

HSRB Determination



DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date June 3, 2010

From Chair, NIOSH HSRB

Subject Report of NIOSH HSRB – Protocol No. HSRB 10-DCAS-NR01 “Energy Employees Occupational Illness Compensation Program of 2000 Special Exposure Cohort Regulation 42 CFR Part 83” Non-Research Determination

To David S. Sundin
Project Officer, DCAS
Through: /Chief, Director, DCAS _____

General Comments and IRB Actions

In your e-mail of June 1, 2010 regarding the subject protocol, you described your project. Your project is to collect information from covered employees suffering from designated illnesses incurred as a result of their employment-based exposures to radiation, beryllium, or silica while in the performance of their duties. This activity is occurring as a result of The Energy Employees Occupational Illness Compensation Program Act of 2000. The information is being collected to make individual determinations on compensation.

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 privately identifiable information is appropriately protected and participation is voluntary.

We have given this activity an HSRB number for our records (HSRB 10-DCAS-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 Fairfield Estill
Cheryl Fairfield Estill, M.S., P.E.

cc:
HSRB 10-DCAS-NR01