

Attachment E1: NIOSH HSRB Approval



DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date March 31, 2010
From Co-Chair, NIOSH HSRB
Subject Report of NIOSH HSRB -- Protocol No. HSRB 10-DSHEFS-01XP "National Survey of U.S. Long-Haul Truck Driver Injury and Health" Approval of Protocol
To William Karl Sieber, Ph.D. M.S.
Project Officer, SB, DSHEFS
Through: /Chief, SB, DSHEFS _____
/Director, DSHEFS _____

General Comments and IRB Actions

I received your revised protocol and consent documents (memo dated 3/15/2010) received 3/23/10 and find that it is responsive to the issues raised in my 2/24/10 expedited review of your original submission. Your protocol was reviewed using the expedited procedure in that it presents no more than minimal risk and involves research using a survey (criterion #7) and the collection of data through noninvasive procedures (observed gender, approximate age/height/weight/cigarette use) (criterion #4) as provided for in 45CFR46.110. Your request for a waiver of documentation of informed consent is granted based on 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 3/31/2010) are approved for one year and will serve as the documents of record for this study (renewal date 3/31/2011). However, if you make any substantive changes, or any adverse reactions occur in any study participants, please notify me immediately.

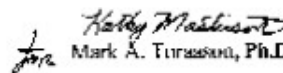
Also, please be advised that non-CDC collaborator, Westat, may not engage in this research until the proper assurances and agreements are in place, prior to engagement.

Protocol Issues – None.

Consent Form Issues – None.

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

End of report


Mark A. Furasson, Ph.D.

cc:
HSRB 10-DSHEFS-01XP

Signature page for human research review – NIOSH HSRB**4 Signatures**

As principal investigator, I hereby accept responsibility for conducting this CDC-sponsored research project in an ethical manner, consistent with the policies and procedures contained in CDC's *Procedures for Protection of Human Research Participants*, and to abide by the principles outlined in federal policies for the protection of human subjects at 45 CFR part 46, 21 CFR part 50, and 21 CFR part 56.

Signature	Date	Remarks
Principal CDC Investigator: <i>William L. F. Ben</i>	<i>3/17/10</i> <i>12/17/07</i>	

As a supervisor of the principal investigator, I hereby accept responsibility for ensuring that this CDC-sponsored research project is conducted in an ethical manner, consistent with the policies and procedures contained in CDC's *Procedures for Protection of Human Research Participants*, and to abide by the principles outlined in federal policies for the protection of human subjects at 45 CFR part 46, 21 CFR part 50, and 21 CFR part 56.

Signature	Date	Remarks
Team Lead: <i>Dawn Sewall</i>	<i>12-18-2009</i>	Check if PI is Team Lead: <input type="checkbox"/>
Branch Official (e.g., Chief or Senior Scientist): <i>Merrill Murray</i>	<i>12-18-2009</i>	Check if PI is Branch Official: <input type="checkbox"/>
Division Official (e.g., Director of Area): <i>WLB</i>	<i>12/27/09</i>	Check if PI is Division Official: <input type="checkbox"/>
	<i>IST B/19/10</i>	

I ensure that this CDC-sponsored research project is consistent with the policies and procedures contained in CDC's *Procedures for Protection of Human Research Participants* and with other applicable policies.

Signature	Date	Remarks
for: Other Clearance Official: Chief, NIOSH HSRB: <i>Kathy Mesterson, Administrator</i>	<i>3/3/10</i>	Expedited Review; Minimal Risk; as provided for in 45CFR46.110 (1)(4); Means of documentation of approval consent granted; Approved for one year; Renewal date 3/3/2011.

5 Additional comments

Submission for conduct of national survey using questionnaire and procedures developed under protocol (SRD 68-DSHEPS-01)-XX, "Survey of Truck Driver Injury and Health: Cognitive Evaluation of Questionnaire and Protocol," approved September 2008.

Privacy Act does not apply to this data collection.

6 Reminder regarding other regulatory clearance processes

The principal investigator is responsible for obtaining other regulatory reviews as needed, which may include OMB clearance under the Paperwork Reduction Act (PRA) for federally sponsored information collections. Approval by or exemption from the IRB is unrelated to OMB clearance requirements under the PRA. For more information on

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whether your study requires clearance under PRA or other regulations, please consult the appropriate officials within your national center.