented populations in clinical trials. Reports from the National Academies of Sciences, Engineering, and Medicine frame lack of representation as a quality problem rather than a social preference.

Speakers emphasized that targeted enrollment of specific populations is scientifically justified when designed to address health disparities or investigate population-specific mechanisms, distinguishing such approaches from exclusion driven by convenience or cost.

Pressures on the Research Enterprise

The latter portion of the session addressed the broader research environment, including substantial federal funding cuts affecting NIH, NSF, NASA, and other agencies. These reductions threaten early-career scientists, institutional research capacity, and long-term innovation. Case examples illustrated how funding instability disproportionately affects research addressing health disparities, community-based studies, and minority-serving institutions, thereby compounding existing inequities.

Strategies for Sustaining Justice in a "Post-DEI" Environment

Despite these challenges, the session offered practical strategies for maintaining justice-centered research. These included reframing inclusion as a scientific requirement, leveraging existing regulatory mandates, diversifying funding sources without compromising participant protections, expanding IRB expertise, and strengthening community partnerships through culturally competent and participatory research models. Audience engagement focused on identifying biased tools within participants' own research fields and discussing how justice can be operationalized through post-market surveillance and adaptive study designs when representativeness is not feasible in early-phase trials.

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Conclusion

This session reaffirmed that justice is not ancillary to ethical research but foundational to scientific excellence, public trust, and meaningful discovery. Historical abuses, contemporary data, and current regulatory frameworks collectively demonstrate that exclusionary research practices undermine both ethics and evidence. In an era of political pressure and funding uncertainty, sustaining justice requires intentional action, regulatory fluency, and a commitment to framing inclusion as essential to good science. Upholding justice ensures that research advances serve all populations equitably and strengthens the integrity of the research enterprise.

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D02: Beyond Emerging Tech: Using Embedded Ethics to Support the Design and Conduct of Clinical Trials

Session Description

Embedded ethics traditionally refers to integrating ethics experts into the development of emerging medical technologies to help anticipate and address ethical and societal concerns. Increasingly, this model is being applied to clinical research, where it can support the ethical design and conduct of trials. This session will explore the role of "ethics and regulatory cores" within three federally funded national research networks. Speakers will share their experiences providing project-specific ethics consultation and discuss how this work contributes to broader efforts to advance ethical and regulatory best practices across the research enterprise.

Learning Objectives

- Describe how ethics and regulatory cores can function in clinical trial networks
- Identify the potential contributions of structured, systematic ethics and regulatory consultation teams for the design and conduct of clinical trials
- Assess the advantages of providing ethics consultations at various stages of the research lifecycle, including trial development, pre-implementation, and active conduct

Speakers

- Joseph Ali, JD
- Emily Largent, JD, PhD, RN
- Stephanie Morain, PhD, MPH
- Jeremy Sugarman, MD, MPH, MA

Significance

Clinical research is inevitably associated with ethical and regulatory issues during its design and implementation. While many of these issues are commonly addressed by investigators, sponsors, regulators and oversight bodies such as Institutional Review Boards and Data Monitoring Committees, others may go unrecognized, especially in clinical trials that involve novel research designs, such as embedded pragmatic clinical trials (i.e., trials that test already proven interventions within the context of usual clinical care and commonly aggregate data from clinical electronic health records). Therefore, in order to help promote the interests of those engaged in such research, it is essential to have mechanisms in place to facilitate identifying such ethical and regulatory issues and develop practical ways to overcome them.

Content

All of the speakers in this session are involved in one or more of three federally funded national networks that are conducting pragmatic clinical trials related to a variety of diseases and conditions: NIH Pragmatic Trials Collaboratory, Pain Collaboratory, and IMPACT Collaboratory. They described each of these networks and their experiences addressing the associated ethics and regulatory activities of each network in turn.

The NIH Pragmatic Trials Collaboratory. The [NIH Pragmatic Trials Collaboratory](#) works to support the design and conduct of innovative embedded pragmatic clinical trials (ePCTs) to establish best practices and disseminate knowledge. Founded in 2012, the Collaboratory has supported 35 large-scale, high-impact Demonstration Project ePCTs, conducted at over 1400 clinical sites and including over 1.2 million patients. Seven Core Working Groups, including an Ethics & Regulatory Core, provide structured consultation with funded projects. Through consultation and related scholarship, the Ethics & Regulatory Core identifies areas of regulatory and ethical uncertainty for ePCTs, helps trials navigate regulatory and ethical issues, and provides a framework for the ethical and regulatory compliant conduct of ePCTs.

Each funded trial meets with the Ethics & Regulatory Core within the first few months of the project. Structured consultations assess: research-related risks, privacy (including HIPAA considerations), data monitoring and oversight, and other regulatory and ethics concerns associated with the project. Meeting minutes of these consultations are documented and shared publicly. Recurring issues identified through consultation include: how to determine if an ePCT involves no more than minimal risk,

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particularly for trials comparing interventions in widespread clinical use outside the research context; approaches to consent, authorization, and notification, including the ethical and regulatory appropriateness of waiving or altering informed consent; and data monitoring, including designing monitoring plans that address distinct features of ePCTs, particularly those related to the use of extant data and corresponding implications for data timeliness and data quality.

The Pain Management Collaboratory. The Pain Management Collaboratory (PMC) supports large-scale pragmatic clinical trials evaluating non-pharmacologic and multimodal pain care delivered within real-world health systems serving Military Service Members, Veterans, and their families. To enable these studies, the PMC Coordinating Center includes cross-cutting work groups, among them the Ethics & Regulatory Work Group, which helps ensure trials are ethically sound, regulatorily compliant, and feasible across diverse institutional settings.

The Ethics & Regulatory Work Group engages investigators through structured consultation beginning at trial entry and continuing throughout study implementation. Activities include review of Human Subjects Worksheets, regular meetings with study teams, ad-hoc consultations for time-sensitive issues, and coordination with IRBs, human research protection programs, and regulatory specialists across the Department of Veterans Affairs and Department of Defense systems. The Ethics & Regulatory Work Group also develops shared resources such as regulatory cross-walks and model consent language.

Consultations address common challenges in pragmatic pain trials, including distinguishing research from quality improvement, aligning multi-site review processes, tailoring monitoring plans, and navigating consent in complex policy environments (e.g., remote consent and secondary data use). A major focus is advancing justice and equity: identifying structural barriers to participation in pragmatic trials, improving recruitment and retention of underrepresented populations, and supporting stakeholder-informed engagement and reporting practices.

IMPACT Collaboratory. The National Institute on Aging (NIA) funded IMPACT Collaboratory seeks to transform dementia care by “building the nation’s capacity to conduct pragmatic clinical trials embedded within healthcare systems for people living with dementia and their care partners.” It accomplishes this, in part, by funding pilot grants for ePCTs designed to test the feasibility and inform the design of future full-scale ePCTs to evaluate non-pharmacological interventions for people living with dementia and their care partners. Throughout the application process, pilot grant applicants consult with representatives from the IMPACT Collaboratory’s nine cores, including the Ethics and Regulation Core. This consultation process includes: a pre-meeting of the IMPACT Collaboratory consult team to review the application and formulate feedback; a first meeting between the consult team and applicant team to share feedback and answer questions; and a second meeting, where the applicant team shares responsive changes, if any, to their application and can seek additional input from the consult team. Additionally, members of the consult team are available to the applicant team and to pilot grant awardees on an ad hoc basis. A goal of embedding expert consultation into the application process is to ensure pilot grant applications are both methodologically rigorous and comply with ethical norms. Common ethical and regulatory issues that arise during the consult process are: how to seek consent from participants who may have diminished capacity to consent to research; whether a waiver of informed consent is appropriate; and whether additional or special protections are needed when research is conducted with vulnerable populations.

Discussion. Overall, experience with embedding ethics into these three national research networks suggests that early ethics consultation can identify ethical issues that were not previously apparent to study teams, which then provides opportunities to address them prior to study implementation. In addition, these approaches seem to streamline regulatory review, reduce protocol amendments, and promote consistent practice across sites. At the same time, variability in institutional interpretation of regulatory requirements remains an ongoing challenge.

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D04: Inclusive Informed Consent: Engaging People with Disabilities in Research Participation

Session Description

People with disabilities (PWDs) remain significantly underrepresented in clinical research, often due to systemic barriers in the informed consent process and a lack of reasonable accommodations. This session will explore the regulatory requirements and flexibilities within the Common Rule that can support inclusive, accessible informed consent practices for individuals with physical or cognitive disabilities. It will also highlight key findings and recommendations from the National Council on Disability's August 2024 report, which outlines actionable steps for healthcare practitioners, study teams, institutions, and federal agencies to reduce bias, improve accessibility, and ensure the meaningful participation of PWDs in clinical trials. Attendees will gain practical strategies for enhancing inclusion through improved consent processes and institutional practices.

Learning Objectives

- Describe key components and regulatory flexibilities in the Common Rule that facilitate effective informed consent, and analyze insights from the National Council on Disability's 2024 report on the exclusion of people with disabilities from clinical trials
- Identify best practices and practical strategies for providing reasonable accommodations in the informed consent process for participants with physical disabilities, and summarize key recommendations from the National Council on Disability to promote inclusive trial participation
- Discuss strategies for assessing and supporting cognitive capacity to consent, including the use of supported decision-making, and examine how researchers, IRBs, and funders can implement NCD recommendations to enhance inclusion of people with disabilities in clinical trials

Speakers

- Maya Sabatello, LLB, PhD
- Franz Castro, MD, MSc, MPH
- Nancy Olson, JD

Authors

Maya Sabatello, LLB, PhD
Katherine E. McDonald, PhD

Content

There are scientific, public health and social justice rationales for inclusion of adults with disabilities in *general* biomedical research. The size of the population (estimated at 29% of US adults), the universality of the phenomenon of disability, the significant health disparities that are experienced by many adults with disabilities underscore the scientific and public health justifications. The social justice ones are grounded in the need to recognize and treat adults with disabilities as equal members of society who are entitled to all rights and benefits as their non-disabled colleagues (Sabatello, 2018).

Yet, there is growing evidence that adults with disabilities are systematically excluded from participation in general population (non-disability specific) biomedical research. Part of the challenge is grounded in existing research ethics regulations that developed during World War II, and the history of abuse of persons with disabilities in research, especially those with questionable consent capacity. Notorious incidents include the horrendous Nazi experimentation on adults with psychosocial conditions, and the Willowbrook case in the US, where children with intellectual disability were intentionally infected with hepatitis to study the disease's development (Rothman and Rothman 1984). The resulting Federal regulations aimed to address these abuses, demanding high level of protection. Accordingly, the regulations often classify people with disabilities as a "vulnerable population" for whom special protection must be given, condition inclusion only as a last resort and if it personally beneficial to the participants, and in cases of individuals who are unable to consent—require proxy or guardian consent.

This seemingly objective criteria, however, does not go into the roots of the problem: the misperception that many adults with disabilities lack consent capacity, regardless of actual abilities. In effort to address this challenge, NIH's policy and the Convention

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on the Rights of Persons with Disabilities highlight that categorical exclusion based on diagnosis of a disability is unacceptable (NIH, 2009; CRPD 2006); the NIH policy further underscores the need for individual-based assessment of competency within the context of a specific research participation decision.

However, ours (McDonald et al, 2022) and others (DeCormier Plosky et al, 2022; NCD 2024) work has shown that this presumption of incompetence remains, and that consent capacity assessment is rarely conducted. Concurrently, guardian consent is overused, also without justifications.

This outcome is alarming. Consent for research participation is a foundational principle in research: it is both legally required and ethically grounded. Moreover, its denial from the adults with disabilities stands in contrast to ongoing efforts to improve understanding of consent forms and processes among other populations that have been historically underrepresented in research. Informed consent forms are also central in reviews of research protocols by Institutional Review Boards (IRBs), serving as first—and sometime last—step in safeguarding the rights and wellbeing of research participants. Yet, research (Nguyen et al, 2025) and our experience indicate that IRBs members are often unfamiliar with disability accessibility in consent forms and processes, adding challenges for recruitment, and ultimately serving as gatekeepers for inclusion of participants with disabilities, also in the absence of scientific justifications.

A common argument for capacity-based exclusion of adults with disabilities from general biomedical research is that these must be grounded in “scientific justifications”—a term that, except for clear risk assessment, is underdefined and overly vague. The result is often a conflation between disability and health disease as well as reinforcement of views that people with disabilities should only be included in studies about their disability(ies) but excluded from other “general” studies; such outcomes are contrary to the medical needs of many adults with disabilities and their preference to have their medical conditions—not disability—treated. The focus on “scientific justifications” merely in their interpretation as risk assessment also ignores the fact that consent capacity is study specific, varies by study complexity and level of risk, and hinges on enabling environments. For example, few IRBs offer consent forms in Braille and American Sign Language; our study on consent form for precision medicine research in plain language further uncovered that standard readability scores (e.g., Flesch-Kincaid, Lexile) mask “hidden complexity” in vocabulary, structure, or logic that undermine understandability (Foley et al, under review).

There is a need for research ethics policies and regulations to evolve toward the responsible, person-centered, and equitable inclusion of adults with disabilities in biomedical research. Such adjustments have taken place with regards to gender, racial, ethnic and sociomedical minorities, as can be observed through the changes that have occurred over the years in the terminology and guidelines of existing regulations, and which often occurred alongside societal developments. To date, these developments have failed to explicitly expand to adults with disabilities, notwithstanding federal and international disability laws such as the Rehabilitation Act, the Americans with Disabilities Act, and Affordable Care Act, and the Convention on the Rights of Persons with Disabilities (Sabatello & McDonald, 2025; Barkoff, 2026).

One example that can be used in the context of consent of adults with adults with intellectual disability is supported Decision-Making (SDM). SDM is a formal or informal legal arrangement that can be used to facilitate first-person consent, maximizes autonomy in research participation decisions, and upholds the individual’s personal choice where the participant remains the decision-maker. In the US, SDM exists in various forms but is explicitly included, as of the time of writing, in more than 30 states that either explicit recognize supported decision-making or require SDM as a least restrictive alternative to guardianship (see the ENGAGE Toolkit: McDonald & Sabatello, 2025). As such, it offers a meaningful way to responsibly include adults with intellectual disability in biomedical research as well.

Although IRBs are mostly known for their power to review proposed research studies, they also have important regulatory, educational, and policymaking roles that can be maxed to deliver on inclusion of people with disabilities in research (Underhill, 2018). They work directly with research institutions, can inform the processes for inclusion, and can require researchers to demonstrate the steps they take to assure responsible inclusion. While a comprehensive discussion is beyond the scope of this article, some key steps can include: requiring researchers to provide clear criteria for exclusion, with justifiable safety considerations serving as the primary reason for exclusion; indicate measures of accessibility and accommodations that will be provided to potential research participants; and demonstrate procedures for standardized, unbiased, and valid assessments to reduce disability bias. As the gatekeepers for inclusion, IRBs should infuse content into the Principle of Justice, and bring about a change and enhance disability inclusion in biomedical research.

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Disclaimer

This submission was prepared by the listed author(s) following the session and reflects their individual perspective. One co-author did not serve as a presenter for the referenced session. Not all session speakers participated in the development of this submission; therefore, the perspectives of all speakers are not represented.



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E02: Research Plot Twists: Addressing and Expecting the Unexpected

Session Description

At first glance, the IRB's most significant effort often seems to come during the initial review of a project—and ideally, everything proceeds smoothly from there. But research is dynamic, and unexpected challenges can arise. When they do, IRB review can become complex and demanding. This session will use discussion and case studies to provide practical guidance on handling protocol deviations, potential unanticipated problems, serious or continuing noncompliance, and other unforeseen issues that may emerge during a study.

Learning Objectives

- Understand the regulatory definitions and responsibilities related to protocol deviations, unanticipated problems, serious noncompliance, and continuing noncompliance
- Discuss strategies for distinguishing between event types and ensuring clear communication among researchers, the IRB, and regulatory authorities
- Examine methods to ensure balanced, timely reviews without allowing a single topic to monopolize discussion
- Apply concepts to real-world examples of deviations, noncompliance, and unanticipated problems

Speakers

- Andrew Hedrick, MPA, CIP
- John D. Horigan, MA, CIP

Significance

Research doesn't always go as planned. Investigators diligently report any number of research issues to IRBs and HRPPs; these can range from things like staffing and funding changes to errors in protocol implementation, and even incidents that come seemingly from out of the blue. How IRBs respond when reviewing these often complex issues is complicated by the web of ethical and regulatory obligations the IRB must navigate. Anecdotally, those in the field of human subjects protection often comment that these discussions are both among the most important IRBs engage in and at the same time among the lengthiest and belabored.

Federal regulations give some shape to these discussions by highlighting essential reporting requirements for institutions and IRBs. Specifically, institutions must have procedures to ensure "prompt reporting to the IRB; appropriate institutional officials; the department or agency head; and the Office for Human Research Protections, HHS... of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB..." [45 CFR 46.108(a)(4), see also 21 CFR 56.108(b) for FDA-regulated research.] For better or worse, the regulatory language leaves much undefined and can result in an IRB over-emphasizing reporting compliance.

This session presented an approach to navigating research incident reports that re-centers the IRB discussion on protection of participants and suggests establishing definitional clarity to guide IRBs on reporting requirements as a secondary consideration. By centering participant protections, IRBs can focus on their primary mission of ensuring ethical conduct of research while protecting participants. Definitional clarity among various types of "reportable" events helps the IRB to navigate its reporting obligations. Parsing protection from reporting requirements may give IRBs a methodical approach to addressing the many reports they review.

Content

Federal regulations require institutions engaged in human subjects research or FDA-regulated clinical investigations to have and follow written procedures for timely reporting of:

- (1) Unanticipated problems involving risks to subjects or others,
- (2) Any serious noncompliance, or
- (3) Any continuing noncompliance.

While regulations establish reporting requirements for these findings, these terms are not defined in the Common Rule or FDA regulation. Each term seems self-explanatory, but considering the complex ways research unfolds, the need for clear and easy-to-apply terminology is apparent; words like "problem," "serious," and "continuing" seem straightforward but reveal a relativity when applied.

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Where regulations leave off, guidance picks up. OHRP's 2007 Guidance on Unanticipated Problems (UPs) provides insight into the agency's interpretation. OHRP establishes the following criteria (paraphrased here) as necessary to defining an incident, experience or outcome as a UP:

- unexpected (re: nature, severity, or frequency) given the research procedures, protocol, consent, or population;
- related or possibly related to participation in the research; and
- suggests that the research places subjects or others at a greater risk of harm (than was previously considered).

The FDA's definitions are no less meaningful even if more involved. This is likely owing to the scope of regulated research (involving drugs, devices, biologics, etc.) which can often involve adverse events (AEs). In its 2009 guidance, the FDA acknowledges the variability in its own terminology stating:

"FDA regulations use different terms when referring to an adverse event. For example, adverse effect is used in 21 CFR 312.64; adverse experience is used in § 312.32; and unanticipated problems is used in § 312.66. For the purposes of this guidance, the term adverse event is used, except when quoting specific regulations. For device studies, part 812 uses the term unanticipated adverse device effect, which is defined in 21 CFR 812.3(s)."

1 See 45 CFR 46.108 and 21 CFR 56.108

2 See: OHRP's "[Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events: OHRP Guidance](#)" 2007

FDA guidance goes on to give more extensive guidance on when an adverse event is reportable.

A close review of FDA's guidance alongside OHRP's reveals meaningful overlap such that in many, if not most cases, the OHRP definition is sufficient to determine reportability.

Together, regulation and guidance still leaves certain gaps; neither agency/office provides insight into how they define serious or continuing noncompliance. Here, institutions have some latitude.

Noncompliance is partly defined in regulatory text as a failure to follow the provisions of the regulations or the determinations of the IRB. It seems a natural extension to include failure to follow the IRB-approved protocol. The terms "serious" or "continuing" still require clear definitions. We offer suggested definitions borrowed from the NCI's Central IRB Initiative (publicly available at NCICIRB.org), and definitions informed by our own past and current work. Definitions of noncompliance, serious noncompliance and continuing noncompliance can help navigate difficult IRB discussions. As a general framing for serious and continuing noncompliance we suggest:

- Serious noncompliance is noncompliance that has a negative impact on participant protections or the conduct of the research. Intentional disregard for regulation, IRB determinations, or the protocol, might also be considered serious.
- Continuing noncompliance is a pattern of noncompliance which left unaddressed might result in increased risk of harm to participants or to the integrity of the research.

In addition to definitions, we suggest decision tools to help navigate review of incidents. Having a decision tool available, or worked into a reviewer form, assists IRBs in meeting regulatory and ethical responsibilities to participants as well as reporting obligations to institutions, sponsors and regulators. The decision tools we highlighted all shared the following:

1. Participants first. The IRB should confirm the investigator has taken adequate steps to stop or otherwise mitigate any risk to participants. A robust corrective and preventive action plan (CAPA) should be first and foremost on the minds of IRB members reviewing an incident report. If there are additional provisions the IRB requires, these can be addressed with the investigator.
2. Reporting second. Once satisfied that participants are safe, IRBs should consider whether the event is reportable to others within or outside the institution. This decision should rely on clear definitions:
 - a. We consider UPs and Noncompliance to be distinct. OHRP's guidance establishes for a UP that the incident, experience, or outcome happens in a context where the research procedures are "given". If the protocol was being followed as approved (i.e. the research procedures are given) then the consideration as a UP is appropriate.
 - b. Noncompliance is a failure to follow the approved protocol, determinations of the IRB or requirements of the regulations. When the protocol is not followed as approved (i.e. the research procedures are not "given") the IRB should consider noncompliance, and potentially serious or continuing noncompliance.

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3 FDA's "Guidance for Clinical Investigators, Sponsors, and IRBs Adverse Event Reporting to IRBs — Improving Human Subject Protection" January 2009

4 *ibid.*

5 Consistent with 45 CFR 46.108(a)(3), changes may be implemented in research without prior IRB approval if doing so is to avoid apparent immediate hazard to subject(s) (see also 21 CFR 56.108(a)(4))

Using this framing we engaged attendees through a series of cases. Through engagement we highlighted the following:

1. "Deviation" doesn't appear in the IRB regulations. The term is used to refer to failure to follow protocol, which is "noncompliance." Sensitivity is warranted here because the term "noncompliance" can cause alarm for investigators and sponsors and could be seen as an escalation. We note that mere noncompliance (i.e. noncompliance that is neither serious nor continuing) still merits consideration of an appropriate CAPA, and could become continuing noncompliance should it repeat.
2. When considering reporting obligations, start with whether the research procedures were followed. Where research procedures were followed, consider the definition of an unanticipated problem; where they were not, consider noncompliance, serious noncompliance, and continuing noncompliance. Returning to this distinction when conversation veered off course helped to recenter the discussion (as it might in an IRB meeting).
 - a. Importantly, our approach here deviates from OHRP's guidance with respect to a specific example of an overdose of an investigational agent. OHRP labels this an unanticipated problem. An overdose is a failure to follow the protocol therefore the research procedures are not given and the incident should instead be considered as noncompliance. An overdose may well be considered serious noncompliance (assuming risk of harm to the participant) and should therefore be reported to OHRP (and others as appropriate).
3. Consideration of "intent" in a definition of noncompliance (serious or continuing) may be equally as subjective as the undefined "serious" or "continuing" in the regulation. Defining "intent" may resolve this. Similarly, policies and procedures might describe how the IRB identifies intentionality and how that may be considered (perhaps as a mitigating or aggravating consideration).
4. One case highlighted a failure of the investigator, sponsor, and IRB to identify a potential risk to participants related to privacy. Discussion started with whether the protocol was followed as written. The answer was 'yes,' but many immediately questioned why and how all three parties missed the privacy issue. We recentered discussion around participant protections and decision pathways for reportable events. Through this we were able to establish that the failure to identify this risk should be addressed as part of corrective action but does not have immediate bearing on protection of participants or reporting. Taking this approach of recentering around participant protections (including CAPA), and following clear definitions of reportable events, helped to organize discussion in a way that ensured the dimensions of the event were all adequately addressed.



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E03: Truth, Lies, and Research: The Paradox of Deception

Session Description

Deception in research presents a complex ethical challenge, seemingly at odds with the principle that participants should be fully informed. Yet in some cases, it may be the only way to study certain behaviors or phenomena. How should IRBs navigate this tension? When does a simplified study description cross the line into deception? Why is it important to distinguish between deception and incomplete disclosure? And how should research be approached when participants are not only misled, but unaware they are participating at all? This session offers a candid examination of the ethical and practical questions surrounding deception in research.

Learning Objectives

- Explore the criteria and regulations that allow for modifications or waivers of the required elements of informed consent
- Identify when research designs involve elements of deception
- Examine ethical issues that arise when research includes deception or lacks fully informed consent

Speakers

- Casey Mumaw, CIP
- Iris L. Jenkins, PhD
- Rachel A. Wenzl, PhD, MPH, CIP

Significance

The use of deception is complicated and contrary to the basic tenets of ethical research that require subjects to be informed about the purpose and nature of research prior to agreeing to participate. It is, however, the only way to study certain phenomena and thus at times a necessary component of research designs. HRPPs must deal with this ethical paradox while also determining if research is exempt or non-exempt, and then consider the regulatory implications of that determination. There is no Common Rule definition of deception, so HRPPs have considerable flexibility, which can be both good and bad, in determining when an activity crosses over into including deception, rather than just being a simplified study description. HRPPs must also consider covert research, in which subjects are never informed that they are participants, and the ethical ramifications of this. Covert research pushes against the boundaries set by regulatory definitions, since some of the people manipulated by researchers may not meet the definition of a human subject, though they are still exposed to the same risks as subjects.

Incomplete disclosure, deception, and covert research all require the principle of respect for persons to be disregarded to varying degrees. For non-exempt research, the criteria for waiver or alterations of informed consent must be considered during review, and HRPPs must consider the balance between the potential benefits of the research and not only the risk to subjects, but the potential breach of public trust such research can represent. The lack of specificity in the Common Rule allows for considerable variation between institutions, which can confuse researchers and lead to gaps in ethical oversight.

Content

Presented on November 8, 2025, at the PRIM&R Annual Educational Conference, this session explored the complicated—and sometimes paradoxical—relationship between **deception, incomplete disclosure, and ethical human subjects research**. Presented by Casey Mumaw (Indiana University), Iris Jenkins (Virginia Tech), and Rachel Wenzl (University of Nebraska–Lincoln), the session sought to provide useful definitions and considerations for deception in research.

The session began by noting that the Common Rule does not explicitly define deception, though it does specifically note that its use is not acceptable in certain Exempt research designs. **Deception** is not mentioned elsewhere in the Common Rule, however, the required elements of informed consent quite clearly imply that subjects must be presented with accurate information about study purposes, procedures, and risks, which would ordinarily preclude deception. In the absence of any formal definition, the presenters noted that HRPPs must have their own carefully considered policies defining **deception** in research.

A central theme of the presentation was the subtle but crucial distinction between two practices that are often mistakenly treated as interchangeable: **deception** and **incomplete disclosure**. The presenters noted that there are important differences between these two designs, which can have regulatory as well as ethical implications.

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Deception includes actively providing participants with false information, while **incomplete disclosure** is limited to the omission of specific details or the use of vague, but accurate, descriptions. While the Common Rule is clear that Exempt research cannot include **deception** without prospective agreement from subjects, there are no requirements for what information must be provided to participants, which gives HRPPs the flexibility to allow **incomplete disclosure** to be included.

This flexibility does not extend to non-Exempt research, however, as the required elements of informed consent at § 46.116 state what information must be provided to participants. The speakers noted that in order for non-Exempt research to include either deception or incomplete disclosure, the reviewing IRB must approve an alteration to the informed consent process, and that this waiver can only apply to minimal risk research, must not adversely affect the rights and welfare of subjects, and that without the waiver, the research could not practicably be conducted. The presenters stressed that “impracticable” does not mean difficult or inconvenient—it requires a robust methodological justification. When IRBs approve alterations or waivers, they effectively substitute their judgment for participants’ autonomy, and this ethical responsibility should not be taken lightly.

The presenters noted that regardless of the level of review or whether a study includes deception or incomplete disclosure, the study should include a subject debriefing at the conclusion of their participation. Debriefing functions as an ethical counterbalance to deception or incomplete disclosure. It restores the transparency that was temporarily withheld and addresses the breach of trust created during the study. While the inclusion of debriefing is the best practice, there are study designs where it may not be feasible, particularly in large-scale field research.

The session also discussed a third form of deception in research, referred to as covert research. In contrast to research that employs deception or incomplete disclosure, but in which participants know they are research subjects, covert research includes study designs in which the subjects are being manipulated and studied without their knowledge or consent. The review of covert research is particularly difficult, since this research may include delivering interventions to individuals from whom data is not collected, which could mean they do not meet the Common Rule definition of human subjects. However, ethical obligations still exist; researchers must consider community harm, manipulation, misinformation, and public trust. IRBs must also consider unanticipated problems involving risks to subjects or others, and so have an obligation to assess study risks.

The presenters—applied the information addressed in the presentation to a series of case studies, designed to illustrate different forms of deception and incomplete disclosure, as well as covert research, while exploring the ethical gray zones that exist in this research, with audience members encouraged to share their experiences and input on the examples shared.

The case studies covered topics on:

- Presentation of false information in surveys
- Manipulation of consumer interest
- Collaboration with political campaigns
- Randomized survey designs
- Blinded experimental interventions

Across all scenarios, the presenters’ institutions (IU, VT, UNL) had some differences in opinion if the presented research designs constituted deception or incomplete disclosure, or on the necessity of debriefing. Audience members were asked to consider each of the scenarios as well, and to indicate how they and their institutions would consider the regulatory and ethical implications, and to share their experiences with similar scenarios.

The presentation concluded noting that deception, incomplete disclosure, and covert research can all fill important roles in human subjects research, but require careful consideration by HRPPs and clearly defined institutional policies to appropriately review.

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F02: Approaches to Ethical Oversight of Research Involving Recently Deceased

Session Description

You might think, “Dead people aren’t human subjects,” and you’d be correct—HHS regulations define a human subject as a “living individual,” and FDA regulations similarly focus on “healthy humans or patients,” excluding decedents. Consequently, research involving deceased individuals is not governed by the same regulations as human subjects research. However, advances in technology, especially around brain death and life support, blur the lines between biological, legal, and social definitions of death, creating complex ethical and regulatory challenges. The absence of uniform oversight does not grant researchers unrestricted freedom, nor does it diminish the relevance of ethical principles like respect for persons, beneficence, and justice. This session will explore research involving recently deceased individuals—such as xenotransplantation—and share best practices from institutions committed to maintaining high ethical standards in this uniquely challenging area.

Learning Objectives

- Clarify the definitions of death from biological, medical, and legal perspectives to create a shared understanding of the term
- Develop a comprehensive understanding of the ethical principles and guidelines that apply to research involving recently deceased individuals
- Describe the process, challenges, and solutions in establishing an institutional committee for the ethical oversight of research involving the recently deceased
- Identify key criteria for evaluating the scientific merit and ethical conduct of research involving the recently deceased

Speakers

- Molly Shiflet, MPH, CIP
- Helen Panageas, CIP
- Joan Margiotta, J.D.

Significance

There are emerging novel clinical interventions that could provide great benefit to patients suffering from serious diseases but that cannot be effectively tested in animals and are not yet safe to test in human subjects. This is especially true in ground-breaking areas such as xenotransplantation research, where investigators seek to gauge the viability of implanting genetically modified animal organs, such as pig kidneys, livers, and hearts, into humans in dire need of transplants who are unlikely to receive a human organ. Increasingly, investigators are requesting that institutions allow them to participate in the development of these interventions by permitting clinical research on recently deceased individuals whose families have agreed to donate their loved one’s body for this purpose. These brain dead decedents are kept on mechanical support during the course of the research, and the research provides valuable data on how a living human body would react to an intervention such as a xenotransplant.

The ethical challenge for institutions is that research on decedents is not governed by human subjects research regulations, which only apply to living persons. Institutions have adapted some of these concepts to create novel oversight committees to review decedent research. These decedent research oversight committees function similarly to IRBs in that their members have a range of expertise, consider and approve protocols based on specific criteria, and provide continuing oversight of studies. Our session focused on the structure and function of these oversight committees at our institutions and how they evaluate decedent research protocols through scientific and ethical lenses, focusing on respect for the individual, minimizing harm to their family members and others, preserving public trust in the organ donation system, and the just allocation of hospital resources. We hope to provide a roadmap for other institutions to consider as they establish their own decedent research oversight committees.

Content

Introduction

The presenters addressed how institutions can provide scientific and ethical oversight of research performed using recently deceased individuals in the absence of federal regulation, which only governs human subjects research. Testing some novel interventions, such as xenotransplantation, using decedents can provide better data than research on animals and will reduce the harm to living humans in eventual clinical trials.

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To fill the regulatory gap, institutions including VUMC and NYU Langone Health created their own policies and oversight committees to review decedent research. The session focused on the creation of those policies and the details of the committees' work.

The NYU Langone Health Experience

NYU Langone Health's (NYU) exploration into advanced transplant research gained momentum in 2019 when NYU engaged in discussions regarding the ethical implications of conducting research involving recently deceased patients. NYU leadership fully embraced this pioneering approach through thoughtful discussions with ethics teams, including those led by noted bioethicist Art Caplan, NYU's general legal counsel, and other key stakeholders. NYU reached institutional consensus to support this groundbreaking research.

To ensure decedents and their families would be safeguarded, a committee akin to an Institutional Review Board was established. The Research on Decedents Oversight Committee guarantees that the rights and safety of the decedents are upheld throughout the research process. The Committee has limited oversight of research with recently deceased individuals. The Committee's oversight does not extend to human subjects, cadavers, or related areas. The approval process is guided by established standards and principles such as:

- Ensuring that adequate consent and authorization procedures are in place.
- Implementing measures to minimize any potential harm to participants.
- Safeguarding privacy and maintaining the confidentiality of all research data.
- Ensuring conflicts of interest (COIs) are managed effectively.
- Research must demonstrate scientific validity.
- Any financial implications are evaluated and addressed according to Institutional rules.
- Research activities do not compromise hospital resources designated for patient care.

Navigating this complex field can be challenging. One significant issue is the ongoing controversy surrounding research involving individuals declared deceased due to cardiopulmonary death. While our policy permits such research, it remains a controversial topic. Additionally, identifying board members poses a challenge since many individuals with the necessary expertise are directly involved in conducting research or are engaged in related areas of ethics, complicating efforts to ensure impartial oversight. Lastly, as new research opportunities are presented, e.g., the exploration of testing other investigational products, such as drugs and devices, on recently deceased individuals, complex ethical and procedural considerations arise, and questions frequently emerge about whether the committee should permit these studies.

The VUMC Experience

At Vanderbilt University Medical Center (VUMC), rapid growth in transplant activity prompted the creation of a formal oversight structure for decedent and organ donation research. Continued expansion in 2024, including record-setting heart transplant activity, coincided with a rise in complex and highly novel research proposals involving decedents and organ donation. These proposals—such as xenogeneic organ support and uncontrolled donation after circulatory death—raised ethical, legal, and regulatory questions that existing review mechanisms were not designed to address.

Initially, such proposals were managed through ad hoc consultations and case-by-case IRB discussions. Recognizing the growing institutional risk and lack of national standardization in this area, VUMC benchmarked with peer institutions and identified three priorities: ensuring regulatory compliance, creating predictability for investigators, and strengthening protections when deceased donor organs are manipulated for implantation into living recipients. This work led to formation of a preliminary advisory group, followed by establishment of the Decedent and Organ Donation Research Oversight Committee (DODROC) in 2024. DODROC includes multidisciplinary representation across ethics, transplant medicine, pathology, legal affairs, and community membership. The committee developed formal infrastructure, including an application process, review criteria, a Manual of Operations, leadership assessment, and integration within the institutional IRB platform to ensure coordinated review.

Early challenges included recruiting experts with limited availability and managing conflicts of interest, defining the appropriate scope of review, and securing investigator buy-in. These were addressed through compensation, alternate membership models, clear communication, and structured coordination with the IRB. Although the committee has not yet reviewed the most complex anticipated cases, it has already strengthened institutional oversight and identified broader ethical concerns. Moving into its second year, DODROC will refine its scope and assess its value-add. Overall, the initiative positions VUMC to support innovation in transplantation science while maintaining rigorous ethical safeguards.

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Conclusions

At the close of the session, the presenters offered best practices, including a uniform definition of a decedent as a person who has been declared dead by criteria for brain death or cardiopulmonary death, and whose body will either be kept functioning during the course of the research or will be part of an intervention that happens immediately after death.

The presenters noted the ethical considerations that a committee should consider when reviewing protocols, including respect for the deceased individual, minimizing harms to surviving family members and others, preserving public trust in the organ donation system, and justly allocating hospital resources.

The presenters recommended that institutions forming committees consider the scope of review, include members with an array of expertise including non-scientists, and staff the committee with human research protections professionals. The presenters suggested model criteria for the approval of protocols, including adequate preliminary data to support the research, justification for using a decedent, a well-defined research plan and comprehensive appropriate authorization form, and details to demonstrate that the decedent will be handled with respect and that the family's privacy will be safeguarded.

Finally, the presenters noted that they expect an increase in decedent research as the data has been successfully used as a basis for expanded access and clinical trials in xenotransplantation, and there is potential to test an array of devices and drugs in decedents.

C07: Innovative and Alternative Strategies for Developing the AAALAC Program Description

Many institutions rely on just one or two people to write the AAALAC Program Description—a time-consuming and complex task. This session offers an alternative approach that involves engaging IACUC members, researchers, and stakeholders across departments to share the workload. Speakers will discuss strategies for planning, writing, and gathering the right documentation to support the Program Description. By involving diverse team members, this method fosters collaboration, gains broader buy-in, and reduces individual burden. Participants will also receive practical tips for identifying and empowering committee leaders to strengthen relationships with key stakeholders.

Learning Objectives

- Discover a structured approach to developing the AAALAC Program Description over one year by actively involving and empowering stakeholders
- Examine ways to organize information efficiently, keeping the Program Description current and linked to relevant documentation
- Explore strategies to engage stakeholders, build key relationships, and ensure accurate responses in the Program Description

Speakers

- Leigh Ann Tulleeson, CPIA
- Deb Hickman, DVM, MS, MBA, DACLAM, DACAW

Significance

Many institutions rely on just one or two high-level leaders to write and revise the AAALAC Program Description (PD). Usually, the writing or re-writing of the PD is done just prior to the PD being due for resubmission, rather than in real time as changes are made programmatically. This session offered an alternative approach to writing, revising, and tracking the documentation for all the claims made in the PD (keeping the AAALAC PD updated at all times) that involves engaging IACUC members, researchers, and stakeholders across departments to share the workload. By involving diverse team members, this method fosters collaboration, gains broader buy-in, increases PD response accuracy, and reduces individual burden, as well as ensuring accuracy. Participants received practical tips for empowering IACUC members and helping them strengthen relationships with key stakeholders. By dividing the work of writing the PD among the IACUC, the AV, the Chair, and the IACUC Admins, collaboration was fostered, and broader programmatic buy-in was gained because the writers were taking ownership of their respective segments and were communicating with other departments. Individual burden was reduced because no one person was responsible for any section which allowed more people to review and find mistakes or inaccuracies.

Content

Dr. Deb Hickman began by providing an overview of the AAALAC accreditation process. Briefly, this process involves a self-assessment, in the form of the program description, which is followed by an onsite evaluation and review by the AAALAC Council on Accreditation (COA). Dr. Hickman reviewed the standards that are used by the COA when evaluating an animal care and use program (please see <https://www.aaalac.org/accreditation-standards/accreditation-standards-overview/> for the most recent standards). She stressed that animal care and use programs are complex and require the active involvement of multiple experts, which is why the COA strongly encourages the input of all stakeholders when performing the self-assessment. Then, she invited Ms. Leigh Ann Tulleeson to continue the discussion.

Leigh Ann Tulleeson described how the HMH IACUC (we) developed a better way to write the Program Description.

First, we considered how to improve workflow while engaging people across the institution, including IACUC members. The PD consists of logical sections easily divided into responsibility areas. Sections were led by the IACUC Chair or administrator along with assigned IACUC members. Deadlines were assigned and updates were presented at IACUC meetings. Stakeholders were individuals “in charge” of that section—such as research animal facility (RAF) management, team health, grants, conflict of interest, clinical veterinary services, etc. Our goal was to create a structured approach to developing the AAALAC PD over one year by actively involving and empowering stakeholders with:

- Clear Expectations about responsibilities;

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- Reasonable Deadlines and Timelines;
- Defined Individual Responsibilities;
- Help Identifying Stakeholders.

To create a structured approach to develop the AAALAC PD, a Google Sheet (AAALAC PD Timeline) was developed to track PD sections, assign IACUC reviewers, responsible stakeholder(s), and the IACUC meetings at which sections would be presented. Each group was tasked with meeting independently, interviewing stakeholders, gathering documentation, editing the document, and presenting findings at an IACUC meeting.

The AAALAC PD Timeline contained two tabs: an AAALAC PD tab with a breakdown of sections, teams, time frame for review and a Congruency tab with columns for the PD sections, relevant SOPs, policies, OLAW Assurance, and corresponding sections of the Guide and AWA. This allowed everyone to confirm the PD accurately reflects workflow in the RAF and that policies and SOPs were in line with regulatory documents.

This method fostered collaboration because IACUC members worked in multiple small groups (each member was in at least two groups). Clear expectations and assignments allowed groups to focus. Bringing stakeholders in during the writing (instead of downstream or to answer questions) meant stakeholders could make changes to policies and SOPs in real time and IACUC members were able to have meaningful conversations with each other and representatives from other departments. One group had a PI, facilities director, veterinarian and administrator. Their different backgrounds allowed them to approach the PD from different perspectives. Having a member who is not familiar with the content review the answer was helpful because they could identify areas that need clarification.

Small groups meant more involvement from individual members, creating buy-in by encouraging ownership and allowing everyone to contribute in meaningful ways. We found IACUC members were proud of the work they completed. Fostering communication with other departments meant more people learned about AAALAC, the AAALAC process, and understood the importance of the PD. Including individuals who have authority to make programmatic changes allowed more time to fix incongruencies between the PD and SOPs/policies and encouraged and strengthened relationships.

Ensuring the PD accurately reflected workflow in the RAF was a significant undertaking. Previously, questions about workflow caused anxiety for people performing the work. There was a disconnect because people who were doing the work wanted to confirm and match what was written in the PD instead of explaining the realities of their workflow. It took reassurance to convince RAF leaders, Team Heath, COI, and others that we were not judging their processes, but just wanted to confirm that the PD reflects their workflow. Through this process, examples of daily work not matching the PD were found and corrected. In some cases the PD was revised to reflect what was happening and in others, policies and SOPs were amended to match the PD.

Once we established that the PD accurately reflected workflow, documentation was verified. To organize information efficiently, keep the PD current and linked to relevant documentation, an additional Google Sheet was created to track responses in the PD with the relevant documentation. The sheet included links to examples of PI records, PAM documentation, animal husbandry care - room logs, etc. Keeping the list of documentation with links helped engage the owners of required documentation, increased buy-in (when people know their documentation will be reviewed, they tend to keep them up to date!), and allowed everyone involved to feel ownership and responsibility for the outcome. Having access to documentation allowed reviewers to verify accuracy of answers.

This collaborative approach significantly reduced individual burden. Creating small groups and assigning them to work on sections of the PD eliminated the need for one or two people to take on the responsibility of the entire document. It reduced pressure on individuals because responsibility was shared and allowed more time for groups to connect with stakeholders to ensure accuracy. It also allowed more people to find mistakes or inaccuracies. The group dynamic created trust and allowed IACUC members (including admins) to rely on each other in ways that we had not before. When information was needed, the request came from a group (a sub-set of the IACUC) rather than one individual, so no individual had to badger other departments.

Changing the approach to writing the PD was transformative. It took what is seen as a tedious, solitary chore and turned it into an opportunity to engage the group, have fun, work in a collaborative environment, and resulted in less burden on individuals who would normally write the PD.

We found that change can be exciting. While all parties understood the importance of the work they were contributing towards, there was also laughing, connecting, and camaraderie.

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D07: Zoo and Aquarium-Research Facility Partnerships

Partnerships between academic institutions and zoos or aquariums present opportunities for scientific advancements in fields ranging from reproductive physiology and conservation to cognitive evolution. However, they introduce unique challenges for IACUCs, including questions about jurisdiction, oversight responsibilities, dual compliance standards, and alignment of institutional policies and animal care practices. This session explored what IACUCs need to know to effectively evaluate and oversee these collaborations. Attendees gained insight into best practices for ensuring ethical and regulatory compliance while supporting productive, interdisciplinary research partnerships.

Learning Objectives

- Identify special issues involved in developing a relationship with a zoo or aquarium for research
- Discuss IACUC review procedures associated with research at zoos and aquariums
- Review regulatory expectations for research activities involving zoo and aquarium animals

Speakers

- Danielle Dai'Re-Benziger, MA, CIP – University of California, Merced
- Julie Marshall, CPIA, CCEP – San Diego Zoo Wildlife Alliance
- John A. Bryan, II, DVM, MS – American Society of Mammalogists

Significance

Partnerships between zoos, aquariums and research facilities are vital to advancing animal research because they combine complementary strengths that neither could fully achieve alone. Zoos and aquariums provide access to a wide diversity of species, including rare and endangered animals, along with long-term behavioral and health data collected in managed care settings. They also operate applied conservation programs that connect directly to real-world species management. Academic and research institutions, in turn, contribute specialized research infrastructure, rigorous experimental design, advanced analytical tools, and access to funding and scholarly networks. When these resources are integrated, they enable more comprehensive and impactful research. Together, they advance science in areas like reproductive physiology and assisted reproduction, cognitive and behavioral studies, and conservation genetics and field-to-lab integration.

Content

The Partnership Landscape: Opportunities and Benefits

Why collaborate?

The panelists started the session discussing examples of zoo and research facility partnerships and why it is so important for these collaborations. These examples included:

- Researchers often collaborate with local zoos and aquariums to access the unique and diverse species housed in these facilities, creating opportunities for studies that would not exist elsewhere. These collaborations frequently focus on behavioral research, taking advantage of animals accustomed to human care and observation.
- In addition, zoos and aquariums routinely collect biological samples (such as blood, hair, or fecal matter) during standard veterinary and husbandry procedures. When surplus samples are available, they can be shared with researchers for secondary analyses, maximizing the scientific value of each collection while minimizing additional impact on the animals.
- It was also noted that opportunities for collaborations between multiple institutions are also common and can be complex at times.
 - An example of a collaboration between a university research team studying a captive population of animals under an NIH grant awarded to the university was discussed with focus on the importance of maintaining clear lines of communication surrounding levels of authority and reporting responsibilities throughout the life cycle of the project.

Oversight Challenges and Jurisdictional Complexities

Determining oversight responsibilities for each institution was discussed. Key points raised during this discussion included:

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- Who holds primary oversight? Is it the research committee at the academic or research institution, the zoo or aquarium research committee, or both? Primary oversight in collaborations between zoos, aquariums, and research institutions does is typically shared between each IACUC.
- Because each partnership and project is unique, the specific responsibilities for animal care and use must be clearly defined on a case-by-case basis. Establishing roles early through formal agreements helps ensure that all ethical, regulatory, and animal welfare standards are consistently met while supporting effective collaboration.

We then discussed models for dual review, creation of IACUC agreements, and best practices for creating effective communication protocols. The importance of defining oversight early in project design was stressed as this is the key to creating the most successful collaborations.

One panelist described a reciprocal approval process used to recognize collaborating institutions' IACUC approvals. This approach streamlines review for multi-institutional studies by allowing one institution to rely on another's approval, reducing duplication while maintaining oversight. A key component of this process is a scope form, which requires collaborators to clearly outline the work being conducted with animals at their specific site. This includes detailed information on the procedures involved, who will perform them, and the training and qualifications of those individuals. The scope form has proven especially valuable for capturing site-specific activities at zoo or aquarium facilities, which are often not fully detailed in an academic institution's IACUC protocol.

Agreements were also discussed, with emphasis on the need to clearly define key responsibilities related to animal care and use. Establishing communication pathways at the outset is equally important. This includes determining whether the principal investigator (PI) will serve as the primary liaison between institutions and their IACUCs, whether the IACUCs will communicate directly with one another, or whether a hybrid approach will be used. Clarifying these roles early helps prevent miscommunication and ensures efficient coordination throughout the project.

IACUC Review Procedures for Zoo and Aquarium Research

Key review questions to include when working with a zoo or aquarium on a research program were then discussed and included:

- Are animal housing and care descriptions specific to the zoo setting?
- Are zoo staff qualifications documented?
- Is there adequate veterinary support and emergency coverage?
- Will separate facility inspections be needed by your committee or could United State Department of Agriculture (USDA) or Association of Zoos and Aquariums (AZA) accreditation inspection documentation suffice?

A panelist then shared an AZA Standardized Research Application Form that was developed to facilitate and expedite the proposal application and review process for single and multi-institutional research projects conducted in AZA accredited zoos and aquariums. This document is available on the AZA website¹ and it was shared with attendees. During this session section 5 – the section focused on impact on the housing institution – was highlighted as the most impactful for IACUCs to consider.

Sample Animal Care at Collaborating Institutions Form

A sample collaboration form used to clarify each party's responsibilities for the various aspects of animal care and use associated with this arrangement when researchers perform work at other facilities and/or with animals not owned by your facility was then shared and discussed. Key questions and items to include in this form include:

- Does the collaborating institution currently operate an internal animal care and use committee (IACUC or other ethics committee)?
- Is the collaborating institution registered as a research facility under USDA certificate?
- Is the collaborating institution registered as an exhibitor under USDA license?
- Does collaborating institution hold AZA accreditation?
- Does collaborating institution hold another accreditation (e.g. AAALAC)?

Best Practices for Success

Best practices were discussed including:

- Create written agreements defining roles/responsibilities.

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- Schedule joint site visits and post-approval monitoring when feasible.
- Foster open communication and cross-training between institutions.
- Keep focus on shared ethical principles—animal welfare and transparency.

Sustaining Oversight

Keys to sustaining oversight for these collaborations were then discussed including:

- Scheduling regular check-ins between institutions.
- Developing shared SOPs when feasible.
- Celebrating successes— use positive reinforcement of collaboration culture.

The session concluded with an open discussion, inviting participants to share their experiences, including successes and areas for improvement. Audience engagement was strong and meaningful, with attendees posing practical questions about collaborative processes and seeking insight into whether others had encountered similar challenges. This exchange fostered a productive dialogue and highlighted shared experiences across institutions.

Conclusion

Key takeaways from this session included:

- Partnerships expand research potential but demand clarity in oversight.
- IACUCs must ensure compliance while fostering collaboration.
- Proactive communication and policy alignment are key to success.

References

1. AZA Standardized Research Application Form. (<https://www.aza.org/research-and-science>)



D05: The Science of Pain, Stress, and Distress in Animal Research: Ethical Foundations, Scientific Impact, and Practical Assessment

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

Speakers

- Deborah Mook, DVM, DACLAM
- Jennie Lofgren, DVM, MS, DACLAM

Significance

Pain, stress, and distress are central considerations in the ethical and scientific conduct of animal research. These experiences are not only ethically relevant but also exert profound effects on physiology, behavior, immune function, and disease progression, thereby influencing data quality and translational validity. Over the past several decades, scientific understanding of pain, distress, and emotion in animals has evolved substantially, reshaping regulatory frameworks and driving the development of refined assessment and pain mitigation strategies. This session reviewed contemporary definitions of pain and distress, explored their ethical and regulatory foundations, summarized evidence demonstrating their impact on research outcomes, and described practical, multimodal approaches for assessment and refinement. Together, these components underscore the importance of integrating laboratory animal welfare science into preclinical study design, oversight, and daily practice to support both animal well-being and rigorous, reproducible research.

Content

The use of animals in biomedical research carries an ethical obligation to recognize and minimize pain, stress, and distress. This obligation is grounded in the recognition that animals are sentient beings capable of experiencing negative affective states and is reinforced by the scientific reality that unmanaged pain and distress introduce variability that can compromise experimental outcomes. As a result, attention to pain and distress occupies a central position at the intersection of ethics, animal welfare science, and research integrity.

Historically, pain and distress were often conceptualized narrowly, with assessment relying primarily on overt clinical signs or reflexive responses. Advances in neuroscience, behavioral biology, and welfare science have since demonstrated that these experiences are multifaceted, species-specific, and context-dependent. Contemporary frameworks increasingly emphasize emotional experience, coping capacity, and behavioral change as critical components of assessment. These advances have informed both regulatory expectations and best practices for refinement.

This article synthesizes current scientific, ethical, and regulatory perspectives on pain, stress, and distress in animal research and highlights practical strategies for assessment and intervention.

Defining Pain, Stress, and Distress

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Pain is widely understood as an unpleasant sensory and emotional experience associated with actual or potential tissue damage. In animals, pain cannot be directly reported and must be inferred from behavioral, physiological, and contextual indicators. Importantly, pain is distinct from nociception: nociception refers to neural detection of a noxious stimulus, whereas pain reflects the conscious, affective experience arising from that input. This distinction has practical implications, as reflexive responses alone may not accurately reflect an animal's subjective experience.

Stress is generally defined as a real or perceived challenge to physiological or psychological homeostasis, accompanied by adaptive responses aimed at restoring balance. Distress represents a more severe state in which coping mechanisms are insufficient, and the animal is unable to return to homeostasis. Distress is therefore characterized by an aversive, sustained negative state that adversely affects well-being.

Both pain and distress are closely linked to emotion. Scientific perspectives increasingly support the view that emotion is a biologically conserved process that regulates behavior and adaptation across species. This understanding reinforces the relevance of emotional experience in animals and provides a conceptual framework for interpreting pain- and distress-related behaviors.

Ethical and Regulatory Foundations

Ethical debates regarding animal research often focus on whether, and under what conditions, it is morally acceptable to cause pain or distress. Contemporary approaches typically adopt a hybrid framework that combines definite limits (such as prohibitions on certain practices or species) with cost-benefit analysis within those limits. Moral relevance is frequently grounded in characteristics such as sentience, the capacity to suffer.

These ethical principles are embedded in regulatory frameworks governing animal research. In the United States, the Health Research Extension Act, the Animal Welfare Act and its regulations, Public Health Service Policy, and *The Guide for the Care and Use of Laboratory Animals* collectively require minimization of pain and distress, appropriate use of anesthesia and analgesia, veterinary oversight, and institutional review through IACUCs. Accreditation programs such as AAALAC International further promote continuous improvement beyond minimum compliance.

Importantly, these frameworks emphasize that compliance is not solely a procedural requirement but a mechanism for operationalizing ethical responsibility and safeguarding scientific integrity.

Scientific Consequences of Unalleviated Pain and Distress

A substantial body of evidence demonstrates that unalleviated pain and distress act as potent biological stressors. Unalleviated pain can result in prolonged activation of the hypothalamic-pituitary-adrenal axis, leading to suppression of immune function, alterations in metabolism, and changes in behavior. In both human and non-human animals, these effects can alter disease development and treatment response. In the context of this session, unalleviated pain in research animals and resulting alterations to immunology and physiology also therefore alter experimental endpoints and can serve as a significant research variable.

In rodent models of oncology, for example, unmanaged post-procedural pain has been associated with reduced natural killer cell activity, increased tumor growth, greater metastatic burden, and decreased survival, even in immunodeficient mice. Conversely, appropriate analgesic and supportive care can mitigate these effects and, in some cases, improve experimental outcomes. This benefit to research outcomes has been demonstrated both with provision of appropriate analgesia at the time of a painful procedure as well as effectively treating pain that develops over time as the result of a disease model. These findings challenge the assumption that analgesia necessarily compromises data and instead highlight pain itself as a significant confounding variable.

Assessment and Refinement Strategies

Effective management of pain and distress requires reliable assessment. Contemporary best practice emphasizes a multimodal approach that integrates behavioral observation, physiological measurement, contextual information, and professional judgment. Structured frameworks such as SOAP (Subjective, Objective, Assessment, Plan) promote consistency within and between those assessing the animals by linking observation to action.

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Validated tools, including grimace scales, behavioral ethograms, loss-of-normal-behavior indicators, and structured scoring systems, enhance sensitivity and reproducibility. However, assessments can be influenced by numerous confounders, including strain, sex, age, circadian rhythm, social context, and observer presence. Awareness of these factors is essential when interpreting findings. A best practice is to utilize triangulation by applying several assessment methods as no one measurement can be counted upon to sensitively and specifically identify and quantify pain in nonhuman animals.

Operational tools such as standardized pain lexicons, decision trees, and documentation templates support alignment across animal care staff, investigators, and oversight committees. Refinement strategies—including multimodal analgesia, palliative care, environmental enrichment, reduced handling, and clearly defined humane endpoints—translate ethical and scientific principles into daily practice.

Future Directions

The field is increasingly moving beyond harm minimization toward promoting positive welfare. Opportunities for building positive welfare include rat tickling and voluntary dosing approaches using highly palatable and preferred sweets. Additionally, advances in digital monitoring, automated behavioral analysis, and remote assessment offer new opportunities to detect pain and distress earlier and reduce observer-related confounding and provide important insights during nocturnal animal's, like rodents, natural periods of activity. Integrating these tools with established welfare frameworks will further strengthen both animal care and research quality.

Conclusion

Pain, stress, and distress are not peripheral considerations in animal research; they are central determinants of both ethical responsibility and scientific validity. Continued integration of welfare science, ethical analysis, and practical assessment tools is essential to ensure that animal research is conducted humanely, transparently, and rigorously. By addressing pain and distress proactively and systematically, the research community can uphold its moral obligations while advancing high-quality, reproducible science.

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E07: Building Compassion Resilience by Understanding Animal Welfare

This session introduces compassion fatigue in animal care and research settings and explores how building compassion resilience can protect staff well-being and enhance animal welfare. Attendees will engage in discussions to identify signs of fatigue, examine its effects on individuals and programs, and collaborate on practical strategies to foster resilience. Participants will explore how these concepts apply to IACUC members, support staff, and researchers, and how strengthening resilience can improve oversight functions like training and post-approval monitoring.

Learning Objectives

- Understand the concepts of compassion fatigue and compassion resilience, including their relevance to all roles within the animal care and use program
- Recognize the signs and impacts of compassion fatigue on personnel and animal welfare, and explore strategies to build resilience while supporting ethical and regulatory research practices
- Identify practical approaches to implementing compassion resilience strategies and develop metrics to evaluate their effectiveness across key IACUC functions

Speakers

- Kirsten Bell, MLAS, LATG, CPIA
- CDR Temeri Wilder, DVM, MPH, DACLAM, DACVPM
- J. Preston Van Hooser, BS

Significance

Compassion resiliency is critical to laboratory animal research because it sustains the emotional capacity, ethical clarity, and professional effectiveness of those who care for and oversee animals. Compassion fatigue (CF), marked by emotional exhaustion, detachment, and reduced efficacy, arises from sustained exposure to animal distress, euthanasia decisions, and moral stressors. In this setting, CF is not a sign of weakness; it reflects deep care coupled with unaddressed needs. Left unmitigated, CF undermines mental health, increases turnover, and erodes the quality and consistency of animal care, ultimately jeopardizing both animal welfare and scientific integrity.

By contrast, compassion resilience (CR) helps staff maintain empathy and effectiveness amidst ongoing stress and ethical complexity. CR anchors daily practice in purpose (belief that one's work meaningfully advances humane science) and moral congruence (alignment between ethical beliefs and professional actions). These foundations transform difficult experiences, such as implementing humane endpoints, into ethically meaningful acts of stewardship rather than sources of personal depletion. Practically, CR strengthens oversight functions, including training, ethical reflection, and post-approval monitoring, by empowering personnel to recognize welfare concerns, advocate for refinement, and communicate openly across teams. Institutions that embed CR through peer support, debrief sessions, transparent endpoint notifications, and recognition programs foster compassion satisfaction, the positive reinforcement that helps to protect staff from CF.

The net effect is a safer, more humane program where staff well-being and animal outcomes are mutually reinforcing; resilient caregivers provide more engaged and consistent care, resilient oversight reduces errors and moral distress, resilient cultures retain skilled professionals and uphold public trust. In short, cultivating CR is an ethical and operational imperative for high-quality animal research.

Content

Compassion fatigue (CF) is a pervasive, often unspoken, occupational hazard in animal research. It emerges from the cumulative burden of caring for animals who may experience morbidity, distress, or euthanasia, and from institutional and societal pressures that make it "hard to talk about work." Building compassion resilience (CR) is essential to protect staff well-being and elevate animal welfare, with tangible benefits across roles, including animal technicians, researchers, veterinarians, IACUC members, and others.

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Common symptoms of CF include intrusive thoughts (recurring images, obsessive worry), altered arousal (anxiety, sleep disturbance), and avoidance (withdrawal, apathy, self-medication). CF doesn't develop because we are weak, can't handle the work, or aren't "cut out" for it. It occurs because we care deeply for our animals – and we ignore our own needs. This message resonated with attendees; one audience member shared how their decision to leave a veterinary technician role for one focused on animal welfare and compliance was motivated by the mental exhaustion of frontline care, reflecting how CF can catalyze role shifts toward systemic impact.

The two foundational pillars of CR, Purpose and Moral Congruence, are the ethical and emotional "why" that sustains resilience and high-quality welfare.

- Purpose is the conviction that daily actions – feeding, enrichment, protocol review – meaningfully advance humane and ethical science. Purpose converts routine tasks into stewardship. We illustrated how visible welfare improvements (comfort, behavior, quality of life) validate institutional values and caregiver contributions, reinforcing that "what I do matters." Importantly, purpose buffers CF by contextualizing difficult experiences (euthanasia, witnessing distress) within a humane mission, shifting the focus from "what happened" to "why we act" to prevent suffering and preserve integrity. A practical example involved co-designing enrichment for social housing. Staff witnessed joyful behavior changes and experienced compassion satisfaction—the positive emotion that restores resilience.
- Moral Congruence is alignment between personal ethics and professional practice; the experience of saying, "my daily work reflects my beliefs about compassion and humane care." Disruptions to this alignment generate moral distress, a major risk factor for CF. High-quality welfare practices link directly to moral congruence: refining procedures to minimize pain, articulating humane endpoints, and empowering team members, from husbandry to IACUC, to advocate for animals. These practices help staff reduce internal conflict and guilt, trust that empathy and obligations coexist, and communicate transparently after challenging events. A live example involved an open debrief following a difficult study: acknowledging scientific gains alongside emotional weight transformed potential dissonance into shared purpose and pride.

Integrating competence into the resilience model, we highlighted that knowledge, skill, and ethical reasoning are the operational backbone of high welfare. Training staff to recognize welfare concerns, advocate for refinement, and participate in IACUC discussions fosters agency over helplessness. This approach aligns expectations for adequately trained personnel outlined in the *Guide*, PHS Policy and AWA/AWR. Competence supports 3Rs-focused outcomes, reducing animal numbers, minimizing pain, and innovating alternatives, while simultaneously strengthening resilience through efficacy.

Next, we connected resilience to supportive team culture. Interdisciplinary collaboration among veterinarians, caretakers, researchers, and the IACUC is essential for normalizing emotional expression and reducing stigma around stress and grief. Shared responsibility distributes the emotional load, easing individual burden. Practical interventions include:

- Regular debrief sessions after humane endpoint decisions to acknowledge emotions and reaffirm alignment with humane principles.
- Peer recognition for welfare advocacy to publicly value the contributions of animal care teams and the IACUC.
- Reflective practices such as gratitude rounds, animal memorials, and commemorations, which honor animals and the people who care for them, creating space to process grief constructively.

The University of Washington's Dare2Care (D2C) program served as a case study. After identifying CF as a community need, UW adopted a novel observational approach – confidential conversations and concept mapping – to surface shared stressors and prioritize actions. D2C's initiatives exemplify CR in practice:

- Inclusion: Sharing research summaries in vivarium rooms; implementing endpoint notifications (cage cards, heart stickers, pre/post emails) to honor relationships and prevent distress from "unexpected goodbyes."
- Peer2Peer support: Providing safe, relatable avenues for staff to discuss grief and anxiety; establishing dedicated phone/email support lines with referrals to professional resources.
- Occupational Health integration: Adding CF and emotional well-being to annual health assessments and embedding CF awareness into initial and specialized animal user training.
- Recognition: Memorials and community commemorations; encouraging authorship/acknowledgment for animal caregivers in publications; launching a Reflection Series to connect welfare outcomes to scientific breakthroughs and to honor care staff contributions.

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- Value: Public appreciation (donated lunches, KudoBoard gratitude posts, certificates, care packages) to affirm the dignity and importance of animal care roles.
- Opportunity: Inviting technicians into IACUC/AAALAC representation, funding conference participation (PRIM&R, AALAS, NWABR), and expanding access to continuing education.
- Openness: Increasing public awareness of biomedical research benefits to build trust and reduce stigma.

We must acknowledge systemic sources of CF: staff feeling unheard or undervalued; limited transparency; understaffing; lack of mental health training; negative public perceptions; and position CR programs as proactive occupational health measures that sit alongside physical safety training. By naming CF as a legitimate workplace hazard and providing concrete tools—such as endpoint notifications, peer support, debriefs, memorials, recognition, and training—institutions can reduce turnover, improve morale, and protect animal welfare through more engaged caregiving.

Audience feedback affirmed both content and delivery: participants recognized the session as a highlight of PRIM&R, noted the presenters' passion and vulnerability, and shared personal stories of transition from frontline veterinary work to compliance to continue championing high standards of animal welfare. This response underscores that CR resonates across career stages and roles, validating lived experiences while offering practical pathways to sustain compassion.

The session closed by inviting personal commitments to resilience – small, sustainable changes like mindful breathing, gratitude journaling, connecting with peers, or engaging in restorative activities outside work. The takeaway was clear: ethical stewardship and reflective practice are mutually reinforcing. When institutions empower staff to understand the “why” behind procedures and provide space to process emotions, compassion remains anchored in professional ethics rather than eroded by exhaustion. That alignment – purpose plus moral congruence – protects caregivers, strengthens oversight, and elevates the welfare of animals and the credibility of the research enterprise.



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F06: Considerations in Communications for Post-Approval Monitoring

Post-Approval Monitoring (PAM) practices can vary widely across institutions and research areas, but one consistent challenge is effective communication with principal investigators and research teams. This session will explore key considerations for conducting successful research monitoring, with a focus on building collaborative relationships through active listening and engagement. Presenters will share real-world examples and examine common barriers that make monitoring conversations difficult, as well as practical strategies monitors can use to navigate these discussions more effectively and constructively.

Learning Objectives

- Develop strategies for effectively communicating during post-approval monitoring visits, using tools such as active listening, meaningful engagement, and setting transparent expectations
- Identify common challenges in post-approval monitoring discussions and explore examples and approaches for fostering educational, collaborative interactions
- Evaluate key considerations in research monitoring for animal studies, particularly when activities extend beyond the approved protocol—and distinguish between monitoring and auditing in such contexts

Speakers

- Sarah Lines, M.S., CCEP
- Stephanie Mar, BS, CPIA

Significance

Effective communication within Post-Approval Monitoring (PAM) is highly significant to the field of animal research because it directly influences the quality, accuracy, and reliability of ongoing oversight. PAM ensures that research activities remain aligned with the IACUC approved protocol through continuing reviews, laboratory inspections, and documentation checks. These monitoring mechanisms protect animal welfare and uphold regulatory compliance, but their success depends heavily on how well PAM personnel communicate with research teams during each interaction.

Communication challenges such as unclear expectations, scheduling obstacles, misunderstandings, and difficulty conveying findings, can create friction or confusion during monitoring visits. Therefore, thoughtful communication strategies are essential to ensure PAM is perceived and experienced as a collaborative, supportive process rather than a punitive one. Central to these strategies is the practice of **active listening**, which helps build trust and promotes open dialogue.

According to the Center for Creative Leadership (CCL), active listening requires **full attention**, including focused engagement with both verbal and nonverbal cues such as eye contact and nodding. This attentiveness reinforces respect and helps PAM personnel accurately understand the researcher's perspective. Maintaining **open-mindedness** by withholding judgment reduces defensiveness and encourages transparency during discussions about protocol adherence or potential deviations. As noted by The Knowledge Academy, demonstrating **empathy** by recognizing and validating emotions strengthens rapport and enhances mutual understanding. Providing **feedback**, including paraphrasing or asking clarifying questions, ensures accuracy and supports effective problem-solving during monitoring interactions.

The benefits of strong communication practices elevate PAM's value to researchers as collaborators and educators while monitoring protocols. CCL emphasizes that active listening conveys value, deepens understanding, fosters psychological safety, and encourages a listening oriented climate that supports continuous improvement. By prioritizing clear, empathetic communication, PAM enhances the effectiveness of oversight, promotes ethical animal care, and strengthens productive working relationships within research environments.

Content

PRIMR25's *Considerations in Communications for Post-Approval Monitoring (F06)* breakout session explored key considerations for conducting successful research monitoring, with a focus on building collaborative relationships through active listening and engagement. The first portion of this session addressed PAM program fundamentals, including regulatory requirements, program definitions, and administration processes. This was followed by a discussion of common challenges programs frequently encounter.

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During the second portion, the speakers shared real-world examples and examined common barriers that make monitoring conversations difficult, as well as practical strategies monitors can use to navigate these discussions more effectively and constructively.

Post-Approval Monitoring Program Fundamentals

Continuing IACUC oversight of animal activities is required by federal laws, regulations, and policies (Table 1). The Animal Welfare Act & Animal Welfare Regulations (AWA&R) FAQs page states that even though the requirement for annual continuing reviews of activities has been eliminated, research facilities should still continue with their PAM programs. Under 9 CFR § 2.31 (c), the IACUC retains the authority to review an animal activity after approval at its discretion. Section IV.C.5 of the Public Health Service Policy (PHS Policy) on Humane Care and Use of Laboratory Animals also states that the IACUC determines the interval appropriate for conducting a continuing review of each previously approved activity. Likewise, the Guide for the Care and Use of Laboratory Animals (The Guide) reiterates that the continuing IACUC oversight of ongoing protocol assessment and regulatory compliance may be facilitated by a variety of mechanisms.

Table 1	
	IACUC functions. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall:
USDA	Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities; 9 CFR 2.31(c)(7)
OLAW	The IACUC shall conduct continuing review of each previously approved, ongoing activity covered by this Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with IV.C.1.-4. at least once every three years. PHS Policy IV.C.5
AAALAC	Continuing IACUC oversight of animal activities is required by federal laws, regulations, and policies. A variety of mechanisms can be used to facilitate ongoing protocol assessment and regulatory compliance. Guide, 8th ed., pp. 33

Post-approval monitoring comprises all protocol monitoring activities conducted following initial IACUC approval. Such activities encompass continuing protocol reviews, laboratory inspections (either integrated with routine facility inspections or conducted independently), observations of procedures and animals, and external regulatory inspections and assessments. The administration of PAM may involve IACUC committee members, animal care staff, veterinary unit personnel, compliance office staff, or collaborative teams comprising multiple stakeholders.

Common Challenges

Common challenges in designing and implementing a PAM program vary across institutions. The initial consideration involves developing a program appropriate for the institution's scale and resources. Factors such as monitoring frequency, personnel involved, and implementation strategies may differ substantially between small and large institutions. Davis et al. (2019) provide valuable insights into these institutional variations in their examination of postapproval monitoring practices at biomedical research facilities. Program structure represents another critical consideration. Institutions must determine whether to establish a formal program with routinely scheduled monitoring sessions or an informal approach relying on protocol continuing reviews and semiannual inspections. Pritt and Smith (2020) offer a comprehensive classification scheme that addresses this particular challenge and provides guidance for program design decisions.

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However, the most significant challenge in successfully implementing a PAM program, and the primary focus of this session, centers on effective communication. The second portion of the session addressed strategies for navigating communications surrounding PAM sessions, informing the research community about the importance of PAM programs, and effectively conveying results from monitoring activities.

Communication Strategies

Various approaches exist for coordinating and conducting PAM visits. The communication strategies presented in this session reflect practices successfully implemented at a large academic research institution, utilizing a three-phase framework: pre-visit, intra-visit, and post-visit. The pre-visit phase emphasized establishing clear communication timelines (Table 2) to ensure all participants are adequately prepared.

Table 2

Pre-Visit | Communication Timeline for Success

Initial Email <i>4-6 Weeks Ahead</i>	• Introduction & Contact • Set Time Frame • Give Selection of Options • Give Decision Deadline
Follow-Up Email <i>4 Weeks Ahead</i>	• Set PAM Date • List Protocols to be Monitored • PAM Lead Up Questions • Attach Documents • Calendar Invite
Reminder Email <i>1 Weeks Ahead</i>	• PAM Date & Time • Confirm PAM Participants & Location • List Protocols to be Monitored • Attach Documents
Reminder Email <i>1 Day Ahead</i>	• PAM Date & Time • Confirm PAM Participants & Location • List Protocols to be Monitored

The intra-visit phase focused on three critical components: introductions, active listening, and visit conclusion (Table 3). During introductions, monitors were encouraged to establish the session's purpose and goals while emphasizing a collaborative partnership approach. The second component incorporates the principles of active listening. Pay attention and be fully present during the PAM visit. Utilize nonverbal and verbal cues (e.g. eye contact, nodding, leaning in, etc.) to indicate engagement. Defer judgment and be open-minded. Show empathy and be patient. Provide feedback to foster psychological safety and facilitate greater understanding. The benefits of creating psychological safety include building a safe space that allows the study team to proactively ask questions about improvements that could be made and increasing openness on what did or did not work. People are quicker to report issues and ask questions when they feel safe. Conclude the session with clarification of next steps, acknowledgment of program strengths, and communication of objective observations.

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Table 3

Intra-Visit | Session Phases of Success

Introductions	• Introduce Individuals • Reason for PAM Session • Goals of the Session • Emphasize Positive Partnership
Active Listening	• Principles ◦ Full Attention ◦ Non-Verbal Cues ◦ Open-mindedness ◦ Empathy ◦ Feedback • Benefits ◦ Conveys Value ◦ Facilitates Greater Understanding ◦ Fosters Psychological Safety ◦ Educational Opportunities ◦ Listening-Oriented Climate
Ending Visit	• Lay Out Next Steps • Follow-up Timeline • Set Report Expectations • Opportunity for Questions • Give Praise & Highlight Improvements • Reiterate PAM Monitor’s Role • Communicate Objective Observations

The post-visit phase centered on improvement and education through comprehensive reporting (Table 4). This structured approach ensured consistent, professional communication throughout the monitoring process while maintaining a supportive partnership with research personnel.

Table 4

Post-Visit | Closing Out PAM Successfully

Report Contents	• PAM Monitor Contact • System Instructions • Informational Links ◦ How to Report Issues / Submit Amendments ◦ Required Documents ◦ Other Relevant Institutional Policies
Visit Findings	• No Issues / Follow-Up Actions • Recommendations / Suggestions • Additional Education • Required Action Items • Further Considerations of Noncompliance Findings

Key Considerations

- Effective PAM program implementation requires attention to several key considerations:
- Understanding the fundamental differences between post-approval monitoring and formal audits
 - Recognizing the multiple purposes PAM serves
 - Identifying when protocol amendments are necessary
 - Determining which findings require escalation
 - Meeting reporting obligations to regulatory oversight bodies

Post-approval monitoring and formal audits serve different institutional purposes and employ distinct approaches (Table 5). PAM functions primarily as an educational and collegial tool designed to maintain research team adherence to approved protocols while identifying opportunities for improvement. In contrast, formal audits focus on compliance verification, regulatory adherence, and deficit correction.

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Table 5

FEATURE	POST-APPROVAL MONITORING	FORMAL AUDIT
Primary Goal	• Educational & Collegial • Keep Research Teams to the Protocol • Helps Identify Areas for Improvement	• Compliance Focused • Verify Adherence to Regulations • Deficit Correction
Nature & Tone	• Supportive • Collaborative	• Formal • Find Evidence of Noncompliance
Outcome	• Simple Report with Recommendations • May Request Protocol Amendment	• Formal Report of Serious Violations • Specific Corrective Actions Deadlines
Initiation	• Part of Program for Oversight ◦ Routine ◦ Scheduled	• Triggered by Report of: ◦ Noncompliance ◦ External requirements ◦ Repeated issues

While federal laws, regulations, and policies mandate continuing IACUC oversight of animal activities, monitoring serves broader purposes including ensuring animal welfare, maintaining research quality, documenting satisfactory performance, providing educational opportunities, facilitating practice improvements, and preparing institutions for external regulatory inspections. These monitoring activities verify protocol compliance, prevent protocol drift, and create opportunities for researcher education and program enhancement. PAM visits often result in protocol amendment requests that can be commonly categorized into three distinct types: best practice, science-dictated, and monitor-directed (Table 6).

Table 6

Best Practices	• Increased pain or distress • Housing changes
Science Dictated	• Change in procedures • Change in study objectives • Switching surgery types • Drug changes • Changes to euthanasia
Monitor Directed	• Change in animal numbers • Personnel changes • After an Adverse Event (AE)

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Certain findings from monitoring visits necessitate escalation to more intensive oversight mechanisms. Four primary circumstances warrant further review through formal audits or for-cause investigations: discovery of significant noncompliance, repeated noncompliance requiring follow-up assessment, external regulatory requirements, and investigations initiated due to complaints or institutional concerns. These escalated reviews employ more rigorous investigative approaches and may result in significant institutional actions, including mandatory reporting to regulatory oversight bodies.

Institutions should establish clear policies, either as standalone documents or incorporated within program descriptions or assurances, detailing procedures for handling and assessing incidents of noncompliance and adverse events. These policies should specify circumstances requiring external reporting. Reporting requirements differ across oversight bodies. The session focused on requirements for the three primary entities overseeing animal care programs in the United States: USDA, OLAW, and AAALAC (Table 7).

Table 7

USDA

Required Reporting

- Failure to adhere to plan for correcting significant deficiency
- Suspension of protocol

OLAW

Required Prompt Reporting

- Any serious or continuing noncompliance with the PHS Policy
- Any serious deviation from the provisions of the Guide [for the Care and Use of Laboratory Animals]
- Any suspension of an activity by the IACUC

AAALAC

Required Prompt Reporting

- Prompt Reporting of events that may present external, regulatory, or legal implications.

The session concluded with case study scenarios examining both favorable and adverse PAM visit outcomes. Participants engaged in discussion regarding institutional approaches to managing each scenario and provided justification for their programmatic processes.

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F07: IACUC SOS! Evaluating Difficult Protocols by Optimizing Your Review Toolkit

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

Speakers

- Jennifer A. Klahn, MA, CPIA
- Elaine N. Joseph, PhD, CPIA

Content

Session F07 began with an overview of the intent of Institutional Animal Care and Use Committee (IACUC) protocol review – specifically, what it is and what it isn't – and explored traditional and unique methods to complete IACUC review of proposed animal care and use activities.

Traditional IACUC protocol review processes often begin with an administrative, veterinary, and/or scientific pre-review. Protocols can often be incomplete when they are first submitted to the IACUC office for consideration for review. A pre-review by an IACUC office administrator and a veterinarian can be helpful to both the investigator and the IACUC (Bradfield et al., 2026, p. 127). It is important to note that pre-reviews are not required by either the Public Health Service (PHS) Policy or the United States Department of Agriculture (USDA) Animal Welfare Act Regulations. Both the PHS Policy and the USDA Animal Welfare Act Regulations require that investigators consult with a veterinarian if proposed procedures will cause more than momentary pain or distress; however, this requirement can be fulfilled during the traditional review process. Following the pre-review, conventional IACUC review processes involve reviews by IACUC members who are appointed by the Chair. This review process can be either designated review, a process that takes place outside of a regularly convened meeting, or full committee review, a process that requires a review during a regularly convened meeting (Bradfield et al., 2026, pp. 131-136).

The content of the IACUC protocol review should be standardized, to ensure that the proposed animal activities are consistent with the most humane care and use of animals and federal regulations, including the PHS Policy and the USDA Animal Welfare Act Regulations (Mohan and Foley, 2019). Aspects of IACUC protocol that should be reviewed remain consistent across institutions and should include, but are not limited to, a clear rationale for the use of animals, a justification for the species chosen and the number of animals proposed, a sequential timeline of proposed procedures, a detailed description of those proposed procedures, use of appropriate anesthetics and analgesia, and humane endpoints and euthanasia (NRC, 2011; Mohan and Foley, 2019). In short, an IACUC protocol review should be a partnership between the IACUC Office, the IACUC itself and the investigator to facilitate the conduct of the ethical use of animals in research and teaching. IACUC protocol review should not be a barrier to performing research or teaching a course involving the use of live animals. Ideally, it should not be creating more administrative burden on investigators. Instead, it should be seen as an opportunity to assist the researcher to improve animal welfare, while conducting research and teaching activities.

Many IACUC protocols can be complex, involve species or procedures unique to the IACUC or institution, or involve anesthetics or procedures the IACUC may not feel comfortable with due to their expertise (or gaps in that expertise). In these situations, it is often helpful to think “outside the box” and unique methods of assisting the IACUC members with protocol review can be valuable.

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The use of pre-approved procedures, particularly if they are created in collaboration with investigators, can assist IACUC members with protocol review. This is especially true if they are unfamiliar with the procedure or set of procedures that the researcher is proposing. If the IACUC has already approved a standard operating procedure for a series of rodent behavioral tests, for example, an IACUC member should feel more confident reviewing protocols that contain rodent behavioral tests. The use of outside consultants when the IACUC is confronted with either a species or procedures that are unique or unfamiliar to them, can also be highly valuable. Both the PHS Policy and USDA Animal Welfare Act Regulations allow for the use of consultants, if they do not vote (Bradfield et al., 2026, p. 130). Lastly, IACUC members should not be afraid to engage the investigator in a conversation about the proposed protocol. After all, the investigator is the one proposing the research and an ideal IACUC review is one that is cooperative with the investigator with the ultimate goal of achieving the researcher's scientific goal while maximizing animal welfare.

Following that introduction, attendees spent the rest of the session participating in small group discussions in which they examined challenging and unusual case studies.

Each of the five case studies presented a scenario with limited information, often over the course of multiple slides (e.g., Part 1, Part 2). Session facilitators read a single slide then provided instructions for the small group discussions, for example, "Discuss how your IACUC would proceed upon receipt of this submission." Approximately five minutes were allotted per slide, after which the facilitators solicited reports from attendees. Because no advance work was done to ensure different program representation at each table, efforts were made to encourage all tables to share some of their small group discussion with the larger group; this ensured that all attendees benefited from the discussion, even if it did not occur at their table.

During the large group reports, attendees were able to ask questions of the facilitators and clarify recommendations provided by other groups. At the end of the session, attendees completed the five cases studies with robust discussion, sharing ideas that could be taken back to their home institution. They were reminded that protocol review is a collaborative activity that can involve external consultants when needed. Thinking creatively, and reaching out to colleagues, is definitely encouraged when dealing with challenging or unusual protocols.

An example of one case study that was discussed during the session is provided here:

Case Study 5: Use of Outdated Anesthesia

The IACUC has received several protocols recently that propose to use tribromoethanol (e.g., Avertin) as an anesthetic in rodents. The anesthetic is proposed for use in a variety of procedures, and it appears that some of the investigators had been using this anesthetic at their previous institutions for quite some time. The IACUC currently has no policy regarding the use or opposition of the use of tribromoethanol as an anesthetic in rodents.

- *What factors do you think the IACUC should consider when reviewing this protocol?*
- *What alternative methods of review or options to assist the IACUC should be considered?*

In this case, the IACUC should consider developing a policy on the use of the drug formerly known as Avertin, specifically, and/or a general policy on the use of non-pharmaceutical grade anesthetics. In either case, the policy should clearly state what is and is not allowed, why exceptions might be permitted, and what conditions would be required for any exceptions (see OLAW FAQ F4 "May investigators use non-pharmaceutical-grade substances in animals?" for factors to consider in evaluating potential adverse consequences of non-pharmaceutical-grade substances). In the absence of a policy, the IACUC can still proceed in this manner, but they will save themselves time in the future by developing an institutional policy on the topic and inviting faculty users to participate in the development of the policy.

In their review of proposals that involve the use of Avertin, the IACUC should look for information explaining why a pharmaceutical-grade alternative drug cannot be used instead. For long-standing projects that have used Avertin, the IACUC may consider whether a pilot should be performed to compare outcomes for procedures done with Avertin versus those that use another anesthetic. If there is institutional support for 3Rs projects, investigators may be more encouraged to conduct such pilots.

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Each IACUC should determine their institutional threshold for what types of activities warrant Full Committee review (FCR). Exceptions to IACUC policies may be something the IACUC feels strongly should go FCR, rather than Designated Member review (DMR), to ensure robust discussion. In theory, a review using the Veterinary Verification and Consultation (VVC) process could be performed for a change in anesthetic, but if the proposed new anesthetic were to be Avertin, and considering the possible side effects of the drug, it would not be advisable to use VVC. See NOT-OD-14-126 for the NIH Guidance on Significant Changes to Animal Activities for more information.

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N15: Navigating Compliance: Real-World IACUC Scenarios

The goal of this session was to explore into the world of research ethics, where real-life dilemmas and compliance challenges unfold behind the scenes of IACUC offices. This session guided 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

- Real-life scenarios were explored, highlighting ethical dilemmas faced by IACUC chairs and staff
- Strategies employed by IACUC chairs and staff were discussed to address and mitigate ethical concerns while upholding animal welfare standards

Speakers

- Jen Bennetch, MS, CPIA
- Rosa Harmon, MS, RVT, CCPIA

Significance

This session was intended to help IACUC members and administrators strengthen their oversight processes by analyzing concrete, complex cases rather than just theoretical guidelines.

Content

Real-world scenarios at a fictional university were presented focusing on programmatic deficiencies such as equipment failure, responses from key units within the institution, unapproved activities, anesthetic errors, inadequate training of lab personnel, reporting requirements, adverse events, safety, corrective and preventive action plans.

Scenario #1

Great Eastern University's IACUC was notified that the HVAC system failed in the animal facility, which houses multiple non-USDA and USDA-covered species. Temperatures were intermittently outside the recommended range for each species; however, the health and safety of the animals were not adversely affected. This deficiency was identified during semiannual facility inspections and reported to the Facilities Management team repeatedly, however, only short-term solutions were applied over a period of three-years.

Scenario #2

During a visit to an investigator's lab at Great Eastern University, a clinical veterinarian was conducting sampling to confirm resolution of a recent outbreak of *F. Rodentium*. When asked to identify all locations where mice might be housed or used, a lab staff member opened a drawer in a cabinet and explained that mice were placed there with enrichment (sometimes with an enrichment maze, sometimes without). These mice had recently been injected with Doxycycline, deemed a hazardous agent at GEU.

The injections were performed appropriately in a biosafety cabinet (BSC) by trained LVTs. However, undergraduate students in the PI's lab had transferred the mice from their home cages to a drawer in the PI's lab post-procedure. When questioned, the students explained that the mice were placed in the drawer to keep them awake for 30 minutes following the injection, as they tended to fall asleep when returned to their home cages.

Upon review, the approved protocol did not include any mention of a post-procedure housing in a drawer or alternative location. The PI is a mathematician with limited experience in animal research. The protocol was not PHS-funded.

Scenario #3

Great Eastern University's IACUC received a self-report regarding the death of ten mice due to an anesthetic error under an approved IACUC protocol. Upon reviewing the protocol, it was found that the anesthetic used and the procedure performed were not described in the protocol (i.e., ketamine and isoflurane, incorrectly transferred to a clear vial, were injected IP instead of ketamine and xylazine).

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This is a PHS supported project and involved recurring noncompliance involving the same lab personnel, a post-doc. The post-doc had previously conducted procedures that were not described under an animal use protocol which prompted retraining. The post-doc previously acknowledged that they had not read the approved IACUC protocol and did not know which procedures were authorized.

Scenario #4

During a feed study at Great Eastern University, two pigs were fatally electrocuted due to a malfunction involving research equipment. A graduate student was demonstrating the equipment to another student when a spark was observed or heard between the equipment and one of the pigs. The equipment was unplugged and relocated, but shortly afterward, a second pig was electrocuted after being startled. Emergency services and the veterinarian were contacted immediately.

An investigation revealed that two damaged extension cords – one with a faulty splice and the other missing a ground pin – had been connected in series. This setup electrified a piece of research equipment, which in turn charged a metal bar running along the animal stalls. All of the pigs in the area received electrical shocks; however, those standing on rubber mats were unharmed. The two pigs that died had stepped off the mats onto a metal grate, allowing the electrical current to ground and resulting in electrocution. The personnel working at the time were also standing on rubber mats.

It was also discovered that a researcher had experienced an electrical shock from the same equipment the day prior but did not report the incident. This was an agricultural study and not PHS-supported.

The audience was asked the following questions:

1. Is this a reportable incident?
2. What actions should the IACUC take?
3. What are the major concerns of this scenario?
4. How should the IACUC and veterinary team respond to this incident?
5. What corrective actions should be taken?
6. Were animals harmed?
7. Is this a reportable incident? If so, to which oversight body(ies)?
8. Who else should be involved in this scenario?

The audience engaged in lively discussions regarding strategies for effectively responding to the example scenarios and sharing their own institutional dilemmas. The following strategies were proposed:

Strategy #1: HVAC failure/slow response by facilities team

- During a convened meeting, the IACUC decided to request support from the Institutional Official and report the matter to OLAW as a programmatic deficiency.
- The AV, Facilities Management, CFO, VP Research Administration, IO, IACUC Chair and Research Compliance met to discuss concerns.
- The new IO committed resources toward an HVAC upgrade that would ultimately provide a long-term resolution.

Strategy #2: Education and Training

- The AV, clinical veterinarian, EH&S animal compliance coordinator, and IACUC Director met with the PI and the lab manager to discuss the procedures. The following corrective actions were implemented: implemented:
 - Enrichment equipment is to be moved and stored to the mouse's Doxycycline injection location, and mice are only introduced to the enrichment maze within a BSC.
 - The enrichment maze is to be left in the BSC or decontaminated with ethanol prior to storage in the laboratory.
 - The enrichment maze should be transported and stored within a larger sealed container to prevent Doxycycline dispersal.
 - Undergraduate students and all lab staff are to be trained on hazardous agent handling.
 - The PI must amend the protocol for clarification on animal housing and enrichment requirements following the injection of Doxycycline.
- The incident is reported to the IACUC.

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Strategy #3: Self-report, protocol violation

A preliminary report of this incident was filed with OLAW via telephone by the IACUC Manager. During a convened meeting, the IACUC reviewed the incident and requested a meeting with the PI and his laboratory staff (i.e., a post-doc and a staff scientist) to discuss the details. The IACUC voted to suspend the post-doc, who was trained by the staff scientist, from participating in animal activities until the review of this matter was complete due to a history of noncompliance. The IACUC also voted to report this incident to the Office of Laboratory Animal Welfare (OLAW) at the NIH, AAALAC, and the prime awardee's IACUC. An in-person interview was conducted between the IACUC, the PI and his laboratory staff. During the interview, the cause of the anesthetic error and the failure to adhere to the approved protocol were discussed.

The post-doc's admission at the time of the previous incident coupled with a lack of demonstrated remorse or recognition of the seriousness of the violations further underscored the IACUC's concerns, particularly when viewed alongside a prior history of noncompliance and led the IACUC to determine that retraining alone would not be sufficient to prevent future violations. The post-doc was prohibited from animal activities indefinitely.

Strategy #4: Serious Adverse Event

This incident represents a near-miss from a human safety perspective and a serious adverse event within the animal care program. A coordinated and thorough response is essential to address immediate concerns and prevent future occurrences.

- Thorough investigation by the Environmental Health & Safety Team, to include relevant stakeholders:
 - Facilities group / electricians
 - Farm Manager
 - College administration
 - IACUC
 - Veterinary staff
- Conduct a formal root cause analysis to identify contributing factors, including equipment failure, procedural gaps, communication breakdowns, and safety culture.
- Identify and implement corrective actions, which may include:
 - Removal and replacement of unsafe equipment
 - Enhanced inspection protocols
 - Improved hazard reporting procedures
 - Review and revise training programs
 - Evaluate facility design and infrastructure
 - Develop a communication plan to share lessons learned and reinforce a culture of safety and compliance
- Report to the IACUC, IO, and AAALAC

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B10: Cultivating a Strong Research Culture

Session Description

Research organizations often navigate internal tensions between promoting faculty independence and innovation and ensuring compliance with ethical and regulatory standards. Balancing these priorities is critical to fostering a strong research culture—one that supports high-quality, ethical, and compliant research practices. The extent to which an institution embraces the principles of a healthy research culture directly impacts participant safety (both human and non-human) and the integrity of research data. This session will examine findings from a study conducted at a non-research-intensive university to explore how research culture develops and how to identify practical strategies for overcoming barriers to building a supportive and effective research environment.

Learning Objectives

- Define the key characteristics of an effective research culture
- Identify factors that positively and negatively influence research culture, including relationships between institutional leadership, researchers, and research administration
- Examine strategies for promoting an effective research culture that strengthens participant protections, supports high-quality research, and reduces detrimental research practices

Speakers

- Josh Mangin, PhD
- Nichelle Cobb, PhD, CIP

Significance

Research culture, defined as the behaviors, values, and norms that shape the research environment, is critical to the modern research organizations because it serves as the foundation for both scientific integrity and institutional success. In an era of shifting federal mandates and technological disruptions like generative AI, understanding how to construct and sustain a resilient and effective research culture is no longer an administrative luxury but rather a prerequisite for maintaining public trust and promoting scientific progress. The degree to which organizations embrace and exhibit the principles of an effective research culture can affect the safety and welfare of research participants (human and non-human) and data integrity.

Organizations that conduct research often experience internal tensions that influence their research culture that can be affected by external factors (e.g., political climate). For example, organizations encourage researcher creativity and faculty independence while ensuring the protection of research participants and meeting compliance requirements. Likewise, researchers and administrators can clash over the complexity of maintaining research compliance and engaging in innovative research.

How can these competing priorities be manifested in a way that promotes a research culture that supports high quality, ethical, and compliant research? To answer this question the session drew upon a qualitative descriptive case-study conducted at regional comprehensive university (RCU) to explore how research culture is constructed and strategies for addressing potential barriers to establishing an effective research culture. Lessons learned from the case study connected to the importance of how mindsets influence and maintain an institution's research culture. Therefore, an essential message of this session was challenging a common mindset of viewing research compliance offices mainly as a policing function to embracing an office essential to collaborative partnership and promoting researcher professional development.

Content

The session began with the presenters outlining three primary objectives: (1) defining what constitutes an effective research culture, (2) identifying the internal and external factors that influence that culture and (3) examining strategies to improve participant protection and research quality while reducing harmful practices.

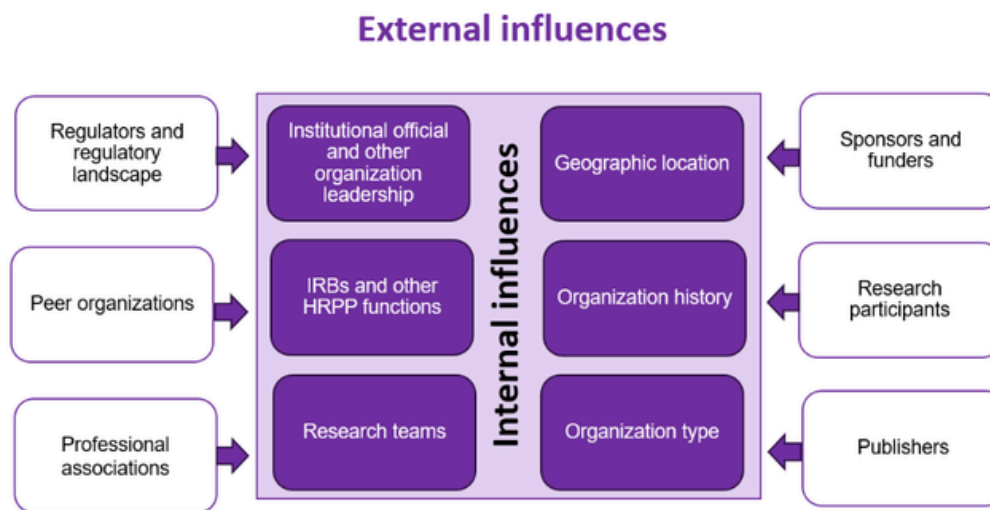
Attendees were asked to imagine their workplace as a swimming pool (Hawkins, 2021) with the purpose of helping them visualize their institutional roles and environment. Elements of the swimming pool prompt guided attendees to determine whether their administrative or compliance office felt like the deep end, a lifeguard stand, or a sunbathing chair; identify key institutional players; and determine internal and external influencers, such as institutional leadership and external funding sources. The swimming pool activity was followed by a de-briefing and segue into introducing the concept of research culture, describing research culture as the who, what, when, how, and why of research (Caschi & Adams, 2020).

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The presenters discussed internal and external influences on research culture (see Figure 1). For example, events in an organization's history can influence research culture to focus on certain initiatives (e.g., community engagement in research or additional scrutiny of biospecimen use). External influences on research culture can be how government regulators act. If Federal agencies conduct frequent audits and inspections, for example, an organization can implement stricter, less flexible approaches to avoid regulatory noncompliance, which can adversely affect relationships between researchers and the compliance/ethics functions and create additional research-related burdens.

Figure 1.



Presenters shared the results of a recently conducted case-study exploring and describing research culture of a regional comprehensive university located in northern New England of the United States. Findings from the case study emphasized practices to help build an effective research culture, such as through identifying and supporting champions who advocate for an effective culture, fostering research collaborations within and outside the institution, and connecting current research initiatives to the institution's historical legacy and locality. Through the discussion of the case, the presenters discussed symbols that help reflect the essence of the university's research culture. One of the symbols, for example, is the lobster, an important image of the region, which reflected the regionality of many of the research projects conducted at the university, as well as the rich history of the university (e.g., the university hosting conferences and trainings and commonly part of those events would include hosting a lobster boil dinner). Attendees were asked to create an icon/mascot that helped represent their institution's research culture, and describe that mascot in one to two words, and share those words on Mentimeter. Examples they provided included: partnership, lone wolf, security guard, mountains, old ship, and floating dumpster.

The presenters made the case that attendees should care about their organizations' research culture because the research culture plays a significant role in the attraction/retention of the talent, prioritizing research participants safety, engaging in data integrity, fostering quality research practices, and promoting public trusts and institutional reputation (Casci & Adams, 2020; Field et al., 2024; McCray et al., 2024). Using human research protection programs (HRPPs) as an example, the presenters explored indicators of positive research culture by role (see Table 1).

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Table 1.

Role	Indicators of an Effective and Positive Research Culture
Organizational Official	• Knowledgeable and expects research teams to be knowledgeable about human research protections • Promotes the independent function of IRBs • Provides adequate resources to support IRBs/HRPP • Solicits constructive feedback about the IRB and HRPP • Establishes an expectation for collegial relationships between research teams and the HRPP/IRB • Fairly investigates complaints received about the IRB/HRPP or research teams • Trusts and listens to the experts/experience of those in the field • Supports community outreach
HRPPs/IRBs	• Have clearly defined responsibilities and collaborate across functional areas (e.g., COI and IRBs sharing information) • Promote decision transparency and base decision-making on regulations • Are knowledgeable and see research teams as partners • Solicit performance feedback from the research community • Conduct ongoing initiatives to improve quality, efficiency, and effectiveness of the HRPPs/IRBs • Work with research teams to ensure they have the necessary skills and knowledge to protect research participants (e.g., using post-approval monitoring as an educational tool)
Research Teams	• View the IRB/HRPP as a partner in protecting research participants and conducting ethical research • Proactively consult with relevant HRPP offices and reach out when questions occur • Report potential noncompliance to relevant offices and committees rather than discovered via audits • Participate in quality improvement efforts • Provide mentorship to other researchers, including about research ethics and regulatory issues

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The presenters asserted that key characteristics of an effective research culture include commitment to high-quality and ethical research, promoting transparency of the research process and results, utilizes and supports mentoring and educational opportunities to train and retain researchers, strong communication from leadership and throughout the organization, and prioritizing supporting and inspiring researchers to conduct research (Casci & Adams, 2020; Field et al., 2024; Johnson, 2013). As the session came to a conclusion, the presenters proposed adopting the mindset that HRPPs and Research Compliance Professionals provides opportunities broader than preventing and addressing research of misconduct; it is about promoting, encouraging, and assisting rigorous, honest, authentic, reliable, and valuable research (De Peuter et al., 2024). This can be accomplished by seeing compliance requirements, such as Responsible Conduct of Research (RCR) training as opportunities for professional development. By viewing required compliance training as professional development, allows compliance professionals to incorporate helpful topics such as leadership development, creativity and innovation, research design, and scientific communication into current RCR programs.

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D10: On Shaky Ground: Best Practices for Handling Research Suspensions

Session Description

Suspending a research activity is one of the most challenging and sensitive actions an IACUC or IRB can undertake. This session will explore the complexities that make suspension decisions feel like navigating a precarious house of cards. Participants will examine key factors contributing to these difficulties and learn practical strategies to prepare for, manage, and respond effectively before, during, and after a suspension to minimize disruption and maintain institutional integrity.

Learning Objectives

- Differentiate between the practical challenges of implementing a suspension and the perceived fears that may influence decision-making
- Clarify the roles and responsibilities of committee members, administrators, and institutional leadership throughout the suspension process
- Identify strategies to address and reduce both actual and perceived difficulties related to suspension decisions

Speakers

- Walter G. Wiles, IV, MS, CPIA
- Carley Emerson, MS, CIP, CCRP

Significance

Deliberating whether to suspend human or animal subject research is among the most challenging responsibilities faced by an IRB or IACUC. Although the regulations clearly describe the authority to suspend research and the procedural steps involved, determining when suspension is warranted is often far less straightforward. Committees must distinguish between genuine concerns that fall within their oversight responsibility and issues driven by uncertainty or risk aversion that may be outside their role.

Established practices for suspending research are essential for both IACUC and IRB programs, as they enable a timely and appropriate response to unexpected risks or instances of noncompliance. Clear procedures allow study activities to be suspended immediately when necessary, protecting human participants, animals, and the integrity of the research. Institutions must understand when suspension is warranted, how it differs from termination, and how to properly document and communicate these decisions in accordance with regulatory requirements. In addition, oversight committees must be able to distinguish between concerns that fall within their authority, issues that should be addressed by other institutional offices, and matters that do not warrant action.

Content

Suspending research activities in human or animal studies is a complex oversight action that requires a clear understanding of regulatory authority, institutional responsibilities, operational considerations, and best practices. In both IRB and IACUC contexts, a suspension involves halting some or all previously approved research activities in response to concerns related to safety, welfare, or regulatory compliance. Although suspensions are sometimes perceived as punitive, they are fundamentally protective measures intended to safeguard research participants, animals, and the integrity of the institution.

In the context of animal research oversight, “activities” include any manipulation of an animal for research, teaching, or training purposes. IACUCs are granted explicit authority under federal regulations, including the Public Health Service Policy and the Animal Welfare Act, to suspend approved activities when they are not conducted in accordance with the approved protocol, applicable regulatory standards, or institutional assurances. Such action requires a majority vote of a convened quorum of the committee. Following a suspension, the Institutional Official, in consultation with the IACUC, is responsible for reviewing the circumstances leading to the action, ensuring that appropriate corrective measures are implemented, and reporting both the suspension and its resolution to the relevant federal oversight agencies, such as OLAW or APHIS.

The suspension process depends on clearly defined roles and responsibilities. Committee members are responsible for reviewing the relevant information, deliberating, and voting on whether a suspension is warranted. Administrative staff support this process by collecting and organizing documentation, facilitating internal communication, maintaining records, and coordinating follow-up activities. The Institutional Official oversees the implementation of corrective actions and fulfills all required external reporting

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obligations. Effective coordination among these groups is essential to ensure that suspensions are managed in a timely, transparent, and regulation-compliant manner.

In the oversight of human subjects research, similar principles apply. IRBs have explicit regulatory authority under 45 CFR 46.113 and 21 CFR 56.113 to suspend or terminate research approval when studies fail to comply with IRB requirements or present unanticipated risks to participants. Depending on the nature and severity of the concerns, a suspension may involve halting all study activities or limiting specific components, such as recruitment, study interventions, or follow-up visits. Research that has been suspended remains under IRB oversight and subject to continuing review until the suspension is lifted or the study is formally terminated.

Research may be suspended for a variety of reasons, including noncompliance with approved protocols or regulations, unanticipated problems involving risk to participants, participant complaints, or concerns related to data integrity. In contrast, voluntary pauses initiated by investigators do not constitute IRB-imposed suspensions and are managed separately.

When considering whether suspension is warranted, oversight bodies must evaluate multiple factors. These include whether the issue meets the definition of serious or continuing noncompliance, whether it qualifies as an unanticipated problem involving risk, and what actions are necessary to protect current participants. Committees also consider appropriate procedures for participant withdrawal, whether and how participants should be notified, and whether reporting to institutional leadership, sponsors, or regulatory agencies is required. In some circumstances, concerns can be effectively addressed through measures short of suspension, such as protocol modifications, participant reconsent, or enhanced monitoring.

Once a suspension is implemented, research teams often face significant operational challenges. Investigators must ensure the continued safety and welfare of enrolled participants or animals, communicate clearly and sensitively with affected individuals, and develop corrective action plans that address the underlying issues. Logistical complexities may arise when access to research systems must be restricted, additional training is required prior to resuming activities, or data analysis and publication efforts must be paused. These challenges are often amplified in multisite or international studies, where maintaining data integrity and coordinating activities across teams and locations requires careful planning and communication.

IRB and IACUC staff also face significant regulatory and compliance challenges during a research suspension. Clearly documenting concerns, issuing timely notifications, coordinating with multiple institutional offices and stakeholders, and preparing required regulatory reports often demand substantial time and effort. Committees must carefully review corrective action plans and determine whether they adequately address the identified issues, meet regulatory expectations, and remain within the committee's scope of authority. The need for communication that is both rapid and precise increases the workload and pressure on oversight bodies, particularly when investigators disagree with the determination or choose to appeal the decision.

In addition to these practical challenges, fear-based concerns frequently arise. These may include worries about potential reputational harm to investigators or the institution, legal or financial liability, delays in scientific progress, loss of funding, or heightened regulatory scrutiny. It is essential to differentiate between genuine risks and perceived fears to ensure that oversight decisions are grounded in objective evidence, regulatory requirements, and the protection of human participants or animals, rather than assumptions or speculation.

Several best practices can facilitate effective management of research suspensions. Clear and comprehensive Standard Operating Procedures promote consistency and set transparent expectations. Checklists assist in tracking documentation, notification responsibilities, and reporting timelines. Open and transparent communication with investigators, institutional leadership, and sponsors helps reduce confusion and preserve trust. Providing structured guidance to research teams can lessen stress and support timely and meaningful corrective actions. Ongoing education for committee members and administrative staff further strengthens understanding of ethical principles, regulatory authority, and compliance obligations, supporting a proactive and thoughtful approach to oversight.

When institutions invest proactively in training, clear communication channels, well-developed policies, and cross-unit coordination, the suspension process is more efficient and less disruptive. Ultimately, successful oversight requires a clear

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understanding of the oversight body's scope of responsibility and a focused approach to those areas within its authority, ensuring the protection of research participants and animals, regulatory compliance, and the preservation of institutional integrity.

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E10: One of these Members is Not Like the Others: Community Member Recruitment, Education, and Retention

Session Description

Recruiting and retaining dedicated non-scientist and non-affiliated members for IRBs and IACUCs is often seen as a critical yet challenging task. These members offer essential perspectives that enrich research ethics deliberations, but finding, welcoming, and engaging them requires intentional effort. This interactive session will highlight innovative strategies to identify and attract community representatives, create a welcoming and meaningful experience, and provide ongoing support to sustain their involvement. Participants will gain practical tools, inspiring success stories, and fresh ideas to build stronger, more diverse, and well-informed committees.

Learning Objectives

- Apply effective strategies for identifying and recruiting community and non-scientist members
- Evaluate various onboarding approaches to support new committee members
- Develop retention techniques and foster a culture that actively values and supports diverse member contributions

Speakers

- Nyssa Towsley, MS, CIP
- Cecilia Brooke Cholka, PhD, CIP
- Rachel A. Murray, MS, CPIA, LATG

Significance

By regulation, both IRBs and IACUCs are required to have community representation in the membership of their respective committees, through ensuring membership of individuals who are otherwise unaffiliated with the institution. The role of a community member on either committee is crucial in ensuring ethical review of research, by representing community attitudes and values during the review process. Unfortunately, recruitment and retention of high quality community members remains a challenge for ethics committees. Current approaches to recruitment of these members can be inadequate for ensuring diversity of perspectives and representation on the committees. Traditional recruitment efforts often rely on informal, word-of-mouth strategies, such as personal referrals from current board members. Individuals within already-known social networks may not reflect the populations or research portfolios under review, underscoring the need for more intentional recruitment practices. Additionally, relying on the networks of affiliated individuals makes it difficult to find truly unaffiliated individuals for a committee; this can be compounded when the institution is the main employer in a region. Oftentimes, these challenges may result in only cursory compliance with these regulatory requirements, rather than resulting in meaningful engagement with the community.

When community members are successfully recruited, onboarding and retention remain a challenge. Community members often report feeling overwhelmed, intimidated, or unwelcome during onboarding processes and during participation in reviews. Careful onboarding, meeting management, and board culture are key to the retention and full engagement of these valuable members.

Content

Recruiting Community Members

This session defines “community member” as a member who is non-scientific and non-affiliate, but we recognize that some community members may be scientific or non-scientist members may be affiliated.

One significant challenge in recruiting community members is communicating with the general public about committees they may not understand or have prior exposure to. Explaining research oversight work requires the use of clear, plain language —often more difficult than anticipated given the complexity of research and compliance functions. Even research compliance professionals frequently note that their own families struggle to understand what they do. To address this, recruitment efforts should frame research within a community impact perspective, clearly connecting institutional research activities to the community. While research outcomes may not always have immediate or direct effects, it is important to articulate how community member participation contributes to ethical decision-making. Emphasizing that community member perspectives are valued and influential is critical, as some potential members may feel their voices are not relevant or will not carry weight.

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Effective recruitment materials should clearly explain what the committee is, what it does, who serves on it, what it reviews, why service is valuable, member expectations, compensation or reimbursement (if applicable), and next steps for expressing interest.

We recommend a broad outreach approach for more successful community member recruitment. Offices should actively seek out diverse community organizations, such as patient advisory groups, support services, faith-based organizations, student groups, LGBTQ+ organizations, parent associations, and volunteer networks. Creativity and inclusivity in outreach strategies can significantly enhance the opportunity to recruit engaged, representative community members. It was noted that IACUC community member recruitment will often differ from IRB member recruitment. While IRBs can easily cast a wide net with their messaging, IACUCs may need to use more targeted outreach methods, due to the sensitivity of their work.

Onboarding Community Members

Thoughtful and comprehensive onboarding processes are essential to long-term success and engagement. Initial onboarding should collect information about the member's experience, areas of expertise, and personal perspectives. This information supports intentional reviewer assignments, promotes diversity of viewpoints, and helps ensure that members are matched with studies where their input will be most meaningful. Recognizing that individuals bring complex and multifaceted experiences strengthens the committee's overall review process.

Clear communication of expectations and benefits is critical from the outset because serving as a reviewer is unfamiliar to most individuals. People want to do a good job and it is important to define what a "good job" is. Training is a key component of onboarding and should include both regulatory requirements and committee-specific expectations. Community members should not be restricted to reviewing limited aspects of research; with appropriate support, they are capable of understanding regulatory frameworks and contributing fully to protocol reviews. Avoid front-loading all regulatory training, as regulatory knowledge develops best over time alongside practical experience reviewing research. Orientation should also address meeting structure, review workflows, and the scope of member responsibilities.

Providing tools such as review checklists, templates, and example reviews can help new members feel prepared. Pairing community members with experienced staff or committee members through shadow reviews or structured mentorship is particularly effective. Mentorship relationships should be intentionally designed to support both participants while remaining flexible to individual interests and needs. Providing community members with opportunities to better understand the research that they help review, such as lab tours or research demonstrations, can further strengthen engagement.

Ongoing feedback and evaluation is invaluable. Regular check-ins, timely constructive feedback, and meaningful evaluations help reinforce good practices, identify growth areas, and demonstrate commitment to the community member experience. Thoughtful onboarding and continued support can make the difference between passive membership and fully engaged, impactful participation.

Keeping Community Members

Retaining community members is important for long-term committee sustainability. Continuous engagement requires intentional planning and support. Several factors should be considered to ensure community members remain active, valued, and committed to committee service.

Meeting structure plays a critical role in participation. Committees should assess whether in-person attendance is required or whether virtual options are feasible, and prioritize flexibility that best supports community members. Assigning protocol reviews and other substantive responsibilities helps ensure members feel meaningfully involved rather than peripheral observers. During meetings, chairs or senior members should intentionally invite community members to share their perspectives, reinforcing that their contributions are valued and preventing unintentional exclusion. Practical considerations significantly impact retention. Meeting times should account for work schedules, and institutions should consider providing support such as parking passes, meals, or travel accommodations. Meetings should also be efficient and well-managed; lengthy or poorly structured meetings can place an undue burden on community members and deter continued participation.

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Ongoing education and professional development are also essential. Community members should have access to continuing education opportunities, offered through multiple modalities whenever possible. When training occurs during meetings, alternative access, such as recorded sessions or follow-up discussions, should be provided. Training should be supported through interactive approaches, such as one-on-one conversations or check-ins, rather than relying solely on lengthy written materials. This allows community members to ask questions, clarify expectations, and better understand the relevance of the training.

Incentives can further support engagement. These may include stipends, gift cards, reimbursement for travel or parking, meals, or other small institutional tokens of appreciation. Opportunities for social connection, such as appreciation events or committee dinners, help foster a sense of belonging.

Ultimately, while logistical and financial support matter, long-term engagement depends on community members believing in the committee's mission and seeing the value of their contributions to ethical research and the advancement of science.



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N16: A Guide for Emerging Leaders in Regulatory Compliance

Session Description

Embarking on a professional journey from individual contributor to leader can be challenging, especially when you don't know what you don't know. This session will provide a crash course on making the transition from senior regulatory compliance staff into leadership. Attendees will gain case examples, strategies, and areas of reflection designed to support success in taking the next professional step.

Learning Objectives

- Apply strategies at various levels of influence, from the personal to the institutional, to make the transition from individual contributor into leadership roles
- Analyze examples from each of these levels of influence, across research compliance units; recognize through these examples the foundational knowledge and skills necessary to transition to leadership, as well as hurdles often faced during that transition
- Leverage existing resources to engage in the professional development necessary for successful transition into a leadership role

Speakers

- Nyssa Towsley, MS, CIP
- Elaine K. Kim, BS, CPIA
- Stephanie Trout, M.S., CPIA

Significance

The field of research protections is ever-evolving, and there is a need to develop the next generation of leaders. Senior individual contributors need to develop leadership skills in order to transition into middle- and upper-management roles. Even those at the senior leadership level still need to practice and hone their leadership skills. Individuals can exhibit leadership skills at any level of an organization, and those skills are indeed needed at all levels of an organization. Effective leaders are able to communicate the stories of their teams and units, and through that communication are able to advocate for resources, garner support for initiatives, and shepherd in changes necessary to continually improve compliance operations.

Content

This session covered three themes: pursuing leadership roles; adapting to leadership and challenges new leaders often face; and how new leaders can interact with senior- and executive-level leadership.

The presenters shared their experiences with making the transition from senior individual contributor to leadership roles.

Primary takeaways from the presenters' experience included:

- Development and learning
 - Seek new opportunities to lead teams/projects.
 - Seek out cross-training within/outside your unit.
- Preparing application materials
 - Distinguish between a resume/CV and a cover letter; submit both.
 - Cover letters can be longer than one page, and are narratives that describe your leadership style and philosophical approach to the work, as well as providing specific examples of achievements/duties in the resume/CV.
 - Include metrics or numerical measurements of your work output wherever possible in materials.
- Interviewing tips
 - Be on the lookout for institutional "red" and "green" flags.
 - "Red flags" are signs that an institution may not be a good fit; examples include
 - Poor communication throughout the process; not being respectful of your time or expertise.
 - Not enough time allotted to interviews for candidate questions, or little/no opportunities to meet stakeholder groups.
 - Inconsistencies between leaders/groups about priorities or hopes for the role being interviewed.
 - Adversarial tones or attitudes regarding compliance.
 - Ask questions during the interview:

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- Ask questions during the interview:
 - Ask different questions of different groups; questions for your potential future boss will differ from questions for potential future direct reports.
 - Ask the same/similar questions of different groups, to check for consistency in goals, priorities, etc.
 - Prioritize questions about culture, the position, and its likely challenges/opportunities first; save logistical questions for the point of offer (e.g.: salary/benefits, schedule, etc.).

Presenters discussed the transition from individual contributor to leadership, and common challenges faced in making that transition, particularly within the same institution.

Themes included:

- Navigating social relationships within the office, particularly during a peer-to-leader transition within an organization
 - Be careful connecting on social media with colleagues, especially subordinates.
 - Be mindful of power dynamics and structures at play with new positions, especially with respect to any former peers.
- Adapting
 - Being a leader is entirely different work from the day-to-day operations of a compliance unit.
- Mentorship
 - You succeed when your team succeeds.
 - Help your team achieve their professional goals.
 - Engage in mentorship for yourself, you still have a lot to learn!
- Delegation
 - Leaders must let go of control of things wherever possible – doing something differently from how you would do it, doesn't mean it's not a good way to do it.
 - Learn to give feedback in a way that allows for variations in style and approach, while ensuring that staff work is high quality and effective.
- Conflict resolution
 - Conflict is inevitable, and is not inherently bad. Conflict only becomes problematic when we view it as two sides opposing each other, rather than both sides facing the problem together respectfully.
 - Effective conflict resolution encompasses:
 - Mindfulness – be aware of your emotions both mentally and physically, during conflict.
 - Redirection – when conflict becomes adversarial, or unproductive, refocus the conversation towards solutions.
 - Curiosity – approach information-gathering from a place of genuine curiosity; a neutral place to reduce defensiveness, e.g. “I’m curious about...” or “Can you help me understand...”
 - Knowledge of resources – consider whether you and/or your team need training on conflict resolution or healthy conflict in the workplace. Utilize resources to support this growth.
 - Networking contacts –impartial third parties to run scenarios past is invaluable (but be mindful of obscuring details for privacy).

The final portion of the session discussed how new leaders can begin to interface with other leaders, especially senior- or executive-level leaders. The basic takeaways stressed the importance of preparing yourself, your group, and your environment.

- Self preparation:
 - Be prepared for the meeting and ready to discuss your agenda items,
 - Work with any subject matter experts (SMEs) or collaborators that are working with you on that item ahead of the meeting.
 - Ensure that you are also aware of when you need to listen and learn in this meeting, assuming you are not the “owner” of this meeting and others are also presenting their own topics for discussion.
 - Consider your goals for this meeting, so that you can look for differences and overlap between groups.

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- Team preparation:
 - Talk with your team ahead of the meeting about the group goal.
 - Ensure everyone has a clear understanding of the goals and resolve questions from the team.
 - Coach the team on how to engage and listen during this meeting.
 - Adjust the agenda to address any additional concerns or questions from the team.
- Meeting Environment:
 - Create a positive environment for discussion.
 - Ensure all attendees feel comfortable to be present, listen actively, and engage.
 - A positive, collaborative meeting environment allows everyone to participate and provides a good foundation to build off in front of leadership and future meetings.

Examples were shared about putting thought into intentional “mood-setting”:

- Create a meeting culture between multiple leaders that lends itself to a productive and engaged environment.
- Post-meeting conversations also benefit, because expectations for interaction were established during the meeting.

Additionally, your leadership goals may need to align more with the project or task at hand.

- The project is a tool to help achieve personal/professional goals, e.g. be in a cycle of “prepare, work, debrief, and repeat.”
- Think about what you want out of your work, e.g. leadership goals for yourself, and creating a peer/mentor community to achieve these goals.
- Relationship-building is required at the senior/executive level to build trust and to align unit directions strategically. Functionality between leaders increases with trust, which is tied to increased understanding of the other leader’s role in the organization.
- Take notice when you attend meetings where it sounds like nothing was accomplished, but your colleagues have a lengthy to-do-list.
- Notice how communication happens, who does the work, and who gets credit for the successes.
- Decide for yourself if that is the environment where you want to emerge as a leader. When you can show up authentically, that is when you, your group, and the organization will succeed.



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A09: PLENARY: AI Policy for Institutional Leaders

Session Description

As AI use in the workplace continues to evolve, it increasingly relies on access to critical institutional data and drives decision-making in the absence of formal policies. Institutional leaders should prepare their offices for use of AI that is guided by clear principles, ethical standards, and well-defined procedures. This ensures AI is applied responsibly, transparently, and effectively—supporting decision-making through thorough analysis and automation while upholding integrity and accountability.

Learning Objectives

- Establish your organization's risk tolerance for AI use by identifying both current and anticipated applications, including the handling of sensitive or confidential data
- Consider the ethical and legal concerns with using institutional data in the context of other privacy policies, data security/sharing, bias mitigation, and confidentiality
- Identify regulatory issues related to intellectual property and international responsibilities for organizations with remote research campuses in the EU, and how these differ from the US

Speakers

- Minal M. Caron, J.D.
- Judy Birk, JD
- Mariette Marsh, MPA, CIP, CHPC, CHRC

Significance

Artificial Intelligence (AI) provides untold, and as of yet, largely unexplored opportunities to support the conduct of human research in an academic setting. Researcher time spent on administrative efforts may be partially or significantly reduced, compliance may be increased through systematic evaluation of content to assess for congruency and completeness, complex data analysis may be enhanced, and previously undetected data patterns may be elucidated.

Importantly, however, the training of AI incorporates historical concepts en masse, which may be proven or unproven and hold the potential for AI to incorporate inaccuracies, bias, or hallucinations into its outcomes.

Universities operate at the intersection of research, education, and public trust. Additionally, these institutions generate and manage large volumes of sensitive data ranging from student records and academic performance to proprietary research and grant-funded projects. Establishing a defined risk tolerance through a clear AI policy helps ensure AI tools are used in ways that protect this data while still supporting innovation in teaching and research.

Ethical and legal considerations are significantly heightened in academic research environments. Universities bear responsibilities not only for upholding academic integrity and protecting intellectual freedom, but also for navigating a complex web of legal obligations - from federal research regulations and funding agency requirements to data privacy laws such as HIPAA and applicable state statutes. Without clear guidelines, AI systems could unintentionally reinforce inequities, misuse data, or compromise confidentiality. A strong policy helps align AI use with institutional values, ensuring transparency, fairness, and accountability in both administrative and academic applications.

International collaborations and cross-border research further complicate the legal landscape for AI use. The European Union's AI Act (2024) classifies AI systems according to risk level and imposes substantial obligations on developers of high-risk AI—obligations that may extend to U.S.-based research institutions conducting work in or with EU partners. These requirements differ significantly from the current U.S. federal posture, which under the Trump administration has shifted toward industry-led self-governance following the revocation of the Biden-era AI executive order. Clear policies help institutions navigate intellectual property rights, data-sharing agreements, and legal obligations across jurisdictions, reducing the risk of violations or funding disruptions.

Ultimately, robust AI policy frameworks for institutions of higher education serve to safeguard students, faculty, and research integrity while enabling institutions to responsibly adopt emerging technologies. It ensures that innovation enhances learning and discovery without compromising ethical standards or legal compliance.

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Introduction

The opportunities for adoption of AI in academic research are seemingly unbounded by the creativity of researchers in their desire to both reduce administrative burden and propel science forward with a speed not previously achievable. However, inherent in the use of AI is each researcher's necessary recognition of its benefits and limitations and the understanding that institutional leadership must address responsible implementation of powerful AI tools.

Use Cases in The Workplace and Research

Researchers are under tremendous pressure to innovate concepts, conduct research in a timely manner, and deliver meaningful results. Each opportunity for innovation must be coupled with a close evaluation of AI output to address the validity of the output and the potential for bias or hallucinations. AI is not inherently generating new information, but is combining, mixing, and distilling vast amounts of information from its training and has the potential to carry along any errors, bias, misinterpretation, or any other unintended information. Human validation, to the extent possible, is a consideration in the use of AI.

For example, AI may be useful to organize and facilitate the writing of large, complex documents or review research materials to validate regulatory compliance. This can save both time and effort. However, care must be taken to avoid unintentionally introducing proprietary materials into the AI tool or failing to identify misinterpretations of regulatory or other compliance assessments.

AI models may assist to identify areas for research interventions in specific populations. However, if the models amplify or replicate bias found in the training data, inaccurate assumptions may be applied to the populations. Similarly, AI may be used to evaluate large amounts of personal, identifiable data with a goal of facilitating policy development or implementation of new programmatic improvements. Trust in researchers can be breached if the data become subject to unintentional data leaks or unauthorized access.

Finally, information collected by AI in clinical care situations may provide opportunities to reduce administrative burden and to assist with diagnosis. However, patient information collected and compiled by an AI tool during clinical care visits may also unintentionally include identifiable information about 3rd parties (e.g., family members) and may raise issues of informed consent if the information is used secondarily for research without participant consent. Additionally, deep learning AI models may be able to accurately identify specific diseases based on patient symptoms. However, AI models may be opaque about the specific criteria they utilize thus raising concerns about reliability, bias, and trust.

Harnessing the power of AI provides science a powerful tool to rapidly advance progress as long as inherent limitations are recognized and managed to maintain trust and minimize risk.

AI Policy for Institutional Leaders: Legal Considerations

As research institutions increasingly adopt AI tools, they face a rapidly evolving legal and compliance landscape. This portion of the presentation surveyed three critical areas: the shifting federal regulatory environment, key legal and compliance considerations, and institutional governance frameworks.

The federal landscape governing AI is in flux. The Biden administration's 2023 Executive Order established a framework for AI safety in research, directing funding through NIH and NSF. The Trump administration revoked that order, signaling a shift toward industry-led self-governance and deregulation. No comprehensive federal AI legislation has been enacted, and a provision that would have preempted state AI laws for ten years was rejected by Congress. As a result, institutions must navigate a patchwork of evolving federal and state requirements, making strong internal governance essential.

Research institutions must grapple with a broad set of intersecting legal obligations when deploying AI. NIH and NSF have made clear that AI-generated content in grant applications may constitute research misconduct, with consequences including grant termination. AI tools used in clinical or research contexts may trigger FDA oversight as medical devices. Intellectual property ownership of AI outputs remains legally unsettled, underscoring the need for clear contractual terms with AI vendors. HIPAA and state law govern how institutions may use patient and research data as AI inputs, particularly when outputs are later commercialized. Voluntary frameworks such as the NIST AI Risk Management Framework and the EU AI Act for institutions with international partnerships - establish benchmarks for transparency, fairness, and bias mitigation.

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The Legal Considerations portion of the presentation concluded with a discussion of governance structures for operationalizing these legal and ethical principles. Institutions may choose a lighter model—in which an executive sponsor oversees a broad AI Governance Committee drawing on input from faculty, legal, IT, finance, and research administration—or a more robust structure that includes a dedicated Chief AI Officer (CAIO) responsible for AI strategy and coordination. The CAIO model is gaining traction at large academic institutions as a way to manage the cross-functional complexity of AI adoption, ensuring that procurement, data governance, cybersecurity, and compliance obligations are addressed cohesively.

Risk Tolerance and Policy Development

Navigating AI adoption in higher education includes key legal and operational considerations, emphasizing the need for structured oversight and responsible implementation.

Institutions should establish clear policies and mechanisms to evaluate and continuously monitor AI systems. This includes identifying and mitigating security risks, as well as ensuring that AI outputs are valid and reliable so as to maintain research integrity and public trust.

Being proactive in identifying and complying with applicable regulatory requirements can eliminate risk when combined with real-time monitoring, clear instruction on how models are used, and encouraging experimentation within approved boundaries. For example, certain AI applications, particularly in healthcare or research, may need to meet specific standards such as FDA clearance for software classified as a medical device; while others may not be applicable for regulated data.

The session highlighted the importance of transparency and trust. Institutions should implement mechanisms that clearly inform users when AI-generated outputs have not been reviewed or verified by a human, helping prevent overreliance on automated systems.

Investing in AI education, training, and research is critical so that the AI tools meet the needs of the institution. This ensures that faculty, staff, and students are equipped to use AI tools effectively and responsibly, while also advancing institutional expertise in this rapidly evolving field.

Finally, having a defined roadmap with clear goals, tools, and ethical boundaries will reinforce ethical and appropriate AI use. Overall, the presentation emphasizes that managing AI in research institutions requires a combination of governance, compliance, transparency, education, and ethical safeguards.



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D08: Elevating Science Literacy: How IOs Can Be Research Advocates

Session Description

Managing your institution's research portfolio is already challenging—but IOs are also often expected to advocate for their institution and research at local, state, and national levels. What do you say? Where do you start? Whom do you even talk to and are they the right person to help advance your institution's research agenda? This session, tailored to the unique challenges IOs face, features a panel discussion on effective communication strategies for engaging a wide range of stakeholders—from local boards of trustees to members of Congress. Engage in active dialogue with peers and come prepared for thoughtful discussion.

Learning Objectives

- Understand practical strategies for effective communication with stakeholders who may not be researchers
- Explore what avenues are available to talk with those whom can advocate for your institution's research program
- Take away some key “survival skills” to utilize at your institution

Speakers

- Sarah Rovito
- Sujatha Sridhar, MBBS, MCE

Significance

The current, rapidly shifting scientific landscape is challenging for Institutional Officials, or IOs, due to a number of internal and external factors: expanding regulatory expectations, increased demand for accountability and transparency, pressure to demonstrate the public value of research, and the varied needs and interests of diverse stakeholder groups. Furthermore, many researchers lack the communication skills necessary to effectively explain complex topics to non-specialist audiences or may be uncomfortable engaging with the public during a time of constrained funding and increased scrutiny.

Content

This session began with a presentation by Sujatha Sridhar, Associate Vice President, Research Compliance at UTHealth Houston, during which she detailed the turbulent landscape for IOs at present. IOs need to manage both internal and external risks, ensure compliance, and represent institutional research interests. IOs must consider the varied needs and interests of stakeholder groups including institutional administration and faculty, patient advocacy groups, local leaders, community organizations, the media, and relevant federal and state agencies.

Furthermore, Sridhar shared that many researchers lack the communication skills necessary to effectively explain complex topics to non-specialist audiences. IOs can overcome this by establishing dedicated training programs focused on translating technical concepts into relatable language, providing individual coaching to bolster communication skills, and promoting interdisciplinary partnerships to ensure that research is translated accurately and compellingly for public consumption.

Sridhar posited that incentives need to be restructured to encourage public engagement by researchers, as the current “publish or perish” model does not reward public outreach. IOs can create new incentives and rewards that encourage broader engagement, add communication to promotion and tenure criteria, create institutional awards to recognize and celebrate faculty and students who excel at public outreach, and launch institutional seed grants to fund projects focused on science communication or public engagement.

Sridhar then cautioned that making science accessible requires dedicated resources beyond the individual researcher, advocating for IOs to build institution-wide infrastructure to support and amplify outreach efforts. This could include creating a centralized communication hub, hosting public science events and open houses, and developing partnerships with community organizations to bring science directly to the public and ensure that subsequent research and outreach efforts are designed to meet community needs. Sridhar concluded her remarks by sharing effective practices for relationship building and public engagement.

The session continued with a presentation by Sarah Rovito, Senior Program Officer and Staff Director of the Strategic Council for Research Excellence, Integrity, and Trust at the National Academies of Sciences, Engineering, and Medicine. She shared relevant National Academies reports and efforts, including the August 2016 “Science Literacy: Concepts, Contexts, and Consequences” consensus study report and the work of the Strategic Council.

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Rovito specifically mentioned the 2023 “On Leading a Lab” workshop and proceedings, a 2024 paper published in *PNAS* on “Trends in US public confidence in science and opportunities for progress,” a 2025 preprint on “A Framework for Assessing the Trustworthiness of Research Findings” (published in *PNAS* in 2026), a 2025 strength of evidence chart, and the 2025 “Rethinking Researcher Assessment and Incentives at U.S. Academic Institutions” workshop (proceedings-in-brief expected in 2026).

Rovito then revisited points made by National Academy of Sciences President Marcia McNutt during her 2025 State of the Science Address, during which McNutt advocated for “rebuild[ing] trust with all members of the public.” In her earlier 2024 State of the Science Address, McNutt emphasized the need to “cultivate trust in science,” noting that this can be accomplished by rewarding researchers at all career levels for producing research that is excellent and trustworthy, emphasizing training in research ethics, supporting excellence in science communication, and countering misinformation.

Rovito shared that the most important action that IOs and researchers can take is to listen to the public, understand issues confronting the public, and talk about the ways that science is working to address these issues. Communicating the value of evidence-based science stemming from well-funded research is critical. She concluded her remarks by sharing effective practices for relationship building and public engagement, many of which overlapped with the earlier set shared by Sridhar.

Effective Practices for Science Communication and Engagement (Sridhar and Rovito)

Engage early and strategically

- Build relationships with partners, community members, and policymakers before you need to ask for funding or support
- Participate in national, state, regional, and local networks to expand visibility and influence

Coordinate and stay consistent

- Work closely with your institution’s government relations and public affairs offices
- Ensure messaging aligns with institutional goals and remains consistent across all audiences

Communicate with clarity and authenticity

- Use clear, jargon-free language that resonates with your audience
- Use available communication toolkits and resources to refine your message
- Understand what matters to your audience and personalize communication, highlighting shared interests

Tell compelling stories

- Share memorable, human-centered stories that illustrate how research touches lives and improves the world
- Frame research goals as solutions to community problems and communicate optimism and forward-looking impact

Demonstrate reliability and transparency

- Strive to be a trusted resource, not just an advocate, by offering credible, evidence-based information
- Acknowledge funding agencies and sponsors

Build ongoing relationships

- Follow up regularly, express appreciation, and maintain long-term engagement with partners, community members, and policymakers
- Extend invites to research events, lab visits, and poster sessions

Respect boundaries and ethics

- Understand distinctions between advocacy and lobbying and comply with all institutional and legal guidelines

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Sridhar and Rovito shared three questions and facilitated a robust audience discussion to conclude the session:

- What is a strategy or tactic that you have found works well for IOs and researchers to communicate with key parties who are not scientists or medical professionals, or to communicate with the public broadly?
- What barriers have you encountered in seeking to communicate with key parties who are not scientists or medical professionals, or to communicate with the public broadly?
- What else should IOs and researchers consider when seeking to increase science literacy and public trust in science and to advocate for science and medical research?

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F08: Survival Skills: Navigating Risk in the Current Research Environment

Session Description

In a rapidly evolving research environment, institutions must remain vigilant to both internal and external changes. This session explores how research leaders can proactively identify, monitor, and evaluate changes that may impact their institutions. Speakers will share practical strategies for staying informed, assessing risks and opportunities, and supporting informed decision making through structured, data-driven approaches.

Learning Objectives

- Recognize and prioritize key stakeholders and their concerns, and implement systems to monitor and respond to evolving conditions
- Design and apply data-informed approaches to evaluate institutional risk and determine organizational risk tolerance
- Synthesize and communicate critical insights to inform and support strategic decision-making

Speakers

- Stacy Pritt, DVM, MS, MBA, CPIA, CHRC, EXCS, EcoP(EAR), DACAW
- Mariette Marsh, MPA, CIP, CHPC, CHRC
- Robert E. Nobles, II, DrPH, MPH

Content

There are many challenges to managing institutional risk, and they can be focused on regulatory requirements or operational needs. Notable recent challenges within the regulatory environment include:

- Keeping up with not just changes to federal regulations, but how they are interpreted.
- For 2025 the notable change was the pending implementation (January 1, 2026) of the revised HHS research integrity regulations (42 CFR Part 93).
- Dealing with increasing research security requirements.
- Responding to changes to oversight and allowability of dual use research of concerned and gain of function research which have not been fully communicated by the federal agencies.
- Pressure to reduce or eliminate animal research.

Notable challenges for research compliance and ethics operations include:

- Managing team stress and/or stability when they are constantly informed of changes that they have to operationalize.
- Determining future risk due to “on the horizon” changes that may or may not be implemented (e.g. overhaul of the framework for the oversight of research with biohazards, potential new edition of the Guide for the Care and Use of Laboratory Animals).
- Maintaining resources to support teams.
- Measuring return on investment.

To respond to these changes, institutional leaders need to focus on three main activities described below:

Recognize and prioritize key stakeholders and their concerns and implement systems to monitor and respond to evolving conditions. Different approaches include forming a System-wide Risk Governance Committee to review all risks, including those originating from the research enterprise, or for smaller systems it can be as simple as maintaining open lines of communication between critical decision-making leaders.

Design and apply data-informed approaches to evaluate institutional risk and determine organizational risk tolerance. Metrics across a System, taking into account both workload, trends in non-compliance, and research growth, can allow for holistic decisions about risk and risk tolerance.

Synthesize and communicate critical insights to inform and support strategic decision-making.

- For example, at the Texas A&M University System, the Research Compliance Office instituted training for all new Institutional Officials, most of whom have never previously served in that role.

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- This training allows them to understand the regulatory and ethical risks in major areas of research compliance (animal, human, biohazard, conflict of interest, and research misconduct) so that they can make effective decisions and establish an appropriate research culture at their institution. Additionally, the risk of continuing with paper-based research committee operations was too high, so the System also implemented a commercial protocol management software system across 12 institutions.
- At the University of Arizona (UA), effectively managing institutional risk and strategy requires identifying key stakeholders, understanding their concerns, and coordinating efforts across leadership offices such as the President, Senior Vice President of Research, and Research Operations. Arizona utilizes a data-informed approach to assess risk, define risk tolerance, and to guide decision-making around resources like budget and staffing. Maintaining a current spreadsheet of volume, staffing, and resources tailored to each program provides a tool to access when there are immediate needs or challenges (e.g. Protocol volume or proposal submissions per staff member, square footage of lab space, or number of approved registered users, or utilizing audit results to direct areas of risk). Ongoing monitoring of policy and operational trends is essential through weekly dialogue between partner offices, along with synthesizing and clearly communicating concerns or needs through numerous avenues. Close collaboration with stakeholders, such as Associate Deans for Research, ensures that decisions remain responsive, strategic, and aligned with institutional priorities.

As a community, we are in this together. We need to pay attention to what is happening around us and gather the right information to ensure that we remain effective and efficient. Additionally, we need to nourish our networks and teams and remain optimistic about the future.

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A01: Bot or Not? Fraud, Data Integrity, and the Role of the IRB in the Online Survey Sphere

Session Description

Web-based data collection has been a widely used method in research for over two decades. In recent years, however, online surveys—especially those offering monetary incentives—have become increasingly vulnerable to fraudulent participation. This session will examine how IRBs can support investigators in identifying and responding to instances of fraud, while also addressing participant concerns related to withheld compensation or negative user ratings. Presenters will discuss the role of institutional policies, SOPs, and guidance documents in promoting ethical and consistent responses to these emerging challenges.

Learning Objectives

- Identify common forms of fraud in online surveys and explore strategies to prevent and mitigate fraudulent responses
- Analyze case studies of suspected survey fraud and evaluate IRB strategies for effective response
- Identify practical tools and procedural approaches IRBs can use to address and manage confirmed incidents in online survey research

Speakers

- Jessie Hemmons, M.S.
- Julie Simpson, Ph.D.

Significance

For the past two decades, researchers have been able to access more diverse, hard-to-reach participant pools through the use of online data collection. More recently, however, online studies have become targets for fraudulent respondents, particularly when researchers offer monetary incentives for participation. In this session, the presenters described the current environment for online data collection from human participants, examined two cases, outlined strategies for researchers and Institutional Review Boards (IRBs) to minimize fraudulent responses and protect data integrity, and discussed the challenges of balancing data integrity with participant welfare.

Content

The presenters opened the session by describing the advantages and challenges of conducting online research. Advantages include greater geographical reach, access to hidden/marginalized/stigmatized populations, increased privacy for participants, convenience and efficiency, larger and more representative samples, ease of data entry and analysis, and reduced resource utilization. The challenges include participant self-selection bias, lack of participant validation, decreased data integrity, repeat respondents, bots, and coordinated human fraud.

Next the presenters provided an overview of the history of online research from 2005 to 2025. In 2005, online surveys were novel and gave researchers access to broader participant pools. There were limited options for hosting surveys, and most had a simple design. There was also limited internet and smartphone access, and most Facebook accounts were connected to real users who saw online advertisements. By 2015, smartphone and internet usage increased significantly, and researchers started conducting interventional research online. Bots, fake social media accounts, and repeat respondents emerged, causing researchers to experience data quality issues. In 2025, there is now a broad market for online research, with multiple tools that offer complex structural design. There has also been a significant rise in fraudulent respondents, with survey farms, coordinated fraud rings, extensive bot activity, and the rise of LLMs used to create personas and respond to survey questions.

Online enrollment in research studies has grown and changed exponentially. Recruitment ads are posted online, which often list the enrollment criteria and incentives. Snowball recruiting (or sharing links) is generally allowed for hard-to-reach populations. Screening surveys ask minimal questions, and often include yes/no questions directly related to eligibility. There is generally no validation of personally identifying information for exempt level protocols, and good faith belief that any participant personally contacting the research team is legitimate.

The presenters discussed a case in the literature (Shaw et al., 2025), known as the “Stormtroopers” paper. The researchers in this paper concluded that 99.75% of respondents to their online behavioral survey were fraudulent, and reported that it took over 90

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hours of work to verify the legitimate respondents. The researchers used a variety of techniques to identify fraudulent respondents and created an implementation guide for online researchers to mitigate fraud. The second case involved one of the presenters, where the researchers discovered direct evidence of coordinated fraud. They applied the recommended bot and fraud checks – collecting IP address, geolocation, and time zone; implementing Qualtrics fraud detectors and reCAPTCHA; and adding irrelevant screening questions and attention check questions. After the study was listed on ClinicalTrials.gov, but prior to posting any recruitment ad, the researchers were bombarded with email inquiries to sign up. The trial required participants to download a remote-monitoring app as part of the study procedures. To investigate suspicious enrollment activity, the researchers decided to check the sensor and keystroke data collected in the app. After digging into the raw data and checking language, app usage, and GPS data, they concluded that 97% of respondents were fraudulent.

The researchers found respondents coordinating to defraud researchers by sharing links, eligibility criteria, and tips for using generative AI to contact research teams and respond to surveys. They found user groups dedicated to sharing study information and providing support, selling research-related services such as VPN access and US email addresses, social media accounts with pre-loaded posts, followers, and content (relevant for language researchers), training sessions for video conference calls and focus groups, and "tech checks" for bypassing fraud detectors in surveys.

The presenters identified the consequences of fraud in online research including invalidating study results, introducing bias, affecting randomization and parity among groups, “faking bad” about negative stereotypes, wasting resources, producing harmful/non-useful outcomes, wasting researchers’ and IRBs’ time and harassing researchers.

Implementing fraud detection techniques in an online study requires balancing different interests. Selecting data integrity monitoring techniques entails a balance between reducing fraudulent responses while ensuring accessibility and privacy for legitimate respondents, especially from marginalized communities. Approaches come at a cost to researchers or to participants and none of them are foolproof in preventing or identifying instances of fraud. Preventative measures may increase the burden on participants, inconvenience or exclude participants, or reduce participant privacy. Removal of participants’ data or determining that they are ineligible for compensation raises questions of equity and justice. After a survey has been administered, researchers must have expertise and time to identify suspicious submissions. This can require substantial time and investment in identifying and removing fraudulent data.

The presenters identified four stages in a study – study design, software features, survey design, and data review – where researchers can implement techniques to prevent and identify fraudulent participants and outlined a host of techniques in each stage. Members of the audience shared their personal experiences with fraudulent responses and offered their own suggestions, including mailing incentives to U.S. postal addresses, and requiring camera-on videoconferencing sessions.

The presenters then recommended actions for IRBs to support researchers, including learning about the issue, revising applications to address fraud prevention, allowing collection of extra data/variables to address/protect data integrity, and considering potential fraud when evaluating complaints about non-payment of incentives when participants are deemed ineligible.

In closing, the presenters recommended that the research community needs to recognize the issue and adapt, stay educated, share resources, develop partnerships between IRBs and researchers to balance privacy with validity and preserve the benefits of online research while protecting the core ethical principles everyone cares about, and above all, remember the goal ~ protecting participants while advancing knowledge. They provided a literature resource for researchers and IRB members to learn more about online fraud and mitigation techniques:



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A04: Potentially Controversial Research Involving Children in 2025: Challenges, Considerations, and Solutions for SBER IRBs

Session Description

Children are recognized as a vulnerable population in research and receive special protections under Subpart D of the HHS regulations (45 CFR 46). Given a shifting policy landscape, research involving children may raise issues that are now controversial, resulting in growing layers of complexity that IRBs must consider when reviewing SBER research. How do IRBs determine what research involving children is appropriate? What easily overlooked factors must IRBs now consider when evaluating submissions and applying federal regulations and guidance? This session will equip attendees with a solid ethical and regulatory framework to thoughtfully evaluate the inclusion of child participants in research in 2025.

Learning Objectives

- Discuss regulatory requirements and available flexibilities for research involving children
- Explore how regulatory frameworks guide decision-making about including minors in research when the context, subject matter, or method may be controversial
- Analyze case studies of research involving children and examine effective IRB review strategies that successfully minimize participant risk

Speakers

- Paul G. Hart, JD, MA, CIP
- Iris L. Jenkins, PhD
- Marianna Azar, BA, MA, PhD ABD

Significance

Research involving children is inherently complex due to the legal and developmental status of minors, but 2025 ushered in a slate of unprecedented challenges, further complicating this area of research. The topic covered in this session is critical because it addresses the modern "triple threat" facing Social, Behavioral, and Educational Research (SBER): evolving regulatory interpretations, heightened political sensitivity around youth-centered topics, and the digital nature of contemporary adolescent life.

The importance of this topic lies in three key areas:

- **Protecting Vulnerable Populations:** Children are legally unable to provide informed consent. As the session highlights, IRBs must master the nuances of Subpart D to ensure that "assent" exceeds a mere "failure to object" and that parental permission is secured or appropriately waived to protect the child's best interests.
- **Navigating Controversial Contexts:** Current research often touches on highly polarized subjects, such as gender identity, radical political ideologies, and reproductive health. This session is vital because it provides a framework for IRBs to evaluate whether the "minimal risk" threshold is exceeded when the subject matter itself may carry social or legal risks for the minor.
- **Regulatory Compliance and Flexibility:** Understanding the specific applications of Exemptions 1 and 2 to research involving children is essential for institutional compliance. Misapplying or inadequately utilizing these regulatory flexibilities can lead to unnecessary exclusion of vulnerable groups (like undocumented minors or wards of the state) from beneficial research that is eligible for exemption from the Common Rule regulatory requirements.

Ultimately, this session aimed to empower IRBs to act as facilitators rather than barriers, allowing for important research on youth experiences while maintaining the highest ethical and legal safeguards.

Content

The session titled "Potentially Controversial Research Involving Children in 2025: Challenges, Considerations, and Solutions for SBER IRBs" addressed the increasingly complex landscape of social, behavioral, and educational research (SBER) involving minors. Presented by Marianna Azar, Paul Hart, and Iris Jenkins, the session incorporated multiple case studies and subsequent audience discussion of the fact patterns in each to explore how Institutional Review Boards (IRBs) can navigate regulatory frameworks to protect child participants while facilitating research on sensitive or controversial topics.

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Regulatory Framework and Additional Protections

The foundation of the discussion was **Subpart D** of 45 CFR 46, which provides additional protections for children involved in research. The session employed an interactive “true or false” exercise to help illustrate the scope of Subpart D and then proceeded to clarify some key definitions, noting that “children” are individuals who have not attained the legal age for consent to treatments or procedures involved in the research under the local jurisdiction's law. A central theme was the IRB’s responsibility to balance risk levels—categorized under 45 CFR 46.404-407—with the potential benefits of the research.

The session also clarified when the Common Rule regulatory requirements do and do not apply and stressed the need for institutions to exercise flexibilities when reviewing non-regulated studies.

Risks in the Current Political Climate

A major point of audience engagement focused on the risks associated with the modern political climate. Research on topics such as **radical political ideologies**, **gender-fluid identity**, and **vaccine hesitancy** have become increasingly polarized.

- **Political Polarization and Identity:** Case Study 2 highlighted research into how high school students with radical ideologies form social identities and engage in online discourse. The IRB must assess if the subject matter itself introduces risks of social or reputational harm that exceed “minimal risk,” especially in an era of heightened digital surveillance and political tension.
- **Gender and School Belonging:** Case Study 5 examined research on how gender-fluid identity affects academic performance and school engagement. The presenters noted that IRBs must consider how local and state laws—which vary significantly regarding gender identity—impact recruitment, the role of school administrators, and the safety of the participants.

Waiving Parental Permission to Facilitate Crucial Research

The session delved into the critical need for **waivers of parental permission** under 45 CFR 46.408(c) to protect children for whom parental permission is not a reasonable requirement.

- **Facilitating Sensitive Research:** For studies involving neglected or abused children, or sensitive topics like sexual health, requiring parental permission may actually increase the risk of harm to the minor. The IRB may waive this requirement provided an “appropriate mechanism” is in place to protect the child.
- **Case Study Example:** In Case Study 3, involving teens seeking Pre-exposure prophylaxis (PrEP) services, the session explored whether Subpart D applies when state law (like in New York) allows minors to consent to treatment for sexually transmitted diseases independently. If a minor can legally consent to the procedure outside of research, the IRB may have more flexibility regarding parental permission.

Undocumented Minors and Wards of the State

One of the most complex topics discussed was the inclusion of **undocumented minors** and **wards of the state** in research.

- **Undocumented Unaccompanied Minors:** Case Study 1 presented a study on the mental health of undocumented minors who arrived in the U.S. without a parent or legal guardian. These children are often in transitional housing or shelters, making the identification of a legal “guardian” for research permission legally and ethically fraught.
- **Wards of the State and Advocate Requirements:** For research involving wards of the state (approved under 45 CFR 46.406 or 407), the IRB must require the appointment of an **advocate** for each child. The advocate must have the background to act in the child’s best interest and cannot be associated with the research team or the guardian organization.
- **Complex Implementation:** The session highlighted that the process for appointing advocates varies by institution. Advocates may be IRB members, ombudsmen, or social workers with no interest in the research. This additional layer of protection is essential for ensuring that vulnerable children who lack traditional parental support are not exploited.

Effective IRB Review Strategies

The presenters concluded that effective IRB review in 2025 and continuing requires looking beyond federal regulations to include an inventory of **state and local laws**. IRBs were encouraged to:

- Use case studies to identify hidden risks in “controversial” subject matter.
- Determine the appropriate order for seeking child **assent** and parental permission.
- Ensure that “mere failure to object” is never construed as affirmative assent.

By utilizing available regulatory flexibilities and maintaining a focus on the welfare of the child, IRBs can support vital research that addresses the unique challenges facing youth today.

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- **Protection of Human Subjects (Common Rule)**, 45 C.F.R. § 46, Subpart A (2018).
- NIH Certificates of Confidentiality:
- <https://grants.nih.gov/policy-and-compliance/policy-topics/human-subjects/coc>

Official Guidance and Institutional Resources

- **Office for Human Research Protections (OHRP)**. (n.d.). *Special Protections for Children Guidance*. U.S. Department of Health and Human Services. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/special-protections-for-children/index.html>.
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Note: The case studies referenced in the presentation (e.g., studies on radical political ideologies and gender-fluid identity) were presented as pedagogical tools to illustrate regulatory application and do not represent published academic papers directly cited for their findings.



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(B01) Through the Looking Glass: How Research Participants and IRBs See Ethics in HIV and SUD Studies

Session Description

IRBs rely on principles, regulations, and judgment to navigate ethical dilemmas, but these frameworks can overlook participants' lived experiences—especially those outside societal norms. Emerging digital health tools and restrictions on “vulnerable” participants may raise privacy and autonomy concerns IRBs don't always anticipate. This panel will explore shifting from a paternalistic model to one that respects participants as moral agents with valuable ethical insights. Through interactive discussions, attendees will learn how incorporating participant perspectives can strengthen ethical oversight, protections, and trust in research.

Learning Objectives

- Compare ethical concerns of IRB professionals and research participants in HIV and SUD studies
- Recognize how participants use personal moral reasoning to navigate research risks and benefits
- Explore strategies to incorporate participant perspectives into IRB reviews to enhance protections and trust

Speakers

- Brenda Curtis, PhD, MsPH

Significance

This topic holds critical importance for the research ethics community because it addresses a fundamental gap between institutional protection frameworks and the lived experiences of research participants. Institutional Review Boards have traditionally operated within rule-based, principle-driven systems focused on procedural compliance. In contrast, participants in HIV and substance use disorder (SUD) research often navigate ethical decision-making through contextual, relational, and socially embedded moral reasoning. This divergence carries significant implications for the effectiveness of human subjects protections.

Understanding participant perspectives is especially crucial in HIV and SUD research, where individuals face layered vulnerabilities including stigma, criminalization, structural inequality, and histories of research exploitation. When IRB assessments of risk and benefit diverge from how participants themselves conceptualize ethical concerns, several problems emerge: informed consent may emphasize risks participants find less salient while overlooking those they experience as most pressing; protective measures may unintentionally undermine dignity; recruitment and retention may suffer when procedures feel ethically misaligned with community norms; and the principle of respect for persons risks becoming procedural rather than substantive.

The presentation's emphasis on shifting from a paternalistic model to one that recognizes participants as moral agents reflects an essential evolution in research ethics. As digital health technologies, precision medicine, and community-engaged research expand, traditional oversight models face growing limitations. Incorporating participant moral reasoning into IRB deliberations can strengthen both ethical integrity and scientific rigor by aligning protections with participants' lived concerns, building authentic trust, reducing participation barriers, and fostering research partnerships rather than one-directional protection. In an era marked by emerging surveillance technologies and renewed restrictions on research with “vulnerable” populations, this shift toward ethical partnership is not optional—it is necessary.

Content

The interactive learning lab Through the Looking Glass: How Research Participants and IRBs See Ethics in HIV and SUD Studies provided a structured, case-based exploration of the disconnect between institutional research ethics frameworks and the moral reasoning employed by research participants. The session was designed as an interactive learning laboratory rather than a traditional lecture and was structured around two detailed case studies drawn from published research on participant perspectives. Mentimeter polling was used throughout to engage attendees in real-time reflection and to surface differences between IRB instincts and participant perspectives.

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Framing: Why Revisit Participant Perspectives Now?

The session opened by establishing the urgency of revisiting participant perspectives: “For decades, IRBs have protected participants through rules and risk categories. But studies with people who use drugs, or those living with HIV, show that participants also practice their own ethical reasoning—sometimes at odds with ours.” This framing positioned the session as an effort to expand and enrich existing IRB practices.

An opening Mentimeter warm-up asked, “What word or phrase comes to mind when you think of ‘research ethics?’” As responses populated in word-cloud format, facilitators narrated emerging patterns, noting the prominence of terms such as consent, protection, and risk, with comparatively fewer references to trust or partnership. This observation served as a transition into examining participant perspectives more closely.

The framing concluded with a visual contrast:

- **IRB Lens:** “Respect for persons means obtaining informed consent.”
- **Participant Lens (Fisher, 2009):** “Respect means not making me a spectacle.”

The session emphasized that IRB logic is often rooted in rules and principles, whereas participant reasoning is grounded in context and relationship. Attendees were asked to consider: “If both are ‘ethical,’ whose definition should guide our review?”

Case 1: Street Recruitment & Stigma

The first case drew from Oransky, Fisher, Mahadevan, and Singer’s (2009) study on recruitment of street drug users in nonintervention HIV risk research. The scenario described a community health worker approaching individuals in a city park, offering \$40, an HIV test, and a short survey, while wearing a badge identifying the research program.

Attendees were invited to consider whether their IRB would approve this method and to reflect on their initial concerns. Poll #1 asked: “What feels most ethically risky in this scenario?” with options focusing on payment, public setting, recruiter approach, or manageability through protocol safeguards. Responses revealed common IRB focal points such as coercion, privacy, and procedural adequacy.

Participant quotations from the study were then presented:

- “If somebody approached me like that, I’d be scared...might be an undercover cop.”
- “What if someone sees me talking to her—they’ll think I’m using again.”
- “I’d do it if she was respectful, explained it private-like.”

Discussion highlighted that participants conceptualized risk in social and relational terms rather than procedural ones. While IRBs may focus on consent documentation and payment thresholds, participants expressed concern about surveillance, stigma, and reputational harm. The badge intended as transparency could increase visibility and perceived risk.

The ethical insight emphasized the distinction between procedural safeguards and contextual dignity—who approaches, where, and how. The practical takeaway was to integrate participant or community advisors to vet recruitment sites and approaches, shifting from abstract risk assessment to context-informed ethical review.

Case 2: Digital Health & Data Privacy

The second case extended the discussion into digital research contexts. Drawing from Rendina and Mustanski (2018), the scenario described a relapse-prevention app collecting GPS and motion data alongside daily mood and craving surveys, with data encrypted and stored on secure servers.

Attendees were asked whether this constituted minimal risk and whether GPS tracking should be considered sensitive data. Polling revealed variation in how IRBs might classify such data. Facilitators probed assumptions underlying minimal-risk determinations and invited attendees to reflect on what would build participant trust in digital studies.

Participant quotations revealed concerns centered on transparency and control:

- “I trust researchers more than app companies, but I still want to know exactly what data they collect.”
- “It’s not that I don’t want to help—I just don’t like the idea of them knowing where I go all the time.”
- “If it’s anonymous and only for research, that’s fine—but I don’t want my info sold or sent anywhere else.”

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The discussion underscored that participants equate ethics with control and visibility, not solely with technical security. The session emphasized that ethical protection does not necessarily equal perceived respect. Proposed strategies included visualizing data flows within consent materials and offering pause or opt-out controls to support ongoing agency.

Group Synthesis: How Ethics Frameworks Must Evolve

The synthesis segment shifted from analysis to application. Attendees reflected on the prompt: “What would ethical partnership look like in your IRB or research practice?”

Small-group discussions generated concrete suggestions, such as collaboratively revising consent language, incorporating community advisors into review processes, and reframing vulnerability as capability rather than deficit. Large-group sharing organized takeaways under three themes:

- **Transparency:** making risk and data practices visible
- **Reciprocity:** balancing participant contribution and researcher responsibility
- **Agency:** treating participants as collaborators in ethics

The synthesis reinforced that participants are not seeking less protection but partnership in defining what protection means.

Wrap-Up Poll & Takeaways

A final Mentimeter poll asked which lesson best captures how IRBs can integrate participant perspectives: moving from compliance to collaboration, redefining vulnerability as capability, building trust through transparency, or treating participants as co-interpreters of risk. The session concluded by reinforcing the central message:

“When we look through the participant’s eyes, ethics shifts from protection to partnership.”

References

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B02: When SBER Meets FDA: A Survival Guide to Support SBE IRBs and Researchers

Session Description

FDA regulations can be overwhelming, especially for the SBER community, which often doesn't encounter—or realize the need for—FDA oversight. However, as innovation and interdisciplinary research grow, SBER studies increasingly include FDA-regulated components. This session will explore how SBER IRBs can support researchers in navigating FDA complexities, covering varied interpretations of FDA-regulated activities, their intersection with SBE research, and best practices for managing reviews and communication.

Learning Objectives

- Identify the common challenges SBE researchers face in FDA-regulated studies
- Learn FDA regulations framework and review the FDA requirements
- Learn to apply FDA regulations based on different interpretations of FDA oversight to various scenarios in SBE research

Speakers

- Kanti Crain, MA, MBA, CIP
- Erin M. Odor, MA, CIP

Significance

U.S. Food and Drug Administration (FDA) regulations can be overwhelming, especially for the Social, Behavioral, and Educational Research (SBER) community. Traditionally, SBER research primarily focuses on minimal risk research involving surveys, interviews, observational studies, and behavioral interventions. There are not many SBER studies that apply FDA oversight. As a result, SBER professionals may not routinely consider FDA regulations in their daily review process.

However, the research landscape is evolving. With increasing innovation and collaboration, SBER studies are found incorporating components that fall under FDA jurisdiction, such as studies that involve mobile applications, wearable devices, or use of investigational FDA-regulated products in behavioral studies. These require SBER IRBs to recognize when FDA regulations apply and to ensure institutional readiness to review such research, as FDA-regulated studies have additional requirements for IRBs and researchers alike.

Content

Introduction

SBER research may become subject to FDA regulations when involving any FDA-regulated investigational products (often drugs, biologics, or medical devices) or when it is conducted in conjunction with a clinical trial or other research that is itself subject to FDA oversight. Even if the primary endpoints are behavioral or social, the use of an FDA-regulated test article can trigger additional regulatory requirements under 21 CFR 50 (informed consent) and 56 (IRB review), 312 (investigational new drugs [INDs]), and/or 812 (investigational device exemptions [IDEs]).

The speakers highlighted implications for FDA-regulated research:

- Before an IRB can review FDA-regulated research, it must be properly registered and authorized to do so as described in FDA guidance (1).
- IRBs have additional review responsibilities, such as making nonsignificant risk and significant risk determinations for medical device studies. Institutional procedures may require IRBs to determine if the FDA oversight is applicable - whether the study meets the FDA definition of a clinical investigation and/or whether an IND or IDE is required.
- The IRB must conduct continuing review of FDA-regulated studies at least annually, regardless of risk level.
- FDA regulations require additional elements of informed consent (e.g., [clinicaltrials.gov](https://www.fda.gov/oc/ohrt/) language) and permit waivers of consent documentation in fewer circumstances than the Common Rule. Electronic consent can be used; however, it must comply with 21 CFR 11.

Next, the speakers provided a high-level introduction to FDA regulations governing clinical trials, beginning with key terminology. SBER professionals may not be aware that many regulatory terms have distinct meanings in the context of FDA-regulated research. For example, there are three distinct definitions of “clinical investigation” (Parts 50 and 56; Part 312; and Part 812), none of which refers to generalizable knowledge, and “human subject” encompasses biospecimens and makes no reference to identifiability.

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The speakers provided a general overview of the criteria for exemption from investigational new drug (IND) and investigational device exemption (IDE) requirements.

Survival Strategies

FDA regulations are not mastered in a day. Below are strategies that SBER professionals can apply to enhance compliance.

SBER IRB offices and administrators:

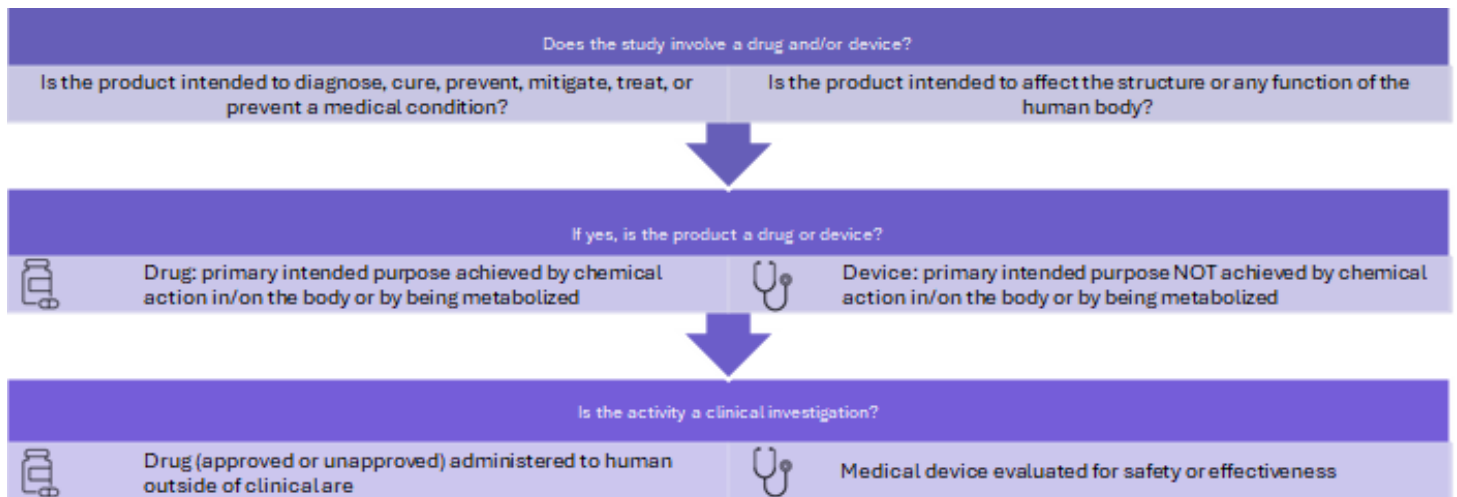
- Identify contact for FDA matters at their institutions (IRB chairs/vice chairs, research administration, general counsel)
- Use existing PRIM&R resources (IRB Forum/PRIM&R Online Community, FDA-focused educational programming, past webinars and workshops)
- Reach out to colleagues at other institutions for advice
- Consider relying on external IRBs (other institutional IRBs or independent IRBs) if their SBER board is not equipped to review FDA-regulated research

SBER investigators:

- Proactively familiarize themselves with FDA regulations and guidance documents
- Collaborate with their local IRB and/or colleagues with more FDA experience
- Stay abreast of regulatory changes by subscribing to FDA-focused newsletters and attending educational sessions

Case studies

Attendees practiced determining if a study would be subject to FDA regulations through interactive case studies using the rubric below.



Case 1: Undergraduate dance students will wear a bodysuit prototype with motion sensors while performing common ballet moves. Information from the sensors will be input into software that analyzes alignment and flexibility to provide personalized recommendations for improving technique.

This study would not be subject to FDA oversight because the motion sensors and software do not meet the definition of a drug or medical device: they are not intended to diagnose, cure, prevent, mitigate, or treat a medical condition, nor are they intended to affect the structure or any function of the human body.

Case 2: A researcher has designed a mobile app that provides a “skill of the day” behavioral technique for decreasing stress. In a six-week study, half of the participants will use the app, and half will download a “daily trivia question” app. Participants will be instructed to open their respective app whenever they feel stressed or anxious. Scores from the Generalized Anxiety Disorder Scale (GAD-7) at baseline and six weeks will be compared to see if the experimental group reported a greater reduction in symptoms of anxiety than the control group.

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This study would be subject to FDA oversight because it is evaluating the effectiveness of a product in reducing symptoms of anxiety as measured by a clinically validated diagnostic scale. The app is a medical device because it does not achieve its intended function via chemical action or by being metabolized. Therefore, the IRB would need to review the study under FDA regulations for IRB and informed consent, as well as the IDE regulations. This example was repurposed from FDA's examples of software functions that are under enforcement discretion (2). Per feedback from the FDA Digital Center of Excellence, devices under enforcement discretion for marketing purposes are still subject to FDA's clinical investigation regulations.

Case 3: A researcher is evaluating a mobile app that helps individuals with asthma record and track their inhaler use, asthma episodes, location at the time of an attack, and potential environmental triggers. The app is intended to help users understand their environment better but does not provide recommendations or influence medical decision-making. Twenty participants with asthma will be recruited to use the app for one week, then complete a usability survey.

This study would not be subject to FDA regulations because the app does not meet the definition of a drug or medical device: it is not intended to diagnose, cure, prevent, mitigate, or treat a medical condition, nor is it intended to affect the structure or any function of the human body. Even though the study targets a particular medical condition, the app's functions are limited to logging and displaying user inputs and location without analyzing the data or providing participant-specific recommendations. This example was adapted from FDA's list of software functions that are not medical device functions (3).

Case 4: Psychology researchers are interested in the short-term effects of Pepto-Bismol on mood. Participants will complete a baseline questionnaire, be given a standard dose of Pepto-Bismol, and complete a final mood questionnaire 15 minutes later.

This study would be considered FDA-regulated because an approved drug product is administered outside of medical practice.

The session concluded with a discussion of helpful resources and audience questions.

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C01: Demystifying the Enigma of FERPA Requirements, Exceptions, and Entanglements Through Varied Perspectives

Session Description

This session will explore the use of Family Educational Rights and Privacy Act (FERPA)-protected data in human participant research, highlighting diverse institutional approaches and the varying roles IRBs play in ensuring FERPA compliance. Unlike HIPAA, FERPA does not permit a privacy board to waive consent requirements, though it includes multiple exceptions—many of which are interpreted differently across institutions.

Speakers will clarify what qualifies as FERPA-protected data and discuss how FERPA regulations affect access to data for research. The session will examine how institutions interpret and apply FERPA differently, particularly when handling data from internal versus external sources. Presenters will also share how IRBs and HRPPs contribute to shaping institutional policies around FERPA, offering practical insights into navigating these complex requirements.

Learning Objectives

- Describe varying institutional interpretations of FERPA, and identify when FERPA applies, including its limitations for both internal and external data access
- Consider how an HRPP can support research subject to FERPA while still protecting participants
- Evaluate institutional approaches to FERPA by examining how IRB roles in compliance shape research practices and policies across diverse settings

Speakers

- Casey Mumaw, CIP
- Marianna Azar, BA, MA, PhD ABD

Significance

Understanding the requirements of the **Family Educational Rights and Privacy Act (FERPA)** is critical for researchers and institutions because it serves as the primary safeguard for student privacy in educational settings. As highlighted in this session, "Demystifying the Enigma of FERPA Requirements," navigating these regulations is essential for maintaining federal funding and avoiding significant legal sanctions.

The topic is particularly important for the following reasons:

- **Financial and Regulatory Risk:** Violations can lead to the suspension or termination of federal education dollars, making compliance a high-stakes priority for any institution receiving Department of Education funds.
- **Protection of Sensitive Data:** FERPA covers a broad range of **Personally Identifiable Information (PII)**, including transcripts, disciplinary records, and biometric data. Understanding what constitutes an "education record" ensures that researchers do not inadvertently disclose protected information.
- **Research Continuity:** While the **Common Rule** allows for certain research exemptions, an IRB cannot waive FERPA requirements. Institutional Review Boards (IRBs) and Human Research Protection Programs (HRPPs) must master the nuances of FERPA exceptions—such as "Legitimate Educational Interest" and the "Studies Exception"—to facilitate valuable research while remaining legally compliant.
- **Shifting Legal Landscapes:** Current political shifts and evolving interpretations of federal privacy laws regarding "ideological indoctrination" or "gender plans" create a complex environment where institutional policies must be precisely aligned with federal expectations to protect both students and the university.

Ultimately, mastering FERPA ensures that the pursuit of knowledge through research does not come at the expense of student privacy rights or the institution's financial stability.

Content

This session provided a comprehensive analysis of the Family Educational Rights and Privacy Act (34 CFR Part 99) and its complex intersection with human subjects research. Presented by Casey Mumaw of Indiana University and Marianna Azar of the New York State Psychiatric Institute, the session sought to clarify how institutions can navigate the "enigma" of FERPA while maintaining robust Human Research Protection Programs (HRPP).

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Regulatory Foundation and Scope

The session began by defining FERPA as a federal law applying to educational agencies or institutions that receive funds administered by the U.S. Secretary of Education. The primary intent of the act is to protect the rights of parents and students regarding education records. Key takeaways regarding the scope of the law included:

- **Transfer of Rights:** Rights belong to the parents until a student reaches the age of 18 or attends a postsecondary institution, at which point the student becomes an "eligible student".
- **Enforcement Risks:** The Department of Education (ED) maintains the authority to sanction entities for violations, with the most severe penalty being the termination of all federal education funding.
- **Defining "Education Records":** These are records directly related to a student and maintained by an institution. The session clarified that while this includes transcripts and financial aid data, it excludes law enforcement records and certain employment records not based on student status. Education records can also include data that might mistakenly be assumed to be HIPAA-protected, such as counseling or university health center records.

The Intersection of FERPA and IRB Oversight

A significant portion of the presentation addressed the friction between the Common Rule (45 CFR 46) and FERPA. A critical distinction was made: while an Institutional Review Board (IRB) has the authority to waive parental consent for non-exempt research under the Common Rule, it cannot waive a FERPA release.

The presenters noted that contemporary use of Exemption Category 1 (Normal Educational Practices) is broad, yet it is the only exemption that lacks inherent privacy protections or requirements for notice. This creates a "privacy gap" where HRPPs must step in to ensure that research eligible for Exemption 1 still respects the underlying privacy requirements of FERPA when ED-funded institutions are involved.

Meaningful Engagement: Institutional Support and Compliance

The session highlighted the necessity of strong institutional support to navigate varying interpretations of FERPA. Because FERPA is not a "one-size-fits-all" regulation, the HRPP must work in tandem with other university offices to determine when data access is permissible.

- **Internal Data Access:** Institutional policy dictates how researchers access internal records. The presenters emphasized that simply being a school official does not grant a person the right to access student records for research purposes.
- **Legitimate Educational Interest:** Discussion centered on how institutions must specifically define this term in their annual notifications. For research to qualify under this exception, the official must need the record to fulfill professional responsibilities.
- **External Data Access:** When researchers seek data from other institutions (such as K-12 districts), the policy of the *holding* institution applies. This often requires a formal written agreement or a "Studies Exception" determination by the school district.

Considerations for Employee-Researchers

One of the more nuanced topics involved handling school employees who carry out research for their own personal academic pursuits (e.g., a teacher conducting a study for their PhD dissertation).

- **Role Conflict:** If an employee has access to FERPA-protected data as part of their job, they are strictly prohibited from accessing that data for a separate research reason unless an exception applies or consent is obtained.
- **Access Limitations:** Even if a school determines that a student-researcher has a "Legitimate Educational Interest" because of their employment, that determination does **not** extend to the other members of their research team.
- **Transparency:** The presenters stressed that a researcher granted an exception must have clear documentation from the official record holder (the school or district) to be included in the IRB submission.

The Requirements for Permission

In cases where no exception applies, researchers must obtain a signed and dated written consent for the release of education records. The presenters outlined the five essential elements of a valid FERPA release:

1. Specification of the records to be disclosed.
2. Identification of the party to whom disclosure is made.
3. The purpose of the disclosure.
4. The time period or event the permission covers.
5. A signature and date from the parent or eligible student.

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Notably, the session clarified that a FERPA release can be integrated into a standard research consent form and does not necessarily need to be a physical paper document. A FERPA authorization is required even for studies eligible for exemption from the Common Rule regulatory requirements, including that of seeking and obtaining informed consent for research participation.

Conclusion

The session underscored that the HRPP's role is not just to check for IRB compliance, but to act as a bridge between the researcher and the institution's privacy obligations. By evaluating institutional approaches to FERPA, IRBs can shape research practices that are ethically sound and legally compliant, even in a shifting political and regulatory landscape.

References

Regulatory and Legal Citations

- **Family Educational Rights and Privacy Act (FERPA)**, 20 U.S.C. § 1232g; 34 C.F.R. Part 99.
- **Protection of Human Subjects (Common Rule)**, 45 C.F.R. § 46 (2018).

Academic and Institutional Resources

- **Secretary's Advisory Committee on Human Research Protections (SACHRP)**. (2018). *SACHRP 2018 recommendations on interpretation of exempt categories 1 and 2 as revised in the 2018 Common Rule*. U.S. Department of Health and Human Services. <https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-b-november-13-2018/index.html>.
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