Research Ethics:
The Protection of Human Subjects

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Office of Research Integrity

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

Why is there an Institutional Review Board (IRB)?

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

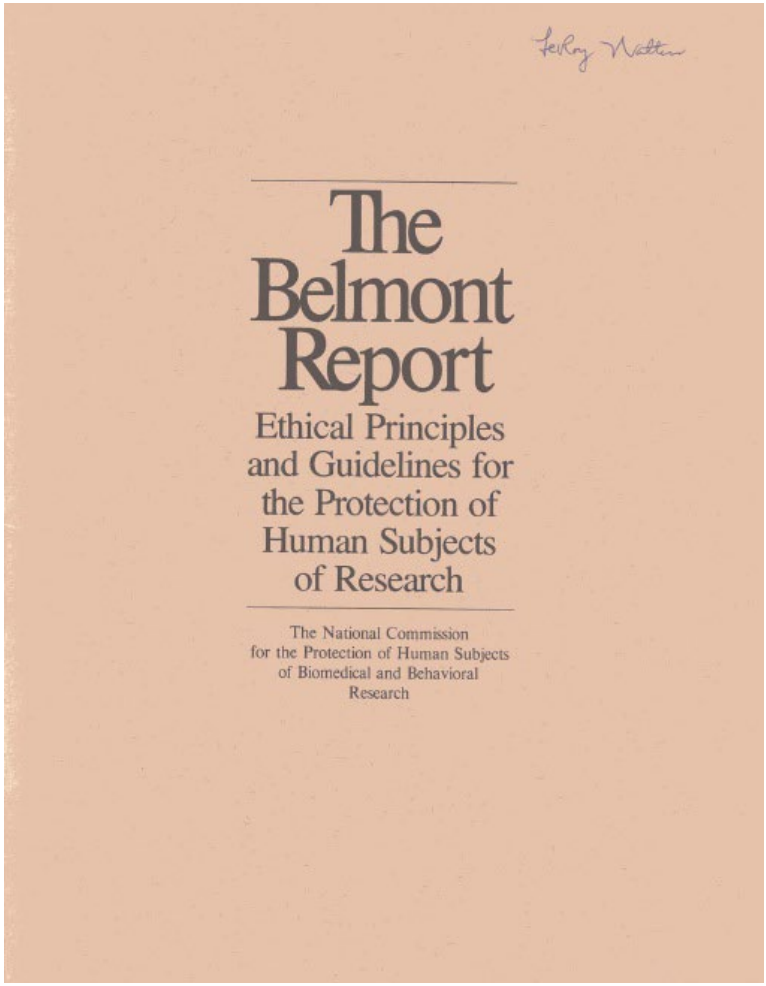
Research abuses start in Tuskegee, Alabama.
A study on the natural history of untreated syphilis, where poor, black males are uninformed of their disease and denied treatment even after a treatment is found in 1947.

1963 Yale University Study to understand why people do cruel, unethical things to others when ordered by an authority figure to do so

Milgram Experiments - Obedience to Authority

Belmont Report

- Justice
- Beneficence
- Respect for Persons



IRB Oversight

Mission

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

Responsibilities

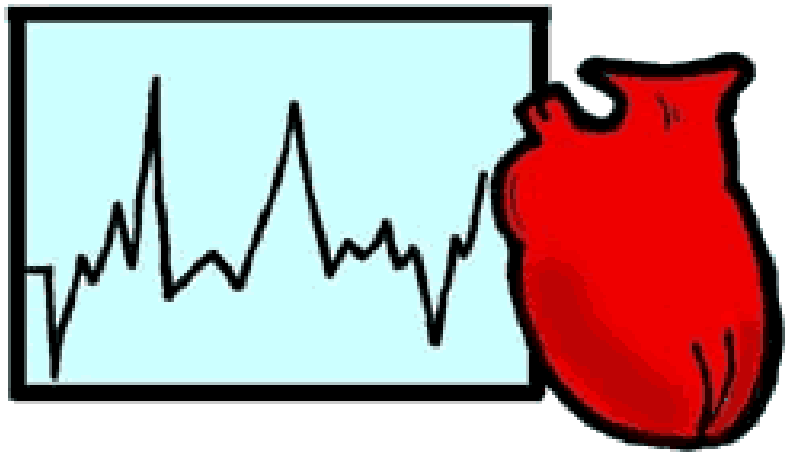
- To safeguard the rights and welfare of human participants.

IRB Membership

- 18 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.

Human Subject Defined

- 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

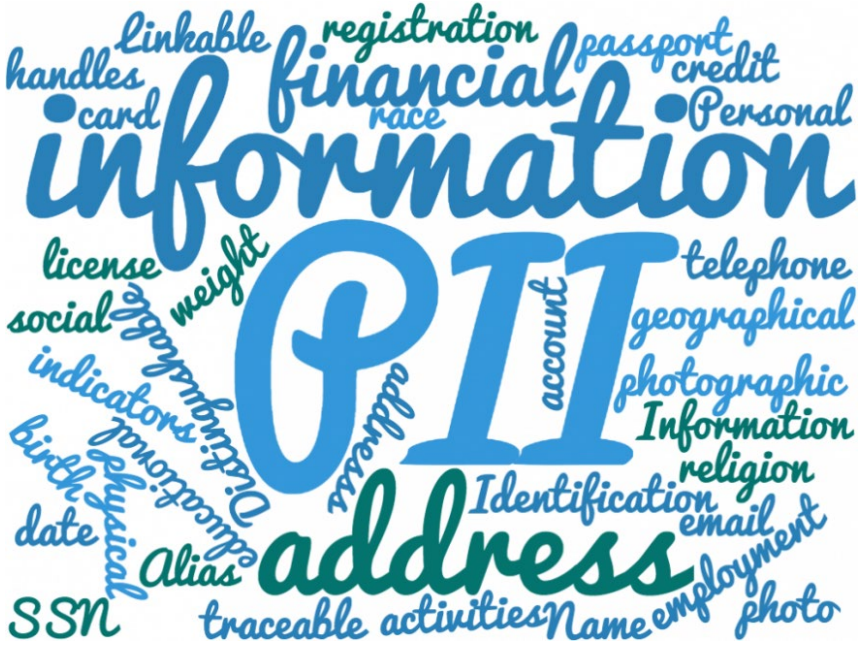
- Surveys & questionnaires
- Interviews & focus groups
- Analyses of existing data or biospecimens
- Cognitive & perceptual experiments
- Medical charts or academic records reviews

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

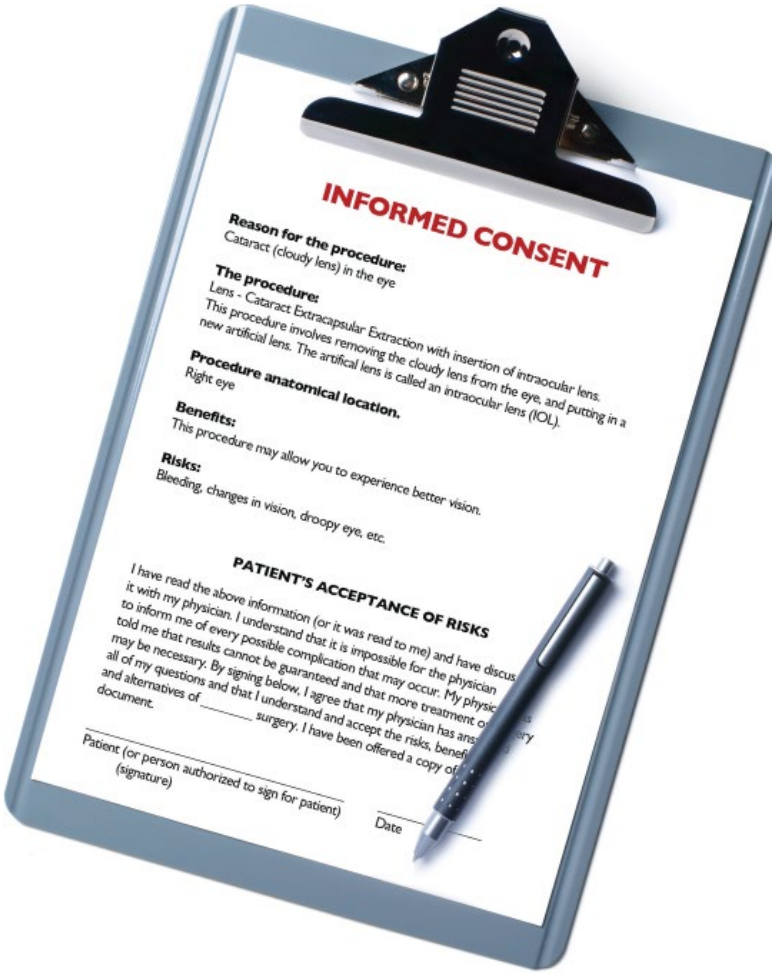
- Risks to subjects are minimized.
- Risks to subjects are reasonable in relation to anticipated benefits.

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

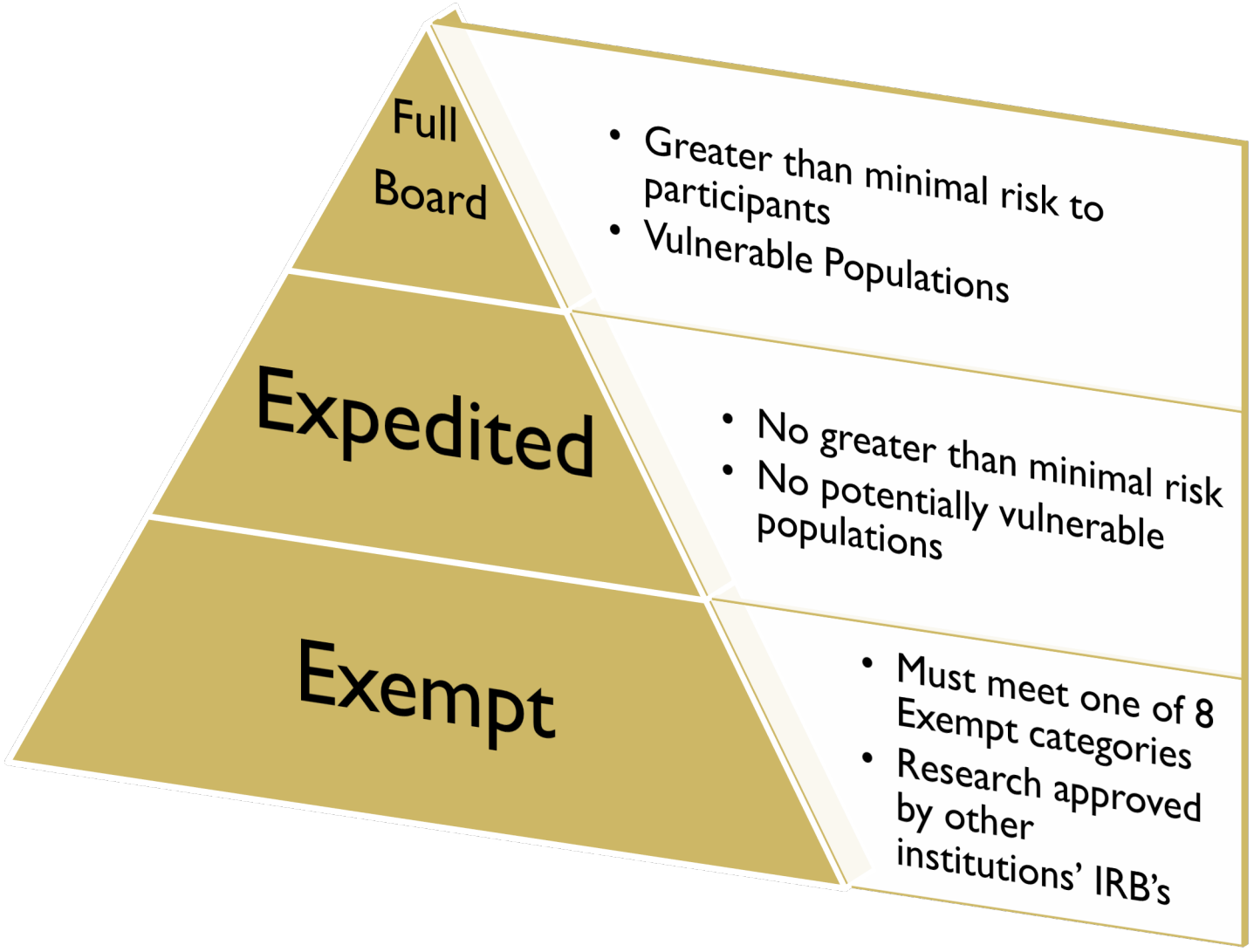
- Confidential
- Anonymous
- Verbal
- Parental Consent
- Child or Youth Assent
- https://www.jmu.edu/researchintegrity/irb/forms/index.shtml



IRB Review Criteria

- Protection of participants' privacy and confidentiality
- Ongoing monitoring of participants' welfare

Levels of IRB Review



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

Helpful Hints

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

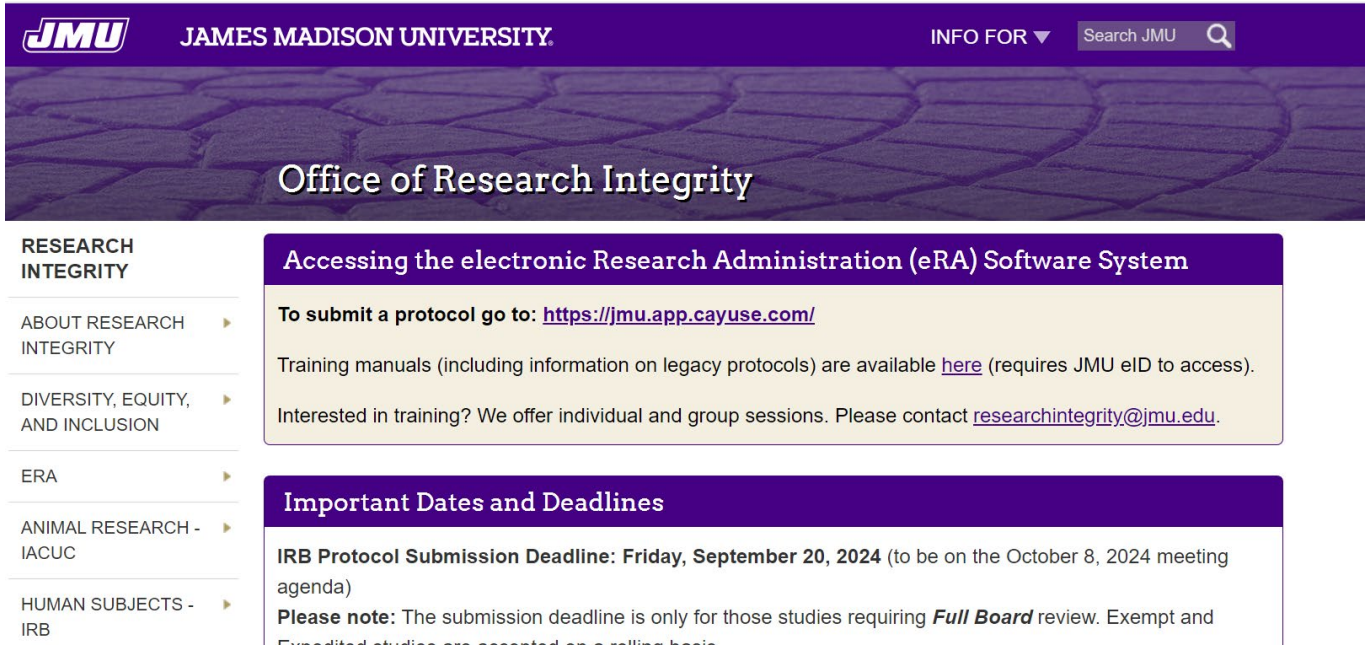
IRB Online Certification Training

- 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

CITI PROGRAM

ORI Website

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



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