Institutional Review Board Overview

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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.
- Duties include reviewing protocols that involve the use of human subjects.
- Assist and guide researchers to help protect the rights of human subjects.

Why Do Human Research Subjects Need Protection?

Trigger Events

- The Nazi Experiments
- Tuskegee Syphilis Study
- Milgram’s Studies
- Rosenhan Studies
- Laud Humprey’s

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

- Studied homosexual behavior in public restrooms.
- Served as the "watch queen" so he could watch and record what they did.
- Got license plate numbers and interviewed them for more information without their knowing.
- He did keep the identities a secret but is this enough?

Ethical Milestones

Nuremberg Code 1947 (Human consent is essential.)

National Commission for the Protection of Human Subjects Biomedical & Behavioral 1974 (First bioethical commission to shape Human Subjects Research.)

Belmont Report 1978

Common Rule 1991

The Belmont Report:

Ethical Principles and Guidelines for the Protection of Human Subjects of Research, April 18, 1979

- **Respect for Persons (“Be courteous”)**
  - People should be autonomous and not used as a means to an end.
  - Allow informed choice where participants can choose for themselves.
  - Provide additional protections for those who need it.
  - Derived concepts: Informed consent, Respect for privacy
- **Beneficence (“Do good”)**
  - We are obligated to protect persons from harm by clearly identifying and maximizing anticipated benefits while minimizing possible risks of harm.
  - Derived concepts: Good research design, Competent investigators,
  - Favorable risk/benefit analysis.
- **Justice (“Be fair.”)**
  - Requires that the benefits and burdens of research be distributed fairly.
  - Derived concepts: Equitable selection of subjects.

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
- Individual grant funding
- University grant funding
- University research
- Liability

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.

A project is not research if…

- Not Research:
  - Scholarly and journalistic activities, including the collection and use of information, that focus on the specific individuals about whom the information is collected (oral history, journalism, biography, literary criticism, legal research, and historical scholarship)
  - Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. These activities are limited to those necessary to allow a public health authority to identify monitor and assess, or investigate potential public health signals onsets of disease outbreak of conditions of public health concerns

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:
  - (i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
  - (ii) A statement that the subject's information or bio specimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.
- A statement that the particular treatment or procedure may involve risks to) that are currently unforeseeable
- Anticipated circumstances under which participation may be terminated by the investigator
- Any additional costs to the subject that may result from participation
- The consequences of a subject's decision to withdraw from the research and procedures for termination of participation

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.

Levels of review - Expedited

- Minimal risk and fit into an “Expedited” category
  - Document review
  - Surveys or interviews
  - Collection of specimens
  - Routine noninvasive procedures

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.

	Expedited Category Descriptions
1	Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application is not required. (b)Research on medical devices for which (i) an investigational device exemption application is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2	Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected.
3	Prospective collection of biological specimens for research purposes by noninvasive means.
4	Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
5	Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non research purposes (such as medical treatment or diagnosis).
6	Collection of data from voice, video, digital, or image recordings made for research purposes.
7	Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

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***. All IRB applications submitted by students will be deleted without review. Application materials are to be found on the Murray State IRB website.
    - Email Subject: Student IRB Submission, first initial last name
    - Email Body:
        - Principal Investigator
        - Faculty Mentor
        - Department
        - Project title
        - Project period
- The principal investigator and faculty mentor will be notified via e-mail of the identification number and receipt of the IRB application, within 48 business hours.

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.

MSU IRB Procedures:

Student Researcher

Incomplete application packets will be returned to the principal investigator, with a memo stating deficiencies. Once corrected, these applications may be resubmitted for review.

- Complete IRB applications will receive an Initial Evaluation by the Compliance Coordinator to determine the content and impact of the project on human subjects. The Compliance Coordinator recommends to an IRB Member one of the following categories:

Exempt from further Review - The Compliance Coordinator provides written reasons for the exemption to the IRB Committee

Expedited Review- the Compliance Coordinator provides written reasons for expedited review to the IRB Chair, Vice Chair, or appointed IRB committee member (only recommended if there is minimal risk to human subjects).

Full Board Review Required- The Human Protections Administrator and Compliance Coordinator provide copies of the application to all members of the IRB for review at the next Human Subjects Review Board meeting.

- The full board meets once per month. If an application requires full board review, the principal investigator will be asked to make a brief verbal presentation of the application at the meeting and to respond to IRB inquiries. A summary of projects approved for exempted or expedited review is reviewed by the full board at the monthly meeting and recorded in the minutes.
- In all cases, the disposition of the IRB application is forwarded to the applicant by the Compliance Manager within two weeks following the decision. Depending upon the type of review required, and whether or not any revisions must be made by the principal investigator, the decision may take from one day to one month or more.

MSU IRB Procedures:
Student Researcher

Continuing Review

- Within a year following approval, the principal investigator will receive an email from IRBNet.org at 60, 30, and on the day of expiration. The principal investigator should complete the Continuing Review Form as soon as possible and return it to the IRB Office.
- If changes *(other than an extension of time)* need to occur the principal investigator should complete the Continuing Review Form as soon as possible and return it to the IRB Office.
- The IRB may observe the project at any time.

Expedited and Exempt Reviews*:

- Allow 2-3 weeks (business days) for Exempt from further review certifications.
- Allow 2-3 weeks (business days) for Expedited approvals.*
- Allow 2-3 weeks for renewals and amendments to expedite and exempt studies.
- Exempt and expedited complete application packets are reviewed in the order received. (If not complete, your application will not be placed in the queue until the complete packet is received.)

Full Board Review*:

- Allow a minimum of 6-8 weeks for Full Committee approvals of initial submissions and amendments.*
- Allow 4 weeks for Full Committee approval of continuing review submissions.

Completed Protocols

- Following data completion researchers are responsible for completing a protocol closure form
- All protocols will be closed 365 days following their approval if a continuation is not filed and approved.
- Any data collected post-closure will be considered misconduct and require data to be destroyed and a formal complaint to be filed.

Allow extra time during holiday and vacation periods. • Note: The IRB Committee does not convene during Fall Break, Winter Break, Spring Break, or Summer.