

CTSA Consortium Child Health Oversight Committee (CC-CHOC)

Pediatric Research Ethics Workgroup (PREW)

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PREW: Accomplishments

- Web-conference: “Comparing IRB Models for Multisite Pediatric Studies”—April 2009
- Participation in "Workshop on Regulatory Issues Affecting Clinical Investigators: Balancing Regulation with the Need for Clinical Research."
 - Sponsors: The Endocrine Society and The Lawson Wilkins Pediatric Endocrine Society
 - Bethesda November 2008
- Reviewed exemplar protocols/consents for genetic research involving children & posted on the wiki
 - Dr. DiMichele—Weill Cornell
 - Dr. Neufeld—Children’s Hospital, Boston
- Calls for protocols with significant variability in IRB reviews
 - Received 3 from University of Colorado

PREW: SGC & KFC Mapping

Strategic Goal Committees

- National Clinical and Translational Research Capability
- Enhancing Consortium-Wide Collaborations

Key Function Committees

- Clinical Research Ethics
- Regulatory Knowledge
- *Participant and Clinical Interactions Resources*

PREW: Current Initiatives

1. Facilitating multicentered pediatric research
 - Ensure excellent protection of children
 - Increase speed & simplify process for investigators
 - Central Pediatric IRB
 - Potential partnering with NICHD Networks
 - How to include all of the various expertise needed?
 - Paid consultants
 - Very large IRB
 - Consider central CTSA Datacenter & DSMB
 - Reciprocal IRB agreements
 - Issues regarding administration, insurance, etc.
 - Rotating IRB
 - PCARN—excellent ethics components in proposals
 - IRBNet
 - Commercial IRB
 - Who pays?
 - Philosophical issues?
2. White paper: “Appropriate referrals for 407 panel review”

PREW: Goals

- Develop working relationships with SGCs
- Continue to build collaboration with other KFCs, workgroups, subcommittees
 - Pediatric Drugs and Devices
 - Pediatric Metrics of Success
 - Pediatric T2 Research
 - Regulatory/Research Ethics IRB group
- Develop and implement one or two facilitated IRB review models
 - RFI completion this summer
- 407 white paper completion by summer 2010