

Research Ethics and the IRB (Institutional Review Board)



**OFFICE OF SPONSORED PROGRAMS
SCHOOL OF GRADUATE STUDIES**

ST. CLOUD STATE UNIVERSITY

Why do we need the IRB?



- An Institutional Review Board (IRB), according to federal law, must evaluate the potential physical or psychological risk of research involving human subjects.
- All proposed human research must be reviewed and approved by an IRB before experimentation begins.
- This includes any surveys or questionnaires to be used in a project.

IRB protects any and all research programs/projects that involve the use of Human Subjects.

Brief History



- **Bad Research Occurring**
 - 1932 – Syphilis Study
 - ✦ Untreated cases of syphilis in black males
 - 28 deaths
 - 1961 – The Milgram Study
 - ✦ Study of obedience and human response to authority
 - Deception and shock theory
 - 2004 – Lilly drug trials
 - ✦ Antidepressant drugs for children under 18
 - Suicide of 19 year old

IRB Governing Body



- **US Department of Health and Human Services (HHS)**
 - Office for Human Research Protections (OHRP)
 - ✦ <http://www.hhs.gov/ohrp/>
 - Human Subject Protection began in 1947

The Belmont Report



Adopted in 1978 as “Ethical Principles and Guidelines for the Protection of Human Subjects”

Guiding Principles

- **Respect for Persons (autonomy & those with reduced autonomy)**
 - Informed consent
- **Beneficence (protect research subjects from harm)**
 - Assessment of risks/benefits – maximize benefits while minimizing risks
- **Justice (who bears the burden? who receives the benefits)**
 - Selection of subjects equitable and unbiased

45 CFR part 46



In the late 1970s and early 1980s, HHS revised and expanded its regulations that are now codified at 45 CFR part 46, subparts A through D.

- ✦ <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

Responsibility of the IRB



- **Determining and Assuring**

1. The welfare and rights of human subjects are adequately protected and informed consent given, if necessary;
2. The human subjects are not placed at unreasonable physical, mental, or emotional risk as a result of research;
3. Necessity and importance of the research outweighs the risks to the subjects
4. The researcher(s) is/are qualified to conduct research involving human subjects.

IRB & Research Methods



Quantitative Methods

- Survey

Qualitative Methods

- Observation
 - ✦ Structured
 - ✦ Participant
- In-depth interviews
- Focus Group Discussions

Overarching Ethical Principles



All researchers are responsible for ensuring that participants:

- Are well-informed about the purpose of the research they are being asked to participate in
- Understand the risks they may face as a result of being part of the research
- Understand the benefits that might accrue to them as a result of participating
- Feel free to make an independent decision without fear of negative consequences

Issues in Data Collection



Quantitative Research

- Anonymity for participants.

Qualitative Research

- Anonymity for participants.
- Protection of participants through the informed consent process favors formalized interaction between researcher and participant.
- Strength of qualitative research methods often lies in the informality of the communication as well as the iterative nature of the research process.

Guidance for Quantitative Research



- **Developing a well-written strong survey or data collection instrument.**
 - Once developed, ask for input from advisors/faculty/Statistical Consulting Center
- **Ensure confidentiality or anonymity.**
 - If applicable, develop a strong coding system and clear plan for data destruction
- **Use implied informed consent whenever possible.**
 - Helps to ensure anonymity

Guidance for Qualitative Research



- **Written informed consent may not always be necessary and may, negatively impact the quality of your research.**
 - Consult the IRB for guidance and work with them to come to acceptable solution -- Protecting the participants and the integrity of your research process
- **Establish clear process and procedures (reduces risk)**
 - No personal identifiers on field notes/transcripts
 - Raw data locked/password protected
 - Share data with **ONLY** those authorized (committee/team)

Guidance for Qualitative Research



- **Balancing Knowledge and Research Role**
 - Maintain confidentially
 - Have a list of resources available to participants
 - Refer to services
- **Dissemination and Confidentially**
 - Tell the story BUT keep the participants information confidential
 - ✦ pseudonyms

The IRB Process



- **IRB**
 - <http://www.stcloudstate.edu/irb/process/default.asp>
- **Review Process**
 - Generally 2 – 3 weeks for expedited and exempt review

Q & A



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