Continuing Review

0.1379 Centers for Disease Control and Prevention
NIOSH HSRB

Date received 3/16/07

Signature Page for Human Research Review
Protocols and Related Documentation

Ann date 4/8/07

Use this signature page when submitting HRPO forms to your center-level Human Subjects Contact. When submitting materials with these forms, please consecutively number all pages, beginning with the protocol title page and followed by consent form(s) and ancillary documents. See *HRPO Guide: Overview* for further details. **NOTE: IRB (Institutional Review Board) refers to the NIOSH HSRB (National Institute for Occupational Safety and Health (NIOSH) Human Subjects Review Board (HSRB) of the CDC Human Research Protection Office (HRPO).**

1 Protocol identifiers

CAN# _____ (optional)

Leave protocol ID blank if not yet assigned.

CDC protocol ID: HSRB 91-DSHEFS-09 Protocol version number _____ version date _____

Protocol title: Generic Consent Form for Health Hazard Evaluations

Amendment number (if applicable): _____

2 Key CDC personnel

	Name and degrees (FirstName LastName, Degrees)	User ID	SEV #	CDC NC/division
Primary contact (required)	Bruce Bernard, MD, MPH	bpb4	16960	NIOSH/DSHEFS
Principal investigator (required)	Bruce Bernard, MD, MPH	bpb4	16960	NIOSH/DSHEFS

SEV # is CDC's Scientific Ethics Verification Number. CDC NC/division is the national center or equivalent and division or equivalent, or coordinating center or office if submitted at that level.

3 Forms submitted with this signature page

Check all that apply in the appropriate column.

IRB-reviewed protocols

- ☐ 0.1250: Initial Review by IRB
- ☒ 0.1251: Continuing Review of Approved Protocol
- ☐ 0.1252: Review of Changes to Approved Protocol
- ☐ 0.1254: Incident Report
- ☐ 0.1254S: Supplemental Adverse Event Report
- ☐ 0.1253: End of Human Research Review
- ☐ 0.1370: CDC's Research Partners
- ☐ 0.1371: CDC Rely on a Non-CDC IRB
- ☐ 0.1372: Outside Institution Rely on a CDC IRB
- ☐ 0.1373: CDC Cover an Individual Investigator

Exempted protocols

- ☐ 0.1250X: Initial Review for Exemption
- ☐ 0.1251X: Continuing Review of Exempted Protocol
- ☐ 0.1252X: Review of Changes to Exempted Protocol
- ☐ 0.1253: End of Human Research Review
- ☒ 0.1370: CDC's Research Partners

4 Signatures

As principal investigator, I hereby accept responsibility for conducting this CDC-sponsored research project in an ethical manner, consistent with the policies and procedures contained in CDC's *Procedures for Protection of Human Research Participants*, and to abide by the principles outlined in federal policies for the protection of human subjects at 45 CFR part 46, 21 CFR part 50, and 21 CFR part 56.

Signature	Date	Remarks
Principal CDC Investigator:		

As a supervisor of the principal investigator, I hereby accept responsibility for ensuring that this CDC-sponsored research project is conducted in an ethical manner, consistent with the policies and procedures contained in CDC's *Procedures for Protection of Human Research Participants*, and to abide by the principles outlined in federal policies for the protection of human subjects at 45 CFR part 46, 21 CFR part 50, and 21 CFR part 56.

Signature	Date	Remarks
Team Lead: Bruce P Bernard	3/9/07	Check if PI is Team Lead: ☑
Branch Official (e.g., Chief or Senior Scientist): Allison Tepper	3/9/07	Check if PI is Branch Official: ☐
Division Official (e.g., Director or ADS): D/D/S WT	3/9/07	Check if PI is Division Official: ☐

I concur that this CDC-sponsored research project is consistent with the policies and procedures contained in CDC's *Procedures for Protection of Human Research Participants* and with other applicable CDC and national center policies.

Signature	Date	Remarks
Chair, NIOSH HSRB: Michael J Colligan	4/6/07	APPROVED
Other Clearance Official: (e.g., Confidentiality Officer, Coordinating Center/Office Official)		

5 Additional comments

This review of the HHE consent form is performed as a courtesy to the HHE program. The HHE program is not viewed as a research activity requiring HSRB oversight

6 Reminder regarding other regulatory clearance processes

The principal investigator is responsible for obtaining other regulatory reviews as needed, which may include OMB clearance under the Paperwork Reduction Act (PRA) for federally sponsored information collections. Approval by or exemption from the IRB is unrelated to OMB clearance requirements under the PRA. For more information on whether your study requires clearance under PRA or other regulations, please consult the appropriate officials within your national center.

3/16/07

Ann date 4/8/07

Request for Continuing Review of IRB-Approved Protocol

Use this form to submit a protocol for continuing review by a CDC IRB or a non-CDC IRB. [See 45 CFR 46.109(e).] See *HRPO Guide: IRB Review Cycle* for further details on how to complete this form.

1 Protocol identifiers

CDC protocol ID: 91-DSHEFS-09 Protocol version number _____ version date 06/07

Protocol title: Generic Consent Form for Health HAzard Evaluations

2 Key CDC personnel

☒ **No change** in key CDC personnel. If no changes, please list only the primary contact and principal investigator.

	Name and degrees (FirstName LastName, Degrees)	User ID	SEV #	CDC NC/division
Primary contact (required)	Bruce P. Bernard, M.D., M.P.H.	bpb4	16960	NIOSH/SHEFS
Principal investigator (required)	Bruce P. Bernard, M.D., M.P.H.	bpb4	16960	NIOSH/SHEFS
Investigator 2				
Investigator 3				
Investigator 4				
Investigator 5				

SEV # is CDC's Scientific Ethics Verification Number. CDC NC/division is the national center (or equivalent) and division (or equivalent), or coordinating center or office if submitted at that level.

List all other CDC investigators, if any. Include name and degrees, user ID, SEV #, CDC NC/division:

3 CDC's research partners

Research partners include *all* direct and indirect recipients of CDC funding (e.g., grants, cooperative agreements, contracts, subcontracts, purchase orders) and other CDC support (e.g., identifiable private information, supplies, products, drugs, or other tangible support) for this research activity, as well as collaborators who do not receive such support. On continuing review, HRPO needs current information on partners that have been added or dropped since the last review and partners that, as of the last review, were receiving support for nonexempt research. See *HRPO Guide: CDC's Research Partners* for further details. Check one of the following.

☒ No research partners are reported with this submission. (This may occur because there are no partners, or because no partners are being added, or because no previously reported partners are still both supported by CDC and engaged in nonexempt research.)

☐ Research partners are listed on form 0.1370, which accompanies this form.

4 Study participants—cumulative demographic frequencies

Have any participants been enrolled in the last 12 months? ☒ yes ☐ no Per PI 3/23/07 Email K Mostow

Report estimated counts (rather than percentages). Include participants at domestic and foreign sites. See *HRPO Guide: IRB Review Cycle* for definitions.

Number of participants	705
Location of participants	
Participating at domestic sites	705
Participating at foreign sites	0
Sex/Gender of participants	
Female	105
Male	600
Sex/gender not available	0
Ethnicity of participants	
Hispanic or Latino	28
Not Hispanic or Latino	677
Ethnicity not available	0
Race of participants	
American Indian or Alaska Native	0
Asian	0
Black or African American	268
Native Hawaiian or Other Pacific Islander	0
White	437
More than one race	0
Race not available	0

Comments on demographics

5 Study status—participant involvement

5.1 Contact status

"Contact" means intervention or interaction with participants, such as recruitment, screening, obtaining consent, enrollment, and collection of data and biological specimens directly from participants. Check one of the following.

☐ Study is not designed to involve research-related contact with participants (e.g., research using existing records); study activities involve only access to or analysis of data or biological specimens and writing reports.

☒ Study is designed to involve contact with participants. Check one of the following:

- ☐ Contact with participants has not yet begun.
- ☒ Contact with participants has begun and continues; this may include follow-up for debriefing or notification of results.
- ☐ Contact with participants is completed; study activities involve only data analysis or report writing.

5.2 Consent status

"Consent" includes adult consent, child assent, and parental permission. Check one of the following.

☐ The IRB previously waived all requirements both to obtain and to document consent in this study.

☐ Although not waived, there is no further need to obtain or document consent (e.g., enrollment is complete).

☒ Participants will be asked to provide consent (with or without documentation).

If you check the third box, please include all current consent, assent, and parental permission materials (e.g., scripts, documents) from each study site with this submission.

6 Study status—overall conduct

Summary of research activities to date. Briefly summarize study progress and interim findings. Include the number of potential subjects who declined enrollment and the number who withdrew from the study. If this study involves a registrable clinical trial, summarize registration status.

We continue to pursue our worksite investigations, Health Hazard Evaluations, to determine whether employees are exposed or harmed from possible work-related health effects from chemical exposures and physical agents. Field evaluations are conducted by a team, including a medical officer, an industrial hygienist, and support staff, as needed. The medical/epidemiological component of the evaluations range from a one or two day visit consisting of a walk-through survey, interviews with employees, and review of available data to larger-scale medical/epidemiologic studies which can include informed consent and questionnaires. More rarely, these investigations can include biological monitoring, limited medical exams, and tests.

Summary of study changes reviewed and approved since the last continuation. Do not include changes submitted with or before approval of this continuation but not yet approved.

Summary of any recent literature or other information relevant to the research study (not limited to information with CDC co-authorship).

Summary of all adverse events to date. In particular, address adverse events that were serious, unexpected (or more frequent or severe than expected), or at least possibly related to the research.

Summary of (a) incidents that are not adverse events and (b) other substantial concerns since last continuation.

List and include copies of progress or monitoring reports on safety or compliance (e.g., site monitor, safety review, DSM report, multi-center trial report, but not reports to PGO).

Summary of remaining research activities, emphasizing future contact with subjects, use of identifiable private data and biological specimens, and preparation of primary reports.

7 Regulation and policy

7.1 Mode of IRB review on CDC's behalf

Location of IRB (check one):

☒ CDC IRB

☐ Non-CDC IRB through IRB authorization agreement [submit form 0.1371 if this is a new request]

Institution or organization providing IRB review: _____

IRB registration number (if known): _____

Federalwide assurance number (if any): _____

IRB-determined level of risk to subjects (check one):

☒ Minimal

☐ Greater than minimal

Suggested level of IRB review (check one):

See *HRPO Worksheet for Expedited Review* for detailed assistance. If relying on a non-CDC IRB, please indicate the level of review that you think is appropriate under human research regulations.

☐ Convened-board review is suggested

Reason for convened review: _____

☒ Expedited review is suggested, under the following categories (check all that apply):

- ☐ 1a Study of drugs not requiring Investigational New Drug exemption from FDA
- ☐ 1b Study of medical devices not requiring Investigational Device Exemption from FDA
- ☒ 2a Collection of blood from healthy, nonpregnant adults; below volume limit, minimally invasive
- ☒ 2b Collection of blood from other adults and children; below volume limit, minimally invasive
- ☒ 3 Prospective noninvasive collection of biological specimens for research purposes
- ☒ 4 Collection of data through routine, noninvasive procedures, involving no general anesthesia, sedation, x-rays, or microwaves
- ☐ 5 Research that uses materials collected solely for nonresearch purposes
- ☒ 6 Collection of data from voice, video, digital, or image recordings made for research purposes
- ☒ 7 Research that uses interview, program evaluation, human factors, or quality assurance methods

Continuing review of research previously approved by the convened IRB where

- ☐ 8a the research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects
- ☐ 8b no subjects have been enrolled and no additional risks have been identified
- ☐ 8c the remaining research activities are limited to data analysis

- ☐ 9 Continuing review of research, not under IND/IDE, where categories 2 through 8 do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified

8 Material submitted with this form

Check all that apply. Describe additional material in the comments section. Required items are indicated. Optional items may be requested by HRPO or the IRB.

☐ Complete protocol (required if research poses more than minimal risk to subjects, is under IND/IDE, or has changed in the past 12 months)

☒ Consent, assent, and permission documents or scripts (required if consent will be sought in the future from prospective subjects or their representatives [see section 5.2])

☐ Other information for recruits or participants (e.g., ads, brochures, flyers, scripts; required if consent will be sought in the future from prospective subjects or their representatives)

☐ Data collection instruments (e.g., questionnaires, interview scripts, record abstraction tools; required if protocol has changes in the past 12 months)

☐ Certification of IRB approval or exemption for research partners (required only for partners being added or for supported/nonexempt partners)

☐ Progress and monitoring reports (recommended when available)

9 Additional comments

[HETAB consent form for biological specimens retained]

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.*

* [If pertinent] In addition, NIOSH would like your permission to store your remaining (blood, urine, other biological material) for future research purposes not related to the current health hazard evaluation. In this case, we would remove any personally identifying information from the stored specimens so that they can no longer be linked to you. There is no direct benefit to you for allowing us to use these specimens for research purposes other than making a contribution to science. You may participate in the health hazard evaluation even if you choose not to allow us to store your specimens anonymously.

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: Public Health Service Claims Office: 301-443-1904. 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.

[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

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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.

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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: Public Health Service Claims Office: 301-443-1904. 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.

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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.

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1. The Public Health Service Act (42 U.S.C 241)
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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.)

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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.