RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: Determination of Dermal and Inhalation Exposure to Workers in the West During Airblast Applications to Trellis Crops Using Open or Closed Cab Equipment

PROTOCOL NO.: AHE36
WIRB® Protocol #[04]20060720

SPONSOR: Agricultural Handlers Exposure Task Force (AHETF)
Macon, Missouri
United States

INVESTIGATOR: Eric D. Bruce, [08]B.S.
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1696 South Leggett Street
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United States

STUDY-RELATED PHONE NUMBER(S): Eric D. Bruce,[08] B.S., Study Director
925-939-4987 (home office, 24 hours)
925-708-5538 (mobile, 24 hours)
[08]

This consent form might contain words that you do not understand. Please ask the study investigator or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

PURPOSE

The Agricultural Handlers Exposure Task Force (AHETF) was formed by a group of pesticide companies. They are conducting a research study to find out how much exposure to pesticide workers may receive while [08]mixing, loading or applying Malathion 8EC or Gowan Malathion 8 (two names for the same pesticide product). The information will be used to learn how and

where this exposure occurs. Participation in the study is voluntary. You are being asked to participate because you are able to perform the activities required for this particular study. About 13 subjects will participate.

PROCEDURES

If you decide to participate in this study, you will be asked to do the following:

1. Provide the following information before the study begins: name, age, years of experience, and general health.
2. Allow study investigators to measure your height and weight.
3. Provide a urine sample for a pregnancy test before the study (females only). Pregnant workers or nursing mothers will not be allowed to participate in the study.
4. Bathe or shower each day before participating in the study.
5. Wash your long-sleeved shirt and long pants each day before participating in the study.
6. Wear long underwear underneath your long-sleeved shirt and long pants. The long underwear will be supplied and collected each day. You will be asked to dress and undress with the assistance of a field investigator of the same sex. However, you will be wearing your choice of undergarments under the long underwear. A changing area will be provided for individual privacy.
7. Perform approximately 4 to 8 hours of [08]mixing, loading or applying a commercial pesticide product according to your normal practices.
8. Wear any personal protective equipment required by the label when handling the pesticide.
9. Have a small tube attached to your shirt collar and connected to a portable air-sampling pump on a belt worn around your waist.
10. Have your face and neck washed with two pieces of cloth, that are moistened with a mild soap solution, when the work is completed. This will be done at the end of each day, and as necessary during the day.
11. Have your hands washed in a mild soap solution one or more times during each day.
12. Allow photographs and videotapes to be taken, edited, and used to show how the study was conducted. [10]The sponsor may use the photographs or videotapes for educational or other purposes [08]related to this study.

RISKS AND DISCOMFORTS

There are no added health risks, beyond your routine pesticide exposure, associated with your participation in this study. [08]You may have some discomfort, and possible heat-induced illness [08](heat stroke), when wearing long underwear underneath normal work clothing on warm days. Wearing an air-sampling pump could be an inconvenience if it gets in the way of your work. There may also be some embarrassment caused by having a field investigator assist in removing your long underwear, and [08]having a video taken of your work with this commercial pesticide. [03] There may be risks or side effects which are unknown at this time.

<<CF-Main Approval Stamp - Approved>>

[0702]Pregnant women cannot be in this study. Women will have pregnancy tests before the decision is made if they can be in the study. If you suspect that you have become pregnant while participating in the study, you must contact the study investigator immediately.

NEW FINDINGS

You will be told about any new information that might change your decision to be in this study.

BENEFITS

You will not directly benefit from your participation in the study. However, the information obtained from this study will be used to help evaluate the exposure risk to agricultural workers who mix, load, and apply pesticides [01]in the future.

COSTS

There will be no costs to you for participation in this study.

PAYMENT FOR PARTICIPATION

You will be paid $100.00 each time you participate in this study. Normally, you will be allowed to participate in the study on only one day. [10]The AHETF does not intend to pay you for any uses of the photographs and videotapes.

ALTERNATIVES

This is not a treatment study. Your alternative is to not participate in this study.

CONFIDENTIALITY

Information from this study will be given to the sponsor. "Sponsor" includes any persons or companies, which are contracted by the sponsor to have access to the research information during and after the study. This information will not be given to your employer.

The information will also be given to the U.S. Environmental Protection Agency (EPA). It may be given to state governmental agencies and [08]government agencies in other countries. Research records, including photographs and videotapes, which identify you and the consent form signed by you will be looked at and/or copied for research or regulatory purposes by:

- the sponsor; [08]and
- Eric [08]D. Bruce, [08]B.S., the Principal Investigator and an agent for the sponsor;

and may be looked at and/or copied for research or regulatory purposes by:

- governmental agencies in other countries;
- the EPA; and

- the Western Institutional Review Board® (WIRB®).

Absolute confidentiality cannot be guaranteed because of the need to give information to these parties. The results of this research study may be presented at meetings or in publications. You will not be identified by name in any reports resulting from this study.

COMPENSATION FOR INJURY

If you are injured as a result of being in this study, treatment will be available from a health professional at a nearby medical facility. The costs of such treatment will be covered by the AHETF. This does not cover any injuries resulting from your normal activities. For further information about this, you may call the office of the AHETF at 660-395-9590.

SOURCE OF FUNDING

Funding for this research study will be provided by the Agricultural Handlers Exposure Task Force (AHETF).

VOLUNTARY PARTICIPATION/WITHDRAWAL

Your employer does not urge, influence, or encourage anyone who works for the company to take part in this research study. Your participation in this study is completely voluntary. You may withdraw from the study at any time and for any reason. Your decision to not participate in the study, or a decision on your part to withdraw from the study, will have no [08]effect whatsoever on your employment status. You may refuse to participate or you may withdraw from the study at any time without penalty or loss of benefits to which you are entitled.

Your participation in this study may be stopped at any time by the study investigator or the sponsor without your consent.

QUESTIONS

If you have questions about this study, or if at any time you feel you have experienced a research-related injury, contact:

Eric [08]D. Bruce, [08]B.S., (Study Director) at 925-939-4987 (collect – [08]home office, 24 hours) or 925-708-5538 ([08]mobile, 24 hours)

Or

David [08]R. Johnson, Ph.D., (sponsor contact) at 660-395-9590 (collect).

If you have questions about your rights as a research subject, you may contact:

Western Institutional Review Board® (WIRB®)
3535 Seventh Avenue, SW

Olympia, Washington 98502
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: ClientServices@wirb.com.

WIRB is a group of people who perform independent review of research.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all your questions.

If you agree to participate in this study, you will be given a signed and dated copy of this consent form [12]and the Experimental Subject's Bill of Rights.

CONSENT

I have read the information in this consent form (or it has been read to me). All of my questions about the study and my participation in it have been answered. I agree to participate in the study.

I authorize the release of my research records, including photographs and videotapes, for research or regulatory purposes to the sponsor, governmental agencies in other countries, the EPA, and WIRB®.

By signing this consent form, I have not given up any of my legal rights.

Date: _____ _____
Subject's Name (print)

_____
Subject's Signature

Date: _____ _____
Person Conducting Informed
Consent Discussion's Name (print)

_____
Person Conducting Informed
Consent Discussion's Signature

----------Use the following only if applicable----------

If this consent form is read to the subject because the subject is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject. The subject freely consented to participate in the research study.

Date: _____ _____

Impartial Witness' Name (print)

_____

Impartial Witness' Signature

Note: This signature block cannot be used for translation into another language. A translated consent form is necessary for enrolling subjects who do not speak English.

[12]EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment, or who is requested to consent on behalf of another, has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be used.

3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or other procedures involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time, and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of a signed and dated written consent form when one is required.

10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

_____ _____

Signature of Subject Date

_____ _____

Signature of Witness Date