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.