

US EPA ARCHIVE DOCUMENT

HSRB Background Information For AHETF Protocol Reviews (June 2006)

Welcome HSRB Members! This directory contains the background information for the upcoming June 2006 meeting of the EPA Human Studies Review Board in which 5 Agricultural Handlers Exposure Task Force (AHETF) protocols for conducting human exposure studies will be reviewed (AHE- 34, 36, 37, 38, & 42). The information provided on this CD includes transmittal documents and the charge questions, general background information pertaining to the manner in which the Agency completes exposure/risk assessments; the AHETF protocols themselves and various documents that the AHETF has developed related to the manner in which it intends to conduct studies; the background documents related to the AHETF protocol review by the Washington Institutional Review Board; and the EPA science and ethics reviews of these protocols.

There are 8 directories on this CD in the AHETF folder which contain multiple documents. These directories include:

- Background information produced by the AHETF pertinent to the manner in which they intend to conduct these studies (3 directories);
 - o 1) AHETF Analytical Method Validation Reports
 - o 2) AHETF Misc. Documents
 - o 3) AHETF SOPs (Standard Operating Procedures) Applicable To Study Conduct
- 4) AHETF Protocols & Institutional Review Board documentation (5 Subdirectories, one for each protocol). Each subdirectory includes:
 - o Protocol AHE-XX
 - o Initial Review Submissions To WIRB (Washington Institutional Review Board) which includes (numerous documents for each protocol): correspondence, submission paperwork, consent form and hospitalization procedures
 - o Approval Documentation From WIRB which includes (numerous documents for each protocol): confirmation letters, review notices, consent form edits, etc.
- 5) EPA Science Review Documents (1 for each protocol & a summary document)
- 6) EPA Ethics Review Document
- 7) EPA Guidance Documents – copies of current Agency guidance and some applicable draft guidance documents that pertain to the conduct of occupational exposure studies
- 8) Primers For Occupational Exposure Assessment – contains copies of 2 Agency Powerpoint© presentations which have been given that provide the basics on the “nuts & bolts” of occupational exposure assessments. Also provided is a short e-movie illustrating one of the commonly used pieces of equipment in agriculture that is the focus of several of the protocols and an excellent primer/overview document generated by Purdue University on pesticide exposure and risk assessment issues.

[Note: Also included on this CD are 2 additional pertinent files, not included in the 8 directories, which are (1) the charge questions to the HSRB panel and (2) a copy of the transmittal memo to the panel.]