Research Ethics: 
The Protection of Human Subjects

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WHY IS THERE AN INSTITUTIONAL REVIEW BOARD (IRB)?

• 1947 – (26) Nazi physicians were tried at Nuremberg, Germany, for research atrocities performed on prisoners of war.
• Examples of some atrocities performed
  - High-Altitude Experiments
  - Freezing Experiments
Nuremberg Code

- The first internationally recognized code of research ethics, issued by the Nazi War Crimes Tribunal.
  - Informed consent of human subjects
  - Experiments should yield fruitful results for the good of society
  - Experiments should be designed and based on results of animal experimentation and a knowledge of the disease or other problem under study
  - Experiment should be conducted to avoid all unnecessary physical & mental suffering & injury
  - Human subjects should be 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.
Milgram Studies

1960s – Yale University

- Basic purpose was to understand why people follow the directions of authority figures even when they are told to do things that are cruel or unethical.
Why Does JMU have an IRB?

- As a recipient of federal funds for research, JMU is required to have an IRB that meets federal requirements to review research protocols involving human subjects and to evaluate both risk and protection against risk for those subjects.
- JMU is required to register with the Federal Office of Human Research Protections (OHRP) through a process called Federal Wide Assurance.
IRB Oversight

Mission
• To oversee and review all research projects that involve research with human subjects.

Responsibilities
• To safeguard the rights and welfare of human subjects.
IRB Membership

- 18 current 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, using methods such as interviews, focus groups, questionnaires, and participant observation.
Human Subjects Research Defined

- Conducting interventions with living human beings such as experiments and manipulations of subjects or subjects' environments
Human Subjects Research Defined

- Observing or recording private behavior (behavior that individuals have a reasonable expectation will not be observed and recorded)
Human Subjects Research Defined

- Obtaining private identifiable information that has been collected about or provided by individuals, such as a school record or identifiable information collected by another researcher or organization.
Examples of Studies that Do Not Require Approval

- Use of secondary data;
  - Research will NOT involve merging any of the data sets in such a way that individuals might be identified
  - Researcher will NOT enhance the public data set with identifiable, or potentially identifiable data
- No private identifiable information accessible to you (NO WAY to link the data to the source);
- No human subject interaction or intervention involved; or
- Program evaluations and quality improvement studies
The IRB uses the following criteria to review your research:

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

- Selection of subjects is equitable (unbiased).
- Informed consent is:
  - sought from each prospective participant or his or her legally authorized representative, and
  - properly documented.
IRB Review Criteria

- Adequate preparation is taken to protect the privacy and confidentiality of subjects.
- Adequate provisions are made for the ongoing monitoring of subjects’ welfare.
Categories of Review

- Full Board
- Exempt
- Expedited

# New Protocols in FY18

<table>
<thead>
<tr>
<th>Category</th>
<th># New Protocols</th>
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<tbody>
<tr>
<td>Full Board</td>
<td>100</td>
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<tr>
<td>Exempt</td>
<td>150</td>
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<tr>
<td>Expedited</td>
<td>300</td>
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Categories of Review – Full Board

- **Full Board Review**
  - **minors** (i.e., persons under the age of 18),
  - a **targeted population** of adults whose ability to freely give informed consent may be compromised (i.e., persons who are socio-economically, educationally, or linguistically disadvantaged, cognitively impaired, elderly, terminally ill, or incarcerated),
  - **pregnant women** and/or **fetuses** who may be put at risk of physical harm,
  - a topic of a **sensitive or personal nature**, the examination or reporting of which may place the research participant at more than minimal risk, or
  - any type of activity that places research participants at **more than minimal risk**.
  - studies with **international** subjects
Categories of Review - Exempt

- Results will not be published or publicly presented outside of the classroom
- Not collecting identifiable data from participants
Categories of Review - Expedited

- **Expedited Review**
  - no more than minimal risks &
  - participants at least 18 years of age or older
  - externally funded research
- Majority of what is conducted here at JMU
Researcher’s Responsibilities

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

- Since October 1, 2000, federal guidelines mandate that all investigators and key personnel directly responsible for the design and conduct of the human subjects’ part of the project be trained prior to working with human subjects.
- Training is valid for up to 3 years.
ORI Website

- Web link: http://www.jmu.edu/researchintegrity/index.shtml
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