Human Subjects Research
and the IRB Process

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Purpose of the IRB:

- Protect Human Subjects
- Meet Federal Government Assurance Requirements
- Protect University and researchers
When (must you apply for IRB approval)

- Any research involving data collected from or about Human Subjects

What is Research?

A systematic investigation designed to develop or contribute to generalizable* knowledge.

45 CFR 46.102 (d)

*Generalizable = knowledge that can be applied to populations outside the study population.
Decision Point

Does your study qualify as research (refer to definition)?

- If No, you don’t need IRB Review
- If Yes, you need IRB review

What is a Human Subject:

A living individual about whom an investigator conducting research obtains:

- data through intervention or interaction with the individual, or
- identifiable private information.

45 CFR 46.102(f)
Decision Point:

Does your study use data from human subjects (refer to definition)?

- If No, you don’t need IRB Review
- If Yes, you need IRB review

Understanding the IRB

Responsibilities of the IRB and Investigators
Institutional Review Board (IRB):

- A Health Sciences campus-wide committee charged with the review of human participants research to assure that the rights and welfare of human participants are adequately protected.

IRB Responsibilities

- Protect research participants
- Assure that risks are minimized and benefits maximized
- Procedures for obtaining informed consent are adequate
- Selection of participants is equitable
- Safeguards for vulnerable participants
Investigator Responsibilities

- Protect research participants
- Ensure all study personnel comply with protocol requirements/determinations of IRB
- Submit changes in research to IRB for approval prior to implementation
- Minimize undue influence in enrolling participants
- Ensure that informed consent is adequate and understandable to participants
- Report unanticipated problems and adverse events

IRB Process:

How does it work?
Types of Review:

- **Exemptions** (45 CFR 46.101(b)) — minimal risk and all study procedures fall into one of the six exemption categories

- **Expedited** (45 CFR 46.110) — minimal risk and all study procedures fall into one of the nine expedited categories

- **Full Committee** — all studies that do not qualify for exempt or expedited review

Application Process; Initial Submission

- Electronic - begins with the routing form

- Refer to IRB submission Guide for help (located on the IRB website)
IRB Conditions of Approval:

- Amendments are to be completed whenever there is a substantive change to the protocol or informed consent.
- Adverse Protocol Reactions/deviations
- Continuing/Periodic re-review
- Termination of Project when complete

Deadlines

- IRB meetings; 3rd Wednesday of the month
- IRB Submission of New Projects; 1st Friday of the month
IRB Staff / Contact Information

- Michelle Brown, IRB Coordinator at extension 64608
- Elaine Fluder MSN, Director Human Research Protections Program at extension 66198
- Kenneth C. Micetich MD, Chairman IRB