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# Inconsistency of IRB review: A research project

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# Inconsistency of IRB Review: a Research Project

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Human Studies Committee

2004 National Conference, April 19, 2004



## “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

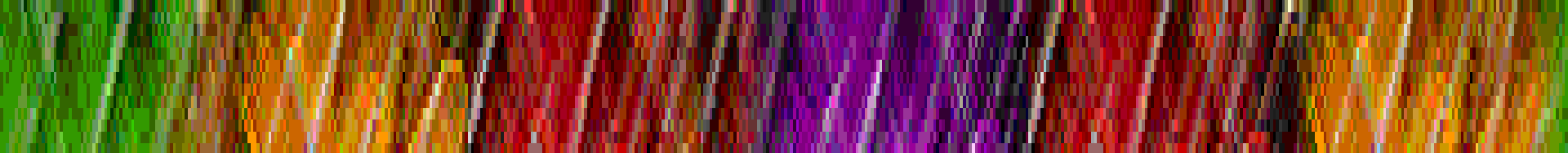
- One mock protocol
  - social/behavioral & biomedical aspects
- New member orientation
- 2 Parts
  - Part I: Notes taken after review of mock protocol
  - Part II: Orientation is modified based on findings
- 2 Groups
  - New IRB members – waiver of consent
  - Existing IRB members – letter/implied consent





# Part I Orientation

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



## **First 1/2 hour**

Bathrooms/parking/vitae

Information in notebook/authorization

Committee structure - Recusing

Ethical Codes: Belmont Report 3 principles

Sensitive Information

Data Monitoring

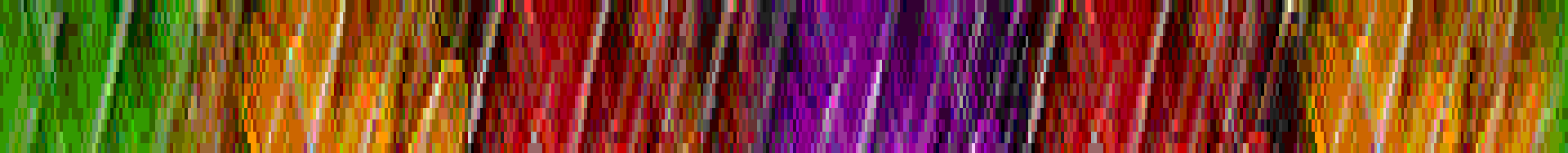
Confidentiality – COC, random code

Third Parties

Minors

Methodology

Research Risk



## **Second 1/2 hour**

In respective committee groups, review protocol

## **Third 1/2 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?