DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Memorandum

Date October 25, 2018

From William G. Lindsley
Lead Reviewer, NIOSH Institutional Review Board

Subject IRB Approval of New NIOSH Protocol 18-DART-03XP, "Online training for law enforcement to reduce risks associated with shift work and long work hours" (Expedited)

To Claire C. Caruso
Project Officer, NIOSH/DART

The NIOSH IRB reviewed the request for approval of new protocol 18-DART-03XP, "Online training for law enforcement to reduce risks associated with shift work and long work hours" and approved the protocol for the maximum allowable period of one year. NIOSH IRB approval will expire on October 25, 2019. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), categories (4) and (7).

The IRB determined the study poses minimal risk to subjects.

COLLABORATOR SITE RESTRICTION: NIOSH study activities may not begin with the following collaborator/site until documentation indicating current IRB approval or an IRB Authorization Agreement to rely on the CDC/NIOSH IRB 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)

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.

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 October 25, 2019.**

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 (513) 533-8591 or e-mail: cin-hsrb@cdc.gov.

Signature Page for Human Research Review

Protocols and Related Documentation

Anniversary Date: 10/25/2019

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.

1 Protocol Identifiers

CAN#: 927ZLGC (optional)

Leave protocol ID blank if not yet assigned.

CDC Protocol ID: 18-DART-03XP Protocol Version Number: 2 Version Date: 10/11/2018

Protocol Title:

Online training for law enforcement to reduce risks associated with shift work and long work hours

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)	Caruso, Claire C (513) 533-8535	zhl1	3569	NIOSH, DART
Principal Investigator Phone Number (required)	Caruso, Claire C (513) 533-8535	zhl1	3569	NIOSH, DART

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

- [x] 0.1250: Initial Review by IRB
- [ ] 0.1251: Continuing Review of Approved 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
- [ ] 0.1370: 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

Exempted Protocols

- [ ] 0.1250X: Initial Review for Exemption
- [ ] 0.1251X: Continuing Review of Exempted Protocol
- [ ] 0.1252X: Review of Changes to Exempted Protocol
- [ ] 0.1253: End of Human Research Review
- [ ] 0.1370: CDC's Research Partners

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: Claire C. Caruso -S Digitally signed by Claire C. Caruso -S Date: 2018.10.11 18:06:07 -04'00'	10/11/2018	

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: Naomi G. Swanson -S Digitally signed by Naomi G. Swanson -S Date: 2018.10.12 08:58:07 -04'00'	10/12/2018	☐ PI is Team Lead
Branch Official (e.g., Chief or Senior Scientist): Naomi G. Swanson -S Digitally signed by Naomi G. Swanson -S Date: 2018.10.12 08:58:38 -04'00'	10/12/2018	☐ PI is Branch Official
Division Official (e.g., Director or ADS): Jennifer L. Topmiller -S Digitally signed by Jennifer L. Topmiller -S Date: 2018.10.15 10:56:16 -04'00'	10/15/2018	☐ 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
For IRB Lead Reviewer William Lindsley /Chair NIOSH IRB: Diane C. Morris -S Digitally signed by Diane C. Morris -S Date: 2018.10.25 11:44:04 -04'00'	10/25/2018	
Other Clearance Official: (e.g., Confidentiality Officer, Coordinating Center/Office Official)		

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.

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.

CDC protocol ID: 18-DART-03XP Protocol version number _____ version date _____

Protocol title: _____

Online training for law enforcement to reduce risks associated with shift work and long work hours

2 Key CDC personnel

	Name and degrees (FirstName LastName, Degrees)	User ID	SEV #	CDC NC/division
Primary contact (required)	Caruso, Claire C PhD	zhl1	3569	NIOSH DART
Principal investigator (required)	Caruso, Claire C PhD	zhl1	3569	NIOSH DART
Investigator 2	Tara (Williams) Hartley	tow9	12081	NIOSH OD
Investigator 3	Hope Tiesman	fto9	15028	NIOSH DSR
Investigator 4	Dan Hartley	dsh3	17813	NIOSH DSR
Investigator 5				NIOSH

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	100
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	
Not Hispanic or Latino	
Ethnicity not available	
Race of participants	
American Indian or Alaska Native	
Asian	
Black or African American	
Native Hawaiian or Other Pacific Islander	
White	
More than one race	
Race not available	

Comments on demographics

This is a new project so no participants have been recruited.

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	☐	☐	☒	☐	_____
Children (including viable neonates)	☐	☐	☒	☐	_____
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 _____
- ☐ 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 19
- ☐ Comprehension tool is provided — pg _____
- ☒ Short form is provided — pg 51
- ☐ 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:

_____

7 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

8 Additional comments

This project will need OMB approval before data collection begins. WSU partners said their IRB will rely on CDC NIOSH IRB.

The pilot study will not collect personally identifiable data. Participants will created their own study identification number and put it on all their surveys and actigraph files. Participants will not share that number with NIOSH and WSU partners.

This Small NORA project has additional funding for FY19 and FY20. We plan to process contracts for FY19 to FY20 with this Washington State University partner, Dr. Lois James.

CDC's Research Partners

Use this form to report current information on CDC's research partners whenever a partner institution or individual is added or information changes. Supply individual name and SEV number only for investigators collaborating with CDC under an individual investigator agreement (IIA). See *HRPO Guide: CDC's Research Partners* and either the *HRPO Worksheet for Basic Tracking of Research Partners* or the *HRPO Worksheet for Advanced Tracking of Research Partners* for details on how to complete this form.

Leave protocol ID blank if not yet assigned.

CDC protocol ID: 18-DART-03XP Protocol version number _____ version date _____

Protocol title: Online training for law enforcement to reduce risks associated with shift work and long work hours

Partner 1 Washington State University (WSU)	**Partner 2**
Institution name: _____ Institution location: Spokane, WA Individual name (IIA only): Lois James PhD Reporting status: Initial report Regulatory coverage: Engaged/exempt Financial support: Contract/subcontract Support award number: PO # 75D30118P01746 Support end date: 12/31/2019 Nonfinancial support: FWA number: 00002946 SEV number (IIA only): 10742999 IRB review status: Relying on CDC IRB IRB approval expiration date: _____ Comments: 1372A sent to PI for WSU signatory to sign 10/19/2018. DCMorris	Institution name: _____ Institution location: _____ Individual name (IIA only): Reporting status: _____ Regulatory coverage: Financial support: _____ Support award number: _____ Support end date: _____ Nonfinancial support: FWA number: _____ SEV number (IIA only): _____ IRB review status: IRB approval expiration date: _____ Comments: _____
Partner 3	**Partner 4**
Institution name: _____ Institution location: _____ Individual name (IIA only): _____ Reporting status: Regulatory coverage: Financial support: Support award number: _____ Support end date: _____ Nonfinancial support: FWA number: _____ SEV number (IIA only): IRB review status: IRB approval expiration date: _____ Comments: _____	Institution name: _____ Institution location: _____ Individual name (IIA only): Reporting status: Regulatory coverage: Financial support: Support award number: _____ Support end date: Nonfinancial support: _____ FWA number: _____ SEV number (IIA only): _____ IRB review status: IRB approval expiration date: _____ Comments: _____

Partner 5	Partner 6
Institution name: _____ Institution location: _____ Individual name (IIA only): Reporting status: Regulatory coverage: Financial support: Support award number: _____ Support end date: _____ Nonfinancial support: FWA number: _____ SEV number (IIA only): _____ IRB review status: IRB approval expiration date: _____ Comments: _____	Institution name: _____ Institution location: _____ Individual name (IIA only): Reporting status: Regulatory coverage: Financial support: Support award number: _____ Support end date: ___ Nonfinancial support: FWA number: _____ SEV number (IIA only): _____ IRB review status: IRB approval expiration date: _____ Comments: _____
Partner 7	**Partner 8**
Institution name: _____ Institution location: _____ Individual name (IIA only): _____ Reporting status: Regulatory coverage: Financial support: Support award number: _____ Support end date: _____ Nonfinancial support: FWA number: _____ SEV number (IIA only): _____ IRB review status: IRB approval expiration date: _____ Comments: _____	Institution name: _____ Institution location: _____ Individual name (IIA only): _____ Reporting status: Regulatory coverage: Financial support: Support award number: _____ Support end date: _____ Nonfinancial support: FWA number: _____ SEV number (IIA only): IRB review status: IRB approval expiration date: _____ Comments: _____
Partner 9	**Partner 10**
Institution name: _____ Institution location: _____ Individual name (IIA only): Reporting status: Regulatory coverage: Financial support: Support award number: _____ Support end date: ___ Nonfinancial support: FWA number: _____ SEV number (IIA only): _____ IRB review status: IRB approval expiration date: _____ Comments: _____	Institution name: _____ Institution location: _____ Individual name (IIA only): Reporting status: Regulatory coverage: Financial support: Support award number: _____ Support end date: ___ Nonfinancial support: FWA number: _____ SEV number (IIA only): _____ IRB review status: IRB approval expiration date: _____ Comments: _____