Appendix F. IRB Approval Letter

DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date January 16, 2014

From Chair, NIOSH IRB (HSRB)

Subject Report of NIOSH IRB -- Protocol No. HSRB 13-DRDS-02XP "Application of a Web-Based Health Survey Tool in Schools" Approval of Protocol

To Ju-Hyeong Park, Sc.D., M.P.H.
Project Officer, FSB, DRDS
Through: /Chief, FSB, DRDS ____ ____
/Director, DRDS ____ ____

General Comments and IRB Actions

I received your revised protocol 1/13/2014 (memo dated 1/9/2014) and find that it is responsive to the issues raised in my 12/20/2013 report for the subject protocol. Your protocol was reviewed using the expedited procedure in that it presents no more than minimal risk and involves the collection of data through routine, noninvasive procedures, involving no general anesthesia, sedation, X-rays, or microwave (category #4); and research that uses interview, program evaluation, human factors, or quality assurance methods (category #7) as provided for in 45CFR46.110. Your request for a waiver of documentation of informed consent is granted per 45CFR46.117 (c)(2) in "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." The revised protocol and consent documents (dated 1/16/2014) are **approved** for one year and will serve as the documents of record for this study (renewal date 1/16/2015). 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-DRDS-02XP