

Protecting people who participate in research

CITI Training Study Guide
Research Involving Workers/Employees

Research Involving Workers – Why They Are a Vulnerable Population

The federal Department of Health and Human Services regulations do not identify workers as a specially protected population.

However, workers may be considered a vulnerable population requiring special IRB attention if there may be pressure from an employer to enroll, and especially if the study could lead to loss of job, career, or benefits due to study findings.

Research Involving Workers – Special Risks

Researcher access to confidential records adds to the vulnerability of workers who participate in workplace studies.

Inappropriate release of individually identifiable health or other personal data could adversely affect a worker's retention of a job, insurance, and other employment related benefits.

Minimizing Confidentiality Risks in Research Involving Workers

The study design must include adequate safeguards to protect the confidentiality of the information collected. The plan should clearly define:

- Control of the collected data;
- Who is authorized/approved to access, use, or disseminate study data or results;
- Disclosure to the subject of who will have access to the data and how it will be used;
- Use of personal identifiers (for example, name, phone number, or medical record number);
- Inclusion of study results in employee personnel or medical records, or in publications.

Research Involving Workers – Special Risks

The research use of genetic data and biological samples creates additional risks to workers.

Ethicists have argued that genetic screening or testing should have no role in the workplace because of potential risk to a worker's continued employment if management obtains such information (e.g. they could decide to let go a worker with specific health risks).

Minimizing Genetic Testing Risks in Research Involving Workers

At a minimum, all planned future uses of biological samples, identifiers, and the resulting data must be fully explained to the participant.

The participant must understand and accept potential risks before beginning the study.
