Appendix Q – NIOSH Model Informed Consent Form

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

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

You have been asked to participate in a NIOSH research study. We explain here the nature of your participation, describe your rights, and specify how NIOSH will treat your records.

(Project Officer - Format your document exactly as typed above)

I. DESCRIPTION

1. Title:

2. Sponsor and/or Project Officer:

3. Purpose and Benefits: (**Project Officer - The benefits for the participant as an individual and as part of a "research" project need to be identified. NOTE: Reimbursement is not a benefit and is more appropriately covered in Section II(6).**

II. CONDITIONS OF THE STUDY

1. **(Project Officer - State here what is going to happen to the subject. Use layman's language, where possible, and avoid jargon.)**

   (Project Officer - Expand this space as necessary. List the test/procedures, their duration(s), and how they are to be administered.)

2. **(Project Officer - State here any risks or discomforts the participant may experience and the level of the risk or discomfort.)**

   If you have any comment about the tests/procedures, you should contact (name, title, phone).

3. **(Project Officer - List here any alternative procedures - and say why they aren't being used OR say there are no alternative test procedures.)**

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 compensation 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 also should contact: **NOTE TO PROJECT OFFICER - The contact point here is generally the project officer with a second contact point being the current Chair of the NIOSH HSRB (Mark A. Toraason, Chair NIOSH HSRB, 513-533-8591).**

5. If you have questions about this research, contact (name and phone number of Project officer). If you have questions about your rights as a member of this study, contact Mark A. Toraason, Chair, NIOSH Human Subjects Review Board, 513-533-8591.

6. Your participation is voluntary and you may withdraw your consent and your participation in this study at any time without penalty or loss of benefits to which you are otherwise entitled. **(Project Officer - the following statement is added if NIOSH employees are used: As a NIOSH employee, it is extremely important that your participation be truly voluntary and that all data obtained about you be kept confidential. If you believe in any way that you have been coerced by any other NIOSH employee to participate, or your data have not been kept confidential, you should immediately bring this to the attention of the Chair of the NIOSH Human Subjects Review Board. The copy of the protocol which includes provisions for including NIOSH employees in this project is available to you upon request from the project officer.)**

   (Project Officer - The project officer also states here what reimbursement, if any, will be provided and how the reimbursement will be prorated if the participant does not complete the study. This would include covering the reimbursement issues, as appropriate, if NIOSH employees are being used as research subjects.)

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 study is finished, or sooner, if appropriate. **(Project Officer – Include this statement, if there are clinically relevant medical or other findings. Also include a statement as to how overall study results will be provided to the participants.)**

III. USE OF INFORMATION

This study is being done by The National Institute for Occupational Safety and Health (NIOSH). NIOSH is part of the Centers for Disease Control and Prevention (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 study, 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 study. You are free to choose not to be in this study. 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 the 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 study.

PARTICIPANT_____Age _____
(signature)

(and Guardian, if required)_____Date_____

I, the NIOSH representative, have accurately described this study to the participant.

REPRESENTATIVE_____Date_____
(signature)

Notes to project officer: If your study excludes minors, you don't need the age or guardian 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 study 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 study 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 study and check what disclosures may be made under that system.