

**CTSA Web Conference
Pediatric Research: Challenges for Institutional Review Boards
Agenda and Summary of Conference Segments
September 11, 2007**

Time	Title	Summary
11:00-11:30	Introduction	Dr. Jennifer Puck offers a welcome to the web conference followed by remarks from Dr. Duane Alexander, Director of NICHD and Dr. Elaine Collier of NCRR. In addition, Dr. Puck provided an overview of the conference and case study outline.
11:30-12:00	Case 1	Presentation and Review of Case Study 1: Maintenance therapy for Systemic Lupus Erythematosus. This case was moderated by Dr. Nancy Bridges.
12:00-12:30	Case 2	Presentation and Review of Case Study 2: Insulin Clamp, BMI and Risk of Diabetes. This case was moderated by Ms. Victoria Pemberton.
12:45-1:15	Case 3	Presentation and Review of Case Study 3: Screening for autism spectrum disorders in infants. This case was moderated by Dr. Rosemary Higgins.
1:15-1:45	Case 5	Presentation and Review of Case Study 5: Emergent intervention for treatment of self inflicted injury. This case was moderated by Dr. Cheryl Boyce.
1:45-2:15	Case 4	Presentation and Review of Case Study 4: Gene therapy for glioblastoma multiforme. This case was moderated by Dr. Malcolm Smith.
2:30-3:15	Presentations(Dr. Mike Carome and Dr. Skip Nelson)	Dr. Carome presented on "Cooperative IRB Review Arrangements for Multicenter Research: Regulatory Considerations" and Dr. Nelson presented on "Applying Additional Safeguards for Children, 21 CFR 50, Subpart D"
3:15-4:00	Presentations(Dr. Bruce Gordon and Dr. Felix Gyi)	Dr. Gordon presented on "NCI Pediatric Central IRB Initiative" and Dr. Gyi presented on "Cooperative IRB Review Arrangements for Multicenter Research: Central IRB Perspective"
4:15-5:00	Expert Panel Discussion and Summary of Conference	The expert panel including Dr. Alex Kon, Dr. Steven Hirschfeld, Dr. Samuel Tilden, Dr. Lainie Ross, Dr. Skip Nelson, Dr. Mike Carome, Dr. Eric Kodish and Dr. David Wendler, held a general discussion and fielded questions from the participants. Following the group discussion, Dr. Kon provided a summary of the conference and issues for the group to consider for the future.