Institutional Review Boards

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Disclaimer

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

Overview

- History
- Role
- Scope
- Responsibilities

History

- 1949: Nuremberg Code
  - No mention of ethical review
- 1953: “Group Consideration of Clinical Research” (NIH Intramural Program)
  - First federal standard
- 1950s: Individual Departments
  - Local review

History

- 1962: Law-Medicine Research Institute
  - Increase in local review
- 1964: Declaration of Helsinki (WMA)
  - "…protocol should be transmitted to an independent committee for consideration, comment and guidance." (Principle 1.2 – 1975)

History

- 1966: “Statement of Policy on Clinical Investigations Using Human Subjects” (PHS)
  - All PHS funded research must be reviewed
- 1974: Code of Federal Regulations (CFR, DHHS)
  - First draft
  - Details on role and responsibilities

History

- 1974: National Research Act
  - Established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
    - 1978: Report on IRBs
    - 1978: Belmont Report
- 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*

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
  - Mediates conflict of interest
    - Physician-investigator – duty to science
    - Physician-advocate – duty to patient/subject

Role

- IRB membership
  - Need minimum of 5 members
    - Gender
    - Range of relevant expertise
    - Non-scientific
    - Not otherwise affiliated with institution
      - "Community" member

Role

- IRB membership
  - Local, autonomous committee
    - Variability in review

Role

- Challenges
  - Group dynamics
    - Observer drift
    - Groupthink
  - Conflict of Interest
    - individual
    - institutional

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

- Application of 45 CFR 46
- Scientific Review?

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)

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

- Assignment
  - Primary
  - Primary/Secondary
  - Subcommittee

Review Process

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

Review Process

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

Other Topics

- NIH/DHHS Policy on Single IRB of Record
- Quality and Effectiveness of Oversight

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

Final Common Rule - sIRB

"Creates a requirement for US-based institutions engaged in cooperative research to use a single IRB for that portion of the research that takes place within the United States, with certain exceptions. This requirement becomes effective 3 years after publication of the final rule."

https://www.federalregister.gov/documents/2017/01/19/2017-01058/federal-policy-for-the-protection-of-human-subjects