## AGENDA

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<tr>
<td>8:10 AM – 8:25 AM</td>
<td>Welcome and Introduction (OHRP)</td>
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| 8:25 AM – 10:20 AM | **Session I: Providing Options and Ensuring Quality in Single IRB Review**  
  **Moderator:** Stephen Rosenfeld, M.D., *Freeport Research Systems, LLC*  
  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. |
| 8:25 AM     | **Session I Introduction**  
  Stephen Rosenfeld, M.D., *Freeport Research Systems, LLC*                                                                            |
| 8:30 AM     | **Ensuring Quality IRB Reviews: Lessons Learned from NCI’s CIRB Initiative**  
  Linda K. Parreco, RN, M.S.; Nurse Consultant, Office of the Deputy Director, Division of Cancer Prevention, National Cancer Institute |
| 8:45 AM     | **Diversifying Options for Single IRBs: An Institution’s Experience With Extending Their IRB Services to Outside Institutions**  
  Ann Johnson, Ph.D.; IRB Director, University of Utah                                                                                 |
| 9:00 AM     | **From Relying to Reviewing: Considerations and Lessons Learned When Establishing a Single IRB**  
  Joshua Fedewa, M.S., CIP; Associate Director, HRPP, University of Texas Southwestern Medical School                                    |
| 9:15 AM     | **Evaluating the Quality of Ethics Review and Promoting Transparency and Accountability in the Era of Single IRBs**  
  Holly A. Taylor, M.P.H., Ph.D.; Research Bioethicist, Department of Bioethics, Clinical Center, National Institutes of Health |
| 9:30 AM     | **Session I Panel Discussion**                                                                                                          |
| 10:20 AM – 10:40 AM | Break                                                                                                                                   |
| 10:40 AM – 12:35 PM | **Session II: Effectively Managing Local Context Concerns in Single IRB Review**  
  **Moderator:** Liza Dawson, Ph.D.; Chief of Bioethics and IRB Chair, Walter Reed Army Institute of Research  
  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. |
| 10:40 AM    | **Session II Introduction**  
  Liza Dawson, Ph.D.; Chief of Bioethics and IRB Chair, Walter Reed Army Institute of Research                                             |
| 10:45 AM    | **Addressing Local Context Issues By Single IRBs in Multi-Site Research**  
  Robert Klitzman, M.D.; Professor of Psychiatry, Columbia University                                                                    |
| 11:00 AM    | **Challenges to Reviewing Clinical Research When Local Context Includes Variation in Infrastructure and Practices**  
  Jonathan Green, M.D., M.B.A.; Director, Office of Human Subjects Research Protections, National Institutes of Health Intramural Research Program |
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| 11:15 AM      | Identifying and Managing Unique Cultural and Socioeconomic Issues in Single IRB Review of Multi-Site Research  
Stephen B. Thomas, Ph.D.; Professor, Health Policy and Management; Director, Maryland Center for Health Equity, University of Maryland; IRB member for the All of Us Research Program |
| 11:30 AM      | Experience With Regionalized Ethics Review Committees in the United Kingdom and Europe  
Sarah J.L. Edwards, Ph.D.; Professor of Bioethics, Department of Science and Technology Studies, University College London |
| 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; Assistant Dean, Human Research Protections and Director, Human Research Protections Program, Johns Hopkins University School of Medicine  
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; Assistant Dean, Human Research Protections and Director, Human Research Protections Program, Johns Hopkins University School of Medicine |
| 1:35 PM      | Lessons Learned From Developing SMART IRB  
Barbara E. Bierer, M.D.; Director, Regulatory Policy, SMART IRB  
Director, Regulatory Foundations, Ethics, and the Law, Harvard Catalyst (CTSC) |
| 1:50 PM      | Reliance Agreements: Common Pitfalls and a Review of the Considerations to Be Included  
Emily Chi Fogler, Esq.; Partner, Verrill Dana LLP |
| 2:05 PM      | Re-Establishing the Role of Relying Institutions in Human Subjects Protection in the Era of the Single IRB  
Kelley O’Donoghue, M.P.H.; Associate Vice President for Human Subject Protection and Director of the Office for Human Subject Protection (OHSP), University of Rochester |
| 2:20 PM      | Working Together to Improve the Single IRB Model: Suggestions from a Multi-Stakeholder Project Team  
Sara B. Calvert, PharmD; Senior Project Manager, Clinical Trials Transformation Initiative |
| 2:35 PM      | Session III Panel Discussion                                                                                                                                 |
| 3:25 PM – 3:30 PM | Break                                                                                                                                 |
| 3:30 PM      | Summary Panel: Where do we go from here?                                                                                                                                 |
| 4:00 pm      | Closing                                                                                                                                 |

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