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Western Institutional Review Board ®

Western International Review Board®

3535 SEVENTH AVENUE, SW, OLYMPIA, WA 98502-5010
P.O. BOX 12029, OLYMPIA, WA 98508-2029

Certificate of Approval

THE FOLLOWING WERE APPROVED:

INVESTIGATOR: Eric D. Bruce B.S.
21 Oak Knoll Court
Walnut Creek, California 94596

BOARD ACTION DATED: 04/26/2006
PANEL: 11
STUDY APPROVAL EXPIRES: 04/26/2007
STUDY NUM: 1078623
WIRB PRO NUM: 20060721
INVEST NUM: 108658
WO NUM: 1-366017-1

SPONSOR: Agricultural Handlers Exposure Task Force (AHETF)
PROTOCOL NUM: AHE37
AMD. PRO. NUM:
TITLE:
Determination of Dermal and Inhalation Exposure to Workers in the East During Airblast Applications to Trellis Crops Using Open or Closed Cab Equipment and During Open-Pour Mixing/Loading a Wettable Powder Pesticide Product

APPROVAL INCLUDES:

Investigator
Protocol (04-03-2006)
Consent Form [S0]

WIRB APPROVAL IS GRANTED SUBJECT TO:

The Board has found that some or all of the subjects are vulnerable to coercion or undue influence by virtue of their employment status. Accordingly, the Board expects that extra care will be taken in the consent process to avoid any coercion or undue influence to participate in the research.

IF YOU HAVE ANY QUESTIONS, CONTACT WIRB AT 1-800-562-4789
This is to certify that the information contained herein is true and correct as reflected in the records of the Western Institutional Review Board (WIRB). WE CERTIFY THAT WIRB IS IN FULL COMPLIANCE WITH GOOD CLINICAL PRACTICES AS DEFINED UNDER THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) REGULATIONS AND THE INTERNATIONAL CONFERENCE ON HARMONISATION (ICH) GUIDELINES.

Association for the Accreditation of Human Research Protection Programs, Inc. — Full AAHRPP Accreditation

Theodore D. Schultz, J.D., Chairman

4/27/2006
(Date)

This document electronically reviewed and approved by Orive, Otto on 4/27/2006 6:26:57AM PST. For more information call Client Services at 1-360-252-2500

ALL WIRB APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:

1. Conduct the research in accordance with the protocol, applicable laws and regulations, and the principles of research ethics as set forth in the Belmont Report.

2. Unless consent has been waived, conduct the informed consent process without coercion or undue influence, and provide the potential subject sufficient opportunity to consider whether or not to participate.

    a. Use only the most current consent form bearing the WIRB "APPROVED" stamp.

    b. Provide non-English speaking subjects with a certified translation of the approved consent form in the subject's first language. The translation must be approved by WIRB.

    c. Obtain pre-approval from WIRB for use of recruitment materials and other materials provided to subjects.

3. Obtain pre-approval from WIRB for any planned deviations that could adversely affect the safety or welfare of subjects, or the integrity of the research data and any changes in the research activity. The only exception is when changes are necessary to eliminate apparent immediate hazards to subjects. Immediately report to WIRB any such emergency changes implemented.

4. Promptly report to WIRB any new information that may adversely affect the safety of the subjects or the conduct of the trial.

    a. Report to WIRB all adverse events that are serious, unexpected and related, within 10 days of the investigator becoming aware of them. Other unexpected adverse events that involve risks to study subjects or others are to be submitted with continuing review reports.

    b. Promptly report to WIRB other unanticipated problems involving risks to human subjects or others. These events do not readily fit the formal definition of Adverse Event, but could impact human subject safety and/or rights. Examples include theft of a computer containing private identifiable subject information, or study staff getting ill from inhaling a study agent.

    c. Provide reports to WIRB concerning the progress of the research, when requested.

5. Report to WIRB any unplanned protocol variance that could adversely affect the safety or welfare of subjects, or the integrity of the research data, within 10 days of becoming aware of the variance. Other unplanned variances may be recorded on a log and submitted with continuing review reports.

Federal regulations require that WIRB conduct continuing review of approved research. You will receive Continuing Review Report forms from WIRB. These reports must be returned even though your study may not have started.

DISTRIBUTION OF COPIES:

Contact	**Company Name**
David R. Johnson Ph.D.	Agricultural Handlers Exposure Task Force (AHETF)
Eric D. Bruce B.S.	Agricultural Handlers Exposure Task Force (AHETF)

SITES: If the PI has an obligation to use another IRB for any site listed below and has not submitted a written statement from the other IRB acknowledging WIRB's review of this research, please contact WIRB's Client Services department.

Address
9813 Glenmark Road, North Rose, New York 14516