IRB Function

The purpose of an IRB is to review research involving human subjects to ensure their rights and welfare are adequately protected.

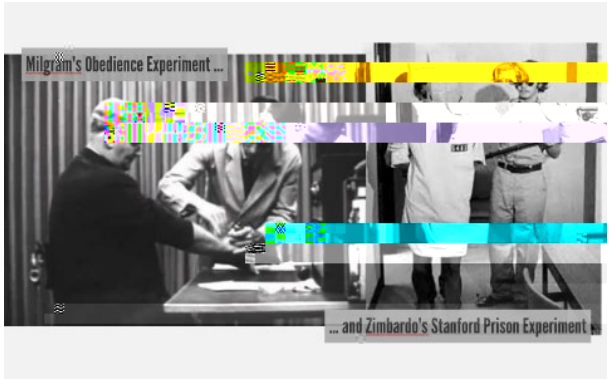
The Role of the IRB Members

- Charged with safeguarding the rights and welfare of human subjects.

Trigger Events:
“What we have learned from history...”

Nazi experimentation on concentration camp prisoners

Tuskeegee Syphilis Study



Milgram Study

Do we have a right to use information gathered unethically?

- Prisoner of War camps in Asia and Europe:
  - Practiced mutilation surgery, tested antibiotics, effects of cold, injured people to study the healing process.

Tuskegee Experiments: Physical Harm

- 1932 took 625 black males and studied the course of syphilis.
- 425 were diagnosed as having syphilis and the remainder were used as a control.
- In 1937 we discovered Penicillin but still did not give it to the men.

Milgram’s Studies: Deception, Emotional Harm

- Participants were asked to administer shocks to a subject (who they believed to be a student) when the subject answered a question incorrectly.
- Compared to Nazi war soldiers who said “I just did what they ordered me to do,” was this a true statement?
- Subjects were told to give what they believed to be painful shocks.
- About 75% continued and even though they did not want too they continued to give the shocks until they told they were approaching the lethal level.
- Subjects were devastated by what they were capable of doing.

Rosenhan Studies

- D.L. Rosenhan (1973) On Being Sane in Insane Places
- Researchers admitted to mental health institutions
- Claimed to hear voices
- Once admitted, no symptoms reported but still not released for months

Laud Humphrey’s Studies

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Federal regulations

- 1974 National Research Act
- 1974 - 45 CFR 46
- 1981 - 45 CFR 46 revised, 21 CFR 50, 21 CFR 56
  - addresses consent and role of IRBs
- 1991 - **“The Common Rule”**

Common Rule

- A federal policy regarding Human Subjects Protection that applies to 17 Federal agencies and offices.
- Applies to agencies that have signed an agreement to uphold.
- Outlines the requirements for assuring compliance by research institutions.
- Outlines the requirements for researchers' obtaining and documenting informed consent.
- Requirements for Institutional Review Board (IRB) membership, function, operations, review of research, and record keeping.
- Outlines protections for vulnerable populations (Subparts B-D).

Title 45 Code of Federal Regulations, Part 46 (45 CFR 46)

- **Subpart A:** Federal Policy for the Protection of Human Subjects **("Common Rule")**
- **Subpart B:** Additional DHHS Protections Pertaining to Research, Development and Related Activities Involving Fetuses, Pregnant Woman, and Human In Vitro Fertilization
- **Subpart C:** Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects
- **Subpart D:** Additional DHHS Protections for Children Involved as Subjects in Research

Summary: Protective mechanisms established by “The Common Rule”

- Institutional assurances of compliance
- Review of research by an IRB
- Informed consent of subjects

Institutional Assurance

MSU has negotiated with the Office for Human Research Protections that all of the institution's human subject research activities, regardless of funding, will be guided by the Belmont Report, will comply with the Common Rule, and other regulations as applicable.

This is referred to as a Federalwide Assurance (FWA).

Why is compliance important?

- Professional ethics
- Statute compliance
- Publication
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How do I know if a project needs IRB review?

- Meets federal definition of “research”
  - Systematic investigation designed to develop or contribute to generalizable knowledge.
- Meets definition of “human subject(s)”
  - A living individual about whom an investigator is conducting research
  - The investigator will obtain information or biospecimen through intervention or interaction
  - OR The investigator will gather data about living individuals that is private AND identifiable.

Criteria for IRB Approval

- **Risks are Minimized** (Consistent with a sound research design and does not unnecessarily expose subjects to risk)
- **Risks are Reasonable in Relation to Benefits**
- **Selection of Subjects is Equitable**
- **Informed Consent will be Sought** for Each Prospective Subject
- **Informed Consent will Be Documented**
- **OR** request form a waiver of informed consent or informed dissent
- Research Plan Adequately Provides for **Monitoring the Data Collected to Ensure Safety** of the Subjects
- Research Plan Adequately **Protects the Privacy of Subjects and Maintains Confidentiality**
- When some or all of the subjects are likely to be vulnerable to coercion or undue influence, **additional safeguards** need to be included in the protocol to protect the rights and welfare of these subjects.

Informed Consent - Options

- Informed Consent with signature
- Informed Consent with verbal agreement on audio or video recording (conjunction with written informed consent)
- Waiver of Consent
  - Waive consent entirely
  - Waive an element of consent
  - Waive document of consent
    - Dissent
    - Assent

Elements of Consent

- Study involves research, purpose of the research, duration of participation,description of procedures and identification of which ones are experimental
- Reasonably foreseeable risks
- Reasonably expected benefits to self and other from research
- Possible Advantageous alternative procedures or treatments (If Any)
- Description of extent of confidentiality of records that ID subject
- Greater than Minimal Risk Research– explanation of whether any compensation and available medical treatments in case of injury AND where to get more information
- Contact for questions AND contact for research related injury (not just minimal risk)
- Statement that research is voluntary, refusal will involve no penalty or loss of benefits to which the subject is otherwise entitled, and may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled

Elements of Consent Cont.

- One of the following statements about any research that involves the collection of deidentifiable private information or identifiable biospecimens:
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Elements of Consent Cont.

- A statement that significant new findings that may relate to the subject's willingness to continue participation will be provided to the subject
- The approximate number of subjects involved in the study
- A statement that biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit
- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed and under what conditions
- Whether the research will or might include whole genome sequencing

IRB Review of Research

All research projects are categorized into one of three categories for the IRB review process. Each category is different in the level of scrutiny and submission procedures.The IRB is responsible for making the final decision of which category a research project falls under.

- Full Board Review
- Expedited
- Exempt from further review

Levels of review - Exempt from Further Review

	Exemption Description
1	Research in normal educational settings
2	Research that only includes interaction involving educational tests, surveys, interviews, or observations of public behavior
3	Research involving benign behavioral interventions, data collection
4	Certain secondary research where informed consent is not required: - Certain secondary research with publicly available biospecimens or information - Secondary research with information recorded by the investigator in such a manner that the identity of the human subject cannot be readily ascertained - Certain HIPPA regulated activities - Certain research activities conducted by or on behalf of the federal government
5	Research and demonstration projects of public benefit and service programs conducted or supported by the federal department of agency that administers the public benefit program
6	Certain taste and food quality evaluations
7	Storage or maintenance of identifiable biospecimens or identifiable private information for future secondary use provided that broad consent has been sought and obtained for the storage, maintenance, and future use.
8	Secondary research where broad consent has been sought and obtained.

Minimal Risk Definition

Minimal risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

Full Board Protocol Review

- Protocols which meet the definition of more than minimal risk
- MSU IRB meets once a month

The IRB has the authority to:

- **Approve**
- **Require modifications** prior to approval
- **Table** until major issues are clarified
- **Disapprove** all research activities including proposed changes in previously approved human subject research.

Required Training

- CITI online human subjects protection training is required every 3 years. Study will not be approved until all researchers are trained.
- See the MSU IRB website for access

MSU IRB Procedures:

Student Researcher

- The principal investigator prepares the IRB application with the assistance and approval of their faculty mentor.
- Appendices labeled PI first initial last name_appendecie title_first initial last name of mentor_vdate of creation (ex. RKemp_online consent_JBrogan_v08292023)
- CITI certificates labeled First initial last name_CITI_date of completion (RKemp_CITI_08292023)
- All files should be put into one folder titled PI first initial last name_faculty first initial last name (RKemp_JBrogan)

MSU IRB Procedures:

Student Researcher

- *The complete application packet is submitted by email to msu.irb@murraystate.edu* by the ***Faculty Mentor only***

MSU IRB Procedures:

Student Researcher

- The Compliance Coordinator conducts an Initial Review to determine that the IRB application is complete and contains the following:
  - Completed Application
  - CITI Certifications for all researchers
  - The final format for online/electronic tests. Questionnaires, etc.
  - Proposed consent (or assent/dissent) forms, including text of oral explanations/scripts
  - Letter (or email) from agency granting permission to use their name
  - Letter (or email) of approval from participating organizations on official letterhead or with official title.
  - Copyrighted tests, questionnaires, etc.… and include evidence of permission to use.
  - All other specially designed or public domain tests. Questionnaires, interview protocols, debriefing, etc.