0.1379 Centers for Disease Control and Prevention Date Received:
NIOSH IRB (HSRB) 08/17/2015 8/21/15 e

Signature Page for Human Research Review BChampagne

Protocols and Related Documentation

Anniversary Date: 09/21/2015

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. **NOTE: IRB (Institutional Review Board) refers to the NIOSH IRB-HSRB (National Institute for Occupational Safety and Health (NIOSH), Human Subjects Review Board (HSRB) of the CDC Human Research Protection Office (HRPO).**

1 Protocol Identifiers

CAN#: 927ZKFN (optional)

Leave protocol ID blank if not yet assigned.

CDC Protocol ID: HSRB HSRB-11-DSR-02XP Protocol Version Number: ____ Version Date: 06/30/2015

Protocol Title:

Workplace Violence Prevention Programs in NJ Healthcare Facilities

Amendment Number (if applicable): 2

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	dvn7	840	NIOSH/DSR
Principal Investigator Phone Number (required)	Marilyn Ridenour	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	Exempted Protocols (All shaded will not apply here)
☐ 0.1250: Initial Review by IRB	☐ 0.1250X: Initial Review for Exemption
☒ 0.1251: Continuing Review of Approved Protocol	☐ 0.1251X: Continuing Review of Exempted Protocol
☐ 0.1252: Review of Changes to Approved Protocol	☐ 0.1252X: Review of Changes to Exempted Protocol
☐ 0.1254: Incident Report	
☐ 0.1254S: Supplemental Adverse Event Report	
☐ 0.1253: End of Human Research Review	☐ 0.1253: End of Human Research Review
☒ 0.1370: CDC's Research Partners	☐ 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	

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 DN: c=US, o=U.S. Government, ou=HHS, ou=CDC, ou=People, 0.9.2342.19200300.100.1.1=1000258775, cn=Marilyn L. Ridenour -S5 Date: 2015.08.17 11:52:40 -04'00')	08/17/2015	

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:	_____	☐ PI is Team Lead
Branch Official (e.g., Chief or Senior Scientist): James W. Collins -S (Digitally signed by James W. Collins -S DN: c=US, o=U.S. Government, ou=HHS, ou=CDC, ou=People, 0.9.2342.19200300.100.1.1=1000645040, cn=James W. Collins -S Date: 2015.08.18 08:15:45 -04'00')	08/18/2015	☐ PI is Branch Official
Division Official (e.g., Director or ADS): Christine R. Schuler -S (Digitally signed by Christine R. Schuler -S DN: c=US, o=U.S. Government, ou=HHS, ou=CDC, ou=People, 0.9.2342.19200300.100.1.1=1001711297, cn=Christine R. Schuler -S Date: 2015.08.18 10:05:56 -04'00')	08/18/2015	☐ 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-HSRB: Diane C. Morris -S (Digitally signed by Diane C. Morris -S DN: c=US, o=U.S. Government, ou=HHS, ou=CDC, ou=People, 0.9.2342.19200300.100.1.1=1000059265, cn=Diane C. Morris -S Date: 2015.09.17 07:52:57 -04'00')	09/17/2015	Contact with participants continues. Consent included.
Other Clearance Official: (e.g., Confidentiality Officer, Coordinating Center/Office Official)	_____	

THIS SECTION FOR CDC/NIOSH IRB-HSRB OFFICE USE ONLY:
Expedited Review ☒ ; Minimal Risk ☒ ; as provided for in 45CFR46.110.
(b) (1) category(s) 5, 7
Approved Review ☒ for one year; **Renewal Date:** 09/21/2016
CDC 0.1250 cites Estimated Subject # is 2050 Subject # to Date is 8070
Approved/Amended Subject # is 8070
COMMENTS: _____
Full/Convened Board Review Approved ☐ Meeting Date Approval: _____

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.

0.1251 Centers for Disease Control and Prevention

Request for Continuing Review of IRB-Approved Protocol

Use this form to submit a protocol for continuing review by a CDC IRB (Ex. NIOSH IRB-HSRB) 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: HSRB HSRB-11-DSR-02XP Protocol Version Number: ____ Version Date: 06/30/2015

Protocol Title:

Workplace Violence Prevention Programs in NJ Healthcare Facilities

2 Key CDC Personnel

No change in key CDC personnel. When checked or not, please cite all CDC and NIOSH investigators.

	Name and Degrees (First Name Last Name, Degrees)	User ID	CDC SEV #	CDC NC/Division
Primary Contact (required)	Marilyn Ridenour	dvn7	840	NIOSH/DSR
Principal Investigator (required)	Marilyn Ridenour	dvn7	840	NIOSH/DSR
Investigator 2	Dan Hartley	dsh3	17813	NIOSH/DSR
Investigator 3	Scott Hendricks	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.

Continue list here of all other CDC and NIOSH investigators, if any. Include name and degrees, user ID, CDC 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.

All CDC partners must be listed on form CDC 0.1370.

Check one of the following.

☐ No research partners are reported with this submission. (Checked when there are **no** non-CDC partners.)

☒ Research partners (non-CDC) are listed on form CDC 0.1370, which accompanies this form.

4 Study Participants—Cumulative Demographic Frequencies

Have any participants been enrolled in the last 12 months? ☒ Yes ☐ No (**If no**, still report total subject # to date.)

Report estimated counts (rather than percentages). Include participants at domestic and foreign sites. [Note: All sub-category totals should be equal; total subject numbers are counted from **beginning** of study conduct until the date completing this form. See also *HRPO Guide: IRB Review Cycle* for definitions.]

Number of Participants	8,070
Location of Participants	
Participating at Domestic Sites	8,070
Participating at Foreign Sites	0
Sex/Gender of Participants	
Female	0
Male	0
Sex/Gender Not Available	8,070
Ethnicity of Participants	
Hispanic or Latino	0
Not Hispanic or Latino	0
Ethnicity Not Available	8,070
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	8,070

1250 cites 2050 subjects increased to 4000 on 7/5/12; increased to 8070 6/20/13.

CDC Form 0.1250 initial review, #5 cited 8,070 number estimated subjects. To exceed subject # cited on CDC 0.1250, an amendment request (CDC forms 0.1252+ 0.1379) needs to be completed/submitted to the NIOSH IRB-HSRB for review/approval. Comments on Demographics:

Workplace Violence Prevention Programs in NJ Healthcare Facilities

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. (If checked, include a cc current consent with submission.)
- ☒ Contact with participants has begun and continues; this may include follow-up for debriefing or notification of results. (If checked, include a cc current consent with submission.)
- ☐ 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 [Please complete all summaries.]

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. [Citing "none" for this summary is incomplete.]

Nurse Survey completed. Home Healthcare Aide Survey completed.

50 hospital interviews conducted with chairs of workplace violence prevention committees.

Continue

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.

Amendment approved on 7/30/2015: see the 6 modifications below that were approved. Continued on page 11.

Continue

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

None.

Continue

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.

Continue

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

None.

Continue

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.

Continue

Summary of remaining research activities, emphasizing future contact with subjects, use of identifiable private data and biological specimens, and preparation of primary reports. [Citing "none" for this summary is incomplete.]

Conduct 40 nursing home interviews with the chairs of workplace violence prevention committees.

Continue

7 Regulation and Policy

7.1 Mode of IRB Review on CDC's Behalf

Location of IRB (Check one.):

☒ CDC IRB (Ex. NIOSH IRB/HSRB)

☐ Non-CDC IRB through IRB Authorization Agreement [Submit form CDC 0.1371 if this is a new request.]

Institution or Organization Providing IRB Review: _____

IRB Registration Number (if known): _____

Federal-Wide 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 (8a, 8b, 8c, or 9) 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 (Cover Memo content can go here.)

Attached are forms 1379, 1251 and 1370 for renewal of study protocol HSRB-11-DSR-02XP. This protocol was amended in July 2015. The amended protocol, which contains the consent and other relevant documents, is also attached.

0.1370 Centers for Disease Control and Prevention

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 completed ethics training documentation 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: HSRB HSRB-11-DSR-02XP Protocol Version Number: ____ Version Date: 06/30/2015

Protocol Title:

Workplace Violence Prevention Programs in NJ Healthcare Facilities

NOTE: Each partner below reflects either a non-CDC **Institution** or non-CDC **Individual** so all fields cannot be completed. At minimum, please provide the name of the Institution/Individual; their City/State; and briefly cite in the Comments field their role in this research (what they will do) and include your estimate of engaged or not. Engaged means either to: 1) interact/intervene with subjects; **or** 2) access private/identifiable information; **or** 3) receive federal funds.

Partner 1

Institution Name: University of North Carolina
Institution Location: Chapel Hill, NC
Individual Name (IIA only): Carri Casteel
Reporting Status: Previously Reported
Regulatory Coverage: Engaged/Non-Exempt
Financial Support: Contract/Subcontract
Support Award Number: HCCJB-2012-45372
Support End Date: 12/31/2015
Nonfinancial Support: No Nonfinancial Support
FWA Number: 4801
SEV Number (IIA only): _____
IRB Review Status: Review By Local IRB
IRB Approval Expiration Date: 03/11/2016
Comments (Their Role in this Research):

Engagement covered by local IRB documentation or agreement to defer once approved. On file DCMorris

Partner 2

Institution Name: Old Dominion University
Institution Location: Norfolk, VA
Individual Name (IIA only): Jim Blando, Emily O'Haga
Reporting Status: Previously Reported
Regulatory Coverage: Engaged/Non-Exempt
Financial Support: Contract/Subcontract
Support Award Number: HCCJB-2012-45374
Support End Date: 12/31/2015
Nonfinancial Support: No Nonfinancial Support
FWA Number: 00000273
SEV Number (IIA only): _____
IRB Review Status: Review By Local IRB
IRB Approval Expiration Date: 03/12/2016
Comments (Their Role in this Research):

Engagement covered by local IRB documentation or agreement to defer once approved. On file DCMorris

Partner 3

Institution Name: University of North Carolina
Institution Location: Chapel Hill, NC
Individual Name (IIA only): Maryalice Nocera
Reporting Status: Previously Reported
Regulatory Coverage: Engaged/Non-Exempt
Financial Support: Contract/Subcontract
Support Award Number: HCCJB-2012-45372
Support End Date: 12/31/2015
Nonfinancial Support: No Nonfinancial Support
FWA Number: 4801
SEV Number (IIA only):
IRB Review Status: Review By Local IRB
IRB Approval Expiration Date: 03/11/2016
Comments (Their Role in this Research):

Engagement covered by local IRB documentation or agreement to defer once approved. On file DCMorris

Partner 4

Institution Name: RTI
Institution Location: Research Triangle Park, NC
Individual Name (IIA only): Anne Kenyon
Reporting Status: Previously Reported
Regulatory Coverage: Not Engaged
Financial Support: Contract/Subcontract
Support Award Number: HCCJB-2012-43996
Support End Date: 05/10/2013
Nonfinancial Support: No Nonfinancial Support
FWA Number: 3331
SEV Number (IIA only):
IRB Review Status: Review By Local IRB
IRB Approval Expiration Date: 06/30/2013
Comments (Their Role in this Research):

RTI completed the 2 surveys; not engaged.

Partner 5

Institution Name: University of Iowa
Institution Location: Dr. Corine Peek-Asa
Individual Name (IIA only):
Reporting Status: Previously Reported
Regulatory Coverage: Not Engaged
Financial Support: Grant
Support Award Number:
Support End Date:
Nonfinancial Support: No Nonfinancial Support
FWA Number:
SEV Number (IIA only):
IRB Review Status:
IRB Approval Expiration Date:
Comments (Their Role in this Research):

Assisted with the initial study protocol which has been completed. Not engaged.

Partner 6

Institution Name: Health Professionals Allied Emplo
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: No Nonfinancial Support
FWA Number:
SEV Number (IIA only):
IRB Review Status:
IRB Approval Expiration Date:
Comments (Their Role in this Research):

Health Professionals Allied Employees assisted with the nurse survey (completed); not engaged.

Partner 7

Institution Name: State of NJ Div. of Consumer Affairs
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: No Nonfinancial Support
FWA Number: _____
SEV Number (IIA only): _____
IRB Review Status: _____
IRB Approval Expiration Date: _____
Comments (Their Role in this Research):

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 (Their Role in this Research):

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 (Their Role in this Research):

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 (Their Role in this Research):

6. Study Status - Overall Conduct: Summary of study changes reviewed and approved since the last continuation. cont.

Modification 1: Attachment C1 (Nursing Home - Evaluation of Workplace Violence Prevention Program: Abstraction form: revised by adding questions A. 1-3 and G. 1a-b from Attachment C2 Nursing Home - Committee Chair Interview form; added Organizational-level Safety Climate questions (H. 1-16). Deleted 3 questions and added minor details for clarification. Pages 35-42.

Modification 2: Attachment C2 (Nursing Home - Committee Chair Interview) will not be utilized as questions A. 1-3 and G. 1a-b incorporated into Attachment C1. Pages 10, 43.

Modification 3: Attachment C3- Nursing Home Incident Information form will not be utilized since we will not be collecting individual worker assault injury data. Pages 8, 10, 18, 48.

Modification 4: Not be requesting that nursing homes provide their workplace violence prevention policies and procedures. Pages 8-9.

Modification 5: Nursing home recruitment target is increased to 40: 20 in New Jersey and 20 in Virginia. Pages 7-8.

Modification 6: Utilize workers compensation data for specific aim 3 for nursing home workers. Page 15.