Attachment F

CDC Institutional Review Board Approval

DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date March 19, 2014

From Chair, NIOSH IRB (HSRB)

Subject Report of NIOSH IRB (HSRB) – Protocol No. HSRB 14-EID-02XP "Total Worker Health for Small Businesses" Approval of New Protocol

To Thomas R. Cunningham, Ph.D.
Project Officer, TREB, EID
Through: /Chief, TREB, EID _____ _____
/Director, EID _____ _____

General Comments and IRB Actions

I received your response 3/26/2014 and find it is responsive to my 2/13/2014 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 or interview (category 7); the collection of data from voice or digital recordings (category 6); and the collection of data through noninvasive procedures (category 4) as provided for in 45CFR46.110. Your request for a waiver of documentation of informed consent is granted per 45CFR46.117(c)(2) in "(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context." This protocol is granted approval for one year (renewal date 3/19/2015). The revised protocol and consent documents will serve as the documents of record for this study (dated 3/19/2014). However, if you make any substantive changes to the protocol, or if 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 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 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

Kathy Masterson
for Mark A. Toraason, Ph.D.

cc:
HSRB 14-EID-02XP