Attachment 5 HSRB Approval

DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date June 9, 2009

From Chair, CDC/NIOSH HSRB

Subject Report of NIOSH HSRB -- Protocol No. HSRB 09-PRL-01XP "Field Evaluation of Prototype Kneel-assist Devices" Approval of Protocol

To Susan Moore, Ph.D.
Project Officer, MIPB, PRL
Through: /Chief, MIPB, PRL ___ ___
/Director, PRL ___ ___

General Comments and IRB Actions

I received your response (memo dated 5/7/09) and find that it is responsive to the issues raised in my 4/28/09 report of the subject protocol. Your protocol was reviewed using the expedited procedure in that it presents no more than minimal risk and involves criterion #4 (research involving collection of data through non invasive procedures) and #7 (research on individual or group characteristics employing survey) as provided for in 45CFR46.110. The revised protocol and consent document (dated 6/9/09) are approved for one year and will serve as the documents of record for this study (renewal date 4/28/2010). 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 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 09-PRL-01XP