DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)

Memorandum

Date October 22, 2019

From Angela M. Morley
Chair, NIOSH Institutional Review Board

Subject IRB Exemption Determination for NIOSH Protocol 19-NIOSH-72, "Formative Research to Inform an Intervention to Improve the Early Detection and Surveillance of Pneumoconiosis in U.S. Coal Miners"

To Emily J. Haas
Project Officer, NIOSH/PMRD

On behalf of the NIOSH Human Research Protection Program (HRPP), I reviewed the request to exempt 19-NIOSH-72, "Formative Research to Inform an Intervention to Improve the Early Detection and Surveillance of Pneumoconiosis in U.S. Coal Miners", and find this research activity is exempt under 45 C.F.R. 46.104(d)(2)(i).

Due to the funding and collection of identifiable, sensitive information the project is determined to be covered by a Certificate of Confidentiality under section 301(d) of the Public Health Service Act.

Since 9/17/2018, the HRPP no longer requires NIOSH investigators to submit continuing review forms for exempt research. This change is not related to the revised Common Rule and is only a standard operating procedure (SOP) change within HRPP. Changes to this protocol may not be implemented until they are reviewed by the NIOSH HRPP and determined to be consistent with the exemption categories.

Please also be advised investigators remain responsible for the ethical conduct of this study and for ensuring appropriate human research protections even for research that is exempt from the regulations governing the protection of human subjects in research.

If you have questions, please contact the HRPP at cin-hsrb@cdc.gov, or by telephone at (513) 533-8591.

Request for Exemption or Review of Changes

Use this form to submit a protocol for exemption from human subject regulations or request review of changes to an existing exempt protocol. See *HRPO Guide: Exempt Review Cycle* for further details on how to complete this form.

1 Purpose

☒ Submit a new/initial protocol for exemption from human subject regulation

☐ Request review of changes to existing exempt protocol

2 Protocol identifiers

CDC protocol ID: 19-NIOSH-72 Protocol version number 1 version date 09/20/2019

Protocol title: Formative Research to Inform an Intervention to Improve the Early Detection and Surveillance of Pneumoconiosis in U.S. Coal Miners

Amendment title or brief descriptor (optional): _____

☐ **No change** in keywords. Suggested keywords (optional). Enter each in separate cell:

formative research	black lung	surveillance
mining	early detection	

3 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	CITI Course Expiration Date	CDC CIO/division
Primary contact (required)	LaTasha R. Swanson, PhD	MRE6	12/25/2021	NIOSH/PMRD
Principal investigator (required)	Emily J. Haas, PhD	WCQ3	12/19/2021	NIOSH/PMRD
Co-Investigator	Cassandra L. Hoebbel	WHD1	12/30/2021	NIOSH/PMRD
Co-Investigator	Brendan Demich	WJC9	12/27/2021	NIOSH/PMRD
Co-Investigator	Dana R. Willmer	DPR4	12/12/2021	NIOSH/PMRD
Co-Investigator				

CITI Course Expiration Date is the latest expiration date for the CITI Biomedical Research and RCR Combined or Social & Behavioral Research and RCR Combined course required by CDC (expires every 3 years). An expiration date must be entered for each investigator. If required training is expired or found expired before IRB review, the protocol will not be reviewed or placed on administrative hold (e.g. cease processing for approval) by HRPO until requirements are met. List all other CDC investigators, if any (name and degrees, user ID, CITI Course Expiration Date, CDC CIO/division):

4 CDC's role in project

Check yes or no for each of the following.

☒y ☐n CDC employees or agents will obtain data by 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.

5 Study Subjects

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

Number of subjects: 113 _____

Comments on demographics study focuses on U.S. mineworkers and mining stakeholders

☐ **No change** in planned study subjects.

6 Regulation and policy

6.1 Exceptions or restrictions on exemptions

Check yes or no for each of the following.

☐y ☒n Research poses greater than minimal risk to participants.
CDC does not exempt research that poses greater than minimal risk to subjects.

☐y ☒n Research involves prisoners (either intentionally or incidentally).

☐y ☒n Research involves interaction with children or obtaining identifiable private information about children through surveys or interviews of others.

6.2 Exemption categories

Check all that apply to the protocol. See *HRPO Worksheet for Exemption from Human Subjects Regulations* for details.

Category 1: Educational practices

☐ 1 Normal educational practices in commonly accepted educational settings

Category 2: Educational tests, surveys, interviews, or observation of public behavior

☒ 2i Recorded in such a manner that identity cannot readily be ascertained

☒ 2ii Disclosure outside the research would not reasonably place subjects at risk of liability or be damaging

☐ 2iii Adults only; identity can readily be ascertained; Limited IRB review required under §46.111(a)(8)

Category 3: Benign Behavioral Interventions and Collection of Information

☒ 3a Brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on subjects; and information obtained is recorded bythe investigator in such a manner that the identity of human subjects cannot readily be ascertained, directly or through identifiers linked to subjects

☐ 3b Brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on subjects; and any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation

☐ 3c Brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on subjects; and the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects; Research involves deceiving the subjects regarding the nature or purposes of the research; Subject authorized the deception through prospective agreement; Limited IRB review required under §46.111(a)(8)

Category 4: Secondary Research for Which Consent in not Required

☐ 4i Identifiable private information or identifiable biospecimens are publicly available

☐ 4ii Information, which may include information about biospecimens, recorded by investigator such that identity of human subjects cannot readily be ascertained; Investigator does not contact subjects, and investigator will not re-identify subjects

☐ 4iii Research use of identifiable health information when that use is regulated by HIPSS as health care operations, research, or public health activities and purposes as those terms are defined in HIPAA **(*Not applicable to CDC*)**

☐ 4iv The research is conducted by, or on behalf of, a Federal department or agency using government generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with applicable federal privacy standards found in the E-Government Act, Privacy Act and the Paperwork Reduction Act

Category 5: Research and Demonstration Projects

☐ 5 Conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads designed to study, evaluate, improve, or otherwise examine public benefit or service programs

Category 6: Taste and Food Quality Evaluation and Consumer Acceptance Studies

☐ 6i Foods that are wholesome without additives, **or**

☐ 6ii If a food is consumed that contains food ingredient at or below the level and for use found to be safe, or agricultural chemical or environmental contaminant at or below level found to be safe, by FDA or approved by EPA or Food Safety and Inspection Service of USDA

Category 7: Storage or Maintenance for Secondary Use for Which Broad Consent is Required

☐ 7 Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use; Limited IRB review required §46.111(a)(8)

Category 8: Secondary Research for Which Broad Consent is Required

☐ 8 Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens was obtained in accordance with §46.111(a)(1) through (4), (a)(6) and (d); Limited IRB review required under §46.111(a)(8)

Note 1: [8i] Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117

Note 2: [8iv] Investigator does not include returning individual research results to subjects as part of the study plan

6.3 Confidentiality protections

CDC supported research commenced or ongoing after December 13, 2016 and in which identifiable, sensitive information is collected, as defined by Section 301(d) of the Public Health Service (PHS) Act, is deemed issued a Certificate of Confidentiality and therefore required to protect the privacy of individuals who are subjects of such research.

☐ Not applicable

☒ Certificate of Confidentiality may be applicable to this study; page 15 of the protocol where the protections are described.

Additional Comments:

This study does not involve the collection of identifiable or sensitive information.

7 Material submitted with this form

Check all that apply. Describe additional material in the comments section.

Clean	Tracked	
☒	☒	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

8 Summary of proposed changes

☒ Not Applicable for new/initial protocols

Describe and justify proposed modifications to the protocol. Include page numbers in reference to clean copy (and tracked copy if possible). Continue summary in supplemental document if necessary.

Version 2 of the protocol includes the following major changes:
-Certificate of Confidentiality was added (see pg. 15, and Appendices H and I).
-The number of interviews were increased from 40 to 50 (see pg. 2, 10).
-Recruitment and data collection venue was changed from a single event (i.e., the Training Resources Applied to Mining annual conference) to various mine health and safety conferences, stakeholder meetings, and mine rescue competitions held between Oct. 2019 and Oct. 2020.
-Information and a verbal consent for audio recording were added to the consent forms (see Appendices H and I).

8 Summary of proposed changes Cont'd

9 Additional comments

10 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. See *HRPO Guide: CDC's Research Partners* for further details. Check one of the following.

☒ No research partners.

☐ Research partners

☐ Additional partners are listed on ancillary 1370 form

Partner 1

Institution name: _____
Institution location: _____
Individual name (IIA only): _____
Reporting status: [Enter Status Here]
Regulatory coverage [Enter Status Here]
Financial support [Enter Status Here]
Support award number: _____
Support end date: _____
Nonfinancial support: [Enter Status Here]
FWA number: _____
SEV number (IIA only): _____
IRB review status: [Enter Status Here]
IRB approval expiration date: _____
Comments: _____

Partner 2

Institution name: _____
Institution location: _____
Individual name (IIA only): _____
Reporting status [Enter Status Here]
Regulatory coverage [Enter Status Here]
Financial support [Enter Status Here]
Support award number: _____
Support end date: _____
Nonfinancial support [Enter Status Here]
FWA number: _____
SEV number (IIA only): _____
IRB review status [Enter Status Here]
IRB approval expiration date: _____
Comments: _____

Partner 3

Institution name: _____
Institution location: _____
Individual name (IIA only): _____
Reporting status [Enter Status Here]
Regulatory coverage: [Enter Status Here]
Financial support: [Enter Status Here]
Support award number: _____
Support end date: _____
Nonfinancial support: [Enter Status Here]
FWA number: _____
SEV number (IIA only): _____
IRB review status [Enter Status Here]
IRB approval expiration date: _____
Comments: _____

Partner 4

Institution name: _____
Institution location: _____
Individual name (IIA only): _____
Reporting status [Enter Status Here]
Regulatory coverage: [Enter Status Here]
Financial support: [Enter Status Here]
Support award number: _____
Support end date: _____
Nonfinancial support: [Enter Status Here]
FWA number: _____
SEV number (IIA only): _____
IRB review status [Enter Status Here]
IRB approval expiration date: _____
Comments: _____

Partner 5

Institution name: _____
Institution location: _____
Individual name (IIA only): _____
Reporting status: [Enter Status Here]
Regulatory coverage: [Enter Status Here]
Financial support: [Enter Status Here]
Support award number: _____
Support end date: _____
Nonfinancial support: [Enter Status Here]
FWA number: _____
SEV number (IIA only): _____
IRB review status [Enter Status Here]
IRB approval expiration date: _____
Comments: _____

Partner 6

Institution name: _____
Institution location: _____
Individual name (IIA only): _____
Reporting status [Enter Status Here]
Regulatory coverage: [Enter Status Here]
Financial support: [Enter Status Here]
Support award number: _____
Support end date: _____
Nonfinancial support: [Enter Status Here]
FWA number: _____
SEV number (IIA only): _____
IRB review status [Enter Status Here]
IRB approval expiration date: _____
Comments: _____

11 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: Emily J. Haas -S Digitally signed by Emily J. Haas -S Date: 2019.09.23 07:17:33 -04'00'	09/23/2019	

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: Audrey F. Glowacki -S Digitally signed by Audrey F. Glowacki -S Date: 2019.09.23 11:02:24 -04'00'	09/23/2019	Check if PI is Team Lead: ☐
Branch Official (e.g., Chief or Senior Scientist): Dana R. Willmer -S Digitally signed by Dana R. Willmer -S Date: 2019.09.23 12:32:01 -04'00'	09/23/2019	Check if PI is Branch Official: ☐
Division Official (e.g., Director or ADS): Lisa J. Steiner -S Digitally signed by Lisa J. Steiner -S Date: 2019.09.24 10:30:23 -04'00'	09/24/2019	Check if PI is Division Official: ☐