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Introduction to Institutional Review Boards (IRBs)

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Topics to be Covered

- ◆ History of IRBs
 - Where did they come from?
- ◆ Roles and responsibilities of IRBs
 - What do they do?



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Section A

*History of IRBs: Where did they
come from?*

History of IRBs

- ◆ 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 of IRBs

- ◆ 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 of IRBs

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

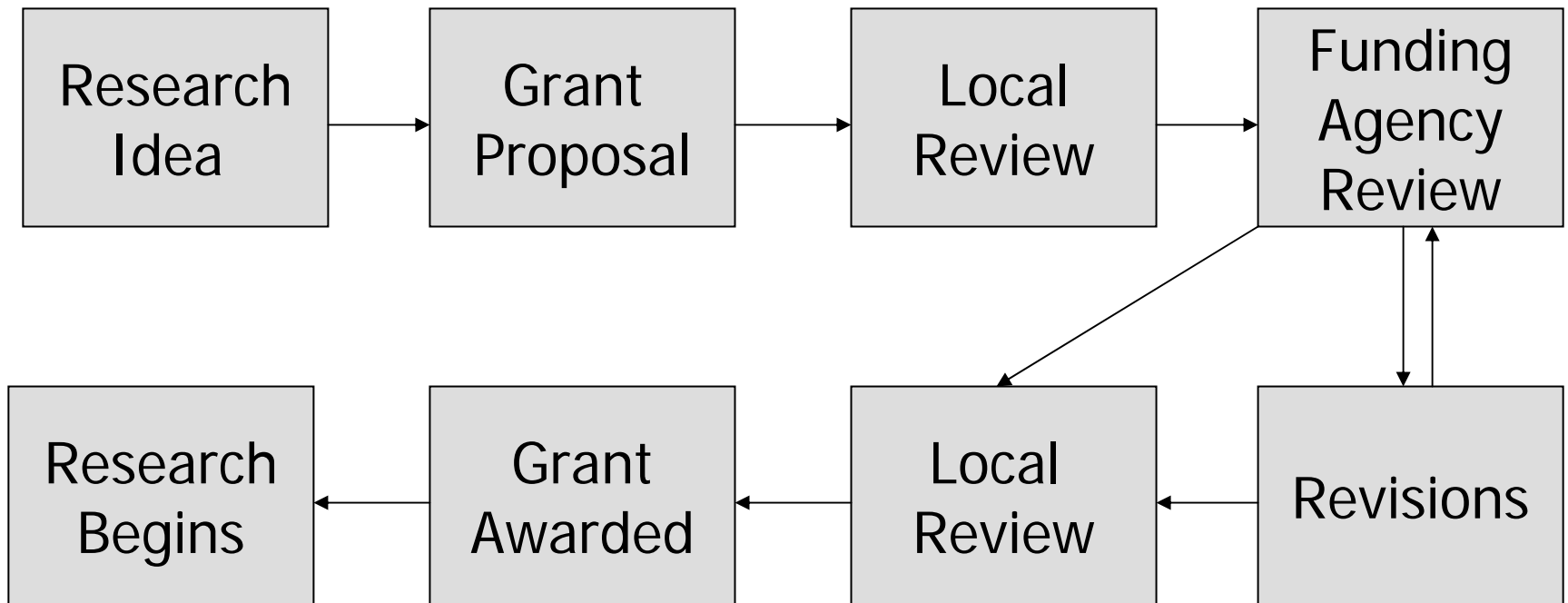
History of IRBs

- ◆ 1982: International Guidelines for Biomedical Research Involving Human Subjects (CIOMS)
 - “All proposals to conduct research involving human subjects must be submitted for review and approval to one or more independent ethical and scientific review committees.” (Guideline 14)

History of IRBs

- ◆ 2004: Institutional Review Board
 - Local ethical review committee
 - Responsibility for the rights and welfare of human subjects

Life of Research Project



Role and Responsibilities

- ◆ Role of the IRB
 - Safeguard rights and welfare of human research subjects
 - Scientific review?

Role and Responsibilities

- ◆ “The IRB needs to take into consideration the scientific merit of the proposal as it pertains to the degree of risk. Protocols with greater than minimal risk in which the results would be compromised due to poor experimental design, insufficient statistical power, and other factors that impact upon the generalizability of the results, require special attention and concern.”

Role and Responsibilities

Role of the IRB

- ◆ Mediates conflict of interest
 - Physician-investigator (duty to science)
 - Physician-advocate (duty to patient/subject)

Review Criteria (46 CFR § 46.111)

1. Risks minimized
2. Risks reasonable when compared with anticipated benefit
3. Selection of subjects equitable

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

Additional Criteria

- ◆ NIH guidelines
- ◆ FDA regulations
- ◆ State law
- ◆ Other recommendations

Necessity of IRB

1. Need review to get Federal funds
2. Other funders require ethics review
3. FDA requires IRB review

Assurance

- ◆ Mechanism by which IRB **assures** Federal government that it will review research according to Code of Federal Regulations
 - Single Project Assurance (SPA)
 - Multiple Project Assurance (MPA)

Assurance

- ◆ Federal Wide Assurance
 - Review regardless of funding mechanism
 - Follow principles of Belmont (U.S.)
 - Provide Office for Human Research Protections (OHRP) with standard operating procedures
 - Follow internationally recognized standard (Non-U.S.)

What Is an IRB?

- ◆ Not branch of OHRP
- ◆ Local, autonomous committee
 - Variability in review

IRB Membership

- ◆ Minimum of five members
- ◆ Breadth of experience
- ◆ Diversity

IRB Membership

- ◆ Sensitive to community issues
- ◆ Aware of standards
- ◆ Additional expertise

IRB Membership

- ◆ Non-scientific
- ◆ Not otherwise affiliated with institution
 - Community member
- ◆ Need five voters

Community Members

- ◆ Coercive and recruitment plans
- ◆ Mistake risk and benefits/fail to disclose financial relationships
- ◆ Stigmatize or undermine privacy
- ◆ Confuse research and treatment
- ◆ Notice unintelligible consent forms



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Section B

Categories of Review

What Is 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

- ◆ Exempt (45 CFR § 46.101)
 - “Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to subjects.”

Categories of Research

- ◆ Expedited
 - “Prospective collection of biological samples for research purposes by non-invasive means”

Categories of Research

- ◆ Expedited
 - “Research on 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.”

Categories of Research

- ◆ Full committee review
 - Research that is neither exempt nor expedited

Review Logistics

- ◆ Initial review
 - Research plan
 - Consent documents
 - Advertisements

Consent Authority

- ◆ Waiver of informed consent
 1. Research on public benefit program
 2. Research not practical without waiver

Consent Authority

- ◆ Waiver of informed consent
 1. Research involves no more than minimal risk
 2. Will not adversely effect welfare
 3. Research not practical without waiver
 4. Subjects will be provided with information

Consent Authority

- ◆ Waiver of **written** consent
 - Only record linking subject to project would be signed form and principal risk is harm from potential breach of confidentiality

Consent Authority

- ◆ Waiver of **written** consent
 - Research involves no more than minimal risk and involves no procedures for which written consent is normally required outside the research context

Review Responsibilities

- ◆ Continuing oversight
 - Annual updates
 - Amendments to study
 - Adverse event reports

Review Responsibilities

- ◆ Record-keeping
 - FDA inspections
 - OHRP oversight

Review Process

- ◆ Assignment
 - Primary
 - Primary/secondary
 - Subcommittee

Review Process

- ◆ Deliberation
- ◆ Decision
 - Approve
 - Approve with stipulations
 - Table
 - Disapprove

Review Process

- ◆ Approve with stipulations
 - Consent
 - Study design
 - Subject selection
 - Risks and discomforts
 - Confidentiality

Review Process

- ◆ Disapprove
 - Consent form
 - Study design
 - Ethical or legal reasons

Review Process

- ◆ Quality of review
 - Comprehensive
 - Monitoring procedures
 - Modifications made
 - Approves readable and complete consent forms
 - Positive evaluation from IRB members
 - Positive evaluation from investigators

Challenges to IRB functions

1. Group dynamics
 - Observer drift
 - Groupthink

Challenges to IRB functions

2. Conflict of interest
 - Individual
 - Institutional

Challenges to IRB functions

- ◆ Remedies for conflict of interest
 - Non-institutional review boards
 - Increased number of non-affiliated members
 - Increased accountability through public disclosure

Summary of Recommendations

1. Regulation of ALL research
2. Evaluation and revision of regulations
3. Education

Summary of Recommendations

4. Reduction in administrative burdens
5. Capacity building
6. Financial support
7. Conflict-of-interest