

e-mail dated 3/13/06:

Subject: Initial Review Submission for Protocol No. AHE42

WIRB:

As Principal Investigator for Protocol No. AHE42, I am making an Initial Review Submission for a study sponsored by the Agricultural Handlers Exposure Task Force (AHETF). AHETF is a consortium of pesticide manufacturers who jointly sponsor worker exposure studies which utilize professionals with experience handling agricultural pesticide products. In this case, the study will involve workers who mix and load a commercially-available liquid fungicide product or who apply the diluted spray mixture to approved crops using closed cockpit aircraft. The workers will be monitored for dermal and inhalation exposure using passive dosimetry techniques.

AHETF is requesting an EXPEDITED Review since the following criteria are met:

1. The study poses no more than minimal risk: workers will wear an extra layer of clothing (which serves as a surrogate for skin and serves to trap chemical that would otherwise reach the skin and be available for absorption) and will handle a commercially approved fungicide product using their normal practices and following all use directions on the product label.
2. Data will be collected by non-invasive means only: exposure data will be collected by washing hands in soapy water and analyzing the wash water, wiping face/neck areas with gauze pads moistened with soapy water and analyzing the pads, analyzing the extra (inner) layer of clothing worn by the workers, and collecting air from the breathing zone of the worker using sorbent tubes and low volume, personal air sampling pumps.

AHETF has received expedited review and approval from WIRB for several previous studies with very similar protocols and consent forms.

The following documents are attached for your review:

- WIRB Initial Review Submission Form (Revised 01-2006)
- Protocol for Study AHE42
- Research Subject Information and Consent Form - English
- Hospitalization Procedures

Note that WIRB already has a current CV for the Principal Investigator.

Please contact me if you have any questions and to let me know a tracking number for this submission when one is issued.

Thank You,

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