Does this project need IRB approval?

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Summary & Objectives

- **Summary:**
  - A brief summary of the history of Institutional Review Boards, and the purpose of the IRB will be provided. Explanation of what types of studies or projects require, or do not require, IRB approval will be reviewed.
- **Objectives:**
  - IRB training
  - Basics of responsible conduct in research (RCR)
  - Basics of Institutional Review Board (IRB) process
  - Basics of patient informed consent

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My training for IRB

PRIM&R
PUBLIC RESPONSIBILITY IN MEDICINE AND RESEARCH

- Additional IRB training
  - Professional organization for IRB's
  - Provide me an "IRB mentor"
- My mentor is at a much different type of facility, but still very helpful

Children's Hospital of Philadelphia RESEARCH INSTITUTE | Institutional Review Board

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Protection of Human Rights in Clinical Research

- **Studies that have people as participants**
  - **Protection of their rights and dignity must be inherent in the design of the study**
    - **Privacy and confidentiality**
    - **Safety**

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Evolution of RCR on Human Subjects

- Nuremburg Code 1949
  - Ethical medical behaviors
  - Every individual should voluntarily consent to participate in the study
  - Consent should be given after the subject has sufficient knowledge of the purpose, procedure, hazards, benefits, of the study
  - Competence of investigator: "study should only be conducted by scientifically qualified persons"

https://www.nejm.org/doi/full/10.1056/nejm199711133372006

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Evolution of RCR on Human Subjects

- Declaration of Helsinki 1964 (updated 2013)
  - Independent review of research protocols by a committee of people who are not associated with the project

https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

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Evolution of RCR on Human Subjects

- Belmont Report 1979
  - Leading document with regard to ethics and health care research
  - Primary propose is to protect subjects and participants in clinical trials
    - Beneficence, justice, respect for persons

THE BELMONT REPORT
Ethical Principles and Guidelines for the Protection of Human Subjects of Research

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Protection of Human Rights

- Respect for Persons = Autonomy = self determination and capacity to make decisions affecting their life, and act on those decisions
  - Some individuals are not able to do this
    - Children, including fetuses
    - Persons with cognitive deficits
    - Prisoners

THE BELMONT REPORT
Ethical Principles and Guidelines for the Protection of Human Subjects of Research

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Protection of Human Rights

- Beneficence = obligation to attend to the well being of individuals
  - Maximize benefits and minimize harm to study participants
    - Includes protection from
      - psychological harm such as embarrassment or distress, or
      - social harms such as loss of employment, or
      - criminal or civil liability
  - Confidentiality is paramount

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Protection of Human Rights

- Justice = fairness in the research process
  - Subjects selected for the study are appropriate for the study, drawn from population of interest

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Privacy and Confidentiality

- Privacy
  - Control over sharing oneself with others
  - A right to be protected, and is in the eye of the participant
- Confidentiality
  - Treatment of information that the individual has disclosed
  - Subjects must be informed how confidentiality will be maintained
  - Its an extension of privacy that pertains to the IRB and HIPAA
  - Is about the data

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Control groups

- Control group or placebo group for comparison
  - Seen in RCT's
  - Declaration of Helsinki (2002)
    - Experimental treatment must be offered to the control group after the data collection is complete, if the results indicate treatment is beneficial

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Evolution of RCR on Human Subjects

- US Department of Health and Human Services Rules and Regulations
  - Incorporated Declaration of Helsinki principles
  - Office for Human Research Protection (OHPR) is one arm of DHHS
- IRB falls under DHHS
  - UJ IRB registered with OHPR
  - Membership updated with OHPR annually

HHS.gov
Office for Human Research Protections

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UJ's IRB

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Institutional Review Board (IRB)

- Review research proposals prior to implementation
  - Ensure rights of research subjects are protected
  - Ensure safety of study design
- Membership guidelines from OHPR
  - At least 5 members
  - One non-scientific member
  - One community member, not affiliated with the institution

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Institutional Review Board (IRB)

- Review research proposals
  - Approve
  - Require modifications
  - Deny
- Arrive at decision based on:
  - Scientific merit
  - Safety: Risk and discomfort to subjects are minimized
    - Risk-benefit ratio
  - Informed consent
  - Privacy and confidentiality

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Protection of Human Rights in Clinical Research

- **Studies that have people as participants**
  - **Protection of their rights and dignity must be inherent in the design of the study**
    - **Privacy and confidentiality**
    - **Safety**

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Institutional Review Board (IRB)

- Types of IRB review
  - Exempt
  - Expedited
  - Full Board Review

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Exempt Review

- Exempt studies are
  - Surveys
    - Exempt, usually
    - UNLESS covers sensitive information, such as drug abuse, sexual behavior, or criminal activity
  - Studies of existing records, provided that the subject can not be identified

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Expedited Review

- IRB chair and one member review the documents
- Occurs when
  - "subjects over 18, using noninvasive procedures routinely employed in clinical practice"
  - Adherence to
    - research standards
    - patient safety/confidentiality

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Full Board Review

- For research that is not eligible for exempt or expedited review
  - Involves more than minimal risk
  - Involves protected populations
    - Children and pregnant women, prisoners, cognitively impaired
  - Involves intentional deception of subjects
  - Procedures (including interview) that are personally intrusive, stressful, or potentially traumatic
    - Stress can be physical, psychological, social, financial, or legal
  - Adherence to research standards and patient safety

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Informed Consent

- Subjects must be fully informed
  - Risks: physical, psychological, or social harm
    - Shouldn't be any risks other than any normal risk associated with participation
  - Benefits
    - Depending on the study
      - No benefit other than you are helping us
      - Ability to improve participation in a task
      - For example…

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Does this project require IRB approval?

- Is it a class assignment for students enrolled in a course?
  - Is the class assignment going to be used in any way outside of class? Such as:
    - Research day presentation
    - **Yes, it requires IRB approval**
  - Is the class project utilizing people outside of UJ (i.e., interviewing employees of XX organization)?
    - **Yes, IRB approval is required.**

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Does this project require IRB approval?

- Is the project studying topics directly related to the class, and being studied in an official college course:
  - Is the class project asking questions that include any risk?
    - Risk = psychological, social, economic, legal harm; sexual activity, drug activity, alcohol activity, illegal activity?
    - Sensitive = This could include something like "challenges in leadership role" or ranking players on a team based on abilities

- **Yes, these all need IRB approval.**

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Does this project require IRB approval?

- Does an outside organization want to come to UJ to study students, faculty, or staff?
  - Individual on campus must be the liaison, and complete the required documentation
  - Depends on the study
    - Sensitive information?
  - **Probably Yes, check with the IRB.**

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Does this project require IRB approval?

- Is the project studying topics directly related to the class, and being studied in an official college course:
  - Completing questionnaires?
  - Participate in interviews?
  - Observation of behaviors?
  - Oral history or questions (qualitative study)?
- **No, these do NOT require IRB approval.**

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Does this project require IRB approval?

- Is the project ONLY for class, and will NOT be used outside of class in any way?
  - Probably **no IRB approval required**
- Is the data being collected from previously published data or publicly available data?
  - Probably **no IRB approval required**
- Is the data going to be used internally only (department, school, administrative purposes)
  - Probably **no IRB approval required**
  - If its going to be used external to the department, school, etc. then **Yes, it needs IRB approval.**

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Subject information should be confidential and anonymous

- How will information be kept confidential?
  - All data collected must be confidential
  - Separate data collected from the approval document so it can not be identified
- If pictures or videos are taken, this should be in the consent form they sign
  - It is. UJ has a consent form to use for pictures and videos
  - It also states that medical information may be used for educational purposes
- **Studies will be—and have been—rejected when confidentiality can not be maintained.**

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Does this project require IRB approval?

- When in doubt, ask the IRB
- Very few areas of black and white
- Lots of areas of gray
- When in doubt, as the IRB
  - = email me (Sara Voorhees)

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UJ IRB submission

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Required Documents

- All posted in MyUJ
  - IRB application
  - Research Description
  - CITI training certificates for ALL involved (student, faculty advisor)
    - I save UJ faculty certificates, so if you submit it once, then I have it

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Any person who submits to IRB

- IRB training modules
  - Faculty training
  - Student training
  - IRB membership training
- Certificate of completion must be included

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Sanford Partnership

- Partnership: University of Jamestown and Sanford Health
  - Primary purpose is for the Physical Therapy Program to have access to Sanford patients for research purposes
  - All studies must go through UJ and Sanford
  - Any study or student project using Sanford employees or Sanford patients also needs to utilize this partnership

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Questions?

- Thank you!

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