APPENDIX E

ACCESS HANDBOOK, CONDUCTING HEALTH STUDIES AT DEPARTMENT OF ENERGY SITES

APPENDIX 2: DOE/CDC INSTITUTIONAL REVIEW BOARD (IRB) PROCEDURES
(Revised 12/6/99)

This section outlines procedures for IRB review of health research and related studies at DOE Facilities when the study is managed by the Department of Health and Human Services (HHS) under the Memoranda of Understanding (MOU) between HHS and DOE.

In 1996, DOE and HHS renewed the MOU, initiated in 1990, under which HHS conducts a program of independent, occupational, and environmental research studies at DOE sites with funding from DOE. Under this MOU, the National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) is the principal HHS agency that conducts health research and related activities involving workers at DOE facilities. Both DOE and HHS are committed to ensuring the scientific integrity and independence of research conducted under the MOU while protecting study subjects from research risks.

Prior to conducting research involving human subjects at DOE facilities, compliance with the requirements of the Federal Policy for Protection of Human Subjects at 10 CFR Part 745 or, where applicable, 45 CFR Part 46 is required. Studies involving human subjects are required to be reviewed by an IRB under both DOE and HHS regulations to ensure that the rights and welfare of all study subjects are protected. In some cases, either DOE or HHS or both may choose to conduct an IRB review of a proposed research study.

The Office for Protection from Research Risks (OPRR), which has responsibility for enforcing the HHS human subjects regulations, requires IRB review by all institutions considered “engaged” in the research. Further, OPRR normally requires review by a local IRB. Generally, a local IRB is in the best position to evaluate the particular circumstances of the research setting and to weigh critical considerations such as local professional and community standards; the availability and feasibility of alternative research methods, institutional policies, and resources; and the needs of differing subject populations. Where local review is not possible, OPRR requires that the reviewing IRB have knowledge about the local setting.

NIOSH investigators have previously involved the local sites by soliciting comments on the scientific, administrative, and ethical aspects of the draft protocols from worker and management representatives at public meetings and by mail for those unable to attend. These comments were submitted to the NIOSH IRB, along with the protocol and

other required documentation, for consideration and deliberation as part of the human subjects' review process prior to beginning a study.

DOE-owned facilities that are the sites for health research and related studies conducted pursuant to the MOU are operated for DOE under contract by profit or non-profit entities. These entities are organizationally independent from and, for a number of purposes, have organizational obligations and interests that are different and potentially divergent from those of DOE. To protect their respective independent obligations and to avoid potential conflicts between their independent interests and those of DOE, DOE contractors' IRBs may wish to review and comment on proposed protocols applicable to DOE sites operated by them as part of, or in addition to, the requirements of the HHS regulations. Reconciling the need to conduct timely research into the health hazards confronting employees at DOE sites with the equally compelling need for review of research protocols by local site's IRB presents unique challenges. This is especially true in multiple site studies where uncoordinated site reviews could significantly delay a study's onset. For this reason, time requirements have been established for the review process described below to allow for local site review while avoiding lengthy delays.

To ensure the protection of the privacy rights of study subjects, to maintain the independence of NIOSH and other HHS agencies to conduct health research and related studies at DOE facilities, to ensure local input in a timely fashion, and to respect the independent obligations and interests of DOE contractors, whether by contract or law; the parties and their assignees to this Agreement
agree to abide by the following procedures concerning the review of research protocols related to DOE facilities:

1. The NIOSH IRB will serve as the IRB of record for purposes of satisfying the requirements of the DOE and HHS human subjects requirements. When a research protocol is ready for IRB review, NIOSH, its contractors, grantees, or cooperative agreement holders will send a copy of the research protocol, including the scientific peer review comments and responses and identification of the DOE sites (preceded by an e-mail alert), to Dr. Susan L. Rose, DOE Office of Science (SC-72) for transmittal within two (2) weeks to the chair of the IRB committee at the DOE facility ("the site IRB') for review and comment. The Office of Science will send via Federal Express the protocol to the DOE site(s) and retain a copy of the receipt for documentation. The DOE site(s) will notify the Office of Science by email when the protocol is received via Federal Express. The review and comment period shall be at least two (2) weeks, but is not to exceed four (4) weeks from the date of receipt of the protocol by the site IRB. In so far as most of these studies will involve existing record systems devoid of personal identifiers, it is expected they will qualify for either an exemption or an expedited review. The chair of the site IRB will send copies of the comments to the NIOSH-designated project officer (who is identified in the protocol), to the Chair of the NIOSH IRB, and to DOE Office of Science (SC-72). Comments from the site IRB(s) must be received by the Chair of the NIOSH IRB within four (4) weeks from the date of receipt by the site IRB for consideration at the NIOSH IRB review of the protocol. If the site IRB review concludes that the research involves more than minimal risk to subjects, or other important issues

are raised, the site IRB official representative, generally the chairperson, should be present in person or through a video conference call at the NIOSH IRB review to resolve the issue.

2. As part of the NIOSH review process, the NIOSH IRB will consider all comments from the site IRB, discuss these with the NIOSH project officer, and provide responses to the site IRB. In the event of a disagreement between the NIOSH IRB and site IRB, a convened meeting of the NIOSH IRB will be held with a representative of the site IRB in attendance. NIOSH IRB will make the final determination regarding approval of the protocol if unresolved conflicts arise.

3. NIOSH grants generally receive their IRB approval from the grantee institution's IRB, rather than the NIOSH IRB. Such approval is obtained prior to submission of the grant proposal to NIOSH, and is an integral part of the grant application process. This approval from the grantee institution's IRB shall be considered provisional. After the grant has been awarded and the scientific peer review has been completed, the grantee will follow the same procedures in (1) with the grantee institution's IRB serving in the role of the NIOSH IRB. As part of the grantee's review process, the grantee's IRB will consider all comments from the site IRB and provide responses to the site IRB. In the event of a disagreement between the grantee's IRB and site IRB, a convened meeting of the grantee's IRB will be held with a representative of the site IRB in attendance. Unresolved conflicts between the grantee's IRB and the site IRB will be referred to the CDC Human Subjects Office for resolution. Notice of this change of procedure will be provided to potential applicants in the Request for Applications.

4. For studies conducted by grant, the grant recipient will provide copies of all IRB approvals, the final protocol, review comments of the protocol by the site IRB, and the grantee's responses to these comments, to DOE Office of Science (SC-72) and to the NIOSH-designated project officer before a study begins.

5. Sites may rely on the responsible NIOSH IRB for review and approval of the protocol if they choose not to form a site IRB, or conversely DOE Office of Science, (SC-72) may make this determination.

6. When HHS agencies conduct outbreak or health hazard investigations, they may need to access personally identified records managed or maintained by DOE contractors. In these cases, the activity is not research and does not require IRB review. However, when information is collected that is beyond the scope of the emergency response, the collection of the information is research. Additionally, other types of activities that constitute research may be undertaken by HHS agencies. When research is conducted and other HHS agencies need to access personally identified records managed or maintained by DOE contractors, the contractors are considered engaged in the research. Local IRB review is required in this case, and the researcher will follow the same general procedures in (1) through (5) above and (7) below. The HHS agency's IRB (or, as appropriate, a funded grantee's IRB) shall serve as the IRB of record.

7. Once a protocol has been approved, it must be reviewed at least annually for the life of the project. The project officer will send to Dr. Susan L. Rose, DOE Office of Science (SC-72), via e-mail, the continuing review application. The Office of Science will forward the continuing review application to the local site for review. The same procedures as described in (1) will be followed.

8. This agreement will be in effect on the date of the later signature and may be modified in writing only with the joint approval of both signature parties or their designees. Cancellation of the agreement may be accomplished only at the expiration of a 90-day advanced notification in writing by either party.

Signed: Susan L. Rose
Approving DOE Official
Dated: 12/6/99

Signed: Marjorie A. Speers
Approving CDC Official
Dated: 12/6/99