Continuing Review + Amendment

0.1379 Centers for Disease Control and Prevention Date received

NIOSH HSRB

4/9/14 e

Signature Page for Human Research Review

Protocols and Related Documentation

Anndate 4/8/14

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).**

Annual Rev 4-8-15

1 Protocol identifiers

CAN# _____ (optional)

Leave protocol ID blank if not yet assigned.

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

Protocol title: Generic Consent Form for HEalth HAzazard 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 P. Bernard, MD, MPH	bpb4	16960	NIOSH/DSHEFS
Principal investigator (required)	Bruce P. 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: Bruce P Bernard	04/05/2014	

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	04/05/2014	Check if PI is Team Lead: ☐
Branch Official (e.g., Chief or Senior Scientist): Allison Tepper	04/09/2014	Check if PI is Branch Official: ☐
Division Official (e.g., Director or ADS): RJB	04/09/2014	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 Chair, NIOSH HSRB: Mark Toraason **Date** 4-8-14 **Remarks** eg date Concurrence form only for all SITE

Other Clearance Official:
(e.g., Confidentiality Officer, Coordinating Center/Office Official)

5 Additional comments

Expedited Review; Minimal Risk; as provided for in 45CFR 46.110 (b)(1) category(s) 2a, 2b, 3, 4, 6, 7;
Approved for one year; Renewal date 4-8-15;
CDC 0.1250 form estimated subject # is ____;
Subject # to date is ____;
Approved/Amended Total Subject # ____;

Annual Rev 4-8-15

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.

APPROVED

4/9/14 e

Request for Continuing Review of IRB-Approved Protocol

Anndate 4/8/14

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: HSRB 91-DSHEFS-09 Protocol version number version date

Protocol title: Generic Consent FOrm for HEalth HAzard Evluations

2 Key CDC personnel

☐ **No change** in key CDC personnel. List all CDC investigators.

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

All CDC partners must be listed on form CDC 0.1370.

Check one of the following.

☒ No research partners are reported with this submission. (This may occur because there are no partners)

☐ 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

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

Number of participants	974
Location of participants	
Participating at domestic sites	974
Participating at foreign sites	0
Sex/Gender of participants	
Female	538
Male	289
Sex/gender not available	146
Ethnicity of participants	
Hispanic or Latino	46
Not Hispanic or Latino	928
Ethnicity not available	0
Race of participants	
American Indian or Alaska Native	0
Asian	0
Black or African American	430
Native Hawaiian or Other Pacific Islander	0
White	475
More than one race	22
Race not available	47

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 Evluations, 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 other supporting 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/epidemiological studies which can include informed consent and questionnaires. more rarely, 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.

None

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

None

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.

None

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

None

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).

None

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

None

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

Request for Review of Changes to IRB-Approved Protocol

Amdate 4/8/14

Use this form to seek approval for changes to a protocol that has received approval by a CDC or non-CDC IRB. [See 45 CFR 46.103(b)(4)(iii).] See *HRPO Guide: IRB Review Cycle* for further details on how to complete this form.

1 Protocol identifiers

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

Protocol title: GGeneric Consent Form for Health Hazard Evaluations

Amendment number: _____

Amendment title or brief descriptor (optional): _____

☐ **No change** in keywords. If no change, please skip to section 2.

Suggested keywords (optional). Enter each term in a separate cell:

2 Key CDC personnel

☐ **No change** in key CDC personnel. Please list all CDC investigators.

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

Check yes or no for each of the following.

☒ y ☐ n CDC employees or agents will obtain data by intervening or interacting with participants.

☒ y ☐ n CDC employees or agents will obtain or use identifiable (including coded) private data or biological specimens.

☐ y ☒ n CDC employees or agents will obtain or use anonymous or unlinked data or biological specimens.

☒ y ☐ n CDC employees will provide substantial technical assistance or oversight.

☒ y ☐ n CDC employees will participate as co-authors in presentation(s) or publication(s).

"Agents" includes on-site contractors, fellows, and others appointed or retained to work at a CDC facility conducting activities under the auspices of CDC.

4 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 review of changes, HRPO needs current information on partners that have been added or dropped since the last review. See *HRPO Guide: CDC's Research Partners* for further details. Check one of the following.

☒ No research partners have been added since the last review.

☐ Research partners have been added and are listed on form 0.1370, which accompanies this form.

5 Study participants—planned demographic frequencies

☒ **No change** in planned demographic frequencies. If no change, please skip to section 6.

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

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

Comments on demographics

6 Regulation and policy

6.1 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): _____

Suggested level of risk to subjects (check one):

☒ Minimal

☐ Greater than minimal

Suggested level of IRB review for the modified protocol (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 is suggested

- ☐ Not eligible for expedited review. For example, poses greater than minimal risk and changes are substantial; involves use of drug, biologic, or device under IND or IDE; involves collection of large amount of blood; use of x-rays or microwaves; anesthesia; or physically invasive procedures
- ☐ Other specified reason:

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

- ☐ Proposed changes to protocol are minor
- ☐ 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 previously collected materials
- ☒ 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

6.2 Vulnerable populations

Check one of the following:

☒ **No change** in vulnerable populations (added or dropped). If no change, please skip to section 6.3.

☐ There is a proposed change in the intention to include or exclude a group of potentially vulnerable subjects, such as pregnant women or fetuses, children, or prisoners.

Please summarize and justify the proposed change, including which groups are affected and where the change is described in the protocol.

6.3 Free and informed consent

Check one of the following:

☒ **No change** in consent process, forms, or approved waivers. If no change, please skip to section 6.4.

☐ There are proposed changes in consent process, forms, or approved waivers.

Please summarize and justify the proposed changes in the consent/assent/permission process (e.g., recruitment, scripts) or in the documentation of consent/assent/permission (e.g., consent forms), including where the changes are described in the protocol. Include any changes related to the HIPAA Privacy Rule. Also describe how it is shown that the modified consent process and documentation are in understandable language (e.g., reading level, comprehension tool, short form, translation).

6.4 Other regulation and policy considerations

Check one of the following:

☒ **No change** in other regulation and policy considerations. If no change, please skip to section 6.5.

☐ There are proposed changes in other regulation and policy considerations.

Please describe and justify changes to any of the following regulation and policy considerations, including where the changes are described in the protocol:

- Exception to PHS policy regarding notification of HIV test results
- Human genetic testing
- Inclusion of a registrable clinical trial or change in registration status
- Plans for long-term storage of identifiable biological specimens
- Involvement of drug, biologic, or device, including Investigational New Drug or Investigational Device Exemption status (See *HRPO Worksheet to Determine FDA Regulatory Coverage* for guidance on whether or not FDA regulations apply.)

6.5 Confidentiality protections

Check one of the following:

☒ **No change** in confidentiality protections (e.g., granted, applied for, denied). If no change, please skip to section 7.

☐ There are proposed changes in confidentiality protections.

Please describe and justify changes to confidentiality protections under a Certificate of Confidentiality (301(d)) or Assurance of Confidentiality (308(d)) or other formal confidentiality protections, including whether requests for these protections are granted, pending, or denied and where these requests are described in the protocol:

7 *Summary of proposed changes*

Describe and justify proposed modifications to the protocol, except for modifications justified above. Include page numbers in reference to clean copy (and marked copy if possible). Continue summary in supplemental document if necessary.

Modification is to utilize new NIOSH Model Consent Form for Health Hazard Evaluation (HHE) program .

8 *Material submitted with this form*

Check all that apply. Describe additional material in the comments section. Clean and marked copies are required for modified materials. Entire documents may not be needed if there is enough context to enable a meaningful review. Optional items may be requested by HRPO or the IRB.

Clean	Marked	
☐	☐	Complete protocol
☐	☐	Consent, assent, and permission documents or scripts
☐	☐	Other information for recruits or participants (e.g., ads, brochures, flyers, scripts)
☐	☐	Data collection instruments (e.g., questionnaires, interview scripts, record abstraction tools)
☐		Certification of IRB approval or exemption for research partners being added

9 *Additional comments*