

Unchecked in Boston: Altered Requirements for Low Risk Research

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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
 - Process for revising Policies and Procedures
 - 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

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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

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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

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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

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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

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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

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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

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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

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Thank you!