Collect and Protect

Eve Birge
Federal Project Officer
U.S. Dept of Education

Wendie Veloz
Federal Project Officer
U.S. Dept of Health
and Human Services

Carmen Arroyo
Senior Program Analyst
ESI Contractor

Collect and Protect Overview

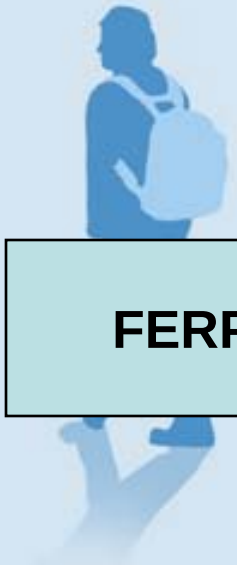
- **Human Subjects Privacy and Confidentiality Regulations**
  - FERPA, PPRA, HIPPA
- **7 Areas of Confidentiality and Participant Protection**
- **Institutional Review Boards**

Regulations Regarding Privacy and Confidentiality

PPRA

Data Collection

- Parental consent for data collection related to 8 protected areas
- Parental notification if collecting any other protected or personal information
- Allows parents to inspect before administration or use of surveys involving protected or personal information



FERPA

Existing Data

- Parental right to inspect existing school records
- Parental right to amend education data
- Parental consent for disclosure of personally identifiable information from education records

8 Protected Areas of PPRA

Under PPRA, parental/guardian consent is required for the following protected areas:

1. Political affiliations
2. Mental and psychological problems
3. Sexual behavior and attitudes
4. Illegal, anti-social, self-incriminating, demeaning behavior
5. Critical appraisal of a close family relation
6. Legally recognized privileged or analogous relationships
7. Religious practices, affiliations, beliefs
8. Income

PPRA and Consent

LEAs must obtain written parental consent before minor students are required to participate in any survey, analysis, or evaluation that is funded, in whole or in part, by the U.S. Department of Education (ED) and that reveals information concerning any of the eight protected areas.

Active Consent

Parent/guardian signifies permission in writing

Passive Consent

Parent/guardian consent assumed unless parent indicates otherwise

FERPA and Confidentiality

The Family Educational Rights and Privacy Act (FERPA) gives parents/guardians rights with respect to their children's education records.

1. Right to inspect and review education records
2. Right to seek to correct education records
3. Right to have some control over disclosure of information from education records

**These rights transfer to student when student turns 18 or attends a postsecondary institution.*

Health Insurance Portability and Accountability Act (HIPAA)

Establishment of national standards and requirements for electronic health care transactions and to protect the privacy and security of individually identifiable health information.

More information is available at:

http://www.ed.gov/policy/gen/guid/fpco/doc/ferpa-hippa-guidance.pdf

Practical Applications…

"Confidentiality is a virtue of the loyal, as loyalty is the virtue of faithfulness."

-Edwin Louis Cole

7 Areas of Confidentiality and Participant Protection

1. Fair Selection of Participants
2. Absence of Coercion
3. Protecting Clients and Staff from Potential Risks
4. Data Collection
5. Adequate Consent Procedures
6. Privacy and Confidentiality
7. Risks and Benefits

1. Fair Selection of Participants

- Target population
  - Age,
  - gender,
  - racial/ethnic background,
  - socio-economic status
- Special populations: homeless youth, foster youth, children of substance abusers, other targeted groups
- Everyone must have a fair chance to receive services and participate in the evaluation

2. Absence of Coercion

- Services cannot be contingent upon participation in data collection and evaluation
- Participation in programs or services is voluntary

3. Protecting Students from Potential Risks

- Identify any foreseeable physical, medical, psychological, social and legal risks or potential adverse effects as a result of the project or data collection activities
- Minimize and protect against potential risks
  - including risks to confidentiality
- Make plans to provide assistance in the event that there are adverse effects to participants

4. Data Collection

- Identify target population
  - Sampling
- Data collected must reflect the population that is being served through your programs and services

5. Adequate Consent Procedures

- Goal: before students or families participate in the services or evaluation they must know everything that is involved
- Describe the purpose and methods of evaluation
- Inform them that participation is voluntary
- Parental/guardian consent and youth assent
  - Documentation of consent or release of information

6. Privacy and Confidentiality

- FERPA and HIPPA
- Data collected by person who does not have a direct impact on students
- Limit access to data
- Ensure identity of participants is kept private
  - Use of coding and identifiers

7. Risks and Benefits

- There are potential risks to implementing programs around sensitive topics.
- The risks are worth the benefits

"No noble thing can be done without risks"

- Michel de Montaigne

Institutional Review Board

A group of five or more individuals whose primary responsibility is to protect the rights and welfare of research subjects

Do I Need an IRB Review?

- The Common Rule for the Protection of Human Subjects in research requires IRB review and approval for:

"any systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

What Does "Generalizable" Mean?

- Results of the evaluation will be distributed (published or presented) to help inform the replication of the program at other sites
- Results of the evaluation may be used to inform policy beyond the location where the program was implemented

Why We Recommend IRB Review

- Cannot use evaluation results to inform larger body of knowledge, practice, or policy beyond local context if no prior IRB approval granted
- IRB process serves as another check for compliance with FERPA, PPRA, and human subjects protection rules

Preparing for IRB Review

- Federal established guidelines
- Specific procedures and requirements are set by IRB within the LEA, local universities or private IRBs (e.g., research firms)

Documentation Requirements

Information verifying:

- Purpose of research
- Data collection procedures (copies of instruments may be required)
- Equitable selection of subjects
- Informed consent procedures
- Methods for ensuring privacy and confidentiality
- Minimized risks to subjects (e.g., protection from physical or psychological harm)
- Benefits of the research and assurance that risks to subjects are reasonable in relation to anticipated benefits

Benefits of IRB Review

- Gives you flexibility to use the evaluation data for more than reporting purposes
- Serves as another “check” on your data collection procedures
- Protects you by ensuring you are in compliance

The Federal Wide Assurance (FWA)

An agreement that a grantee will abide by Common Rule requirements when engaged in covered research.

- Grantees can apply at: http://www.hhs.gov/ohrp
- Valid for 3 years & renewable
- Verification of current Federal Wide Assurance: http://ohrp.cit.nih.gov/search/asearch.asp#ASUR

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For Questions and Additional Information

Jeffery W. Rodamar

Protection of Human Subjects Coordinator

U.S. Department of Education
Telephone: 202-260-3353
Fax: 202-205-0765
e-mail: jeffery.rodamar@ed.gov
http://www.ed.gov/about/offices/list/ocfo/humansub.html