Attachment L

IRB Approval

DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date May 5, 2014

From Chair, NIOSH IRB (HSRB)

Subject Report of NIOSH IRB (HSRB) – Protocol No. HSRB 13-DART-04XP "Evaluating Interventions for Airplane Cargo Baggage Handling" Approval of New Protocol

To Ming-Lun Lu, Ph.D.
Project Officer, OSHFB, DART
Through: /Chief, OSHFB, DART ____ ____
/Director, DART ____ ____

General Comments and IRB Actions

I received your revised protocol 4/25/2014 (memo dated 4/10/2014) and find it is responsive to the issues raised in my 3/24/2014 report #2 for the subject protocol. This protocol was initially reviewed 7/24/2013 (report #1). Your protocol was reviewed using the expedited procedure in that it presents no more than minimal risk and involves noninvasive procedures routinely used in clinical practice (category 4), materials that have been collected solely for non-research purposes (category 5) collection of data from voice, video, digital, or image recordings (category 6), and a human factors evaluation (category 7) as provided for in 45CFR46.110. This protocol is granted approval for one year (renewal date 5/5/2015). The revised protocol will serve as the document of record for this study (dated 5/5/2014). 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 Mastrorocco
for Mark A. Toraason, Ph.D.

cc:
HSRB 13-DART-04XP