DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Memorandum

Date May 13, 2022

From Kathleen MacMahon, DVM, MS
IRB Reviewer, NIOSH Institutional Review Board

Jennifer M. Lincoln, PhD, CSP
Co-Chair, NIOSH Institutional Review Board

Subject IRB Approval of New NIOSH Protocol 22-NIOSH-01, "Evaluating an Intervention Designed to Reduce Fatigue among Taxi Drivers" (Expedited)

To Cammie Chaumont Menendez, PhD, MPH, MS
Project Officer, NIOSH/DSR

The NIOSH IRB reviewed the request for approval of new protocol 22-NIOSH-01, "Evaluating an Intervention Designed to Reduce Fatigue among Taxi Drivers." 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), categories (4) and (7). This protocol has been approved by the IRB. Continued review is not required for this protocol since it is eligible for expedited review. Please note that the protocol does not include in-person interaction. Should the investigator seek to initiate any in-person interaction with subjects, the investigator should contact the DLO Associate Director for Science for COVID-19 requirements.

The IRB found the additional protections required by Subpart B are in place for pregnant women, human fetuses and neonates involved in the research.

COLLABORATOR SITE RESTRICTION: NIOSH study activities may not begin with the following collaborators/sites until documentation indicating current IRB approval or IRB Authorization Agreement has been received by the NIOSH Human Research Protection Program (HRPP) and the PI has been notified by the HRPP this restriction has been lifted and study activities may begin:

Washington State University (WSU)

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.

This study is a clinical trial. Please post the consent form on Regulations.gov after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol. 45 C.F.R. 46.116(h).

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 at (513) 533-8591 or by 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: 22-NIOSH-01 Protocol version number 1.0 Version date 03/16/2022

Protocol title: Evaluating an Intervention Designed to Reduce Fatigue among Taxi/Rideshare Drivers

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

Fatigue	Intervention	Safety
Motor Vehicle	Training	Actigraph

2 Key CDC personnel

	Name and degrees (FirstName LastName, Degrees)	User ID	CITI Course Expiration Date	CDC CIO/Division
Primary Contact (required)	Cammie Chaumont Menendez	fxf8	09/09/2024	NIOSH/DSR
Principal Investigator (required)	Cammie Chaumont Menendez	fxf8	09/09/2024	NIOSH/DSR
Co-Investigator	Christina Socias-Morales	wzo4	12/03/2024	NIOSH/DSR
Co-Investigator				
Co-Investigator				
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 or staff engaged in the conduct of the research, if any (name and degrees, user ID, CITI Course Expiration Date, CDC CIO/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.

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: 180

Comments on demographics: Mostly men, 30% Black, about half are foreign-born, see "study population"

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	☐	☒	☐	☐	36
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
- ☐ 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 39-40
- ☐ 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

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 58 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

External Peer Reviews - Laura Barger, PhD (Sleep Health and Performance Training Expert), Erin Flynn-Evans, PhD (Sleep Science expert). See Appendix for External Peer Review Comments and Responses.

Partners to be assigned after contract award.

Continued from 5.3 - §46.116(a)(4): the estimated time that would be required, the compensation for their time, and how the information they provide will be protected and who will have access to it. The information about the study has been summarized into a PowerPoint presentation that the prospective participant can watch or review while the

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: Flywheel
Institution location: San Francisco, CA
Individual name (IIA only): Hansu Kim
Reporting status: Initial Report
Regulatory coverage: Not Engaged
Financial support: No Financial Support
Support award number:
Support end date:
Non-financial support: No Financial Support
FWA number:
HS Training (IIA only): [Enter Status Here]
IRB review status: Not Applicable
IRB approval expiration date:
Comments: Not engaged in Human Subjects research. DCMorris 5/13/2022

Partner 2

Institution name: West Virginia University
Institution location: Morgantown, West Virginia
Individual name (IIA only): Robert Stansbury
Reporting status: Initial Report
Regulatory coverage: Not Engaged
Financial support: No Financial Support
Support award number:
Support end date:
Non-financial support: No Financial Support
FWA number:
HS Training (IIA only): [Enter Status Here]
IRB review status: Not Applicable
IRB approval expiration date:
Comments: Not engaged in Human Subjects research. DCMorris 5/13/2022

Partner 3

Institution name: Washington State University
Institution location: Spokane, Washington
Individual name (IIA only): Steve James, Lois James
Reporting status: Initial Report
Regulatory coverage: Engaged/Non-Exempt
Financial support: Contract/Sub-Contract
Support award number: 75D30121C11954
Support end date: 75D30121C11954
Non-financial support: Identifiable Private Information
FWA number: 00002946
HS Training (IIA only): [Enter Status Here]
IRB review status: Relying on CDC IRB
IRB approval expiration date:
Comments: Engaged in Human Subjects research. Waiting for signed IAA from WSU. DCMorris 5/13/2022

Partner 4

Institution name: San Francisco Municipal Transportation Agency
Institution location: San Francisco, California
Individual name (IIA only): Kate Toran
Reporting status: Initial Report
Regulatory coverage: Not Engaged
Financial support: No Financial Support
Support award number:
Support end date:
Non-financial support: No Financial Support
FWA number:
HS Training (IIA only): [Enter Status Here]
IRB review status: Not Applicable
IRB approval expiration date:
Comments: Not engaged in Human Subjects research. DCMorris 5/13/2022

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: Cammie K. Chaumont Menendez -S Digitally signed by Cammie K. Chaumont Menendez -S Date: 2022.03.16 15:28:27 -04'00'	03/16/2022	

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): James W. Collins -S Digitally signed by James W. Collins -S Date: 2022.05.02 16:34:44 -04'00'	05/02/2022	Check if PI is Branch Official: ☐
Division Official (e.g., Director or ADS): Christine R. Schuler -S Digitally signed by Christine R. Schuler -S Date: 2022.05.03 09:49:41 -04'00'		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)		