

Appendix E

IRB approval letter



DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date July 21, 2010

From Co-Chair, NIOSH HSRB

Subject Report of NIOSH HSRB -- Protocol No. HSRB 10-DSR-03XP "Evaluation of Ordinances to Prevent Workplace Violence in Convenience Stores" Approval of Protocol

To Harlan Amandus, Ph.D.
Project Officer, AFEB, DSR
Through: /Chief, AFEB, DSR _____
/Director, DSR _____

General Comments and IRB Actions

I received your revised protocol and consent document (memo dated July 13, 2010) and find that it is responsive to the issues raised in my July 1, 2010, expedited review of your original submission. Your protocol was reviewed using the expedited procedure in that it represents not more than minimal risk in that it involves research that uses previously collected materials (criterion #5), and uses interview methods (criterion #7) as provided for in 45 CFR 46.110. Your request for a waiver of documentation of informed consent is approved as provided for in 45 CFR 46.117(c) (1) in that [(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.] The revised protocol and oral consent documents dated 7/21/10 are **approved** for one year and will serve as the documents of record for this study (renewal date 7/21/2011). However, if you make any substantive changes, or any adverse reactions occur in any study participants, please notify me immediately.

Also, please follow-up with Kathy Masterson regarding all non-CDC collaborators/partners to ensure that the proper agreements are in place, prior to their engagement.

Protocol Issues – None.

Consent Form Issues – None.

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

End of report


Mark A. Toraason, Ph.D.

cc:
HSRB 10-DSR-03XP

