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IRB CONSIDERATIONS FOR EDUCATION RESEARCH

SPEAKER: NYSSA TOWSLEY, MS, CIP

Nyssa Towsley

EDUCATION

MS - Research Administration -Johns Hopkins
BA - Poli Sci - University of Minnesota - Twin Cities

EXPERIENCE

Education & Outreach Manager, VCU HRPP
IRB Analyst, VCU HRPP
Clinical Research Coordinator, VCU Health
Regular national conference presenter
Certified IRB Professional (CIP)

Learning Objectives

- Define “human subjects research” and determine when IRB review is necessary for education research projects
- Describe the three levels of IRB review (exempt, expedited, and full board) and discuss examples of ed research at each level
- Articulate the requirements for the education research exemption category and discuss allowable methods of data collection under that exemption
- Discuss common challenges and researcher questions relating to education research, in both K-12 and postsecondary settings

IRB Review: The "When"

Human Subjects Research

Not all projects involving people require IRB review. Only "Human Subjects Research" has this requirement. But what exactly is "Human Subjects Research" and when is IRB review required?

The "HSR" Equation

IRB Review only required when BOTH regulatory definitions are met

RESEARCH

"**Systematic investigation** … designed to develop or contribute to **generalizable knowledge**"

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HUMAN SUBJECT

A **living** individual, **about whom** an investigator either:

- obtains information/biospecimens through interaction or intervention, AND/OR
- obtains, uses, studies, analyzes, or generates identifiable, private information/biospecimens

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IRB REVIEW REQUIRED

RESEARCH: THE BREAKDOWN

"Systematic Investigation"

- Predetermined system, method plan
- Studies specific question/hypothesis
- Involves data/specimen collection and qualtitative/quantitative analysis of info/specimens

"Designed to Develop or Contribue to"

- Investigator intentionality

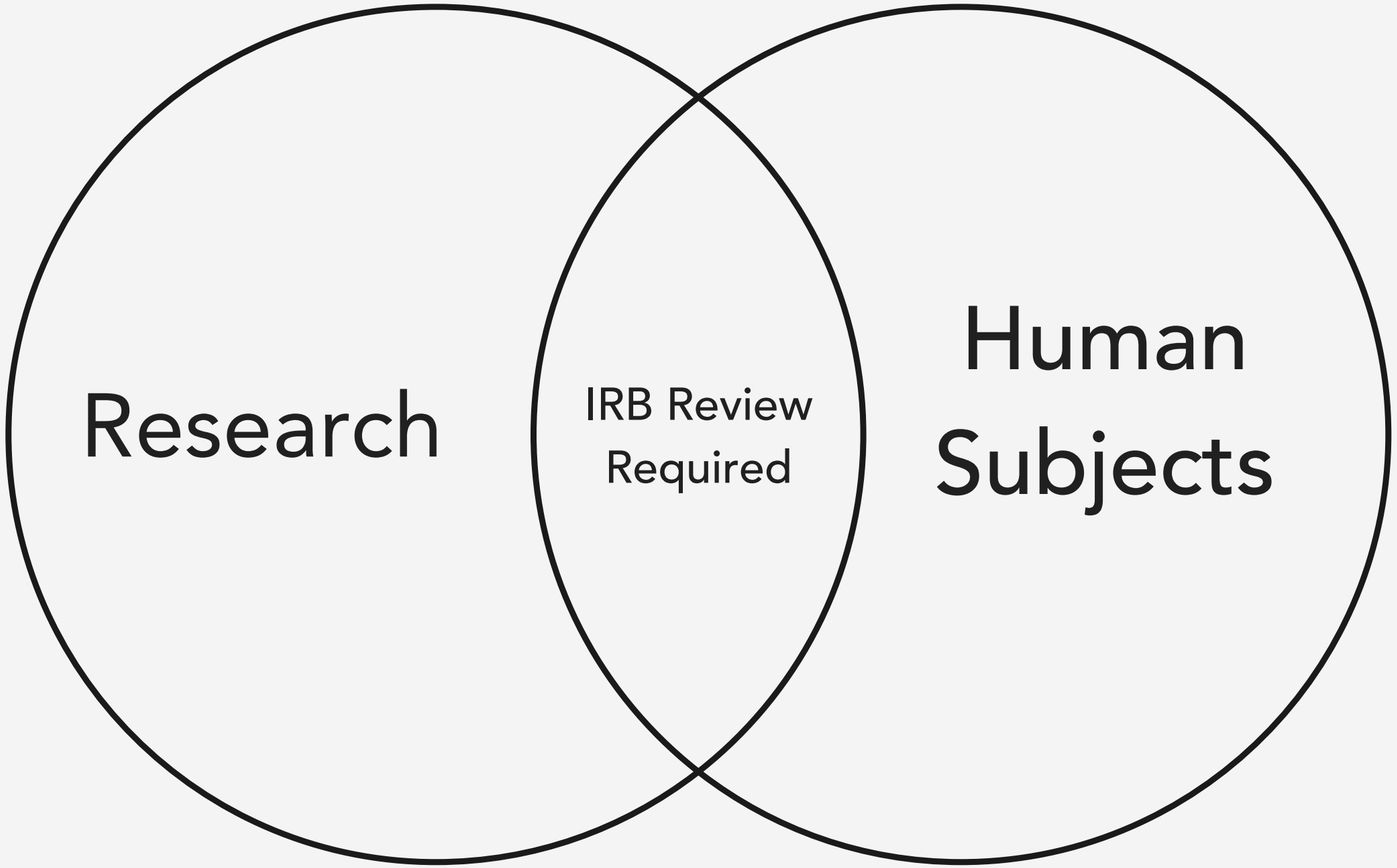
"Generalizable Knowledge"

- Info that can be used to draw general conclusions outside of a given entity/institution
- Contribute to a body of knowledge
- Benefit extends beyond current program/institution
- Intent to publish may **suggest** generalizability; not a sufficient criterion on its own
- Qualitative research may not be "generalizable," but does contribute to an overall body of knowledge

The IRB Review Diagram

Research without Human Subjects:

- Animal research
- Research on deceased individuals
- "Bench" research



Human Subjects without Research

- Restaurant satisfaction survey
- Writing a biography
- COVID Contact Tracing

IRB Review: How Much?

The Three Levels of IRB Review

The IRB provides differing levels of oversight depending on the risk level of the research project. But what are these review levels and what are the requirements for each?

Review Levels

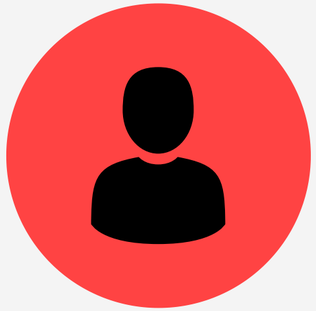
The level of oversight provided to a project is directly proportional to the level of risk involved in the project

Risk Level

Full Board/Full Committee Review

Greater Than Minimal Risk

Minimal Risk



Expedited/Single Reviewer Review

Risk Level

"Exempt" 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.

Regulatory Definition

MINIMAL RISK EXAMPLES

Activities that are (Generally) Minimal Risk*	Activities that are Greater than Minimal Risk
• Interviews/focus groups/surveys • Educational assessments • Collecting saliva samples • Collecting small amounts blood via venipuncture from healthy individuals • Blood pressure monitoring • MRIs without contrast • Observations of public behavior • Cognitive assessments • Retrospective review of publicly-available data • Retrospective analysis of stored biospecimens • Using leftover samples that are being collected for non-research purposes	• Administration of investigational drugs • Implantation of an investigational device • Collecting large amounts of blood, or collecting blood from non-healthy individuals • Invasive biopsies or sample collection • Radiation exposure (X-rays, PET scans, etc) • MRIs with contrast • Experimental psychological treatment programs • Mobile medical applications that use health information to directly inform care of the research subject (e.g., applications that provide insulin dosing recommendations)

*Note: Any of the activities in the "minimal risk" column could be considered greater than minimal risk, depending on the circumstances. For example:
conducting interviews with people who have had abortions, about their abortion experience, in a country where abortion is not legal. Always consider the cultural/social/legal context in which the research is taking place.

FULL BOARD/FULL COMMITTEE REVIEW

Reserved for Riskiest Studies

- Full board/full committee review is conducted on research that is greater than minimal risk, or research that is minimal risk, but doesn't qualify for lower level of review

Review Conducted by Group

- A committee of at least 5 people conduct the review of the research

Ongoing Oversight

- "Continuing Review" required at least annually
- All changes, no matter how minor, must be submitted for review and approval prior to implementation

Requires Consent or Consent Waiver

- Requirement to obtain or waive consent for all research activities

EXPEDITED/SINGLE REVIEWER REVIEW

Study Activities Must Meet Requirements

- ALL activities proposed in the research must meet the definition of "minimal risk"
- ALL research activities must fall into one or more of 7 pre-determined categories

Review Conducted by an Individual

- A single IRB member may conduct expedited review

Ongoing Oversight

- "Continuing Review" is generally not required. WOU requires a 5-year check-in for expedited research
- All changes, no matter how minor, must be submitted for review and approval prior to implementation

Requires Consent or Consent Waiver

- Requirement to obtain or waive consent for all research activities

"EXEMPT" REVIEW

Study Activities Must Meet Requirements

- ALL activities proposed in the research must meet the definition of "minimal risk"
- ALL research activities must fall into one or more of 8 pre-determined categories

What does "exempt" mean?

- Exempt means "exempt from the regulations"
- However, WOU requires exempt research to be submitted to IRB - procedures here

Ongoing Oversight

- "Continuing Review" is not required. WOU requires a 5-year check-in for exempt research
- Changes must be submitted prospectively, in case exempt status/category(ies) is impacted by changes

Consent?

- WOU requires minimal information be provided to subjects for exempt research, if interacting/intervening
- Less detailed and formal than consent

EXEMPT "CONSENT" REQUIREMENTS AT WOU

- **A statement that the activity involves research**
  - "I am asking you to participate in a research study on …."
  - "For this research study, I am ask you to …"
  - "This research study is on …"
- **A statement that participation is voluntary**
- **A statement that adequate provisions are in place to protect privacy**
  - "We will protect your privacy/information by…"
- **A description of the procedures**
  - Clearly differentiate between required classroom activities and research activities
  - "I am asking you to …."
  - "In this research study, you would …."
- **Name and contact info for researcher**
  - Best practice for student researcher is to offer contact info for student and faculty advisor

Education Research: The Exemption

The vast majority of education research can qualify for exemption

Exempt category 1 is the category covering education research. Let's dive into the category and its requirements

EXEMPT CATEGORY 1: EDUCATION RESEARCH -- REQUIREMENTS

- **Conducted in established or commonly accepted educational settings**
  - Schools, universities
  - After school programs; medical residencies; post-doc arrangements, etc.
- **Involves normal educational practices**
  - Not entirely novel; generally accepted by professionals in the field
  - or: would the classroom activity (proposed in the study) occur even if no research was conducted at the site?
- **Is not likely to adversely impact students' opportunity to learn**
  - Research procedures should not interfere with students' ability to learn required content
  - Research procedures should be minimally disruptive
- **Is not likely to adversely impact the assessment of educators**
  - Research procedures should be minimally disruptive

Exempt Category 1: Education Research

COMMONLY INCLUDES:

- research on regular and special education instructional strategies
- research on effectiveness/comparison of instructional techniques, curricula, or classroom management methods.

EXEMPT CATEGORY 1: ALLOWABLE DATA COLLECTION METHODS

- **Some exempt categories limit the data collection methods allowed for that category**
  - ex: category 4: only secondary data use; no primary data collection; category 2: surveys/interviews with adults only

- **Differentiate between research and non-research**
  - ex: differentiate between new assignment added to curriculum which is required, vs optional assessment of new assignment

- **Cat 1 is expansive. Allows data collected via:**
  - Surveys
    - pre/post tests/assessments
  - Interviews/focus groups
    - audio/video recording
  - Secondary data use
    - student records (i.e.: grades)

- **Be clear about your data collection methods**
  - For secondary data: be clear about which variables used, how obtained, and what identifiers (if any) are collected as well

Expedited/FB Education Research -- How and Why

WHEN MIGHT EDUCATION RESEARCH BE EXPEDITED/FB?

- While Exempt Cat 1 allows for the inclusion of children, IRBs have the prerogative to require higher levels of review
- May be desirable/necessary when working with vulnerable populations (i.e.: children in K-12 settings)

WHAT MAKES EXPEDITED/FB EDUCATION RESEARCH DIFFERENT?

- Formal parental permission process required; assent from children may be required (depending on age, maturity, etc., of child subjects)

WHAT SHOULD I DO DIFFERENTLY?

- Discuss options with IRB/IRB Chair
- If conducting research in K-12 settings, make a plan for obtaining parental permission/assent from children

Education Research and Review Levels: Examples

Exempt, Expedited, Full Board

What does education research at each of these levels look like?

EXEMPT EDUCATION RESEARCH

Research Plan/Design

- A researcher wishes to investigate the impact of using a creativity activity at the beginning of her university marketing 101 class sessions on student engagement with class activities and performance in the class overall
- The instructor plans to use the creativity activity in the normal class curriculum, at minimum as an icebreaker for each class session
- She plans to evaluate the impact of the creativity activity by observing students' participation rates in class, looking at student grades and course evaluation data at the end of the class and comparing to a previous class that did not use the activity

Why is it Exempt?

- Adult participants (college students); minimal risk/non-sensitive information
- The creativity activity is administered to everyone as required part of class (no randomization)
- Analysis limited to observation and comparing grades and course eval data -- use of existing data/observation means no additional interventions that might interfere with class time

Ethical/Regulatory Considerations

- Exempt "consent" process still required at WOU -- which activities require consent?
- FERPA?
- Considerations for access to historical data -- individual level or aggregate? Identifiable or anonymized? Consent?

EXPEDITED EDUCATION RESEARCH

Research Plan/Design

- A researcher would like to test a new way of teaching grammar with elementary school students, at a private tutoring center
- Students randomized into two groups: one to receive new method of teaching; one to receive traditional method
- On the second day, students switch groups, so that both groups receive both teaching methods
- The researcher will receive ungraded assessments from both groups in order to compare instruction methods

Why is it Expedited? (Category 7)

- Use of vulnerable population (elementary school students)
- The introduction of a new, researcher-designed method of teaching
- Not FB, though, because risk remains minimal -- students receive both methods, so unlikely to adversely impact their required learning; information is not sensitive; risks to privacy/confidentiality low

Ethical/Regulatory Considerations

- Students should have the opportunity to receive both methods of instruction -- one is not guaranteed to be effective
- Parental permission and assent requirements must be addressed

Example adapted from Columbia University IRB: https://www.tc.columbia.edu/institutional-review-board/irb-blog/get-to-know-a-review-category-expedited-category-7/

FULL BOARD EDUCATION RESEARCH

Research Plan/Design

- A researcher would like to assess the effectiveness of educational curriculum and instructional practices within juvenile detention centers
- Classroom observations within juvenile detention centers' educational settings will be conducted
- Data on student academic achievement and enrollment will be extracted from juvenile detention facilities, as well as data regarding enrollment and academic achievement for juveniles after being released from detention
- Information on student/detainee criminal history and recidivism data to be collected, also demographics

Why is it Full Board?

- Incredibly vulnerable population: children AND prisoners
- Highly sensitive information

Ethical/Regulatory Considerations

- Prisoner representative required in review process
- Parental permission and assent requirements must be addressed
- Extreme caution with sensitive data required

Example adapted from a DoJ-funded research project, titled "Strengthening Education in Short-term Juvenile Detention Centers" Accessed from: https://www.ojp.gov/pdffiles1/ojjdp/grants/251118.pdf

Common Challenges for Education Research

Education research can come with challenges, which may differ between K-12 and Postsecondary settings

Let's take a look at some common challenges presented by education reseach

Postsecondary Contexts

EXTRA CREDIT AS COMPENSATION

- Allowable, but ethically dicey
- Concerns re: coercion/undue influence, sample bias

AVOIDING COERCION AND UNDUE INFLUENCE

- If offering extra credit, provide an **equivalent** alternative activity
- Consider using proxies or passive recruitment methods to recruit students, particularly from your own classrooms
- Design systems that mask who does and doesn't participate from the researcher/instructor

"CONSENT" PROCESS

- WOU requires an abbreviated consent process for exempt research when interacting or intervening; consider how this will be done
- Clearly differentiate between required course content and optional research activities

FERPA Considerations

FERPA IN POSTSECONDARY SETTINGS

- Utilizing "education records" covered by FERPA in research invokes certain requirements
- Education Records: records that are “directly related to a student; and maintained by an educational agency or institution or by a party acting for the agency or institution.”
- Excludes "directory information," (defined in this WOU policy) which can be shared; however, students can opt-out of sharing directory information
- Consult with IRB Chair/registrar to determine FERPA procedures

FERPA IN K-12 SETTINGS

- Procedures will vary, depending on the school
- May be required to obtain signed consent for release of FERPA records
- Work with the K-12 institution where research is taking place to determine procedures

THANK YOU!

Nyssa's LinkedIn:
www.linkedin.com/in/nyssa-towsley-cip-06760452

RESOURCES

- OHRP Decision Charts
- 45 CFR 46 Exemption Categories
- List of Expedited Categories
- OHRP FAQ: Research With Children
- OHRP FAQ: Exempt Determinations
- OHRP FAQ: Informed Consent
- WOU IRB Webpage
- WOU Student Records Webpage

Questions?