The goal of research

• “The object of research is to extend human knowledge of the physical, biological, or social world beyond what is already known. But an individual’s knowledge properly enters the domain of science only after it is presented to others in such a fashion that they can independently judge its validity.”

*Committee on Science, Engineering, and Public Policy, National Academy of Sciences, National Academy of Engineering, & Institute of Medicine, 1995, p. 3.
Ethics

◦ What is right (or wrong) conduct?
◦ What are our duties (obligations) to others?
◦ What is appropriate to do in a specific context or situation?
◦ Derived from moral values about what is good (or bad) for society
Compliance

• “Cooperation or obedience: Compliance with the law is expected of all.”

(www.dictionary.com)
In science

Ethics + Compliance

= “Responsible Conduct of Research” (RCR)
(Applies to individuals and institutions)
The “Federal” Responsible Conduct of Research Areas

- Publication Practices and Responsible Authorship
- Data Acquisition, Management, Sharing and Ownership
- Mentor/Trainee Relationships
- Peer Review
- Animal Use
- Human Subject Use
- Conflicts of Interest and Commitment
- Collaborative Science
- Misconduct
Ethical Research

• Requires attention during the planning of a project, the conduct of the work, and the reporting of the results.

• Know the federal regulations pertaining to your project, know local policies, and know the state ethics laws.
Student Requirements

• Know if you need IRB or IACUC approval before you start your project.
• Understand your responsibilities
• Learn the expectations of the funding source –
  – Do you need RCR certification?
Institutional Animal Care and Use Committee (IACUC)

- Any use of animals requires approval by the IACUC.
- Must have approval prior to starting your work.
- The IACUC meets once each month to review submissions.
Animal Use

- Requires interaction with the IACUC, the attending veterinarian, and the director of the laboratory animal facilities.
- There is a regulatory burden for use.
- Seek assistance with protocol development.
IACUC Process

• Online form (LEO Research Administration System)
• Students cannot submit forms; the form must be submitted by your faculty mentor.
• There is one level of review.
• Allow four to six weeks for approval.
Institutional Review Board (IRB)

- Ohio University has two IRBs.
  - Biomedical
  - Social / Behavioral
- Each board meets once a month to review submissions.
- You must receive approval prior to interacting with research subjects.
IRB Process

• Online form (LEO Research Administration System)
• Students may submit forms but must have an advisor approve the proposal.
• Allow six to eight weeks for approval for non-exempt projects.
What is a Human Subject?

• A living individual about whom an investigator conducting research obtains:
  – Data through intervention or interaction with the individual
  – Identifiable private information
What is “Research”

• Research is a systematic investigation, including research development, testing and evaluation designed to contribute to generalizable knowledge.
Human Subject Research

• Must meet both of the previous definitions
  – That said, it is not always easy to know if your project does or does not meet these definitions.
Review Levels

• Are based on Risk level
  – Exempt
    • Minimal risk reviewed by ORC staff
  – Expedited
    • Minimal risk reviewed by IRB
  – Full Board
    • Greater than minimal risk reviewed by IRB
What is “Minimal Risk”

• “Risk”
  – The probability and magnitude of harm or discomfort anticipated in the research

• “Minimal Risk”
  – Risk not greater in and of itself than that ordinarily encountered in daily life or during routine physical or psychological examinations or tests.
Exempt Research

• “Exempt” does not mean “not covered”
• It means it is exempt from review by the IRB
• The Office of Research Compliance determines if a study meets the criteria to be considered “Exempt.”
Exempt

• Most undergraduate research should fall into this category since you are not yet advanced enough in your careers and skills to engage in research that puts participants at risk.

• Usually approvals are quicker and the research is completed in a shorter time frame.
Expedited

- Minimal risk but doesn’t fit in one of the six exempt categories.
- “Expedited” does not mean “Faster”
- It means it can be reviewed by one or more members of the IRB instead of the full board
Full Board

• Your projects should not be in this category unless you are affiliated with an established senior researcher in an ongoing project.
Consent Forms

- Consent is a process not a form.
- If you are doing Exempt research you can waive the signatures. You can waive the signatures on the form.
- Write the consent forms carefully the first time and read the template.
Common Causes for Delays

- Poorly developed projects
- Poorly written forms
- Missing Information
- Submitting without sufficient lead time
- Failing to fully address the issues that are sent to you the first time
- Not having CITI training for everyone
Common Errors

• Asking for a waiver of signature, then asking them to sign the consent form.
• Not obtaining and submitting a letter of support if one is needed.
• Using someone else’s form as a template and leaving part of their project in your form.
Responsibility

• Submitting in time
• Responding promptly to issues
• Not starting before approval
• Reporting changes
• Understand that everyone on the project is ultimately responsible for the actions of each person.
https://www.ohio.edu/research/compliance/

email compliance@ohio.edu

or call 740-593-0664