Attachment 6: Institutional Review Board Approval

DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date December 23, 2013

From Chair, NIOSH IRB (HSRB)

Subject Report of NIOSH IRB (HSRB) – Protocol No. HSRB 13-HELD-03XP "Factors Influencing the Transmission of Influenza" Approval of New Protocol

To William, G. Lindsley, Ph.D.
Project Officer, ACIB, HELD
Through: /Chief, ACIB, HELD ____ ____
/Director, HELD ____ ____

General Comments and IRB Actions

I received your response (memo dated 12/5/2013, received 12/9/2013) and find it is responsive to my 12/5/2013 report for the subject protocol. Your protocol was reviewed using the expedited procedure in that it presents no more than minimal risk and involves a prospective collection of biological specimens for research purposes by non-invasive means (category #3); collection of data through non-invasive procedures routinely employed by clinical practices (excluding X-rays) (category #4); and research on individual or group characteristics or behavior, surveys, interview, focus group, program evaluation, human factors evaluation, quality assurance methodologies, etc. (category #7) as provided for in 45CFR46.110. This protocol is granted approval for one year (renewal date 12/23/2014). The revised protocol and consent forms will serve as the documents of record for this study (dated 12/23/2013). However, if you make any substantive changes to the protocol, or if any adverse reactions occur in any study participants, please notify me immediately.

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 13-HELD-03XP