Research Ethics:
The Protection of Human Subjects

Presented by: Gilli Guy
(Slides by Cindy Morgan)
Office of Research Integrity & Compliance

1947 – Nuremberg Trials
United States of America v. Karl Brandt- 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

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

Early 1960s

Public Announcement

WE WILL PAY YOU $4.00 FOR ONE HOUR OF YOUR TIME

Persons Needed for a Study of Memory

*We will pay five hundred New Haven men to help us complete a scientific study of memory and learning. The study is being done at Yale University.

*Each person who participates will be paid $4.00 (plus 50c carfare) for approximately 1 hour's time. We need you for only one hour: there are no further obligations. You may choose the time you would like to come (evenings, weekdays, or weekends).

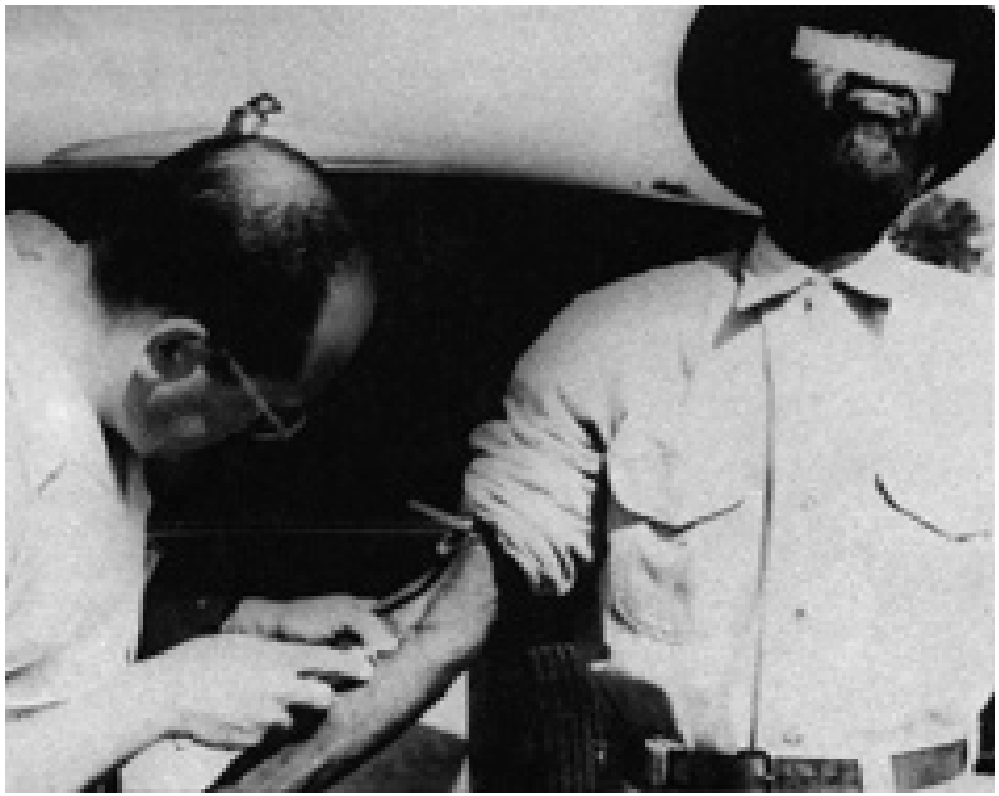
***No special training, education, or experience is needed. We want:**

Factory workers	Businessmen	Construction workers
City employees	Clerks	Salespeople
Laborers	Professional people	White-collar workers
Barbers	Telephone workers	Others

All persons must be between the ages of 20 and 50. High school and college students cannot be used.

*If you meet these qualifications, fill out the coupon below and mail it now to Professor Stanley Milgram, Department of Psychology, Yale University, New Haven. You will be notified later of the specific time and place of the study. We reserve the right to decline any application.

*You will be paid $4.00 (plus 50c carfare) as soon as you arrive at the laboratory.

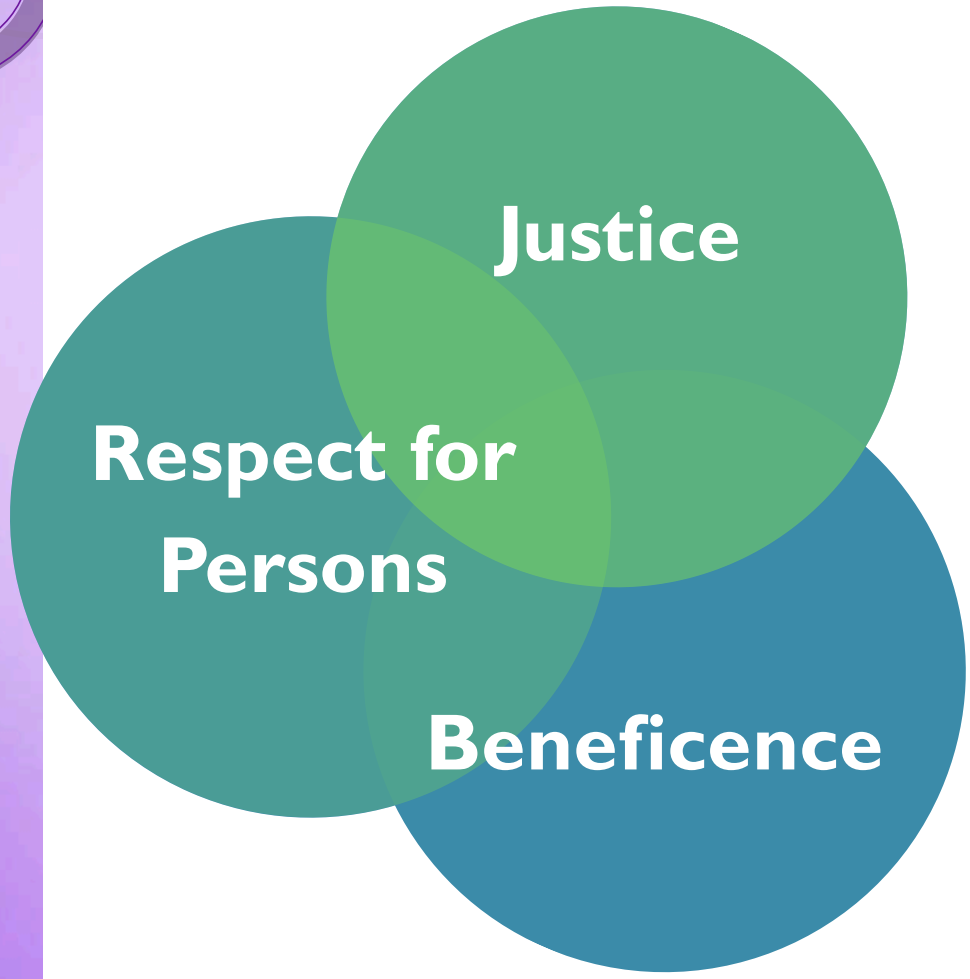


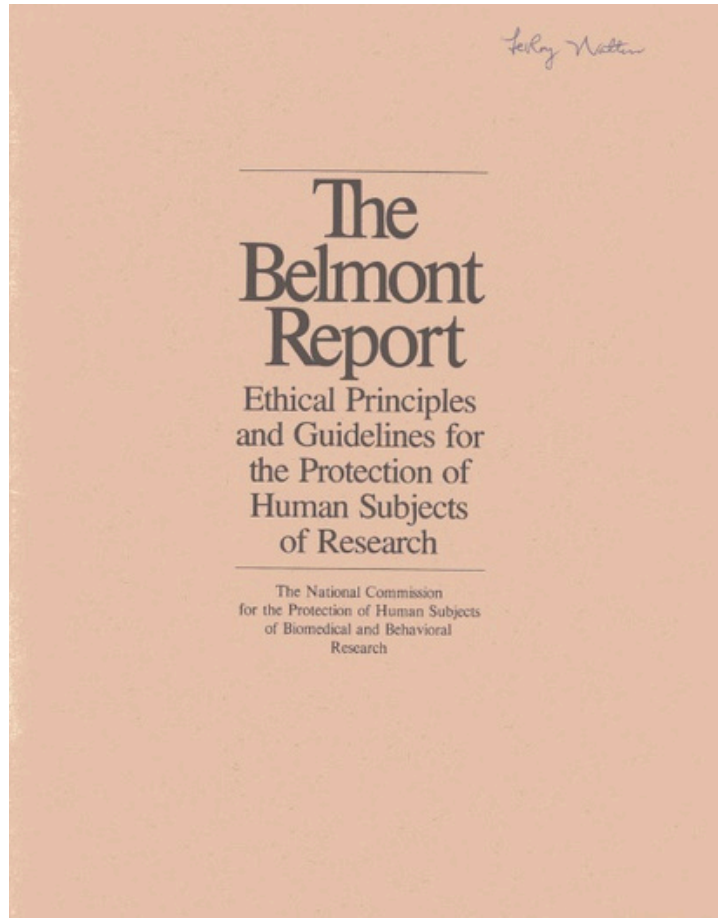
Research abuses start in Tuskegee, Alabama.
A study on the natural history of untreated syphilis, where poor, black males are uninformed of their disease and denied treatment even after a treatment is found in 1947.

Tuskegee Syphilis Study

1932 - 1972

Belmont Report





National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

IRB Oversight

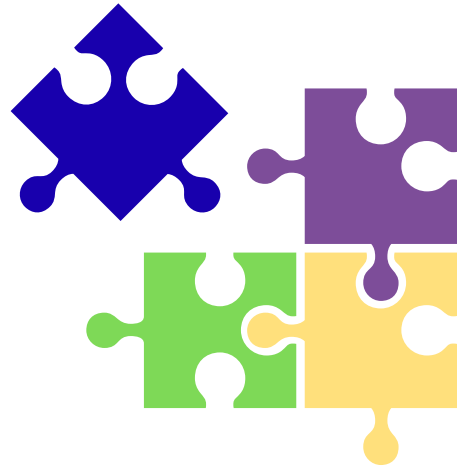
Mission

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

Responsibilities

- To safeguard the rights and welfare of human participants.

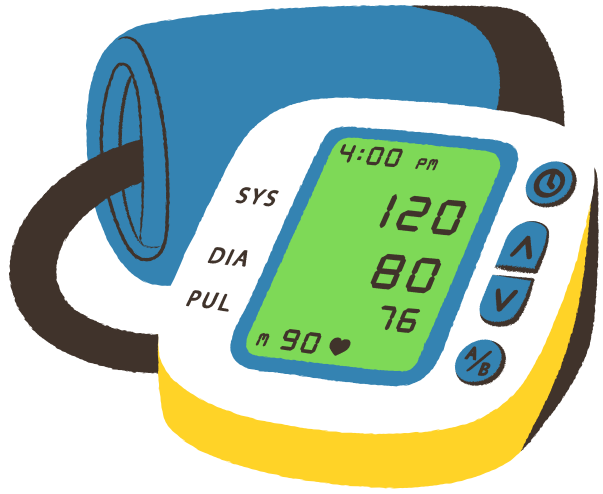
IRB Membership



- 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.

45 CFR 46.102(l)

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.

45 CFR 46.102(e)(1)

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?

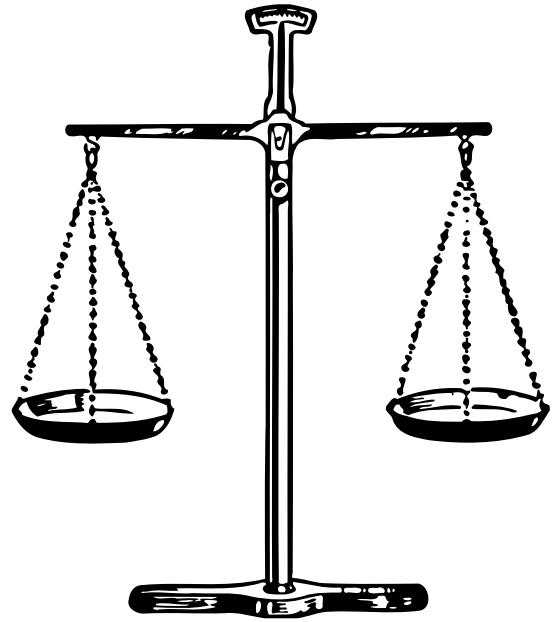
- Secondary data
- No private identifiable information
- No human subject interaction or intervention involved; or
- Program evaluations and quality improvement studies

IRB Review Criteria

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

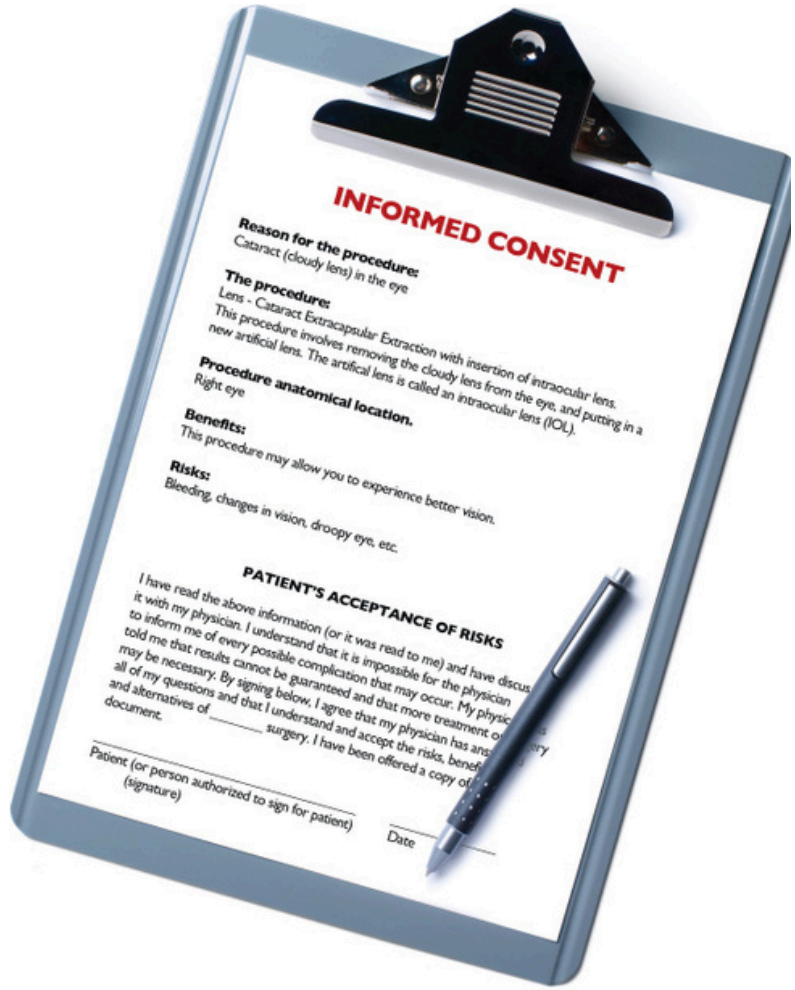
IRB Review Criteria

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



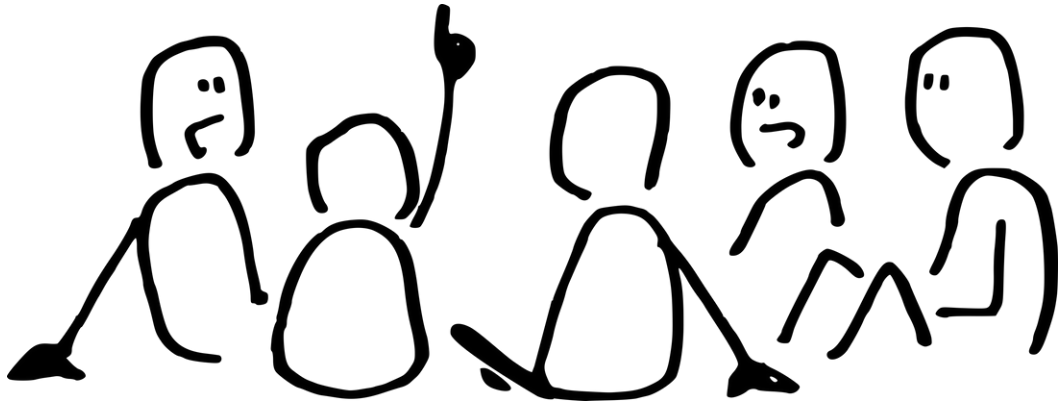
Types of Informed Consent

- Confidential
- Anonymous
- Verbal
- Parental Consent
- Child or Youth Assent
- https://www.jmu.edu/research/integrity-compliance/human-research/forms/

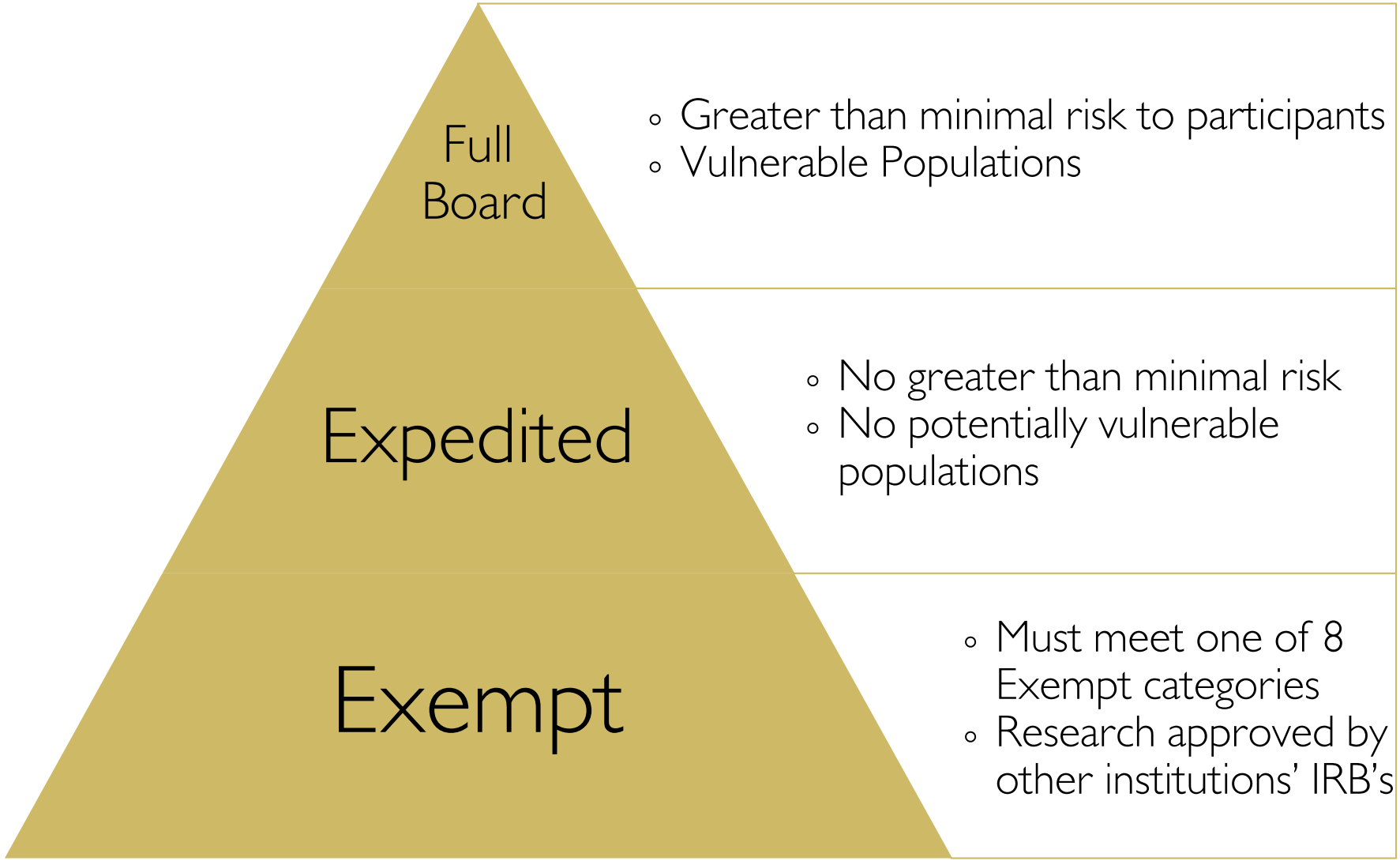


IRB Review Criteria

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



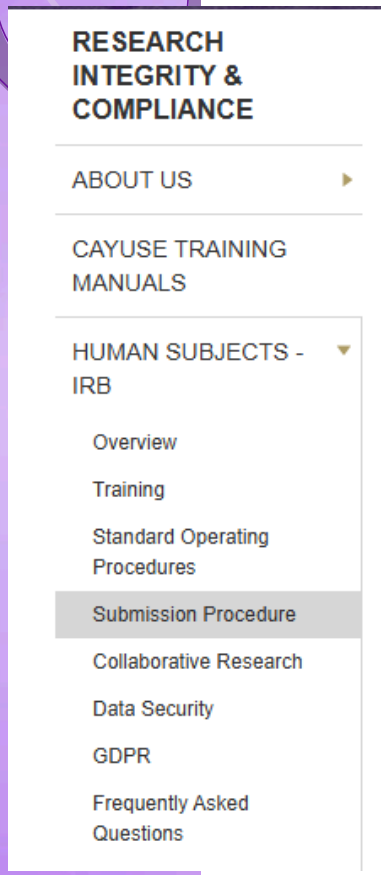
Levels of IRB Review



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

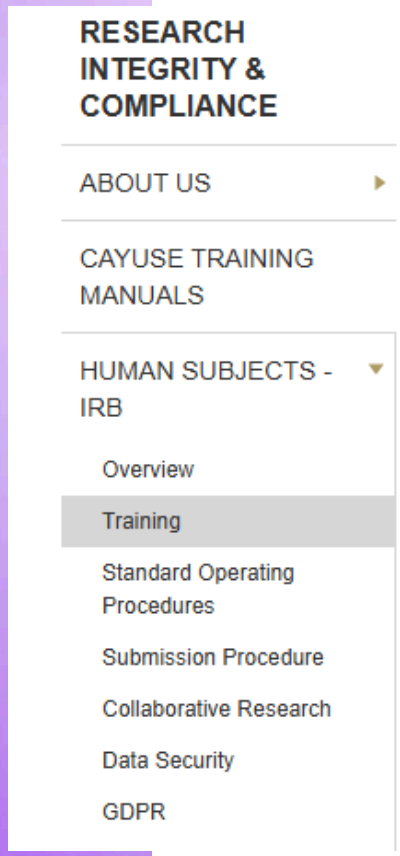


- Give yourself enough time!
- Complete the online form clearly and completely
- Ask for help

https://www.jmu.edu/research/integrity-compliance/human-research/irbsubmit.shtml

IRB Online Certification Training

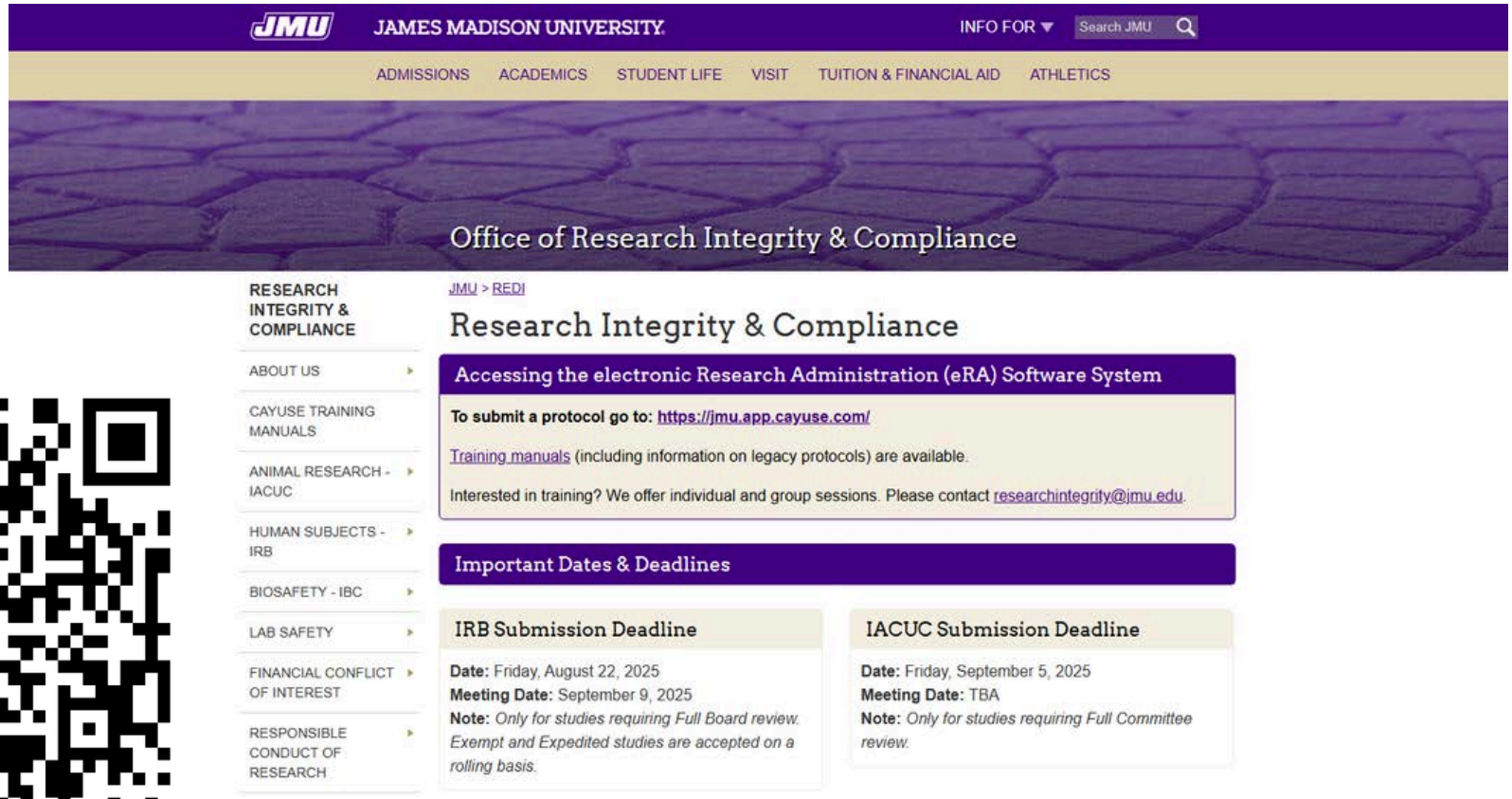
- Federally mandated
- ***IRB Social/Behavioral Research Course – Basic Course***
- **Valid for up to 3 years**
- Accepted by other institutions https://www.jmu.edu/research/integrity-compliance/human-research/irbtraining.shtml



CITI PROGRAM

ORIC Website

- Web link: www.jmu.edu/research/integrity-compliance



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