

NAVIGATING THE IRB

Workshop for Research Week

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Chair, IRB

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IRB



**ST. MARY'S
UNIVERSITY**

WHAT I HOPE TO DO TODAY:

To understand the regulatory decisions IRB members have to make in their review

What are the fundamental decisions the IRB looks at?

What are the regulatory steps in the decision process?

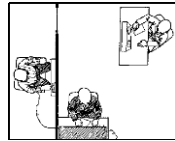
To discuss ways to write to address those IRB decisions

WHY IRB?



IRB History @IRBHistory – 4m

It seemed like a good idea at the time. Scientists sometimes get carried away. RT [@StanleyMilgram](#) [@Tuskogee](#) [@HeLaCells](#)



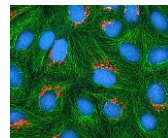
StanleyMilgram @StanleyMilgram – 40yrs

People follow authority, even when they think they hurt others. No one was really harmed. Really. Nightmares don't count.



Tuskogee @Tuskogee – 40yrs

Free health care in exchange for letting us study you. We didn't tell anyone we study syphilis. Darn penicillin!



HeLaCells @HeLaCells – 60yrs

They were too ignorant to understand what we were doing. They even thought we had cloned their mother!

WHAT ARE THE FUNDAMENTAL DECISIONS?

Risk/ Benefit

Not: Is this good research?
although that addresses the benefit

Risks of harm

- Economic
- Legal
- Physical
- Psychological
- Social
- moral
- Prevalence of risk
- Magnitude of Consequence

WHAT ARE THE INHERENT RISKS?

CASE: A study interviews adult subjects who are Licensed Professional Counselors about their cognitive and emotional responses to clients with a history of sexual trauma. Subjects will be solicited from license rosters of the local region.

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CASE: A study interviews adult subjects who have sought mental health treatment for sexual trauma. Subjects will be solicited from a client list of a community mental health agency that specializes in sexual assault care.

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CASE: A study interviews female adolescents who have sought mental health treatment for sexual trauma. Subjects will be solicited from a client list of a community mental health agency that specializes in sexual assault care.

WHAT ARE THE INHERENT RISKS?

Public health data indicates that HIV transmission is greatest among homosexual males aged 18-24. This study surveys males who self-identify as homosexual about sexual practices using the Sex Knowledge Inventory and the Sexual Risk Survey. The Sex Knowledge Inventory (McHugh, 1950) is an 80-item inventory that assesses attitudes, information and misconceptions concerning marital sexual behavior. Sexual Risk Survey (SRS) was developed for measuring risky sexual behavior among college students and asks specific aspects of sexual risk taking such as sex with uncommitted partner, impulsive sex and risky anal sex.

WHAT ARE THE INHERENT RISKS?

This study evaluates the effectiveness of a program offered by Metropolitan Health District (COSA) to change gay young men's risky sexual behaviors. Participants in an educational group will be assessed before and after 6 weeks of meetings using the sexual practices using the Sexual Risk Survey. Sexual Risk Survey (SRS) was developed for measuring risky sexual behavior among college students and asks specific aspects of sexual risk taking such as sex with uncommitted partner, impulsive sex and risky anal sex.

HOW TO MITIGATE THE RISKS?

Are these risks necessary for the research question?

Remove unnecessary risks

Do the procedures minimize risks as much as possible?

Alternative procedures

Precautions: referral for professional treatment

Do the subjects understand the nature of the risk?

Informed consent

COMMON ISSUES RE: RISK

1. Ignore risks

1. Is there an inherent risk of interviewing sexual assault victims?
2. Is there an inherent risk of surveying sexual practices?

2. Overstate the risks

1. Study provides mental health referral information to all Licensed Professionals in case they feel distress or discomfort from the nature of the interview. Is that necessary?

3. Subjects may not understand the risks

1. Informed consent document

3. WHAT IS THE LEVEL OF REVIEW?

1. Not regulated research

1. No IRB review needed

2. Exempt category

1. Minimal risk
2. One of 8 data collection methods (interview, survey)

3. Expedited category

1. Minimal risk
2. One of 11 non-exempt data collection methods (collection of bodily fluids, hair, or nails; non-invasive sensors)

4. Full review

1. Vulnerable population
2. More than minimal risks, inherent in the research have been minimized as much as possible

BASIC DECISION TREE

Is this regulated research?

“a systematic investigation designed to develop or contribute to generalizable knowledge” (45 CFR 46.102(d))

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“a systematic investigation designed **to develop or contribute to generalizable knowledge**” (45 CFR 46.102(d))

Common problems:

No literature review identifying a body of professional literature that this study can contribute to.

BASIC DECISION TREE

1. Is this regulated research?

“a systematic investigation
designed to develop or contribute to
generalizable knowledge” (45 CFR 46.102(d))

Common problems:

It appears that the PI “intends” the research to contribute to the prof lit, but the design doesn’t allow that

BASIC DECISION TREE

Is this regulated research?

“a systematic investigation designed to develop or contribute to generalizable knowledge” (45 CFR 46.102(d))

Not regulated research

Program Evaluation, Quality Improvement, Class Projects

1. IS IT REGULATED RESEARCH?

CLASS PROJECTS POLICY

Class assignments intended to engage students with people and problems outside the classroom do not require IRB review and approval if they meet all the following criteria:

- **minimal risk;**
- **anonymous data collection;**
- **voluntary participation;**
- **oral or written informed consent;**
- **has no vulnerable population (children, prisoners, or pregnant women);**
- **has a limited sample (on-campus or limited to one organization)**
- **and is not designed for publication outside the university.**

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BASIC DECISION TREE

Is this regulated research?

“a systematic investigation designed to develop or contribute to generalizable knowledge” (45 CFR 46.102(d))

Not regulated research

“...unless a research purpose...” (45 CFR 46.102(d))

BASIC DECISION TREE

2. Does this qualify as Exempt category research?

Minimal risk; deidentified data;
one of these data collection methods

Survey

Interview

Observation of public behavior not considered private

Educational tests (cognitive, diagnostic, aptitude, achievement)

“...established educational settings...not likely to adversely impact students... or instructors...[includes] instructional techniques, curricula, or classroom management methods. “

Benign behavioral interventions

Secondary research with deidentified data

IS THIS EXEMPT CATEGORY?

CASE: A study interviews adult subjects who are Licensed Professional Counselors about their cognitive and emotional responses to clients with a history of sexual trauma. Subjects will be solicited from license rosters of the local region.

Minimal risk; deidentified data; interview

IS THIS EXEMPT CATEGORY?

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Minimal risk; deidentified data; interview

IS THIS EXEMPT CATEGORY?

A study investigates the benefits of regular exercise on one's mood. Subjects will be recruited from local running and bicycle clubs and from local gyms. Subjects will complete the Beck Depression Inventory, the Substance Abuse Subtle Screening Inventory, and a questionnaire about the frequency and intensity of exercise.

Minimal risk; deidentified data; interview

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Risks are ameliorated; deidentified data; interview

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IS THIS EXEMPT CATEGORY?

A study investigates an alternative means to measure VO_2 max during exercise. Healthy undergraduate subjects will run on a treadmill while wearing respiratory monitoring mask and electrocardiogram monitor until they reach exhaustion. Data collection consists of carbon dioxide concentration of exhaled air during strenuous exercise.

**WHAT ARE THE MOST COMMON
METHODS OF DATA COLLECTION
IN YOUR DISCIPLINE?**