

**CTSA Consortium Child Health Oversight Committee (CC-CHOC)  
Pediatric Research Ethics Workgroup (PREW)  
June 22, 2009  
2:00 PM – 3:00 PM ET**

**Agenda : Pediatric Compact Document**

- I. **Goal: Outline of key elements by July 21<sup>st</sup>, SACHRP meeting**
- II. **Three themes, although not necessarily three sections**
  - A. **Note:** The more feasible the Process & Performance themes are, the more likely we can anticipate acceptance and adherence.
  - B. **Principles: Suggested Topics**
    - Compliance with pertinent regulations such as 45CFR46 and 21CFR50 and guidance documents such as ICH E6 and ICH E11
    - Recognition that outcome measures and assessments should be population specific
    - Recognition that assessment schedules should accommodate families and be age appropriate
    - Recognition that local experience should be an important determinant of risk for interventions and assessments
    - Recognition that data sharing is a goal and that the permission, assent and consent process should anticipate future uses of data and specimens
    - Recognition that variations are possible in the circumstances of when permission, assent and consent are required and when either the initial process can be waived for emergency research or when parental permission can be waived for certain infectious diseases or psychiatric conditions
    - Recognition that monitoring is context dependent
    - Recognition of a hierarchy of evidence in making extrapolations and interpreting data
    - Recognition that the responsibility of an IRB is for human subject protection
  - C. **Process: Suggested Topics**
    - Health care providers with experience with the population of interest and the condition of interest should be part of the review
    - Local experience should be an important determinant of risk so data regarding local experience with assessments and interventions should be available. Absent adequate local data, literature should be used to guide risk determination
    - Criteria for supplemental monitoring such as a recommendation for an Independent Data Monitoring Committee should be proactively developed
    - Communication plan between relevant parties such as investigators, institutional offices, sponsors, funding organizations and regulatory authorities should be proactively developed
    - Information regarding other competent assessments of a proposed study, for example other IRBs or review groups, should be shared
    - Definitions of responsibilities among review parties such as Scientific Review Group, Independent Data
  - D. **Performance: Suggested Topics**
    - For initial review of a study, first IRB will review in one cycle based on regularly scheduled meetings
    - IRB summary review will be attached to protocol package for delivery to other IRBs

- A protocol coordinator will append initial IRB summary review to protocol and distribute concurrently to additional sites.
- For initial review of a study already approved by a recognized IRB, review in one cycle based on regularly scheduled meeting. Review may be abbreviated and should be informed by deliberations of first IRB to review.
- Each subsequent IRB summary review will be attached to protocol package for delivery to protocol coordinator
- Protocol amendments will follow the same process of initial IRB review and subsequent distribution to other IRBs