

**Comparing IRB Models for Multisite Pediatric Studies
Thursday, April 23, 2009**

This conference is sponsored by the National Center for Research Resources and the Eunice Kennedy Shriver National Institute for Child Health and Human Development. The purpose is to learn in a structured manner about different models for IRB evaluation of multisite pediatric clinical research protocols.

The information from this conference plus an accompanying Request for Information will be used by the Pediatric Research Ethics Workgroup of the Clinical and Translational Science Awards (CTSA) Consortium Child Health Oversight Committee to select a model for a pilot to determine what should be adopted by the CTSA Consortium to facilitate multisite pediatric research.

Please note that all times are estimates. Actual time will be determined by the dynamics of the discussion.

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| 11:00- 11:10 | Welcome and Introduction | Alexander Kon, <i>University of California, Davis</i> |
| 11:10 - 11:25 | High level review on steps to protocol activation | Susan Shurin, <i>National Institutes of Health</i> |
| 11:25 - 11:40 | Current Office of Human Research Protections regulations | Julie Kaneshiro, <i>Office for Human Research Protections</i> ; Ivor Pritchard, <i>Office for Human Research Protections</i> |
| 11:40 - 11:50 | CRpac's Efforts to Promote Consideration of Other Models of Efficient, Consistent, and Rigorous IRB Review | Phil Budashewitz, <i>National Institutes of Health</i> |
| 11:50 - 11:55 | Overview of structure of Panel Discussions | Steven Hirschfeld, <i>Eunice Kennedy Shriver National Institute of Child Health and Human Development</i> |
| 11:55 - 12:45 | Panel 1: Central IRB Model | Jacquelyn Goldberg, <i>National Institutes of Health</i> ; Lynn Cates, <i>Department of Veterans Affairs</i> ; Nayesh Kamani, <i>Children's National Medical Center</i> ; Stacey Berg, <i>Baylor College of Medicine</i> ; Steven Davis, <i>Cleveland Clinic</i> ; Daniel Nelson, <i>University of North Carolina at Chapel Hill</i> |
| <i>Break (12:45-1:00)</i> | | |
| 1:00 - 1:45 | Panel 2: Reciprocal IRB Agreement Model | Michele Russell-Einhorn, <i>Dana Farber Cancer Institute</i> ; Theresa O'Lonegan, <i>University of Colorado, Denver</i> ; Alison Lakin, <i>University of Colorado, Denver</i> ; Keith Norris, <i>Charles Drew University</i> |
| 1:45 - 2:35 | Panel 3: Rotating IRB Model | Michael Dean, <i>University of Utah</i> ; John Stillman, <i>University of Utah</i> ; Sally Jo Zuspan, <i>University of Utah</i> ; Ronald Maio, <i>University of Michigan</i> ; James Chamberlain, <i>George Washington University</i> ; Carol Nicholson, <i>National Institutes of Health</i> ; Daniel Kavanaugh, <i>Health Resources and Services Administration</i> |
| 2:35 - 3:25 | Panel 4: Commercial IRB Model | Stephen Rosenfeld, <i>Western IRB</i> ; David Forster, <i>Western IRB</i> ; Raffaella Hart, <i>Biomedical Research Alliance of New York</i> ; James Saunders, <i>New England IRB</i> ; Theresa Straut, <i>Chesapeake IRB</i> ; Amy Schwarzhoff, <i>Chesapeake IRB</i> ; Jon Davis, <i>Tufts University</i> |
| <i>Break (3:25-3:40)</i> | | |
| 3:40 - 4:30 | Closing Discussion: Panel will comment on the various models and address specific questions | Alexander Kon, <i>University of California, Davis</i> ; Robert 'Skip' Nelson, <i>Food and Drug Administration</i> ; Debbie Gipson, <i>University of North Carolina</i> ; Vicki Pemberton, <i>National Institutes of Health</i> ; Theresa O'Lonegan, <i>University of Colorado, Denver</i> ; Francis Crawley, <i>Good Clinical Practice Alliance-Europe</i> ; Julie Kaneshiro and Ivor Pritchard, <i>Office of Human Research Protections</i> |