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

for Mark A. Toraason, Ph.D.

cc:
HSRB 10-DSHEFS-01XP

New Protocol

0.1379 Centers for Disease Control and Prevention Date received
NIOSH HSRB 3/31/10

PI Response to 2/24/10 Report

Signature Page for Human Research Review
Protocols and Related Documentation

Use this signature page when submitting HRPO forms to your center-level Human Subjects Contact. When submitting materials with these forms, please consecutively number all pages, beginning with the protocol title page and followed by consent form(s) and ancillary documents. See *HRPO Guide: Overview* for further details. **NOTE: IRB (Institutional Review Board) refers to the NIOSH HSRB (National Institute for Occupational Safety and Health (NIOSH) Human Subjects Review Board (HSRB) of the CDC Human Research Protection Office (HRPO).**

1 Protocol Identifiers

CAN# **927Z8PA** (optional)

Leave protocol ID blank if not yet assigned.

CDC protocol ID: 10 DSHEFS-01XP U.S. Long-Haul

Protocol version number 2 version date 3/10

Protocol title: National Survey of Truck Driver Injury and Health

Amendment number (if applicable):

2 Key CDC personnel

	Name and degrees (FirstName LastName, Degree)	User ID	SEV #	CDC NCI/division
Primary contact (required)	William K. (Karl) Sieber, Ph.D., M.S.	WKS1	14470	NIOSH/DSHEFS/SB
Principal investigator (required)	William K. (Karl) Sieber, Ph.D., M.S.	WKS1	14470	NIOSH/DSHEFS/SB

SEV # is CDC's Scientific Ethics Verification Number. CDC NCI/division is the national center or equivalent and division or equivalent, or coordinating center or office if submitted at that level.

3 Forms submitted with this signature page

Check all that apply in the appropriate column.

IRB-reviewed protocols	Exempted protocols
☐ 0.1250: Initial Review by IRB	☒ 0.1250X: Initial Review for Exemption
☐ 0.1251: Continuing Review of Approved Protocol	☐ 0.1251X: Continuing Review of Exempted Protocol
☒ 0.1252: Review of Changes in Approved Protocol	☒ 0.1252X: Review of Changes to Exempted Protocol
☐ 0.1254: Incident Report	
☐ 0.1254S: Supplemental Adverse Event Report	
☐ 0.1253: End of Human Research Review	☒ 0.1253: End of Human Research Review
☐ 0.1370: CDC's Research Partners	☐ 0.1370: CDC's Research Partners
☐ 0.1371: CDC Rely on a Non-CDC IRB	
☐ 0.1372: Outside Institution Rely on a CDC IRB	
☐ 0.1373: CDC Cover an Individual Investigator	

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: William [illegible]	3/17/10 12/17/09	

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: [signature]	12-18-2009	Check if PI is Team Lead: ☐
Branch Official (e.g., Chief or Senior Scientist): [signature]	12-18-2009	Check if PI is Branch Official: ☐
Division Official (e.g., Director or ADS): [signature]	12/29/09 DBT 3/19/10	Check if PI is Division Official: ☐

I concur 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. APPROVED

Signature	Date	Remarks
for Chair, NIOSH HSRB: Kathy Masterson, Administrator	3/31/10	Expedited Review; Minimal Risk; as provided for in 45 CFR 46.110 (b)(1); Waiver of documentation of informed consent granted; Approved for one year; Renewal date 3/31/2011.
Other Clearance Official: (e.g., Confidentiality Officer, Coordinating Center/Office Official)		

5 Additional comments

Submission for conduct of national survey using questionnaire and procedures developed under protocol HSRB 08-DSHEFS-01-XP, 'Survey of Truck Driver Injury and Health: Cognitive Evaluation of Questionnaire and Pretest', 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

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