

Attachment F: HSRB Non-Research Determination

2009-12-02 13:53

Mesterton

513648C407 >>

Fax Server

2 / 1



DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date December 2, 2009

From Co-Chair, NIOSH HSRB

Subject Report of NIOSH HSRB – Protocol No. HSRB 09-DSHEFS-NR05 “Hazard Surveillance Survey of Workers in the HCSA Sector – Phases 2 and 3” Non-Research Determination

To James Boiano, M.S., C.I.H.
Project Officer, SB, DSHEFS
Through: /Chief SB, DSHEFS _____
/Director DSHEFS _____

General Comments and IRB Actions

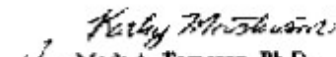
I have reviewed your request (E-mail dated 12/1/09 and attached 12/1/09 memo) for a Non-Research determination of the subject protocol. Your protocol involves the collection of information for the testing of a web-based surveillance tool (Phase 2) and implementation of the tool (Phase 3). It is noted here that phase 1 of this NORA project was reviewed and approved by the NIOSH HSRB (HSRB 09-DSHEFS-01XP). Subsequent to the HSRB review, you requested a Non-Research determination of Phase 1. Your request was understandable because of the surveillance nature of the project. However, I denied the request because the HSRB had already completed the review at your request, and a strong rationale for negating the review was lacking. At that time, I recommended that you request a Non-Research determination of Phases 2 and 3 prior to submission for HSRB review.

According to the 45 CFR 46.101(b)(2), Phases 2 and 3 may not require HSRB if they are surveillance rather than research. I have used CDC Guidelines for Defining Public Health Research and Public Health Non-Research and determined, based on your descriptions, that Phases 2 and 3 do not meet the criteria of research and do not require HSRB review.

However, the prevailing ethical standards for public health practice and privacy still apply. You should assure that participants understand the purpose, procedures, risks and benefits and that participation is optional. You should assure that participants are aware of whether or not you will maintain their privately identifiable information and you should assure that it is appropriately protected.

If there is a change in your activity, please request another determination. We have given this activity an HSRB number for your records (HSRB 09 DSHEFS NR05) and will file this memo with supporting documentation. If you have any questions about this matter please free to contact me at 513-533-8207.

End of report


Mark A. Tomason, Ph.D.

cc:
HSRB 09-DSHEFS-NR05