DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date November 26, 2014

From Chair, NIOSH IRB (HSRB)

Subject Report of NIOSH IRB (HSRB) – Protocol No. HSRB 14-OMSHR-11XM "Investigating the Implementation and Evaluation of Top-ranked HSMS Elements" Approval of New Exempt Protocol

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

General Comments and IRB Actions

I reviewed your request to exempt protocol HSRB 14-OMSHR-11XM "Investigating the Implementation and Evaluation of Top-ranked HSMS Elements" and find this research activity is **exempt** under 45CFR 46.101 category (b)(2) "Educational tests, surveys, interviews, adults only, data not identifiable." This determination is valid for a period of three years through 11/26/2017. However, we strongly encourage investigators to close out exempt protocols as soon as CDC/NIOSH staff are no longer engaged in the research activity, rather than waiting for a reminder of the three-year expiration date.

Also please be advised investigators remain responsible for the ethical conduct of this study and for ensuring appropriate human research protections even for research exempt from the regulations governing the protection of human subjects in research.

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), 0.1252X (exempt 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 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), 0.1251X (exempt continuing review request), 0.1370 (non CDC collaborator, if have), a copy of your current consent form (if still consenting or recruiting). An electronic submission of your continuing review may facilitate review, but it is not required.

Protocol Issues – None.
Consent Form Issues – None.
Addenda Issues (Scripts, questionnaires, brochures, etc.) – None.

End of report

Mark A. Toraason, Ph.D.

cc:
HSRB 14-OMSHR-11XM

NEW EXEMPT

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. **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).**

Annual date 11-26-17

1 Protocol identifiers

CAN# **93902K2** (optional)

Leave protocol ID blank if not yet assigned.

CDC protocol ID: HSRB 14-OMSHR-11 XM Protocol version number 1.0 version date 10.31.14

Protocol title: Investigating the Implementation and Evaluation of Top-ranked HSMS Elements

Amendment number (if applicable):

2 Key CDC personnel

	Name and degrees (FirstName LastName, Degrees)	User ID	SEV #	CDC NC/division
Primary contact (required)	Emily J. Haas, PhD	wcq3	17314	NIOSH/OMSHR
Principal investigator (required)	Emily J. Haas, PhD	wcq3	17314	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: Emily Gibson	10/30/14	

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: Robert Peters	10/29/14	Check if PI is Team Lead: ☒
Branch Official (e.g., Chief or Senior Scientist): Dana R. Wilmer	10/29/14	Check if PI is Branch Official: ☐
Division Official (e.g., Director or ADS): J H Weber	11/18/14	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 Chair, NIOSH HSRB: Mark Tomeson **Date** 11-26-14 **Remarks** Category 2a Waive documentation of informed consent

Oth (e.g.
Exempt Review; as provided for in 45CFR46.101. (b) category(s) 2a
Approved Review for 3 years; Renewal Date: 11/26/17
CDC 0.1250X cites Estimated Subject # is 100
Subject # to Date is _____
COMMENTS: _____

5 Additional comments

100 participants
Renewal date 11/26/2017

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

Request for Exemption from Human Subjects Regulations

Use this form to submit a protocol for exemption from human subjects regulations. See *HRPO Guide: Exempt 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 14- OMSHR-11XW Protocol version number 1.0 version date 10/31/2014

Protocol title: Investigating the Implementation and Evaluation of Top-ranked HSMS Elements

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

2 Key CDC personnel

	Name and degrees (FirstName LastName, Degrees)	User ID	SEV #	CDC NC/division
Primary contact (required)	Emily Haas, PhD	wcq3	17314	NIOSH/OMSHR
Principal investigator (required)	Emily Haas, PhD	wcq3	17314	NIOSH/OMSHR/HFB
Investigator 2	Robert Peters	rep8	8696	NIOSH/OMSHR/HFB
Investigator 3	Patrick Yorio, PhD	wjc8	19923	NIOSH/OMSHR/HFB
Investigator 4	Dana Willmer, PhD	dpr4	5881	NIOSH/OMSHR/HFB
Investigator 5	Kyle Stanyar, PhD	ygm1	3706	NIOSH/OMSHR/HFB

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 role in project

Check yes or no for each of the following.

☒y ☐n CDC employees or agents will obtain data by 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: Exempt Review Cycle* for definitions.

Number of participants	100
Location of participants	
Participating at domestic sites	100
Participating at foreign sites	0
Sex/Gender of participants	
Female	0
Male	0
Sex/gender not available	100
Ethnicity of participants	
Hispanic or Latino	0
Not Hispanic or Latino	0
Ethnicity not available	100
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	100

Comments on demographics

6 Regulation and policy

6.1 Exceptions or restrictions on exemptions

Check yes or no for each of the following.

☐y ☒n Research poses greater than minimal risk to participants.
CDC does not exempt research that poses greater than minimal risk to subjects.

☐y ☒n Research involves prisoners (either intentionally or incidentally).
These exemptions do not apply to research involving prisoners.

☐y ☒n Research involves interaction with children or obtaining identifiable private information about children through surveys or interviews of others.
The exemption at category 2 is restricted when children are research subjects.

6.2 Exemption categories

Check all that apply. See *HRPO Worksheet for Exemption from Human Subjects Regulations* for details.

Educational practices

- ☐ 1 Normal educational practices in commonly accepted educational settings

Educational tests, surveys, interviews, or observation of public behavior

- ☒ 2a Adults only; data are not identifiable
- ☐ 2b Adults only; data may be identifiable but are not potentially damaging
- ☐ 2c Children; limited to use of educational tests or observations of public behavior when the investigators do not participate in the activities being observed
- ☐ 3a Public officials or candidates
- ☐ 3b Federal statute requires confidentiality during and after research

Existing data, documents, records, pathological specimens, or diagnostic specimens

- ☐ 4a Publicly available sources
- ☐ 4b Information recorded by the investigator such that participants cannot be identified, directly or through linked identifiers

Research and demonstration projects (subject to the approval of the HHS Secretary)

- ☐ 5a Public benefit or service programs
- ☐ 5b Procedures for obtaining benefits or services under those programs
- ☐ 5c Possible changes in or alternatives to those programs or procedures
- ☐ 5d Possible changes in methods or levels of payment for benefits or services under those programs

Taste and food quality evaluation and consumer acceptance

- ☐ 6a Foods that are wholesome without additives
- ☐ 6b Foods that contain an ingredient, chemical, or contaminant at a level found to be safe

7 Material submitted with this form

Check all that apply. Describe additional material in the comments section.

- ☒ Complete protocol
- ☐ Documentation in support of exemption 3b, if applicable (e.g., §308(d) Assurance of Confidentiality)
- ☒ 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