DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Memorandum

Date September 27, 2017

From Kathy Masterson, CIP
IRB Administrator, NIOSH Institutional Review Board

Subject IRB Approval of Continuation of NIOSH Protocol 11-DSR-02XP, "Workplace Violence Prevention Programs in NJ Healthcare Facilities" (Expedited)

To Marilyn Ridenour, BSN, MBA, MPH, CPH
Project Officer, DSR, NIOSH

The NIOSH IRB has reviewed and approved your request to continue protocol 11-DSR-02XP for the maximum allowable period of one year and it will expire on September 21, 2018. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), Categories (7) and (5).

The IRB determined that 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 September 21, 2018.**

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.

0.1379 Centers for Disease Control and Prevention Date Received:
NIOSH Institutional Review Board 07/28/2017

Signature Page for Human Research Review

Protocols and Related Documentation

Anniversary Date: 09/21/2017

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#: 927ZKFN (optional)

Leave protocol ID blank if not yet assigned.

CDC Protocol ID: 11-DSR-02XP Protocol Version Number: ____ Version Date: _____

Protocol Title:

Workplace Violence Prevention Program in NJ Healthcare Facilities

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)	Marilyn Ridenour, BSN, MPH	dvn7	840	NIOSH/DSR
Principal Investigator Phone Number (required)	Marilyn Ridenour, BSN, MPH	dvn7	840	NIOSH/DSR

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: Marilyn L. Ridenour -S5 Digitally signed by Marilyn L. Ridenour -S5 Date: 2017.07.27 06:48:32 -04'00'	07/27/2017	

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: Marilyn L. Ridenour -S5 Digitally signed by Marilyn L. Ridenour -S5 Date: 2017.07.27 06:47:15 -04'00'	07/27/2017	☒ PI is Team Lead
Branch Official (e.g., Chief or Senior Scientist): James W. Collins -S Digitally signed by James W. Collins -S Date: 2017.07.28 08:51:27 -04'00'	07/28/2017	☐ PI is Branch Official
Division Official (e.g., Director or ADS): Christine R. Schuler -S Digitally signed by Christine R. Schuler -S Date: 2017.07.28 13:43:19 -04'00'	07/28/2017	☐ 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
/Chair NIOSH IRB: Kathy J. Masterson -S Digitally signed by Kathy J. Masterson -S Date: 2017.09.27 12:48:34 -04'00'	09/27/2017	Subject contact continues
Other Clearance Official: (e.g., Confidentiality Officer, Coordinating Center/Office Official)		Approved for IRB Co-Chair, Gail McConnell, VMD, MPH

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 Continuing Review of IRB-Approved Protocol

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

1 Protocol identifiers

CDC protocol ID: 11-DSR-02XP Protocol version number _____ version date _____

Protocol title:

Workplace Violence Prevention Program in NJ Healthcare Facilities

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 (FirstName LastName, Degrees)	User ID	SEV #	CDC NC/division
Primary contact (required)	Marilyn Ridenour, BSN, MPH	dvn7	840	NIOSH/ DSR
Principal investigator (required)	Marilyn Ridenour, BSN, MPH	dvn7	840	NIOSH/ DSR
Investigator 2	Dan Hartley, EdD	dsh3	17813	NIOSH/ DSR
Investigator 3	Scott Hendricks, MS	sah5	12713	NIOSH/ DSR
Investigator 4				NIOSH/
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. Include name and degrees, user ID, SEV #, CDC NC/division:

3 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. On continuing review, HRPO needs current information on partners that have been added or dropped since the last review and partners that, as of the last review, were receiving support for nonexempt research. See *HRPO Guide: CDC's Research Partners* for further details. Check one of the following.

☐ No research partners are reported with this submission. (This may occur because there are no partners, or because no partners are being added, or because no previously reported partners are still both supported by CDC and engaged in nonexempt research.)

☒ Research partners are listed on form 0.1370, which accompanies this form.

4 Study participants—cumulative demographic frequencies

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

Report estimated counts (rather than percentages). Include participants at domestic and foreign sites. See *HRPO Guide: IRB Review Cycle* for definitions.

Number of participants	8,040
Location of participants	
Participating at domestic sites	8,040
Participating at foreign sites	
Sex/Gender of participants	
Female	0
Male	0
Sex/gender not available	8,040
Ethnicity of participants	
Hispanic or Latino	0
Not Hispanic or Latino	0
Ethnicity not available	8,040
Race of participants	
American Indian or Alaska Native	0
Asian	0
Black or African American	0
Native Hawaiian or Other Pacific Islander	0
White	0
More than one race	0
Race not available	8,040

Comments on demographics

Form 1250 cites 2050 subject; increased to 4000 subjects 7/5/2012; increased to 8070 6/20/2013.

5 Study status—participant involvement

5.1 Contact status

"Contact" means intervention or interaction with participants, such as recruitment, screening, obtaining consent, enrollment, and collection of data and biological specimens directly from participants. Check one of the following.

☐ Study is not designed to involve research-related contact with participants (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 participants. Check one of the following:

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

5.2 Consent status

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

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

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

☒ Participants 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.

6 Study status—overall conduct

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.

As of 7/27/2017, 10 nursing home interviews conducted with chairs of the workplace violence prevention committee.

Manuscripts published:
1. Workplace violence and training required by new legislation among NJ nurses. Ridenour M, Hendricks S, Hartley D, Blando J. Journal of Occupational and Environmental Medicine 2017 April; Volume 59 (4): e35-e40.
2. Hospital security director background, opinions, and the implementation of security programs. Blando J, Ridenour M, Hartley D, Nocera M. Journal of Applied Security Research 2017 (in press).
3. Hospital security director background, opinions, and the implementation of security programs. Blando J, Ridenour M, Hartley D, Nocera M. Journal of Healthcare Protection and Management 2017; Vol. 33:1; pp. 89-105.

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.

None.

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

None.

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.

None.

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

None

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.

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

Conduct 30 nursing home interviews with the chairs of the workplace violence prevention committees.

7 Regulation and policy

7.1 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 if this is a new request]

Institution or organization providing IRB review: _____

IRB registration number (if known): _____

Federalwide assurance number (if any): _____

IRB-determined 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

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, 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 materials collected solely for nonresearch purposes
- ☐ 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

8 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)

☒ Consent, assent, and permission documents or scripts (required if consent will be sought in the future from prospective subjects or their representatives [see section 5.2])

☒ 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)

☒ Data collection instruments (e.g., questionnaires, interview scripts, record abstraction tools; required if protocol has changes in the past 12 months)

☒ Certification of IRB approval or exemption for research partners (required only for partners being added or for supported/nonexempt partners)

☐ Progress and monitoring reports (recommended when available)

9 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: 11-DSR-02XP Protocol version number _____ version date _____

Protocol title: Workplace Violence Prevention Program in NJ Healthcare Facilities

Partner 1 University of North Carolina Institution name: _____ Institution location: Chapel Hill, NC Individual name (IIA only): Carri Casteel Reporting status: Previously reported Regulatory coverage: Not engaged Financial support: Contract/subcontract Support award number: HCCJB-2012-45372 Support end date: 12/31/2015 Nonfinancial support: No financial support FWA number: 4601 SEV number (IIA only): IRB review status: Review by local IRB IRB approval expiration date: 3/21/2018 Comments: Not engaged. Study closed at UNC 2/6/2017.	**Partner 2** Old Dominion University Institution name: _____ Institution location: Norfolk, VA Individual name (IIA only): Jim Blando, Emily O'Hagen Reporting status: Previously reported Regulatory coverage: Engaged/non-exempt Financial support: Contract/subcontract Support award number: HCCJB-2016-02098 Support end date: 9/29/2017 Nonfinancial support: FWA number: 00000273 SEV number (IIA only): _____ IRB review status: Review by local IRB IRB approval expiration date: 5/18/2018 Comments: _____
Partner 3 University of North Carolina Institution name: _____ Institution location: Chapel Hill, NC Individual name (IIA only): Maryalice Nocera Reporting status: Previously reported Regulatory coverage: Not engaged Financial support: Contract/subcontract Support award number: HCCJB-2012-45372 Support end date: 12/31/2015 Nonfinancial support: FWA number: 4801 SEV number (IIA only): _____ IRB review status: Review by local IRB IRB approval expiration date: _____ Comments: Not engaged. Study closed at UNC 2/6/17.	**Partner 4** RTI Institution name: _____ Institution location: Research Triangle Park, NC Individual name (IIA only): Anne Kenyon Reporting status: Reporting status? Previously reported Regulatory coverage: Not engaged Financial support: _____ Support award number: HCCJB-2012-43996 Support end date: 05/10/2013 Nonfinancial support: FWA number: 3331 SEV number (IIA only): _____ IRB review status: Review by local IRB IRB approval expiration date: 06/30/2013 Comments: RTI completed 2 surveys. Not engaged.

Partner 5 University of Iowa

Institution name: _____
Institution location: Iowa City, IA
Individual name (IIA only): Corine Peek-Asa
Reporting status: Previously reported
Regulatory coverage: Not engaged
Financial support: Grant
Support award number: _____
Support end date: _____
Nonfinancial support:
FWA number: _____
SEV number (IIA only): _____
IRB review status:
IRB approval expiration date: _____
Comments: ~~Assisted~~ with the initial study protocol. Not engaged.

Partner 6 Health Professionals Allied Employees (HPAE)

Institution name: _____
Institution location: Emerson, NJ
Individual name (IIA only): _____
Reporting status: Previously reported
Regulatory coverage: Not engaged
Financial support: No financial support
Support award number: _____
Support end date: _____
Nonfinancial support:
FWA number: _____
SEV number (IIA only): _____
IRB review status:
IRB approval expiration date: _____
Comments: ~~HPAE~~ assisted with the nurse survey. Not engaged.

Partner 7 State of NJ Division of Consumer Affairs

Institution name: _____
Institution location: Trenton, NJ
Individual name (IIA only): _____
Reporting status: Previously reported
Regulatory coverage: Not engaged
Financial support: No financial support
Support award number: _____
Support end date: _____
Nonfinancial support:
FWA number: _____
SEV number (IIA only): _____
IRB review status:
IRB approval expiration date: _____
Comments: ~~Not~~ engaged.

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: _____

Partner 9

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 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: _____