

# CHAPTER 1

## THE NEED TO PROTECT WORKERS AS HUMAN RESEARCH SUBJECTS

### Key Points:

- When workers are the subjects of research, the design of the study must assure that the rights and welfare of subjects are protected.
- Projects with workers as subjects are considered “research” when the *intent* of the study is for the information to be used for purposes beyond health monitoring and care of the individual.
- The unique vulnerabilities of workers who are research subjects include the threat or possibility of coercion; potential effects on job retention, job advancement, and insurability; and possible loss of personal and family privacy.

## The Challenge

### The Common Good Versus the Individual Worker-Subject

It sounds like the story line for a gothic novel: research using human subjects. In fact, it is the daily challenge faced by researchers who perform research using human subjects. It is the conflict between respect for individual privacy and rights versus the need for increased knowledge for the advancement of science and for the benefit of the human population. This becomes an even greater challenge when the individual subjects are the objects of research through circumstances beyond their control such as workers exposed to potential hazards in the workplace. It is the classical ethical dilemma—the common good versus the individual’s rights and autonomy.

Everyone who conducts federally funded biomedical experiments, clinical trials with new drugs, or other *research* using human beings must follow a set of ethical guidelines designed to protect the people—or subjects—who volunteer for such studies. These guidelines, collectively known as the “Common Rule,”<sup>1</sup> set requirements to protect “human research subjects” or “worker-subjects,” not only from bodily harm but also from social and economic loss and from abuses of their dignity and autonomy.

The Common Rule gives research subjects the right to: (1) full and understandable information about the study and its risks and benefits, (2) choose freely whether or not they will participate, and (3) to be assured that the study, as described, has been evaluated for its risks and benefits to subjects.

The Common Rule also supports an expectation of privacy: study volunteers are told to what degree individual data about them will be kept confidential, and to what extent privacy can be assured. The rule considers the special cases of society’s most vulnerable members, including children and the mentally ill who may not be able to fully understand the project or prisoners who may not be free to give or withhold consent.

While the Common Rule chiefly concerns research recognized as having the potential for physical or emotional risks—such as trials of new cancer therapies—it also protects volunteers who:

- Test new non-medical products and equipment.
- Fill out behavioral surveys.
- Enroll in workplace health effect studies.
- Provide blood samples for genetic research.

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<sup>1</sup> The Common Rule for the Protection of Human Subjects in Research, or the “Federal Policy for the Protection of Human Subjects,” has been adopted by 17 federal agencies. For the Department of Health and Human Services, the rule appears in the Code of Federal Regulations as 45 CFR 46. For the Department of Energy, the rule is in 10 CFR 745.

The Common Rule covers “research,” but the guidelines become less clear when research mixes with other necessary and valuable activities. Is an activity “research” if its primary purpose is to fight a fast-moving epidemic, pinpoint a source of contaminated meat, or identify the best safety gear for firefighters?

These gray areas can be particularly troublesome when workers are asked to participate in a *health study* on the job. A study may raise questions and conflicting interpretations of its intended benefits and possible risks. Each group involved may see that it has something to gain—or lose—as a result of the study. There may be very real threats to worker-subjects participating in the study and/or to other stakeholders from the results of the study. For example:

- Worker-subjects may want to know:
  - Are the study results likely to lead to better protection of their health?
  - Are they really free to refuse to participate?
  - Will data about them as individuals be given to management, used to exclude them from some benefit, or even used to do away with their jobs?
- Both management and unions may fear that the study results will be interpreted to justify—or undermine—a management decision, influence contract negotiations, affect workers’ compensation, or alter an employer’s liability.
- Community members may question the relationship between the study objective and the company’s environmental or product safety record.
- Local officials may worry about the study’s impact on their efforts to attract new industry or the possible closure of a plant important to the local economy.
- Taxpayers may question a study’s basic worth—will the results really justify the costs; will the study lead to a new entitlement program?

Refer to Chapter 5, Stakeholders: “Their Interests, Concerns and Responsibilities,” for more details on the concerns of various groups or stakeholders.

These diverse personal, legal, and economic concerns create unique problems for the conduct of occupational research and unique ethical issues about the rights and welfare of the workers being studied. The Department of Energy (DOE) has been faced with especially challenging circumstances where health studies collect information that adds to the “body of knowledge” (i.e., “research”) but also monitors and protects the health of workers (“non-research”). Drawing primarily on DOE’s experience with congressionally mandated health studies, this report: (1) identifies some of the ethical concerns common to studies that involve the worker community and (2) suggests ways to approach and resolve these concerns.

### **What is a Worker Study?**

Studies that involve the worker community are typically conducted for one of two purposes: (1) to identify the effects of the work environment on worker health or safety or (2) to test the use of equipment and systems. In the first instance, epidemiologists, statisticians, medical personnel, occupational safety and health personnel, or health

physicists may conduct the research. In the second, human factors engineers or psychologists may be the principal investigators.

This report focuses primarily on the first type of research. For the purposes of this discussion, “worker studies” are defined as “research” that: *(1) involves current and/or former workers as subjects and (2) is designed to increase understanding of the health effects of occupational exposure to radiation, chemicals, and other potential hazards.*

Much of this research may be epidemiological in its approach and may require access to various types of worker records including medical, occupational, and environmental health data, and exposure assessment or dosimetry data. Other studies may require an individual to submit to specialized testing, physicals, screening exams, and interviews. Some worker studies may seek to evaluate the effectiveness of existing standards to: (1) establish the levels of protection necessary to prevent or minimize illnesses related to occupational or environmental exposures or (2) to identify workers at risk of future diseases. The results of these studies can provide a basis for protecting the health of the worker community. They can also pose a significant risk of harm to the physical, emotional, or economic well being of the worker-subject.

### History of Occupational Health Studies in DOE

Occupational health studies conducted by DOE and its predecessor agencies date back to the 1940s. From its inception, the U.S. nuclear program considered the health of workers in its facilities to be its responsibility. Both medical monitoring and biological research were conducted to protect workers’ health and to identify the effects of occupational exposure to ionizing radiation and to the chemicals and materials used in its facilities. Public concern about the extent of human exposure to radiation and toxic chemicals during the Cold War period also increased the demand for worker health and biomedical studies. By the 1960s, records from these programs were being used to assess the longer-term effects of occupational exposures on current and former employees.

In this report, the term “worker studies” chiefly refers to research that involves current and/or former workers as subjects and that is designed to increase understanding of the human health effects of occupational exposure to radiation, chemicals, and other potential hazards.

In the 1970s, researchers, funded by the Atomic Energy Commission’s Division of Biology and Medicine to conduct laboratory and clinical studies involving human subjects, voluntarily adopted the regulations codified in 1974 by the Department of Health, Education, and Welfare (HEW) for protection of human subjects when conducting HEW-funded programs.

Epidemiological studies of DOE worker populations require access to records, including medical, radiation, and other monitoring records compiled for individual workers during their employment. The Privacy Act of 1974 protects these and similar records from unauthorized access.

In contrast to the Privacy Act, the Freedom of Information Act (FOIA), also passed in 1974, permits release of, or access to, these individual records provided that the individual subject of the record cannot be identified by, or linked to, the information released.

DOE worker health studies received additional impetus in the 1980s and 1990s from the availability of sophisticated new tools for detecting lower levels of workplace hazards, for studying biological effects at the molecular level, and for managing large electronic databases.

In the National Defense Reauthorization Act of 1993, Congress directed DOE to study the health of former workers in defense nuclear facilities to look for links between on-the-job exposure to hazards and adverse health effects. Worker health studies are being conducted not only by DOE contractors and grantees but also by universities, unions, the National Institute of Occupational Safety and Health (NIOSH), and other federal agencies. (See Appendix A for an expanded account of DOE's worker surveillance studies and research activities and Appendix B for a summary of NIOSH's approach to workplace studies.)

### Worker Studies are Research

**Research** using human subjects, funded by federal agencies, whatever the topic and whoever performs it, is subject to review under the **Common Rule**. In order to effectively protect the rights of workers it is necessary to define what activities constitute "research" and ensure that the meaning of "human subject" is clear.

**Research** is the "systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." The activity is research when the intent is to extend the information gathered beyond the individual—***even when that decision is made later, after the data have been collected, or the research is part of a larger non-research project.***

**Human subjects** are "living individuals about whom an investigator conducting research obtains data through (1) intervention or interaction with the individuals or (2) their identifiable private information." **Intervention** or **interaction** include not only physical procedures, like drawing blood, but manipulation of a subject's environment, administering questionnaires, and the use of private information from which the individual can be identified—***even if the information was not collected specifically for the study.***

"**Designed,**" meaning **intent**, is the key word in the regulatory definition of research for the purpose of classifying public health activities as either research or non-research. The major difference between research and non-research lies in the **primary intent** of the activity.

The Centers for Disease Control and Prevention (CDC) provides decision-making criteria in its guidelines for distinguishing research from public health practice and other “non-research” activities (see Appendix C). In summary, CDC defines “research” and “non-research” in the following manner:

### Attributes of “Research”

A study is viewed as “research” when the: (1) intent of the project is to gather data and contribute to generalizable knowledge to improve public health practice; (2) intended benefits of the project may or may not include study participants but always extend beyond the study participants, usually to society; and (3) data collected exceed requirements for care of the study participants.

Generalizable knowledge means new knowledge or information that is added to a body of knowledge. Knowledge that can be generalized is collected under systematic procedures that reduce bias, allowing the knowledge to be applied to populations and settings different from the ones from which it was collected. Generalizable, for purposes of defining research, does not refer to the statistical concept of population estimation or to the traditional public health method of collecting information from a sample to understand health in the population from which the sample came.

A public health activity is one undertaken in an urgent or emergency situation, usually because of an identified or suspected imminent health threat to the population but sometimes because the public and/or government authorities perceive an imminent threat that demands immediate action. The primary purpose of the activity is to document the existence and magnitude of a public health problem in the community and to implement appropriate measures to treat the disease or reduce the health threat. Holding public health activities to a standard of studying every case in order to classify an activity as non-research is not practical or reasonable. (See Appendix C for the complete text of the CDC’s *Guidelines for Defining Public Health Research and Public Health Non-Research*.)

### Attributes of “Non-Research”

The intent of a “non-research” is to identify and control a health problem. The intended benefits of the project are primarily or exclusively for the participants or the participants’ communities; data collected are needed to assess and/or improve the health of the participants or the participants’ communities; and project activities are not experimental.

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If a project includes multiple components and at least one of these components is designed to produce generalizable knowledge, then the entire project is classified as research unless the components are separable for regulatory purposes.

If a project is designed both to monitor or treat individuals and to gather generalizable knowledge about a worker population, the requirements to protect participating workers as human research subjects will apply.

The intended use of collected data *may not* change without revisiting the question of “Is it research?” A non-research project may produce generalizable knowledge after the project is undertaken even though generating this knowledge was not part of the original, primary intent. In this case, since the primary intent was not to generate or contribute to generalizable knowledge, the project does not possess the attributes of research at the outset. However, if subsequent analysis of identifiable private information is undertaken to generate or contribute to generalizable knowledge, the analysis constitutes human subjects research that may require Institutional Review Board (IRB) review.

For example, monitoring of individual workers as part of an established occupational medical program is *not* considered research nor is collection of data solely for remedial treatment of workers. However, data already collected in these activities may be sought because it can provide generalizable knowledge and serve as the basis for research.

If a request is made to use the data obtained in monitoring or treating individual workers in order to study other or more general groups of workers, then the intended use becomes “research.” At that point, the workers whose data will be analyzed must be considered research subjects.

In a January 1998 memo, Secretary of Energy Federico Peña reaffirmed DOE’s commitment to protecting human subjects and specifically required that studies using “worker populations or subgroups” be considered human subjects research. (See Appendix D for the text of Secretary Peña’s memo.)

As a consequence, researchers, employers, and others involved in worker studies must comply with all applicable federal regulations and ensure that risks to participating workers are addressed. *Those who fund, approve, and conduct worker health studies must also fully understand these risks and their own responsibilities for avoiding or reducing them.*

“Studies involving current or past employees of DOE, its predecessor agencies, and their contractors are subject to the regulations governing the protection of human subjects in research.”

Federico Peña, Secretary of Energy,

### Workers are a Vulnerable Population

In research with human subjects, National Institutes of Health (NIH) regulations require that special consideration be given to protecting the welfare of *vulnerable populations*—individuals whose ability to give informed consent to participate in

research is, in some way, compromised. In guidance on protecting human subjects, NIH additionally recognizes that employees may be a vulnerable group chiefly because they may experience management pressure to participate in a study, not to participate, or to respond to a study in some way the employer may perceive as advantageous.

The unique risks to workers who are subjects in occupational and health-related research include the potential impact of study findings on individual entitlements; the potential to impair family relationships; and possible threats to job retention, job advancement, and insurability through real or perceived coercion to participate or due to study results. The findings from worker studies may have significant financial implications for individuals, corporations, and the government.

Workers who feel pressured to consent to a study or who are placed in situations where their ability to give informed consent is compromised, diminished, or negated, or the results can affect their livelihood or personal security, can thus be classified as vulnerable and in need of special consideration.

In addition to the possibility of coercion, worker subjects also face risks in the areas of *privacy* and *confidentiality*. Access by one or several organizations to both research data about an individual *and* that person's occupational records—especially health records—increases the chance of a breach of confidentiality. The possibility that research data about the worker could become part of a record that is provided to insurance carriers, or the employer, is a specific risk for worker research subjects.

### Vulnerability of Worker Research Subjects

Workers face unique risks when they are subjects of research. These risks include:

- Possibility of coercion .
- Potential effects on job retention, job advancement, and insurability.
- Possible loss of personal and family privacy.

Creating an ethical framework that addresses these special risks of worker studies requires a considered and balanced approach, and researchers must follow rules to protect and inform anyone who participates as a human research subject. Although the answers are not always simple, the special issues and concerns related to research involving worker populations must be recognized and considered in all phases of study design and implementation. In short: *worker-subjects must be protected at least as fully as any other human subjects participating in research.*

## Summary

Workers are vulnerable subjects. Their rights to privacy and to be protected from physical, personal, and economic harm must be protected to the maximum extent possible.