0.1379

Continuing Review Centers for Disease Control and Prevention

NIOSH HSRB

Date received

NIOSH/OMSHR

NIOSH/OMSHR



Primary contact

Principal investigator

(required)

Signature Page for Human Research Review 3/20/15he Protocols and Related Documentation Ann date 4/4/15

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).

Jennica Bellanca, MS

Jennica Bellanca, MS

1	Protocol identi	ifiers	С	AN# 927ZKW	(optional)
	Leave protocol ID blank CDC protocol ID: 13-Ol Protocol title: Information Amendment number (if	MSHR-03XP onal Needs of Underground Miner		ol version numb	per 2 version date 5/16/2013
2	Key CDC perso	onnel			
		Name and degrees (FirstName LastName, Degrees)	User ID	SEV#	CDC NC/division

(required)
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.

WJE9

WJE9

12351

12351

3 Forms submitted with this signature page

Check all that apply in the appropriate column. IRB-reviewed protocols **Exempted protocols** 0.1250: Initial Review by IRB 0.1250X: Initial Review for Exemption ☑ 0.1251: Continuing Review of Approved Protocol 0.1251X: Continuing Review of Exempted Protocol 0.1252X: Review of Changes to Exempted 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 0.1253: End of Human Research Review 0.1370: CDC's Research Partners 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

4	Signati	ıres
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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
Principal CDC Investigator:
3/9/15

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
Team Lead:

Check if PI is Team Lead:

Check if PI is Branch Official:

Division Official (e.g., Director or ADS):

Check if PI is Division Official:

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 D Lane C Morris for Chair, NIOSH HSRB:

Date 4/3/15

Remarks Conta & With Darticipants Continu

Other Clearance Official:

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

Minimal risk

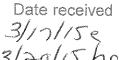
5 Additional comments

45CFR 46.110 (b)(1) category(s)
Approved for one year; Renewal date $4-4-16$
CDC 0.1250 form estimated subject # is
Subject # to date is
Approved/Amended Total Subject # is/65

Expedited Review: Minimal Risk: as provided for in

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.





Request for Continuing Review of IRB-Approved Protocol Anndate 4/4/15

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.

Protocol identifiers 1

CDC protocol ID: 13-OMSHR-03XP

Protocol version number 2 version date 5/16/2013

Protocol title: Informational Needs of Underground Coal Miners

Key CDC personnel 2

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)	Jennica Bellanca, MS	WJE9	12351	NIOSH/OMSHR
Principal investigator (required)	Jennica Bellanca, MS	WJE9	12351	NIOSH/OMSHR
Investigator 2	Brianna Eiter, PhD	viy3	12465	NIOSH/OMSHR
Investigator 3	Lisa Steiner, PhD	ins6	2910	NIOSH/OMSHR
Investigator 4	Brendan Demich	wjc9	8824	NIOSH/OMSHR
Investigator 5	Tim Orr	TAO9	4564	NIOSH/OMSHR

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:

Jacqueline Jansky jgi7 13769 NIOSH/OMSHR; Blaine Connor vsi4 19486 NIOSH/OMSHR

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.

M	to research partners	are reported wi	ith this submission. (This may occur	because ther	e are no partners)
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Research partners are listed on form 0.1370, which accompanies this form.

Total to date of Jerified with PI.

Study participants—cumulative demographic frequencies 4

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.

165 71 Number of participants Location of participants Participating at domestic sites Participating at foreign sites Sex/Gender of participants Female Male Sex/gender not available Ethnicity of participants Hispanic or Latino 0 Not Hispanic or Latino Ethnicity not available Race of participants American Indian or Alaska Native 0 0 Asian 0 Black or African American 0 Native Hawaiian or Other Pacific Islander White More than one race

Comments on demographics

Race not available

Numbers include all subject for tasks in protocol (20 + 145)

nclude all subject for tasks in protocol (20 + 145)
1250 cites 20 subjects thereased to 165 on 6/19/13.

Ach

Study status—participant involvement 5

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.

The study is currently in the midst of data collection. 13 subjects have participated in the direct observation, 7 subjects have participated in the SME questionnaire, 50 subjects have participated in the general preference questionnaire, and 1 subject has participated in the CTA. We believe that recruitment is complete for the direct observation and general preference questionnaire, but may be reopened if data saturation is not reached (within IRB limits). All other tasks are still actively recruiting subjects.

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.

No changes have been made to the protocol since the last review.

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

N/A

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.

N/A

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

N/A

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).

N/A

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

The direct observation and general preference data is currently being analyzed through quantitative and qualitative methodologies. This data has been de-identified but still includes some sensitive information, such as date of birth. The other research tasks (SME questionnaire and CTA) are still in the data collection phase, and therefore will still involve direct contact with subjects for recruitment and testing.

7 Regulation and policy

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 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): Study of drugs not requiring Investigational New Drug exemption from FDA 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 CM \$ 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 $\boxtimes 6$ Collection of data from voice, video, digital, or image recordings made for research purposes \square 7 Research that uses interview, program evaluation, human factors, or quality assurance methods Continuing review of research previously approved by the convened IRB where 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 no subjects have been enrolled and no additional risks have been identified ■ 8b 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)

	nt, assent, and permission documents or scripts (required if consent will be sought in the future from rospective subjects or their representatives [see section 5.2])
Other i	information for recruits or participants (e.g., ads, brochures, flyers, scripts; required if consent will be bught in the future from prospective subjects or their representatives)
	ollection instruments (e.g., questionnaires, interview scripts, record abstraction tools; required if protocol as changes in the past 12 months)
	cation of IRB approval or exemption for research partners (required only for partners being added or for apported/nonexempt partners)
Progre	ss and monitoring reports (recommended when available)

9 Additional comments

Changes in personnel reflect changes that were made with the HSRB office inbetween reviews. No additional personnel has otherwise been added.