On Differing Approaches to Measuring and Ensuring IRB Effectiveness

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On Differing Approaches to Measuring and Ensuring IRB Effectiveness

October 17, 2024

Introduction

This webinar represents the culmination of efforts by the Office for Human Research Protections (OHRP) and the U.S. Food and Drug Administration (FDA) to convene interested parties to examine approaches for measuring the effectiveness of Institutional Review Boards (IRBs) in protecting human subjects. The Government Accountability Office (GAO) recommended that HHS convene stakeholders for this purpose in a 2023 report on the subject.

A panel of experts discussed four possible approaches for attempting to measure IRB effectiveness that emerged from previous meetings with stakeholders. These included: (1) post-approval monitoring to verify compliance with IRB requirements, relevant regulations, and institutional policies; (2) accreditation and peer review; (3) the experience of study participants; and (4) the quality of IRB deliberations. Presentations were followed by a closing discussion.

Opening Remarks

- *Karen Giardiello, Supervisory Regulatory Counsel, Office of Clinical Policy (OCLP), FDA*

Ms. Giardiello welcomed everyone and expressed her appreciation to OHRP, especially Ms. Azar, as well as to the moderator and distinguished speakers.

She explained that Congress asked GAO to review IRB effectiveness in 2021, and in 2023 GAO issued its report: Institutional Review Boards: Actions Needed to Improve Federal Oversight and Examine Effectiveness (GAO Report 23-104721). GAO's fourth recommendation was this:

> The Secretary of Health and Human Services should ensure that OHRP and FDA convene stakeholders to examine approaches for measuring IRB effectiveness in protecting human subjects and implement the approaches as appropriate. These could include effectiveness measures; peer audits of IRB meetings and decisions; mock protocols; surveys of IRB members, investigators, and human research participants; or other approaches.

The topic is a challenging one, and there are no validated performance measures related to human subject protection. To respond to GAO's recommendation, OHRP and FDA have convened experts to suggest approaches and invited the Secretary's Advisory Committee on Human Subject Protections (SACHRP) to deliberate on the subject. Four methods of measuring effectiveness were mentioned repeatedly, and each of the four will be explored in today's webinar.

Introductions and Setting the Stage

- *Moderator: Holly Taylor, MPH, PhD*

Dr. Taylor thanked FDA, OHRP, and the panel for the work they have done in preparation for the webinar. She also thanked her colleague, Holly Fernandez-Lynch, with whom she Co-Chairs the Consortium to Advance Effective Research Oversight (AEREO), whose deliberations informed Dr. Taylor's thoughts for this discussion.

Measuring IRB effectiveness is a longstanding challenge, not a new one. It is beyond question hard to do. Dr. Taylor offered a diagram that portrayed quality as a Venn diagram with three intersecting circles, with effectiveness between the other two:

- Presence of procedural and structural factors to promote effectiveness,
- Effectiveness in achieving outcomes, and
- The appropriate approach to achieving effectiveness (fair, efficient, avoidance of burden).

Considering what IRBs do, there are four key outcomes of Interest:

- Protect participants (and communities),
- Promote socially valuable research,
- Foster a culture of ethical concern at an institution, and
- Promote public trust in research and the research enterprise (the "Holy Grail"!)

Why don't we already have ways to pinpoint and measure each of these outcomes? Dr. Taylor pointed out that desirable IRB outcomes can be subjective and amorphous, making them hard to operationalize as measures. We do not yet know how to judge the effectiveness of Human Research Protection Programs (HRPPs) or IRBs, either individually or collectively. We also do not know how to compare their performance with each other, either within categories (for example, IRBs at academic medical centers) or across categories (for example, commercial IRBs vs. IRBs at academic medical centers).

Dr. Taylor presented a diagram showing the "pieces of the puzzle." The research proposal drafted by a researcher/study team is submitted to the HRPP. The HRPP orchestrates the review of the research proposal by conducting a pre-review. Once ready, the research proposal is forwarded to the IRB to deliberate and come to a decision. The actual conduct of the study is the responsibility of the researcher /study team, but an annual report comes to the HRPP through the continuing review process, if required. The approach to measurement should encompass the entirety of the HRPP's responsibilities but not hold it responsible for pieces of the puzzle it cannot control. The remarks to follow should help consider how these pieces fit together, as well as what other pieces are missing.

On Measuring IRB Effectiveness through Post-Approval Compliance Monitoring

- *Rachel Lally, MPH, CIP, Assistant Vice President for Research, Penn State University*

Ms. Lally reported on Penn State's efforts to streamline IRB review and considered how such improvements relate to IRB effectiveness. She suggested that IRB effectiveness is not the same as efficiency, though consistency may be relevant. The most meaningful measure must be how well human subjects are protected, which is not about paperwork.

Turnaround time. Penn State's HRPP took a close look at turnaround time for project approval. They asked:

- Why is approval being delayed?
- Where can education and outreach be more effective?
- What other data do we need to inform next steps?

Penn State's IRB analysts successfully improved their turnaround time only to find that researchers had increased theirs. Ms. Lally stressed the importance of collaboration and communication. The HRPP focused on collecting data related to where researchers were having trouble getting their submissions right and creating clear guidance based on that information to help researchers understand requirements and why meeting them is important. One example is showing how sections of the proposal corresponded to sections of an article that might be published about their study.

Post-approval audits of the IRB review process found both administrative and substantive issues to be addressed. HRPP leadership and staff discussed the process thoughtfully to see where further improvements might be relevant. For example, as a result of these discussions, the HRPP can take a more risk-based approach to monitoring and development of policies and procedures.

PACTS. To provide feedback to guide continued improvements, Penn State established Proactive Audits for Continued Training (PACTS). The program begins its work, which is intended to be educational and preventative, before participants are enrolled. A quality assurance team provides guidance on best practices for issues such as recruitment, consent, data management, modifications, how to handle unexpected events, reportable information, and study closure. Through PACT, teams have an opportunity to work through problems in advance.

Can post-approval monitoring measure IRB effectiveness? Ms. Lally suggested that it probably can help, but resources are required to do it well. She stressed that Penn State's HRPP was fortunate to work in an institution that is willing to provide strategic planning support and resources to make the process work smoothly. Nevertheless, regulatory changes continue to increase with no commensurate increase in funding support. This is a challenge for all HRPPs.

In conclusion, Ms. Lally summarized:

- Post-approval monitoring may help assess IRB effectiveness.
- Different stakeholders have different perspectives. It will not help to just add more rules.
- Nuanced data can help inform the process.
- Resources are needed to measure effectiveness appropriately, including identifying areas in which improvements are possible.

Ms. Lally observed that the institutional culture around the cost and importance of human subject protections is often a barrier to measuring effectiveness. This needs to change.

On Measuring and Ensuring HRPP and IRB Effectiveness through Accreditation

- *Nichelle Cobb, PhD, CIP, Senior Advisor for Strategic Initiatives for AAHRPP*

Dr. Cobb described the approach the Association for the Accreditation of Human Research Protection Programs (AAHRPP) has taken to assessing the effectiveness of HRPPs and IRBs. AAHRPP now has over 20 years of experience in visiting sites and reviewing HRPP programs to determine whether they can meet AAHRPP's standards. Dr. Cobb stressed that the accreditation program assesses far more than regulatory compliance. An accredited IRB must demonstrate:

- Periodic assessment of the quality, efficiency, and effectiveness of IRBs and the HRPP as a whole;
- IRB member and staff education, training, and evaluation;
- Management of conflicts of interest for both IRB and research team members;
- Communication among components of the HRPP to ensure that the IRB has appropriate context for its review; and
- Emergency planning.

Trained peer reviewers visit the HRPP site to review both written materials and practice. The reviewers' findings are evaluated by a council of experts before accreditation is granted.

Learnings. Dr. Cobb reflected on what AAHRPP has learned about what makes an IRB effective. She stressed that IRBs can only be effective if they are part of an effective HRPP program. If you have the best IRB in the world, she said, if that is all that is working, human subject protection may still not be effective.

IRBs are a necessary but not sufficient component of the effort to protect the rights and welfare of research participants. Many other elements must be functioning well for the entire program to succeed. Examples include scientific review, institutional safety committees, community engagement initiatives, and data security reviews. Research teams are on the front line of human subject protection; if they do not execute the research plan as approved, there may be harms the IRB could not prevent or mitigate.

Communication and coordination are critical if IRBs are to fulfill their mission. Is the IRB appropriately resourced by the institution? Is information shared or siloed? How well do research teams, relying institutions, key elements within the organization, and the IRBs themselves communicate? Peer reviewers do not assess the IRB in isolation, but rather consider how the entire system is working to protect human subjects.

Survey findings. Lastly, Dr. Cobb presented data from a 2021 survey of accredited organizations on the perceived impact of accreditation on the HRPP community. AAHRPP used a professional survey center to reach 253 HRPP administrators from accredited organizations. There were 103 responses (a 41% response rate). The majority of survey participants said they thought accreditation strengthened the protection of human participants (73.3%), improved the quality of IRB or Ethics Committee (EC) review (72.3%), improved the organizations' ability to comply with applicable regulations (69.3%), and helped to build trust within the human research protection community (61.4%). The majority of survey respondents felt that accreditation had done each of the following either "quite a bit" or "a great deal":

- Encouraged periodic assessment of compliance and quality, efficiency, and effectiveness of the HRPP;
- Helped to improve the organization's HRPP policies and procedures;
- Helped to improve the organization's compliance with applicable regulations and guidelines;
- Helped to improve the organization's protection of research participants; and
- Improved the knowledge of human research for the IRB chair, IRB staff, and IRB members.

Dr. Cobb closed with a "quintessential quote" from a survey respondent that underlines the value of accreditation in enhancing IRB effectiveness: "Earning accreditation really enhanced the way our IRB members and staff look at themselves. They understood that they were holding themselves to very high standards—not only adhering rigorously to the regs but also committing themselves and the organization to continuous quality improvement."

On Measuring and Ensuring HRPP and IRB Effectiveness through Peer Review

- *Benjamin Mooso, MS, CCRP, IRB Director at UC San Diego, and CARE-Q*

Mr. Mooso explained how the Consortium for Applied Research Ethics Quality (CARE-Q) seeks to foster effective IRB review through intensive program reviews by and for IRB professionals. The network of peers was created by the University of California and Stanford University. IRBs can be certified through CARE-Q by participating in an affordable five-year program. Operating without overhead, this approach makes accreditation financially accessible to a wider array of academic institutions than might otherwise participate.

CARE-Q is a collegial program that offers an opportunity for two-way learning, as the reviewers take promising practices home to their own institutions. It uses the current regulatory framework as a basis for review. As membership changes, the organization evolves.

Measurement strategy. Mr. Mooso stated that the IRB's effectiveness is measured using a risk-based approach to review of studies (initial and ongoing). For example, reviewers assess whether the IRB is letting the "perfect be the enemy of good" in minimum risk studies and whether it is doing due diligence on studies above minimum risk. They also look at the IRB office operations, including the balance of work and life experienced by staff. Mr. Mooso held that burned-out people will be less effective and less able to innovate. Reviewers also perform a program needs assessment that considers the use of best practices and analyzes gaps that offer room for improvement.

Peer reviewers reach their conclusions in several ways. The review comprises:

- *Review of written policies and procedures.* This component is guided by regulations and by HHS guidance: IRB Written Procedures: Guidance for Institutions and IRBs (2018).
- *Interviews with staff, members, and investigators.* The interviews are used to assess whether the institution's policies and procedures are really being followed, how people are supported, and other key elements of effectiveness.
- *Observation of IRB meetings.* Direct observation of deliberations helps peers understand how the IRB reaches its conclusions.

Mr. Mooso acknowledged that the approach is not without limitations. First, it is a snapshot in time. Also, it only looks at the IRB and does not attempt to take participants' experience into account. It requires member buy-in to make sure that peers are reviewing IRBs as they need to be reviewed. Finally, the approach is still new to the IRB community, and it will take some time to build confidence that it is working.

The Participant Experience as a Proxy for IRB Effectiveness

- *Luke Gelinas, PhD, Senior IRB Chair, Advarra*

Dr. Gelinas focused his remarks on the proposal to use participant experience as a measure for IRB quality. He raised two major concerns about this proposal. He closed his presentation by reflecting on the nature and responsibilities of IRBs, leading to an alternative proposal.

The question explored by the speaker is this: What role, if any, should participant experiences play in evaluating the quality of IRB review? He suggested that participant feedback about their experiences in a study should only be used to evaluate the quality of the IRB in domains for which the IRB is responsible. Given the area in which IRB responsibilities and participant experiences intersect, would participants' experiences be a reliable indicator of IRB quality?

First reason for caution. Dr. Gelinas proposed two reasons for caution. First, he held that using participant experience as a guide to IRB quality will be unreliable in an important range of cases due to the inherent gap between the IRB review and what actually transpires in studies. For example, he challenged listeners to imagine a study in which participant experience is used as a way of measuring whether the IRB did a good job of protecting participants from harms. Such an approach might involve surveying or interviewing participants, ascertaining whether they were harmed during research, and then attempting to draw inferences about the quality of IRB review based on whether or how many harms are identified. What is wrong with this approach?

Dr. Gelinas held that no matter how good a job the IRB had done in its review of the study, some participants may have been harmed due to a variety of factors the IRB could not control and could not have predicted. Thus, relying on participant experiences in this way is likely to yield high false positive rates—events (harms) that are mistakenly taken to warrant concerns about IRB review. Further, no matter how bad a job the IRB does, no participants may be harmed. Relying on participant experience in this way is also likely to yield high false negative rates—failure to identify concerning events even when the quality of IRB review is low.

The explanation for this is built into the uncertain nature of risks and harms. IRBs are enjoined to minimize risks and ensure a reasonable risk-benefit balance. However, it is not possible to completely eliminate risks from research; risks are by their nature uncertain, and whether risks lead to actual harms is often beyond the control of IRBs. Therefore, using participants' experience of harms is not likely to be a reliable indicator of IRB quality.

Dr. Gelinas further observed that this concern can be generalized beyond risks and harms to other aspects of participant experience susceptible to contingency and chance. Once the IRB reviews a study, any number of factors out in the world can impact participant experiences, for good or ill. The element of chance undermines the reliability of using participant experience as a reliable proxy for IRB quality in many cases.

Second reason for caution. For participant experience to be a reliable guide to the quality of IRB review, participants must be attuned to the responsibilities of the IRB versus the responsibilities of other relevant parties. In situations in which a concern is identified, it may be difficult for a participant to know whether the responsibility for what has gone wrong is attributable to researchers or to the IRB.

For example, consider a participant who has a negative experience during informed consent (IC). The challenge is that IC mixes together, in ways not always easily separated, the responsibilities of the IRB and the responsibilities of researchers. The IRB is responsible for reviewing the IC process and ensuring its adequacy, but the research team is responsible for explaining the contents of the consent form, engaging in a discussion of the study, answering questions, and so on. Some deficiencies in IC might be due to deficiencies in the approved process, but others might be due to failures on the part of the research staff– for example, a failure to communicate clearly and respectfully.

Dr. Gelinas did not feel that it was hopeless or impossible to design methods that use participant experience as a marker for IRB quality in certain domains. However, such efforts must be precise and fine-grained about the aspects of IRB review that are being evaluated so that they only assess elements for which the IRB is responsible. The evaluation method must also control for various possible confounders, given the gap between IRB review and what actually transpires in studies, the difficulty of differentiating stakeholder responsibilities, and other considerations.

Taking a step back, Dr. Gelinas stressed that it is the regulatory framework that gives IRBs their mandate and authority. Why not measure the quality of IRB review primarily by assessing how well IRBs do at ensuring that research satisfies the regulatory criteria? This would mean asking a different question: Given the information the IRB had, were they really justified to conclude that the study as planned was such as to minimize risks, exhibited a reasonable risk-benefit balance, and met other regulatory requirements?

On Measuring and Ensuring IRB Effectiveness Through the Quality of IRB Deliberations

- *Laura Stark, PhD, Associate Professor at the Center for Medicine, Health, and Society, Vanderbilt University*

Dr. Stark began by sharing key findings from research that used an ethnographic approach to study three IRBs. She conducted interviews with individual members of each of these IRBs and with a national sample of IRB Chairs (Stark, 2012). In her remarks, she sought to:

- Draw attention to the quality of the IRB's decision-making process;
- Introduce two empirically grounded concepts to help IRBs define, measure, and assess IRB decision-making effectiveness; and
- Provide resources for additional empirically driven findings that came out of her work.

Dr. Stark noted that there are strengths and weaknesses to two possible approaches to studying IRB deliberations. One approach, used in Stark's work, is to study the review process while it is underway to understand the dynamics of decision-making, though this approach requires further research to be well defined; a second approach is to evaluate how decisions were made post-hoc, which depends on recall and might not be accurate.

Dr. Stark introduced two empirically grounded concepts to describe decision-making dynamics. First, "warrants" are justifications people give for their opinions, including IRB members. Dr. Stark observed that all the members bring some sort of expertise to the review process. They differ, for example, in their fields of knowledge, their familiarity with the local community, and their personal context. One member may have expertise in many areas. A scientist may also be a neighborhood leader or a caretaker. It is important to consider how seriously different members' views are taken and why. What is seen as a legitimate claim? What are the practical implications of the way an IRB assesses the varying "warrants" of its members?

Dr. Stark's ethnographic study also pointed to the importance of a second concept, local precedents, in IRB decision-making. She noted that the concept comes from English common law, under which what has legal validity in a new case is influenced strongly by past decisions in similar cases. Audits have shown that the same protocol may yield different decisions by different IRBs, and this has often been read as showing the subjectivity of IRBs and demonstrating their ineffectiveness. However, while this is sometimes the case, it is often true that each IRB is fair and consistent according to its own history and is following established precedents for comparable studies.

Nevertheless, Dr. Stark's more recent work shows that an IRB's interpretations, as well as rules, may change over time and across institutions. This is part of what makes multi-site research challenging. Changes in staff and IRB membership can refresh or entrench local precedents. Studies of effectiveness must therefore take into account both local precedent as a predictive factor in decision-making and shifts in perspective over time due to a variety of causes.

Panel Discussion and Audience Questions

Dr. Taylor asked Dr. Gelinas what information about the participant experience could be used to assess effectiveness. Dr. Gelinas clarified his proposed approach to measuring IRB effectiveness, which is based on retrospective analysis of questions such as these: Were there risks the IRB failed to minimize, or were they right on target? Were there adverse events at a higher rate than might be expected?

Next steps. Dr. Taylor invited panelists to reflect on next steps in determining how IRB effectiveness could be measured.

Dr. Cobb suggested that more information is needed on the impact of the HRPP and the IRB on the conduct of the study. What do people think about what the HRPP is doing? Further input from the community could help answer this question. She also felt the field had not yet reached consensus on the components of effectiveness, although work is being done in that area. The field needs to agree on "what works."

Ms. Lally pointed to the need for consensus on what is meant by "effectiveness." People in the research community have very different perspectives on what justifies saying, "we are doing a good job."

Dr. Gelinas said he would like to see improvement in how the community and participant perspectives are incorporated in the IRB process. Dr. Taylor agreed. For example, it is important to ask who on the IRB represents the local population from which the sample might be drawn.

Components of effectiveness. Dr. Taylor commented that although speakers have identified some components of effectiveness, we do not know yet how to measure any of them well. Examples are Dr. Stark's findings on expertise and precedents.

Dr. Stark said another important component in effectiveness is trust. Does the IRB trust the researchers? Do researchers trust the IRB members? She suggested that relationship building should be part of any staff or IRB member's job description. We often assess the performance of "atomized" individuals without understanding that it is the relationships among them that lead to effectiveness. Dr. Taylor agreed that trustworthiness is a critical component in effectiveness. The Holy Grail of effectiveness would be public trust.

Dr. Cobb suggested that one approach to assessing IRB effectiveness is to look at a suite of characteristics that an IRB (or HRPP) exhibits. For example, we agree on the need for a robust scientific review and good consultation with the community. Dr. Taylor rejoined, however, that the field still lacks the tools needed to determine whether these things are being done well.

Is compliance enough? Dr. Taylor noted that a baseline for measuring effectiveness is surely whether or not the IRB is following the regulations. She added that not everyone is at the baseline. But is effectiveness more than simple compliance?

Mr. Mooso responded that meeting the regulations is part of effectiveness, but in some cases an IRB might be compliant with the regulations but still less than effective because of failure to take the community perspective, relevant scientific data, or other information fully into account.

Dr. Gelinas wondered whether panelists really meant the same thing by compliance. To him, assuring the science behind the study is sound is part of compliance. The IRB has to find that the study is worth doing, the risks are reasonable, and the risks are minimized. How big a concept is compliance?

Dr. Taylor was not sure that all IRBs have the expertise to consider the science behind the study design and relate it to risk and benefits. If this is the baseline, there is variability. Dr. Stark said fairness and trust that the rules are being followed are important, but the fact that IRBs sometimes make different determinations may not mean that the IRBs are ineffective. Inconsistency may point to something else that needs further study.

Ms. Lally stressed the importance of IRBs being seen as supporting good science rather than police bent on enforcing the rules. Are we doing our jobs in a way that promotes trust and teamwork? Dr. Taylor observed that good collaboration takes adequate funding and time. Dr. Cobb added that while some IRBs are well resourced and staffed, some lack the support they need to reach the level of compliance, let alone anything beyond it. This can lead to the question of whether an internal IRB is the right strategy for that institution.

Dr. Taylor said she did not think that standardization was the same thing as effectiveness. The goal is not for everyone to come to the same conclusion. Some consistency is good, but consistency is not an appropriate measure for effectiveness.

The role of the researcher. A member of the webinar audience asked, "What is the role of the researcher in all this? How can researchers be brought into the effort to ensure IRB effectiveness?" Dr. Gelinas appreciated the question and stressed that it is the researchers who interact with study participants. They have an obligation to listen to people with sympathy and engage them in the research. The IRB is not the sole guarantor of ethical research.

Dr. Cobb suggested that it was important to talk with research teams and recognize that they do care about protecting participants, which is apparent from interviews of study teams conducted during AAHRPP site visits. They are not given enough credit. IRBs and researchers have a shared interest in reducing unnecessary administrative burdens. Mr. Mooso stressed that when trust breaks down and an adversarial relationship prevails between research teams and IRBs, IRB effectiveness is diminished, and science is stymied as well.

Dr. Stark said that her interviews showed that IRB members who spoke to researchers in person were more successful. Using a phone call or Zoom might work better than emails and improve communication. Dr. Gelinas cited a recent webinar in which the speaker suggested using Zoom rather than a succession of emails to complete essential revisions in expedited review (Ryan, 2024).

Dr. Taylor closed by expressing appreciation to sponsors, panels, and audience members.

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SPEAKER BIOGRAPHIES

Holly Taylor, *MPH, PhD*
Research Bioethicist, NIH Clinical Center

Holly A. Taylor, PhD, MPH, is a member of the faculty of the Department of Bioethics at the Clinical Center of the National Institutes of Health. She is a nationally recognized expert on the review and oversight of human subject research and on research ethics consultation. She co-leads two national collaboratives dedicated to advancing knowledge and practice in these areas: the Consortium to Advance Effective Research Ethics Oversight (www.AEREO.org) and the Clinical Research Ethics Consultation Collaborative (www.iths.org/CRECC). Dr. Taylor conducts quantitative and qualitative research in the field of research ethics, including informed consent for research participation and subject selection, as well as the review and oversight of research and research ethics consultation. She also has longstanding interests in public health ethics issues related to infectious disease and has published on HIV, pandemic preparedness, Ebola, and Covid-19. She also has served on multiple institutional review boards and data monitoring committees.

Rachel Lally, *MPH, CIP*
Assistant Vice President for Research, Penn State University

Rachel Lally, MPH, CIP is an Assistant Vice President for Research at the Pennsylvania State University. She is responsible for overseeing compliance programs related to IRB, IACUC and safety within Penn State's Office for Research Protections. Rachel completed her undergraduate degree in Behavioral Neuroscience and Education at Colgate University, earned a master's degree from Columbia's Mailman School of Public Health, and has over 20 years of experience working in clinical research and research administration, with an expertise in human subjects research. Rachel worked with a number of IRBs in New York City before landing at Penn State and has participated in many local and national meetings related to improving the way IRBs do their work, with a focus on protecting human subjects while moving science forward.

Nichelle Cobb, *PhD, CIP*
Senior Advisor for Strategic Initiatives for AAHRPP

Nichelle Cobb, PhD, CIP, is the Senior Advisor for Strategic Initiatives for the Association for the Accreditation of Human Research Protection Programs (AAHRPP) and previously a site visitor for AAHRPP and member of AAHRPP's Council on Accreditation. Prior to joining AAHRPP, she was the Director of the Health Sciences Institutional Review Boards (IRBs) for 16 years at the University of Wisconsin-Madison and has worked with IRBs for 20+ years. Nichelle has been involved in single IRB work for more than a decade and was instrumental in the development of the SMART IRB Reliance Agreement and serves as a Senior Advisor and Ambassador for SMART IRB, a federally funded project to support the implementation of single IRB. In addition, Nichelle is a member of the SMART IRB Harmonization Steering Committee and has co-led working groups to harmonize IRB and Human Research Protection Program (HRPP) practices, such as for reportable events, ancillary reviews, continuing review, and local context. Nichelle also has been a member and co-chair of human subjects research content planning committees for the Public Responsibility in Medicine and Research (PRIM&R) annual Advancing Ethics in Research Conference, contributed to IRB Management and Function, 3rd Edition, authored academic articles on single IRB and informed consent, and developed and taught PRIM&R courses for new IRB administrators and about the Common Rule. She has been invited to many regional and national meetings to speak on issues affecting HRPPs and especially IRBs.

Benjamin Mooso, *MS, CCRP*
IRB Director at UC San Diego, and CARE-Q

Ben Mooso, MS, CCRP, is the current director for the Office of IRB Administration at UC San Diego where he has served for three years and is a co-chair for the Executive Committee of the Consortium for Applied Research Ethics Quality (CARE-Q) developed by the University of California and Stanford. Ben began his career as a basic and animal researcher studying genitourinary cancers at UC Davis and the VA in Sacramento, eventually becoming involved with the VA IRB. Ben parlayed these experiences into a role in clinical research administration at UC Davis' Emergency Medicine Department before joining the UC Davis IRB and eventually leading the UC San Diego IRB. Ben has been described as a "policy nerd" by his colleagues and enjoys the challenge of making IRBs more efficient without sacrificing subject protections. Ben appreciates any opportunity to work with colleagues on advancing the national discussion around IRB efficiencies and efficacy.

Luke Gelinas, *PhD*
Senior IRB Chair, Advarra

Luke Gelinas, PhD, is the Senior IRB Chair Director at Advarra, where he provides analysis and guidance on complex ethical issues arising in the course of clinical research study design and human participant protection. Previously, Luke led collaborative and multi-stakeholder projects addressing foundational and practical issues in research ethics including social media use, clinical trial priority-setting, and has explored the ethical and regulatory parameters paying research participants. His written work has appeared in leading medical and bioethics journals, and frequently lectures on various issues surrounding research ethics and human participant protection. Luke holds a PhD in Philosophy with a concentration in Ethics from the University of Toronto and an MA in Religion from Yale Divinity School.

Laura Stark, *PhD*
Associate Professor at the Center for Medicine, Health, and Society, Vanderbilt University

Laura Stark, PhD, is Associate Professor at Vanderbilt University's Department for Medicine, Health, and Society. She is author of *Behind Closed Doors: IRBs and the Making of Ethical Research*, which was published in 2012 by University of Chicago Press. She has published several other works on the history of medicine, morality, and the modern state, and pieces on social theory. Her second book, *The Normals: A People's History* is under contract with Chicago Press. This book explores the lives of "normal control" research subjects enrolled in the first clinical trials at the US National Institutes of Health after World War II. Laura received her PhD from Princeton University, was a Postdoctoral Fellow in Science in Human Culture at Northwestern University and held a Stetten Fellowship at the Office of NIH History at the National Institutes of Health. She was on faculty at Wesleyan University before joining Vanderbilt in 2012.