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# Inconsistency of IRB review: A research project

Sarah Fowler-Dixon
*Washington University School of Medicine in St. Louis*

# Inconsistency of IRB Review: a Research Project

Sarah Fowler-Dixon, PhD
Washington University School of Medicine
Human Studies Committee

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# “The Team”

- Sarah Fowler-Dixon Frankel, PhD
  - Specialty: curriculum & instruction
- Melissa Torres, MSW(c)
  - Specialty: social/behavioral methodology
- Morgan Taylor
  - Specialty: research ethics

# What We Already Know

IRB reviews are inconsistent

# What We Want to Know

Can the training IRB members receive reduce inconsistency?

# Evolution of Orientation at WU

- Oral discussions
  - handouts in a large notebook
- Large notebook reorganized
  - All the HSC guidelines, federal & ethical codes were covered
- Folder
  - Mock protocol included
- Folder and Website
  - Information on-line shown
  - Still includes mock protocol

# Background

- Majority of reviewers come from a biomedical background.
- HSC full boards have difficulty understanding social/behavioral research.
- Reviewers are divided into New Protocol Committee, Subcommittee, Continuing Review Committee
- All data collected anonymously.

# The Study Design

- One mock protocol
  - social/behavioral & biomedical aspects
- New member orientation
- 2 Parts
  - Part I: Notes taken after review of mock protocol
  - Part II: Orientation is modified based on findings
- 2 Groups
  - New IRB members – waiver of consent
  - Existing IRB members – letter/implied consent

# Part I Orientation

- 1 1/2 to 2 hours
- Provides practical experience with the mock protocol
- Emphasizes selected material
- 74 reviewers took part

**First ½ hour**

Bathrooms/parking/vitae

Information in notebook/authorization

Committee structure - Recusing

Ethical Codes:  Belmont Report 3 principles

Sensitive Information

Data Monitoring

Confidentiality – COC, random code

Third Parties

Minors

Methodology

Research Risk

**Second ½ hour**

In respective committee groups, review protocol

**Third ½ hour**

As a whole, discuss pertinent parts of protocol.  Begin with NPC, SUB, CRC.

# Findings

- Problems with:
  - Benefit
    - Types of benefit
  - Deception research
    - Deliberate or omission
  - Voting
    - Approve with contingencies
    - Disapprove

# Other findings

- Did well identifying:
  - Equitable subject selection
  - Confidentiality and how that should be maintained
  - Sensitive information
  - Methodology
    - Drug testing
  - Consent omissions

# Part II Orientation

- 3 hours
- Provides practical experience with mock protocol
- Emphasizes the Belmont Report
  - Providing a global context rather than individual pieces
- Uses website – so more visuals
- Thus far, 8 reviewers

**First hour**

Basic Information

Bathrooms/parking/vitae

signing Authorization

Levine/Informed Consent books

general announcements

Committee structure

3 Committees

Number of primary reviewers

Personal Conflict of Interest - stressed

Recusing

Contact before a committee meeting

Staff review after a committee meeting

Ethical & Federal Codes - mention

Common Rule: 45 CFR 46

FDA Protection of Human Subjects: 21 CFR 50

FDA Establishment of IRB: 21 CFR 56

Nuremberg Code

Declaration of Helsinki

## Belmont Report – emphasize

**Respect for Persons**

Informed consent

a. 8 elements of consent

b. alteration/exclusion of elements – K forms

Vulnerable Populations

a. Minors – consent/assent

b. Third Parties

**Beneficence**

1. Risk vs. Benefit

a. Research Risk – use Assessing Risk Guideline

1. minimal risk
2. greater than minimal risk
3. minor increase over minimal risk

**Beneficence**

2. Methodology
   a. Types of Research: social/behavioral & biomedical
   b. Deception studies
   c. Statistical analysis
   d. Use of investigational drugs/devices
   e. Standard questionnaires vs. other questionnaires

3. Data Monitoring – Use Data Monitoring Guideline
   a. Committee vs Plan
      1. Plan can have more than one person monitor

4. Confidentiality
   a. Types of coding and what that means
   b. Sensitive Information
   c. COC, what it is and when it's needed.

**Justice**

1. Equitable Subject Selection
   a. inclusion/exclusion criteria

11. Voting on the Protocol and what that means/does not mean
    a. Approve
    b. Approve with contingencies
    c. Back to Committee
    d. Disapprove – no benefit
12. Presenting the Protocol – Use Reviewer's Sheet
    a. what to discuss
13. Contents of Notebook

**Second ½ hour**

1. Starting the review – consent form then protocol then forms
2. Discrepancy between forms and protocol, go with protocol and ask PI to verify contents of protocol
3. In respective committee groups, review protocol

**Second ½ hour**

1. As a whole, discuss pertinent parts of protocol.
   a. Begin with NPC, SUB, CRC.

# Preliminary Findings – Part II

- Still collecting data
- Thus far
  - Reviewers have a better understanding of benefit
  - More objective review
  - Use of disapproval and meaning of approve with contingencies

# Preliminary Findings – Part II

- Concerns that remain the same from Part I
  - Drug testing
  - Possible deception
  - Handling of confidentiality
  - Sensitivity of questionnaire

# What does this prove?

- Reviews will never be completely consistent.

- How we educate/do not educate our reviewers does matter and influences protocol review.

# Future Research

Randomize new members to two groups of orientation to see which is more effective and how it influences the review.

Which is more influential, orientation or committee chair?