Research Ethics:
The Protection of Human Subjects

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Office of Research Integrity
Why is there an Institutional Review Board (IRB)?

1947 – Nuremberg Trials
20 Nazi Physicians and 3 Nazi officials were tried for research atrocities performed on POW’s and concentration camp victims
Nuremberg Code

- The first internationally recognized code of research ethics.
  - Informed consent from participants
  - Experiments yield fruitful results for the good of society
  - Experiment conducted to avoid all unnecessary physical & mental suffering & injury
  - Human participants at liberty to withdraw from the study at any time
Tuskegee Syphilis Study – 1932 - 1972

Research abuses start in Tuskegee, Alabama. A study on the natural history of untreated syphilis, where poor, black males are uninformed of their disease and denied treatment even after a treatment is found in 1947.
1963 Yale University Study to understand why people do cruel, unethical things to others when ordered by an authority figure to do so
Belmont Report

- Justice
- Beneficence
- Respect for Persons
IRB Oversight

**Mission**

- To oversee and review all research projects that involve research with human participants.

**Responsibilities**

- To safeguard the rights and welfare of human participants.
IRB Membership

- 20 members
- At least 5 members
  - 1 scientist,
  - 1 non-scientist, and
  - 1 person not affiliated with the institution
- Members with varying backgrounds
- Diverse membership (gender, race, cultural background)
What Research Must Be Reviewed?

- All research at JMU that involves:
  - humans
  - human tissue – or –
  - records gathered on human subjects
What is Human Subjects Research?

- You have designed a study to collect information in a *systematic* way designed to *develop* or *contribute* to a field of *generalizable* knowledge.
A human subject is a living individual about whom an investigator conducting research obtains

1. data through intervention or interaction with the individual; or
2. identifiable private information.
Human Subjects Research Defined

- Interacting with living human beings in order to gather data about them
Systematic Investigations

- Surveys & questionnaires
- Interviews & focus groups
- Analyses of existing data or biospecimens
- Cognitive & perceptual experiments
- Medical charts or academic records reviews
Public vs. Private Behavior

- Observing or recording private behavior (behavior that individuals have a reasonable expectation will not be observed and recorded)
Private Identifiable Information

- Audio-recordings
- Video-recordings
- Photographs
- Detailed demographics
- Medical records
- Academic records
- Student ID #’s
- Names, SSNs, Addresses, etc.
What Isn’t Research?

- Secondary data
- No private identifiable information
- No human subject interaction or intervention involved; or
- Program evaluations and quality improvement studies
IRB Review Criteria

- Risks to subjects are minimized.
- Risks to subjects are reasonable in relation to anticipated benefits.
IRB Review Criteria

- Selection of participants is unbiased
- Informed consent is:
  - sought from each prospective participant or his or her legally authorized representative, and
  - properly documented.
Types of Informed Consent

- Confidential
- Anonymous
- Verbal
- Parental Consent
- Child or Youth Assent

https://www.jmu.edu/researchintegrity/irb/forms/index.shtml
IRB Review Criteria

- Protection of participants’ privacy and confidentiality
- Ongoing monitoring of participants’ welfare
Levels of IRB Review

**Full Board**
- Greater than minimal risk to participants
- Vulnerable Populations

**Expedited**
- No greater than minimal risk
- No potentially vulnerable populations

**Exempt**
- Must meet one of 8 Exempt categories
- Research approved by other institutions’ IRB’s
Your Responsibilities

- Obtain consent *before* involving participants in the research or using data collected from them
- Educate the participants about risks and benefits
- Keep participants informed about research progress and findings
IRB Online Certification Training

- Federally mandated
- **IRB Social/Behavioral Research Course** – *Basic Course*
- **Valid for up to 3 years**
- Accepted by other institutions

https://www.jmu.edu/researchintegrity/irb/irbtraining.shtml
Helpful Hints

- Give yourself enough time!
- Complete the online form clearly and completely
- Ask for help
- [https://www.jmu.edu/researchintegrity/irb/irbsubmit.shtml](https://www.jmu.edu/researchintegrity/irb/irbsubmit.shtml)
ORI Website

- **Web link:**
  [http://www.jmu.edu/researchintegrity/index.shtml](http://www.jmu.edu/researchintegrity/index.shtml)

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