DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date April 3, 2013

From Chair, NIOSH IRB (HSRB)

Subject Report of NIOSH IRB -- Protocol No. HSRB 13-OMSHR-02XP "Virtual Reality to Train and Assess Emergency Responders" Approval of Protocol

To Launa Mallett, Ph.D.
Project Officer, HFB, DMRO, OMSHR
Through: /Chief, HFB, DMRO, OMSHR ____ ____
/Director, DMRO, OMSHR ____ ____

General Comments and IRB Actions

I received your revised protocol (memo dated 3/23/2013) and find that it is responsive to the issues raised in my 3/14/2013 report for the subject protocol. Your protocol was reviewed using the expedited procedure in that it presents no more than minimal risk and involves a human factors evaluation (category 7) as provided for in 45CFR46.110. Your request for a waiver of documentation of informed consent is granted per 45CFR46.117 (c) (1) in "(1) that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern. The revised protocol and consent document (dated 4/3/2013) are **approved** for one year and will serve as the documents of record for this study (renewal date 4/3/2014). However, if you make any substantive changes, or any adverse reactions occur in any study participants, please notify me immediately. Protocol incidents need to be reported to NIOSH IRB by phone or E-mail within 2 working days; and reported formally [send CDC form 0.1254 + 0.1379] within 2 weeks.

If you choose to make changes to your approved protocol, the changes must be reviewed and approved prior to implementation by submitting via hard copy CDC forms 0.1379 (signature page), 0.1252 (amendment request), 0.1370 (non CDC collaborator, if have), a clean copy of the revised protocol and a highlighted copy (track changes or pen/ink) of the revised protocol (all changes highlighted). Electronic submission of your amendment request may facilitate review, but it is not required. The general procedure for requesting annual continuing review is to send 45-60 days prior to renewal date completed hard copy forms CDC 0.1379 (signature page), 0.1251 (continuing review request), 0.1370 (non CDC collaborator, if have), a copy of your current consent form (if consenting or recruiting currently). An electronic submission of your continuing review may facilitate review, but it is not required.

Protocol Issues, Consent Form Issues, Addenda Issues – None.

End of report

Mark A. Toraason, Ph.D.

cc:
HSRB 13-OMSHR-02XP

NEW PROTOCOL

0.1379 Centers for Disease Control and Prevention Date received

2/14/13 (hc)
2/6/13 (elec)

Signature Page for Human Research Review
Protocols and Related Documentation

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.

Annual - 4-03-14

1 Protocol identifiers

Leave protocol ID blank if not yet assigned.

CDC protocol ID: HSRB 13-OMSHR-02XP Protocol version number 1 version date 1/8/2013

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)	Launa Mallett, Ph.D.	ljm7	6980	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: Lauren Mallett PhD	1-9-2013	

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: Lauren Mallett PhD	1-9-2013	Check if PI is Team Lead: ☒
Branch Official (e.g., Chief or Senior Scientist): Joel M. Vaughts	16/JAN/2013	Check if PI is Branch Official: ☐
Division Official (e.g., Director or ADS): Dana G. Willmer	2/5/13	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: Mark Torrence	4-3-13	Waiver of Documentation IC
Other Clearance Official: (e.g., Confidentiality Officer, Coordinating Center/Office Official)		

5 Additional comments

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

Approved for one year; Renewal date 4-03-14.

CDC 0.1250 form estimated subject # is 150;

Subject # to date is _____;

Approved/Amended Total Subject # is _____.

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

2/14/13 (hc)
2/6/13 (dbc)

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: HSRB 13-OMSHR-02XP Protocol version number 1 version date 1/8/2013

Protocol title: Virtual Reality to Train and Assess Emergency Responders

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

training	mining	

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)	Launa Mallett, Ph.D.	ljm7	6980	NIOSH/OMSHR
Investigator 2	Michael Brnich, Jr., B.S., CMSP	tzb9	14987	NIOSH/OMSHR
Investigator 3	Erica Hall, M.S.	eoh7	16954	NIOSH/OMSHR
Investigator 4	Timothy Bauerle, M.A.	wjo6	16598	NIOSH/OMSHR
Investigator 5	Jacqueline Jansky	jgi7	13769	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 (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	150
Location of participants	
Participating at domestic sites	150
Participating at foreign sites	0
Sex/Gender of participants	
Female	0
Male	0
Sex/gender not available	150
Ethnicity of participants	
Hispanic or Latino	0
Not Hispanic or Latino	0
Ethnicity not available	150
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	150

Comments on demographics

Demographics are not available. There is little gender, ethnic, or racial diversity in the study population. Therefore, most participates are likely to be white males.

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	☐	☒	☐	☐	_____
Children (including viable neonates)	☐	☐	☐	☒	_____
Prisoners	☐	☐	☐	☒	_____

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.

Pregnant women: As mentioned in the IRB Protocol, the study is open to rank-and-file miners, mine rescue team members, mine safety professionals, and miner training instructors. Based on the demography of these populations, it is reasonable to expect that most participants in the current study will be white males. However, because the training will come at a minimal risk, and because we have no reason to suspect that pregnant women will be at any increased risk compared other participants in the study, pregnant women will be allowed to participate in the study.

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 7 / 10
- ☐ 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 ____
- ☐ 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))	☐	☐	☒	☐
Assurance of Confidentiality (308(d))	☐	☐	☒	☐

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