DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Memorandum

Date May 25, 2017

From Angela M. Morley
Chair, NIOSH Institutional Review Board

Subject IRB Approval of Amendment for NIOSH Protocol 17-PMRD-02XM, "Mobile Proximity Initial User Feedback" (Exemption)

To Jennica Bellanca
Project Officer, NIOSH/PMRD

The NIOSH Human Research Protection Program (HRPP) received your submission for review of changes to exempt protocol 17-PMRD-02XM, "Mobile Proximity Initial User Feedback." I find this research activity remains exempt under 45 CFR 46.101(b)(2). The following modifications were reviewed and approved.

1. Increase number of participants.

As a reminder, additional changes to this protocol may not be implemented until they are reviewed and determined to be consistent with the exemption categories**.** Also, you will be asked to confirm that no changes have occurred in the protocol or the related science that would affect the ethical appropriateness of the research or this exemption from the current expiration date of **January 27, 2020**.

Please be reminded that the investigators remain responsible for appropriate human research protections even for research that is exempt from regulations for protecting human subjects.

If you have any questions, please contact the HRPP at cin-hsrb@cdc.gov, or by telephone at (513) 533-8591.

Request for Review of Changes to Exempted Protocol

Use this form to seek exemption for changes to a protocol that HRPO has deemed exempt from human subjects regulations. See *HRPO Guide: Exempt Review Cycle* for further details on how to complete this form.

1 Protocol identifiers

CDC protocol ID: 17-PMRD-02XM Protocol version number 3 version date 5/24/17

Protocol title: MOBILE PROXIMITY INITIAL USER FEEDBACK

Amendment number: _____

Amendment title or brief descriptor (optional): _____

☒ **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)	Jennica Bellanca	wje9	12351	NIOSH/OMSHR/PMRD
Principal investigator (required)	Jennica Bellanca	wje9	12351	NIOSH/OMSHR/PMRD
Investigator 2	Justin Helton	ndhi1	4309	NIOSH/OMSHR/PMRD
Investigator 3	Michael McNinch	msv1	17841	NIOSH/OMSHR/PMRD
Investigator 4	Dana Willmer	dpr4	5881	NIOSH/OMSHR/PMRD
Investigator 5	LaTasha Swanson	mre6	11983	NIOSH/OMSHR/PMRD

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. 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: Exempt Review Cycle* for definitions.

Number of participants	250
Location of participants	
Participating at domestic sites	250
Participating at foreign sites	0
Sex/Gender of participants	
Female	0
Male	0
Sex/gender not available	250
Ethnicity of participants	
Hispanic or Latino	0
Not Hispanic or Latino	0
Ethnicity not available	250
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	250

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 to the modified protocol. 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 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.

The participant number is being increased from 175 to 250 (page 2).

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.

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

All materials are located in one document.