Institutional Review Boards

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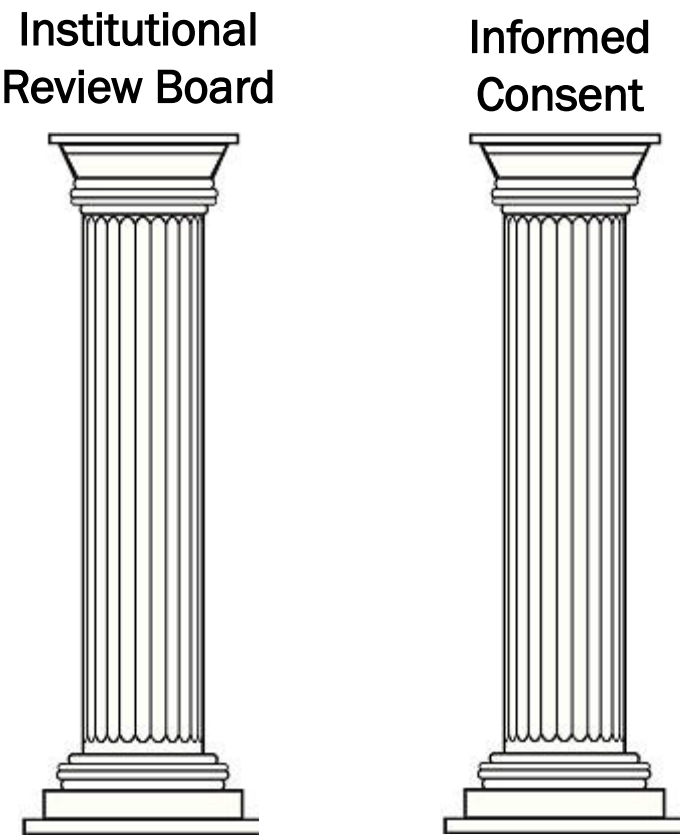
Disclaimer

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 subject



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

Overview

- History
- Role
- Scope
- Responsibilities

History

- 1949: Nuremberg Code
  - No mention of ethical review
- 1964: Declaration of Helsinki (WMA)
  - "…protocol should be transmitted to an independent committee for consideration, comment and guidance." (Principle 1.2 – 1975)

History

- 1974: National Research Act
  - Established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
- 1981: Revised CFR (DHHS Only)
- 1991: Common Rule
- 2018: Revised Common Rule

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."

Ethical Requirements: Independent Review

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

Emanuel *et al* (2000) *JAMA*

Role

- Review and Oversight
  - Component of Human Research Protection Program
- IRB membership
  - Need minimum of 5 members
  - Local, autonomous committee
    - Variability in review

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INDEPENEDENT?

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

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  5) Informed consent will be documented
  6) Safety monitoring provisions
  7) Special protections for vulnerable subjects

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SCIENTIFIC REVIEW?

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)

Categories of Research

- Not Human Subject Research
- Exempt from IRB Review
- Expedited Review
- Full Committee Review

Review Process

- Initial Review
  - Research plan
  - Consent documents
  - Advertisements

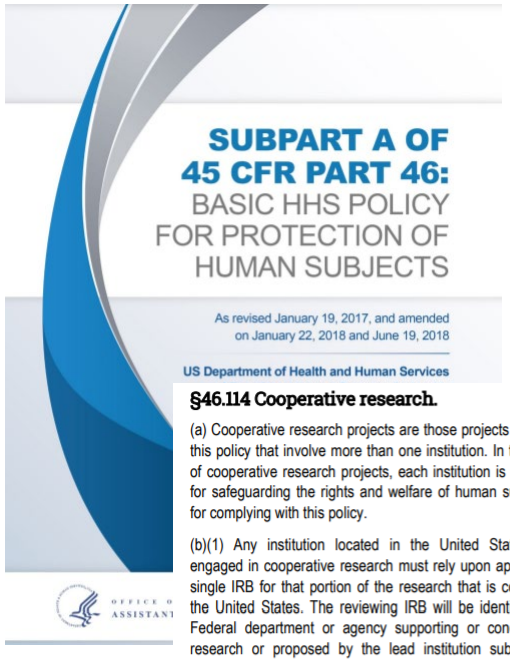
Review Process

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

Review Process

- Continuing Review
  - Annual updates
  - Amendments to study
  - Adverse event reports

Single IRB of Record



SUBPART A OF 45 CFR PART 46:
BASIC HHS POLICY FOR PROTECTION OF HUMAN SUBJECTS

As revised January 19, 2017, and amended on January 22, 2018 and June 19, 2018

US Department of Health and Human Services

§46.114 Cooperative research.

(a) Cooperative research projects are those projects covered by this policy that involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy.

(b)(1) Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.

(2) The following research is not subject to this provision:

(i) Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or

(ii) Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.

(c) For research not subject to paragraph (b) of this section, an institution participating in a cooperative project may enter into a joint review arrangement, rely on the review of another IRB, or make similar arrangements for avoiding duplication of effort.

Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research

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

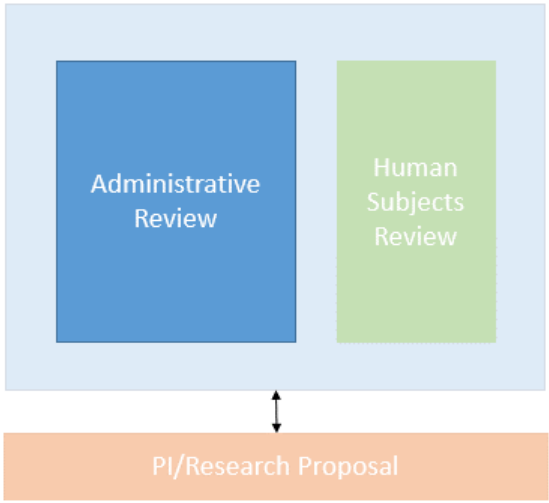
This policy applies to the domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research, whether supported through grants, cooperative agreements, contracts, or the NIH Intramural Research Program. It does not apply to career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

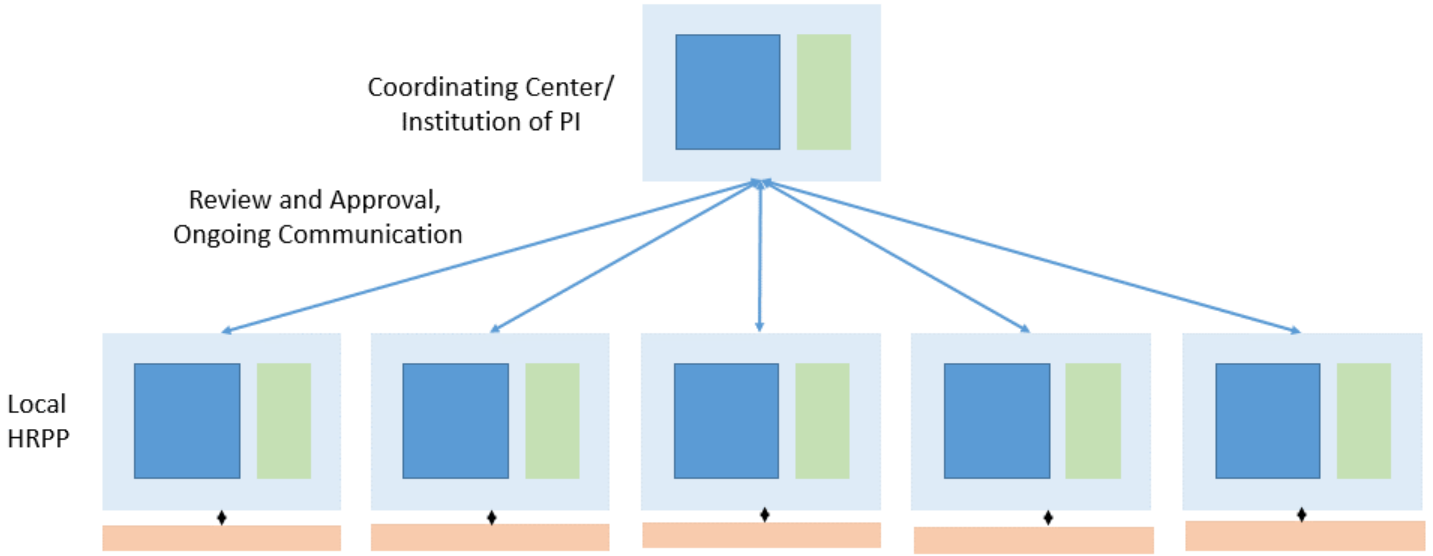
Human Research
Protection Program



Local IRB Review

Single IRB of Record

Before sIRB Policy



Multi-center Trial

1 IRB REVIEW

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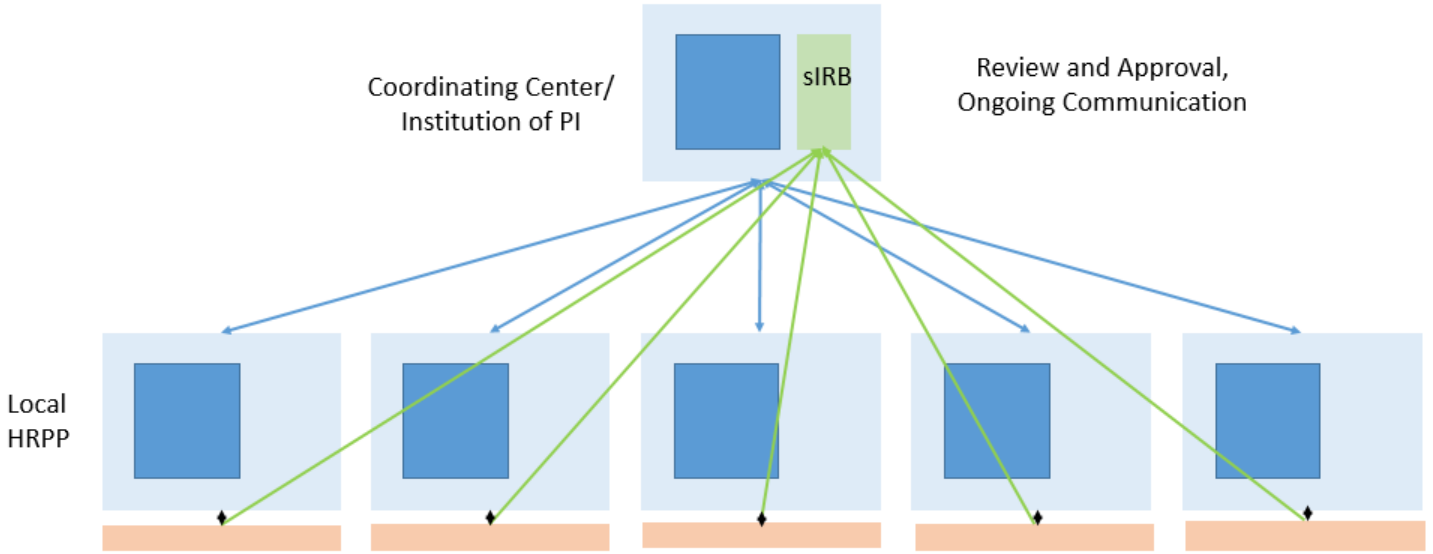
5 IRB REVIEWS

6 IRB REVIEWS

Single IRB of Record

After sIRB Policy



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