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Section D: Institutional Review Boards (IRBs)

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Background: U.S. IRBs

- 1974–1978: National Commission for the Protection of Human Subjects in Behavioral and Biomedical Research

- Produced *Belmont Report*, which defined principles for ethical research

U.S. Regulations

- Overseen by Office for Human Research Protections (OHRP), DHHS
- Institution agrees it will review all federally funded human research (or all human research, depending on how “assurance” is written)
- “Federalwide Assurance” (FWA) from OHRP “assuring” that institution is in compliance with law

U.S. Regulations

- Review locally at institution—not at U.S. government level

- Independent committee
  - At “awardee’s” institution
  - At “performance site”

Committee Composition

- At least five members, varying backgrounds
- At least one non-scientist
- At least one member from outside of institution
- Gender balance

Administrative Requirements

- Keep records of all communication
- Keep minutes
- Review at least once per year

Review Requirements

- Risks are minimized to extent possible
- Risks are reasonable in relation to anticipated benefits
- Selection of subjects is equitable and justified
- Consent elements, documentation
- Procedures for data monitoring
- Confidentiality protected

Expedited Review vs. Full Committee

- According to U.S. rules, certain types of research may be reviewed by only one committee member
  - Lower-risk research
  - Low-risk changes to existing research

- IRB itself must determine which category of research is being conducted

Challenges with IRB/REC Process

- Only able to review what is submitted, not what occurs in the field
- Not all committees make the same decisions about the same protocols
  - Is this a problem or not?

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- Some committees have inadequate training
  - Then tend to focus more on science or budget or just consent form
- Some committees have inadequate funding
  - Unable to copy or review in advance
  - Unable to meet in person very often

Multi-site Research

- Different models
  - Many sites within one country
  - Different sites in different countries

- Issues in multi-site review
  - Generally must be reviewed at every site
  - Not all committees decide the same way
  - Time consuming
  - What to do if reviews conflict?

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- Centralized model being tried as “pilot” approach