Ethical Issues in Research with Human Participants

The Belmont Report

- A report published in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

Three Principles

- Respect for Persons
  - Individuals should be treated as autonomous agents
  - People with diminished autonomy are entitled to protection
- Beneficence
  - Maximize benefits and minimize risks
- Justice
  - Equality in the distribution of benefits and risks

Applications

- Informed consent
  - Information
  - Comprehension
  - Voluntariness
- Assessment of benefits and risks
- Selection of subjects

NOTES

- In 1924, Carney Landis, a grad student in psychology at the University of Minnesota, exposed subjects to stimuli designed to provoke a strong emotional reaction and then took photos of their faces. He made them smell ammonia, look at pornographic pictures, reach their hand into a bucket containing slimy frogs. But the climax of the experiment arrived when he carried out a live white rat on a tray and asked them to decapitate it with a butcher knife. If they refused (1/3), he did it while they looked on.

The IRB

- The IRB is charged with protecting human participants involved in research by Stetson University faculty, staff, and students
- The IRB reviews research protocols, the informed consent process, and the procedures used to enroll participants to ensure that research is conducted ethically and in compliance with federal regulations

- The IRB has the authority to approve, require modifications in, or deny proposed research
- In making these decisions, the IRB compares the potential benefits of the research to the risks participants may be exposed to
- Matt Schrager (chair), Dejan Magoc, Michele Skelton, John Rasp, Chris Ferguson, Kirsten Davis, Toni Ballesteros, and Rick Medlin

IRB Myths?

- I only need the IRB to approve my research if I'm going to publish it
- The IRB will help me make sure I have a well-designed study
- I can work out the details of my research after the IRB approves the concept

Do I Need IRB Approval?

- HHS defines research as "a systematic investigation designed to develop or contribute to generalizable knowledge"
- If this activity involves obtaining information about living individuals through intervention or interaction with those individuals, then it is research involving human participants and may require IRB approval

- Research that does not involve intervention or interaction with participants but obtains information that is individually identifiable and is private may also require IRB approval

NOTES

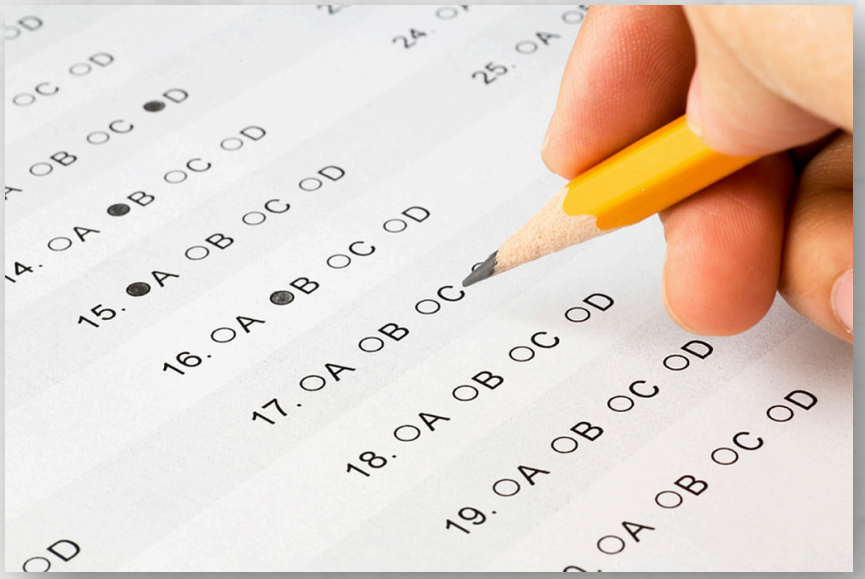
- Private = individuals could reasonably expect that their behavior will not be observed or that the information they provide will not be made public

How Do I Get Started?

- All faculty, staff, and students must complete the National Institutes of Health online training course, "Protecting Human Research Participants," and upload a certificate of completion to MentorIRB before submitting a research protocol
- The course can be found at: https://phrp.nihtraining.com/users/login.php

What's My Level of Review?

- EXEMPT research typically involves no foreseeable risks and anonymous data, does not include a vulnerable population, and falls into one of six specific categories
- The IRB decides if your research is exempt



- EXPEDITED reviews may be permissible for research in which data are identifiable, risks are minimal, or video or audio recordings are being made

- FULL BOARD reviews are required for research that does not qualify for an exemption or an expedited review
- More than minimal risk, deception, sensitive or incriminating information, or participants from a vulnerable population

Exempt Categories

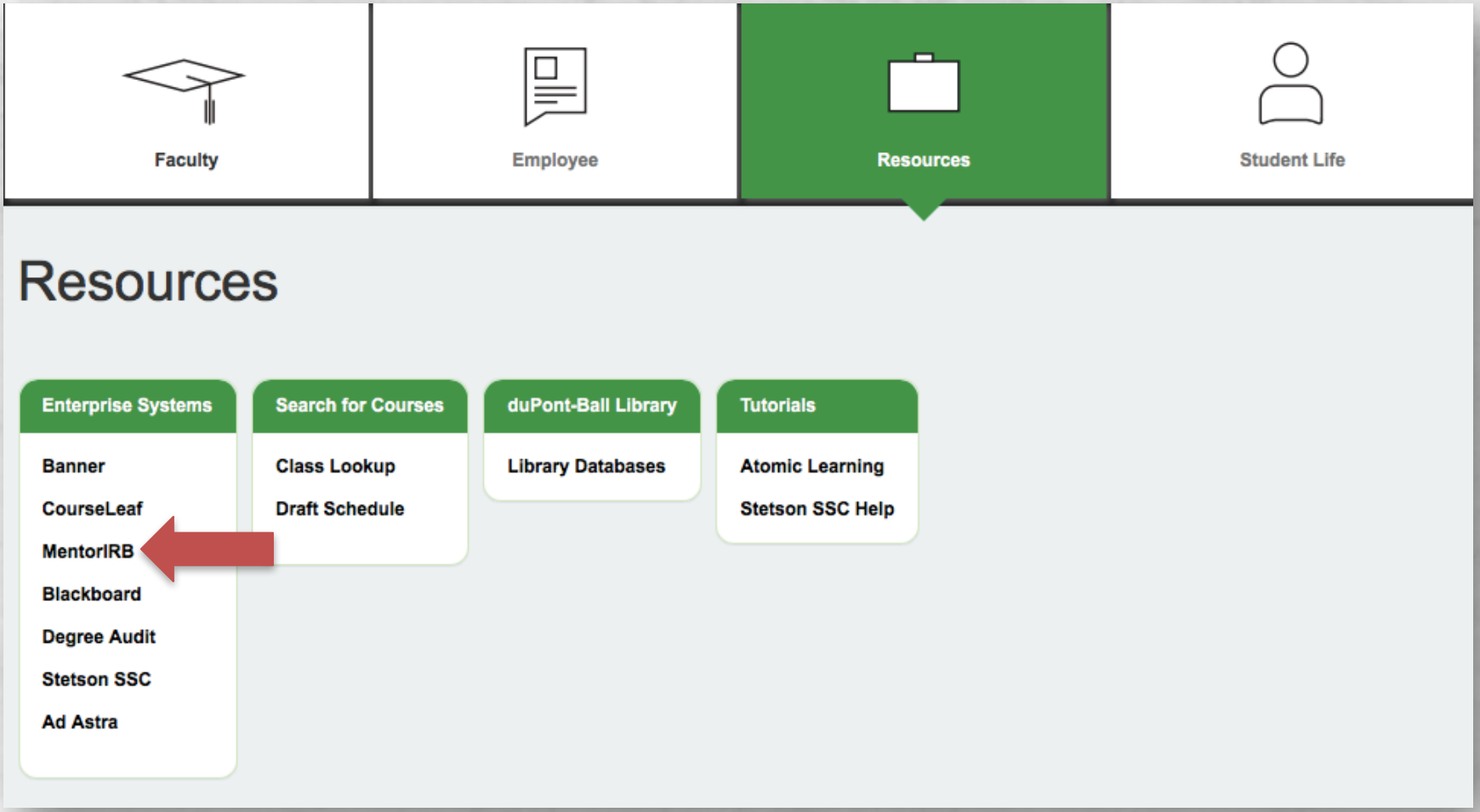
- Research conducted in established or commonly accepted educational settings, involving normal educational practices
- Research involving the use of educational tests, surveys, interview procedures, or the observation of public behavior UNLESS the information is identifiable and disclosure of the information could be harmful to subjects

- Research involving the analysis of existing data, documents, and records if these sources are publicly available OR if the information is recorded by the investigator in such a manner that subjects cannot be identified

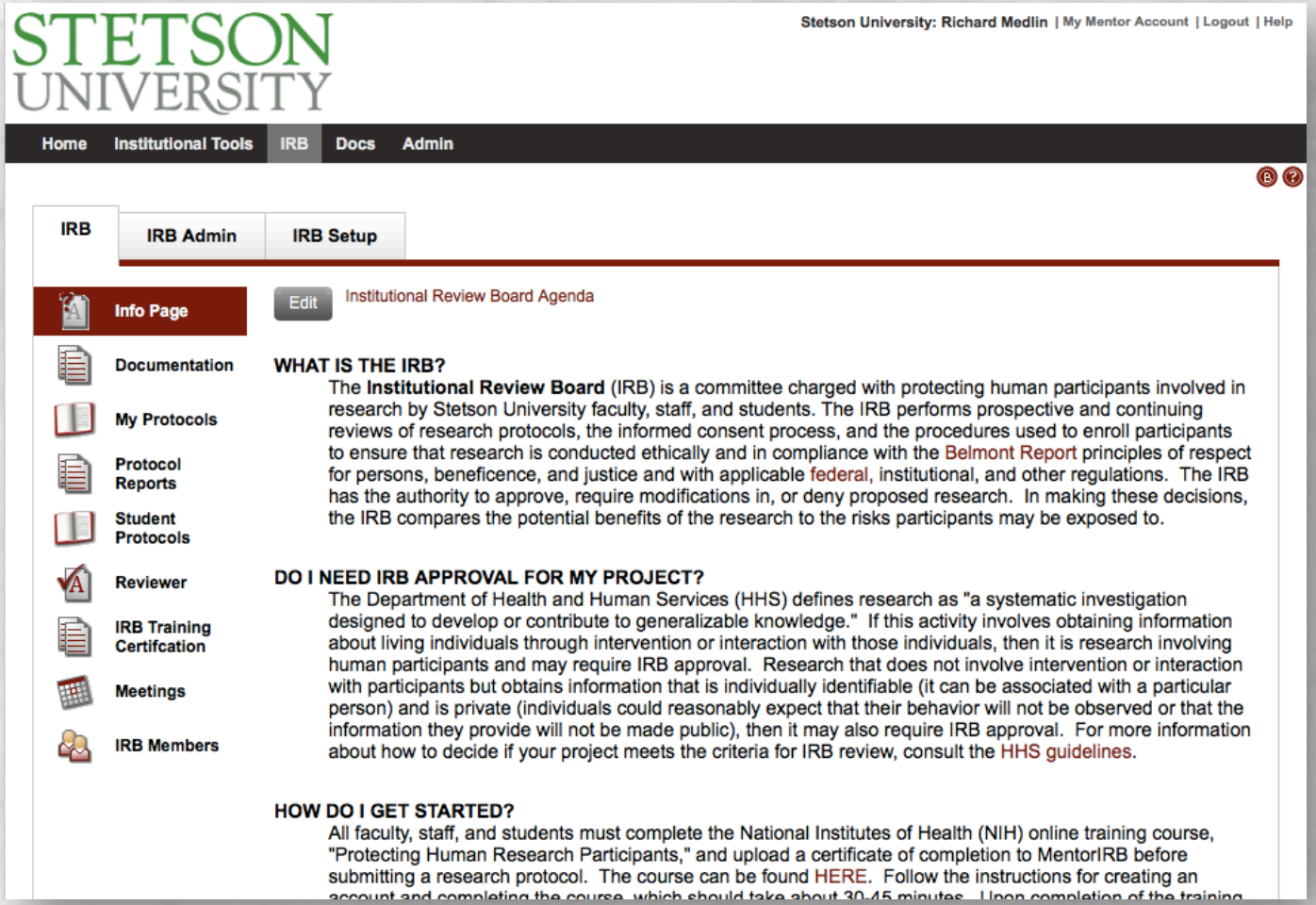
What About FERPA?

- FERPA prohibits schools from disclosing personally identifiable information from education records to a third party without students' written consent
- Exceptions include de-identified data and directory information
- Teachers are usually considered to be "school officials" with a "legitimate educational interest" in the information

How to Find MentorIRB



MentorIRB Info Page



NOTES

- What if I have students under 18 in my class?
- What's the difference between research and a class assignment?
- What if I need to use audio/video recordings?
- What happens to the data after the study is over?
- What is sensitive/incriminating information?
- What if I don't want participants to know exactly what the research is about—is that deception?
- Is asking uncomfortable questions a "risk"?

NOTES

- If the participants are the students in my class, does that violate “voluntariness”?
- How do I keep data secure and confidential?
- How do I protect my participants privacy?
- What if I’m measuring things like stress, anxiety, depression, etc.?
- What are the ethical issues with online studies?