DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Memorandum

Date December 7, 2020

From Kathy Masterson
IRB Administrator, NIOSH Institutional Review Board

Subject IRB Approval of Continuation of NIOSH Protocol 17-DSR-05XP, "Assessment of Occupational Injury among Fire Fighters Using a Follow-back Survey" (Expedited)

To Suzanne Marsh, MPA
Project Officer, DSR, NIOSH

The NIOSH IRB has reviewed and approved your request to continue protocol 17-DSR-05XP for the maximum allowable period of one year and it will expire on December 14, 2021. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), Categories (4), (5), and (7).

The IRB determined the study poses no more than minimal risk to subjects.

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

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 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 December 14, 2021.**

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 CDC Human Research Protection Program (513) 533-8591 or e-mail: cin-hsrb@cdc.gov.

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Memorandum

Date December 7, 2020

From Kathy Masterson
IRB Administrator, NIOSH Institutional Review Board

Subject IRB Approval of Amendment to NIOSH Protocol 17-DSR-05XP, "Assessment of Occupational Injury among Fire Fighters Using a Follow-back Survey" (Expedited)

To Suzanne Marsh, MPA
Project Officer, DSR, NIOSH

The NIOSH IRB reviewed and approved your request to amend protocol 17-DSR-05XP, "Assessment of Occupational Injury among Fire Fighters Using a Follow-back Survey":

I. Remove investigator Butler (title page and page 4);
II. Changes in investigator summaries (page 4);
III. Change in data analysis to a case series.

The action was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), Categories (4), (5) and (7).

Reminder: IRB approval of protocol # 17-DSR-05XP will still expire on December 14, 2021.

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 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

Use this 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.

1 Protocol identifiers

Leave protocol ID blank if not yet assigned.

CDC protocol ID: 17-DSR-05XP Protocol version number _____ version date _____

Protocol title: Assessment of Occupational Injury among Fire Fighters Using a Follow-back Survey

Amendment number (if applicable): 2

2 Key CDC personnel

	Name and degrees (FirstName LastName, Degrees)	User ID	CITI Course Expiration Date	CDC CIO/Division
Primary contact (required)	Suzanne M Marsh, MPA	smm2	12/20/2021	NIOSH
Principal investigator (required)	Suzanne M Marsh, MPA	smm2	12/20/2021	NIOSH

CITI Course Expiration Date is the latest expiration date for Biomedical Research and RCR Combined **or** Social & Behavioral Research and RCR Combined course required by CDC (expire every 3 years). In addition, all required training must be verified for each Investigator by the lead CIO/Division. CDC CIO/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 page

Check all that apply in the appropriate column.

IRB-reviewed protocols

- ☐ 0.1255: Initial Review by an Institutional Review Board
- ☒ 0.1257: Request for Subsequent Action of IRB Approved Protocol

Exempted protocols

- ☐ 0.1255X: Request for Exemption or Review of Changes

Additional protocol actions

- ☐ 0.1254: Incident Report
- ☐ 0.1254S: Supplemental Adverse Event Report
- ☐ 0.1371: CDC Rely on a Non-CDC IRB
- ☐ 0.1372: Outside Institution Rely on a CDC IRB
- ☐ 0.1370: CDC's Research Partners
- ☐ 0.1260: End of Human Research Review

4 Additional comments

5 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: Suzanne M. Marsh -S Digitally signed by Suzanne M. Marsh -S Date: 2020.11.16 14:34:17 -05'00' Document conflicts of interest, if any, below:		

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): Audrey A. Reichard -S Digitally signed by Audrey A. Reichard -S Date: 2020.11.16 15:33:39 -05'00'		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: 2020.11.18 16:20:09 -05'00'		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)		

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 CIO/Division.

Request for Subsequent Action of IRB-Approved Protocol

Use this form to submit a protocol for continuing review or amendment by a CDC IRB or a non-CDC IRB. [See 45 CFR 46.109(e).] See *HRPO Guide: Non-Exempt Review Cycle* for further details on how to complete this form.

1 Protocol identifiers

CDC protocol ID: 17-DSR-05XP Protocol version number 3 Version date 11/13/2020

Protocol title: Assessment of Occupational Injury among Fire Fighters Using a Follow-back Survey

☒ Continuing Review
☒ Review of changes

☐ *Requesting transition to the 2018 Common Rule *(*Optional)*

Note: This may require changes to the study, including informed consent documents, to comply with the 2018 Common Rule

2 Key CDC personnel

☐ **No change** in key CDC personnel. If no changes, please list only the primary contact and principal investigator.

	Name and degrees (First Name, Last Name, Degrees)	User ID	CITI Course Expiration Date	CDC CIO/Division
Primary contact (required)	Suzanne M Marsh, MPA	smm2	12/20/2021	
Principal investigator (required)	Suzanne M Marsh, MPA	smm2	12/20/2021	
Co-Investigator	Steve Miles	hev2	09/29/2023	
Co-Investigator	Audrey Reichard, MPH, OTR	akr5	12/29/2021	
Co-Investigator				
Co-Investigator				

Notice: *Re-Verify if required CITI training is expired or found expired for any personnel listed on this protocol. Lapse in current training can result in removal from the study or suspension of the study 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 subjects.
☐ y ☒ n CDC employees or agents will obtain or use identifiable (including coded) private data or biospecimens.
☒ y ☐ n CDC employees or agents will obtain or use anonymous or unlinked data or biospecimens.
☒ 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

Have any subjects been enrolled in the last 12 months? ☒ yes ☐ no

Total number of subjects needed for study: 960 Total number of subjects enrolled to date: 60

Comments on sample size: 645 cases have been identified; just over a quarter of these could not be reached due to lack of correct contact info.

4.1 Contact status

Check one of the following.

☐ Study is not designed to involve research-related contact with subjects (e.g., research using existing records); study activities involve only access to or analysis of data or biological specimens and writing reports.

☒ Study is designed to involve contact with subjects. Check one of the following:

- ☐ Contact with subjects has not yet begun.
- ☒ Contact with subjects has begun and continues; this may include follow-up for debriefing or notification of results.
- ☐ Contact with subjects is completed; study activities involve only data analysis or report writing.

4.2 Consent status

"Consent" includes adult consent, child assent, and parental permission. Check one of the following.

☐ The IRB previously waived all requirements to obtain consent in this study.

☐ Although not waived, there is no further need to obtain or document consent (e.g., enrollment is complete).

☒ *Subjects will be asked to provide consent (with or without documentation).

** If you check the third box, please include all current consent, assent, and parental permission materials (e.g., scripts, documents) from each study site with this submission.*

5 Study status—overall conduct *(This section can be skipped for amendments)*

[Comment 5.1] Summary of research activities to date. Briefly summarize study progress and interim findings. Include the number of potential subjects who declined enrollment and the number who withdrew from the study. If this study involves a registrable clinical trial, summarize registration status.

Study was approved by OMB 10/11/18 (No. 0920-1244). Beginning on 10/17/18, potential cases were identified from NEISS-Work and saved in a file. The file included injured firefighters meeting case criteria and treated on or after 9/1/2018, at a participating hospital ED. The file was securely sent to the NIOSH principal investigator who verified which cases likely met the criteria and should be contacted. The Consumer Product Safety Commission (CPSC) continues to identify potential cases from NEISS-Work and request contact information from hospitals. NIOSH continues to review files as they are provided. Cases appearing to meet the criteria are notified by mail and provided "opt out" information (see pre-interview letter). After two-weeks, information for these cases is given to CPSC contracted telephone interviewers. Cases not appearing to meet case criteria are excluded. During 2020, interviews were suspended starting in March while CPSC was on maximal telework due to SARS-COV-2. Once CPSC returned to in-person work early during the summer of 2020, interviews resumed. At this time, cases that occurred during the suspension were retroactively identified and contacted for interview also.

[Comment 5.2] Summary of study changes reviewed and approved since the last continuation. Do not include changes submitted with or before approval of this continuation but not yet approved.

No study changes have been approved since IRB renewal was received in 2019

[Comment 5.3] Summary of any recent literature or other information relevant to the research study (not limited to information with CDC co-authorship).

N/A

[Comment 5.4] Summary of all adverse events to date. In particular, address adverse events that were serious, unexpected (or more frequent or severe than expected), or at least possibly related to the research.

No adverse events related to the research have occurred

[Comment 5.5] Summary of (a) incidents that are not adverse events and (b) other substantial concerns since last continuation.

While no adverse events related to the research have occurred, SARS-COV-2 halted CPSC's ability to identify cases while CPSC staff were on maximal telework and no new cases were identified from March 2020 to early summer 2020. While the interviewers continued interviews from previously identified cases, no additional interviews were conducted until CPSC returned to their office in the summer of 2020. This study is targeting a population of first responders (i.e., firefighters) that have been impacted by additional work from safety precautions and medical responses related to SARS-COV-2. While the response rate was lower than expected previously, the impact of the virus may further negatively affect the survey response rate.

[Comment 5.6] List and include copies of progress or monitoring reports on safety or compliance (e.g., site monitor, safety review, DSM report, multi-center trial report, but not reports to PGO).

N/A

[Comment 5.7] Summary of remaining research activities, emphasizing future contact with subjects, use of identifiable private data and biological specimens, and preparation of primary reports.

Potential respondent selection will continue on a regular basis through mid-2022. NIOSH receives periodic updates on completed interviews. The number of completed responses continues to be lower than expected. Events including the earlier partial government shutdown and government agencies going on maximal telework in 2020 due to SARS-COV-2 halted both case identification and data collection. Once data collection is completed in 2022, NIOSH will complete quality assurance checks and analyses. Final reports are anticipated to be released in 2023 or 2024.

NIOSH never receives the respondent contact information and neither CPSC nor the interviewers will be contacting respondents after a completed interview. Upon completion of the interviews, CPSC will destroy the respondent contact information as prescribed by the study protocol. Any potentially identifiable data collected during the interviews will be maintained confidential data the NIOSH CPSC

6 Regulation and policy

6.1 Vulnerable populations

Check one of the following:

☐ **Change** in vulnerable populations (added or dropped).

☒ **No Change**

6.2 Free and informed consent

Check one of the following:

☐ **Change** in consent process, forms, or approved waivers.

☒ **No Change**

6.3 Other regulation and policy considerations

Check one of the following:

☐ **Change** in other regulation and policy considerations.

- Exception to PHS policy regarding notification of HIV test results
- Human genetic testing
- Inclusion of a registrable clinical trial or change in registration status
- Plans for long-term storage of identifiable biological specimens
- Involvement of drug, biologic, or device, including Investigational New Drug or Investigational Device Exemption status (See *HRPO Worksheet to Determine FDA Regulatory Coverage* for guidance on whether or not FDA regulations apply.)

☒ **No Change**

6.4 Confidentiality protections

Check one of the following:

☐ **Change** in the applicability of Certificates of Confidentiality protections.

☒ **No Change**

7 Summary of proposed changes

Describe and justify proposed modifications to the protocol. Include page numbers in reference to clean copy and marked copy. Continue summary in supplemental document if necessary.

Two broad changes were made to the protocol:

1) There were changes to the project team. One of our NIOSH co-investigators left NIOSH for employment elsewhere. Her information has been removed from the protocol (see pages 1 and 4 in the marked copy and pages 1 and 4 in the clean copy). In addition, changes were made to the summaries for the principal investigator and one of the other co-investigators (see page 4 in the marked and clean copies of the protocol).
2) Considering the lower than expected response rate, the project team decided not to weight the data. The data will be analyzed as a case series and no attempts will be made to generalize the data. The project team will not identify any of the respondents individually and will include only aggregated summaries of the data in any products that are developed based on this research. See proposed modifications to the protocol on pages 6, 7, 9, 10, 12, 14, 15 (marked copy) and pages 6, 7, 9, 10, 12, 13, 14, (clean copy).

8 CDC's research partners

Research partners include *all* direct and indirect recipients of CDC funding (e.g., grants, cooperative agreements, contracts, subcontracts, purchase orders) other CDC support (e.g., identifiable private information, supplies, products, drugs, or other tangible support and collaborators who do not receive such support. Include current information on partners added or dropped since the last review using form 0.1370. Check one of the following:

☒ No research partners have been added since the last review.

☐ Research partners have been added and are listed on form 0.1370, which accompanies this form.

☐ One or more research partners no longer collaborate for this study, and are listed as follows:

9 Material submitted with this form

Check all that apply. Describe additional material in the comments section. Required items are indicated. Optional items may be requested by HRPO or the IRB.

☒ Complete protocol (required if research poses more than minimal risk to subjects, is under IND/IDE, or has changed in the past 12 months) ***Required clean/marked copy for amendment***

☒ Consent, assent, and permission documents or scripts (required if consent will be sought in the future from prospective subjects or their representatives ***Required clean/marked copy for amendment if applicable***

☐ Other information for recruits or participants (e.g., ads, brochures, flyers, scripts; required if consent will be sought in the future from prospective subjects or their representatives) ***Required clean/marked copy for amendment if applicable***

☐ Data collection instruments (e.g., questionnaires, interview scripts, record abstraction tools; required if protocol has changes in the past 12 months) ***Required clean/marked copy for amendment if applicable***

☐ Certification of IRB approval or exemption for research partners (required only for partners being added or for supported/nonexempt partners) ***Required for amendments relying on a non-CDC IRB***

☐ Progress and monitoring reports (recommended when available)

10 Additional comments

11 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. I have also re-verified that the required CITI training has not expired for personnel listed on this protocol.

Signature	Date	Remarks
Principal CDC Investigator: Suzanne M. Marsh -S Digitally signed by Suzanne M. Marsh -S Date: 2020.11.16 14:18:40 -05'00'		

12 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 if this is a new request]

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

For amendments, changes are:

☒ Minor ☐ More than minor

Suggested level of IRB review(check one):

☐ Convened-board review is suggested

Reason for convened review:

☒ 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

Continuing review of research previously approved by the convened IRB where

- ☐ 8a the research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects
- ☐ 8b no subjects have been enrolled and no additional risks have been identified
- ☐ 8c the remaining research activities are limited to data analysis
- ☐ 9 Continuing review of research, not under IND/IDE, where categories 2 through 8 do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified