IRB for the Scholarship of Teaching & Learning: Students as Human Subjects Using the New Common Rule

Mary Riedford and Ted Myatt
University of Rhode Island
Office of Research Integrity

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MISSION: To ensure research conducted at URI is safe, ethical, and compliant; to facilitate the conduct of research; to comply with applicable regulations, laws, and institutional polices; and thereby, promote a culture of integrity in research.

- Human Subjects Protections
  - *Institutional Review Board (IRB)*
- Animal Subjects Protections
  - *Institutional Animal Care and Use Committee (IACUC)*
- Biological Safety
  - *Institutional Biosafety Committee (IBC)*
- Conflict of Interest in Research
  - *Conflict of Interest Management Committee (CIMC)*
- Research Misconduct
- Export Control
- Responsible Conduct of Research (RCR)
- Research Dive Safety

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Goals

- Differentiate Human Subject Research from Program Evaluations
- Introduce Human Subject Research requirements.
- Discuss how Family Educational Rights and Privacy Act (FERPA) impacts research and program evaluation in educational settings.
- Explain how change in Common Rule have made human subject research in the classroom easier

Before you Begin to Use Classroom Data – *Consider the following Questions?*

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- What are your goals:
  - Designed to test hypothesis?
  - Designed to be published?
- What will you be doing?
  - Is it a routine operation of your class?
  - Students aware of research?
  - Students taught in same manner?
- What data will you use?
  - Student's identifiable data? (FERPA)
  - Pre and post tests linked to grades?
  - Aggregate data?

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Research vs. Evaluation

Research

- Produces generalizable knowledge
- Scientific inquiry based on intellectual curiosity
- Advances broad knowledge and theory
- Controlled setting

Evaluation

- Provides information for decision makers on specific programs
- Judges merit or worth
- Policy & program interests of stakeholders paramount

Intent is Key - What is the intent of the project?

Evaluate your program? Provide framework for new teaching method to be generalized? Is there an intent to publish?

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Program Evaluation activities are not considered Human Subject Research when:

- They do not involve experimental or nonstandard interventions;
- Their intent is only to provide information for and about the setting in which they are conducted;
- They are conducted as part of the standard operating procedures of the setting; and
- They are (usually) not subject to peer review.

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What is Program Evaluation?

- Inform decisions
- Identifies improvements [i.e. formative evaluation]
- Provides information about the success of programs [i.e. summative evaluation] according to predefined **goals** and **objectives**.

- Program Evaluation focuses on *making judgments* about the program, to **improve** or **further develop** program effectiveness, and **inform decisions** about future programming, and/or **increase understanding**.

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What is Human Subject Research?

- Must be BOTH Research and involve Human Subjects

- HHS defines **RESEARCH** at 45 CFR 46.102(l) as follows:
  - **Research** means a **systematic investigation**, including research development, testing and evaluation, designed to **develop or contribute to generalizable knowledge**. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

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What is Human Subject Research?

- HHS define **human subject** at 45 CFR 46.102(e)(1) as follows: NEW
  - Human subject means a **living individual** about whom an investigator (whether professional or student) conducting research:
    - (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
    - (ii) Obtains, uses, studies, or analyzes the generates private information or biospecimens.

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The Family Education Rights and Privacy Act (FERPA):

- **FERPA regulations supersede IRB regulations.**
- Regardless of whether you are conducting **human subject research** or **program evaluation**, you need to be aware of FERPA
  - Applies to all educational agencies and institutions that receive federal funding (e.g., public elementary and secondary schools, universities).
  - Aims to protect the privacy of Student Education Records.
    - Education records **include any record containing personally identifiable information (PII)**
    - **Examples** include documents with a *student's name / ID number, class rosters*, grade lists, place of birth, etc.

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Access to student records

- As **instructors** – full access to student educational records
  - Does not apply to **RESEARCH**.

- As **researcher** - for research purposes, FERPA applies and consent is required,
  - *unless* one of the *exceptions* to consent as outlined in FERPA is met.

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Exceptions to requiring consent

- The only Personally Identifiable Information (PII) obtained constitutes "directory information" (i.e., name, address, telephone number, date and place of birth, honors and awards, and dates of attendance) and the student has not opted out of having his/her information included in the directory.
  - Each educational institution designates what information is considered directory information.
  - At URI, Enrollment Services maintains the list of students who have opted out of the directory.

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Exceptions to requiring consent

- The release is to an authorized representatives of state / local educational authorities for an audit or evaluation of federal or state supported education programs, or for the enforcement of or compliance with federal legal requirements related to those programs.
  - Investigators must provide IRB with evidence that they are acting as **authorized representatives** of a state or local educational authority and that their **audit or evaluation** meets the conditions described above (e.g. a Memorandum of Understanding between University and educational authority).

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Exceptions to requiring consent

- The release is to organizations conducting studies for or on behalf of educational agencies or institutions to develop, validate or administer predictive tests; administer student aid programs; or improve instruction.
  - A written agreement which meets criteria listed in FERPA between the University and the educational agency or institution is required. The agreement must include:
  - The determination of the exception.
  - The purpose, scope, and duration of the study.
  - The information to be disclosed.
  - That information from education records may only be used to meet the purposes of the study stated in the written agreement and must contain the current requirements in 34 CFR 99.31(a)(6) on re-disclosure and destruction of information.
  - That the study will be conducted in a manner that does not permit personal identification of parents and students by anyone other than representatives of the organization with legitimate interests.
  - That the organization is required to destroy or return all PII when no longer needed for the purposes of the study.
  - The time period during which the organization must either destroy or return the information.

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De-Identified Data

- Education records may be released without consent under FERPA if all personally identifiable information has been removed including:
  - Student's name and other direct personal identifiers, such as the student's social security number or student number.
  - Indirect identifiers, such as the name of the student's parent or other family members; the student's or family's address, and personal characteristics or other information that would make the student's identity easily traceable; date and place of birth and mother's maiden name.
  - Biometric records, including one or more measurable biological or behavioral characteristics that can be used for automated recognition of an individual, including fingerprints, retina and iris patterns, voiceprints, DNA sequence, facial characteristics, and handwriting.
  - Other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstances, to identify the student with reasonable certainty.

- At the University level, de-identified data may be obtained from the registrar.

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New Common Rule Consent Requirements (Expedited & Full Board)

- "**Key Information Section**" is required
  - URI incorporated this starting in May 2018.
- Key information must be presented at beginning
  - Concise
  - Easy to comprehend
  - Information the participant would want to know

Consent Form for Research

The 2018 changes to the Common Rule (45 CFR 46) require that consent forms "must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research." This key information is only required to be included for non-exempt research (i.e., Expedited or Full Board review).

STUDY TITLE

List the formal study title (i.e., title as it appears on the IRB Application). If the formal study title is too long or includes technical terminology, you may consider creating a brief title that participants will better understand.

PRINCIPAL INVESTIGATORS

List the Principal Investigator and any other study personnel that participants may need to contact. Include appropriate contact information

Example:

Principal Investigator: Jane Smith, Ph.D. Office: (402) 472-1000 Email: jsmith@uri.edu
Secondary Investigator: John Doe, Ph.D. Office (402) 472-2000 Email: jdoe@uri.edu

KEY INFORMATION

Important information to know about this research study:

- The purpose of the study is to: <<briefly describe study purpose>>.
- If you choose to participate, you will be asked to: <<do what, when, where, and how>>.
- This will take approximately <<period of time>>.
- Risks or discomforts from this research include: <<briefly describe/or state minimal risks>>.
- The study will: <<description of potential direct benefits to subjects – or no benefits>>.
- You will be paid: <<X>> amount for your participation
- You will be provided a copy of this consent form.
- Taking part in this research project is voluntary. You don't have to participate and you can stop it at any time.

INVITATION

"Key Information" – will vary by protocol

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- PI must think from participant's perspective
- Is this coercive?
- Will test results be returned to participants?
- What is offered to a student who choses not to participate?

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Consent Requirements

- Consent form must:
  - Specify the records to be disclosed;
  - State the purpose of the disclosure;
  - Identify the party to whom the disclosure is to be made; and
  - Include a dated student signature

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Consent Process and Coercion

- Participation must be voluntary.
  - Participation in a specific project may **not be** a course requirement.
  - Use unrelated member of research team to consent students in your class.
- In no way may a student's grade be affected by his/her desire not to participate.
  - Hold data until end of of semester after final grades have been assigned.

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Consent Tips

- **Consent is a PROCESS** – the consent form is simply a record of the process.
- Consent process and document, should fully explain your research.
  - Who may participate?
  - What is required of participant (in time and activity)
  - How participant may contact you?
  - Explain risks and benefits.
  - How may participant withdraw from research?

Protecting Confidentiality & Anonymity

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- The IRB must assure privacy and confidentiality for research participants.
  - **Anonymity** Means the project does not collect identifying information of individual subjects (e.g., name, address, Email address, etc.), or the project cannot link individual responses with participants' identities. A study should not collect identifying information of research participants unless it is essential to the study protocol.
  - **Confidentiality:** Means the information disclosed will be held with the expectation that it will not be divulged to others outside of the research team.

The IRB considers:

- What confidential information is being accessed, recorded, and/or shared in the proposed research
- Whether access to confidential information is necessary to answer the research question
- How participants are identified
- Who has access to identifiable information
- Who invites participants to enroll in a study
- The sensitivity of the information to be accessed in a study
- What other special protections should be in place to assure privacy and confidentiality for research participants

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How to proceed if you will be conducting human subject research?

- **No human subject research may begin without IRB approval.**
  - Approval may not be granted after the fact.
- URI's IRB requires:
  - Training in ethical research (CITI Human Subjects Research)
  - Submission of an IRB Application through IRBNet.

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How to get started???

- URI employs an **online submission** program – www.IRBNet.org
  - **Electronic portal** to upload IRB application
  - Register is new USER
- IRBNet is a **self-contained system**
  - All IRB forms are available within IRBNet.
  - Templates for consent, assent are available within IRBNet.

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Getting started???

- Human Subjects Research Training
  - URI employs **CITI** **www.CITIprogram.org**
  - **Basic Course in Human Subject Research**
  - Takes approximately two hours to complete

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Effect of Changes in Common Rule on Classroom Research

- Most classroom research is now classified as **exempt**
- "Exempt" by federal regulation does not meet definition of Human Subject Research (HSR) - **BUT**
- 90% of all URI HSR is **exempt** and it requires IRB review
- URI has a new exempt IRB Application
  - Exempt Application is only 5 pages (as opposed to 21).

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IRB
Exempt Research Application
January 2019

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HUMAN RESEARCH PROTECTIONS PROGRAM

*Please complete this form if you believe your project to fall under an Exempt Category of 45 CFR Part 46.104. Please review the **Exempt Category criteria below** and the **Exempt Category Guidance** documents carefully, including the definitions and limitations. Check the appropriate **Exempt Category(s)** that your research falls under. Applications that do not meet the criteria for exempt review will be withdrawn and you will be asked to complete the INITIAL IRB APPLICATION and submit as a NEW STUDY.*

1) EXEMPT CATEGORY

Category	Citation	Description	Conditions/Allowances/Limitations	
1	104(d)(1)	Research in established or commonly accepted educational settings, involving normal educational practices.	· Not likely to adversely impact students' opportunity to learn or assessment of educators providing instruction	☐
2	104(d)(2)	Research only includes interactions involving educational tests, surveys, interviews, or public observation (including visual or auditory recording) if at least one of the following criteria is met:	· Data Collection Only; · May include visual or auditory recording; · May NOT include intervention, only interactions	
		(i) Recorded information cannot readily identify the subject (directly or indirectly/linked)	· Surveys & Interviews: No Children; · Educational tests or observations of public behavior: Can only include children when investigators do not participate in activities being observed	☐
		(ii) Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation)	· Surveys & Interviews: No Children; · Educational tests or observations of public behavior: Can only include children when investigators do not participate in activities being observed	☐
		(iii) Information is recorded with identifiers or code linked to identifiers	· No Children	☐
3	104(d)(3)(i)	Research involving Benign Behavioral Interventions (BBI) through verbal, written responses, (including data entry or audiovisual recording) from adult subject who prospectively agrees and at least one of the following met:	· No Children; · May not include medical interventions; Subject prospectively agrees; (ii) BBI must be: · Brief in duration · Painless/harmless · Not physically invasive · Not likely to have a significant adverse lasting impact on subjects · Unlikely that subjects will find interventions offensive or embarrassing (iii) No deception unless participant prospectively agrees.	
		A. Recorded information cannot readily identify the subject (directly or indirectly/linked): **OR**		☐
		B. Any disclosure of responses outside of the research would not reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation); **OR**		☐
		C. Information is recorded with identifiers & IRB conducts limited review		☐

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Exempt Application

- Designed to streamline application process
- Deletes many question on long IRB application form

What is required to submit to IRB??

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- **REQUIRED:**
  - IRB Application – likely exempt application
  - CITI certificates for ALL personnel
  - IRBNet Signatures (PI, and co-Is).
  - Consent Forms
- **MAY BE REQUIRED**
  - Surveys
  - Advertisement

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Another Option – Blanket protocol

- **Blanket protocol for research**
  - Language Department under Dr. LeAnne Spino-Seijas
- One exempt application
  - All faculty members submitted CITI certificates
  - Gave a more extensive description of multiple examples of the research possible
  - Enables all faculty to engage in classroom research using same protocol

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IRB Application Process –PI perspective

- 2-4 weeks (95% protocols require 2 submissions)
- Typical progression
  - IRBNet Protocol created – package #1
    - Administrative review – PI makes changes before IRB review
    - IRB Review – decision letter rendered
  - PI submits modification – package # 2
    - IRB Review -

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Why IRB review is important?

- The primary purpose of the IRB is to protect the rights and welfare of the human subjects.
- A source of valuable feedback.

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Getting started

- CITI training – Basic Course for Human Subject Research
  - www.citiprogram.org
- Register for IRBNet.org
  - Training on IRBNet available URI website
    - https://web.uri.edu/research-admin/office-of-research-integrity/human-subjects-protections/irbnet-access-and-guidance/
- For more information visit our website: https://web.uri.edu/research-admin/office-of-research-integrity/human-subjects-protections/

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What to do if you are unsure if your project is human subject research?

- Talk with us – we will help determine if IRB review is necessary.
- Heather Paskalides: hpaskalides@uri.edu / 401-874-4328
- Mary Riedford: mcriedford@uri.edu / 401-874-4813