



## Memorandum

Date June 25, 2009

From Chair, NIOSH HSRB

Subject Report of NIOSH HSRB – Protocol No. HSRB 09-PRL-NR04 “Survey of Coal Mine Safety Interventions” Non-Research Determination

To Linda J. McWilliams, M.S.  
Project Officer, SRSB, PRL  
Through: /Chief SRSB, PRL \_\_\_\_\_  
/Director, PRL \_\_\_\_\_

### General Comments and IRB Actions

You submitted a full protocol to request an initial review of a new protocol by the CDC/NIOSH Institutional Review Board (Human Subjects Review Board) on June 15, 2009. In reviewing this protocol, it appears that your reason for conducting this project is to review your intervention program for the NIOSH Mining Program. Your project will “evaluate whether mine operators are familiar with NIOSH research, whether they recognize it as useful, whether they have adopted such measures in their mines, and whether it has improved the safety and health of their mine employees.”

I have determined that this proposed activity does not meet the criteria of research as defined by DHHS. Specifically, the federal regulations for the protection of human subjects at 45CFR46.102 (d) define research as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” In 1999, CDC further developed guidelines, “Guidelines for Defining Public Health Research and Public Health Non-Research.” According to the 1999 CDC guidelines, “When the purpose is to assess the success of an established program in achieving its objectives in a specific population and the information gained from the evaluation will be used to provide feedback to the program, the evaluation referred to as program evaluation, is non-research. In the non-research scenario, the evaluation is used as a management tool to monitor and improve the program.” Since you have an established technology transfer program for the NIOSH mining program and you are evaluating the effectiveness of this program to make improvements, I believe this activity to be non-research and not subject to the review by the NIOSH HSRB.

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 any privately identifiable information is appropriately protected.

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If there is a change in your activity, please request another determination. Please be aware that the research versus non-research guidelines are expected to be revised at the HHS Office of Human Research Protections. Therefore, future activities that may seem similar should be brought to my attention for another determination.

We have given this activity an HSRB number for our records HSRB 09-PRL-NR04 and will file this memo with the supporting documentation. If you have any questions about this matter, please feel free to contact me at (513) 841-4476.

**End of report**

  
Cheryl F. Estill, M.S., P.E.

cc:  
HSRB 09-PRL-NR04