DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date January 26, 2009

From Chair, NIOSH HSRB

Subject Report of NIOSH HSRB -- Protocol No. HSRB 08-DSR-06XP "Occupational Injuries and Illnesses Among Emergency Medical Services (EMS) Workers: A NEISS-Work Telephone Interview Survey" Approval of Protocol

To Audrey Reichard, M.P.H., O.T.R.
Project Officer, SFIB, DSR
Through: /Chief, SFIB, DSR ____ ____
/Director, DSR ____ ____

General Comments and IRB Actions

I received your response on 1/21/09 (memo dated 1/16/09) and find that it is responsive to the issues raised in my 12/5/08 report. I have reviewed the subject protocol using the expedited procedure in that it presents no more than minimal risk and involves criterion #7 (research employing a telephone survey); and criterion #5 (research involving materials that have been collected or will be collected solely for nonresearch purposes) as provided for in 45 CFR 46.110. Your request for a waiver of documentation of informed consent is approved under 45 CFR 46.117(c). This protocol is granted approval for one year (renewal date 12/5/2009). The revised protocol and consent document will serve as the documents of record for this study (dated 1/26/09). However, if you make any substantive changes to the protocol, or if any adverse reactions occur in any study participants, please notify me immediately.

Additionally, for engaged collaborator, the US Consumer Product Safety Commission (CPSC), included with your E-mail approval is a completed CDC 0.1372A agreement for the CPSC FWA (federalwide assurance) signatory, Patricia M. Semple, to sign and return same to the NIOSH HSRB Office. Upon receipt, the HSRB Chair, Co-Chair or Administrator will also sign. The last step will be for the CPSC FWA signatory (or designee) to update their FWA on the HHS OHRP website "linking" CDC's FWA with CPSC's FWA. For engaged collaborator the National Highway Safety Administration (NHTSA), please follow-up with your NTHSA contact, Gamunu Wijetunge, so that NTHSA may obtain an approved FWA, etc. Please contact Kathy Masterson to help you with this. The proper assurances and agreements must be in place prior to their engagement in this study.

Protocol Issues – None.
Consent Form Issues – None.
Addenda Issues (Scripts, questionnaires, brochures, etc.) – None.

End of report

Kathy Masterson
for Cheryl Fairfield Estill, M.S., P.E.

cc:
HSRB 08-DSR-06XP