Continuing Review

0.1379 Centers for Disease Control and Prevention Date received
NIOSH HSRB 3/15/2011

Signature Page for Human Research Review
Protocols and Related Documentation

Ann date 4/8/11

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

HSRB 91-DSHEFS-09

CAN# _____ (optional)

Leave protocol ID blank if not yet assigned.

CDC protocol ID: HSRB~~91-DSHEFS-90~~ 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 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	03/09/2011	

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	03/09/2011	Check if PI is Team Lead: ☒
Branch Official (e.g., Chief or Senior Scientist): Allison Tepper	3.11.2011	Check if PI is Branch Official: ☐
Division Official (e.g., Director or ADS):	3/14/11	Check if PI is Division Official: ☐

APPROVED

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: Mark Toraason	4-7-11	No Change in Conduct
Other Clearance Official: (e.g., Confidentiality Officer, Coordinating Center/Office Official)		Expedited Review: Minimal Risk; as provided for in 45CFR46.110 (2a)(2b),(3),(4),(6) & (7); Approved for one year; Renewal date 4/8/2012

5 Additional comments

Note: The 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. K Newton

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.

Date received
3/15/11

Appr date 4/8/11

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

HSRB 91-DSHEFS-09

CDC protocol ID: ~~HSEB91-DHEFS-09~~ HSRB 91-DSHEFS-09 Protocol version number version date

Protocol title: Generic Consent Form for Health Hazard Evaluations

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, M.D., M.P.H	bpb4	16960	NIOSH/DSHEFS
Principal investigator (required)	Bruce P. Bernard, M.D., M.P.H	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	7,409
Location of participants	
Participating at domestic sites	7409
Participating at foreign sites	0
Sex/Gender of participants	
Female	1,495
Male	5,778
Sex/gender not available	136
Ethnicity of participants	
Hispanic or Latino	629
Not Hispanic or Latino	4,496
Ethnicity not available	2,284
Race of participants	
American Indian or Alaska Native	0
Asian	98
Black or African American	1,732
Native Hawaiian or Other Pacific Islander	1
White	2,100
More than one race	0
Race not available	3,482

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