Amendment Request Rcvd 4/23/14 elec

0.1379

Centers for Disease Control and Prevention
NIOSH HSRB

Date received
4/24/14 he

Signature Page for Human Research Review
Protocols and Related Documentation Ann date 4/3/15

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 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# _____ (optional)

Leave protocol ID blank if not yet assigned.

CDC protocol ID: HSRB 13-OMSHR-02XP Protocol version number 2 version date 04/21/2014

Protocol title: Virtual Reality to Train and Assess Emergency Responders

Amendment number (if applicable): _____

2 Key CDC personnel

	Name and degrees (FirstName LastName, Degrees)	User ID	SEV #	CDC NC/division
Primary contact (required)	Launa Mallett, Ph.D.	ljm7	6980	NIOSH/OMSHR
Principal investigator (required)	Cassandra Hoebbel, Ph.D.	whd1	15328	NIOSH/OMSHR

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	Remarks
Principal CDC Investigator: [signature]	4/22/2014	

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: Laura Mallett PhD	4-21-2014	Check if PI is Team Lead: ☐
Branch Official (e.g., Chief or Senior Scientist): [signature]	4/22/2014	Check if PI is Branch Official: ☐
Division Official (e.g., Director or ADS): Dana Wilmer	4/22/14	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
Chair, NIOSH HSRB: Mark Toraason	4-30-14	No increased Risk. Changed: PI, Site, and increased Participants to 210.
Other Clearance Official: (e.g., Confidentiality Officer, Coordinating Center/Office Official)		Waiver Doc IC 45CFR46.117(c)(1)

Expedited Review; Minimal Risk; as provided for in 45CFR 46.110 (b) (2) and (b)(1) category(s) 7;

5 Additional comments

Approved for one year; Renewal date 4-3-15.
CDC 0.1250 form estimated subject # is 150;
Subject # to date is 70;
Approved/Amended Total Subject # is 210.

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.

APPROVED

Date received
4/24/14 hc

Request for Review of Changes to IRB-Approved Protocol

Ann date 4/3/15

Use this form to seek approval for changes to a protocol that has received approval by a CDC or non-CDC IRB. [See 45 CFR 46.103(b)(4)(iii).] See *HRPO Guide: IRB Review Cycle* for further details on how to complete this form.

1 Protocol identifiers

CDC protocol ID: HSRB 13-OMSHR-02XP Protocol version number 2 version date 04/21/2014

Protocol title: Virtual Reality to Train and Assess Emergency Responders

Amendment number: _____

Amendment title or brief descriptor (optional): Create field test version of the Mine Escape Post-Simulation Questionnaire

☒ **No change** in keywords. If no change, please skip to section 2.

Suggested keywords (optional). Enter each term in a separate cell:

_____ _____ _____

_____ _____ _____

2 Key CDC personnel

☒ **No change** in key CDC personnel. Please list all CDC investigators.

	Name and degrees (FirstName LastName, Degrees)	User ID	SEV #	CDC NC/division
Primary contact (required)	Launa Mallett, Ph.D.	ljm7	6980	NIOSH/OMSHR
Principal investigator (required)	Cassandra Hoebbel, Ph.D.	whd1	15328	NIOSH/OMSHR
Investigator 2	Jennica Bellanca	wje9	12351	NIOSH/OMSHR
Investigator 3	Brianna Eiter	viy3	12465	NIOSH/OMSHR
Investigator 4	William Helfrich	wmh3	15711	NIOSH/OMSHR
Investigator 5	Brendan MacDonald	ihn5	12939	NIOSH/OMSHR

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:

Jason Navoyski, isb2, 12804, NIOSH/OMSHR

Timothy Orr, tao9, 4564, NIOSH/OMSHR

Patrick Roth, wju5, 18783, NIOSH/OMSHR

Michael Brnich, Jr., tsb9, 14987, NIOSH/OMSHR

Timothy Bauerle, wjo6, 16598, NIOSH/OMSHR

Jacqueline Jansky, jgi7, 13769, NIOSH/OMSHR

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. On review of changes, HRPO needs current information on partners that have been added or dropped since the last review. See *HRPO Guide: CDC's Research Partners* for further details. 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.

5 Study participants—planned demographic frequencies

☐ **No change** in planned demographic frequencies. If no change, please skip to section 6.

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

Number of participants	210
Location of participants	
Participating at domestic sites	210
Participating at foreign sites	0
Sex/Gender of participants	
Female	0
Male	0
Sex/gender not available	210
Ethnicity of participants	
Hispanic or Latino	0
Not Hispanic or Latino	0
Ethnicity not available	210
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	210

Comments on demographics

[insert comment] (original protocol called for 150 participants, we plan on recruiting more 1250 cities / 150 subjects. Increase to 210 4/30/14

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 if this is a new request]

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 for the modified protocol (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 is suggested

- ☐ Not eligible for expedited review. For example, poses greater than minimal risk and changes are substantial; 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):

- ☒ Proposed changes to protocol are minor
- ☐ 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

Check one of the following:

☒ **No change** in vulnerable populations (added or dropped). If no change, please skip to section 6.3.

☐ There is a proposed change in the intention to include or exclude a group of potentially vulnerable subjects, such as pregnant women or fetuses, children, or prisoners.

Please summarize and justify the proposed change, including which groups are affected and where the change is described in the protocol.

6.3 Free and informed consent

Check one of the following:

☐ **No change** in consent process, forms, or approved waivers. If no change, please skip to section 6.4.

☒ There are proposed changes in consent process, forms, or approved waivers.

Please summarize and justify the proposed changes in the consent/assent/permission process (e.g., recruitment, scripts) or in the documentation of consent/assent/permission (e.g., consent forms), including where the changes are described in the protocol. Include any changes related to the HIPAA Privacy Rule. Also describe how it is shown that the modified consent process and documentation are in understandable language (e.g., reading level, comprehension tool, short form, translation).

Cassandra Hoebbel has assumed the role of priniple investigator, replacing Launa Mallett. These changes are reflected in the consent form.

6.4 Other regulation and policy considerations

Check one of the following:

☒ **No change** in other regulation and policy considerations. If no change, please skip to section 6.5.

☐ There are proposed changes in other regulation and policy considerations.

Please describe and justify changes to any of the following regulation and policy considerations, including where the changes are described in the protocol:

- 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.)

6.5 Confidentiality protections

Check one of the following:

☒ **No change** in confidentiality protections (e.g., granted, applied for, denied). If no change, please skip to section 7.

☐ There are proposed changes in confidentiality protections.

Please describe and justify changes to confidentiality protections under a Certificate of Confidentiality (301(d)) or Assurance of Confidentiality (308(d)) or other formal confidentiality protections, including whether requests for these protections are granted, pending, or denied and where these requests are described in the protocol:

7 *Summary of proposed changes*

Describe and justify proposed modifications to the protocol, except for modifications justified above. Include page numbers in reference to clean copy (and marked copy if possible). Continue summary in supplemental document if necessary.

Page 3 (Marked & Clean) - Study Team and Roles is updated to reflect the most current study team as per 2/28/14 email correspondence between Cassandra Hoebbel and Kathy Masterson

Page 5 (Marked) & Page 4 (Clean) - Total recruitment estimate updated to 210 from previous value of 150

Page 5 (Marked & Clean) - Details of classroom setting participants explained; details of new participant subsample breakdown

Page 6 (Marked & Clean) - Logistics of classroom setting recruitment and experimentation are added.

Page 7 (Marked & Clean) - Emphasizes no changes to recruitment for classroom setting participants, explains changes in consent form.

Page 9 (Marked) & Pages 8-9 (Clean) - Explains consistency in learning objectives despite technogical adaptations between MRET Lab and classroom setting versions. Provides provisions for updated post-simulation questionnaire for use in classroom setting.

Pages 12-13 (Marked) & Page 12 (Clean) - Explains differences in risks and benefits between classroom setting and MRET Lab participants. Simulator sickness risk is lower in classroom setting participants, and provisions are made to minimize risk of confidentiality breach in classroom setting participants.

Pages 13-14 (Marked) & Page 13 (Clean) - Emphasizes no differences to recruitment protocol or script, explains minimal changes to consent form.

Page 15 (Marked) & Page 14 (Clean) - Emphasizes that same emergency procedures as outlined for off-site BG4 data collection will be used for classroom setting participants.

Page 16 (Marked & Clean) - Updated Appendix page to commodate revised Classroom Setting Emergency Response Post-Simulation Questionnaire.

8 Material submitted with this form

Check all that apply. Describe additional material in the comments section. Clean and marked copies are required for modified materials. Entire documents may not be needed if there is enough context to enable a meaningful review. Optional items may be requested by HRPO or the IRB.

Clean	Marked	
☒	☒	Complete protocol
☒	☒	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 being added

9 Additional comments