Attachment E

DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date December 11, 2015

From Angela M. Morley, J.D., M.P.H.,
Chair, NIOSH IRB

Subject IRB Approval of New Protocol HSRB 15-WSD-01XP, "Assessing Safety and Health Hazards for Oil and Gas Extraction Workers" (Expedited)

To Kyla Retzer
Project Officer, WSD

NIOSH's IRB has reviewed the request for approval of new protocol HSRB 15-WSD-01XP, "Assessing Safety and Health Hazards for Oil and Gas Extraction Workers" and has approved the protocol for the maximum allowable period of one year. NIOSH IRB approval will expire on December 10, 2016. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110, category 7. The IRB approved the requested waiver of documentation of informed consent under 45 CFR 46.117(c)(2).

The IRB determined that the study poses minimal risk to subjects.

As a reminder, the IRB must review and approve all human subjects research protocols at intervals appropriate to the degree of risk, but not less than once per year. There is no grace period beyond one year from the last IRB approval date. It is ultimately your responsibility to submit your research protocol for continuation review and approval by the IRB along with available IRB approvals from all collaborators. Please keep this approval in your protocol file as proof of IRB approval and as a reminder of the expiration date. **To avoid lapses in approval of your research and the possible suspension of subject enrollment and/or termination of the protocol, please submit your continuation request along with all completed supporting documentation at least six weeks before the protocol's expiration date of December 10, 2016.**

Any problems of a serious nature must be brought to the immediate attention of the NIOSH IRB, and any proposed changes to the protocol should be submitted as an amendment to the protocol for NIOSH IRB approval before they are implemented.

If you have any questions, please contact the NIOSH Human Research Protection Program at (513) 533-8591 or by e-mail: cin-hsrb@cdc.gov.

cc:
HSRB 15-WSD-01XP

0.1379

Centers for Disease Control and Prevention
NIOSH IRB (HSRB)

Date Received: ~~10/23/2015~~ 12/1/15e

Signature Page for Human Research Review
Protocols and Related Documentation

Anniversary Date: _____

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 IRB-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 15-WSD-01XP Protocol Version Number: 2 Version Date: 11/30/2015

Protocol Title:

Assessing Safety and Health Hazards for Oil and Gas Extraction Workers

Amendment Number (if applicable): _____

2 Key CDC Personnel

	Name and Degrees (First Name Last Name, Degrees)	User ID	CDC SEV #	CDC NC/Division
Primary Contact Phone Number (required)	Kyla Retzer, 907-229-2743	kgz7	7580	NIOSH/WSD
Principal Investigator Phone Number (required)	Kyla Retzer, 907-229-2743	kgz7	7580	NIOSH/WSD

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	Exempted Protocols (All shaded will not apply here)
☒ 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
☐ 0.1252: Review of Changes to Approved Protocol	☐ 0.1252X: Review of Changes to Exempted 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 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 Signed	Remarks
Principal CDC Investigator: Kyla D. Retzer -S (Digitally signed by Kyla D. Retzer -S DN: c=US, o=U.S. Government, ou=HHS, ou=CDC, ou=People, cn=Kyla D. Retzer -S, 0.9.2342.19200300.100.1.1=1000894179 Date: 2015.10.23 09:56:13 -06'00')	10/23/2015	

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 Signed	Remarks
Team Lead: N/A AMM		☐ PI is Team Lead
Branch Official (e.g., Chief or Senior Scientist): N/A AMM		☐ PI is Branch Official
Division Official (e.g., Director or ADS): Max J. Kiefer -S (Digitally signed by Max J. Kiefer -S DN: c=US, o=U.S. Government, ou=HHS, ou=CDC, ou=People, cn=Max J. Kiefer -S, 0.9.2342.19200300.100.1.1=1000874635 Date: 2015.12.01 09:56:59 -07'00')	12/01/2015	☐ 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 Signed	Remarks
/Chair NIOSH IRB-HSRB:	12/11/15	
Other Clearance Official: (e.g., Confidentiality Officer, Coordinating Center/Office Official)		

APPROVED

THIS SECTION FOR CDC/NIOSH IRB-HSRB OFFICE USE ONLY:
Expedited Review ☒; Minimal Risk ☒; as provided for in 45CFR46.110.
(b) (1) category(s) 2
Approved Review ☒ for one year; **Renewal Date:** 12-11-16
CDC 0.1250 cites Estimated Subject # is _____ Subject # to Date is _____
Approved/Amended Subject # is _____
COMMENTS: _____
Full/Convened Board Review Approved ☐ Meeting Date Approval: _____

5 Additional Comments

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
12/1/15e

Request for Initial Review by an Institutional Review Board

Use this form to submit a protocol for its first review by a CDC IRB or a non-CDC IRB. If seeking review by a non-CDC IRB, also include form 0.1371. See *HRPO Guide: IRB Review Cycle* for further details on how to complete this form.

1 Protocol identifiers

Leave protocol ID ~~blank if not yet assigned.~~ HSRB

CDC protocol ID: 15-WSD-01XP

Protocol version number 2, version date ~~October 14, 2015~~ 11/20/2015

Protocol title: Assessing Safety and Health Hazards for Oil and Gas Extraction Workers

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

oil and gas extraction

worker safety and health

2 Key CDC personnel

	Name and degrees (FirstName LastName, Degrees)	User ID	SEV #	CDC NC/division
Primary contact (required)	Kyla Retzer, MPH	kgz7	7580	NIOSH WSD
Principal investigator (required)	Kyla Retzer, MPH	kgz7	7580	NIOSH WSD
Investigator 2	Christa Hale, DVM, MPH	hgk5	8048	NIOSH WSD
AMM Investigator 3	Sophia Ridl (SJABSolutions) on-site Contractor		12493	
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 (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. See *HRPO Guide: CDC's Research Partners* for further details. Check one of the following.

☒ No research partners.

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

5 Study participants—planned demographic frequencies

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

Number of participants	500
Location of participants	
Participating at domestic sites	500
Participating at foreign sites	0
Sex/Gender of participants	
Female	25
Male	475
Sex/gender not available	0
Ethnicity of participants	
Hispanic or Latino	100
Not Hispanic or Latino	400
Ethnicity not available	0
Race of participants	
American Indian or Alaska Native	25
Asian	10
Black or African American	30
Native Hawaiian or Other Pacific Islander	0
White	410
More than one race	25
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]

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 (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

- ☐ Not eligible for expedited review. For example, poses greater than minimal risk; 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):

- ☐ 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

Characterize the intention to include each of the following vulnerable populations. Choose one option in each row, and indicate the page(s) where inclusion or exclusion is justified in the protocol.

	Targeted	Allowed	Excluded	NA	Page(s)
Pregnant women or fetuses	☐	☐	☒	☐	16
Children (including viable neonates)	☐	☐	☒	☐	16
Prisoners	☐	☐	☐	☒	

Describe other groups of potentially vulnerable subjects intended to be included or excluded, such as neonates of uncertain viability or nonviable neonates, persons with mental disabilities, or persons with economic or educational disadvantages.

6.3 Free and informed consent

Characterize requested changes to required features of the informed consent process. If a waiver is requested, enter the page number of the protocol where the waiver is justified.

Which exceptions to the consent process are requested? Check all that apply:

☐ Waiver or alteration of elements of informed consent for adults pg _____

☐ Waiver of assent for children capable of providing assent pg _____

☐ Waiver of parental permission pg _____

Which exceptions to documentation of informed consent are requested? Check all that apply:

- ☒ Waiver of documentation of informed consent for adults — pg 16-17
- ☐ Waiver of documentation of assent for children capable of providing assent — pg
- ☐ Waiver of documentation of parental permission — pg
- ☐ Waiver or alteration of authorization under HIPAA Privacy Rule — pg

How is it shown that the consent process is in understandable language? Check all that apply:

- ☒ Reading level has been estimated — pg 16
- ☐ Comprehension tool is provided — pg
- ☐ Short form is provided — pg
- ☐ Translation planned or performed
  - ☐ Certified translation/translator — pg
  - ☐ Translation and back-translation to/from target language(s) — pg
  - ☐ Other method (specify:) — pg

6.4 Other regulation and policy considerations

Check all that apply.

If requesting the exception to the PHS policy on informing those tested about HIV serostatus, enter the page number of the protocol where the waiver is justified.

- ☐ Exception is request to PHS informing those tested about HIV serostatus. — pg
- ☐ Human genetic testing is planned now or in the future.
- ☐ This study includes a registrable clinical trial.
- ☐ This study involves long-term storage of identifiable biological specimens.
- ☐ This study involves a drug, biologic, or device.

  See HRPO Worksheet to Determine FDA Regulatory Coverage for guidance on whether or not FDA regulations apply.

- ☐ This study will be conducted under an Investigational New Drug (IND) exemption or Investigational Device Exemption (IDE).

  IND/IDE number(s):

6.5 Confidentiality protections

If at least one research site is within the US, then check either Granted, Pending, or No in each row. If no sites are within the US, then check NA in each row.

	Granted	Pending	No	NA
Certificate of Confidentiality (301(d))	☐	☐	☒	☐
Assurance of Confidentiality (308(d))	☐	☐	☒	☐

Describe any other formal confidentiality protections that are planned or are in place: