APPENDIX F

EXCERPT FROM THE ACCESS HANDBOOK: CONDUCTING HEALTH STUDIES AT DEPARTMENT OF ENERGY SITES

CONDUCTING A WORKER HEALTH STUDY AT A DEPARTMENT OF ENERGY (DOE) SITE BY NON-DOE AGENCIES

CONDUCTING A WORKER HEALTH STUDY AT A DOE SITE BY NON-DOE AGENCIES

The federal policy for the Protection of Human Subjects is called the Common Rule. For DOE, it is codified in title 10, Code of Federal Regulations, Part 745 (10 CFR 745). Before health studies can be undertaken, 10 CFR 745 requires that the project or protocol be reviewed and approved by the institutional review board (IRB) to determine whether subjects are at risk, and if so, whether the risk is acceptable. In addition to review by the researcher's IRB, for health studies conducted at DOE sites, review and approval by the site IRB are also required. The local IRB can best evaluate particular circumstances of the research setting and weigh critical considerations, such as local professional and community standards, the availability of alternative sources of treatment, institutional policy and resources, and the needs of differing subject populations.

Once a researcher has received funding to conduct a health study at a DOE facility, the researcher must submit the study protocol, including informed consent statements and documentation of other IRB reviews, to the chair of the site IRB. If the study is to be conducted at multiple DOE facilities, each IRB must be provided with the materials necessary for that site's IRB review.

Upon completion of the IRB review, the IRB chair will place a copy of the study protocol, IRB documentation, and any associated information in the public reading room to make these documents available to potential study subjects.

Health studies of workers at DOE sites often involve researchers' use of site records. These records may contain site occupational, medical and work histories, and exposure information. These DOE site records may be either federal or contractor-owned records.

At DOE sites "access" to records and information gives researchers the ability to do any or all of the following at a DOE site:

- Review record systems.
- Review classified material (for researchers with appropriate security clearance).
- Take sample copies of records.
- Make copies necessary for research.
- Obtain copies of electronic records and the documentation necessary to understand them.
- Observe work and processes in progress.
- Talk privately to workers.
- Collect exposure data.
- Hold meetings with all interested parties.

Access to Research Data and Personal Records

The conditions under which an employer or another party may have access to personal information gathered for a study or to analyze results must be clearly explained to the study participants. Federal and state laws vary in the privacy protection given these kinds of information. For example, the Privacy Act of 1974 protects personal information held

in federal agency records from unauthorized disclosure. Only the subject of a protected record has access to that record, with certain exceptions such the “routine use” of the data (defined below).

Contractor Records

Not all records at federal agency sites are federal records. Some records belong to the contractors and may not be subject to laws governing the management of and access to federal records. Contractors' records are governed by the specific terms of their agency contracts. In particular, access to these records is governed by the terms of those contracts and by the law, including the agency's Freedom of Information Act regulations on contractor records (10 C.F.R. 1004.3(e)).

To carry out studies, researchers may require access to records and data owned by agency contractors. Contractor-owned records needed for health research that contain personal identifiers are made available under the access authority of the ownership-of-records clause of the governing contract and access is subject to the Privacy Act.

The IRB review should ensure that the research protocol protects the confidentiality of contractor-owned records made available in worker health studies. Many states impose additional, independent requirements to protect the confidentiality of records used for research.

Federal Records

The Privacy Act of 1974 establishes safeguards for the protection of some of the records the government collects and maintains on individuals. It specifically mandates that the government prevent disclosure of information in agency Privacy Act “systems of records” without the consent of the individual to whom they pertain except under certain conditions. These conditions include situations where disclosure would be required under the Freedom of Information Act and in other situations including where disclosure would be for a “routine use.”

A Privacy Act **system of records** is a group of any records about an individual under the control of a federal agency from which the information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual.

Many federal contracts have an **ownership of records** clause that specifies which records are considered government-owned even though they are in the custody of a contractor. This “ownership” clause extends Privacy Act protection to these records, however, these records, including records containing personal identifiers may be made available to health researchers under “routine use” provisions.

A Privacy Act **routine use** is a use of such record for a purpose that is compatible with the purpose for which it was collected and maintained. The federal agency must publish

in the Federal Register notices of all agency Privacy Act Systems of Records, including in each notice a list of routine uses for that system.