

Attachment E – IRB Approval



DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date June 3, 2009

From Chair, NIOSH HSRB

Subject Report of NIOSH HSRB -- Protocol No. HSRB 09-PRL-02XP "Assessing the Safety Culture of Coal Mining" Approval of Protocol

To Katherine A. Margolis (previously Klein), Ph.D.
Project Officer, SRSB, PRL
Through: /Chief, SRSB, PRL _____
/Director, PRL _____

General Comments and IRB Actions

I received your response (memo dated 5/19/09) and find that it is responsive to the issues raised in my 5/7/09 HSRB report of the subject protocol. Your protocol was reviewed using the expedited procedure in that it presents no more than minimal risk and involves criterion #7 [Research on individual group characteristics or behavior (including but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurances methodologies] as provided for in 45CFR46.110. Your request for a waiver of signed documentation of informed consent is granted. The revised protocol and consent documents are **approved** (dated 6/3/09) and will serve as the documents of record for this study. This protocol is granted approval for one year (renewal date 5/7/2010). However, if you make any substantive changes to the protocol, or if any adverse reactions occur in any study participants, please notify me immediately.


We received signed agreements (CDC forms 0.1373A) for non-CDC collaborators, Drs. Shurberg and Haber and effective 6/3/09 are approved to be engaged in this research.

Protocol Issues – None.

Consent Form Issues – None.

Addenda Issues (Scripts, questionnaires, brochures, etc.) – None.

End of report


Cherie Fairfield Estill, M.S., P.E.

cc:
HSRB 09-PRL-02XP