OHRP AND FDA WEBINAR SUMMARY AND RESOURCES

On Differing Approaches to Measuring and Ensuring IRB Effectiveness

By Saraf Salim

October 17, 2024, the U.S. Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) Office of Clinical Policy (OCLP) co-hosted a live public webinar to hear from research ethics professionals and the public about differing approaches to measuring institutional review board (IRB) effectiveness in protecting human subjects in research.

The webinar was part of OHRP's and FDA OCLP's efforts to address the fourth recommendation in a 2023 report by the U.S. Government Accountability Office (GAO), GAO-23-104721, INSTITUTIONAL REVIEW BOARDS: Actions Needed to Improve Federal Oversight and Examine Effectiveness (U.S. GAO, 2023). The recommendation in the report provided the following:

> 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 convened panel included five distinguished speakers who discussed four possible approaches to measure IRB effectiveness. The approaches were informed by previous discussions OHRP and FDA OCLP had with the regulated community on the topic and 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.

Each speaker gave a presentation before participating in a panel discussion in which members of the public had the opportunity to contribute their thoughts and ask the speaker questions. Opening remarks were provided by Karen Giardiello, Supervisory Regulatory Counsel for FDA OCLP, who presented the webinar topic and welcomed speakers for the event. Holly Taylor, a Research Bioethicist at the Clinical Center of the National Institutes of Health (NIH), moderated the webinar and set the stage by noting that the challenge of measuring IRB effectiveness is not new and discussed how desirable IRB outcomes can be subjective and amorphous, which makes them hard to operationalize as measures.

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The first speaker, Rachel Lally, Assistant Vice President for Research at the Pennsylvania State University, reported on efforts her institution has taken to streamline IRB review and consider how their efforts may impact IRB effectiveness and suggested that while IRB effectiveness may not be the same as efficiency, consistency in the process may be relevant for an IRB to be effective. Nichelle Cobb, Senior Advisor for Strategic Initiatives for the Association for the Accreditation of Human Research Protection Programs (AAHRPP), reflected on her organization's assessment of the effectiveness of human research protection programs (HRPPs). Dr. Cobb presented data from a survey of accredited organizations and suggested IRBs can only be effective if they are part of an effective HRPP program and communication and coordination are critical for IRBs to fulfill their mission.

Benjamin Mooso, IRB Director at the University of California San Diego and co-chair for the Executive Committee of the Consortium for Applied Research Ethics Quality (CARE-Q), discussed the peer review process CARE-Q provides and explained that reviewers assess an IRB's effectiveness

through a risk-based approach to the review of studies and the burden on IRB staff, and perform a needs assessment for potential improvements. Luke Gelinas, the Senior IRB Chair for Advarra, explored the role of participant experiences as a measure for IRB quality, and cautioned that this may be unreliable due to a gap between IRB review and how study personnel may conduct the approved protocol, Dr. Gelinas also mentioned it is important to consider that participants may have negative experiences due to a variety of factors that are unrelated to an IRB's review or within their control.

The last presentation was given by Laura Stark, Associate Professor at the Center for Medicine, Health, and Society at Vanderbilt University, who discussed the dynamics of decision-making and approaches to studying IRB deliberations. Dr. Stark, who in 2012 authored the book *Behind Closed Doors: IRBs and the Making of Ethical Research* in which she interviewed members of three IRBs and a sample of IRB Chairs, discussed how IRB members used "warrants" when justifying their expertise or statements during IRB deliberations and that the same protocol reviewed different decisions by different IRBs but often each IRB is fair through their own established local precedents. She noted that studies of IRB effectiveness should consider the impact of warrants and local precedent on the quality and effectiveness of IRB decision-making.

During the panel discussion, Dr. Taylor invited panelists to reflect on next steps in how IRB effectiveness could be measured and discuss components of effectiveness, if regulatory compliance is enough, and the role of the researcher in IRB effectiveness and protecting participants. The speakers suggested more information is needed on the impact of the HRPP and the IRB on study conduct and the need for consensus on what is meant by "effectiveness."

Overall, the speakers noted the importance of collaboration and resource support to promote IRB effectiveness beyond regulatory compliance efforts. They emphasized the necessity of trust between research teams and IRBs for IRB effectiveness to support good science and protect research participants.

The speakers' biographies, slides, webinar recordings, and summary reports are available on OHRP's website.

Disclaimer: The opinions expressed are those of the author and do not necessarily reflect the policy of the U.S. Department of Health and Human Services.

References

Office, U. S. G. A. (2023, January 17). Institutional Review Boards: Actions Needed to Improve Federal Oversight and Examine Effectiveness. Institutional Review Boards: Actions Needed to Improve Federal Oversight and Examine Effectiveness | U.S. GAO. www.gao.gov/products/gao-23-104721

Stark, L. (2012). *Behind Closed Doors: IRBs and the Making of Ethical Research.* University of Chicago Press.

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