IRB and Ethics
Pediatric Research

Barbara Illowsky Karp, MD
National Institutes of Health
Bethesda, MD

Joan A. Conry, MD
Children's National Medical Center
Washington, D.C.

ASENT Feb 23, 2012

Key issues identified in Ethics and IRB/ pediatric research

- Definitions
  - of minimal risk/minor increase over minimal risk
  - of disease or condition

- Inconsistency of review between different IRBs
  - Defining risk level
  - Determining approvability

Key issues identified in Ethics and IRB/ pediatric research

- Consent
  - Legally- authorized representative
  - Consent form length and complexity

- Assent
  - Standards for when needed, how obtained
  - Standards for assent forms
  - Recognizing and respecting dissent

Key issues identified in Ethics and IRB/ pediatric research

- Aging out--- what happens with samples and data when minor reaches adulthood

Key issues : potential solutions

- Clearer regulatory guidance, standards, and definitions

- Shorter informed consents; use of supplementary materials

- Alternative informed consent processes

- Increased consistency among IRB based on clearer guidance
- Increased use of centralized IRB review with "reliances"