Equivalent Protections: Altered Requirements for Minimal Risk Research

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Learning objectives

- Describe how the flexibility in the federal regulations has been used to reduce some IRB requirements for minimal risk research by providing equivalent protections
- Identify which research is eligible for equivalent protections
- Explain how the equivalent protections might apply to existing or future research

Q: Who makes the IRB rules?

A1: The federal government, **IF** it has authority:

- 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

Q: Who makes the IRB rules? (2)

A2: We do, **IF** federal government doesn't have authority ("flexibility")

To be ethical, must provide "equivalent protections"

- Research with appreciable risks
  - federal rules needed
- Low-risk research
  - lesser requirements still protect subjects

"Minimal Risk"

"The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ***ordinarily encountered*** in daily life or during the performance of ***routine*** physical or psychological examinations or tests"

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

Your action? Nothing, IRB will determine if next renewal should be in 2019

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

New exempt categories

Your action?

4.0 Review Path Determination

4.1 Review Path Determination

- ○ This project meets the regulatory definition of Not Human Subject Research (NHSR). Examples are Quality Assurance, Quality Improvement projects, or studies that involve obtaining anonymous data/tissues or coded data; Or BU/BMC is not "engaged" in human subjects research.
- ○ BU/BMC (the Relying Institution) cedes IRB review to another institution (the Reviewing Institution) under an Authorization Agreement.
- ◉ This study fits into one or more of the federal Exempt categories or the study does not have to follow federal guidelines and fits into one or more of the Equivalent Protections Exempt categories.
- ○ None of the above. This study requires Expedited review or the review of the Full Board.

New exempt categories

Your action?

6.0 Exemption Categories

6.1 Categorical Exemptions

Certain types of human research studies can be designated as exempt if all of the study activities fit into one or more specific categories and the study is minimal risk. Research on prisoners (incarcerated subjects) and on drugs/devices does NOT qualify for Exempt review. Research that must follow federal requirements does NOT qualify for categories (7), (8), (9), or (10)..

Please select the most appropriate exempt categories from the list below.

New exempt categories

Your action?

(7) Research without federal funding on adults able to consent for themselves investigating individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

○

(8) Research without federal funding on children using survey procedures, interview procedures, or observation of public behavior where the investigator participates in the activities being observed.

○

New exempt categories

Your action?

(9) Research without federal funding involving materials (data, documents, records, or specimens) that have been or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

(10) Research without federal funding involving materials (data, documents, records, or specimens) that have been collected for research purposes when the consent for the research does not preclude such additional 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

Your action? Nothing, IRB will determine if expedited or full board

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

Your action? May submit request for one parent 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

Your action? May keep subjects in study when they are incarcerated

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

Your action? May submit request to have 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

Your action? Nothing

Thank you!

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Other Changes

- Protocol in INSPIR application
- Approval letters for consent form modifications
- Research requiring Legally Authorized Representatives
- Deadline for reporting Unanticipated Problems
- Translated consent form attestation
- Review of planned protocol exceptions