NAVIGATING THE IRB

Dr. Jennifer S. Linvill, IRB Administrator

September 2019

INTRODUCTION

- Starting Points: HRPP & IRB
- Human Subjects Research
- Types of Research: Exempt & Non-exempt
- Informed Consent
- Special Considerations: FERPA, HIPAA, PHI
- External Collaborations
- Required Training
- Submitting an Application to IRB for Review

PURDUE'S HUMAN RESEARCH PROTECTION PROGRAM (HRPP)

- Integrate the diverse elements of the HRPP
  - Support Purdue's IRB
  - Provide regulatory expertise and guidance
  - Provide education for research personnel
  - Facilitate collaborative research with external IRBs
  - Maintain records related to regulatory compliance
  - Conduct post-approval monitoring of research

PURDUE'S HUMAN RESEARCH PROTECTION PROGRAM (HRPP)

- Implements Purdue's commitment to:
  - Protecting human research subjects
  - Applying Belmont Report principles:
    - Respect for Persons (voluntary informed consent)
    - Beneficence (risks do not outweigh benefits)
    - Justice (fairness)

INSTITUTIONAL REVIEW BOARD (IRB)

- An IRB is a committee that performs ethical review of proposed research.
- An IRB must have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.
- Must have a non-scientist and a member who is not affiliated with the home institution.

WHY DOES MY RESEARCH NEED TO BE REVIEWED BY THE IRB?

- Purdue University's Federalwide Assurance (FWA) with the U.S. Department of Health and Human Services states that all research being conducted under the auspices of this institution is subject to review and approval by the IRB.
- Written approval from the IRB must be in place ***before*** any interventions or interactions with human participants actually begin.

WHEN TO ENGAGE THE HRPP

- Engage the HRPP when the answer to both of the following questions is “yes”
  - Does the activity meet the definition of research?
  - Does the activity involve human subjects?

- If you are uncertain if a review is required, use the Cayuse IRB submission tool for a determination.

HOW DO I KNOW IF MY ACTIVITY IS RESEARCH?

- *Research*
  - "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." 45 CFR 46.102(d)

    - Generalizable: The data and/or conclusions are intended to apply more broadly beyond the individuals studied, or beyond a specific time and/or location, such as to other settings or circumstances.

HOW DO I KNOW IF MY ACTIVITY IS RESEARCH?

- *Human Subjects*
  - "a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information." 45 CFR 46.102(f)
    - Interaction: Communication or interpersonal contact between a member of the research team and the individual. Surveys – whether in-person, web-based, mail, email, phone, etc. – are an interaction between researchers and individuals.
    - Obtain: Record in any fashion (writing, video, voice recording, etc.) for research purposes and retain for **any** length of time.
      - This includes so-called "**third party**" or "**secondary subject**" situations in which researchers obtain information about one individual through interaction with another individual.

IRB REVIEW IS REQUIRED EVEN FOR…

- Simple surveys
- Research projects conducted by students
- Research to be conducted in other countries
- Collecting data through an intervention or interaction with human subjects even if you are not collecting identifying information

TYPES OF IRB REVIEWS

Exempt Research

Non-Exempt Research (Expedited or Full Board Review)

EXEMPT RESEARCH

- All of the research activities fall under one or more of the exemption categories specified by the federal regulations.
- The significance of exempt status
  - the research activity is not monitored by the IRB
  - Assuming the project does not change, it also is not subject to continuing IRB oversight
- Exemption does not lessen the ethical obligations to subjects and depending on the circumstances the investigator may still be required to
  - obtain informed consent
  - protect confidentiality
  - minimize risks
  - address problems or complaints

EXEMPT CATEGORY 1

Research conducted in established or commonly accepted educational settings, that specifically involves normal education practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction, such as:

a) research on regular and special education instructional strategies; or

b) research on the effectiveness of, or the comparison, among instructional techniques, curricula, or classroom management methods.

EXEMPT CATEGORY 2

Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met**:**

a) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; or

b) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

c) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

***NOTE**: DOES NOT APPLY for **individuals under the age of 18**.

EXEMPT CATEGORY 3: BENIGN BEHAVIORAL INTERVENTIONS

Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection.

*See additional criteria.

**Does not allow for deceiving of the subjects.

EXEMPT CATEGORY 4

Secondary research for which consent is not required. Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

- The identifiable private information or identifiable biospecimens are publicly available;
- Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects.

EXEMPT CATEGORY 6

- Taste and food quality evaluation and consumer acceptance studies:

a) if wholesome food without additives are consumed; **OR**

b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Good Safety and Inspection Service of the U.S. Department of Agriculture.

RESEARCH THAT IS NON-EXEMPT

- Vulnerable populations (those with limited or compromised autonomy):
  - Children (under age 18)
  - Prisoners
  - Persons with mental, emotional, or physical disabilities
  - Persons who are economically disadvantaged
- Observations must be of a public behavior *and* in a public setting.
  - Classrooms and medical settings are not considered public.
- "Identifiable information"
  - Information by which a subject can be identified directly (e.g., name, PU ID number, SS number, email address, etc.), indirectly by triangulating multiple variables, (i.e., age, sex, race, profession, etc.), or through codes with links to the identity of a subject.

ELIGIBILITY FOR EXPEDITED REVIEW

- Expedited: the “expeditious” part of the process is not going through full board review.
- **Minimal risk**
  - the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those **ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.**

EXAMPLES OF EXPEDITED REVIEW

- “Collection of data through noninvasive procedures”
- “Collection of data from voice, video, digital, or image recordings made for research purposes…”
- “Research on individual or group characteristics or behavior…”
- “Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture…”
- “Prospective collection of biological specimens for research purposes by noninvasive means…”

FERPA & HIPAA CONSIDERATIONS

- If FERPA requirements apply to your research you will need to speak with the Data Custodian/Steward at the research site
  - Purdue Registrar
  - School Superintendent
- If HIPAA requirements apply to your research you will need to speak with the Privacy Officer at the research site
  - Chief Legal Officer
  - Privacy Officer

USE OF PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH

- Use this chart to determine what the IRB requires in an application prior to review or approval when Protected Health Information is involved in research:
  - **Applications Proposing to Use Protected Health Information (PHI) for Research**

EXTERNAL COLLABORATORS

- Use this flowchart to determine the type of agreement required when non-Purdue researchers will serve as key personnel on an IRB protocol:
  - **External Collaborator Sites Flowchart**

INFORMED CONSENT

- Describe the overall experience that will be encountered.
- Describe the benefits that subjects may reasonably expect to encounter.
- Describe any alternatives to participating in the research project.
- Regulations require that the subject be told the extent to which their personally identifiable, private information will be held in confidence.
- Regulations prohibit waiving or appearing to waive any legal rights of subjects.
- Regulations provide for the identification of the contact person(s) who would be knowledgeable to answer questions of subjects about the research, rights as a research subject, and research-related injuries.
- Regulations require a statement regarding voluntary participation and the right to withdraw at any time.

COMMON RULE UPDATES

- **CONSENT FORM UPDATES REQUIRED BY JANUARY 21, 2019:**

  Key Information

  Please take time to review this information carefully. This is a research study. Your participation in this study is voluntary which means that you may choose not to participate at any time without penalty or loss of benefits to which you are otherwise entitled. You may ask questions to the researchers about the study whenever you would like. If you decide to take part in the study, you will be asked to sign this form, be sure you understand what you will do and any possible risks or benefits.

  RESEARCHER MUST ALSO ADD THE FOLLOWING:

  •A sentence that explains in simple terms what the study is about and why you are conducting the study.

  •Summarize how long the research project will take place (in approximate, hours, days, weeks, or months).

  •Include a statement about potential risks and potential benefits of the study.

INFORMED CONSENT RESOURCES

- IRB Consent Form Builder
  - https://www.irb.purdue.edu/application-forms/
  - Caution: The consent form must be research specific!
- IRB Standard Operating Procedure #320, “Informed Consent Requirements”
  - https://www.irb.purdue.edu/docs/new/Signed%20IRB%20SOPs%2012.5.17.pdf
- Federal Regulations and Guidance
  - https://www.hhs.gov/ohrp/regulations-and-policy/guidance/informed-consent-tips/index.html
  - The statement regarding voluntary participation and the right to withdraw at any time can be taken almost verbatim from the regulations found at 45 CFR 46.116 [a][8])

BASIC CRITERIA FOR IRB PROTOCOLS

- **Know the study population**
  - Identify vulnerable populations
  - How will you access or approach this population?
  - Who will be included and/or excluded?
- **Recruitment process**
  - How to minimize coercion or undue influence
  - What methods (advertisements, flyers, news articles will you use)?
- **Consent process**
  - All participants must be willing to participate and give their consent
  - A consent form is required for most non-exempt
  - Outline the risk(s), procedure(s), duration, and other important factors to be considered before participating in the research
- **Risks and risk mitigation**
  - Study design elements geared to reduce the probability and magnitude of a potential risk
- **Managing identification of study subjects**
  - How to protect the confidentiality of subject data (e.g. physical security)
  - Retention periods for identifiable data

REQUIRED CITI TRAINING

- CITI Training is an online course that teaches the history, requirements, and current protections required for research with human subjects.
- **CITI Human Subjects Research Basic Course** is required for *all* investigators and study personnel.

RESEARCHER TRAINING RESOURCES

- IRB's CITI Registration Instruction Sheet:
  - https://www.irb.purdue.edu/training/
- Purdue Information for Researcher Training:
  - http://www.purdue.edu/research/regulatory-affairs/researcher-training/

RESOURCES

- Application Forms
  - https://www.irb.purdue.edu/application-forms/
- CITI Training
  - https://www.irb.purdue.edu/training/
- Researcher Guide
  - https://www.irb.purdue.edu/training/
- When Should I Report Study Problems to the IRB?
  - https://www.irb.purdue.edu/application-forms/
- Standard Operating Procedures
  - https://www.irb.purdue.edu/docs/new/sops-web.pdf
- Updates and Improvements
  - https://www.irb.purdue.edu/irbs/recent-improvements.php

IRB CONTACT INFORMATION

Purdue, West Lafayette Campus

YONG Hall, Room 1032

Phone: (765) 494-5942

irb@purdue.edu

Walk-in Hours: Thursdays from 2:00 – 4:00 or by appointment