UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

March 8, 2011

MEMORANDUM

SUBJECT: Ethics Review of Completed AHETF Open Cab Airblast Scenario Worker Exposure Monitoring Study

FROM: Kelly Sherman
Human Research Ethics Review Officer
Office of Pesticide Programs

TO: Steve Knizner, Associate Director
Health Effects Division

REF: Bruce, Eric D. (2010) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Open Cab Equipment in California Trellis Crops. Study Number AHE62. 283 p. (MRID 48289611) **[Volume 1]**

Bruce, Eric D. (2010) IIRB Correspondence Report for Cluster Report AHE62. 327 p. (MRID 48289614) **[Volume 2]**

Bruce, Eric D. (2010) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Open Cab Equipment in New York Trellis Crops. Study Number AHE63. 247 p. (MRID 48289612) **[Volume 3]**

Bruce, Eric D. (2010) IIRB Correspondence Report for Cluster Report AHE63. 295 p. (MRID 48289615) **[Volume 4]**

Bruce, Eric D. (2010) Determination of Dermal and Inhalation Exposure to Workers During Airblast Applications of Liquid Sprays Using Open Cab Equipment in Oklahoma Tree Nuts. Study Number AHE64. 236 p. (MRID 48289613) **[Volume 5]**

I have reviewed the available information concerning the ethical conduct of the research reported in the referenced documents, which describe the execution and results of a series of three field studies in which dermal and inhalation exposure of professional pesticide applicators was monitored as they applied liquid pesticides to orchard and trellis crops using an airblast sprayer drawn by a tractor with no cab (known as an "open cab"). If these studies are determined to be scientifically acceptable, I find no barrier in regulation to EPA's reliance on them in actions under FIFRA or FFDCA.

1.0 Background and Ethics-related Chronology

Three separate field studies were conducted, each monitoring workers while they sprayed trellis or tree crops in three different states in the U.S where open cab airblast equipment is used in production agriculture. The studies are summarized in Table 1.

Table 1. Study Summary

Study ID	State	Crop	Number of Monitored Workers	Gender	Ages
AHE62	CA	Grapes	3	All male	43-79
AHE63	NY	Grapes	5	All male	28-66
AHE64	OK	Pecans	5	All male	47-74

The background and ethics-related chronology for each field study are summarized below.

1.1 AHE62

The scenario design and protocol for AHE62 were approved by the overseeing IRB, the Independent Investigational Review Board, Inc. (IIRB), of Plantation, Florida, in July 2008 and submitted to EPA for review in August 2008. The protocol and EPA's review dated September 23, 2008 were discussed by the Human Studies Review Board (HSRB) at its October 2008 meeting. The HSRB review was generally favorable, and the Board's December 30, 2008 final report concluded, with respect to ethics, that "[i]f revised as suggested by the Board in its review, the research described in these three protocols is likely to meet the applicable requirements of 40 CFR part 26, subparts K and L."

Following the HSRB review, the protocol, consent form, California Experimental Research Subject's Bill of Rights (CaBOR), and recruitment materials for AHE62 were revised to address EPA, California Department of Pesticide Regulation (CDPR), and HSRB comments. The revised documents were submitted to IIRB in March 2009 and approved in April 2009. Three subsequent amendments were approved by IIRB in June, July, and November 2009.

Subject monitoring for AHE62 took place in July 2009. Three male subjects between the ages of 43 and 79 were monitored for dermal and inhalation exposure while applying pesticide sprays using open-cab airblast equipment to grapes in California. There was one reported deviation during the field phase of the research, and one reported deviation during the analytical phase. I noted one unreported deviation.

A detailed chronology of the ethics-related study activities for AHE62 is provided in Table A in Attachment 1. A summary of amendments and reported and unreported deviations from all studies is provided in Table 2, on page 11.

1.2 AHE63

The scenario design and protocol for AHE63 was approved by IIRB in July 2008 and submitted to EPA for review in August 2008. The protocol and EPA's review dated September 23, 2008 were discussed by the HSRB at its October 2008 meeting. The HSRB review was generally favorable, and the Board's December 30, 2008 final report concluded, with respect to ethics, that "[i]f revised as suggested by the Board in its review, the research described in these three protocols is likely to meet the applicable requirements of 40 CFR part 26, subparts K and L."

Following the HSRB review, the protocol, consent form, and recruiting materials for AHE63 were revised to address EPA and HSRB comments. The revised documents were submitted to IIRB on January 16, 2009, and approved on January 19, 2009. Two subsequent amendments were approved by IIRB in July and August 2009.

Subject monitoring for AHE63 took place in July and August 2009. Five male subjects between the ages of 28 and 66 were monitored for dermal and inhalation exposure while applying pesticide sprays using open-cab airblast equipment to grapes in New York. There was one reported deviation during the field phase of the research, and two reported deviations during the analytical phase. I noted no unreported deviations.

A detailed chronology of the ethics-related study activities for AHE63 is provided in Table B in Attachment 1. A summary of amendments and reported and unreported deviations from all studies is provided in Table 2, on page 11.

1.3 AHE64

The scenario design and protocol for AHE64 was approved by IIRB in July 2008 and submitted to EPA for review in August 2008. The protocol and EPA's review dated September 23, 2008 were discussed by the HSRB at its October 2008 meeting. The HSRB review was generally favorable, and the Board's December 30, 2008 final report concluded, with respect to ethics, that "[i]f revised as suggested by the Board in its review, the research described in these three protocols is likely to meet the applicable requirements of 40 CFR part 26, subparts K and L."

Following the HSRB review, the protocol, consent form, and recruiting materials for AHE64 were revised to address EPA and HSRB comments. The revised documents were submitted to IIRB on January 16, 2009, and approved on January 19, 2009. Two subsequent amendments were approved by IIRB in June and September 2009.

Subject monitoring for AHE64 took place in August 2009. Five male subjects between the ages of 47 and 74 were monitored for dermal and inhalation exposure while applying pesticide sprays using open-cab airblast equipment to pecans in Oklahoma. There was one reported deviation during the field phase of the research, and one reported deviation during the analytical phase. I noted no unreported deviations.

A detailed chronology of the ethics-related study activities for AHE64 is provided in Table C in Attachment 1. A summary of amendments and reported and unreported deviations from all studies is provided in Table 2, on page 11.

2.0 Completeness of Submission:

The checklist used by EPA to verify satisfaction of the requirements of §26.1303 as they apply to the report of this research appears as Attachment 1 to this review. This review considers the 6 study volumes identified on pages 1-2, plus the Heat Index Records from the Raw Data (which were provided separately by the AHETF, upon request from EPA [via an email from V. Canez to K. Sherman, 3/8/11]). The Heat Index records are included as Attachment 4 to this review.

3.0 Protocol Amendments:

3.1 AHE62

Following EPA's and HSRB's reviews, the protocol, consent form, and recruiting materials were revised to address EPA, HSRB, and CDPR comments. The revised materials were submitted to IIRB on March 27, 2009, and approved on April 1 and 6, 2008.

In early June 2009, the AHETF consulted EPA about three changes to the AHE62 protocol, and EPA ultimately approved the changes. On June 19, 2009, the AHETF submitted to IIRB an amendment encompassing the three changes, and IIRB approved the amendment on June 23, 2009. Each of the three changes is discussed below.

1) The first change was to amend the inclusion criteria to allow participation by individuals who normally wear two layers of clothing (the inclusion criteria previously stated that only workers who normally wear one layer of clothing would be eligible to participate). The change was in response to a discovery by the AHETF that many airblast applicators in Fresno County normally wear two layers of clothing (for example, a typical shirt and pants under a cloth

coverall). To accommodate these workers and increase the pool of potentially eligible workers, the AHETF sought to amend the inclusion criteria. EPA approved the change provided that the workers who normally wear two layers agree to substitute their normally-worn inner layer of clothing for the long underwear dosimeter provided by the AHETF. The change was acceptable to EPA from an ethics perspective because it neither requires participants to wear less clothing than they normally would, nor results in subjects wearing a third layer of clothing, which could increase the risks of heat-related illness.

2) The second change was to expand the permissible recruitment area to any county in California or Washington if the county previously specified in the protocol (Fresno County, California) does not provide a sufficient number of eligible growers. The change appeared to be necessary because many potential subjects in Fresno County might not be eligible to participate because they normally wear Tyvek coveralls, or because their Pest Control Advisor, winery, or raisin packer might not approve the use of either of the two surrogate compounds.

3) The third change was to remove the efficient configuration requirement if the recruitment area is expanded.

On July 22, 2009, the AHETF submitted an additional amendment to IIRB to add to the list of approved test substances a malathion end-use product preferred by some growers. EPA approved the addition of this product to the list of possible surrogates, and IIRB approved the amendment on July 22, 2009.

In November 2009, the AHETF submitted an amendment to specify the analytical methods to be used for head patches; IIRB approved the amendment on November 24, 2009.

In EPA's view, the amendments to AHE62 are not problematic from an ethics perspective because they do not increase risks to subjects or jeopardize informed consent. I defer to the EPA science reviewer about whether these amendments are important from a science perspective.

3.2 AHE63

Following EPA's and HSRB's reviews, the protocol, consent form, and recruiting materials were revised to address EPA and HSRB comments. The revised materials were submitted to IIRB on January 16, 2009, and approved on January 19, 2009.

On June 26, 2009, the AHETF submitted to IIRB two proposed recruitment letters that would be sent to grape growers in New York State before the initial recruiting telephone calls. The letters were approved by IIRB on the same day that they were submitted.

On July 17, 2009, the AHETF submitted to IIRB an amendment encompassing the changes listed below. IIRB approved the amendment on July 21, 2009.

1) The first change was a modification to the recruitment process to allow for use of the two recruitment letters that were approved by IIRB on June 26, 2009. In EPA's view, adding this new step to the recruitment process does not raise ethics concerns because (a) researchers intend to send one of the two letters to all of the grape growers whose names appear on the master list of New York grape growers; (b) the letters have been IRB-approved; and (c) the letters may help to increase the number of growers who are willing to take part in an initial recruitment telephone conversation.

2) The second change was to reduce the heat index threshold for stopping the research from 120° F to 105° F. The change was made, in part, to address concerns from the HSRB that the previous heat index threshold of 120° F was too high. EPA supports this change because it increases protection for subjects.

3) The third change was to revise the dermal exposure sampling procedure to specify that the inner dosimeters would be cut into 6 sections after collection rather than 2 sections. Analyzing the dosimeters in more sections allows the AHETF to determine body-specific residues for more body parts, which may be important because this exposure scenario is expected to result in relatively high dermal exposure potential. It may be useful have to ability to more precisely pinpoint the areas of highest exposure. This change does not impact any ethics considerations.

4) The fourth change was to revise the analytical methods to make them more appropriate for whole-body dosimeters sectioned into 6 pieces. This change does not impact any ethics considerations.

5) The fifth change was to clarify in the protocol the AHETF's raw data retention policy. The following sentence was added to the protocol:

   > "In accordance with GLP regulations (40 CFR 160.195) and SOP AHETF-6.A, raw data will be retained in archives as long as the AHETF or other registrant holds a research or marketing permit to which the study is pertinent."

   This change does not impact any ethics considerations.

In EPA's view, the five changes encompassed in this amendment are not problematic from an ethics perspective because they do not increase risks to subjects or jeopardize informed consent, and they were approved by IIRB before implementation. I defer to the EPA science reviewer about whether these changes are important from a science perspective.

The AHETF submitted an additional protocol amendment to IIRB on August 13, 2009, changing the procedures for chemical analysis of the head patches. This amendment does not affect any ethics considerations, but I defer to the EPA science reviewer about whether this amendment is important from a science perspective.

3.3 AHE64

Following EPA's and HSRB's reviews, the protocol, consent form, and recruiting materials were revised to address EPA and HSRB comments. The revised materials were submitted to IIRB on January 16, 2009, and approved on January 19, 2009.

On June 15, 2009, the AHETF submitted to IIRB two proposed recruitment letters that would be sent to Oklahoma pecan growers before the initial recruiting telephone calls, plus an amendment encompassing the changes discussed below. IIRB approved the letters and the amendment on June 19, 2009.

1) The first change was a modification to the recruitment process to allow for use of the two recruitment letters which were submitted in conjunction with the amendment. In EPA's view, adding this new step to the recruitment process does not raise ethics concerns because (a) researchers intend to send one of the two letters to all of the pecan growers whose names appear on the master list of Oklahoma pecan growers; (b) the letters have been IRB-approved; and (c) the letters may help to increase the number of growers who are willing to take part in an initial recruitment telephone conversation.

2) The second change was to expand the permissible recruitment area from Tulsa County, Oklahoma, to also include the adjacent Oklahoma counties of Creek, Okmulgee, Wagoner, Rogers, Washington, and Osage. The reason for the change was that obtaining a list of nut growers in Oklahoma was proving difficult, and indications were that open cabs are less prevalent than closed cabs in Oklahoma. Only pecan grower names could be obtained, but this represents the majority of nut crops in Oklahoma. The U.S. Census of Agriculture indicates there are 95 growers of pecans in Tulsa County that grow the minimum necessary acreage (at least 5 acres). Based on response rates from other studies, the AHETF observed that a list of 95 growers was likely too small to yield 5 potentially eligible growers. Expanding the recruitment area to include the surrounding counties results in a list of 279 growers which should provide a sufficient number of potentially eligible growers. In EPA's view, this change is not problematic from an ethics perspective because it does not increase risks to subjects or jeopardize informed consent. I defer to the EPA science reviewer about whether this change is important from a science perspective.

3) The third change was to remove the efficient configuration requirement if the recruitment area is expanded.

4) The fourth change was to revise the dermal exposure sampling procedure to specify that the inner dosimeters would be cut into 6 sections after collection rather than 2 sections. Analyzing the dosimeters in more sections allows the AHETF to determine body-specific residues for more body parts, which may be important because this exposure scenario is expected to result in relatively high dermal exposure potential. It may be useful have to ability to more precisely pinpoint the areas of highest exposure. This change does not impact any ethics considerations.

5) The fifth change was to revise the analytical methods to make them more appropriate for whole-body dosimeters sectioned into 6 pieces. This change does not impact any ethics considerations.

On September 14, 2009, the AHETF submitted to IIRB a second protocol amendment, changing the study director from Eric D. Bruce to Larry D. Smith. The effective date for the change in study director was September 14, 2009, after the close of the study. This amendment does not affect any ethics considerations. IIRB approved the amendment on September 16, 2009.

4.0 Protocol Deviations:

4.1 AHE62

4.1.1 Reported Deviations

There was one reported deviation during the field phase of AHE62. Inner and outer head patch field fortifications were performed in duplicate rather than in triplicate. In addition, no samples were taken for the higher fortification level (100 ug) for the inner head patches. The deviation occurred because a researcher initially fortified head patch matrices in a way that was not in accordance with the relevant SOP (AHE-8.E.5). The error was discovered while still in the field, so correct matrices were fortified. However, there were only enough extra fortification vials remaining for duplicate samples and there were no vials available for the 100 ug high fortification rate for inner head patches. This deviation occurred on July 2, 2009, and was reported to IIRB on September 2, 2009. On September 3rd, IIRB acknowledged the deviation and concluded that it did not place subjects at increased risk. In EPA's view, this deviation is not significant from an ethics perspective. I defer to the EPA science reviewer about whether this deviation is important from a science perspective.

There was one reported deviation in the analytical phase of the research. Field fortification solutions for some lots were not verified to establish concentration. This deviation raises no ethical issues, but I defer to the EPA science reviewer on whether it affects the scientific integrity of the data.

4.1.2 Unreported Deviations

I noted one unreported deviation during the field phase of AHE62. Subject A2 was monitored for only 174 minutes, although the protocol requires a minimum 4-hour monitoring period. This deviation raises no ethical issues, but I defer to the EPA science reviewer on whether it affects the scientific integrity of the data.

4.2 AHE63

4.2.1 Reported Deviations

There were two reported deviations during the field phase of AHE63. One subject (A5) applied only 2 tank loads of spray mixture and sprayed for only 2 hours, although the protocol specifies "Each MU shall consist of a period of at least 4 hours of spraying and at least 3 tank loads of the spray mixture." The deviation occurred because the pesticide needed to be applied at a specific concentration in order to achieve efficacy. It was not possible to increase the spray volume or reduce the tractor ground speed to reach the protocol-required targets without sacrificing efficacy.

The second deviation was that the highest stratum (56 to 100 lbs active ingredient) was not filled; the highest amount of active ingredient sprayed by a subject in this study was 48 lbs. This deviation occurred because New York grape applicators typically apply at a rate of 32 lbs active ingredient per day, and thus could not achieve the amount in stratum 5 without working an abnormally long day. Both of the deviations occurred between July 28 and August 6, 2009, and were reported to IIRB on September 11, 2009. On September 15th, IIRB acknowledged the deviation and concluded that it did not place subjects at increased risk. The deviation does not raise ethical issues because the expected exposure as a result of this deviation is not out of the range of safe exposures based on pre-study evaluations of risk. I defer to the EPA science reviewer about whether this deviation is important from a science perspective.

There also were two method deviations related to analysis of carbaryl in inner dosimeters and face/neck wipe samples that were reported to IIRB. These analytical deviations raise no ethical issues, but I defer to the EPA science reviewer on whether they affects the scientific integrity of the data.

4.2.2 Unreported Deviations

I noted no unreported deviations during the field phase of AHE63.

4.3 AHE64

4.3.1 Reported Deviations

There was one reported deviation during the field phase of AHE64 that involved departures from the protocol-required minimum application time, number of spray loads, and active ingredient strata. Four of the five subjects (A2, A3, A4, and A5) each sprayed only 2 tank loads of spray mixture for less than 4 hours each, contrary to the protocol requirement that subjects should be monitored for a minimum of 4 hours and apply at least 3 tank loads. In addition, the lowest stratum (5 to 9 lbs active ingredient) was not achieved by any of the subjects. The reason given for the deviation was that highest label rate was required for controlling the target pest. It was not possible to increase the spray volume or reduce the tractor ground speed and still achieve efficacy. Application times were dictated by the grower spray patterns and orchard configurations. The deviation occurred between August 22-29, 2009, and was reported to IIRB on September 18, 2009. On September 23, 2009, IIRB acknowledged the deviation and indicated that no additional action was required. The deviation does not raise ethical issues because the expected exposure as a result of this deviation is not out of the range of safe exposures based on pre-study evaluations of risk. I defer to the EPA science reviewer on whether this deviation raises science issues.

There also was one method deviation in the analytical phase, related to analysis of carbaryl in inner dosimeters, reported to IIRB. This deviation raises no ethical issues, but I defer to the EPA science reviewer on whether it affects the scientific integrity of the data.

4.3.2 Unreported Deviations

I noted no unreported deviations during the field phase of AHE64.

Table 2. Summary of Protocol Amendments and Deviations			
Study ID	**Amendments**	**Deviations**	
		Field Phase	**Analytical Phase**
AHE62	1. Amended to incorporate comments from EPA, California Department of Pesticide Regulation, and HSRB. 2. ***Protocol Amendment 1*** • Inclusion criteria amended to allow participation of workers who normally wear two layers of clothing. • Recruitment area expanded to allow any county in CA or WA. • Removed efficient configuration requirement if recruitment area is expanded. 3. ***Protocol Amendment 2*** • Added a new malathion product to possible test products (the active ingredient malathion was already an approved surrogate) 4. ***Protocol Amendment 3*** • Specified the analytical methods to be used for head patches	Reported: 1. On study day 1, inner and outer head patch field fortifications were conducted in duplicate instead of triplicate, and on study day 1, no samples were taken for the higher fortification level (100 ug) for the inner head patches. Unreported: 1. Subject A2 was monitored for 174 minutes, although the protocol requires a minimum 4-hour period.	1. Field fortification solutions for some lots were not verified to establish concentration
AHE63	1. Amended to incorporate comments from EPA and HSRB. 2. ***Protocol Amendment 1*** • Recruitment process modified to permit use of recruitment letters • Reduce heat index stopping rule from 120° F to 105° F • Amend dermal exposure sampling procedure to specify that the inner dosimeters would be cut into 6 sections rather than 2 sections • Revise analytical methods to make them appropriate for dosimeters cut into 6 pieces • Amend protocol to clarify the AHETF's raw data retention policy 3. ***Protocol Amendment 2*** • Amended analytical method for head patches	Reported: 1. Subject A5 applied only 2 tank loads and sprayed for only 2 hours, although the protocol specifies that each subject should apply a minimum of 3 tank loads over a minimum time of 4 hours; also, the highest stratum (56 to 100 lbs a.i.) was not achieved; the highest amount sprayed was 48 lbs a.i. Unreported: 1. None	1. The analytical laboratory deviated from methodologies related to analysis of carbaryl in inner dosimeters 2. The analytical lab deviated from methodologies related to analysis of carbaryl in face/neck wipe samples
AHE64	• Amended to incorporate comments from EPA and HSRB. • ***Protocol Amendment 1*** • Recruitment process modified to permit use of recruitment letters • Recruitment area expanded to allow counties adjacent to Tulsa County, OK. • Removed efficient configuration requirement if recruitment area expanded. • Amended dermal exposure sampling procedure to specify that the inner dosimeters would be cut into 6 sections • Revise analytical methods to make appropriate for dosimeters cut in 6 sections 3. ***Protocol Amendment 2*** • The study director was changed from Eric D. Bruce to Larry D. Smith, effective September 14, 2009 (after study closure)	Reported: 1. Subjects A2, A3, A4, A5 each applied only 2 tank loads and sprayed for less than 4 hours, although the protocol specifies that each subject should apply a minimum of 3 tank loads over a minimum time of 4 hours. Also, the lowest stratum (5 to 9 lbs a.i.) was not achieved; the lowest amount sprayed was 10 lbs a.i. Unreported: 1. None	1. The analytical laboratory deviated from analytical methodologies related to analysis of carbaryl in inner dosimeters

5.0 Recruiting

The three-phase recruiting process outlined in the protocol and SOPs AHETF-11.K.O, 11.L.0, and 11.M.0 appears to have been followed in all three studies. An initial grower universe list was generated from published lists or databases. Duplicate entries and growers with missing phone numbers were suppressed, to produce the master grower lists (which ranged in size from 330 names to 4,064 names in the three studies). After protocols were finalized and signed by the study director, qualifying calls were placed to the names on the master grower list, and the lists were narrowed by eliminating names based on responses to qualifying questions, being unreachable, or lack of interest in participating in the research. The resulting lists contained names of growers who were qualified and interested in participating in the research. For the final stage of recruiting, the study director contacted and/or visited all qualified growers, to identify growers who could participate in a timeframe and schedule to allow the study to be conducted efficiently. Table 2 in each of the Study Reports (Volume 1, p. 38; Volume 3, p. 32; Volume 5, p. 33) details the number of growers/workers in each stage of the recruitment process.

The AHETF encountered difficulties recruiting growers for AHE62. This study required open cab airblast equipment and bush trellis crops in commercial production. In the initial phase of recruiting, lists of growers of grapes, blackberries, blueberries, boysenberries, loganberries, and raspberries were generated. Because less than 0.3% of the growers grew a trellis crop other than grapes, and none of the "other bush crop" growers qualified for inclusion in the study, the remainder of the recruitment efforts were directed toward grape growers. Recruitment initially focused on Fresno, California, but the many of the qualified handlers in Fresno wore additional personal protective equipment (PPE) (for example, coveralls or rain suits) or did not want to use the surrogate chemicals listed in the protocol, and therefore could not be recruited. Due to these difficulties, the protocol was amended to allow recruitment from all counties in California and Washington (see discussion of the protocol amendment in section 3.1of this review). The early-phase recruitment efforts resulted in a master grower list containing 4,064 names. The relatively large master grower list yielded a small qualified grower list (259 names), however, because a great majority of the growers who were contacted were not qualified because they wore chemical-resistant PPE, grew less than 10 acres, did not use open cab equipment, refused the interview, or were not able to be contacted. Ultimately, the 259 names on the qualified grower list only yielded 4 growers on the eligible grower list because many of the growers were either unwilling to participate or unable to use either of the planned surrogates. Three of the 4 eligible growers were ultimately monitored in AHE62. The fourth grower did not participate because his Pest Control Advisor did not approve use of either of the AHETF surrogates, and instead recommended a different pesticide.

5.1 Subject Representativeness

At the conclusion of the field phase of each of the studies, the AHETF conducted a survey of area experts to evaluate the representativeness of the growers/applicators

participating in the study. These surveys were responsive to the HSRB's request that the AHETF attempt to characterize whether the monitored workers were typical of that type of worker/grower in the particular region.

For AHE62, four out of five area experts that responded to the survey opined that the growers/applicators were typical. The fifth local farm expert, who was from San Joaquin County, commented that the study acreage seemed to be smaller than would be typical for San Joaquin County. He also speculated that the study acreage seemed to be larger than would be typical for Fresno County, although he said that he said that he is not very familiar with Fresno. He said that he thought the acreage was typical for El Dorado County.

For AHE63, three of the four local farm experts who responded to the survey agreed that the study participants were typical of local grape growers/applicators in the county where the study cluster was performed. The fourth expert said that the types of airblast sprayers used in the study were not entirely representative since the Kinkelder airblast sprayer, an older model sprayer that is more prone to producing drift, was not included in the study.

For AHE64, four out of the seven local farm experts who responded to the survey agreed that the study participants were typical of local pecan growers/applicators in the counties where the study cluster was performed. Of the three experts who did not agree that the study participants were typical, one indicated that a typical grower would have larger acreage than the pecan groves encountered in this study. The other two experts opined that the pecan growers in the study were not typical because most pecan growers in the area use closed cabs, not open cabs.

6.0 Consent Process

The consent process outlined in the protocols and SOPs was closely followed in all studies. There were no reported deviations related to the consent process, and I did not note any unreported deviations related to consent during my review of the study reports. Twelve of the 13 subjects completed the consent process in English, and none of the subjects used a witness.

7.0 Subject Demographics

Demographic information on the monitored subjects is summarized in Table 3 below.

Table 3: Subject Characteristics			
	Number of Subjects		
	AHE62	AHE63	AHE64
Males	3	5	5
Females	0	0	0
Completed consent process in English	2	5	5
Completed consent process in Spanish	1	0	0
Self-identified as non-reader and used witness	0	0	0
Employment Farm Owner or Operator	2	5	5
Farm Employee	1	0	0
Commercial Applicator	0	0	0
Years of Experience	8-30	4-39	3-40
Age Range	43-79	28-66	47-74
Requested Results	3	5	5
Withdrew	0	0	0
Removed from participation by AHETF	0	0	0

7.1 Health Status

Prospective subjects were asked about their health status during the consent process, using the procedures described in SOPs AHETF-11.B.4 and AHETF-11.C.1. No prospective subjects were eliminated due reported health status. The inclusion criteria in the protocol state that subjects must report "good general health with no medical conditions that could impact their ability to participate in the study" in order to be eligible to participate (protocol section 2.1).

8.0 Monitoring

Exposure monitoring was conducted without incident. No subjects withdrew from the research. No adverse events or other incidents of concern were reported.

8.1 Heat Index

The greatest risk to subjects in this research is that of heat-related illness. The SOP titled "Identification and Control of Heat Stress" (AHETF-11.G.1) provides information about recognition of conditions that contribute to heat-related illness, measures to minimize the risk of heat-related illness, measures to be taken if a worker is affected by heat-related illness, procedures for AHETF researchers to monitor environmental conditions, and stopping rules related to heat-related illness. The version of the SOP that was in place at the time that these three field studies were conducted (AHETF-11.G.1) provided that the research should not begin, or should be halted, if the ambient heat index (temperature adjusted for humidity and direct sunlight) was greater than or equal to 120° F. In November 2009 (after this research was completed), the SOP was revised to lower the heat index threshold from 120° F to 105° F (revised version is AHETF-11.G.2).

Although the SOP in effect at the time of the research specified a heat index threshold of 120° F, the protocols for AHE62 and 63 were amended to lower the heat index threshold to 105° F. The protocol for AHE64 was not revised in the same manner – the heat index threshold for AHE64 remained at 120° F.

Table 4, below, provides the maximum heat index measurements in AHE62, 63, and 64. None of the measured heat index values exceeded the cut-off values of 105° F or 120° F.

Table 4. Heat Index Values (°F)

Study ID	A1		A2		A3		A4		A5	
	Time	Heat Index	Time	Heat Index	Time	Heat Index				
AHE62	0723	<80	0622	<80	0742	<80				
	0816	<80	0651	<80	0814	<80				
	0901	<80	0720	<80	0910	91				
	1001	<80	0810	<80	0958	93				
	1112	83	0835	<80	1038	93				
					1126	95				
AHE63	A1*		A2		A3		A4		A5	
	0820	<80	1000	<80	1000	<80	*Ambient temperature did not reach 70 °F*		*Ambient temperature did not reach 70 °F*	
	0920	<80	1100	<80	1100	<80				
	1020	<80	1200	<80	1200	<80				
	1120	<80	1300	<80	1300	<80				
	1220	95								
	1320	98								
	1420	85								
	1520	98								
	1620	88								
	1720	94								
	1820	95								
AHE64	A1*		A2		A3		A4		A5	
	1003	<80	0930	<80	1100	88	0850	<80	0834	<80
	1102	92	1026	81	1200	91	0950	<80	0930	<80
	1201	82			1300	94	1052	<80	1030	<80
	1301	82								
	1401	83								

* The heat index values for fluctuated due to passing periods of cloudiness.

"Caution" = heat index between 80-89°F
"Extreme caution" = heat index between 90-104°F

8.1.1 AHE62

When subject A1 was monitored, the heat index rose into the "caution" range (heat index between 80-89° F; see SOP AHETF-11.G.1). As documented in Supplement 1 and reported in the worker observation log for subject A1 (p. 45, Volume 2), the study director announced the "caution" heat index at 11:12 am, in compliance with SOP AHETF-11.G.1. Eight minutes later (11:20 am), the log states that the subject "confirmed he still felt fine." The spraying was complete at that point, and the log

reports that at 11:21 am, the subject rode to the staging area in the Study Director's vehicle.

When subject A3 was monitored, the heat index rose into the "Extreme Caution" category. According to the raw data report (see Supplement 1), the observer was also the weather monitor, so separate notification of the observer was not necessary. It does not appear that the worker was in danger of suffering heat illness at any point during the study. The log shows that the worker talked to the nurse and drank Gatorade at 8:02 am, resumed spraying at 8:18 am, and "checked with nurse" at 11:10 am, saying that he "feels ok" (p. 47-49, Volume 2).

8.1.2 AHE63

When subject A1 was monitored, the heat index rose into the "Caution" and "Extreme Caution" categories. According to the raw data report (see Supplement 1), the person responsible for monitoring the weather notified the observer of the heat index category changes, in compliance with SOP AHETF-11.G.1. It does not appear that the worker was in danger of suffering heat illness at any point during the study. The worker observation log shows that the worker got a drink and "stated he was fine" at 10:11; took a break and had lunch between 11:10 and 12:11; drank water and "stated he was feeling fine" at 13:35; had more to drink and "stated he is feeling fine" at 15:09; "stated he was feeling fine" at 16:15; and had a drink at 17:37 (p. 40-41, Volume 4).

8.1.3 AHE64

When subject A1 was monitored, the heat index rose into the "Caution" and "Extreme Caution" categories. According to the raw data report (see Supplement 1), the person responsible for monitoring the weather notified the observer of the heat index category changes, in compliance with SOP AHETF-11.G.1. It does not appear that the worker was in danger of suffering heat illness at any point during the study. The worker observation log shows that the worker had a drink at 07:43; "stated he was feeling fine" at 09:27; took a break for lunch between 12:11 and 13:11. (p. 39-40, Vol. 6).

When subject A2 was monitored, the heat index rose into the "Caution" range. According to the raw data report (see Supplement 1), the person responsible for monitoring the weather notified the observer and researchers of the heat index category changes, in compliance with SOP AHETF-11.G.1. It does not appear that the worker was in danger of suffering heat illness at any point during the study.

When subject A3 was monitored, the heat index rose into the "Caution" and "Extreme Caution" categories. According to the raw data report (see Supplement 1), the person responsible for monitoring the weather notified the observer and researchers of the heat index category changes, in compliance with SOP AHETF-11.G.1. It does not appear that the worker was in danger of suffering heat illness at any point during the study. The worker observation log shows that the worker had a drink at 10:11 am. (p. 42, Volume 6).

9.0 Applicable Ethical Standards

The following provisions of 40 CFR 26 Subpart Q, as amended effective August 22, 2006, define the applicable ethical standards, which read in pertinent part:

> §26.1703: Except as provided in §26.1706, . . . EPA shall not rely on data from any research involving intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or a child.
>
> §26.1705: Except as provided in §26.1706, . . . EPA shall not rely on data from any research initiated after April 7, 2006, unless EPA has adequate information to determine that the research was conducted in substantial compliance with subparts A through L of this part. . . .

In addition, §12(a)(2)(P) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) applies. This passage reads:

> In general, [i]t shall be unlawful for any person . . . to use any pesticide in tests on human beings unless such human beings (i) are fully informed of the nature and purposes of the test and of any physical and mental health consequences which are reasonably foreseeable therefrom, and (ii) freely volunteer to participate in the test.

10.0 Findings

10.1 Responsiveness to EPA and HSRB reviews

EPA's and HSRB's comments on these protocols were satisfactorily addressed before the research was conducted. Please see Attachment 3 for details.

10.2 Prohibition of research involving intentional exposure of pregnant or nursing women or of children

All enrolled subjects were at least 18 years old and there were no female subjects. The prohibition in 40 CFR §26.1703 of research involving intentional exposure of pregnant or nursing women or of children under 18 was satisfied.

10.3 Substantial compliance with 40 CFR 26 subparts A through L

40 CFR §26.1705 requires that EPA have "adequate information to determine that the research was conducted in substantial compliance with subparts A through L of this part." Within this range, only subparts K and L are directly applicable to the conduct of third-party research such as this. The study reports for AHE62, AHE63, and AHE64 document compliance with subparts K and L.

10.4 Compliance with 40 CFR §26 subpart M

As is documented in Attachment 2 to this review, the central requirements of 40 CFR §26 subpart M, §26.1303 to document the ethical conduct of the research were satisfactorily addressed.

10.5 Compliance with FIFRA §12(a)(2)(P)

The requirement of FIFRA §12(a)(2)(P) that human subjects of research be "fully informed of the nature and purposes of the test and of any physical and mental health consequences reasonably foreseeable therefrom," and "freely volunteer to participate in the test," was met for this study.

11.0 Conclusion

This study reports research conducted in substantial compliance with the requirements of 40 CFR 26 subparts A through L. In its conduct it met all applicable ethical standards for the protection of human subjects of research, and all requirements for documentation of ethical conduct of the research were satisfied. If this study is determined to be scientifically valid and relevant, there is no regulatory barrier to EPA's reliance on it in actions under FIFRA or §408 of FFDCA.

Attachment 1: Ethics-related study chronologies (Tables A-C)
Attachment 2: §26.1303 completeness checks
Attachment 3: Responsiveness to EPA and HSRB Comments on protocols (Table D)
Attachment 4: Heat Index Records from Raw Data for AHE62, AHE63, AHE64

Ethics-Related Study Chronologies

Table A: AHE62	
Date	
10/21-22/08	HSRB reviewed protocol and approved with recommendations
3/27/09	Submitted documents to IIRB to amend protocol, consent form, and product risk statements (following October 2008 HSRB meeting)
4/1/09 & 4/6/09	IIRB approves revised documents
4/20/09	Protocol finalized and signed by Study Director
4/21/09	Phase 1 recruiting (creation of grower list). 4/21/09 to 7/27/09
5/12/09	Phase 2 recruiting (calls to grower list). 5/12/09 to 8/14/09
6/01/09	Phase 3 recruiting (site visits and participant selection) - 6/01/09 to 8/14/09
6/19/09	Submission to IIRB of **Protocol Amendment 1** to include workers normally wearing 2 cloth layers and expand recruitment area
6/23/09	Approval of **Protocol Amendment 1** by IIRB
7/02/09, 7/20/09	Two subjects monitored (MUs A1, A2)
7/16/09	Submission of annual progress report to IIRB
7/22/09	Submission to IIRB of **Protocol Amendment 2** adding an additional malathion product
7/22/09	Approval of **Protocol Amendment 2** by IIRB
7/24/09	Third subject monitored (MU A3)
7/25/09	Submission of supplemental information for Progress Report to IIRB
7/29/09	Approval by IIRB of ongoing research (i.e., extension granted)
9/02/09	**Protocol Deviation 1** reported to IIRB • Deviation occurred 7/02/09 • Inner and outer head patch fortification deficiencies
9/03/09	IIRB acknowledges **Protocol Deviation 1**; no further action required
11/21/09	Submission to IIRB of **Protocol Amendment 3** specifying the analytical method and LOQ for head patches
11/24/09	Approval of **Protocol Amendment 3** by IIRB
02/23/10	Close out report submitted to IIRB
02/25/10	IIRB accepts Study Completion Report; study considered closed
4/19/10	**Laboratory Deviation** reported to IIRB • Deviation occurred 6/05/09 • Field fortification solution concentration not verified
4/20/10	IIRB acknowledges **Laboratory Deviation**; no further action required

Ethics-Related Study Chronologies

Table B: AHE63	
Date	
10/21-22/08	HSRB reviewed protocol and approved with recommendations
1/16/09	Submitted documents to IIRB to amend protocol, consent form, and product risk statements (following October 2008 HSRB meeting)
1/19/09	IIRB approves revised documents
1/23/09	Protocol finalized and signed by Study Director
6/09/09	Phase 1 recruiting (creation of Master Grower List and Qualified Grower List). 6/9/09 to 7/17/09
6/26/09	Grower letters submitted to and approved by IIRB
7/10/09	Phase 2 recruiting (calls to Qualified Grower List). 7/10/09 to 7/27/09
7/15/09	Phase 3 recruiting (site visits and participant selection) - 7/15/09 to 8/5/09
7/16/09	Annual progress report submitted to IIRB
7/18/09	Submission to IIRB of **Protocol Amendment 1** to allow use of recruitment letters, lower the heat index threshold from 120° F to 105° F, change dermal sampling procedure (dosimeter cut into 6 sections, not 2), and clarify raw data retention policy
7/21/09	Approval of **Protocol Amendment 1** by IIRB
7/28/09 - 8/06/09	Five subjects monitored (MUs A1, A2, A4, A4, A5)
7/29/09	IIRB approves ongoing research and annual progress report (submitted on 7/16/09)
8/13/09	Submission to IIRB of **Protocol Amendment 2** providing changes in analytical procedures
8/13/09	Approval of **Protocol Amendment 2** by IIRB
9/11/09	**Protocol Deviation 1** reported to IIRB • Deviations occurred 7/28/09-8/06/09 • Involved departures from minimum spray time and spray load requirements; highest stratum not achieved
9/15/09	IIRB acknowledges **Protocol Deviation 1**; no further action required
7/06/10	**2 analytical deviations** reported to IIRB • Deviations occurred 8/19/09, 4/20/10 • Deviations from analytical methodologies related to analysis of carbaryl in inner dosimeters and face/neck wipe samples
7/09/10	IIRB acknowledges 2 **analytical deviations**; no further action required
07/15/10	Close out report submitted to IIRB
07/20/10	IIRB accepts Study Completion Report; study considered closed

Ethics-Related Study Chronologies

Table C: AHE64	
Date	
10/21-22/08	HSRB reviewed protocol and approved with recommendations
1/16/09	Submitted documents to IIRB to amend protocol, consent form, and product risk statements (following October 2008 HSRB meeting)
1/19/09	IIRB approves revised documents
1/23/09	Protocol finalized and signed by Study Director
3/02/09	Phase 1 recruiting (creation of Master Grower List and Qualified Grower List). 3/2/09 to 7/29/09
6/15/09	Submission to IIRB of **Protocol Amendment 1** to allow use of recruitment letters, expand grower search area, and change dermal sampling procedure (dosimeter cut into 6 sections, not 2)
6/19/09	Approval of **Protocol Amendment 1** by IIRB
7/07/09	Calls to growers on Master Grower List. 7/07/09 to 7/28/09
7/16/09	Phase 2 recruiting (calls to Qualified Grower List). 7/16/09 to 8/16/09
7/16/09	Annual progress report submitted to IIRB
8/04/09	IIRB approves ongoing research and annual progress report (submitted on 7/16/09)
8/10/09	Phase 3 recruiting (site visits and participant selection) - 8/10/09 to 8/24/09
8/22/09 - 8/29/09	Five subjects monitored (MUs A1, A2, A4, A4, A5)
9/14/09	Submission to IIRB of **Protocol Amendment 2** changing study director and Change in Principal Investigator Form
9/16/09	Approval of **Protocol Amendment 2** by IIRB
9/18/09	**Protocol Deviation 1** reported to IIRB • Deviations occurred 8/22/09 - 8/29/09 • Involved departures from minimum spray time and spray load requirements; lowest stratum not achieved
9/23/09	IIRB acknowledges **Protocol Deviation 1**; no further action required
7/10/10	**Analytical deviation** reported to IIRB • Deviation occurred 5/4/10 • Deviation from analytical methodologies related to analysis of carbaryl in inner dosimeters
7/13/10	IIRB acknowledges **analytical deviation**; no further action required
07/22/10	Close out report submitted to IIRB
07/23/10	IIRB accepts Study Completion Report; study considered closed

§ 26.1303 Check for Completeness of Reports of Human Research Submitted for EPA Review AHE62 (MRID 48289614)

Any person who submits to EPA data derived from human research covered by this subpart shall provide at the time of submission information concerning the ethical conduct of such research. To the extent available to the submitter and not previously provided to EPA, such information should include:

	Requirement		Y/N	Comments/Page References
(a) Copies of all of the records relevant to the research specified by §26.1115(a) to be prepared and maintained by an IRB	§1115(a)(1): Copies of • all research proposals reviewed, • scientific evaluations, if any, that accompany the proposals, • approved sample consent documents, • progress reports submitted by investigators, and reports of injuries to subjects.		Y n/a Y Y	Initially addressed in protocol Progress Rpt 244 Close Out Report 318
	§1115(a)(2): Minutes of IRB meetings which shall be in sufficient detail to show • attendance at the meetings; • actions taken by the IRB; • the vote on these actions including the number of members voting for, against, and abstaining; • the basis for requiring changes in or disapproving research; • a written summary of the discussion of controverted issues and their resolution.		Y	p. 303 [Approval of Ongoing Research for AHE62] All other post-protocol approval reviews were done under expedited procedures and minutes were not created.
	§1115(a)(3): Records of continuing review activities.		Y	301
	§1115(a)(4): Copies of all correspondence between the IRB and the investigators.		Y	17-327
	§1115(a)(5): • A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; • any employment or other relationship between each member and the institution		N	Already available to EPA
	§1115(a)(6): Written procedures for the IRB in the same detail as described in § 26.1108(a) and § 26.1108(b).		N	Already available to EPA
	§1115(a)(7): Statements of significant new findings provided to subjects, as required by § 26.1116(b)(5).		n/a	
(b) Copies of all of the records relevant to the information identified in §26.1125(a)-(f)	§1125(a) A discussion of:	(1) The potential risks to human subjects;	Y	Addressed in protocol
		(2) The measures proposed to minimize risks to the human subjects;	Y	Addressed in protocol
		(3): The nature and magnitude of all expected benefits of such research, and to whom they would accrue;	Y	Addressed in protocol
		(4) Alternative means of obtaining information comparable to what would be collected through the proposed research; and	Y	Addressed in protocol
		(5) The balance of risks and benefits of the proposed research.	Y	Addressed in protocol
	§1125(b): All information for subjects and written informed consent agreements as originally provided to the IRB, and as approved by the IRB.		Y	Orig. submitted 73-105,148-151 Approved 154-213, 220-241
	§1125(c): Information about how subjects will be recruited, including any advertisements proposed to be used.		Y	Addressed in protocol Flyers (Spanish&English) 149-150
	§1125(d): A description of the circumstances and methods proposed for presenting information to potential human subjects for the purpose of obtaining their informed consent.		Y	Addressed in protocol
	§1125(e): All correspondence between the IRB and the investigators or sponsors.		Y	17-327
	§1125(f): Official notification to the sponsor or investigator, in accordance with the requirements of this subpart, that research involving human subjects has been reviewed and approved by an IRB.		Y	Original approval provided in protocol submission; approved amendments 148, 152-3, 279
(c) Copies of sample records used to document informed consent as specified by §26.1117, but not identifying any subjects of the research			Y	220 English 230 Spanish
(d) If any of the information listed in paragraphs (a) through (c) of this section is not provided, the person shall describe the efforts made to obtain the information.			n/a	

§ 26.1303 Check for Completeness of Reports of Human Research Submitted for EPA Review AHE63 (MRID 48289615)

Any person who submits to EPA data derived from human research covered by this subpart shall provide at the time of submission information concerning the ethical conduct of such research. To the extent available to the submitter and not previously provided to EPA, such information should include:

Requirement			Y/N	Comments/Page References
(a) Copies of all of the records relevant to the research specified by §26.1115(a) to be prepared and maintained by an IRB	§1115(a)(1): Copies of • all research proposals reviewed, • scientific evaluations, if any, that accompany the proposals, • approved sample consent documents, • progress reports submitted by investigators, and reports of injuries to subjects.		Y n/a Y Y	Initially addressed in protocol Progress Rpt 105 Close Out Report 198
	§1115(a)(2): Minutes of IRB meetings which shall be in sufficient detail to show • attendance at the meetings; • actions taken by the IRB; • the vote on these actions including the number of members voting for, against, and abstaining; • the basis for requiring changes in or disapproving research; • a written summary of the discussion of controverted issues and their resolution.		Y	p. 163 [Approval of Ongoing Research for AHE63] All other post-protocol approval reviews were done under expedited procedures and minutes were not created.
	§1115(a)(3): Records of continuing review activities.		Y	100
	§1115(a)(4): Copies of all correspondence between the IRB and the investigators.		Y	13-219
	§1115(a)(5): • A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; • any employment or other relationship between each member and the institution		N	Already available to EPA
	§1115(a)(6): Written procedures for the IRB in the same detail as described in § 26.1108(a) and § 26.1108(b).		N	Already available to EPA
	§1115(a)(7): Statements of significant new findings provided to subjects, as required by § 26.1116(b)(5).		n/a	
(b) Copies of all of the records relevant to the information identified in §26.1125(a)-(f)	§1125(a) A discussion of:	(1) The potential risks to human subjects;	Y	Addressed in protocol
		(2) The measures proposed to minimize risks to the human subjects;	Y	Addressed in protocol
		(3): The nature and magnitude of all expected benefits of such research, and to whom they would accrue;	Y	Addressed in protocol
		(4) Alternative means of obtaining information comparable to what would be collected through the proposed research; and	Y	Addressed in protocol
		(5) The balance of risks and benefits of the proposed research.	Y	Addressed in protocol
	§1125(b): All information for subjects and written informed consent agreements as originally provided to the IRB, and as approved by the IRB.		Y	Orig. submitted – In protocol submission; also 54-64 Approved 67-97
	§1125(c): Information about how subjects will be recruited, including any advertisements proposed to be used.		Y	Addressed in protocol; 96-97 Flyers (Spanish&English) 67, 81
	§1125(d): A description of the circumstances and methods proposed for presenting information to potential human subjects for the purpose of obtaining their informed consent.		Y	Addressed in protocol
	§1125(e): All correspondence between the IRB and the investigators or sponsors.		Y	13-219
	§1125(f): Official notification to the sponsor or investigator, in accordance with the requirements of this subpart, that research involving human subjects has been reviewed and approved by an IRB.		Y	Original approval provided in protocol submission; approved amendments 66, 95, 159,174,194
(c) Copies of sample records used to document informed consent as specified by §26.1117, but not identifying any subjects of the research			Y	202 (English); None of the subjects in this study chose to use the Spanish version of the forms
(d) If any of the information listed in paragraphs (a) through (c) of this section is not provided, the person shall describe the efforts made to obtain the information.			n/a	

§ 26.1303 Check for Completeness of Reports of Human Research Submitted for EPA Review AHE64 (MRID 48289616)

Any person who submits to EPA data derived from human research covered by this subpart shall provide at the time of submission information concerning the ethical conduct of such research. To the extent available to the submitter and not previously provided to EPA, such information should include:

Requirement			Y/N	Comments/Page References
(a) Copies of all of the records relevant to the research specified by §26.1115(a) to be prepared and maintained by an IRB	§1115(a)(1): Copies of • all research proposals reviewed, • scientific evaluations, if any, that accompany the proposals, • approved sample consent documents, • progress reports submitted by investigators, and reports of injuries to subjects.		Y n/a Y Y	Initially addressed in protocol Progress Rpt 156 Close Out Report 200
	§1115(a)(2): Minutes of IRB meetings which shall be in sufficient detail to show • attendance at the meetings; • actions taken by the IRB; • the vote on these actions including the number of members voting for, against, and abstaining; • the basis for requiring changes in or disapproving research; • a written summary of the discussion of controverted issues and their resolution.		Y	p. 182 [Protocol Amendment 2] p. 195 [Approval of Ongoing Research for AHE64] All other post-protocol approval reviews were done under expedited procedures and minutes were not created.
	§1115(a)(3): Records of continuing review activities.		Y	156
	§1115(a)(4): Copies of all correspondence between the IRB and the investigators.		Y	14-217
	§1115(a)(5): • A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; • any employment or other relationship between each member and the institution		N	Already available to EPA
	§1115(a)(6): Written procedures for the IRB in the same detail as described in § 26.1108(a) and § 26.1108(b).		N	Already available to EPA
	§1115(a)(7): Statements of significant new findings provided to subjects, as required by § 26.1116(b)(5).		n/a	
(b) Copies of all of the records relevant to the information identified in §26.1125(a)-(f)	§1125(a) A discussion of:	(1) The potential risks to human subjects;	Y	Addressed in protocol
		(2) The measures proposed to minimize risks to the human subjects;	Y	Addressed in protocol
		(3): The nature and magnitude of all expected benefits of such research, and to whom they would accrue;	Y	Addressed in protocol
		(4) Alternative means of obtaining information comparable to what would be collected through the proposed research; and	Y	Addressed in protocol
		(5) The balance of risks and benefits of the proposed research.	Y	Addressed in protocol
	§1125(b): All information for subjects and written informed consent agreements as originally provided to the IRB, and as approved by the IRB.		Y	Orig. submitted – In protocol submission; also 54-64 Approved 66-86
	§1125(c): Information about how subjects will be recruited, including any advertisements proposed to be used.		Y	Addressed in protocol; 153-4 Flyers (Spanish&English) 88, 89
	§1125(d): A description of the circumstances and methods proposed for presenting information to potential human subjects for the purpose of obtaining their informed consent.		Y	Addressed in protocol
	§1125(e): All correspondence between the IRB and the investigators or sponsors.		Y	14-217
	§1125(f): Official notification to the sponsor or investigator, in accordance with the requirements of this subpart, that research involving human subjects has been reviewed and approved by an IRB.		Y	Original approval provided in protocol submission; approved amendments 152, 182
(c) Copies of sample records used to document informed consent as specified by §26.1117, but not identifying any subjects of the research			Y	203 (English); None of the subjects in this study chose to use the Spanish version of the forms
(d) If any of the information listed in paragraphs (a) through (c) of this section is not provided, the person shall describe the efforts made to obtain the information.			n/a	

Responsiveness to Major EPA and HSRB Comments

Table D. Responsiveness to Major EPA and HSRB Comments on Protocols for AHE62, AHE63, AHE64 (reviewed at the October 2008 HSRB Meeting)	
EPA or HSRB Comment	**Addressed before executing AHE62, AHE63, AHE64?**
1. Characterize representativeness of subjects	Yes
1. 5 monitoring units in each cluster, each from a different farm, is needed to ensure that the design and analyses are scientifically sound.	Only 1 worker monitored per employer
2. Select of Local Site Coordinators with demonstrable training and expertise in survey implementation to ensure optimal recruiting and thereby enhance the usefulness of the data	Yes
3. The Local Site Coordinator, the Principal Field Investigator, the Field Facility, the Analytical Facility, and the Principal Analytical Investigator must be identified in the protocol	Yes, addressed prior to study initiation
4. Any key members of the research team who will have contact with the research subjects or their identifiable data must receive and document their recent (not expired) training in human subjects' protection	Yes, and relevant SOP subsequently revised (SOP AHETF-10.C.4)
5. Revise subject recruitment plan to specifically address the probability that subjects may also be growers.	Yes (SOP AHETF-11.B.4)
6. Remove risks of agricultural work from the listing of risks related to the research.	Yes
7. Identify risks of pesticide products that are due to scripting.	Yes
8. Harmonize the lists of eligibility factors in the protocol and the consent form	Yes
9. The number of potentially eligible workers linked to each grower, the numbers attending initial group meetings, attending individual consent interviews, signing consent forms, subsequently withdrawing or being withdrawn, and completing participation should all be recorded and reported	Yes

ATTACHMENT 4:

Heat Index Records from Raw Data for

AHE62, AHE63, AHE64

AHETF Study No.: AHE62

HEAT ILLNESS PROCEDURES AND MEASUREMENT OF HEAT INDEX DURING MONITORING

Date: 7/2/09
Page: 1 of 2

Applies to MU: A1

Procedures Checklist:

☑ Medical professional on site (name, title): Michael McColm EMT

☑ Nearest medical facility identified: Sablan Medical Center

☑ Heat Illness poster is posted on site, subject informed
☑ Water and sports drinks available, subject informed
☑ Shady or cool area available for breaks: Orchard near mix/load area

☑ Remind workers of heat illness risks, suggest they drink before and during monitoring

☑ Heat Illness Symptoms and Treatment Chart available for researchers to refer to

Environmental Conditions at Start of Monitoring:

Location of Monitoring: Baker Farms

Equipment ID: Temperature: Kestrel 3000 #1
Relative Humidity: Kestrel 3000 #1

Start of Monitoring: Temperature: 66 °F Relative Humidity: 62 %

Subject in Direct Sun at Start of Monitoring? ☑ No ☐ Yes

Heat Index at Start of Monitoring (from chart, adjusted for sun if needed): <80 °F

Heat Index Category at Start of Monitoring:
- ☑ Not Applicable (< 80)
- ☐ Caution (80 – 89)
- ☐ Extreme Caution (90 – 104)
- ☐ Danger (105 – 129)
- ☐ Extreme Danger (> 130)

☑ Observer(s) Informed of Initial Heat Index Category

Did Ambient Temperature Reach 70 °F? ☐ No ☑ Yes, at (enter time): 0749
If Yes, record heat index in the following table and indicate actions taken

Completed By Sarah Rosenheck Date 7/2/09

Date: 7/2/09
Page: 2 of 2

Temperature and Humidity must be checked periodically and Heat Index must be measured at least hourly if ambient temperature is 70 °F or higher. After each measurement, indicate what actions were taken, such as:

- None necessary
- Notified researchers of Category change
- Requested observer or medical professional to check subject for signs of illness
- Moved subject to shady environment for rest or examination
- Stopped monitoring

More detailed documentation of subject treatment should be made on the worker observation forms by the observer (in consultation with medical professional).

Temperature, Relative Humidity, and Heat Index Measurements

Time / Initials	Ambient Temperature (°F)	Relative Humidity (%)	Subject in Direct Sun (Y or N)	Heat Index (°F) (from chart, adjusted for sun if needed)	Heat Index Category
0723/SAR	69	58	N	<80	NA
Actions: none necessary					
0816/SAR	73	43	N	<80	NA
Actions: none necessary					
~~0901~~ 0901/SAR	76	42	N	<80	NA
Actions: none necessary					
1001/SAR	77	45	N	<80	NA
Actions: none necessary					
1112	83	39	N	83	CAUTION
Actions: Notified Observer of Category Change					
Actions: SDB 7/2/09					
Actions:					

Should be recorded for 1112

SDB 7/27/09

HEAT ILLNESS PROCEDURES AND MEASUREMENT OF HEAT INDEX DURING MONITORING

Date: 7/20/09

Applies to MU: A2

Procedures Checklist:

☒ Medical professional on site (name, title): Mike M'Colm EMT-1

☒ Nearest medical facility identified: Lodi Memorial Hospital

☒ Heat Illness poster is posted on site, subject informed

☒ Water and sports drinks available, subject informed

☒ Shady or cool area available for breaks: Garage or House

☒ Remind workers of heat illness risks, suggest they drink before and during monitoring

☒ Heat Illness Symptoms and Treatment Chart available for researchers to refer to

Environmental Conditions at Start of Monitoring:

Location of Monitoring: Lodi, CA

Equipment ID: Temperature: Kestrel 3000 #1

Relative Humidity: Same

Start of Monitoring: Temperature: 62 °F Relative Humidity: 65 %

Subject in Direct Sun at Start of Monitoring? ☒ No ☐ Yes Sun not up w/in 30 minutes, sun is up

Heat Index at Start of Monitoring (from chart, adjusted for sun if needed): <80 °F

Heat Index Category at Start of Monitoring:

- ☒ Not Applicable (< 80)
- ☐ Caution (80 – 89)
- ☐ Extreme Caution (90 – 104)
- ☐ Danger (105 – 129)
- ☐ Extreme Danger (> 130)

☒ Observer(s) Informed of Initial Heat Index Category

Did Ambient Temperature Reach 70 °F? ☐ No ☒ Yes, at (enter time): 0720

If Yes, record heat index in the following table and indicate actions taken

Completed By SDB

Date 7/20/09

Date: 7/20/09
Page: 2 of 2

Temperature and Humidity must be checked periodically and Heat Index must be measured at least hourly if ambient temperature is 70 °F or higher. After each measurement, indicate what actions were taken, such as:

- None necessary
- Notified researchers of Category change
- Requested observer or medical professional to check subject for signs of illness
- Moved subject to shady environment for rest or examination
- Stopped monitoring

More detailed documentation of subject treatment should be made on the worker observation forms by the observer (in consultation with medical professional).

Temperature, Relative Humidity, and Heat Index Measurements					
Time / Initials	**Ambient Temperature (°F)**	**Relative Humidity (%)**	**Subject in Direct Sun (Y or N)**	**Heat Index (°F) (from chart, adjusted for sun if needed)**	**Heat Index Category**
0622/EDB	63	62	Y	N/A <80	N/A
Actions: None necessary					
0651/EDB	64	59	Y	<80	N/A
Actions: None necessary					
0720/EDB	70	52	Y	<80	N/A
Actions: None necessary					
0810/EDB	73	44	Y	<80	N/A
Actions: None necessary					
0835/EDB	72	50	Y	<80	N/A
Actions: None necessary					
Actions: EDB 7/20/09					
Actions:					

HEAT ILLNESS PROCEDURES AND MEASUREMENT OF HEAT INDEX DURING MONITORING

Date: 7/24/09
Page: 1 of 2

Applies to MU: A3

Procedures Checklist:

☒ Medical professional on site (name, title): Michelle Carson, RN

☒ Nearest medical facility identified: Marshall Medical Center

☒ Heat Illness poster is posted on site, subject informed

☒ Water and sports drinks available, subject informed

☒ Shady or cool area available for breaks: Research truck, shed

☒ Remind workers of heat illness risks, suggest they drink before and during monitoring

☒ Heat Illness Symptoms and Treatment Chart available for researchers to refer to

Environmental Conditions at Start of Monitoring:

Location of Monitoring: 49er Vineyard, Camino, CA

Equipment ID: Temperature: Kestrel 3000 #1
Relative Humidity: same

Start of Monitoring: Temperature: 65 °F Relative Humidity: 54 %

Subject in Direct Sun at Start of Monitoring? ☐ No ☒ Yes

Heat Index at Start of Monitoring (from chart, adjusted for sun if needed): < 80 °F

Heat Index Category at Start of Monitoring:
- ☒ Not Applicable (< 80)
- ☐ Caution (80 – 89)
- ☐ Extreme Caution (90 – 104)
- ☐ Danger (105 – 129)
- ☐ Extreme Danger (> 130)

☒ Observer(s) Informed of Initial Heat Index Category

Did Ambient Temperature Reach 70 °F? ☐ No ☒ Yes, at (enter time): ≈ 0800
If Yes, record heat index in the following table and indicate actions taken

Completed By [signature] Date 7/24/09

Date: 7/24/09
Page: 2 of 2

Temperature and Humidity must be checked periodically and Heat Index must be measured at least hourly if ambient temperature is 70 °F or higher. After each measurement, indicate what actions were taken, such as:

- None necessary
- Notified researchers of Category change
- Requested observer or medical professional to check subject for signs of illness
- Moved subject to shady environment for rest or examination
- Stopped monitoring

More detailed documentation of subject treatment should be made on the worker observation forms by the observer (in consultation with medical professional).

Temperature, Relative Humidity, and Heat Index Measurements					
Time / Initials	**Ambient Temperature (°F)**	**Relative Humidity (%)**	**Subject in Direct Sun (Y or N)**	**Heat Index (°F) (from chart, adjusted for sun if needed)**	**Heat Index Category**
0742/EDP	67	53	Y	<80	N/A
Actions: None necessary					
0814/EDP	74	56	Y	<80	N/A
Actions: None necessary					
0910/EDP	82	33	Y	81+10=91	EXTREME CAUTION
Actions: Observer = Weather Monitor, so observer notified.					
0958/EDP	84	34	Y	83+10=93	EXTREME CAUTION
Actions: None Necessary					
1038 EDP	84	29	Y	83+10=93	EXTREME CAUTION
Actions: None Necessary					
1126 EDP	86	32	Y	85+10=95	EXTREME CAUTION
Actions: None — Monitoring Complete					
Actions: EDP 7/24/09					

HEAT ILLNESS PROCEDURES AND MEASUREMENT OF HEAT INDEX DURING MONITORING

Date: 7/28/2009
Page: 1 of 3

Applies to MU: A1

Procedures Checklist:

☑ Medical professional on site (name, title):
Barbara Siders, LVN
☑ Nearest medical facility identified:
Westfield Memorial Hospital, Westfield, NY
☑ Heat Illness poster is posted on site, subject informed
☑ Water and sports drinks available, subject informed
☑ Shady or cool area available for breaks:
Home
☑ Remind workers of heat illness risks, suggest they drink before and during study
☑ Heat Illness Symptoms and Treatment Chart available for researchers to refer to

Environmental Conditions at Start of Monitoring:

Location of T/RH Monitoring: On-Site

Equipment ID: Temperature: RMR383HGA
Relative Humidity: RMR383HGA

Start of Monitoring: Temperature: 71 °F Relative Humidity: 88 %

Subject in Direct Sun at Start of Monitoring? ☐ No ☑ Yes

Heat Index at Start of Monitoring (from chart, adjusted for sun if needed): NA °F

Heat Index Category at Start of Monitoring:
☑ Not Applicable (< 80)
☐ Caution (80 – 89)
☐ Extreme Caution (90 – 104)
☐ Danger (105 – 129)
☐ Extreme Danger (> 130)

☑ Observer(s) Informed of Initial Heat Index Category

Did Ambient Temperature Reach 70 °F? ☐ No ☑ Yes, at (enter time): NA
If Yes, record heat index in the following table and indicate actions taken

Completed By [signature] Date 7/28/2009

Date: 7/28/2009
Page: 2 of 3

Temperature and Humidity must be checked periodically and Heat Index must be measured at least hourly if ambient temperature is 70 ºF or higher. After each measurement, indicate what actions were taken, such as:

- None necessary
- Notified researchers of Category change
- Requested observer or medical professional to check subject for signs of illness
- Moved subject to shady environment for rest or examination
- Stopped monitoring

More detailed documentation of subject treatment should be made on the worker observation forms by the observer (in consultation with medical professional).

Temperature, Relative Humidity, and Heat Index Measurements					
Time / Initials	**Ambient Temperature (ºF)**	**Relative Humidity (%)**	**Subject in Direct Sun (Y or N)**	**Heat Index (ºF) (from chart, adjusted for sun if needed)**	**Heat Index Category**
0820 AK	71	88	Y	NA	NA
Actions: None					
0920 AK	73	86	Y	NA	NA
Actions: None					
1020 AK	75	82	Y	NA	NA
Actions: None					
1120 AK	79	61	Y	NA	NA
Actions: Notified observer AK 7/28/2009					
1220 AK	83	50	Y	95 ~~85~~ RE	Extreme Caution
Actions: Notified observer					
1320 AK	86	48	Y	98	Extreme Caution
Actions: Notified observer					
1420 AK	84	47	N	85	Caution
Actions: None – overcast AK 7/28/2009					

Date: 7/28/2009
Page: 3 of 3

Temperature and Humidity must be checked periodically and Heat Index must be measured at least hourly if ambient temperature is 70 ºF or higher. After each measurement, indicate what actions were taken, such as:

- None necessary
- Notified researchers of Category change
- Requested observer or medical professional to check subject for signs of illness
- Moved subject to shady environment for rest or examination
- Stopped monitoring

More detailed documentation of subject treatment should be made on the worker observation forms by the observer (in consultation with medical professional).

Temperature, Relative Humidity, and Heat Index Measurements

Time / Initials	Ambient Temperature (ºF)	Relative Humidity (%)	Subject in Direct Sun (Y or N)	Heat Index (ºF) (from chart, adjusted for sun if needed)	Heat Index Category
AK 1520	83	60	Y	98	Extreme Caution
Actions: None					
1620 AK	83	58	N	88	Caution
Actions: Overcast					
17 (RE) 1720 AK	82	60	Y	94	Extreme Caution
Actions: None					
1820 AK	83	52	Y	95	Extreme Caution
Actions: None					
Actions: AK 7/28/2009					
Actions:					
Actions:					

HEAT ILLNESS PROCEDURES AND MEASUREMENT OF HEAT INDEX DURING MONITORING

Date: 7/30/2009
Page: 1 of 2

Applies to MU: A2

Procedures Checklist:

☑ Medical professional on site (name, title): Barbara Siders, LPN
☑ Nearest medical facility identified: Brooks Memorial Hospital, Dunkirk NY
☑ Heat Illness poster is posted on site, subject informed
☑ Water and sports drinks available, subject informed
☑ Shady or cool area available for breaks: Home
☑ Remind workers of heat illness risks, suggest they drink before and during study
☑ Heat Illness Symptoms and Treatment Chart available for researchers to refer to

Environmental Conditions at Start of Monitoring:

Location of T/RH Monitoring: On - Site

Equipment ID: Temperature: RMR383HGA
Relative Humidity: RMR383HGA

Start of Monitoring: Temperature: 66 °F Relative Humidity: 87 %

Subject in Direct Sun at Start of Monitoring? ☐ No ☑ Yes

Heat Index at Start of Monitoring (from chart, adjusted for sun if needed): N/A °F

Heat Index Category at Start of Monitoring:
☑ Not Applicable (< 80)
☐ Caution (80 – 89)
☐ Extreme Caution (90 – 104)
☐ Danger (105 – 129)
☐ Extreme Danger (> 130)

☑ Observer(s) Informed of Initial Heat Index Category

Did Ambient Temperature Reach 70 °F? ☐ No ☑ Yes, at (enter time): 09 28
If Yes, record heat index in the following table and indicate actions taken

Completed By [signature] Date 7/30/2009

Date: 7/30/2009
Page: 2 of 2

Temperature and Humidity must be checked periodically and Heat Index must be measured at least hourly if ambient temperature is 70 °F or higher. After each measurement, indicate what actions were taken, such as:

- None necessary
- Notified researchers of Category change
- Requested observer or medical professional to check subject for signs of illness
- Moved subject to shady environment for rest or examination
- Stopped monitoring

More detailed documentation of subject treatment should be made on the worker observation forms by the observer (in consultation with medical professional).

Temperature, Relative Humidity, and Heat Index Measurements					
Time / Initials	**Ambient Temperature (°F)**	**Relative Humidity (%)**	**Subject in Direct Sun (Y or N)**	**Heat Index (°F) (from chart, adjusted for sun if needed)**	**Heat Index Category**
1000 AL	73	79	Y	NA	NA
Actions: None					
1100 AL	73	78	Y	NA	NA
Actions: None					
1200 AL	75	71	Y	NA	NA
Actions: None					
1300 AL	76	71	Y	NA	NA
Actions: None					
Actions:					
Actions:					
Actions:					

HEAT ILLNESS PROCEDURES AND MEASUREMENT OF HEAT INDEX DURING MONITORING

Date: 8/3/2009
Page: 1 of 2

Applies to MU: A3

Procedures Checklist:

☑ Medical professional on site (name, title): Barbara Sides, LPN
☑ Nearest medical facility identified: Westfield Memorial Hospital, Westfield, NY
☑ Heat Illness poster is posted on site, subject informed
☑ Water and sports drinks available, subject informed
☑ Shady or cool area available for breaks: Shed
☑ Remind workers of heat illness risks, suggest they drink before and during study
☑ Heat Illness Symptoms and Treatment Chart available for researchers to refer to

Environmental Conditions at Start of Monitoring:

Location of T/RH Monitoring: On-Site

Equipment ID: Temperature: RMR383HGA
Relative Humidity: RMR383HGA

Start of Monitoring: Temperature: 67 °F Relative Humidity: 64 %

Subject in Direct Sun at Start of Monitoring? ☐ No ☑ Yes

Heat Index at Start of Monitoring (from chart, adjusted for sun if needed): 67 °F

Heat Index Category at Start of Monitoring:
☑ Not Applicable (< 80)
☐ Caution (80 – 89)
☐ Extreme Caution (90 – 104)
☐ Danger (105 – 129)
☐ Extreme Danger (> 130)

☑ Observer(s) Informed of Initial Heat Index Category

Did Ambient Temperature Reach 70 °F? ☐ No ☑ Yes, at (enter time): 0912
If Yes, record heat index in the following table and indicate actions taken

Completed By [signature] Date 8/3/2009

Date: 8/3/2009
Page: 2 of 2

Temperature and Humidity must be checked periodically and Heat Index must be measured at least hourly if ambient temperature is 70 °F or higher. After each measurement, indicate what actions were taken, such as:

- None necessary
- Notified researchers of Category change
- Requested observer or medical professional to check subject for signs of illness
- Moved subject to shady environment for rest or examination
- Stopped monitoring

More detailed documentation of subject treatment should be made on the worker observation forms by the observer (in consultation with medical professional).

Temperature, Relative Humidity, and Heat Index Measurements					
Time / Initials	**Ambient Temperature (°F)**	**Relative Humidity (%)**	**Subject in Direct Sun (Y or N)**	**Heat Index (°F) (from chart, adjusted for sun if needed)**	**Heat Index Category**
1000 AK	73	59	Y	NA	NA
Actions: None					
1100 AK	76	56	Y	NA	NA
Actions: None					
1200 AK	75	64	Y	NA	NA
Actions: None					
1300 AK	76	60	Y	NA	NA
Actions: None					
Actions:					
Actions:					
Actions:					

HEAT ILLNESS PROCEDURES AND MEASUREMENT OF HEAT INDEX DURING MONITORING

Date: 8/5/2009
Page: 1 of 1

Applies to MU: A4

Procedures Checklist:

☑ Medical professional on site (name, title): Barbara Sidens, LPN
☑ Nearest medical facility identified: Brooks Memorial Hospital, Dunkirk, NY
☑ Heat Illness poster is posted on site, subject informed
☑ Water and sports drinks available, subject informed
☑ Shady or cool area available for breaks: Shed
☑ Remind workers of heat illness risks, suggest they drink before and during study
☑ Heat Illness Symptoms and Treatment Chart available for researchers to refer to

Environmental Conditions at Start of Monitoring:

Location of T/RH Monitoring: On-Site

Equipment ID: Temperature: RMR383HGA
Relative Humidity: RMR383HGA

Start of Monitoring: Temperature: 62 °F Relative Humidity: 74 %

Subject in Direct Sun at Start of Monitoring? ☐ No ☑ Yes

Heat Index at Start of Monitoring (from chart, adjusted for sun if needed): 62 °F

Heat Index Category at Start of Monitoring:
☑ Not Applicable (< 80)
☐ Caution (80 – 89)
☐ Extreme Caution (90 – 104)
☐ Danger (105 – 129)
☐ Extreme Danger (> 130)

☑ Observer(s) Informed of Initial Heat Index Category

Did Ambient Temperature Reach 70 °F? ☑ No ☐ Yes, at (enter time): _____
If Yes, record heat index in the following table and indicate actions taken

Completed By [signature] Date 8/5/2009

HEAT ILLNESS PROCEDURES AND MEASUREMENT OF HEAT INDEX DURING MONITORING

Date: 8/6/2009
Page: 1 of 1

Applies to MU: A-5

Procedures Checklist:

☑ Medical professional on site (name, title): Barbara Siders LPN
☑ Nearest medical facility identified: Westfield Memorial Hospital Westfield, NY
☑ Heat Illness poster is posted on site, subject informed
☑ Water and sports drinks available, subject informed
☑ Shady or cool area available for breaks: Shed
☑ Remind workers of heat illness risks, suggest they drink before and during study
☑ Heat Illness Symptoms and Treatment Chart available for researchers to refer to

Environmental Conditions at Start of Monitoring:

Location of T/RH Monitoring: On-Site

Equipment ID: Temperature: RMR383HGA
Relative Humidity: RMR383HGA

Start of Monitoring: Temperature: 64 °F Relative Humidity: 75 %

Subject in Direct Sun at Start of Monitoring? ☐ No ☑ Yes

Heat Index at Start of Monitoring (from chart, adjusted for sun if needed): 64 °F

Heat Index Category at Start of Monitoring:
☑ Not Applicable (< 80)
☐ Caution (80 – 89)
☐ Extreme Caution (90 – 104)
☐ Danger (105 – 129)
☐ Extreme Danger (> 130)

☑ Observer(s) Informed of Initial Heat Index Category

Did Ambient Temperature Reach 70 °F? ☑ No ☐ Yes, at (enter time): _____
If Yes, record heat index in the following table and indicate actions taken

Completed By [signature] Date 8/6/2009

HEAT ILLNESS PROCEDURES AND MEASUREMENT OF HEAT INDEX DURING MONITORING

Date: 8/22/2009
Page: 1 of 2

Applies to MU: A1

Procedures Checklist:

☑ Medical professional on site (name, title): Barbara Sides

☑ Nearest medical facility identified: Okmulgee Memorial Hospital, Okmulgee, OK

☑ Heat Illness poster is posted on site, subject informed

☑ Water and sports drinks available, subject informed

☑ Shady or cool area available for breaks: Inside Home

☑ Remind workers of heat illness risks, suggest they drink before and during study

☑ Heat Illness Symptoms and Treatment Chart available for researchers to refer to

Environmental Conditions at Start of Monitoring:

Location of T/RH Monitoring: On-Site

Equipment ID: Temperature: RMR383HGA
Relative Humidity: RMR383HGA

Start of Monitoring: Temperature: 65 °F Relative Humidity: 62 %

Subject in Direct Sun at Start of Monitoring? ☑ No ☐ Yes

Heat Index at Start of Monitoring (from chart, adjusted for sun if needed): 65 °F

Heat Index Category at Start of Monitoring:
- ☑ Not Applicable (< 80)
- ☐ Caution (80 – 89)
- ☐ Extreme Caution (90 – 104)
- ☐ Danger (105 – 129)
- ☐ Extreme Danger (> 130)

☑ Observer(s) Informed of Initial Heat Index Category

Did Ambient Temperature Reach 70 °F? ☐ No ☑ Yes, at (enter time): 0857
If Yes, record heat index in the following table and indicate actions taken

Completed By Pam Reed Date 8/22/2009

Temperature and Humidity must be checked periodically and Heat Index must be measured at least hourly if ambient temperature is 70 ºF or higher. After each measurement, indicate what actions were taken, such as:

- None necessary
- Notified researchers of Category change
- Requested observer or medical professional to check subject for signs of illness
- Moved subject to shady environment for rest or examination
- Stopped monitoring

More detailed documentation of subject treatment should be made on the worker observation forms by the observer (in consultation with medical professional).

Temperature, Relative Humidity, and Heat Index Measurements

Time / Initials	Ambient Temperature (ºF)	Relative Humidity (%)	Subject in Direct Sun (Y or N)	Heat Index (ºF) (from chart, adjusted for sun if needed)	Heat Index Category
1003/ FES 8-22-09	79.2	54	N	NA	NA
Actions: None necessary					
* 1102/ FES 8-22-09	91.6	37	N	92	Extreme Caution
Actions: notified researchers of category change					
1201/ FES 8-22-09	82	49	N	82	Caution
Actions: notified researchers of change to caution					
1301	83	45	N	(WE) FES 8-22-09 ~~NA~~ 82	(WE) & Caution FES 8-22-09
Actions: none necessary					
1401	83	41	N	83	Caution
Actions: none necessary					
Actions: DK 8/22/2009					
Actions:					

* Temperature monitor was in sun while truck was moved and the ambient temp. was closed to 81.6 not 91.6 FES 8-22-09

HEAT ILLNESS PROCEDURES AND MEASUREMENT OF HEAT INDEX DURING MONITORING

Date: 2/24/2009
Page: 1 of ___

Applies to MU: A2

Procedures Checklist:

☑ Medical professional on site (name, title): Barbara Siders LVN
☑ Nearest medical facility identified: Creek Nation Community Hospital, Okemah, OK
☑ Heat Illness poster is posted on site, subject informed
☑ Water and sports drinks available, subject informed
☑ Shady or cool area available for breaks: Home
☑ Remind workers of heat illness risks, suggest they drink before and during study
☑ Heat Illness Symptoms and Treatment Chart available for researchers to refer to

Environmental Conditions at Start of Monitoring:

Location of T/RH Monitoring: On-Site

Equipment ID: Temperature: RMR383HGA
Relative Humidity: RMR383HGA

Start of Monitoring: Temperature: 76 °F Relative Humidity: 58 %

Subject in Direct Sun at Start of Monitoring? ☐ No ☐ Yes

Heat Index at Start of Monitoring (from chart, adjusted for sun if needed): 76 °F

Heat Index Category at Start of Monitoring:
☑ Not Applicable (< 80)
☐ Caution (80 – 89)
☐ Extreme Caution (90 – 104)
☐ Danger (105 – 129)
☐ Extreme Danger (> 130)

☑ Observer(s) Informed of Initial Heat Index Category

Did Ambient Temperature Reach 70 °F? ☐ No ☑ Yes, at (enter time): NA
If Yes, record heat index in the following table and indicate actions taken

Completed By [signature] Date 2/24/2009

Date: 8/22/2009
Page: 2 of 2

Temperature and Humidity must be checked periodically and Heat Index must be measured at least hourly if ambient temperature is 70 ºF or higher. After each measurement, indicate what actions were taken, such as:

- None necessary
- Notified researchers of Category change
- Requested observer or medical professional to check subject for signs of illness
- Moved subject to shady environment for rest or examination
- Stopped monitoring

More detailed documentation of subject treatment should be made on the worker observation forms by the observer (in consultation with medical professional).

Temperature, Relative Humidity, and Heat Index Measurements					
Time / Initials	**Ambient Temperature (ºF)**	**Relative Humidity (%)**	**Subject in Direct Sun (Y or N)**	**Heat Index (ºF) (from chart, adjusted for sun if needed)**	**Heat Index Category**
0930 AL	78	58	N	NA	NA
Actions: None					
1026 AL	80	54	N	81	Caution
Actions: Notified researchers					
Actions:					
Actions: AL 8/22/2009					
Actions:					
Actions:					
Actions:					

HEAT ILLNESS PROCEDURES AND MEASUREMENT OF HEAT INDEX DURING MONITORING

Date: 8/25/2004
Page: 1 of 2

Applies to MU: A3

Procedures Checklist:

☑ Medical professional on site (name, title): Barbara Siders LPN
☑ Nearest medical facility identified: OSU Medical Center Tulsa, OK
☑ Heat Illness poster is posted on site, subject informed
☑ Water and sports drinks available, subject informed
☑ Shady or cool area available for breaks: Shed
☑ Remind workers of heat illness risks, suggest they drink before and during study
☑ Heat Illness Symptoms and Treatment Chart available for researchers to refer to

Environmental Conditions at Start of Monitoring:

Location of T/RH Monitoring: On-Site

Equipment ID: Ternperature: RMR383HGH
Relative Humidity: RMR383HGH

Start of Monitoring: Temperature: 78 °F Relative Humidity: 65 %

Subject in Direct Sun at Start of Monitoring? ☑ No ☐ Yes

Heat Index at Start of Monitoring (from chart, adjusted for sun if needed): 78 °F

Heat Index Category at Start of Monitoring:
☑ Not Applicable (< 80)
☐ Caution (80 – 89)
☐ Extreme Caution (90 – 104)
☐ Danger (105 – 129)
☐ Extreme Danger (> 130)

☑ Observer(s) Informed of Initial Heat Index Category

Did Ambient Temperature Reach 70 °F? ☐ No ☑ Yes, at (enter time): N/A
If Yes, record heat index in the following table and indicate actions taken

Completed By [signature] Date 8/25/2004

Date: 8/25/2004
Page: 2 of 2

Temperature and Humidity must be checked periodically and Heat Index must be measured at least hourly if ambient temperature is 70 ºF or higher. After each measurement, indicate what actions were taken, such as:

- None necessary
- Notified researchers of Category change
- Requested observer or medical professional to check subject for signs of illness
- Moved subject to shady environment for rest or examination
- Stopped monitoring

More detailed documentation of subject treatment should be made on the worker observation forms by the observer (in consultation with medical professional).

Temperature, Relative Humidity, and Heat Index Measurements					
Time / Initials	**Ambient Temperature (ºF)**	**Relative Humidity (%)**	**Subject in Direct Sun (Y or N)**	**Heat Index (ºF) (from chart, adjusted for sun if needed)**	**Heat Index Category**
1100 AK	84	59	N	88	Caution
Actions: None - Already notified researcher.					
1200 AK	86	59	N	91	Extreme Caution
Actions: Notified researchers of change.					
1300 AK	87	60	N	94	Extreme Caution
Actions: None					
Actions:					
Actions: AK 8/25/2004					
Actions:					
Actions:					

HEAT ILLNESS PROCEDURES AND MEASUREMENT OF HEAT INDEX DURING MONITORING

Date: 8/28/2009
Page: 1 of 2

Applies to MU: A-14

Procedures Checklist:

☑ Medical professional on site (name, title): Barbara Siders, LVN
☑ Nearest medical facility identified: Claremore Regional Hospital, Claremore, OK
☑ Heat Illness poster is posted on site, subject informed
☑ Water and sports drinks available, subject informed
☑ Shady or cool area available for breaks: Home
☑ Remind workers of heat illness risks, suggest they drink before and during study
☑ Heat Illness Symptoms and Treatment Chart available for researchers to refer to

Environmental Conditions at Start of Monitoring:

Location of T/RH Monitoring: On-Site

Equipment ID: Temperature: RMR383HGA
Relative Humidity: RMR283HGA

Start of Monitoring: Temperature: 68 °F Relative Humidity: 82 %

Subject in Direct Sun at Start of Monitoring? ☑ No ☐ Yes

Heat Index at Start of Monitoring (from chart, adjusted for sun if needed): 68 °F

Heat Index Category at Start of Monitoring:
☑ Not Applicable (< 80)
☐ Caution (80 – 89)
☐ Extreme Caution (90 – 104)
☐ Danger (105 – 129)
☐ Extreme Danger (> 130)

☐ Observer(s) Informed of Initial Heat Index Category

Did Ambient Temperature Reach 70 °F? ☐ No ☑ Yes, at (enter time): 0850
If Yes, record heat index in the following table and indicate actions taken

Completed By [signature] Date 8/28/2009

Date: 8/28/2009
Page: 2 of 2

Temperature and Humidity must be checked periodically and Heat Index must be measured at least hourly if ambient temperature is 70 ºF or higher. After each measurement, indicate what actions were taken, such as:

- None necessary
- Notified researchers of Category change
- Requested observer or medical professional to check subject for signs of illness
- Moved subject to shady environment for rest or examination
- Stopped monitoring

More detailed documentation of subject treatment should be made on the worker observation forms by the observer (in consultation with medical professional).

Temperature, Relative Humidity, and Heat Index Measurements					
Time / Initials	**Ambient Temperature (ºF)**	**Relative Humidity (%)**	**Subject in Direct Sun (Y or N)**	**Heat Index (ºF) (from chart, adjusted for sun if needed)**	**Heat Index Category**
0950 AC	74	75	N	NA	NA
Actions: None					
1052 AC	78	74	N	NA	NA
Actions: None					
Actions:					
Actions: AC 8/28/2009					
Actions:					
Actions:					
Actions:					

AHETF Study No.: AHE 64

HEAT ILLNESS PROCEDURES AND MEASUREMENT OF HEAT INDEX DURING MONITORING

Date: 8/29/2009
Page: 1 of 2

Applies to MU: AS

Procedures Checklist:

☑ Medical professional on site (name, title): Barbara Siders, LVN

☑ Nearest medical facility identified: Craig General Hospital, Vinita, OK

☑ Heat Illness poster is posted on site, subject informed

☑ Water and sports drinks available, subject informed

☑ Shady or cool area available for breaks: Shed

☑ Remind workers of heat illness risks, suggest they drink before and during study

☑ Heat Illness Symptoms and Treatment Chart available for researchers to refer to

Environmental Conditions at Start of Monitoring:

Location of T/RH Monitoring: On-Site

Equipment ID: Temperature: RMR383HGA
Relative Humidity: RMR383HGA

Start of Monitoring: Temperature: 68 °F Relative Humidity: 71 %

Subject in Direct Sun at Start of Monitoring? ☑ No ☐ Yes

Heat Index at Start of Monitoring (from chart, adjusted for sun if needed): 69 °F

Heat Index Category at Start of Monitoring:
- ☑ Not Applicable (< 80)
- ☐ Caution (80 – 89)
- ☐ Extreme Caution (90 – 104)
- ☐ Danger (105 – 129)
- ☐ Extreme Danger (> 130)

☑ Observer(s) Informed of Initial Heat Index Category

Did Ambient Temperature Reach 70 °F? ☐ No ☑ Yes, at (enter time): 0834
If Yes, record heat index in the following table and indicate actions taken

Completed By [signature] Date 8/29/2009

Temperature and Humidity must be checked periodically and Heat Index must be measured at least hourly if ambient temperature is 70 ºF or higher. After each measurement, indicate what actions were taken, such as:

- None necessary
- Notified researchers of Category change
- Requested observer or medical professional to check subject for signs of illness
- Moved subject to shady environment for rest or examination
- Stopped monitoring

More detailed documentation of subject treatment should be made on the worker observation forms by the observer (in consultation with medical professional).

Temperature, Relative Humidity, and Heat Index Measurements

Time / Initials	Ambient Temperature (ºF)	Relative Humidity (%)	Subject in Direct Sun (Y or N)	Heat Index (ºF) (from chart, adjusted for sun if needed)	Heat Index Category
0930 AR	74	74	N	NA	NA
Actions: None					
1030 AC	78	68	N	NA	NA
Actions: None					
Actions:					
Actions: AC 8/29/2009					
Actions:					
Actions:					
Actions:					