Vulnerable Subjects - Research Involving Workers/Employees

Excerpted from: The Department of Energy Guidebook *Creating an Ethical Framework for Studies that Involve the Worker Community* and "Workers as Research Subjects: A Vulnerable Population", Susan L. Rose, PhD and Charles E. Pietri, BA from *J. Occup Environ Med.* 2002;44:801-805. Used with permission.

Introduction

The protection of the rights and welfare of human research subjects is required by federal, state, and local laws, as well as institutional policies. The Common Rule, adopted by 17 federal departments and agencies (codified by the Department of Health and Human Services at 45 CFR 46, the Department of Energy at 10 CFR 75, and other federal departments at their corresponding titles of the CFR), defines the standards and processes researchers and institutions must follow to safeguard human subjects. There are special provisions in the Common Rule for the protection of vulnerable populations.

Learning Objectives

After completing this module, you should be able to describe:

- Why workers are a vulnerable population.
- Special protections that should be considered when designing studies that involve workers.
- How the Common Rule may not adequately protect workers as subjects.
- While workers may be study subjects for political as well as scientific reasons, why is scientific validity and adherence to the Common Rule still expected.

Vulnerable persons are considered to be those who may be less able to protect themselves and their interests relative to other persons in a given setting or situation. Such individuals have diminished autonomy.

If the term "vulnerability" is limited to include only those groups usually considered at-risk (children, prisoners, pregnant women and fetuses/neonates), as indicated in 45 CFR 46 parts B, C, and D, then worker subjects will not receive appropriate additional protection from harm.

However, "vulnerability" of a worker as a research study subject, can be referred to as "paycheck vulnerability." This occurs when studies are conducted in the workplace, especially in those workplaces that pose real or perceived health and safety risks. Such workplace environments are as varied as educational institutions, chemical factories, hazardous waste cleanup sites, research laboratories, military settings, weapons production facilities, clinical and research laboratories in hospitals and academic medical centers, NASA spacecraft, power plants, and aircraft cabins. While each of these workplaces presents different scenarios for the employee and provides different study opportunities, "vulnerability" is related to the fact that the employer often encourages worker participation.

The potential for coercion lies in pressure brought to bear to enroll (or not enroll) in a study that may lead to loss of job, career, or benefits due to study findings. This vulnerability is often a low priority and subtle issue. Unions too often promote worker participation with the expectation or hope that "entitlements" may follow study findings. This is also coercion.

Workers Are in Effect a "Vulnerable" Population and Subject to Employment Related Risks

Why are workers vulnerable?

During recruitment, workers may experience pressure from supervisors to participate, not to participate, or to respond to a study in a way the employer or union may promote or perceive as advantageous to the organization.

The ability to give informed consent may be compromised, diminished, or negated. A worker may not feel comfortable asking questions or foregoing participation.

The results of the study may affect the livelihood or personal security of the worker or other workers. For example, an employer may find out that a worker is not performing job duties as expected. This could adversely affect the worker's job and could result in job restriction or loss. Access to personnel or medical records as a part of the research activities may also have a negative effect. For example, researchers may identify a worker who repeatedly failed a credentialing examination as part of reviewing personnel records. This may result in a supervisor, who is one of the researchers, providing opportunities to other employees. The employer may also find out through the study results that an employee is impaired or has been made ill by the workplace.

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What are the workplace risks?

Risks from the impact of study findings may include:

- Effects on individual entitlements
- Impairment of family relationships
- Possible threats to job retention
- Peer pressure
- Constraints to job advancement, and
- Inability to obtain and/or retain mortgage due to job loss or job restrictions
- The findings from research studies also may present significant financial implications for corporations, unions, or the government
- Genetic issues affecting family and/or future health decrements

These risks, if properly addressed, can be effectively managed to avoid or minimize harming workers.

Why do we need these studies?

Research involving workers can have a significantly positive effect on the workplace. Health and safety of workers has been improved over the decades through workplace studies that broadened understanding of exposure pathways, control methodologies, and better detection techniques and devices. Some studies may, however, pose risk of harm to the physical, emotional, and economic well being of the worker who elects to participate. Use of identifiable records without individual consent may create additional concerns.

What are possible study benefits?

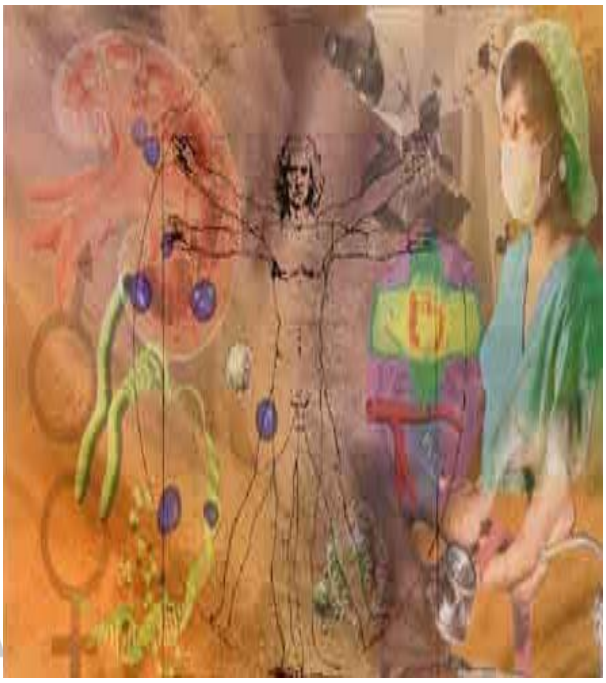
Benefits from the impact of study findings may include:

- Improvements in workplace safety
- Development of educational or training opportunities for employees
- Increased access to services that may not have been previously available
- Improvement in job satisfaction

Why are these studies research and not operational improvements or observations?

A study becomes "research" when the *intent* of the project is to gather data and contribute to generalizable knowledge, to improve health practice, and to extend benefits of the project beyond the individual study participants. Studies also become "research" because data may be gathered with experimental (unapproved) diagnostics. They are also "research" when studies involve altering conditions for some workers but not others to determine impact.

Studies with Workers Require Review by the Institutional Review Board (IRB)



The Common Rule ideally requires the establishment of a formally and appropriately constituted IRB to oversee the protection of human research subjects. Wherever possible or feasible, local IRBs overseeing workplace studies should have a worker member or worker consultant as needed.

When the researcher is not employed by an organization at the study site, the local IRB review may be coordinated with an IRB at the researcher's home institution, or the home institution IRB may be the sole IRB of record. Because of the nature of occupational work sites, the non-biomedical nature of the study, and the fact that work sites are not attuned to these types of studies, creative solutions may need to be found for IRB review.

The Research Plan and Communication with Stakeholders

Once a study has been determined to meet the definition of research (for example, not medical surveillance or public health), a human subjects research plan should be given top priority. Such a plan is a review process that includes:

- A well-designed protocol with a records management strategy.
- An objective, hypothesis and appropriate end-points
- A locale-sensitive method of communicating and interacting with workers
- Review by an appropriate IRB

All stakeholder roles should be considered when balancing the risks and benefits of the research. The IRB's role includes continued involvement through oversight, site reports, and consideration of new issues as they arise during the study. Ideally, the research plan should recognize and involve all stakeholders from the outset. A complete research plan should assure accurate and full stakeholder communication, appropriate scientific peer review, IRB review, and dedication of adequate resources to ethical issues, as well as to the conduct of the study.

IRBs may be concerned with risks posed by "paycheck vulnerability." The "paycheck vulnerability" relationship between subjects and employers is complicated by:

- The ambiguous definition of "research" (45 CFR 46.102(d))
- The employee relationship with the employer's occupational medicine physician (analogous perhaps to the clinician-researcher conflict)
- Unstated or organizational agendas promoting studies to determine or to suppress environmental risk, or to obtain "entitlements"
- Supervising personnel/researchers asking for biospecimens from an employee
- Organizational ownership of personnel and occupational health records

Employer ownership of employee records and the absence of a human subjects protection system in settings where little to no research with human subjects occurs may increase the risks to participants and may make studies more difficult to identify and manage correctly under accepted elements of worker **and** human subjects research protection.

Historically, ethical expectations often have not been implemented routinely in workplace research. However, enlightened employers in the private sector, especially where hazardous materials are used or liability issues prevail, have adopted excellent scientific and human subject review systems. Adherence to federal regulation is required in public sector sites or federally funded studies, but is voluntary in private sector sites for non-federally funded studies. Public sector sites **cannot** be assumed to recognize human subjects research as such and widespread education is needed as are requirements tied to funding.

Research environments have many settings where workers or employees may be "coerced" into serving as study subjects. These differ from work sites like factories or weapons plants or industry because they have, or should have a culture of compliance, an IRB, and research-related policies. Nontraditional settings do not have these features, and thus require education and culture change to protect subjects. This effort can "follow the funding" when federal money is involved.

All "stakeholders" must be made aware of and participate in addressing the special needs and issues that apply to research using *workers* as study subjects. The numbers of worker-related studies has increased significantly in recent years due to employee health and safety fears and/or political concerns about exposures and risks to workers' health from a liability perspective.

Privacy: The Biggest Worker Issue of All?

Hippocrates stated that:

Whatever, in connection with my professional service, or not in connection with it, I see or hear, in the life of men, which ought not to be spoken of abroad, I will not divulge, as reckoning that all such should be kept secret.

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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. To avoid or minimize these risks, the study design must include adequate safeguards to protect the confidentiality of the information collected. A plan for the proper management of study data and records should clearly define the:

- 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

Where several studies are in progress with the same worker population, the risks to privacy and confidentiality are likely to increase, requiring even more diligence in the management of confidential data by investigators and by those monitoring the studies.

Contact and consent materials and research plans must detail the risks, the safeguards, as well as limits to confidentiality allowed by law. The IRB, the researcher, and the subject must be informed of the limits and loopholes in the privacy laws governing workplace medical and research records, as well as ownership of data (that may or may not be property of the employee) and applicable state/local laws. The privacy situation currently is clouded by Federal Laws (HIPAA) and by many state laws that address specific situations such as genetic testing and privacy. Newer technologies and electronic transmission of medical records exceed historic legal protections available for privacy. The Privacy Act of 1974 allows "routine user" access for "researchers" (and others) to obtain federally "owned" occupational medicine records. The collection of federal employee information was originally designed to provide information for government use and secondarily to offer records (including occupational records) for health and safety research (hence the "routine user" clause). In practice, this has become a major loophole for giving personal, private, identified health and personnel information to a variety of "routine users." It is problematic and is mentioned here to inform the reader, who may know HIPAA (The Privacy Rule) but may not be aware of the Privacy Act of 1974.

The research use of genetic data and biological samples creates additional and complex ethical issues (see also Genetic Information Nondiscrimination Act [GINA] of 2008). Ethicists and researchers have argued that genetic screening or testing should have no role in the workplace because of employment risk associated with genetic screening or testing. At a minimum, when studies or medical monitoring include the collection of biological samples, all planned future uses of that samples, identifiers, and the data obtained from the samples, must be fully explained and accepted by the participant before beginning the study. Federal or state guidance applying to use of biological materials in hospitals or biomedical studies also applies to the use of such materials in studies in the workplace.

Summary

The Common Rule should apply to studies in the work place. Workers as study subjects are a vulnerable population and additional considerations for their protections in research are needed.

Research Involving Workers/Employees

The Director of Nursing Services at a local hospital has asked a colleague, who is a seasoned investigator, to conduct research to determine the causes of burnout among nurses caring for different types of patients. The investigator will collect data from nurses at several hospitals throughout the region, using focus groups held during work hours. In order to increase the number of nurses participating in the research, the Director wants to mandate that nurses attend the focus groups as part of their employment.

- As the investigator would you have any concerns about the recruitment of subjects to participate in the research? How might you address these concerns with the Director?

  You might explain that one concern is the potential for undue influence or pressure on the nurses to participate no matter how well intentioned the Director of Nursing in scheduling the focus groups during work hours. There may be a perception that not participating would affect their employment. The nurses may feel pressured to respond, or not respond, in a certain way during the face-to-face sessions with other nurses. Another concern is that the mandate to participate in the research negates the nurses' choice. Participating in research is voluntary and not a condition of employment as a nurse. You might suggest providing information about the research to the nurses by using posters, email, or during scheduled work meetings. The information should emphasize that participation is voluntary.

- Does the use of focus groups raise any concerns about the confidentiality of the nurses' responses? Are there alternative

	methods for collecting data? Would focus group reticence compromise valid data collection?
	Participating in a focus group means that fellow nurses will hear each other's responses. Nurses may choose not to share certain information about themselves and their opinions; however, what they share may not be held in confidence by others in the focus group. Unless it is critical for the research design, the investigator should consider a more private method for data collection such as individual interviews or a paper or web-based survey.

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