



DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date August 30, 2012

From Chair, NIOSH IRB (HSRB)

Subject Report of NIOSH HSRB – Protocol No. HSRB 11-DSR-02XP “Workplace Violence Prevention Programs in NJ Healthcare Facilities” Approval for Amendment

To Marilyn Ridenour Project Officer, AFEB, DSR Through: /Chief, AFEB, DSR ____ ____
/Director, DSR ____ ____

General Comments and IRB Actions

I have reviewed your request to amend protocol HSRB 11-DSR-02XP “Workplace Violence Prevention Programs in NJ Healthcare Facilities” using the expedited criteria outlined in 45 CFR 46.110 (b) (2) category in that it involves minor changes to a previously approved protocol; (b) (1) categories (5) and (7); and that no additional risks have been identified since the last review. The revised protocol and consent documents will serve as the documents of record for this study (dated 8/30/2012). A waiver of documentation of informed consent is still approved per 45CFR46.117 (c)(2) in “(2) 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 next review date for this protocol is 9/21/2012. This amendment is approved. However, if you make any substantive changes to the protocol, or if any adverse reactions occur in any study participants, please notify me immediately.

Also, please follow-up with Kathy Masterson regarding the roles of the following to ensure the proper assurances and agreements are in place for all engaged non-CDC collaborators, i.e., 1) Health Professionals and Allied Employees (HPAE) Union-Emerson, NJ; 2) Dr. Peek-Asa, University of IA-Iowa City; 3) State of New Jersey, Division of Consumer Affairs, Board of Nursing-Newark, NJ; 4) Dr. Carri Casteel, University of North Carolina; and 5) Emily O’Hagan. Thank you.

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

End of report


Mark A. Toraason, Ph.D.

cc: HSRB 11-DSR-02XP