Attachment D3:
HETAB Consent Form
(Consent form for biological specimens discarded)

[20011-12 HETAB consent form for biological specimens discarded]

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH (NIOSH)
CENTERS FOR DISEASE CONTROL AND PREVENTION
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

CONSENT TO PARTICIPATE IN A HEALTH HAZARD EVALUATION

You have been asked to participate in a NIOSH health hazard evaluation of (problem) at (company/location). We explain here the nature of your participation, describe your rights, And specify how NIOSH will treat your records.

I. DESCRIPTION

1. Title:

2. Project Officer:

3. Purpose and Benefits:

This health hazard evaluation was requested by (requestor) because of (reported illness/exposures). The purpose of this evaluation is [to determine if (health effect a) is associated with (exposure b)]. Your participation may benefit you, your co-workers, and possibly other people, as a result of what is learned from this health hazard evaluation. Other benefits to you from participating in this evaluation include receiving the information from the results of the free medical tests described in Section II in this consent (below).

II. CONDITIONS OF THE HEALTH HAZARD EVALUATION

1. The health hazard report will include (some or all of) the following procedures: *[*the following are examples:]*

A. A questionnaire about your work history, health history, and health-related activities, including any sensitive topics). [The questionnaire will be administered by a NIOSH representative.] [You will be asked to complete the questionnaire yourself, but a NIOSH representative will (be present to) (assist you and) check it for completeness (when you return it).] It should take from __ to __ minutes.

B. Blood tests for _____ and _____. (#) tubes (about __ teaspoons) of blood will be taken from a vein in your arm. The needle stick may produce momentary discomfort and possibly some residual soreness and discoloration of the skin due to blood leaking from the vein; this discoloration may last a few days but is generally harmless. Infrequently, the procedure causes someone to faint. This blood draw procedure should take only a few minutes.

C. Pulmonary function tests. You will be asked to breathe in as deeply as you can and forcefully blow out as quickly and completely as possible through a tube that you place in your mouth. You will be asked to do this at least (three) (five) times, and possibly several more times. This test may be tiring, and you may feel momentary lightheadedness or chest discomfort. If, at any time, you feel unable to continue, the test will be terminated. The test typically takes five to ten minutes.

D. Urine tests for _____ and _____. You will be asked to urinate, in private, into a container that a NIOSH representative will provide. The only time involved is that required to produce the urine specimen and return it to the technician.

E. Chest x-ray. A single back-to-front chest x-ray will be made. If, as occasionally happens, this x-ray is not of adequate quality, or if your chest is too large to fit on a single film, another chest x-ray will be made. The radiation exposure will be about 30 millirems (mrem) per film. The National Council on Radiation Protection and Measurements recommends an occupational exposure limit of 2000 mrem per year and a general population limit of 100 mrem per year from sources other than medical and natural background.

All together, including time spent waiting your turn at the various test stations, your participation should take about __ minutes.

Your (blood, urine, other biological material) will be used only for the tests specified above. The specimen(s) will be identified only by an arbitrary number, which can be linked to you only by the medical investigators, not the laboratory. The specimens will be retained for six months after the health hazard evaluation final report is issued in order to re-test the specimens in case a question about the original analysis arises. After this period they will be destroyed. In the event that a NIOSH researcher sees a reason to perform additional tests beyond those described in this form or to save your (blood, urine, other biological material) for future uses beyond this six-month period, NIOSH will contact you first and will not perform any additional tests or save your (blood, urine, other biological material) unless you provide written consent.

2. There are some possible disadvantages to your participation. One disadvantage, besides the slight discomfort and inconvenience from the medical tests as previously described, is that a test result may be outside the range of "normal" even though nothing is wrong. This could result in a recommendation for further medical evaluation that, ultimately, may not have been necessary. If you have any comments about the tests/procedures, you should contact (name, title, phone).

_____

3. All of the procedures described above are standard medical tests; [there are no alternative procedures OR Alternative procedures are (less reliable) OR (riskier) OR (more difficult to interpret) OR (more time-consuming.]*

4. Injury or harm from this project is unlikely. But if it results, medical care is not provided, other than emergency treatment. If you are injured through negligence of a NIOSH employee you may be able to obtain reimbursement under Federal Law. If you want to file a claim against the Federal government your contact point is: General Law Division of OGC, request the Claims Office: (202) 233-0233. If you are injured or harmed through the negligence of a NIOSH contractor, your claim would be against the contractor, not the federal government. If an injury or harm should occur to you as the result of your participation, you should contact (project officer's name, title, phone) or (name, phone), the chair of the NIOSH Human Subjects Review Board.

5. If you have questions about this health hazard evaluation, contact (name and telephone of project officer). If you have questions about your rights as a member of this health hazard evaluation, contact (name, title, phone of Chair, HSRB).

6. Your participation is voluntary and you may withdraw your consent and your participation in this health hazard report at any time without penalty or loss of benefits to which you are otherwise entitled.

7. NIOSH will provide you and your doctor (if you wish) with all findings from your medical tests (and any other examinations). We will do this when the health hazard report is finished, or sooner, if appropriate. The overall health hazard report results (without names or other personal identifying information) will be provided to the company and union (or other employee representative); the company is required to post a copy of the final report in a place accessible to employees for a period of 30 days. In addition, if you so request, NIOSH will send you a copy of the final report.

III. USE OF INFORMATION

This health hazard evaluation is being done by The National Institute for Occupational Safety and Health (NIOSH). NIOSH is part of the Centers for Disease Control (CDC), a government agency in the Department of Health and Human Services. We collect this information in order to learn about various kinds of work hazards that may influence the health of the American worker.

NIOSH is allowed to collect and keep information about you, including your results from this health hazard evaluation, along with your social security number (if applicable), because of three laws passed by Congress. These laws are:

1. The Public Health Service Act (42 U.S.C 241)
2. The Occupational Safety and Health Act (29 U.S.C. 669)
3. The Federal Mine Safety and Health Act of 1977 (30 U.S.C. 951)

You will decide whether you want to provide us with this information by being in this health hazard evaluation. You are free to choose not to be in this health hazard evaluation. It is up to you. If the information we are collecting is maintained and retrieved by personal identifiers, such as your name and social security number, it will become part of the CDC record system and we will protect it to extent allowed by law. You should know, however, that there are conditions under the Privacy Act when we could be authorized to release this information to outside sources. These conditions under which we might release this information are listed in Appendix A (the Privacy Act).

IV. SIGNATURES

I have read this consent form and received a copy of the conditions for data release under the Privacy Act (Appendix A). I agree to participate in this health hazard evaluation.

PARTICIPANT_____Age _____
(signature)

(And Guardian, if required)_____Date__
_____

I, the NIOSH representative, have accurately described this health hazard evaluation to the participant.

REPRESENTATIVE_____Date_____
(Signature)

(Project Officer - This page is not part of the consent document. It is to be used when you plan to send medical findings to the participant's physician.)

REQUEST AND AUTHORIZATION FOR RELEASE OF INFORMATION

I, _____, request and permit the project officer to inform the following physicians or health care facilities (whose names and addresses I have entered below) of any significant findings from this health hazard evaluation that concern me. (Do not leave blank. Write "No" where you do not wish to give a name and address.)

1. My personal physician(s):

   Dr. _____

   Street _____

   City _____State_____Zip_____

   _____

2. Other physician or health care facilities:

   Dr. _____

   Street _____

   City _____State_____Zip_____

   _____
   Participant
   (And Guardian if required)_____Date_____

1 copy to participant

1 copy to project officer

Appendix A

The Information you provide will become part of the CDC Privacy Act System, 09-20-0147, "Occupational Health Epidemiological Studies and EEOICPA Program Records" and may be disclosed to

- **Appropriate state or local heath departments to report communicable diseases;**
- **A State Cancer Registry to report cases of cancer where the state has a legal reporting program providing for confidentiality;**
- **Private contractors assisting NIOSH;**
- **Collaborating researchers under certain circumstances to conduct further investigations;**
- **One or more potential sources of vital statistics to make determinations of death, health status or to find last known address;**
- **The Department of Justice or the Department of Labor in the event of litigation;**
- **Congressional offices assisting an individual in locating his or her records;**
- **The Department of Justice to assist in determining the eligibility for compensation to uranium workers or their survivors [optional but must be used if health hazard evaluation pertains to uranium workers]**

You may request an accounting of the disclosures made by NIOSH.
Except for these and other permissible disclosures authorized by the Privacy Act, or in limited circumstances required by the Freedom of Information Act, no other disclosures may be made without your written consent.

NOTE TO PROJECT OFFICER

This is an example of the listing for one NIOSH system of records. You need to verify which system applies to your health hazard evaluation and check what disclosures may be made under that system.