Disclaimer

The views expressed in this talk are mine. They do not represent the position or policy of the NIH, DHHS, or US government.
Key Points

Two pillars in protection of human subjects

Institutional Review Board

Informed Consent
Key Points

• Institutional Review Boards (IRBs) are responsible for the review and oversight of human subject research

• IRBs are guided in their review by Federal Regulations (46 CFR 46.111 and 21 CFR 56)

• IRBs are LOCAL, they develop their own policy and practice

• When in doubt, ask the IRB
Ethical Requirements: Independent Review

- Review of research (design, population, risk/benefit) by unaffiliated individuals to:
  - Assure public/social accountability
  - Minimize impact of potential researcher COI

Emanuel et al (2000) *JAMA*
Transformative Effects of IRBs

• “Unquestionably, their very existence has tempered the inevitable propensity of researchers to pursue investigations without dispassionately weighing the risks they are asking others to assume or fully informing their subjects of them.”

Edgar and Rothman (1995) Milbank Q
Conflict of Interest

“This looks like exciting work! Let’s make sure the plan is scientifically sound and appropriately protects the subjects.”

This might be a cure!
Overview

• Role
• Scope
• Responsibilities
• Review
Role

• Review and Oversight
  – Component of Human Research Protection Program

• IRB membership
  – Need minimum of 5 members
  – Local, autonomous committee
    • Variability in review
Role

• Challenges
  – Conflict of Interest
    • Individual
    • Institutional
  – Group dynamics
    • Observer drift
    • Groupthink
Scope

• Necessity of IRB
  – Need review to get Federal funds
  – Other funders require ethics review
  – FDA requires IRB review
Scope

• Federal Wide Assurance
  – Mechanism by which IRB assures Federal government that it will review research according to 45 CFR 46
    • Review regardless of funding mechanism
    • Follow principles of Belmont (US)
    • Follow internationally recognized standard (Non-US)
Responsibilities

• Review Criteria (46 CFR § 46.111)
  1) Risks minimized
  2) Risks reasonable when compared with anticipated benefit
  3) Selection of subjects equitable
Responsibilities

• Review Criteria (46 CFR § 46.111)
  4) Informed consent will be sought
  5) Informed consent will be documented
  6) Safety monitoring provisions
  7) Special protections for vulnerable subjects
Responsibilities

• Additional Criteria
  – NIH Guidelines
  – FDA Regulations
  – State Law
  – Other recommendations
Review of “Research”

- “Research: A systematic investigation including research development, testing and evaluation, designed to contribute to generalizable knowledge.”

  45 CFR § 46.102 (e)
Review

• Categories of Research
  – Not Human Subject Research
  – Exempt from IRB Review
    • No more than minimal risk
    • Meets one of 8 criteria (e.g. Data collection without identifiers)
Review

• Categories of Research
  – Expedited Review
    • No more than minimal risk
    • Can be reviewed by Chairperson or experienced reviewer
  – Full Committee Review
Review

• Initial Review
  – Research plan
  – Consent documents
  – Advertisements
Review Process

- Deliberation
- Decision
  - Approve
  - Approve with stipulations
  - Defer
  - Disapprove
Review Process

• Continuing Review
  – Annual updates
    • For protocols reviewed by Full Committee
  – Amendments to study
  – Adverse event reports
Single IRB of Record


Notice Number: NOT-OD-16-094

Key Dates
Release Date: June 21, 2016
Effective Date: New Date - January 25, 2018 as per issuance of NOT-OD-17-076

Purpose
The National Institutes of Health (NIH) Policy on the Use of a Single Institutional Review Board of Record for Multi-Site Research establishes the expectation that all sites participating in multi-site studies involving non-exempt human subjects research funded by the National Institutes of Health (NIH) will use a single Institutional Review Board (sIRB) to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects at 45 CFR Part 46. This policy, which is consistent with 45 CFR Part 46.114, is intended to enhance and streamline the process of IRB review and reduce inefficiencies so that research can proceed as expeditiously as possible without compromising ethical principles and protections for human research participants.

Scope and Applicability
This policy applies to the domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research, whether supported through grants, cooperative agreements, contracts, or the NIH Intramural Research Program. It does not apply to career development, research training or fellowship awards.

This policy applies to domestic awardees and participating domestic sites. Foreign sites participating in NIH-funded, multi-site studies will not be expected to follow this policy.

Consistent with the Roles and Responsibilities section, applicants/offerors will be expected to include a plan for the use of an sIRB in the applications/proposals they submit to the NIH. The NIH’s acceptance of the submitted plan will be incorporated as a term and condition in the Notice of Award or in the Contract Award. This policy also applies to the NIH Intramural Research Program.
Single IRB of Record

Human Research Protection Program

- Administrative Review
- Human Subjects Review

PI/Research Proposal
Single IRB of Record

Before sIRB Policy

Coordinating Center/Institution of PI

Review and Approval, Ongoing Communication

Local HRPP

Multi-center Trial

1 IRB REVIEW

+ 

5 IRB REVIEWS

6 IRB REVIEWS
Single IRB of Record

After sIRB Policy

Coordinating Center/Institution of PI

Review and Approval, Ongoing Communication

1 IRB REVIEW

Local HRPP

Multi-center Trial
Single IRB of Record

• Evaluations
  – Underway

• Outcomes
  – Unclear
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