

AGRICULTURAL HANDLERS EXPOSURE TASK FORCE

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April 28, 2006

Mr. Richard Dumas
United States Environmental Protection Agency
Ariel Rios Bldg. (Mailcode 7508P)
1200 Pennsylvania Ave. NW
Washington, DC 20460

Subject: AHETF Protocols and IRB Materials

Dear Mr. Dumas:

The purpose of this submission is to provide the documents necessary for the review of Agricultural Handlers Exposure Task Force (AHETF) field-monitoring study protocols by the Human Subjects Review Board (HSRB) at their June 27 to 29, 2006 meeting. Enclosed are the study protocols and supporting documentation from the Institutional Review Board (IRB) review for five studies (Study Nos. AHE34, AHE36, AHE37, AHE38, and AHE42). These five studies are scheduled to be conducted during the summer of 2006.

The enclosed protocols represent five studies that the AHETF is submitting for review by USEPA and the HSRB at their late June meeting. We apologize for the delay in sending these documents to you. The competing pressures to finalize the details of dynamic, seasonal field studies and have the resulting study protocols reviewed and approved by the IRB, USEPA and HSRB have created new logistical challenges for all stakeholders.

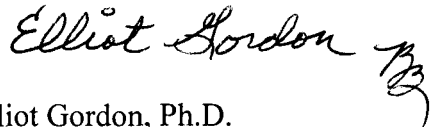
As you know, the design framework for all AHETF studies are similar with respect to worker recruitment and sample collection procedures and differ only by the timing, location, surrogate product, and specific worker activity. AHETF studies conform to a series of standardized, uniform procedures that ensure the protection and proper treatment of study participants. In addition, AHETF uses a single IRB (Western Institutional Review Board, Olympia Washington) which results in a consistent "informed consent" form used in these worker monitoring studies. Based on these similarities between studies, we suggest that AHETF study protocols be reviewed as a single group during the June HSRB meetings.

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Recognizing the unique characteristics and purpose of these studies, AHETF is requesting the opportunity to present information to the HSRB which will facilitate their review of these studies. As discussed, we believe a brief presentation outlining the background and purpose of the AHETF and the role that individual field studies play in the larger generic regulatory database (AHEDTM) being developed by AHETF would be very helpful to the HSRB. It is expected that this presentation by a representative of the AHETF to the HSRB should not take more than 60 minutes. As mentioned to you earlier today, we are making this same request to Mr. Paul Lewis.

If there is any additional information or clarification needed regarding the subject study protocols, please contact me.

Best regards,

A handwritten signature in cursive script that reads "Elliot Gordon" followed by a stylized flourish.

Elliot Gordon, Ph.D.
Chair, Administrative Committee
Agricultural Handlers Exposure Task Force