

Protecting people who participate in research

CITI Training Study Guide
Records-Based Research

The Power of Records-Based Research

- No in-person interaction is needed for meaningful research that still involves human subjects.
- Researchers can test hypotheses by analyzing records – medical, motor vehicle, criminal justice, or school records.
- A researcher using medical records must also comply with HIPAA.
- A researcher using student records must also comply with FERPA (Family Educational Rights and Privacy Act).

Human Subjects Issues in Records-Based Research

- Risks may include invasion of privacy – not all records-based research requires a subject's active consent.
- Risks may include breach of confidentiality – such as information obtained under a relationship of trust (e.g. doctor/patient).
- Disclosure of some kinds of information (e.g., drug addiction; mental illness) could place a subject at risk of criminal or civil liability, or damage financial standing, employability or reputation.

Minimizing Risks in Records-Based Research

- Risk of invasion of privacy: Obtain active consent
 - Potential problems with informed consent:
 - ✦ May be impracticable
 - ✦ May compromise the goal of the research
 - ✦ Could put the subject at greater risk
 - IRB could waive informed consent if:
 - ✦ No more than minimal risk to the subject;
 - ✦ Subjects rights and welfare will not be damaged;
 - ✦ Research could not practicably be carried out without the waiver;
 - ✦ When appropriate, subjects provided with pertinent information afterward.

Minimizing Risks in Records-Based Research

- Risk of breach of confidentiality determined by:
 - ✦ Sensitivity of the requested informational records; and
 - ✦ Whether information is recorded with “identifiers.”
- Researcher must consider importance of identifiers to answering the research questions.

Minimizing Risks in Records-Based Research

If research cannot be conducted anonymously, IRB needs answers to these questions:

- ✦ What kind of identifiable information will be collected?
- ✦ Who will have access to the identifiable information?
- ✦ Where will the information be kept?
- ✦ What kinds of codes or encryption will separate research data from subject identifiers?
- ✦ How will limitations on access be ensured?
- ✦ How will research staff be trained about confidentiality?
- ✦ How long will identifiable information be kept?
- ✦ How will identifying information be disposed of when no longer required?

When Might Records-Based Research Be Exempt?

- Information already exists; and
- Sources of information are publicly available (any person can obtain the data);
or
- Recorded information contains no identifiers.

When Might Records-Based Research Be Expedited?

- The research poses no more than minimal risk; and
- The research meets one of the expedited review categories.