

Attachment 13

Institutional Review Board Approval

Effective 9/9/2011, I have assigned the below described Non-Research activity HSRB/IRB number/title HSRB 11-DRDS-NR03 “Coal Workers Health Surveillance Program (CWHSP).”

Thank you, Anita.

Kathy.

Kathy Masterson, CIP
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From: Toraason, Mark A. (CDC/NIOSH/DART)

Sent: Friday, September 09, 2011 5:45 PM

To: Wolfe, Anita L. (CDC/NIOSH/DRDS)

Cc: Storey, Eileen (CDC/NIOSH/DRDS); Weston, Ainsley (CDC/NIOSH/DRDS); Toraason, Mark A. (CDC/NIOSH/DART); Trout, Douglas (CDC/NIOSH/DSHEFS); Masterson, Kathy J. (CDC/NIOSH/OD)

Subject: RE: IRB R/NR determination for CWHSP -- HSRB 11-DRDS-NR03

Dear Anita Wolfe:

I have reviewed the renewal of Coal Workers Health Surveillance Program (CWHSP) that you submitted for a research nonresearch determination. This is a congressionally-mandated medical examination program for monitoring the health of underground coal miners. This program, which includes both a health surveillance and an autopsy component, has been useful in providing tools for protecting the health of miners, and also documenting trends and patterns in the prevalence of coal workers' pneumoconiosis.

The CWSHP meets the definition of surveillance which is defined in CDC *Guidelines for Defining Public Health Research and Public Health Non-Research* as “a series of ongoing systematic activities, including collection, analysis, and interpretation of health-related data essential to planning, implementing, and evaluating public health practice closely integrated to the dissemination of data to those who need to know and linked to prevention and control. “

The CDC Guidelines defines surveillance as public health nonresearch. As a nonresearch activity, the CWHSP does not require review by the NIOSH IRB.

It is recognized that a NIOSH IRB approved human subjects research project (HSRB-06-DRDS-01) is imbedded in the CWHSP, and that NIOSH policy states that if a component of an activity is human subjects research, the entire activity is human subjects research. In this case, however, the policy does not apply because the purpose of the research project is to assess the transition from using film based chest radiographs to digital chest images. While the imbedded project will contribute to generalizable knowledge that may be used by the CWHSP, the surveillance continues independently of the digital image evaluation project.

Kathy Masterson will provide a nonresearch number for this CWSHP and the NIOSH IRB will maintain a record of this designation.

Mark Toraason, Ph.D., Director, HRPP, Chair, IRB