APPENDIX A

HISTORICAL BACKGROUND ON WORKER HEALTH STUDIES AT THE DEPARTMENT OF ENERGY

Protecting the health of their workers has long been considered a basic responsibility of government agencies and private industry. Soon after the entry of the United States into World War II and the inception of the U.S. nuclear program, the U.S. Department of Energy (DOE) and its predecessor agencies took steps to evaluate and protect the health of its workers. The Health Division of the Manhattan Engineer District (MED) was established at the University of Chicago in July 1942 for the purpose of monitoring worker exposures, assessing the impact of these exposures on worker health, and the effectiveness of existing occupational protection standards. Workers benefited by the potential for early detection and treatment of untoward effects if any occurred, and by improved protection standards.

The Health Division mounted a two-pronged program of medical monitoring and biological research. The initial focus of both approaches was the short-term effects of occupational exposure to ionizing radiation and radioactive materials, some of which (like uranium) were also known to be chemically toxic. Mandatory, on-site medical surveillance of active workers used established clinical tests. Security-conscious personnel maintained workers' medical records, including test results, in hardcopy form in secured facilities. Ironically, record maintenance in secured facilities under strict security classification created a dilemma that still exists at some sites: when their patients worked in secured facilities, private physicians had, and sometimes still have, difficulty in determining their occupational exposure as well as communicating with them about their classified work with nuclear or chemically toxic materials.

Despite the urgency of the MED's wartime mission, studies based on workers' occupational health records and clinical and basic research involving workers as subjects were conducted in keeping with the principles of medical ethics in practice in the United States at the time. After the war, studies sponsored by the Atomic Energy Commission (AEC) that succeeded MED in 1947, that involved active workers were governed by the ethical principles of medical and research practices set forth in the internationally accepted Nuremberg Code.

In the 1950s, greater awareness of the long-term health risks of exposure to low levels of radiation and the increasing use of radiation and radioactive materials in industry and medicine prompted the AEC to initiate long-term follow-up studies. The purpose of these studies was to better protect the health of active and future workers.

Early in the 1960s, a series of studies were undertaken that demonstrated the feasibility of using plant records as the basis for long-term follow-up studies (epidemiology) to monitor mortality among selected AEC employees. In 1964, the AEC initiated a more broadly based five-year pilot project that further established the feasibility of using existing employee and other facility records for follow-up studies to monitor the health and mortality experience of employees to determine if adverse health effects observed were related to their employment experience

The 1960s were also a time of growing recognition in the U. S. and Europe of the need to protect *all* human subjects from research risks. This trend reflected both renewed interest in protecting human rights and concerns about the use or misuse of newly expanding capabilities in two areas: the detection of biological injury or abnormalities at the cellular level even in the absence of clinical signs and symptoms, and the compilation and management of large electronic databases.

During the 1960s and 1970s, the AEC laboratories began establishing their own Institutional Review Boards (IRB)–or the equivalent–or making arrangements with existing IRBs to provide the necessary reviews of human studies protocols. Documentation shows that these laboratories were required to comply with human research protection policies of the AEC or the National Institutes of Health (NIH).

In 1974, Congress passed three new laws that would profoundly affect worker studies. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was established by the National Research Act of 1974. The Commission's charge was to examine the protections of the rights, welfare, and well-being of human research subjects, which many observers feared had slipped from the expectations set after World War II by the Nuremberg Code. Their work would lead over the decade to the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (1978). In the same year, the Department of Health, Education, and Welfare (DEHW) codified 1966 NIH policies on protecting subjects. In 1976, DOE's predecessor agency, the Energy Research and Development Administration (ERDA), published similar policies to DHEW on the protection of subjects in research. By 1991, 16 Federal agencies had adopted the Federal Policy for the Protection of Human Subjects, known as the "Common Rule" in the form of regulations applicable to all human subjects research these agencies conduct or sponsor. DOE adopted the Common Rule as Part 745 of Title 10 of the Code of Federal Regulations (10 CFR 745).

Two other 1974 laws set new requirements for the privacy and confidentiality of records held by Federal agencies. The ***Freedom of Information Act*** (FOIA) was written to assure that records in the possession of Executive Branch agencies and departments are accessible to the public. However, records identifiable with specific individuals were exempted from disclosure (unless the identities could be removed or they were required as part of a legal proceeding). The Privacy Act established protection of personnel, occupational medicine, and other records from unauthorized access or other misuse by Federal agencies. Each act complements the other, providing legitimate public access to information while protecting the privacy of individuals.

Under the terms of FOIA and the ***Privacy Act***, worker occupational health records are subject to disclosure only in forms that assure that records cannot be identified with specific individuals.
During the late 1970s and early 1980s, an increasing number of records-based worker studies conducted by DOE and by other agencies were voluntarily submitted for IRB review because of growing concerns about their potential impact on workers.
The concerns centered not only on the kinds of information traditionally found in workers' records but also on new data sources. During the 1980s, rapid development of sophisticated genetic technologies enabled researchers to extract a large amount of data about an individual's genetic makeup from blood and other biological samples. This new capability to identify genetic patterns known or suspected to be predictors of disease introduced the potential for additional invasions of worker privacy and created even more complex ethical concerns.

In the past decade, DOE, other federal agencies, states, universities, unions, and private industry have continued to design and carry out research studies to identify links between on-the-job exposure to hazards and adverse health effects. In the National Defense Reauthorization Act of 1993, Congress directed DOE to study the health of former workers in defense nuclear facilities. These studies are being conducted by DOE and its contractors and grantees, as well as by other federal agencies, such as the National Institute of Occupational Safety and Health (NIOSH), and their grantees that include universities and unions. On the recommendation of the Secretarial Panel for the Evaluation of Epidemiologic Research Activities (SPEERA) for the U.S. Department of Energy in 1990, DOE and its contractors continued to conduct descriptive epidemiological studies of active and former workers in DOE facilities. Analytic studies, however, were transferred to NIOSH management.

Many of these studies employ the powerful new technologies for managing data electronically as well as cataloging genetic and physiological detail about the research subjects.

Because workers participating in these studies face unique risks—real or perceived coercion; real or potential loss of benefits or employment; real or potential social or economic impacts—the workers in these health studies should be recognized and treated as a vulnerable population that deserves special ethical considerations.