DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date October 16, 2014

From Chair, NIOSH IRB (HSRB)

Subject Report of NIOSH IRB (HSRB) – Protocol No. HSRB 14-OMSHR-08XM "Assessing the Impact of Organizational and Personal Antecedents on Proactive Health/Safety Decision Making" 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-08XM "Assessing the Impact of Organizational and Personal Antecedents on Proactive Health/Safety Decision Making" and find this research activity is **exempt** under 45 CFR 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 10/16/2017. 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

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

cc:
HSRB 14-OMSHR-08XM