



Memorandum

Date May 21, 2018

From Gail L. McConnell
Co-Chair, NIOSH Institutional Review Board

Subject IRB Approval of New NIOSH Protocol 18-DSR-01XP, “Surveillance of Nonfatal Injuries Among Law Enforcement Officers” (Expedited)

To Hope M. Tiesman
Project Officer, NIOSH/DSR

The NIOSH IRB reviewed the request for approval of new protocol 18-DSR-01XP, “Surveillance of Nonfatal Injuries Among Law Enforcement Officers” and approved the protocol for the maximum allowable period of one year. NIOSH IRB approval will expire on May 21, 2019. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), category (7).

The IRB determined the study poses minimal risk to subjects.

A waiver of documentation of informed consent is granted per 45 CFR 46.117 (c) (2).

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:

US Consumer Product Safety Commission (CPSC)

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 May 21, 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-hsrp@cdc.gov.



Signature Page for Human Research Review

Protocols and Related Documentation

Anniversary Date: 05/21/2019

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#: 893909S2 (optional)

Leave protocol ID blank if not yet assigned.

CDC Protocol ID: 18-DSR-01XP + Protocol Version Number: 1 Version Date: 03/16/2018

Protocol Title:

Surveillance of Nonfatal Injuries Among Law Enforcement Officers

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)	<u>Hope M Tiesman PhD</u> <u>(304) 285-6067</u>	<u>fto9</u>	<u>15028</u>	<u>NIOSH.DSR</u>
Principal Investigator Phone Number (required)	<u>Hope M Tiesman</u> <u>(304) 285-6067</u>	<u>fto9</u>	<u>15028</u>	<u>NIOSH.DSR</u>

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

- 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: Hope M. Tiesman -S Digitally signed by Hope M. Tiesman -S Date: 2018.03.12 13:35:16 -04'00'	<u>03/12/2018</u>	

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:	_____	<input type="checkbox"/> PI is Team Lead

Branch Official (e.g., Chief or Senior Scientist): James W. Collins -S Digitally signed by James W. Collins -S Date: 2018.03.14 11:26:11 -04'00'	<u>03/14/2018</u>	<input type="checkbox"/> PI is Branch Official
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Division Official (e.g., Director or ADS): Christine R. Schuler -S Digitally signed by Christine R. Schuler -S Date: 2018.03.16 13:19:53 -04'00'	<u>03/16/2018</u>	<input type="checkbox"/> PI is Division Official
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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 Co-Chair Gail McConnell /Chair NIOSH IRB: Diane C. Morris -S Digitally signed by Diane C. Morris -S Date: 2018.05.21 09:27:21 -04'00'	<u>05/21/2018</u>	
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-DSR-01XP



Protocol version number 1 version date 03/16

Protocol title: _____

Surveillance of Nonfatal Injuries Among Law Enforcement Officers

2 Key CDC personnel

	Name and degrees (FirstName LastName, Degrees)	User ID	SEV #	CDC NC/division
Primary contact (required)	<u>Hope Tiesman PhD</u>	<u>fto9</u>	<u>15028</u>	<u>NIOSH DSR</u>
Principal investigator (required)	<u>Hope Tiesman PhD</u>	<u>fto9</u>	<u>15028</u>	<u>NIOSH DSR</u>
Investigator 2	<u>Suzanne Marsh MPA</u>	<u>smm2</u>	<u>10690</u>	<u>NIOSH DSR</u>
Investigator 3	<u>Audrey Reichard, MPH</u>	<u>akr5</u>	<u>8049</u>	<u>NIOSH DSR</u>
Investigator 4	_____	_____	_____	<u>NIOSH</u>
Investigator 5	_____	_____	_____	<u>NIOSH</u>

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	_____	990
Location of participants		
Participating at domestic sites	_____	990
Participating at foreign sites	_____	
Sex/Gender of participants		
Female	_____	
Male	_____	0
Sex/gender not available	_____	990
Ethnicity of participants		
Hispanic or Latino	_____	
Not Hispanic or Latino	_____	
Ethnicity not available	_____	990
Race of participants		
American Indian or Alaska Nativ	_____	
Asian	_____	
Black or African American	_____	
Native Hawaiian or Other Pacific Islander	_____	
White	_____	
More than one race	_____	
Race not available	_____	990

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	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Children (including viable neonates)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	_____
Prisoners	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	_____

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
- 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))	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Assurance of Confidentiality (308(d))	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

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**



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-DSR-01XP

Protocol version number 1 version date 03/16/2018

Protocol title: Surveillance of Nonfatal Injuries Among Law Enforcement Officers

<p>Partner 1 Consumer Product Safety Commission</p> <p>Institution name: _____ Institution location: <u>Bethesda, MD</u> Individual name (IIA only): _____ Reporting status: <u>Initial report</u> Regulatory coverage: <u>Engaged/exempt</u> Financial support: <u>Other funding</u> Support award number: <u>interagency agreement</u> Support end date: <u>ongoing</u> Nonfinancial support: <u>No financial support</u> FWA number: _____ SEV number (IIA only): _____ IRB review status: <u>Relying on CDC IRB</u> IRB approval expiration date: _____ Comments: <u>1372A sent for approval 5/15/2018. DC Morris</u></p>	<p>Partner 2 Police Foundation</p> <p>Institution name: _____ Institution location: <u>Washington, DC</u> Individual name (IIA only): _____ Reporting status: <u>Initial report</u> Regulatory coverage: <u>Engaged/exempt</u> Financial support: <u>No financial support</u> Support award number: _____ Support end date: _____ Nonfinancial support: _____ FWA number: _____ SEV number (IIA only): _____ IRB review status: <u>Relying on CDC IRB</u> IRB approval expiration date: _____ Comments: <u>Engaged (support) research not involving human subjects. DCMorris</u></p>
<p>Partner 3 National Institute of Justice</p> <p>Institution name: _____ Institution location: <u>Washington, DC</u> Individual name (IIA only): _____ Reporting status: <u>Initial report</u> Regulatory coverage: <u>Engaged/exempt</u> Financial support: <u>Other funding</u> Support award number: <u>interagency agreement</u> Support end date: <u>9/30/2021</u> Nonfinancial support: _____ FWA number: _____ SEV number (IIA only): _____ IRB review status: <u>Relying on CDC IRB</u> IRB approval expiration date: _____ Comments: <u>Not engaged. DCMorris</u></p>	<p>Partner 4 University of Texas</p> <p>Institution name: _____ Institution location: <u>El Paso, Texas</u> Individual name (IIA only): _____ Reporting status: <u>Initial report</u> Regulatory coverage: <u>Engaged/exempt</u> Financial support: _____ Support award number: _____ Support end date: _____ Nonfinancial support: <u>No financial support</u> FWA number: _____ SEV number (IIA only): _____ IRB review status: <u>Relying on CDC IRB</u> IRB approval expiration date: _____ Comments: <u>Not engaged. DCMorris</u></p>

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