SPRING 2024 IRB STUDENT INFORMATION SESSION

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Overview

- Welcome introductions
- What, Who, Where, Why, and How of the IRB
- IRB Processes, what the IRB needs
- Types of research and levels of risk
- Common questions the IRB asks
- Questions*

WHAT IS THE IRB?

- Administrative oversight body established for the protection of the **RIGHTS** and **WELFARE** of human research subjects
- Mandated under regulations ("The Common Rule") issued by the U.S. Department of Health and Human Services, last updated in 2018
- IRB has the authority to review, approve, exempt, disapprove, monitor, require modifications, or suspend **HUMAN SUBJECTS RESEARCH** (**HSR**) that fall within its scope
- Protocols MUST be approved by the IRB under its policies and procedures BEFORE HSR can commence

WHAT IS THE IRB?

- IRB REVIEWS ANY **RESEARCH** INVOLVING HUMAN SUBJECTS
  - "…STUDIOUS INQUIRY OR EXAMINATION; *ESPECIALLY* INVESTIGATION OR EXPERIMENTATION AIMED AT THE DISCOVERY AND INTERPRETATION OF FACTS, REVISION OF ACCEPTED THEORIES OR LAWS IN THE LIGHT OF NEW FACTS, OR PRACTICAL APPLICATION OF SUCH NEW OR REVISED THEORIES OR LAWS." - MERRIAM-WEBSTER
- THIS **MAY** INCLUDE, BUT IS **NOT** LIMITED TO…
  - THESES, DISSERTATIONS
  - STUDENT, FACULTY, AND/OR STAFF RESEARCH PROJECTS
  - CLASS RESEARCH PROJECTS OR ASSESSMENTS
  - PROJECTS BY OUTSIDE INVESTIGATORS BEING CONDUCTED AT THE UNIVERSITY, INCLUDING THOSE UNIVERSITY FACULTY/STUDENTS/STAFF MAY BE PART OF

Who is the IRB?

- At the University, IRB activities involve the following individuals and groups:
  - Chief Research Officer – responsible for all research activity conducted at the University of Scranton (Dr. David Marx, Associate Provost)
  - IRB Administrator - responsible for the management and administration of the IRB function and its policies and procedures (Ms. Kate Yerkes, Assistant Provost)
  - IRB Committee - chaired by an experienced faculty member and comprised of appointed faculty and staff. The Committee is responsible for reviewing HSR projects that meet the criteria defined within its policy, (Chair, Dr. Bryan Burnham, Psychology)
  - Departmental Review Boards (DRBs) - chaired by a faculty member from departments authorized under the IRB Policy to review and approve some HSR projects (E.g., Psychology, OT/PT)

Why is the IRB needed (where does it come from)?

- Many historical events led to the requirement for HSR to be regulated and monitored
  - Nazi human experimentation → Nuremberg Code
  - Tuskegee Syphilis Study
  - Willowbrook Hepatitis Study
- Many groups and laws define ethical and appropriate HSR, such as
  - Declaration of Helsinki (World Medical Association)
  - National Commission for the Protection of Human Subject of Biomedical and Behavioral Research Report ("Belmont Report")
  - Health Insurance Portability and Accountability Act (HIPAA)

How do I know that need the IRB?

- Student researchers may be part of a research project led by a faculty member(s), which generally require the IRB
- student researchers may conduct HSR of their own for academic work (class projects, dissertations/theses, assessments)
- **Generally**, class projects are not likely to require the IRB, ***unless*** the data will be presented externally

How do I know that need the IRB?

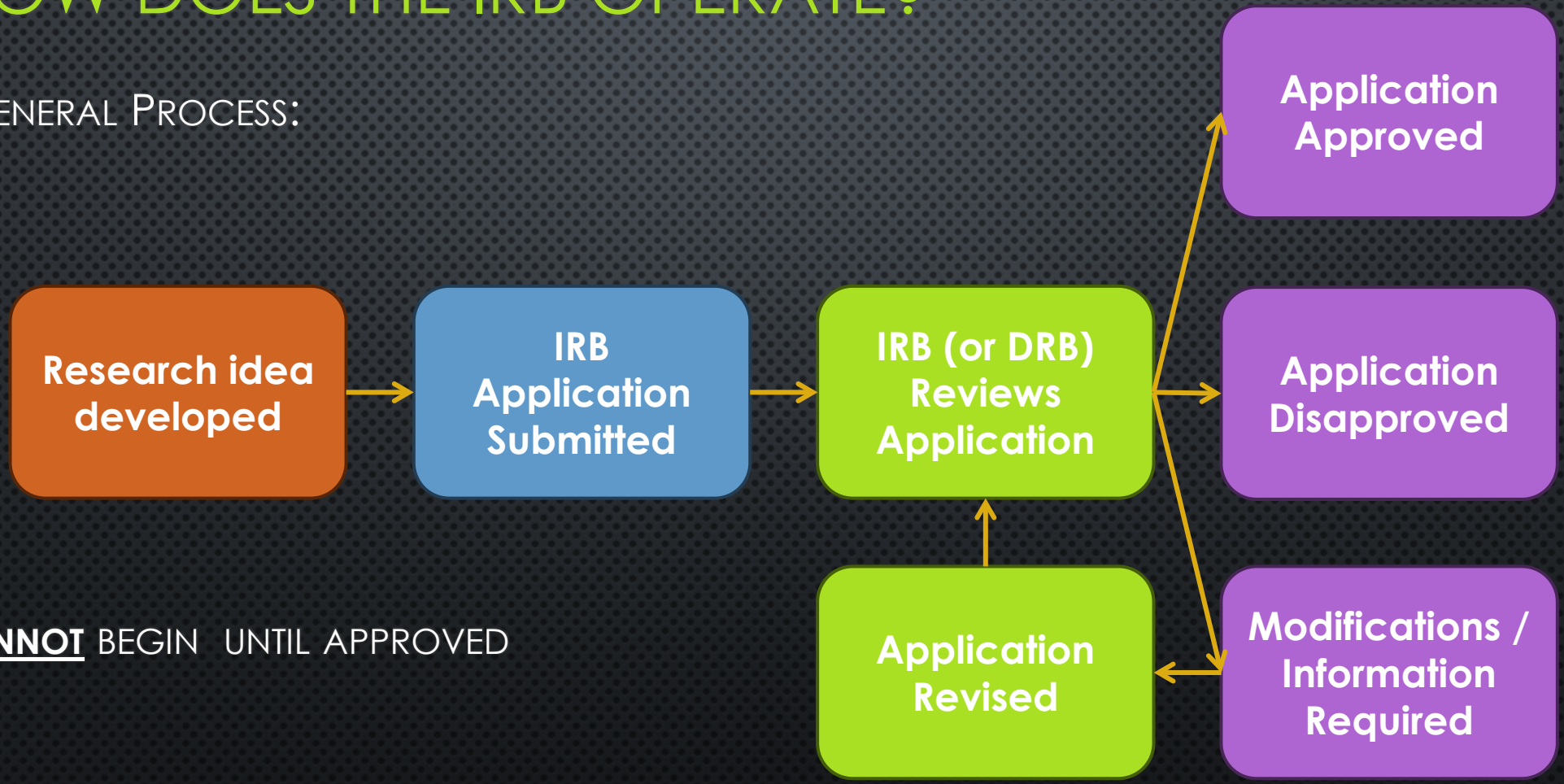
- IRB review is necessary when a project is both
  - **(1) Research**
    - A *systematic* investigation designed to develop or contribute to generalizable knowledge
    - May be tricky to decide if what you are doing is Research. Typically, if you are preparing a presentation or publication that summarizes your research activity, it is most likely research
    - However - Publication alone does not make it research, and research may still be happening even if publications are not planned
  - **(2) involving human subjects**
    - A living individual about whom an investigator is conducting research
    - Obtaining Biospecimens, conducts interventions, surveys, tests, etc.

How do I know that need the IRB?

- Where IRB review is ***usually*** **not** necessary:
  - Journalism or Oral History Activities (unless knowledge generalized beyond the persons/group)
  - Literature reviews
  - Classroom activities only with members of the class, if…
    - no more than minimal risk
    - no sensitive information collected
    - data are not disseminated
  - Institutional Research; Program, Department, or Course-related assessment

HOW DOES THE IRB OPERATE?

- **VERY** GENERAL PROCESS:



- HSR **CANNOT** BEGIN UNTIL APPROVED

IRB Processes and Procedures

- IRB Committee usually meets one per month, perhaps once over summer
- length of the IRB review depends upon several factors:
- (1) completeness/thoroughness of the IRB application:
  - Should include sufficient information for others to understand the project
  - include all documents (consent forms, surveys, recruitment information)
- (2) level of risk/review
  - exempt and expedited projects do not require the full IRB committee to review
  - full committee reviews will generally take at least one month
- Regardless of level, the IRB may ask questions for further information or for Modifications to be made, which will lengthen the process

WHAT INFORMATION DOES THE IRB NEED?

- IRB process includes two types of applications ("Exempt" or "Expedited/Full") that gather information needed to help the IRB determine what level of review, approval, and oversight is needed
  - **Exempt**: research that is (1) ***minimal risk*** (no greater risk of harm or discomfort than daily life), and (2) ***anonymous*** (no personally identifiable information is known/used/collected)
  - **Expedited**: research that is (1) ***no more than minimal risk,*** and (B) the involvement of human subjects will be in one or more of the federally defined categories
  - **Full**: research that involves (1) ***more than minimal risk,*** or (2) one or more vulnerable populations (e.g., minors, pregnant women, prisoners)
- Undergraduate student applications may **only** be submitted by a faculty or staff member, but Graduate student applications may be submitted directly by the student

What information does the IRB need?

- For either application, The IRB **NEEDS** to know about:
  - History and background of the project (abbreviated literature review)
  - The purpose/intent of the research, including plans for sharing what you learn
  - description of the research subjects and how they are selected and recruited
  - Research design and methodology
  - How the investigators will interact with the research subjects
  - **ALL** documents that will be used/distributed (surveys, consent forms, communications, recruitments, etc.)
  - Description of any potential risks subjects may encounter and how they will be minimized
  - Any personally identifiable information about subjects that the researchers know/have, or will be obtained (if any) and how confidentiality will be maintained (and if not, why)
  - How data will be stored and protected, and who will have access

Training Requirements

- IRB approved training is required for all investigators
- The Collaborative Institutional Training Initiative (CITI Program)
  - Online program to teach about ethical treatment of human research subjects
  - All Investigators and study personnel **MUST** complete with a minimum score of 80%
  - IRB needs documentation that you have completed the program
- Steps:
  - Go to http://www.citiprogram.com
  - Select "Register"
  - Step 1 - Participating Institutions: University of Scranton
  - Step 2 - Create a username and password
  - Complete remaining contact and information fields
  - Check the course you are required to complete (Group 1 – Social and Behavioral Investigators)

Informed Consent

- Informed Consent is a fundamental part of HSR from the federal regulation:
  - "The informed consent process involves three key features: (1) disclosing to potential research subjects information needed to make an informed decision; (2) facilitating the understanding of what has been disclosed; and (3) promoting the voluntariness of the decision about whether or not to participate in the research."
- Consent must be legally and prospectively obtained before participation in research begins
- Special steps may need to be taken for minors or other protected populations

INFORMED CONSENT

- STANDARD ELEMENTS OF INFORMED CONSENT THAT MUST BE ADDRESSED:
  - A STATEMENT DESCRIBING THE RESEARCH, ITS PURPOSES, AND EXPECTED DURATION
  - A STATEMENT THAT THE RESEARCH IS VOLUNTARY, THAT THERE IS NO PENALTY FOR NOT PARTICIPATING, AND THAT THE SUBJECT CAN DISCONTINUE PARTICIPATION
  - ANY REASONABLY FORESEEABLE RISKS OR DISCOMFORTS TO THE SUBJECT;
  - ANY BENEFITS TO THE SUBJECT OR TO OTHERS WHICH MAY REASONABLY BE EXPECTED FROM THE RESEARCH, OR STATEMENT THAT THERE MAY BE NO DIRECT BENEFIT
  - DISCLOSURE OF APPROPRIATE ALTERNATIVE PROCEDURES OR COURSES OF TREATMENT, IF ANY;
  - STATEMENT DESCRIBING THE EXTENT, IF ANY, TO WHICH CONFIDENTIALITY OF RECORDS IDENTIFYING THE SUBJECT WILL BE MAINTAINED;
  - WHO TO CONTACT FOR ANSWERS TO QUESTIONS ABOUT THE RESEARCH AND RESEARCH SUBJECTS' RIGHTS, AND WHOM TO CONTACT IN THE EVENT OF A RESEARCH RELATED INJURY TO THE SUBJECT
  - CONTACT INFORMATION FOR THE IRB ADMINISTRATOR

COMMON IRB QUESTIONS

- Request that the application include more information about the project
  - For example, application only provides a sentence or two about the background. The IRB doesn't have enough information to understand what the project is about or what the researcher plans to do.
- Request documents that have not been provided
  - For example, investigator will send an email invitation to potential participants, but did not include the actual text of the email
- Revise documents to be sure they do not overpromise or understate elements of informed consent or the project
  - A form or survey says there is "***NO RISK***" to participation
  - Survey responses may be described as anonymous, but the investigator will send the survey via email and is inviting participants to share their email for a voluntary incentive.
  - Consent form fails to note that participation is voluntary and there is no penalty for discontinuing

Lastly, about risk

- IRB is mainly concerned about potential risks to human research subjects
- There is **NEVER NO RISK**, even with exempt research
- Risk may be minimal, or greater then minimal
  - Minimal risk means that the likelihood and magnitude of harm or discomfort is not greater than those risks or harm that are ordinarily experienced in daily life
  - Greater than minimal risk means that the likelihood and magnitude of harm or discomfort is not is higher than daily life, and can be physical, emotional, psychological, etc.
  - Breach of confidentiality is a risk the IRB examines