Institutional Review Board Training Series

Research Using Protected Data

UtahStateUniversity

January 27, 2026
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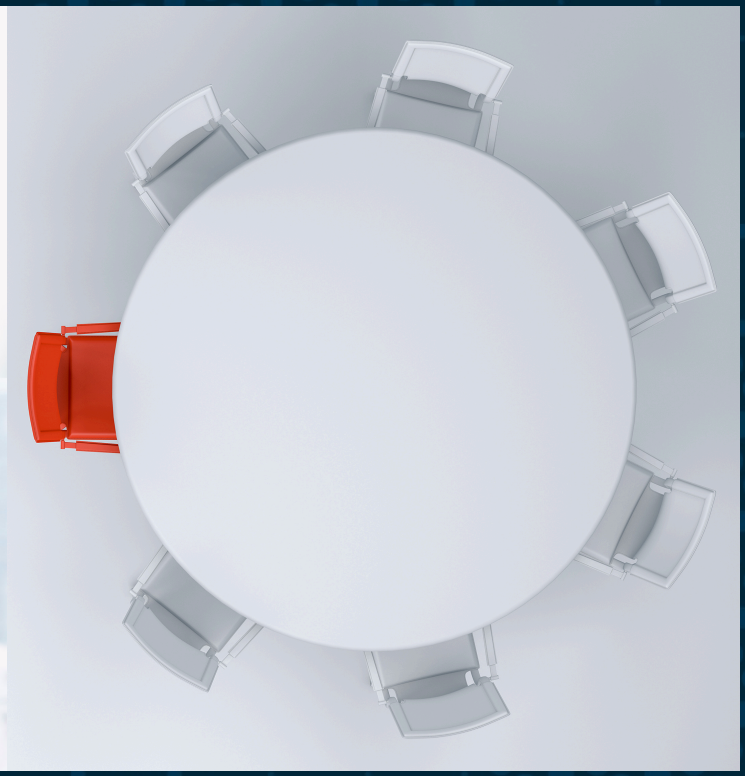
The Institutional Review Board



The Human Research Protection Program

VP for Research

Responsible for overseeing all aspects of USU's Human Subjects Research portfolio & ensuring appropriate access to resources for a well-functioning Human Research Protection Program (HRPP)

Human Research Protections Office

Manages the day-to-day aspects of implementing and overseeing the HRPP, including:

- Researcher training
- Coordination with COI, IBC, ICOI, SPO processes
- Receiving complaints, concerns, and questions from research participants

The IRB

Reviews all proposed human subjects research at Utah State University according to:

- Established ethical standards,
- Policies & procedures, and
- Best practices

Researchers

Responsible for carrying out and overseeing research with human participants in a manner that:

- Complies with the terms of IRB's review,
- Ensures adequate resources and training for the safe conduct of the research, and
- Takes proactive steps to ensure the health, safety, and well-being of research participants

More Info available at https://research.usu.edu/hrp/

Session Objectives

- Identify when HIPAA, FERPA, or the PPRA applies
- Understand what is and is not permitted without authorization or consent
- Anticipate compliance issues early in study design
- Come away ready to design a research project that emphasizes participant trust and participant privacy

“Research” with a “Human Subject”

“Research”

Research means a **systematic investigation**, including research development, testing and evaluation, designed to develop or contribute to **generalizable knowledge**.

A “systematic investigation” is a process that involves the formulation of a hypothesis, exploration of a theme, or establishment of research questions, and the collection and/or analysis of data or information that will lead to a conclusion that addresses the hypothesis, themes, or research questions.

“Generalizable knowledge” is knowledge that is expressed in theories, principles, and statements of relationships that can be widely applied to our experiences and is usually created to share with other people, such as through presentations and publications.

“Human Subject”

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, analyzes, or generates identifiable private information or identifiable biospecimens.

Intervention includes both physical procedures by which information or biospecimens are gathered (e.g.,venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

The Health Insurance Portability and Accountability Act (HIPAA)

What is HIPAA?

… and what isn't it?

- HIPAA is a privacy regulation.
- It governs **Protected Health Information (PHI).**
- It does **not** cover information voluntarily disclosed directly by the participant about whom the information pertains.
- It does **not** cover all types of health information.
- It is **not** the only health-related privacy regulation.

Protected Health Information (PHI)

Protected Health information is:

- Any individually identifiable health information in any form which are held or obtained by a Covered Entity or its Business Associate.
- Health information is any information, including demographic data, that relates to:
  - The individual's past, present, or future mental health or condition;
  - The provision of health care to the individual; or
  - The past, present, or future payment for the provision or health care to the individual.

Covered Entity

- Health care providers who electronically transmit health information
- Health plans
- Prescription drug insurers
- Health maintenance organizations
- Long-term care insurers

… and their Business Associates

How Can You Use PHI in Research?

- An Authorization
- Waiver or Alteration of Authorization
- De-Identified Data
- Limited Data Set
- Activities Preparatory to Research

Authorization for the Use of Protected Health Information

- Written permission from the individual
- Specifically identifies the PHI sought, who will access it, how it will be used, and for how long
- Can be combined with informed consent (but is not the same as informed consent)
- USU IRB makes a template available

Authorizations

Practical Tips

- Work with the Covered Entity early in your research planning.
  - Some entities might have their own required Authorization templates.
  - Outside the State of Utah, many states have their own required Authorization elements. You must comply with those requirements if you are receiving PHI from that location.
- Consider Alterations for initial contact.

Waiver or Alteration of Authorization

A waiver or alteration allows researchers to access PHI under certain conditions without permission from the individual. The conditions include:

- Researchers show that there is minimal risk to participant privacy, by demonstrating that:
  - There is an adequate plan to protect the identifiers from improper use and disclosure;
  - There is an adequate plan to destroy the identifiers at the earliest opportunity unless there is a health or research-related justification for retaining the identifiers (such as: the information used combined with the research data might inform that person's treatment); and
  - There are adequate assurances that the PHI will not be reused or disclosed to any other person or entity;
- It is impracticable to conduct the research without the waiver or alteration
- The research team has implemented adequate privacy provisions
- The information sought is the minimum necessary to complete the research

Waivers or Alterations of Authorization

Practical Tips

- Work with the entity that will release the PHI early.
  - They may have their own Privacy Board, or standards beyond those required by HIPAA for the release of PHI
- If the organization is a smaller one, prepare to assist them with HIPAA compliance.
  - They may not have a system or process for securely transferring data, or for managing and tracking AoDs.
- You can seek an Alteration for contact information
  - This helps you recruit people to your study using the Authorization process.

De-Identification

- Can only be done in one of two ways:
  1. De-Identification by a qualified statistician;
  2. Removal of HIPAA-identifiers for the individual, the individual's relatives, the individual's household members, and the individual's employer, which must also *not permit the covered entity to have actual knowledge that the remaining information could be used to identify the individual*.

Limited Data Set

- Must be agreed upon using a Data Use Agreement executed by the appropriate Sponsored Programs Representative and the Covered Entity.
- Excludes most HIPAA identifiers, but allows some dates and geographic information to stay in the set of data shared.

Activities Preparatory to Research

- Allows access to Protected Health Information **only to prepare a study**
- No data may leave the covered entity or be analyzed beyond ascertaining the feasibility of conducting the study
- No contact with individuals permitted

The Family Educational Rights and Privacy Act (FERPA)

What is FERPA?

… and what isn't it?

- FERPA is a privacy regulation.
- It governs **Identifiable Education Records.**
- It does **not** cover information voluntarily disclosed directly by the participant about whom the information pertains.
- It does **not** cover all types of education records.
- It is **not** the only education-related privacy regulation.

Identifiable Education Records

An identifiable education record is one that is:

- Directly related to a student;
- Maintained by the institution or a party acting on its behalf;
- The identity of the student can be ascertained with reasonable certainty.
  - This includes both direct and indirect identifiers.

Identifiable Education Records

Includes:

- Grades
- Transcripts
- Course enrollments
- Advising notes
- Disability accommodations

Does not include:

- Notes made for the sole reference and in the sole possession of the maker
- Law enforcement unit records
- Employment records unrelated to student status (i.e. your employee also happens to be a student)

How Can You Use Education Records in Research?

Permission

School Official Exception

De-Identified Data

Directory Information

Permission

- Must be in writing
- Must specify the records to be disclosed
- Needs to state the purpose of the release
- The recipient of the records must be identified

The USU IRB makes templates specifically for FERPA-protected records available, *and* its Informed Consent templates meet the required elements of a valid FERPA Authorization.

School Official Exception

- Applies when researchers are acting on behalf of the institution
- Must demonstrate that it is in the student's legitimate educational interest
- Must demonstrate that the institution retains control over the use of the data

School Official Exception

Practical Tips

- The USU IRB has a template memorandum for use with the cognizant Dean's Office, which is an agreement between the Dean's Office and the researcher to have the researcher conduct educational research on its behalf, identifies the LEI, and specifies that the institution will retain control over the data.
- Important to work early with the Dean's Office to execute these agreements and plans.
- Often preferable when working with one's own students' records

De-Identified Student Data

- Can use used if there is no reasonable basis on which to believe the records can be re-identified
- Limited applicability with small samples of one's own students
- Several pathways for access at Utah State University

Directory Information

Directory Information is that information which an institution or school district identifies as not being a privacy violation, and agrees that it might release. It *often* includes:

- Names
- Addresses and Email Addresses
- Participation in officially recognized activities and sports
- Photographs

Directory Information

Practical Tips

- Just because it is Directory Information does not mean you can use it if you have access to it.
- Every school district and institution of higher education gets to say what its Directory Information is. It is not the same across educational entities.
- Just because an entity identifies some information as Directory Information does not mean they must release it.
- Many entities have their own formal request process for releasing Directory Information; it's important to work closely with the entity authorized to release information.
- Teachers, instructors, and classroom aides are almost never the authorized individuals for sharing this type of information. Central offices – like Registrar's Offices, Enrollment Management Offices, and Principals' Offices – are typically the only places that can grant access to this information.

Top Three FERPA Compliance Issues

1. Using your own students' data absent one of the approved ways to do it listed above.

2. Obtaining information from someone unauthorized by the institution or district to release it.

3. Not properly identifying a record as an education record.

Utah Student Privacy & Data Protection Laws (Utah PPRA)

Section 53E-9-203: Activities Prohibited without Prior Written Consent – Validity of Consent

- The researchers **must** obtain written parental permission to survey any Utah preK-12 student regarding any of the following:
  - Any psychological or psychiatric examination, test, or treatment;
  - Any survey, analysis, or evaluation in which the purpose or effect is to cause the student to reveal information, whether identifiable or not, about the student or the student's family's:
    - Political affiliations or political philosophies;
    - Mental or psychological problems;
    - Sexual behavior, orientation, gender identity, or attitude;
    - Illegal, anti-social, self-incriminating, or demeaning behavior;
    - Critical appraisals of individuals with whom the student or family member has close family relationships;
    - Religious affiliations or beliefs;
    - Legally recognized privileged and analogous relationships, such as those with lawyers, medical personnel, or ministers; and
    - Income, except as required by law.

Section 53E-9-203: Activities Prohibited without Prior Written Consent – Validity of Consent

Parental Consent is only effective if:

- The parent has been given written notice of the educational or survey questions to be asked of the student
- The copy of the instrument is made available at the school
- There is “reasonable opportunity” for a parent to obtain information concerning:
  - The records or information that will be examined or requested;
  - The means by which the information is to be obtained;
  - The purposes for which the records or information are needed;
  - The entity or persons who will have access to personally identifiable information, if applicable; and
  - A method by which parents can grant permission to access or examine the personally identifiable information collected.
- A parent must be given two weeks between the disclosure and giving informed consent for their child’s participation.

Key Principle

- As an instructor, clinician, etc. – you're holding, in confidence, someone else's data. It is still theirs, even while under your care and control.

Like watching a friend's puppy. You've got to be prepared to give it back, and let the friend know where it is and how it's doing.

Questions to Ask Yourself in Your Research Planning Process

- What data am I using?
- Where do the data come from?
- Who legitimately controls them?
- **What role am I acting in when I access them?**


Q&A

Thank You

Follow Up Questions? irb@usu.edu

UtahStateUniversity