EXECUTIVE SUMMARY

Protecting the rights and welfare of human research subjects is required whenever the United States government funds research. The "Common Rule for the Protection of Human Subjects in Research," a regulation that has been adopted by 17 federal departments and agencies, defines the standards and processes researchers and research institutions must follow to safeguard human subjects.

When workers are the subjects of research, additional care must be exercised to assure that their participation is truly voluntary and that data collected about individual workers are kept confidential. Protecting workers against risks of coercion and loss of privacy is especially important in workplaces such as Department of Energy (DOE) facilities, where numerous studies are underway on the effects of occupational exposure to radiation, chemicals, and other potential hazards. Many of these studies require that investigators obtain access to occupational records and collect medical and genetic data on individual workers.

Because worker studies often draw upon records from routine occupational medical surveillance, researchers, employers, and other key stakeholders may not always recognize that a study is "research." However, when data are collected for multiple purposes (medical monitoring *and* epidemiological research) or when data initially collected for other purposes are later used in research, the Common Rule applies. Individuals and groups involved in worker studies need to consider the possibility that a given study**C**or some component of it**C**fits the definition of research, thus requiring human subjects protection.

The rights and welfare of workers are best served when **all stakeholders** in worker studies understand the broad ethical principles that underlie the regulations that protect human subjects. The principles of ***beneficence***, ***justice***, and ***respect for persons*** establish the right of all research subjects to privacy, fair treatment, autonomy, and self-determination, and protection from harm.

To protect these rights, the Common Rule requires that each prospective research subject give voluntary "informed consent" to his or her participation in a study. For consent to be informed, participants must have adequate, understandable descriptions of the study purpose, what is expected of them, and any benefits and/or risks they may experience. For consent to be voluntary, they must not face coercion or reprisal for their decisions.

The Common Rule also requires the establishment of a formally constituted Institutional Review Board (IRB) to oversee the protection of human subjects in research. The IRB examines each proposed study for its effects on subjects' rights and welfare. Local or site IRBs, whose members know the work force and the workplace, must review all proposed and continuing studies. 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.

Researcher access to confidential records poses unique risks to workers in occupational studies—making them a ***vulnerable*** population. Inappropriate release of individually identifiable health or other personal data collected in a study could adversely affect a worker-subject's access to—or retention of—jobs and insurance and may pose additional social and economic risks. To avoid or minimize these risks, the study design should 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: (1) control of the use of data by others, (2) disclosure of that use to the subject, (3) use of personal identifiers, and (4) dissemination of study data and results. Where several studies are in progress with a single 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.

The research use of genetic data and biological samples creates additional and complex ethical issues. Because of risks associated with a worker-subject's employment security and genetic screening (one-time genetic testing of employees), some ethicists and researchers have argued that genetic screening should have no role in the workplace. When studies include the collection of biological samples, all planned future uses of the samples and the data obtained from the samples, must be fully explained in the informed consent process.

In addition to the workers and the researchers, many other stakeholders have concerns and responsibilities that should be considered in a worker study. The employer, the union, the researcher's home institution, the IRB, the funding agency, the local community and larger public, and government at appropriate levels must actively work in partnership to follow the applicable guidelines and to attempt to reconcile potentially conflicting expectations or activities.

Building on the foundation of the Common Rule, stakeholders can collaborate to create and maintain an ethical framework to mitigate issues and resolve concerns that arise during the study. The research plan should involve all stakeholders from the outset and assure accurate and full communication, appropriate scientific peer and IRB reviews, and dedication of resources to ethical issues. For example, investigators must consider the effects of a worker's right to withdraw from a study and decide how withdrawals will affect the data analysis.

The research plan must also allot time and resources for: (1) preliminary notification of the worker community, (2) periodic consultation among the stakeholders, and (3) dissemination of preliminary and final research results. An environment of cooperation among stakeholders will improve the protection of study subjects and will also ensure the overall success of the study by increasing participation in the research, or causing undue anxiety in the affected community.

This document also encourages communities or sites to establish a research information clearinghouse as a means to announce, coordinate, and track worker studies to help achieve broad stakeholder cooperation and to avoid the replication of research.

The appendices to this document provide additional resources useful to the creation of an ethical framework for a worker study. The attachments offer IRB-approved forms and documents that have been used in health studies of current and former workers at one DOE site. These examples may help researchers and other stakeholders in worker studies to develop similar materials adapted to their own specific needs, or they may be used unchanged if appropriate.