

Attachment E - HSRB Documentation



DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date January 23, 2009

From Chair, NIOSH HSRB

Subject Report of NIOSH HSRB – Protocol No. HSRB 09-OCAS-NR01 “Energy Employees Occupational Illness Compensation Program Act Dose Reconstruction Interviews and Forms” Non-Research Determination

To David S. Sundin
Project Officer, OCAS

Through: Chief, Director, OCAS *AE-1/22/09*

General Comments and IRB Actions

In your e-mail of January 21, 2009 regarding the subject protocol, you described your project. Your project is to collect exposure information from energy employees who are suffering from designated illnesses incurred as a result of their employment-based exposures to radiation, beryllium, or silica. This activity is occurring as a result of The Energy Employees Occupational Illness Compensation Program Act. The information is being collected to make individual determinations as to employees exposures for the possibility of lump sum payment and medical benefits.

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.” There is no intent in the present activity to develop generalizable knowledge. Instead the goal is to make exposure decisions about particular individuals to determine their compensation.

However, the prevailing ethical standards for public health practice and privacy still apply. You should assure that participants privately identifiable information is appropriately protected.

We have given this activity an HSRB number for our records (HSRB 09-OCAS-NR01) 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-OCAS-NR01