

USU Institutional Review Board Training Series: Data Collection with Children in Schools

April 8, 2024

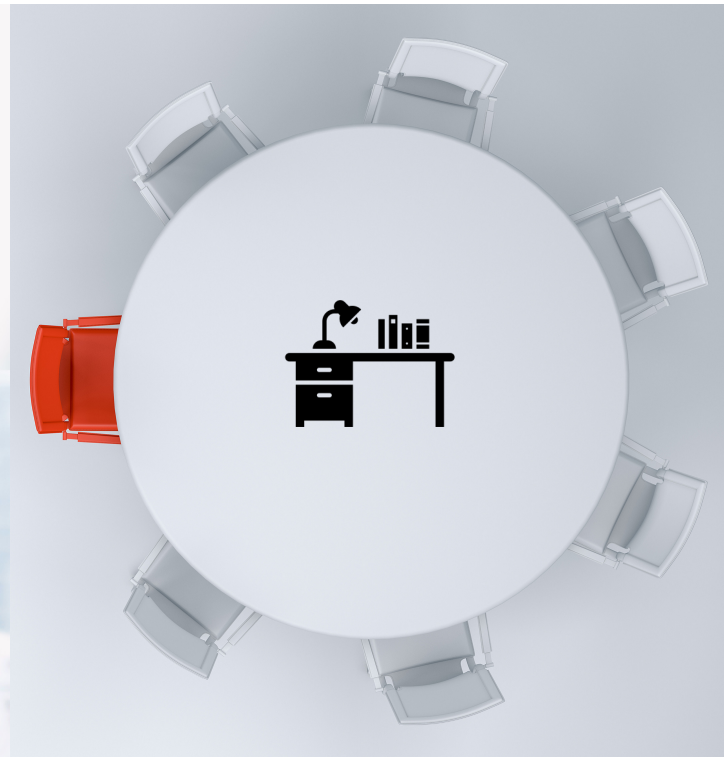


UtahStateUniversity

*Ron Gillam, IRB Chair & Professor,
Communicative Disorders & Deaf
Education*

*Nicole Vouvalis, Executive Director
of Human Research Protections*

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

Utah State University IRB Review Standards

Utah State University's Institutional Review Board conducts its reviews according to two prevailing ethical standards:

Belmont Report

- Respect for Persons
- Justice
- Beneficence

45 C.F.R. 46 (The Common Rule)

- Subpart A: General Review standards
- Subparts C, D: Vulnerable Population Requirements

Subpart D: Children

“**Children** are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.”

45 C.F.R. 46.402(a)

Subpart D: Children Overview of Requirements

- No more than minimal risk **OR**
- Greater than minimal risk, but there must be a direct benefit to the children involved
- Written parental permission
- Written child assent, when appropriate for age & maturity
- Wards of the state require an *in loco parentis* permission

Key Considerations for the School Setting

- Recruitment Processes
- Parental Informed Consent Process
- Child Assent Requirements
- How FERPA impacts data collection activities
- When teachers are researchers
- Navigating teachers conducting research on or with their own students

Recruitment

- Recruitment is the *start* of the informed consent process.
 - Recruitment steps
 - Recruitment materials
 - Support from the school partner
- FERPA can be your recruitment friend
 - Use Directory Information
 - Know what your school partners can and can't give, and be prepared to educate K-12 administrators on that information

Recruitment – Things to Keep in Mind

- Identifiable Education Records are protected by FERPA
 - Especially relevant in the special education context
 - Two-step recruitment process asks parents for permission to review education records and screen only from respondents
- Work in Utah K-12 schools requires district approval
 - School-based approvals may also be required depending on school and district policies
 - Governing Board approvals are required for public charters

Parental Informed Consent Process

Process	IRB IC Selection	Limitations
Research team will use Directory Information to email parents informed consent documents to be signed and returned; children will give written assent	No waiver or alteration	None!
Research team will send consent documents home in child's backpack for parents to sign and return; children will give written assent.	No waiver or alteration	Generally not effective where the research team requires the entire class' participation
Research team will partner with school to implement research – parents will receive a consent form using Directory Information to opt out.	Waiver of documentation of informed consent	Opt out is not permitted where any identifiable education records will be used in the research – FERPA demands an affirmative agreement
Research team will partner with a school to implement a research project – children will bring home informed consent documents for parents to sign.	Waiver of all requirements for informed consent	This method is not permitted where any identifiable education records will be used in research – FERPA demands an affirmative agreement

Parental Informed Consent Process

Informed Consent is required to be presented in “language easily understood” by the prospective participant or their guardian.

Generally, Spanish translations are a minimum requirement for USU IRB approval.

Charted: What languages Utahans are speaking



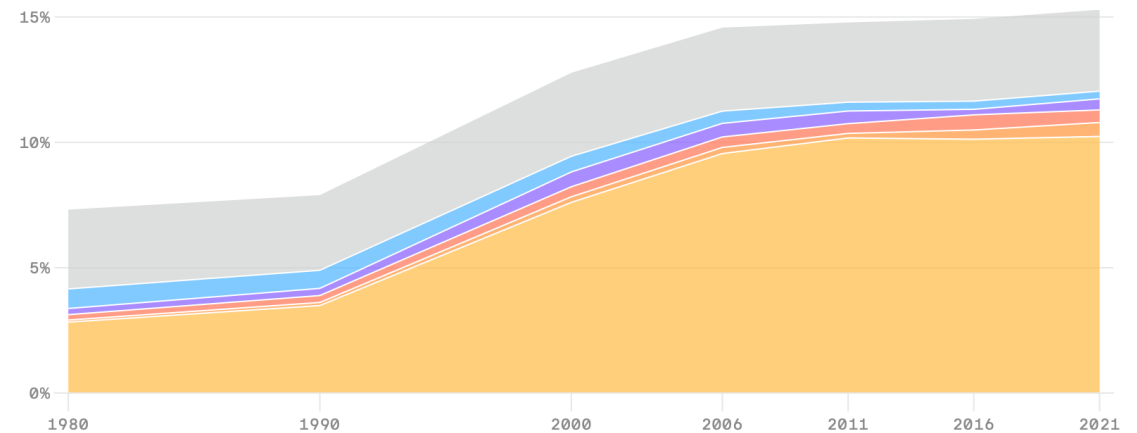
Erin Alberty



Share of Utahns who speak a language other than English at home

Decennially, 1980-2000; Every five years, 2006-2021

Spanish Portuguese Chinese Micronesia or Polynesia German Other



Parental Informed Consent Process

Utah Code: Student Privacy & Data Protection

- Prohibits, absent specific parental consent, *whether the information gathered is identifiable or not*, any “psychological or psychiatric examination, test, or treatment” as well as “any survey, analysis, or evaluation” where the student will reveal their or any family member’s:
 - Political affiliations or political philosophies;
 - Mental or psychological problems;
 - Sexual behavior, orientation, or attitudes;
 - 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 (e.g. for free and reduced school lunch purposes)

Parental Informed Consent Process

Utah Code: Student Privacy & Data Protection, continued

Parental informed consent is only valid if:

- Parents have an opportunity to review, **both** at the school as well as online, the “exact survey” to be administered to the child;
- They have a two week period within which to request information from the research team after first being notified of the data collection or analysis effort;
- Researchers answer any questions they receive about:
 - The records or information that will be reviewed or requested;
 - The means by which the records or information will be reviewed;
 - The means by which the information will be obtained;
 - The purposes for which the records or information are needed (i.e. no deception, misinformation, or incomplete information);
 - The entities or persons who will have access to any personally identifiable information; and
 - The method by which a parent of a student can grant permission to access or examine any personally identifiable information (i.e. confidentiality limitation!)

Parental Informed Consent Process


Utah Code: Student Privacy & Data Protection, continued

Parental informed consent for the activities previously mentioned is only valid for:

- The specific activity described in the informed consent document. Data may not be retained for future research purposes.
- As long as the parent retains their authorization. Just as with HIPAA, a parent can withdraw their authorization at any time; this means the study team must have a way to identify the student's data and destroy it.
- The research and educational purpose articulated; none of this data is permitted to enter the Student Achievement Backpack (the term for a Utah student's electronic learner profile and academic records).

Child Assent Requirements

Subpart D: [T]he IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved.



Child Assent Best Practices

- Use spatial separations in your document (e.g. shapes, bubbles)
- Include pictures of procedures and equipment you'll use
- Model the research procedures in person or in a video
- Ask comprehension questions to ensure the child understands what you have explained
- Run your assent document through readability software and ensure it is age-appropriate

The Salt Lake Tribune

Only 48% of Utah 3rd graders read at grade level; here's how lawmakers hope to boost that

By 2027, state officials hope to have 70% of Utah third graders reading on grade level.

Informed Consent

=

Parental Permission

+

Child Assent

+

Documentation (if not waived)

FERPA

- Protects **identifiable education records** from unauthorized disclosure or even access
- *Allows* (but does not require) schools to release Directory Information
- Permits parents to opt out of any sharing whatsoever of their child's information
- Requires specific, affirmative parental consent to share identifiable education records outside of Directory Info

FERPA & Research



Parents or guardians must sign informed consent documents for use or access of their child's education records

Work with all of your stakeholders: the USU IRB and the school. Some schools or districts have their own forms and processes they want to use for providing access to FERPA protected records.



FERPA's Exceptions

- Directory Information
- Records that have been fully de-identified by the school's Registrar or Academic Records Office
- Records released for the student's legitimate educational interests
- **Conducting studies for, or on behalf of, the educational institution in order to:**
 - a) Develop, validate, or administer predictive tests;
 - b) Administer student aid programs; or
 - c) Improve instruction

Teachers: Participants or Researchers?

Human Subject

A living person about whom an investigator conducting research obtains information through intervention or interaction with that person and uses, studies, or analyzes that information; or about whom the investigator obtains, uses, studies, analyzes, or generates identifiable private information

Investigator/Researcher

An individual performing various tasks related to the conduct of human subjects research activities. Such involvement includes:

Obtaining information about living individuals by interacting or intervening with them for research purposes; obtaining identifiable private information about living individuals for research purposes; obtaining the voluntary informed consent of individuals to be subjects in research; or studying, interpreting, analyzing, identifiable private information or data for research purposes.

“Investigators can be physicians, scientists, nurses, administrative staff, teachers, and students, among others.”

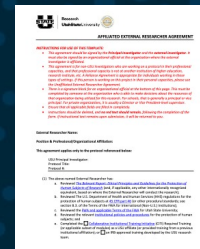
Teachers: Participants or Researchers?

Researcher Tasks:

- Recruiting families to your study
- Obtaining informed consent of parents or students
- Implementing a teaching or behavioral intervention
- Collecting research data from children that would not be collected in the course of normal classroom activities
 - Think: recordings, social validity questionnaires, etc.

Adding Your Teacher-Researcher

Teachers who are also researchers must be trained in human subjects research ethics, and they must give the USU IRB oversight of their activities as a researcher.



Your Students & Your Subjects



Your Students & Your Subjects

- Use existing data
- Involve an unrelated third party
- See if your school is interested in the benefits of your research project
- Minimize overlap between core content and research procedures





Resources

- USU Policy 534: Protection of Minors – [Policy & Procedures](#)
- April 17 Utah Student Data Privacy Training 9:30 to 12:30 – [Information Here](#)
- Utah Code [Section 53E-9-203](#) – Activities Requiring Specific Parental Consent
- USU IRB Informed Consent & Assent Templates – [Box Folder](#) (Includes FERPA Authorization Template)
- USU IRB Guidance – [Working with your own students](#)
- Request a Consultation – [Submission Form](#)
- Ask The IRB Slack – [Invite Link](#)

Q & A

Q & A

Thank You!

Please use the feedback link on our home page (or scan this QR code) to request topics for future IRB trainings.

Keep an eye on our homepage, socials, and the Office of Research Newsletter for Fall 2024 Training Information!

