

Appendix E: HSRB Approval Letter



DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date June 9, 2009

From Chair, CDC/NIOSH HSRB

Subject Report of NIOSH HSRB -- Protocol No. HSRB 09-DSR-01XP "Increasing Adoption of CROPS (Cost Effective Roll-Over Protective Structures) by Farmers and Manufacturers" Approval of Protocol

To David Hard, Ph.D.
Project Officer, AFEB, DSR
Through: /Chief, AFEB, DSR _____
/Director, DSR _____

General Comments and IRB Actions

I received your response on 5/19/09 and find it responsive to the issues raised in my 4/2/09 expedited review/report regarding the subject protocol. Your protocol was reviewed reviewed using the expedited procedure in that it presents no more than minimal risk and involves criterion #7 (research on individual or group characteristics employing survey); criterion #5 (research involving materials that have been previously collected); and criterion #6 (Collection of data from voice, video, digital, or image recordings) as provided for in 45CFR46.110. Your protocol is approved for one year (renewal date 4/2/2010). The revised protocol (dated 6/9/09) will serve as the document of record for this study. However if you make any substantive changes, or any adverse reactions occur in any study participants, please notify me immediately.

Additionally, please follow-up with Kathy Masterson regarding partners New York Center for Agricultural Medicine; and Virginia Farm Bureau Mutual Insurance Company to ensure that the proper assurances and agreements are in place prior to engagement. Engaged means to either: 1) interact or intervene with subjects; 2) access private identifiable information; or 3) receive federal funds.

Protocol Issues – None.

Consent Form Issues – None.

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

End of report

Kathy Masterson
for Cheryl Fairfield Estill, M.S., P.E.

cc:
HSRB 09-DSR-01XP