Unchecked in Boston: Altered Requirements for Low Risk Research

Fanny Ennever, PhD, CIP
Manager, Regulatory Policy Development
Office of Human Research Affairs
Boston Medical Center and Boston University Medical Campus

Context

Boston Medical Center and Boston University Medical Campus IRB

• Two institutions, one Human Research Protection Program
• Unchecked the box in 2011
• Institutional commitment to seek AAHRPP accreditation
  o Process for revising Policies and Procedures
  o Opportunity to implement flexibility
    (aka Equivalent Protections)
Scope

Conservative rollout – does not apply if:

- Money from the federal government
- Grant
- Payment for clinical services
- Oversight by FDA (drugs and devices)
- A promise to follow the federal rules
  - To OHRP (we did until 2/14/2011)
  - To non-federal sponsor

Equivalent Protections #1
Extended approval period for minimal risk research

**Three-year** (instead of one-year) approval – most eligible minimal risk research

- Minimal risk from beginning
- Minimal risk because in follow-up or data analysis only
Equivalent Protections #2
New exempt categories

Exempt research – shorter consent, easier to modify

New categories
7. Socio-behavioral with adults
8. Surveys/interviews with children
9. Existing or future data not collected for research
10. Existing data collected for research

Equivalent Protections #3
New expedited categories

Expedited review – minimal risk, not reviewed by full board

New categories for eligible submissions
10. Blood collection >2x/week, ≤550 ml/8 weeks
11. Minimally invasive tissue collection
12. Radiation ≤0.1 mSv
Equivalent Protections #4
Parent permission

• Federal regulations require permission of both parents where a minor increase over minimal risk to child with no direct benefit to child
• If eligible, IRB can require one parent’s permission

Equivalent Protections #5
When subjects become prisoners

• Federal regulations require all interventions on an enrolled subject stop if s/he becomes incarcerated until IRB approves inclusion
• If eligible, don’t have to get IRB review
Equivalent Protections #6
Father’s permission for fetal research

• Federal regulations require father’s permission for research benefitting only the fetus
• If eligible, IRB can require only mother’s permission

Equivalent Protections #7
IRB recordkeeping

• If eligible, IRB does not have to justify inclusion of pregnant women in minimal risk research
• If eligible, IRB does not have to justify allowing abbreviated consent for screening
Thank you!