What is the IRB?

- Institutional Review Board
- Reports to the Provost
- Reviews all research involving human subjects conducted by EU faculty and students
- Ensures the safety and welfare of research subjects

Compliance with “Federal Policy for the Protection of Human Subjects”
Who is on the IRB

- Tamarah Smith, Cabrini College, is the outside member
- We consult with Tom Dahlstrom and Jacqueline Irving as needed for issues involving research on more than 100 EU students and/or alumni
Why are there IRBs anyway?

- Abuses of human research subjects
  - Nazi experiments
  - Tuskegee Syphilis Study
  - Stanford University prison experiment
  - Research and experiments on prisoners
- To ensure benefits to participants are greater than the risks
- To provide extra protections to members of vulnerable populations
Why do research ethics matter?
Why do research ethics matter?
But this could never happen on a college campus
What does the IRB do?

- Review all research involving human subjects that is conducted at EU
- Promote ethical human research
- Ensure research participants are treated justly
- Assesses research projects to ensure they are operating for the common good
Research Ethics Training

- 3 hours or less
- NIH certificate
- Standardized
- Externally developed and tested
- Looks good on C.V.’s
- Free

- More General Resources on Research Ethics
- Trainings on Ethics and Human Subjects Research
What is Research?

- Systematic investigation
- Generalizable knowledge

*Definition comes from the *Federal Regulations*
What types of research require IRB approval?

• Research with humans
• Observation of or interaction with human subjects that results in data or generalizable knowledge
• Research you want to make publicly available
• Research you want to publish in a professional or peer-reviewed publication

• See page 8 of the IRB manual for guidance
Who should submit an IRB application?

• Submit if the research is ANY of the following:
  • Sponsored by units of EU
  • Performed by, or involves, EU faculty, staff, and/or students, regardless of where the study is performed
    • Includes thesis and dissertation
  • Conducted using University-owned facilities or equipment
  • The Principal Investigator is affiliated with EU
  • External researchers who intend to use EU students as participants
    • First, they must submit a request for permission to conduct studies to the Office of the Vice President for Student Development.
Who should **not** submit IRB applications?

- Students conducting class projects with no intention to use the results for something other than the course assignment
- Researchers using publicly available data or records/data with no personal identifiers
- Researchers compiling data about people that is **NOT** generalizable **OR** will **NOT** be **shared**
What if I’m not sure I need IRB approval?
Do you need to apply for IRB approval to conduct your research?

1. Will your research involve collecting data or observations from human subjects (participants) or analyzing data generated by studying human subjects?
   a. If yes, then please proceed to the next question.
   b. If no, then IRB review is not required. You may exit the questionnaire.

2. Will your research be based entirely upon a study of historical documents, archives, or artifacts that are more than 70 years old?
   a. If yes, then IRB review is not required. You may exit the questionnaire.
   b. If no, then please proceed to the next question.

3. Will your research be based entirely upon existing records or previously acquired specimens that do not have any personal identifying information attached? “Existing” and “previously acquired” means that the records or specimens already exist and are not being collected in connection with this research.
   a. If yes, then IRB review is not required. You may exit the questionnaire.
   b. If no, then please proceed to the next question.

4. Will your research be based entirely upon material or information that is already publicly available?
   a. If yes, then IRB review is not required. You may exit the questionnaire.
   b. If no, then please proceed to the next question.

5. Will the results of your research be publicly disseminated?
   Public dissemination includes, but is not limited to, thesis, professional conference presentation held on or off campus (poster or oral presentation), journal article or book publication, or grant application.
   a. If yes, then IRB review is required. Please exit the questionnaire and submit the required application to the IRB for review.
   b. If no, then please proceed to the next question.

6. Will your research involve participants who are considered to be a “special population”?
   Special populations include, but are not limited to, individuals who are either incapable or legally unable to grant informed consent for their own participation (such as persons with certain mental disabilities or persons under age 18), prisoners, or undocumented immigrants.
   a. If yes, then IRB review is required. Please exit the questionnaire and submit the required application to the IRB for review.
   b. If no, then please proceed to the next question.
Do I need IRB approval?

- Human subjects?
- Using only archives, or artifacts > 70 years old?
- Only records without personal information?
- Public information?
- Public dissemination?
- Special populations?
- Sensitive topics?
Does Your Project Require an Application to the Cornell IRB Office?

Decision Tree #1

Will you, a member of your research team or a collaborator, observe, interact with, or intervene with individuals to gather information that will be used for research? Examples:
- Surveys, questionnaires, focus groups, interviews
- Games, experiments in physical or in electronic environments
- Physical or biomedical procedures – imaging, scanning, blood collection, anthropomorphic procedures
- Diet, nutrition studies, taste tests
- Studies examining effectiveness of educational tools or curricula
- Use of instruments or devices, including phones, to collect data or monitor or influence behavior
- Passive observation of public behavior (in physical or online environments, including social media)
- Studies examining individuals’ responses to manipulation of their physical or online environment
- Another activity that involves observation of, or interaction with, individuals to gather information for research

YES

Is the information being collected "about" individuals?

YES

The focus of the project is on people or their opinions, perceptions, choices, decisions regarding themselves or how methods, policies, procedures, organizations etc. affect them or their environment.

Is this a class project?

YES

Is the sole intent of the project to meet course requirements, with no intention to use the results for something other than the course assignment?

YES

Does the project involve stories that will or may draw broad conclusions about the population, cultures, norms, and practices; even if no research hypothesis is being tested or validated?

NO

Refer to IRB Decision Tree #2 on Existing/Secondary data

NO

Not human participant research. No application to the IRB office is needed.

NO

Research will use only existing data
What if I’m not sure I need approval?

• Outside references worth checking:
  • Cornell University IRB (IRB Decision tree)
  • University of Alabama in Huntsville IRB
  • Swarthmore College IRB

• Email irb@eastern.edu to be certain if you are not sure
  • Remember – no retroactive approvals!
I need to apply, now what?

• Read the IRB Manual
• Download and complete the IRB application
• Prepare all supporting documentation
  • NIH Certificate for Research Ethics
  • Consent statements
  • Research questions, scripts, forms, etc.
  • Letters of support
• Get advisor or department chair support
• Email irb@eastern.edu
• Give yourself extra time for the process and the research
The IRB Application

- Most recent can be found at [http://www.eastern.edu/offices-and-centers/institutional-review-board/irb-downloadable-files-and-forms](http://www.eastern.edu/offices-and-centers/institutional-review-board/irb-downloadable-files-and-forms)
- Must be filled out in its entirety in order to be reviewed
- Include all required documents in your submission
  - Can submit multiple files
  - Submit in .doc, .docx, or .pdf please
Common Application Problems

• Waiting to get faculty approval
• Not completing the entire application
• Not submitting all of the supporting documentation
• Not checking all the boxes necessary
• Checking too many or the wrong boxes
• Not including reasoning for not using written consent
• Contradictory answers
• Not having letter(s) of support/permission
• Not having interview questions, survey, etc. attached
• Insufficient protections for vulnerable populations
Who are “vulnerable” or “special” classes of research subjects?

- Pregnant women, human fetuses, and neonates
- Prisoners
- Children
- Cognitively impaired persons
- Students and employees (in certain situations)
- Minorities
- Economically and/or educationally disadvantaged
- AIDS/HIV+ subjects
- Terminally ill subjects
Abstract

• Give sufficient detail for us to understand what you are proposing to do so that we understand the experiment as we review the application
• Be sure it is consistent with your consent form, survey/questions, entire application, etc.
• Be sure to state your research hypothesis/objective and reasoning
• Give details about procedures and methods
• Notation about dissemination may help
Anonymous, Confidential, or Intentionally Identified

• Anonymous – no identifiers to link identity to response; no face-to-face interviews, no face-to-face collection; internet surveys cannot collect IP or email addresses, Facebook or LinkedIn profiles, etc.

• Confidential – you may be able to or can connect identities to responses, but you are not identifying individuals in your research

• Intentionally Identified – you are intentionally identifying your research subjects; may include the use of video, pictures, etc.
Risks and Benefits

- These are REQUIRED and must be identified
- Risks – can be minimal; may be significant
  - Must address how they will be minimized
  - Must have plan for how to deal with risks
- Benefits – for society and the individual
  - For individual, try for more than “they will have had the experience of participating in a research study”
- Problems here are often due to applicants assuming we are thinking what they are OR being unclear about risks/benefits
Common Consent Form Problems

- Not explaining photography or video or audio recording
- Not explaining risks and benefits
- Not explaining length of time needed for study
- Missing statement about withdrawing
- Missing info about compensation
- Their contact info and irb@eastern.edu
- Spelling and grammar mistakes
- Not having additional languages (if needed)
Do I need a letter of support?

- If at EU and fewer than 100 students – No*
- If at EU and more than 100 students – Yes – you will need to have your project reviewed by IRB, Student Development, and Institutional Research
- Are you doing the work elsewhere? Probably Yes
- Rule of thumb: If your research involves a location/people associated with that location/contacting people associated with a particular location you need a letter.

*currently, but this will be revisited soon
What does IRB approval mean?

• The research application you submitted is approved by the IRB for 1 calendar year
• You can start your research project
• Can request extensions (additional year at a time)
• Can make amendments and modifications

• Note – cannot get retroactive approval!