

INSTITUTIONAL REVIEW BOARD
AND YOU:
Little Teddy goes to Harvard:
A Cautionary Tale.

Institutional Review Board (IRB): Ethics in Research

- IRB's Charge: To assure ethical conduct of research with humans and animals at Park University, in compliance with U.S. Federal regulations (45 CFR 46).
- THIS APPLIES TO YOU IF YOU ARE DOING: Surveys for Senior Projects or Honors theses; You intend to present or publish results; masters theses, Doctoral Research, undergrad class research that involves surveying other people, experiments with vertebrate animals, etc. (see park.edu/IRB for details).

What's New at IRB This Year?

- **1. Expanded Representation:**
 - Douglas Burns (Biology, CLAS)
 - Lisa Bunkowski (History, CDL)
 - Lora Cohn (Comm. Arts, CLAS)
 - Amber Dailey-Herbert (CETL, School of Ed.)
 - Michael Eskey (CJ, CDL)
 - Dennis Kerkman (Psych. & Soc., CLAS)
 - Nicolas Koudou (Business, Grad School)
 - Denis Lowe (school of Ed.)
 - Kevin Payne (Psych & Soc., CLAS)
 - Ann Schultis (Library)
 - Denny Okerstrom (Humanities, CLAS)
 - **2. Legal Counsel, Courtney Goddard (General Counsel's Office, not a member of IRB but provides IRB with legal advise)**
 - **3. New, Improved Online Application Process**
 - (We had 74 Applications between Spring Break and April 18 last year).
 - Last spring's software glitches have been fixed.
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Research

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graph TD; Research[Research] --- Archival[Archival]; Research --- Naturalistic[Naturalistic Observations]; Research --- Intrusive[Intrusive];
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- Types of
- Research

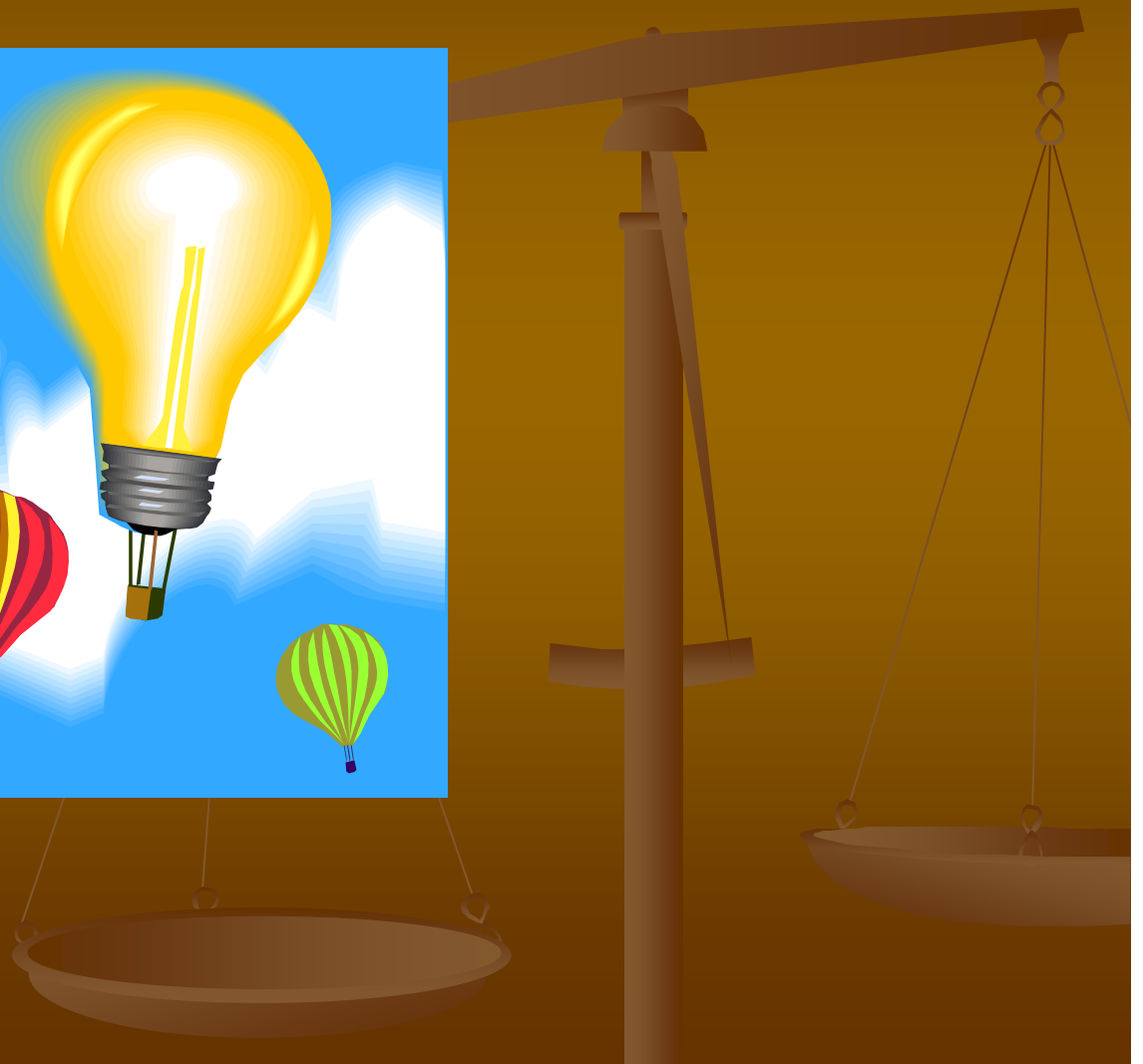
Archival
(library,
Govt Records,
TV programs, etc.)
Anything that does
not involve you
recording observations
of human or animals
NO IRB App.
Required.*

**Naturalistic
Observations**
without intervention
(e.g., observing parental
disciplinary behaviors
In Public Places)
NO IRB app.
is Required.

Intrusive:
Surveys,
focus groups,
Manipulative
experiments.
IRB Required.

*Unless Personal Identifying info is collected (HIPPA).

Research is a Many Splendored Thing



Science gone
awry:
“The road to Hell is
paved with Good
Intentions.”



Dr. Frankenstein was trying to use science to bring people back to life.



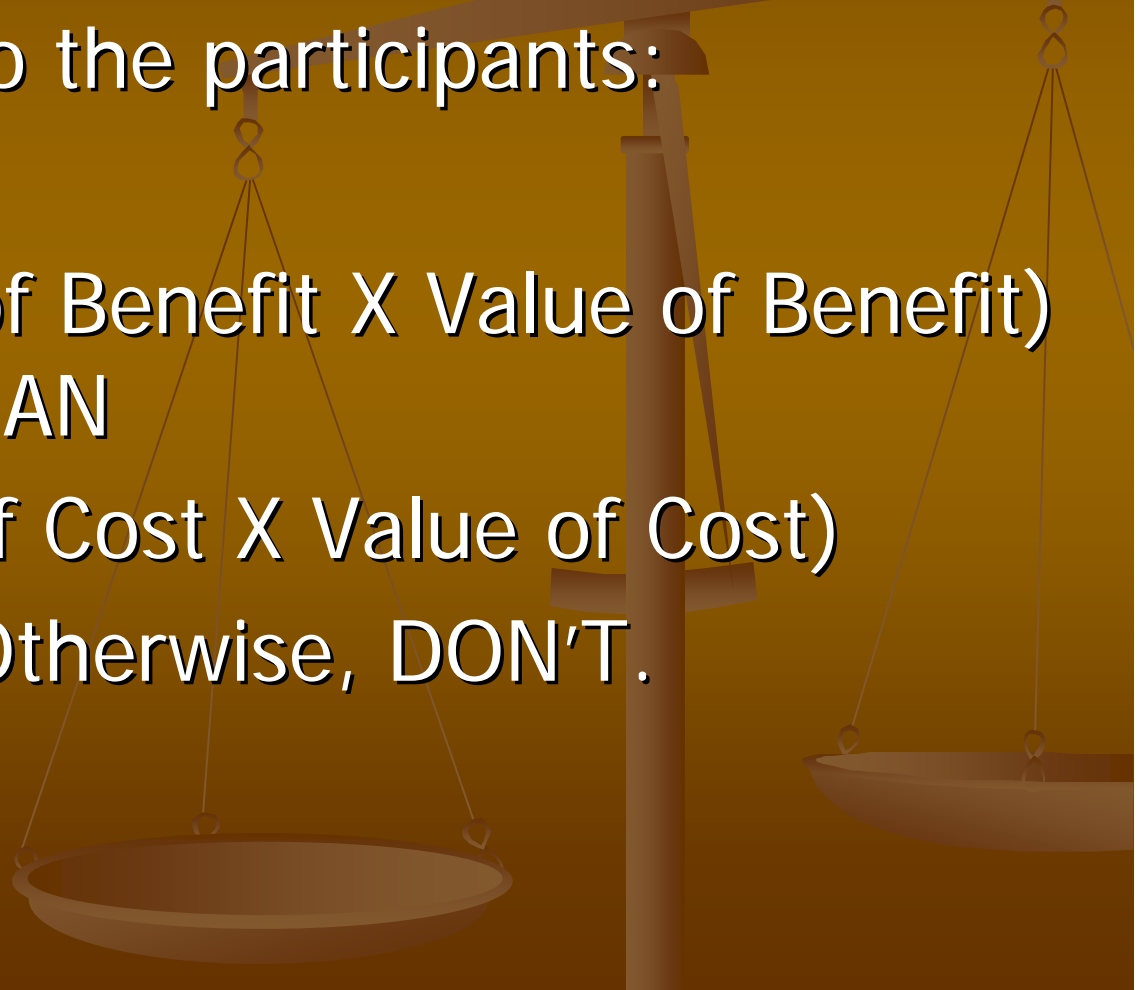
Dr. Josef Mengele, NAZI “Angel of Death”, *thought* was doing his patriotic duty for his country’s war effort.

5. Moral: The person who wants to do the research is uniquely disqualified from being able to tell if it is ethically proper.

Policy: Even if you think your research project fits the definition of “exempt”, we still need for you to fill out the Application and let a member of the IRB verify that it is exempt.

Decision Theory and Minimizing Risk:

- Weighing Potential benefits to science versus potential risks to the participants:
- IF (Probability of Benefit X Value of Benefit) IS GREATER THAN (Probability of Cost X Value of Cost) THEN DO IT. Otherwise, DON'T.



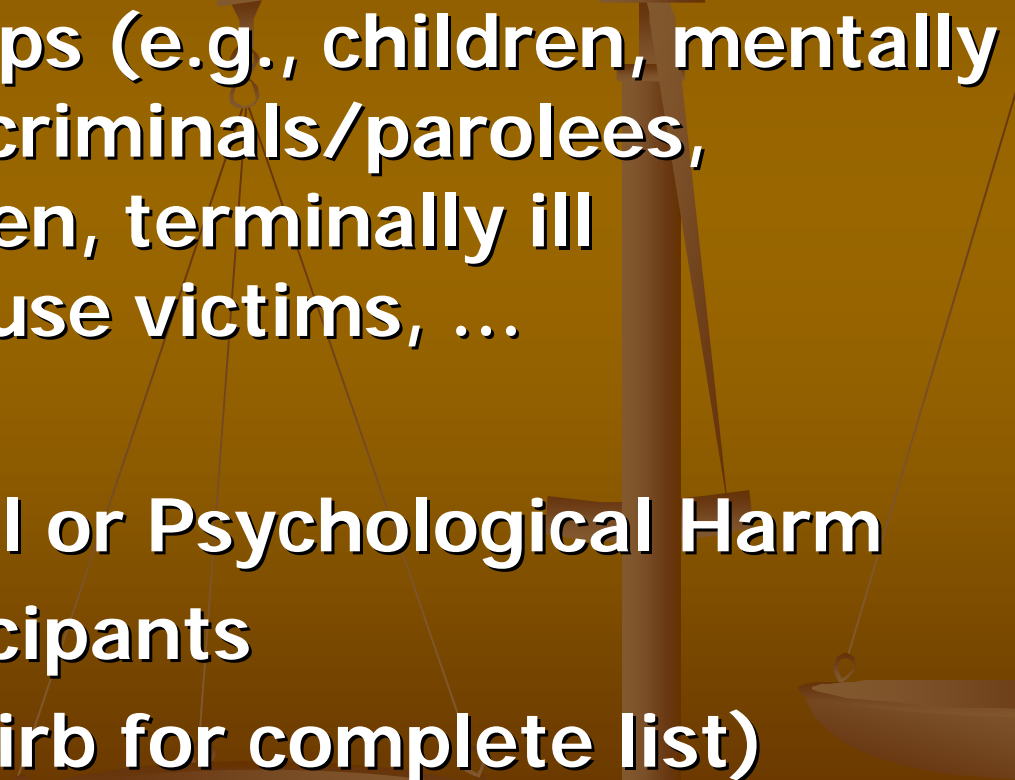
Three IRB Classifications of Research

- Exempt
- Expedited
- Full Board Review
- Definitions:
- <http://www.park.edu/irb/>

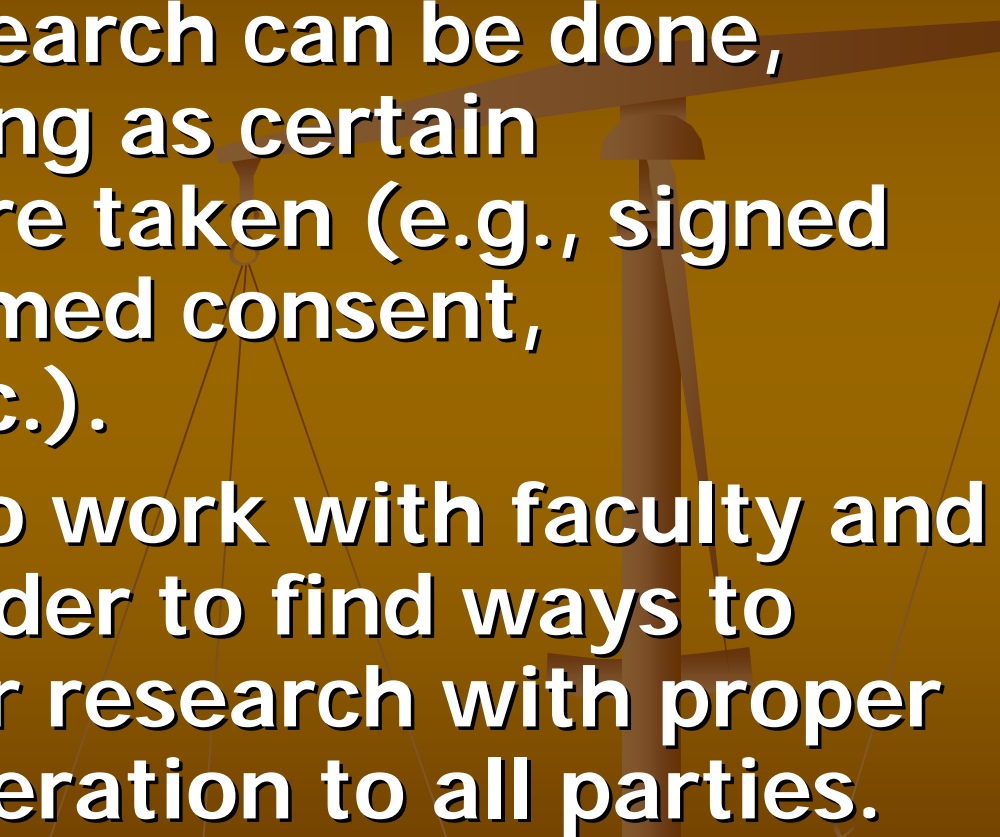


Is it exempt?

Red Flags:

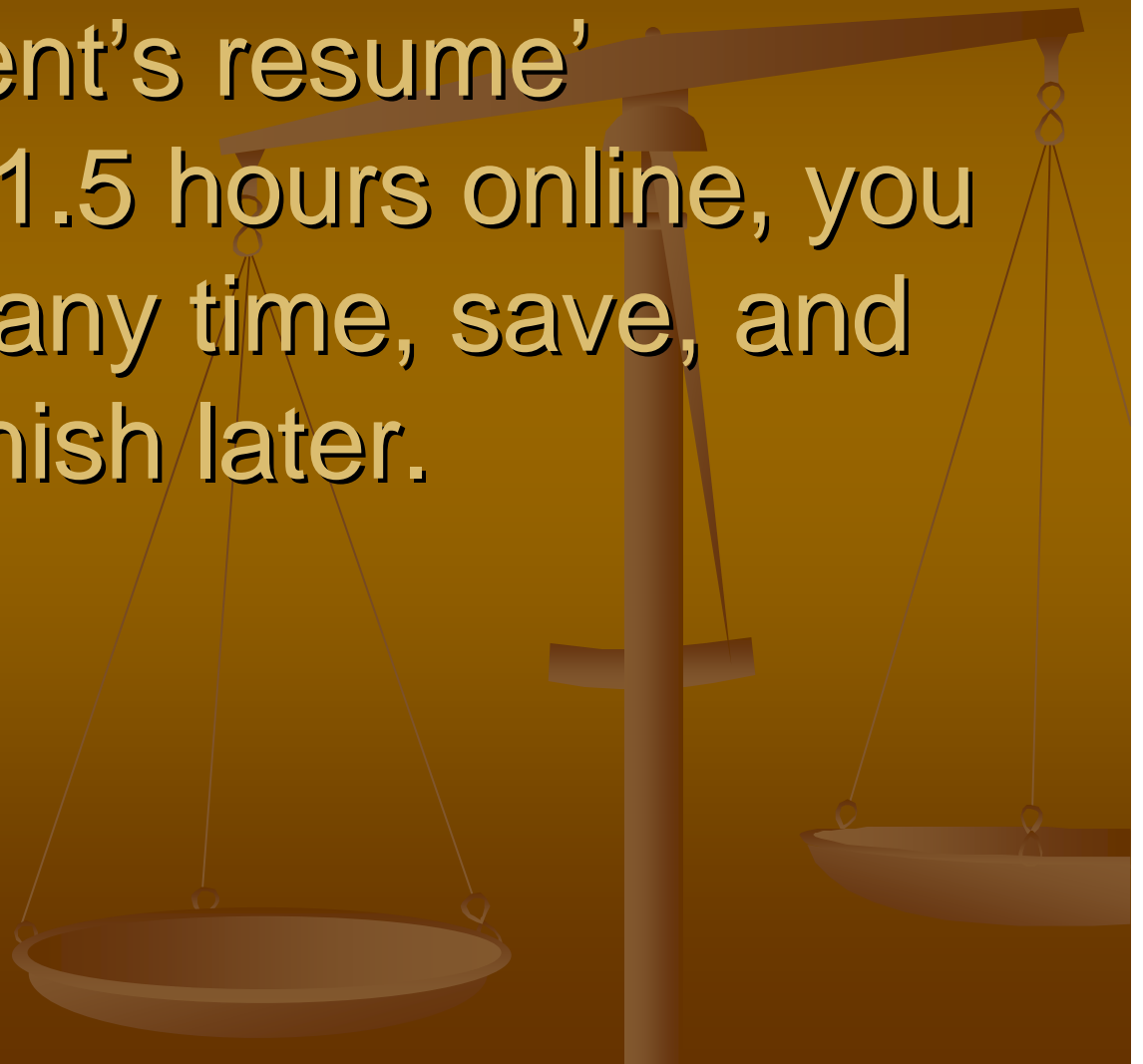
- A. Protected groups (e.g., children, mentally ill individuals, criminals/parolees, pregnant women, terminally ill individuals, abuse victims, ...)
 - B. Deception
 - C. Risk of Physical or Psychological Harm
 - D. Touching participants
 - E. (see park.edu/irb for complete list)
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WHAT IF MY STUDY IS NOT EXEMPT?

- Almost all research can be done, ethically so long as certain precautions are taken (e.g., signed letter of informed consent, debriefing, etc.).
 - IRB's role is to work with faculty and students in order to find ways to complete their research with proper ethical consideration to all parties.
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IRB Certification Process: Something for you and your student's resume'

Takes about 1.5 hours online, you
can stop at any time, save, and
finish later.



Sample Questions from the NIH IRB Certification Exam

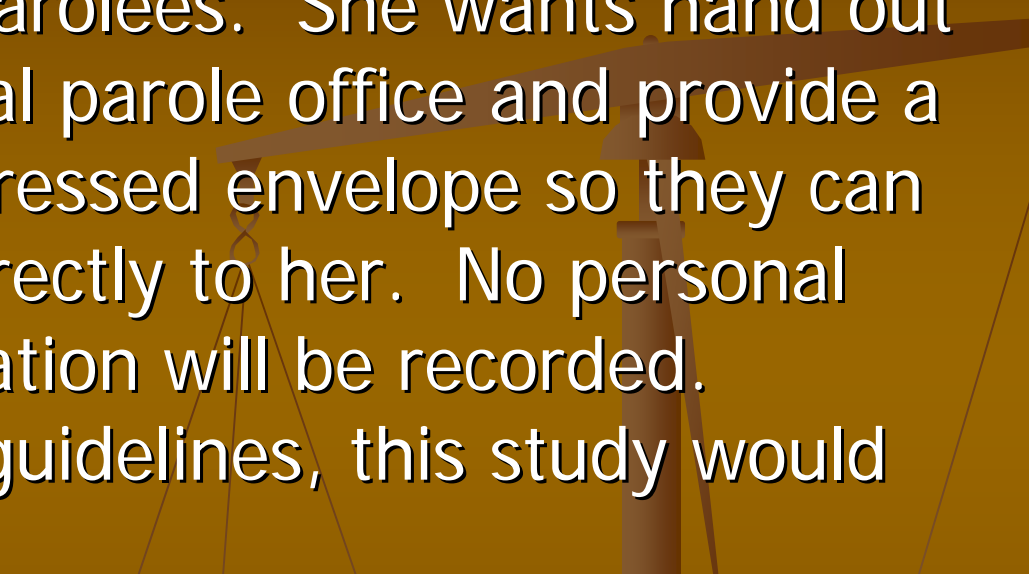
1. A student and his/her Human Sexuality Instructor wish to conduct a survey of university students' sexual orientations and activities by sending out an internet-based questionnaire to all students enrolled at the University. This research

- A. does not require IRB to be informed.
- B. is exempt
- C. is expedited
- D. requires full IRB board review

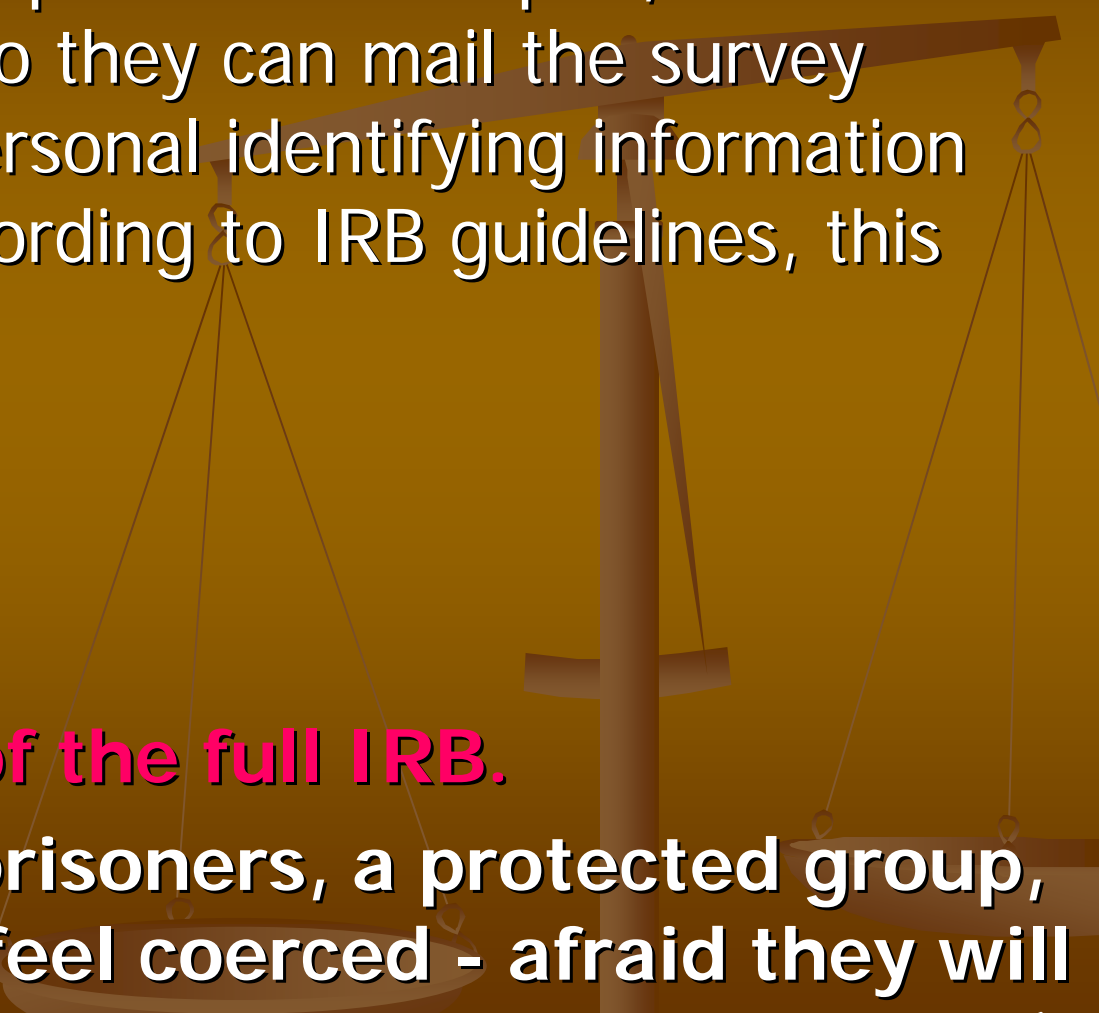
1. A student and his/her Human Sexuality Instructor wish to conduct a survey of university students' sexual orientations and activities by sending out an internet-based questionnaire to all students enrolled at Park University. This research:

- A. does not require IRB to be informed.
- B. is exempt
- C. is expedited
- ***D. requires full IRB board review**

Why? Because sexual activities/orientation are classified as "sensitive topics" by US Federal Regulations.

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- 2. A Criminal Justice student wishes to conduct a study to see if Attention Deficit Disorder is more frequent among parolees. She wants hand out surveys at the local parole office and provide a stamped, self-addressed envelope so they can mail the survey directly to her. No personal identifying information will be recorded. According to IRB guidelines, this study would be:

- A. exempt
- B. expedited review
- C. requires a vote of the full IRB.



■ A Criminal Justice student wishes to conduct a study to see if Attention Deficit Disorder is more frequent among parolees. She wants hand out surveys at the local parole office and provide a stamped, self-addressed envelope so they can mail the survey directly to her. No personal identifying information will be recorded. According to IRB guidelines, this study would be:

■ A. exempt

■ B. expedited review

■ **C. requires a vote of the full IRB.**

■ (Parolees are like prisoners, a protected group, because they may feel coerced - afraid they will be sent back to prison if they don't participate.)

The IRB Application



- If you are going to collect any data from anybody under the auspices of Park University, even if it is anonymous (e.g., surveymonkey.com), then you **MUST**
- 1. Complete the NIH Human subjects certification program
 - <http://www.park.edu/irb/>
- 2. you **MUST** fill out the IRB Application

Why? Because the person who is doing the study is singularly **DISQUALIFIED to decide if it is ethical or not (vested interest).**

NEW PROCESS: All IRB applications **MUST have a Park Faculty Supervisor AND Faculty supervisor must approve Application before it goes to IRB.**

When in Doubt,

- Ask Your IRB rep.
 - Douglas Burns (Biology, CLAS)
 - Lisa Bunkowski (History, CDL)
 - Lora Cohn (Comm. Arts, CLAS)
 - Amber Dailey-Herbert (CETL, School of Ed.)
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