DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Memorandum

Date November 15, 2023

From Suzanne E. Tomasi, DVM, MPH, DACVPM
IRB Reviewer, NIOSH Institutional Review Board

Subject IRB Approval of New NIOSH Protocol 23-NIOSH-04, "Assessing Fatigue and Fatigue Management in U.S. Onshore Oil and Gas Extraction" (Expedited)

To Alejandra Ramirez-Cardenas, MPH
Project Officer, NIOSH/WSD

The NIOSH IRB reviewed the new protocol 23-NIOSH-04, "Assessing Fatigue and Fatigue Management in U.S. Onshore Oil and Gas Extraction." The IRB determined the study poses minimal risk to subjects. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), category (4) and (7). Continued review is not required for this protocol since it is eligible for expedited review.

The request for waiver of documentation of informed consent is granted per 45 C.F.R. 46.117 (c)(1).

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.

The subjects must have attained the legal age for consent to procedures involved in the research, under the applicable law of the jurisdiction(s) in which the research will be conducted.

If other institutions involved in this protocol are being awarded NIOSH funds through the CDC Procurement and Grants Office (PGO), you are required to send a copy of this IRB approval to the CDC PGO award specialist handling the award. You are also required to verify with the award specialist that the awardee has provided PGO with the required documentation and has approval to begin or continue research involving human subjects as described in this protocol.

Investigators are required to report incidents to the HRPP in accordance with CDC/NIOSH policy and procedure. 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 (513) 533-8591 or e-mail: NIOSH IRB Mailbox.

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. See *HRPO Guide: Non-Exempt Review Cycle* for further details on how to complete this form.

1 Protocol identifiers

Leave protocol ID blank if not yet assigned.

CDC protocol ID: 23-NIOSH-04 Protocol version number 1 Version date 11/14/2023

Protocol title: Assessing Fatigue and Fatigue Management in U.S. Onshore Oil and Gas Extraction

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

Oil and Gas Industry	Actigraphy	
Fatigue	Sleep	

2 Key CDC personnel

	Name and degrees (FirstName LastName, Degrees)	User ID	CITI Course Expiration Date	CDC CIO/Division
Primary Contact (required)	Alejandra Ramirez-Cardenas. MPH	nxa5	06/27/2026	NIOSH/WSD
Principal Investigator (required)	Alejandra Ramirez-Cardenas. MPH	nxa5	06/27/2026	NIOSH/WSD
Co-Investigator	Imelda Wong, PhD	kwn0	05/29/2025	NIOSH/DSI
Co-Investigator	Kenneth Scott, PhD	snx4	10/28/2024	NIOSH/WSD
Co-Investigator	David Caruso	ake3	01/21/2025	NIOSH/WSD
Co-Investigator	Kaitlin Wingate, MPH	ofm8	07/18/2026	NIOSH/WSD

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 or staff engaged in the conduct of the research, if any (name and degrees, user ID, CITI Course Expiration Date, CDC CIO/division):

Cammie Menendez fxf8 9/10/2024 NIOSH-DSR
Ryan Hill MPH gii9 1/17/2025 NIOSH-WSD
Bradley King PhD bfk2 12/12/2024 NIOSH-WSD
Kendra Broadwater xgh1 1/10/2026 NIOSH-WSD
Barbara Alexander PhD vot3 4/13/2023 NIOSH-DFSE
Christa Hale hgk5 2/11/2025 NIOSH-WSD
John Snawder PhD jts5 7/11/2025 NIOSH-WSD
Eric Esswein PhD eje1 6/24/2025 NIOSH-WSD

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.

***NOTE: If both options above are checked "NO" this does not meet the requirement for reliance on a Non-CDC IRB**

☐ 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 Study Subjects

Report estimated counts (rather than percentages). Include study subjects at domestic and foreign sites.

Total count of study subjects: 90

Comments on demographics: The convenience samples will include OGE workers, field-level supervisors, senior H&S leadership, and scientific researchers who are SMEs in occupational fatigue. OGE workers are predominantly males ages 18 and older. The sample is expected to be similar to the workforce as a whole, which is predominantly non-Hispanic white with Hispanic workers being the second largest racial/ethnic group. OGE work is concentrated where there are shale formations across the U.S.

5 Regulation and policy

5.1 Suggested 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: _____

Federal-wide assurance number: _____

Suggested level of risk to subjects (check one):

☒ Minimal

☐ Greater than minimal

Suggested level of IRB review (check one):

☒ 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, non-pregnant 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

5.2 Additional Considerations

Indicate the extent to which the following populations will be included in the research. 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	☐	☐	☒	☐	41
Prisoners	☐	☐	☐	☒	
Children (including viable neonates)	☐	☐	☐	☒	

Describe other groups of potentially vulnerable subjects intended to be included or excluded, such as individuals with impaired decision making capacity and economically or educationally disadvantaged individuals

5.3 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 43
- ☐ 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 47
- ☒ Comprehension tool is provided pg 60
- ☐ Short form is provided pg
- ☒ Translation planned or performed
  - ☒ Certified translation/translator pg n/a
  - ☐ Translation and back-translation to/from target language(s) pg
  - ☐ Other method (specify:) pg

5.4 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. pg ____

☐ Exception is request to PHS informing those tested about HIV serostatus.

☐ Human genetic testing is planned now or in the future.

☐ This study is 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):

5.5 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. Indicate one of the following:

☐ Not applicable

☒ Certificate of Confidentiality maybe applicable to study; pg 77 of the protocol where the protections are described.

Additional Comments:

5.6 Clinical Trial

Is this a clinical trial? ☐ Yes ☒ No

Clinical trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Please answer the following questions. If the answers to the 4 questions are yes, the study meets the definition of a clinical trial.

☐ y ☐ n Does the study involve human participants?
☐ y ☐ n Are the participants prospectively assigned to an intervention?
☐ y ☐ n Is the study designed to evaluate the effect of the intervention on the participants?
☐ y ☐ n Is the effect being evaluated a health-related biomedical or behavioral outcome?

Studies intended solely to refine measures are not considered clinical trials.
Studies that involve secondary research with biological specimens or health information are not clinical trials.

6 *Material submitted with this form*

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

☒ Complete protocol

☒ Peer reviewers' comments or division waiver (NIOSH)

☒ 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

7 Additional comments

All materials included in the appendeces of the protocol.

8 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: University of Colorado, School of Public Health
Institution location: Denver, CO
Individual name (IIA only): Natalie Schwatka, Karely Villareal Hernandez
Reporting status: Initial Report
Regulatory coverage: Engaged/Non-Exempt
Financial support: Other Funding
Support award number:
Support end date:
Non-financial support: [Enter Status Here]
FWA number:
HS Training (IIA only): [Enter Status Here]
IRB review status: Relying on CDC IRB
IRB approval expiration date:
Comments: Fully executed NIOSH IRB Authorization Agreement 1372Ac 9/27/2023

Partner 2

Institution name: Emeritus Health and Safety LLC
Institution location: Denver, CO
Individual name (IIA only): Eric Esswein
Reporting status: Initial Report
Regulatory coverage: Engaged/Non-Exempt
Financial support: Contract/Sub-Contract
Support award number:
Support end date:
Non-financial support: [Enter Status Here]
FWA number:
HS Training (IIA only): CITI Human Subject Training-Y
IRB review status: Relying on CDC IRB
IRB approval expiration date:
Comments: Individual Investigator Agreement fully executed 8/30/2023

Partner 3

Institution name: Synergy America
Institution location:
Individual name (IIA only): John Snawder, Katilin Wingate
Reporting status: Initial Report
Regulatory coverage: [Enter Status Here]
Financial support: Contract/Sub-Contract
Support award number:
Support end date:
Non-financial support: [Enter Status Here]
FWA number:
HS Training (IIA only): CITI Human Subject Training-Y
IRB review status: Relying on CDC IRB
IRB approval expiration date:
Comments: 1372Ac fully executed 5/9/2023

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:
Non-financial support: Other Tangible Support
FWA number:
HS Training (IIA only): [Enter Status Here]
IRB review status: [Enter Status Here]
IRB approval expiration date:
Comments:

9 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: Alejandra Ramirez-cardenas -S Digitally signed by Alejandra Ramirez-cardenas -S Date: 2023.11.14 13:47:13 -07'00'	02/08/2023	

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:		Check if PI is Team Lead: ☐
Branch Official (e.g., Chief or Senior Scientist):		Check if PI is Branch Official: ☐
Division Official (e.g., Director or ADS): Rebecca Guerin -S Digitally signed by Rebecca Guerin -S Date: 2023.11.14 16:18:18 -05'00'	11/14/2023	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	Date	Remarks
National Center Human Subjects Contact:		
Other Clearance Official: (e.g., Confidentiality Officer, Coordinating Center/Office Official)		