

2020 OHRP EXPLORATORY WORKSHOP

Practical & Ethical Considerations for Single IRB Review

Thursday | September 17, 2020 | 8:10AM - 4:00PM ET

Live Webcast from Bethesda, Maryland

AGENDA

Time	Sessions
8:10 AM – 8:25 AM	Welcome and Introduction (OHRP)
8:25 AM – 10:20 AM	<p>Session I: Providing Options and Ensuring Quality in Single IRB Review Moderator: Stephen Rosenfeld, M.D., MBA; <i>Freeport Research Systems, LLC</i></p> <p>Single IRB review of collaborative multi-site research can reduce inconsistencies and improve the quality of reviews. However, the single IRB mandate could result in a small number of IRBs amassing more responsibility and importance over a large proportion of federally funded research. Encouraging more institutions to serve as single IRBs is one way to diversify single IRB options and could promote a culture of quality reviews that inspires confidence. This session will share experience on how institutions create options for single IRB reviews, and explore measures to promote quality ethics review and human research protections.</p>
8:25 AM	<p>Session I Introduction Stephen Rosenfeld, M.D., MBA; <i>Freeport Research Systems, LLC</i></p>
8:30 AM	<p>Ensuring Quality IRB Reviews: Lessons Learned from NCI's CIRB Initiative Linda K. Parreco, RN, M.S.; <i>Nurse Consultant, Office of the Deputy Director, Division of Cancer Prevention, National Cancer Institute</i></p>
8:45 AM	<p>Diversifying Options for Single IRBs: An Institution's Experience With Extending Their IRB Services to Outside Institutions Ann Johnson, Ph.D.; <i>IRB Director, University of Utah</i></p>
9:00 AM	<p>From Relying to Reviewing: Considerations and Lessons Learned When Establishing a Single IRB Joshua Fedewa, M.S., CIP; <i>Associate Director, HRPP, University of Texas Southwestern Medical Center</i></p>
9:15 AM	<p>Evaluating the Quality of Ethics Review and Promoting Transparency and Accountability in the Era of Single IRBs Holly A. Taylor, Ph.D., M.P.H.; <i>Research Bioethicist, Department of Bioethics, Clinical Center, National Institutes of Health</i></p>
9:30 AM	Session I Panel Discussion
10:20 AM – 10:40 AM	Break
10:40 AM - 12:35 PM	<p>Session II: Effectively Managing Local Context Concerns in Single IRB Review Moderator: Liza Dawson, Ph.D.; <i>Chief of Bioethics and IRB Chair, Walter Reed Army Institute of Research</i></p> <p>There are questions about whether local context issues receive adequate consideration in single IRB review of collaborative multi-site research. This session will examine what might constitute legitimate local context concerns and how single IRBs could best ensure that they receive appropriate attention and accommodation.</p>
10:40 AM	<p>Session II Introduction Liza Dawson, Ph.D.; <i>Chief of Bioethics and IRB Chair, Walter Reed Army Institute of Research</i></p>
10:45 AM	<p>Addressing Local Context Issues By Single IRBs in Multi-Site Research Robert Klitzman, M.D.; <i>Professor of Psychiatry, Columbia University</i></p>
11:00 AM	<p>Challenges to Reviewing Clinical Research When Local Context Includes Variation in Infrastructure and Practices Jonathan M. Green, M.D., M.B.A.; <i>Director, Office of Human Subjects Research Protections, National Institutes of Health Intramural Research Program</i></p>

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11:15 AM	How Might a Single IRB for Multisite Research Address Local Culture, Race and Social Class of Potential Human Subjects? Stephen B. Thomas, Ph.D.; <i>Professor, Health Policy and Management, and Director, Maryland Center for Health Equity School of Public Health, University of Maryland, College Park and IRB member for the All of Us program</i>
11:30 AM	Experience With Regionalized Ethics Review Committees in the United Kingdom and Europe Sarah J.L. Edwards, Ph.D.; <i>Professor of Bioethics, Department of Science and Technology Studies, University College London</i>
11:45 AM	Session II Panel Discussion
12:35 PM – 1:30 PM	Lunch
1:30 PM - 3:25 PM	Session III: Sharing Responsibilities and Distinguishing Roles in the Single IRB Era Moderator: Megan Kasimatis Singleton, J.D., M.B.E., CIP; <i>Assistant Dean, Human Research Protections and Director, Human Research Protections Program, Johns Hopkins University School of Medicine</i> The transition to single IRB review for cooperative research requires institutions to change how they conduct oversight of research. Even when IRBs are no longer the IRBs of record, their institutions continue to have legal and ethical responsibilities for protecting research participants. This session will explore the challenges and adjustments for relying institutions as they implement the single IRB mandate. This may also present opportunities for improving oversight of the conduct of research at the institutions.
1:30 PM	Session III Introduction Megan Kasimatis Singleton, J.D., M.B.E., CIP; <i>Assistant Dean, Human Research Protections and Director, Human Research Protections Program, Johns Hopkins University School of Medicine</i>
1:35 PM	Reliance Agreements: Considerations and Responsibilities Beyond IRB Review Emily Chi Fogler, Esq.; <i>Partner, Verrill Dana LLP</i>
1:50 PM	Establishing the Role of the Relying Institution in Human Subjects Protection in the Era of Single IRB Kelley O'Donoghue, M.P.H., CIP; <i>Associate Vice President for Human Subject Protection and Director of the Office for Human Subject Protection (OHSP) at the University of Rochester</i>
2:05 PM	Working Together to Improve the Single IRB Model: Suggestions from a Multi-Stakeholder Project Team Sara B. Calvert, PharmD; <i>Senior Project Manager, Clinical Trials Transformation Initiative (CTTI)</i>
2:20 PM	SMART IRB: Lessons Learned and Opportunities Ahead Barbara E. Bierer, M.D.; <i>Director, Regulatory Policy, SMART IRB and Director, Regulatory Foundations, Ethics, and the Law, Harvard Catalyst (CTSC)</i>
2:35 PM	Session III Panel Discussion
3:25 PM	Summary Panel: Where do we go from here?
4:00 pm	Closing