Protocol: EMD-004
Submitted by: Kim Lerner, Chairman, Independent Investigational Review Board
Date: September 11, 2006

The following is intended to substantiate that review of the research study noted above was reviewed in compliance with EPA requirements. If any other documentation is necessary or revisions to the practice or documentation of records by the Independent Investigational Review Board is required, please advise.

	Requirement	Y/N	Comments
all information relevant to the proposed research specified by § 26.1115(a)	(1) Copies of • all research proposals reviewed,	Copies by SC	Protocol 4/13/06 Revised Protocol 7/12/06
	• scientific evaluations, if any, that accompany the proposals,	" "	MSDS sheets – WV29-01, EUS26-15,EUS26-16,
	• approved sample consent documents,	See attached	Changes made to icf by Committee – Initial Approval **ATTACHMENT 1A** Revised Protocol: **ATTACHMENT 1B**
	• progress reports submitted by investigators, and reports of injuries to subjects.	NA	Approval letter informs PI that study was approved for 1 yr – minutes document basis for determination – not yet due
	(2) Minutes of IRB meetings . . . in sufficient detail to show	See attached	Minutes 4/18/06–**ATTACHMENT 2A** Minutes 7/25/06 –**ATTACHMENT 2B**
	• 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;	See attached	Initial Approval: Committee works sheets: EPA Protocol Checklist – **ATTACHMENT 3 A** and Research Search Evaluation Form and ICF checklist **ATTACHMENT 3 B**
	• a written summary of the discussion of controverted issues and their resolution.	n/a	No issues "controverted", satisfactory findings documented in minutes and committee worksheets
	(3) Records of continuing review activities.	n/a	n/a for protocols
	(4) Copies of all correspondence between the IRB and the investigators.	Copies by SC	research submissions by site and approval documentation from IRB
	(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;	See attached	Membership roster is reviewed/updated annually includes required elements and is posted on the IIRB web site. **ATTACHMENT 4**
	• any employment or other relationship between each member and the institution, for example, full-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant.	See attached	**ATTACHMENT 4**
	(6) Written procedures for the IRB in the same detail as described in §26.1108(a) and §26.1108(b).		Sent by email to John Carley at EPA

	(7) Statements of significant new findings provided to subjects, as required by §26.1116(b)(5).	n/a	n/a for protocols
and the following additional information, to the extent not already included	§1125(a) a discussion of: (1) The potential risks to human subjects; (2) The measures proposed to minimize risks to the human subjects; (3) The nature and magnitude of all expected benefits of such research, and to whom they would accrue; (4) Alternative means of obtaining information comparable to what would be collected through the proposed research; and (5) The balance of risks and benefits of the proposed research.		The information addressing these issues is supported in the documentation provided by the Sponsor and Investigator and documentation of the IRB analysis and findings is documented in the Protocol Checklist, the Research Search Evaluation Form, changes to the ICF required by the IRB and Board minutes (**ATTACHMENTS 1, 2, 3A, and 3B)**
	§1125(b): All information for subjects and written informed consent agreements as originally provided to the IRB, and as approved by the IRB.	Copies by SC See attached	**ATTACHMENT 1** reflects Committee changes
	§1125(c): Information about how subjects will be recruited, including any advertisements proposed to be used.	See attached	**ATTACHMENT 5**
	§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.	See attached	**ATTACHMENT 5**
	§1125(e): All correspondence between the IRB and the investigators or sponsors.		Overlaps §1115(a)(4) above
	§1125(f): Official notification to the sponsor or investigator. . . that research involving human subjects has been reviewed and approved by an IRB.	Copies by SC	Note: The letter includes all of the documents that were approved/reviewed are listed and that the notification letter to the investigator includes approval period, requirement for changes to the protocol and advertisements to be reported to the IRB and that new risk information (SAE/AE), deviations or problems be reported to the IIRB.

Attachment 1A

INFORMED CONSENT AUTHORIZATION TO PARTICIPATE AS A RESEARCH STUDY SUBJECT

Title of Study: (EMD-004) Test of Personal Insect Repellents

Principal Investigator: Scott P. Carroll, Ph.D.

Site of Investigation: Carroll-Loye Biological Research
711 Oak Ave
Davis, CA 95161

Sponsor: EMD Chemicals, Inc.

Participant's Name: _____

You are being asked to participate in a research study. Your participation is voluntary. The information in this Informed Consent Form explains the study. You will receive a copy of this form, and you may take it home and think about it before making your decision. If you have any questions, or do not understand anything in this form, please ask the Principal Investigator to explain any words or information you do not clearly understand.

Nature and Purpose

Carroll-Loye Biological Research is conducting this research study in order to develop effective mosquito repellents, in three different dosage forms with an industry standard and no treatment as a positive control. compare as a negative control.

The purpose of the study is to ~~test~~ the repellent characteristics of the test materials in the field with mosquitoes. The information gathered will be used to develop personal repellents for future commercial marketing. Deep Woods Off!™ contains DEET 20% is an approved repellent that will be used as the positive control.

The sponsor EMD Chemicals, Inc. has contracted Carroll-Loye Biological Research to conduct the study. Scott Carroll, Ph.D. of Carroll-Loye Biological Research is the Principal Investigator in charge of the study.

SUBJECT SELECTION

You have been offered an opportunity to participate in this research study because you are a male or female and 18 years of age or older. If you are a female of child bearing potential you cannot be pregnant or breastfeeding.

Approximately 20 volunteers will be enrolled in this field research study.

Study Duration

This study will require one field site visit ~~not including the screening visit~~. A screening visit is required within 14 days of the ~~study~~ visit.

Field site

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Study Procedures
Study Design

~~The study will test three different test materials.~~ You will be randomly (by chance) assigned to receive one of three investigational formulations (Lotion, Pump, and Aerosol), DEET and no treatment. For each material treatment you will have a pre-measured amount of test material applied to either your forearms or lower legs. You will not have a choice as to which group you are assigned. ~~You may also have one test material on one of your forearms or lower legs and a different test material on the other~~. Neither you nor the principal investigator will know which of the study materials you are receiving; however, this information can be made available if medically necessary.

Screening Visit

Within 14 days of the study visit you will go to the laboratory and you will provide some basic information during a pre study visit with a researcher. If you agree to participate in the research study you will have your limb surface measured in order to calculate the dosage of test material you will need.

If you are a female, you will perform a pregnancy test using an Over the Counter (OTC) pregnancy kit in the morning prior to the start of the study. The results of your test will be verified a female technician that is qualified to make that determination. If you are pregnant, you will not be allowed to participate in the study.

Procedures

The study material will be applied by a Carroll-Loye technician. The skin surfaces to be treated are first cleansed with a ~~mild low~~ fragrance soap, rinsed with isopropanol (35%), and then towel dried. The test products are applied to your forearms or lower legs with two fingertips as evenly as possible using a light rubbing motion.

You will enter into the test area within 10 minute of having treatments applied. You and a partner will continuously monitor your own exposed arms or legs and those of your partner for mosquitoes that land. If any mosquitoes land you will remove them immediately. Every five minutes a project leader will announce the beginning of the next five-minute interval. At each transition to a new interval you will record the number of mosquitoes that landed on your own treated skin on a data sheet.

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RESTRICTIONS

- You must not be hypersensitive to mosquito bites
- Must not be sensitive to any of the test product ingredients
- ~~Must not have used repellents within one week prior to the start of the study~~
- Must refrain from smoking or alcoholic beverages during the tests

RISK/DISCOMFORTS

A Material Safety Data Sheet (MSDS) will be provided for review prior to participation in the study. According to the MSDS, the proposed formulation is flammable. The material may cause skin, respiratory and eye irritation. If excessive inhalation it can cause respiratory irritation, headache and dizziness. If ingested it may cause temporary gastric distress.

If at anytime you feel ill, inform the Principal Investigator (or any of the study monitoring personnel), and you will be taken to receive medical attention. You may remove yourself for any reason from the study at anytime.

Measures will be implemented to remove mosquitoes before they have an opportunity to bite. However you might get bitten by one or more mosquitoes.

PREGNANCY RISKS

The risks to the unborn are unknown and maybe hazardous. **If you are a woman of childbearing potential, it is important that you do participate in this study if you are, or if you think you may be pregnant.**

UNKNOWN / UNFORESEEABLE RISKS

In addition to the risks and discomforts listed above, there may be some unknown or infrequent and unforeseeable risks associated with the use of this formulations including allergic reaction or interaction with a medication. ~~The research test subject~~ you will be informed in a timely manner both verbally and in writing of any new information, findings or changes to the way the research will be performed that might influence his willingness to continue participation in this study.

RESEARCH RELATED INJURIES

If the research test subject is injured as a result of being in this study, treatment will be available from a health professional who is either on call or on site. Carroll-Loye Biological Research will cover the costs of such treatment. This does not cover any injuries resulting from normal work activities. For further information about this, the research test subject should call the office of Carroll-Loye Biological Research (530) 297-6080. Financial compensation for non-study related injuries for such things as lost wages, disability or discomfort due to injury is not available from Carroll-Loye Biological Research.

You <u>DO NOT</u> waive your legal rights by signing this form.

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RIGHT TO WITHDRAW OR REMOVAL FROM STUDY
I understand that I am free to withdraw from this study at any time, and I agree to inform the Principal Investigator immediately if I intend to withdraw. It is understood that my decision to participate in this study or to withdraw from this study will not influence the availability of my future medical care and will involve no penalty or loss of benefits to which I am otherwise entitled. I may withdraw from this study at any time.

I agree that the Principal Investigator in charge of the study can remove me from this study without my consent for any reason, including, but not limited to:

a. His/her judgment that any condition or circumstance may jeopardize my welfare or the integrity of the study.
b. My failure to follow the instructions of the investigator(s).
c. If the study is stopped by the sponsor and/or Principal Investigator participating in the study prior to completion.

TREATMENT ALTERNATIVE
Since this study is not intended to provide any therapeutic or other health-related benefit, your alternative is to not participate in this study.

BENEFITS
There are no immediate benefits to you from your participation other than compensation for your participation.

OFFER TO ANSWER ANY QUESTIONS ABOUT THIS STUDY
If you have any questions or problems during this study, or if you think that you may have experienced a research-related injury, you should contact Scott Carroll of Carroll-Loye Biological Research at (530) 297-6080.

If you have any questions regarding your rights as a research volunteer, please contact Kim Lerner, Chairman of the Independent Investigational Review Board, Inc. at toll free (877) 888-IIRB (4472) during regular working hours. The Independent Investigational Review Board is a committee established for the purpose of protecting the rights of volunteers in a research study.

COSTS AND REIMBURSEMENT
There will be no costs to the research study participant from participating in this study

For participation in the study, each research study participant will receive a cash payment of $15 per hour. Payment will be made at the end of the study or whenever the test subject withdraws from the study.

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CONFIDENTIALITY

Representatives from the Sponsor, EMD Chemicals, Inc., the U.S. Environmental Protection Agency (EPA), the Food and Drug Administration (FDA) and the Independent Investigational Review Board, Inc. Review Board (an independent committee that reviewed the ethical aspects of this study to help protect the rights and welfare of study participants) may have access to all non-personal information collected in this study. Because of the need to release information to these parties absolute confidentiality cannot be guaranteed. Any information or reports published as a result of this study would not identify you by name, or any other personal identification.

CONSENT AND SIGNATURES

I have read, in a language that I understand well, and understand the information, which has been stated above. I have received satisfactory answers to all of the questions, which I have asked. I hereby voluntarily consent to take part in this study and to be a research study participant in this study. I authorize the use and disclosure of my medical information, and do **not** waive my legal rights by signing this Informed Consent Form. I shall receive a copy of the signed Informed Consent Authorization.

Date/Time	**Print** Subject Name	**Sign** Subject Name
Date/Time	Scott Carroll **Print** Carroll-Loye Biological Resarch Representative	**Sign** Carroll-Loye Biological Research Representative

Independent Investigational Review Board, Inc.
Approval: / /06

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Signature Date

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Attachment 1B

INFORMED CONSENT AUTHORIZATION TO PARTICIPATE AS A RESEARCH STUDY SUBJECT

Title of Study: (EMD-004) Test of Personal Insect Repellents

Principal Investigator: Scott P. Carroll, Ph.D.

Site of Investigation: _____
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Sponsor: EMD Chemicals, Inc.

Participant's Name: _____

You are being asked to participate in a research study. Your participation is voluntary. The information in this Informed Consent Form explains the study. You will receive a copy of this form, and you may take it home and think about it before making your decision. If you have any questions, or do not understand anything in this form, please ask the Principal Investigator to explain any words or information you do not clearly understand.

NATURE AND PURPOSE

Carroll-Loye Biological Research is conducting this research study in order to develop effective mosquito repellents. *Many people are interested in having new and better insect repellents available to them. The insect repellents that we will study were developed from amino acids that are naturally occurring substances in animals. More studies are needed to determine how well such new insect repellents work.*

The purpose of the study is to test how well new lotion, pump spray and aerosol insect repellent products work outdoors against mosquitoes. These three products are similar to some already being sold. The information *gained from the study* will be used to develop *improved insect* repellents for future commercial marketing. *During the study we will first measure how much insect repellent you put on your own arms and legs in a visit to the study laboratory, and train you to use a mechanical mosquito catcher. On a later date, we will go to a field site to test the insect repellents against mosquitoes in nature.*

The sponsor, EMD Chemicals, Inc. has contracted Carroll-Loye Biological Research to conduct the study. Scott Carroll, Ph.D., of Carroll-Loye Biological Research is the Principal Investigator in charge of the study.

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SUBJECT SELECTION

You have been offered an opportunity to participate in this research study because you *read* and *speak English, consider yourself to be in good physical condition and are* 18-~~55~~ years of age. If you are a female of child bearing potential, you cannot be pregnant or breastfeeding.

Approximately *30* volunteers will be enrolled in this field research study.

STUDY INTRODUCTION AND DURATION

Schedule of visits and time required to participate in the study

Activity	*Visit 1 (1-21 days before the field test)*	*Visit 2*
1. Orientation and Dosage visit	*X*	
2. Field study visit		*X*
Total time	*2-3 hours*	*8-14 hours*

Visit 1 for Orientation and determining Dosage

Within 21 days before the field study visit you will go to the laboratory and meet with a researcher to perform introductory activities for the repellent study. The researcher will also tell you more about what you will experience while participating and what is expected of you. You will work with a researcher to determine how much insect repellent you apply. Completing those measurements will take 1.5-2.0 hours.

You will also be shown how to use a handheld mosquito catching device called an aspirator. These devices resemble flashlights except that they have a small electric fan and suction tube rather than a light bulb. You will carry one of these devices with you during the field study. During this visit you will also practice removing mosquitoes from a small area of your arm with the aspirator. This training and practice will take about ½ to 1 hour.

The total time for Visit 1 activities will be about ~~1.5-2.5~~ 2-3 hours.

Visit 2 for the Field Test against Mosquitoes

The study will also require one visit to the ~~site of the~~ field ~~study~~ site. The field site visit will most likely require approximately 10 hours of your time. However, it may require as few as 8 hours (including travel time) and as many as about 14 hours, depending on how long the repellents remain effective. Bathrooms are available, and meals, drinks and snacks will be provided. There is a small chance that weather conditions will require that the test be canceled or rescheduled. The Principal Investigator will inform you in a timely manner if that happens.

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Study Duration .
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Study Procedures .

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STUDY PROCEDURES

Study Design

The study will test three different insect repellent products, namely a lotion, a pump spray and an aerosol spray. You will be randomly (by chance) assigned to receive one or two of the three products, so your chance of receiving any one of them is about one-in-three or two-in-three. In addition, one subject will test another commercial repellent containing the well-known active ingredient 'deet'. You will have about a one-in-twenty to one-in-thirty chance of being the subject who tests the deet product instead of one of the experimental products. You will not have a choice as to which repellent product or products you receive. For each product assigned to you, you will have an amount typical of what people commonly use applied to your forearms or lower legs. Experienced personnel will also be present to record the activity of mosquitoes by exposing their own arms or legs without repellent applied. However, you will not be asked to expose untreated skin and should avoid doing so.

If you are a female, you will perform a pregnancy test using an Over the Counter (OTC) pregnancy kit in the morning prior to the start of the study. The results of your test will be verified *by* a female technician that is qualified to make that determination. If you are pregnant, you will not be allowed to participate in the study.

Procedures

Visit 1

At the laboratory, a researcher will measure the length and circumference of your forearm and lower leg. You will then practice using the products to decide how you best like to apply them and how much you would apply to your forearm or lower leg in order to have thorough and even coverage. The researcher will answer any questions you have about the application. Once you have a method you are satisfied with, you will wash your arms and lower legs with soap and water and dry them with a towel. The researcher will then place three small "bracelets" made of medical gauze around your arm or leg. You will then spray that area, including the bracelets, with a repellent, and a technician will remove the gauze and weigh it to determine how much spray has clung to its surface. Similarly, we will ask you to apply an amount of the lotion repellent product to your skin that you think gives complete and even coverage. We will use the amounts you apply in this part of the study to determine how much repellent people normally apply.

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You will also spend 15-30 minutes practicing catching mosquitoes in a laboratory cage, using an aspirator. You will be shown how to place both arms in a screen cage and turn on the aspirator using the switch on the handle. Two mosquitoes will be released in the cage. A small area (less than ½ of your forearm) will be uncovered, with no insect repellent applied. You will carefully watch the

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Screening Visit
Within 14 days of the study visit you will go to the laboratory and you will provide some basic information during a pre study visit with a researcher. If you agree to participate in the research study you will have your limb surface measured in order to calculate the dosage of test material you will need.

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You will enter into the test area within 10 minute of having treatments applied. You and a partner will continuously monitor your own exposed arms or legs and those of your partner for mosquitoes that land. If any mosquitoes land you will remove them immediately. Every five minutes a project leader will announce the beginning of the next five-minute interval. At each transition to a new interval you will record the number of mosquitoes that landed on your own treated skin on a data sheet.

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mosquitoes as they fly in the cage. Once they land on your skin, you will watch carefully to see if their needle-like mouths are placed against your skin. A researcher will be present to instruct and guide you. You may carefully move your arms to get better views and access to the mosquitoes. Once you observe a mosquito mouth touching your skin, you will immediately attempt to catch the mosquito in the plastic nozzle of the mosquito catcher. The researcher will first demonstrate the procedure to you using his or her own arms. You may practice as many times as you wish, and the researcher will be certain that your use of the mosquito catcher is correct. The mosquitoes used for this training are reared in the laboratory and free from diseases.

Visit 2

At the field site, the subjects and researchers will gather in an area without biting mosquitoes. You should not leave this area until instructed by a researcher.

You will be given an aspirator to suck any mosquitoes that land on your treated skin and attempt to bite you once the test begins. A researcher will show you again how to operate it. You will also be introduced to the technicians and other researchers who will assist you during the test. You will be instructed to call on them whenever you have questions about using the aspirator, protecting yourself from a mosquito, or reporting on a mosquito that lands on skin treated with repellent.

Before the repellent is applied, a technician will guide you in washing the lower arms and legs with mild, low fragrance soap, rinsing them with a spray of ethyl alcohol (mixed with an equal part of water), and then drying them with a clean towel. A technician will then apply insect repellents to your forearms or lower legs to give even, complete coverage of the skin. The amount of repellent applied on any one arm or leg will be no more than about ¼ teaspoon. You will also be given protective material to prevent bites on other parts of your arms and legs, plus a head net.

During the field test you and the Investigator will not know which repellent you are using. The study is done this way because knowing which repellent you are using can change the results of the study. If you start having any side effects from the repellent, the investigators can find out what you are taking in order to help you. Please ask the investigator if you have any questions at all about this kind of study.

The Principal Investigator or one of his technicians will guide you into the area of the field site in which mosquitoes are active approximately 15 minutes after you have had the test repellents applied. You and a partner will watch your own exposed arms or legs and those of your partner for mosquitoes that land for one minute. A technician will let you know when the one-minute period begins and

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ends. If any mosquitoes land and attempt to bite the skin with repellent, you will remove them immediately with the mosquito catcher. If at any time you have difficulties using the mosquito catcher you should push the mosquito from your skin with the plastic nozzle of the catcher. You may also use your finger to brush any mosquito aside. If you brush a mosquito aside watch carefully because it may quickly return to your skin. You will report the number of mosquitoes that attempted to bite your own treated skin on a data sheet during the one-minute period when asked by a technician who will record it on a data sheet. If more than one mosquito attempts to bite you on your treated skin in one of the one-minute periods you should immediately cover that skin with the protective mesh or clothing provided. Every 15 minutes a project leader will announce the beginning of the next one-minute period for testing the treated skin and watching for mosquitoes that might attempt to bite it.

RESTRICTIONS

- You must not be hypersensitive to mosquito bites
- *You must* not be sensitive to any of the test product ingredients
- *You must* not have used repellents within *three days* prior to the start of the study
- *You must not use perfumed products after 9 PM the night before the study*
- *You must* refrain from smoking or alcoholic beverages during the tests

RISK/DISCOMFORTS

If at anytime you feel ill, inform the Principal Investigator (or anyone else who is also assisting to direct the study) immediately, and you will be taken to receive medical attention at the nearest hospital. You may also request access to standard first aid materials (such as bandages, antiseptics, and mild antihistamines) and request first aid assistance at any time. You may remove yourself for any reason from the study at anytime. At least one qualified researcher will remain with the other test subjects if other researchers depart with an injured or ill subject.

The *spray repellents contain alcohol and are flammable. The repellents* may cause skin, *lung* and eye irritation. *Excessive* inhalation can cause *lung* irritation, headache and dizziness. *Swallowing the products* may cause temporary *stomach* distress. *You may obtain more information about the safety of the repellents by asking the Principal Investigator, and he will provide you with the official "Material Safety Data Sheets" which give safety details similar to those found on commercial product labels.*

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In addition, even if you have not had a serious skin reaction to a mosquito bite previously, it is possible that such a reaction could occur if you receive any bites during this study. Swelling, redness and itching near the site of the bite are all symptoms of an allergic reaction to a mosquito bite. You should inform the Principal Investigator or one of his technicians if you are having such a reaction. There will be a first aid kit at the field site with treatments to reduce allergic symptoms from bites. Inform the Principal investigator if you are allergic to any nonprescription medicines. At least one technician with current first aid training will be present during the field test.

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In addition, there is a slight possibility that you will contract a disease carried by mosquitoes if you are bitten, such as West Nile virus or encephalitis. This test is being conducted in an area in which such viruses have not been detected by state health or mosquito control agencies for at least a month, so the risk is probably low that any individual mosquito that might bite you carries a disease. In addition, since you are wearing repellent and other protective measures, and are carefully watching for mosquitoes that land and try to bite, you are probably at no more risk than you would experience when engaged in normal outdoor activities in a similar rural area at the same time of year.

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The US Centers for Disease Control estimates that about 1-in-5 people who become infected with West Nile Virus will develop West Nile fever. For up to two weeks after the test, be alert for any flu-like symptoms (unusual tiredness or unusually severe headaches, body aches, fever, or a rash on the trunk of the body). About 1-in-150 infected people will develop more serious symptoms including neck stiffness, stupor, disorientation and possibly coma and paralysis.

Most people (about 4 out of 5) who are infected with West Nile virus will not develop any type of illness. Since you will work to quickly remove mosquitoes before they have an opportunity to bite, and few of the mosquitoes present are likely to carry the virus, your chances of getting West Nile fever or another disease from a mosquito bite are probably extremely small.

If you experience any of the symptoms described above in the month following the field test you should contact a medical practitioner and inform the Principal Investigator.

Put Back in

PREGNANCY RISKS

The risks to the unborn are unknown and *if* you are a woman of childbearing potential, it is important that you do *not* participate in this study if you are, or if you think you may be pregnant. *Pregnancy will be self-checked by each female volunteer on the morning of the repellent test using an OTC test kit provided by the Study Director. Results of each such*

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Staff

APPROVED BY
Independent IRB

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Signature Date

Initials: _____
Date: _____

test will be immediately verified by direct inspection by a female technician trained to make that assessment.

OK

UNKNOWN / UNFORESEEABLE RISKS

In addition to the risks and discomforts listed above, there may be some unknown or infrequent and unforeseeable risks associated with the use of *this product*, including allergic reaction or interaction with a medication. You will be informed in a timely manner both verbally and in writing of any new information, findings or changes to the way the research will be performed that might influence *your* willingness to continue participation in this study.

RESEARCH RELATED INJURIES

If you are injured as a result of being in this study, *medical* treatment will be available from a health *care facility that* is *aware of the study*. Carroll-Loye Biological Research will cover the costs of such *medical* treatment. *If necessary, Carroll-Loye Biological Research will transport you to receive medical attention and pay costs associated with the reasonable and appropriate treatment for any injuries incurred as a result of participation in the study. For further information about this, ~~the research test subject~~ you should call the office of Carroll-Loye Biological Research (530) 297-6080.*

You DO NOT waive your legal rights by signing this form.

OK

TREATMENT ALTERNATIVE

Since this study is not intended to provide any therapeutic or other health-related benefit, your alternative is to not participate in this study.

OK

BENEFITS

There are no immediate benefits to you from your participation. *However, by serving as a participant you may assist in making new insect repellent products available to consumers.*

OFFER TO ANSWER ANY QUESTIONS ABOUT THIS STUDY

If you have any questions or problems during this study, or if you think that you may have experienced a research-related injury, you should contact Scott Carroll of Carroll-Loye Biological Research at (530) 297-6080.

If you have any questions regarding your rights as a research volunteer, please contact Kim Lerner, Chairman of the Independent Investigational Review Board,

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Deleted: This does not cover any injuries resulting from normal work activities. For further information about this, you should call the office of Carroll-Loye Biological Research (530) 297-6080. Financial compensation for non-study related injuries for such things as lost wages, disability or discomfort due to injury is not available from Carroll-Loye Biological Research.

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I understand that I am free to withdraw from this study at any time, and I agree to inform the Principal Investigator immediately if I intend to withdraw. It is understood that my decision to participate in this study or to withdraw from this study will not influence the availability of my future medical care and will involve no penalty or loss of benefits to which I am otherwise entitled. I may withdraw from this study at any time.

I agree that the Principal Investigator in charge of the study can remove me from this study without my consent for any reason, including, but not limited to:

a. His/her judgment that any condition or circumstance may jeopardize my welfare or the integrity of the study.
b. My failure to follow the instructions of the investigator(s).
c. If the study is stopped by the sponsor and/or Principal Investigator participating in the study prior to completion.

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Inc. at toll free (877) 888-IIRB (4472) during regular working hours. The Independent Investigational Review Board is a committee established for the purpose of protecting the rights of volunteers in a research study.

COSTS AND REIMBURSEMENT

There will be no costs to the research study participant from participating in this study

For participation in the study, each research study participant will receive a cash payment of $15 per hour. Payment will be made at the end of *each visit* or whenever the test subject withdraws from the study.

CONFIDENTIALITY

Carroll-Loye Biological Research will retain records of this study indefinitely. You may access your own records by contacting the ~~Study Director~~ P.I. Representatives from the Sponsor, EMD Chemicals, Inc., the U.S. Environmental Protection Agency (EPA) and the Independent Investigational Review Board, Inc. Review Board (an independent committee that reviewed the ethical aspects of this study to help protect the rights and welfare of study participants) may have access to all non-personal information collected in this study. Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed. Any information or reports published as a result of this study *will* not identify you by name, or any other personal identification.

STATEMENTS OF UNDERSTANDING

Right to withdraw or removal from study

I understand that I am free to withdraw from this study at any time, and I agree to inform the Principal Investigator immediately if I intend to withdraw. It is understood that my decision to participate in this study or to withdraw from this study will not influence the availability of my future medical care and will involve no penalty or loss of compensation to which I am otherwise entitled. I may withdraw from this study at any time.

I agree that the Principal Investigator in charge of the study can remove me from this study without my consent for any reason, including, but not limited to:

a. *His/her judgment that any condition or circumstance may jeopardize my welfare or the integrity of the study.*
b. *My failure to follow the instructions of the investigator(s).*
c. *If the study is stopped by the sponsor and/or Principal Investigator participating in the study prior to completion.*

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CONSENT AND SIGNATURES
I have read, in a language that I understand well, and understand the information, which has been stated above. I have received satisfactory answers to all of the questions, which I have asked. I hereby voluntarily consent to take part in this study and to be a research study participant in this study. I authorize the use and disclosure of my medical information, and

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Date: _____

Consent and signatures

I have read, in a language that I understand well, and understand the information which has been stated above. I have received satisfactory answers to all of the questions, which I have asked. I hereby voluntarily consent to take part in this study and to be a research study participant in this study. I **do not** waive my legal rights by signing this Informed Consent Form. I shall receive a copy of the signed Informed Consent Authorization.

authorize the use and disclosure of my medical information, and, I

Date/Time	**Print** Subject Name	**Sign** Subject Name
Date/Time	Scott Carroll **Print** Carroll-Loye Biological Resarch Representative	**Sign** Carroll-Loye Biological Research Representative

Independent Investigational Review Board, Inc.
Approved ~~4/18/06~~; Revised 7/25/06.

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Signature Date

Initials: _____
Date: _____

Attachment 2 A p.1

APRIL 18, 2006
MINUTES

PRESENT:
Kim Lerner, Chairman
Anita Mc Sharry, Vice Chairman
David Wells, MD
Edward Wiederhorn
Shari Somerstein, R.Ph.
George Garbarino

ABSENT:
Rabbi Akiva Mann

ALSO PRESENT:
Glenn Moran, DO
Marcos Rejtman, DO

I. CALL TO ORDER

The meeting was called to order at 10 :00 AM, by Chairman, Kim Lerner. The meeting was held at 6738 West Sunrise Blvd., Suite 102, Plantation, FL 33313.

II. APPROVAL OF THE APRIL 11, 2006 MINUTES

The minutes of the meeting held April, 11, 2006 were reviewed and unanimously approved as reviewed.

III. REVIEW PROTOCOLS

A. (EMD-004) Test of Personal Insect Repellents
Principal Investigator Scott P. Carroll, Ph.D.

- Approval Clinical Research Protocol dated: April 13, 2006
- Informed Consent Form (Ver. 4/18/06)
- MSDS for WV29-01, EU26-16, EU26-15
- California Experimental Subject's Bill of Rights
- Site Questionnaire

The Committee reviewed and approved the Investigator's qualifications, the Research Protocol, Informed Consent Form, MSDS and the California Experimental Subject's Bill of Rights for the above noted study. The Site Questionnaire addressing subject recruitment and mechanism for obtaining consent were reviewed and accepted as submitted. The Committee evaluated the risks and that the risks to the subjects were minimized, including consideration of alternate mechanism to collect the information. The benefits to the subjects, sponsor and public were addressed and a reasonable risk/benefit ratio is established. Minor informed consent revisions were directed by the Committee (see consent changes for details) to clarify research elements. The consent as revised contains all necessary consent elements. It was determined that the research protocol includes IIRB and EPA required elements.

ACTION: Motion was made and seconded to approve the Investigators, Clinical Research Protocol, Informed Consent Form,

Attachment 2A p2

MSDS and the California Experimental Subject's Bill of Rights for the above noted study. Unanimously approved. Based on the duration of the study and the risks to the subjects, the approval is granted for a one year period, with a progress report required prior to continued approval. See Approval letter for Investigator's responsibilities.

B. (EMD-003) Test of Personal Insect Repellents
Principal Investigator Scott P. Carroll, Ph.D.

- Approval Clinical Research Protocol dated: April 13, 2006
- Informed Consent Form (Ver. 4/18/06)
- MSDS for; WV29-01, EU26-16, EU26-15
- California Experimental Subject's Bill of Rights
- Site Questionnaire

The Committee reviewed and approved the Investigator's qualifications, the Research Protocol, Informed Consent Form, MSDS and the California Experimental Subject's Bill of Rights for the above noted study. The Site Questionnaire addressing subject recruitment and mechanism for obtaining consent were reviewed and accepted as submitted. The Committee evaluated the risks and that the risks to the subjects were minimized, including consideration of alternate mechanism to collect the information. The benefits to the subjects, sponsor and public were addressed and a reasonable risk/benefit ratio is established. Minor informed consent revisions were directed by the Committee (see consent changes for details) to clarify research elements. The consent as revised contains all necessary consent elements. It was determined that the research protocol includes IIRB and EPA required elements.

ACTION: Motion was made and seconded to approve the Investigators, Clinical Research Protocol, Informed Consent Form, MSDS and the California Experimental Subject's Bill of Rights for the above noted study. Unanimously approved. Based on the duration of the study and the risks to the subjects, the approval is granted for a one year period, with a progress report required prior to continued approval. See Approval letter for Investigator's responsibilities.

Attachment 2B p1

JULY 25, 2006
MINUTES

PRESENT:
Kim Lerner, Chairman
Anita Mc Sharry, Vice Chairman
David Wells, MD
Edward Wiederhorn
Rabbi Akiva Mann
Shari Somerstein, R.Ph.
George Garbarino

ABSENT:

ALSO PRESENT:
Glenn Moran, DO
Marcos Rejtman, DO

I. CALL TO ORDER

The meeting was called to order at 10:00 AM, by Chairman, Kim Lerner. The meeting was held at 6738 West Sunrise Blvd., Suite 102, Plantation, FL 33313.

II. APPROVAL OF THE JULY 18, 2006 MINUTES

The minutes of the meeting held July 18, 2006 were reviewed and unanimously approved as reviewed.

Attachment 2B p2

(from the minutes of the 7/25/06 meeting - IV. OTHER BUSINESS)

F. Revised Protocol dated 7/12/06 and Revised Informed Consent Form (Ver. 7/25/2006) EMD-003: Scott P. Carroll, PhD

The Independent Investigational Review Board, Inc. had an opportunity to review the Revised Protocol and the revised Informed Consent Form for the above noted research study. The Revised Protocol is unanimously approved as submitted. The revised Informed Consent Form is unanimously approved as revised. The Informed Consent Form has been revised to accommodate the Revised Protocol. The approved revised Informed Consent Form is identified as Version 7/25/2006 and stamped, "Approved 7/25/2006". All current subjects and future volunteers must sign the revised consent forms. It was determined that the revisions did not impact the initial determination regarding the risks to subject and risk/benefit ratio.

G. Revised Protocol dated 7/12/06 and Revised Informed Consent Form (Ver. 7/25/2006 EMD-004: Scott P. Carroll, PhD

The Independent Investigational Review Board, Inc. had an opportunity to review the Revised Protocol and the revised Informed Consent Form for the above noted research study. The revision includes the addition of preliminary dosage determination and a practice visit, the treatment of the balance of risks and benefits, and recruiting methods.

The Revised Protocol is unanimously approved as submitted. The revised Informed Consent Form is unanimously approved as revised. The Informed Consent Form has been revised to accommodate the Revised Protocol. The approved revised Informed Consent Form is identified as Version 7/25/2006 and stamped, "Approved 7/25/2006". All current subjects and future volunteers must sign the revised consent forms. It was determined that the revisions did not impact the initial determination regarding the risks to subject and risk/benefit ratio.

Attachment 3A

INDEPENDENT INVESTIGATIONAL REVIEW BOARD INC.

EPA PROTOCOL CHECKLIST

#: EMD 004

	YES	NO	NA	Notes
Title and Protocol number version date	✓			
Index/Page #'s	✓			
Sponsor contact info	✓			
Study population • Inclusion/Exclusion criteria • Number of subjects • Number of SItes	✓			equitable inclusion excl. preg-nursing site questionnaire supports protocol
Nature and Purpose of study including • **Balance of risks and benefits of research** • **Alternate means of obtaining comparable information**	✓			no alternative @ this time risk managed by training staff monitoring & qualification of the research
Study Design	✓			
Duration of the study	✓			
All Field Procedures including • **Potential Risk to Human Subjects, measures to minimize risk** • **Nature and magnitude of expected benefits and to whom they accrue**	✓			
Restrictions	✓			
Birth Control/Pregnancy testing				preg testing
Withdrawal/voluntary/(involuntary by Sponsor/PI/**EPA**).				1 day duration (if no b/c rq
Study monitoring/Audit/Compliance with Regulatory Authorities	✓			will be reviewed by EPA
Confidentiality/Disclosure of data/not identified in publications • (EPA)/absolute confidentiality not guaranteed	✓			see also ICF
Supplies/shipping/storage	✓			related to preparty
Assignment of subject numbers				randomization assigned
Recording of data/Case report forms	✓			
Deviations from protocol	✓			
Adverse Events	✓			
Study records/Source documents				PI Sponsor resp.
Termination of study				can be terminated by PI/EPA

Consenting of subjects i.e. description of circumstances and methods proposed for presenting information to potential Subjects see site questionnaire

Notes:

Attachmt 3 B p1

Research Evaluation Form

SECTION 1: INFORMED CONSENT CHECKLIST

PROTOCOL #: Emp-004 Final Yes ☑ No ☐ Date 13 April 2006

	YES	NO	NA	Notes
INTRODUCTION				
Title	✓			
Name of Investigators/Address/Tel. #	✓			
Invitation to participate in a research study and why	✓			
Evaluate study population vulnerability	✓			equitable - educated >18
Pediatric/Assent			✓	Adults only
NATURE/PURPOSE				
Clear explanation of the purpose (layman's term)	✓			revised
STUDY DESIGN				
# of subjects/sites	✓			study design
Duration of the study	✓			justified to
Double Blind/Information available	✓			provide data
All procedures, placebo, randomization, dose escalation	✓			
Blood Sampling			✓	
Restrictions	✓		[illegible]	
RISK AND DISCOMFORTS				
Foreseeable risks and discomforts	✓			Risk Minimized
Placebo/ out of control/worsening of disease/Precautions	✓			
Risks to Newborn	✓			revised
Potential for interaction/addiction/allergy	✓			
Unknown /Unforeseeable risks/Reporting New Risks	✓			
BENEFIT				
Description of benefits	✓			
ALTERNATIVE PROCEDURES				
Disclosure of alternative treatments, procedures	✓			
VOLUNTARY PARTICIPATION/WITHDRAWAL				
May withdraw consent even after signing form (voluntary)	✓			
will not go against future care/no penalty or loss of benefits	✓			
Involuntary withdraw	✓			
PAYMENT Include payment & breakdown	✓			
COMPENSATION/COST FOR PARTICIPATION				
Compensation for injury	✓			
Do not waive legal rights	✓			
Any additional cost for participation	✓			
CONFIDENTIALITY				
IIRB, Sponsor, FDA access, absolute confid not guaranteed				
Use of initials for publication				No HIPAA
Does not expire/revoke in writing/access to information				yes.
QUESTIONS/CLOSING				
Who to contact in case of emergency/questions/24 hr	✓			
IIRB for rights as a study participant	✓			
Required signatures/competency to consent	✓			

Investigators Brochure Date: MSDS SAE Reports: Ø Package Insert: Ø

Genetic ICF Yes ☐ No ☒ Photographic ICF Yes ☐ No ☒ Other ICF/Addendum Yes ☐ No ☒

☐

Screening Findings

[signature]

SECTION 2: RISK CHECKLIST

Risks to the unborn:

☐ Males only no known fetal risks

☐ Males only known fetal risks (address in icf)

☐ Post Menopausal Women - Protocol requires medical documentation of PM status/Surg Sterilization status

☐ Post Menopausal Women - Protocol does not require medical documentation of PM status/Surg Sterilization status: **Note in approval letter required!**

☐ includes WOCBP and Protocol describes BC

☐ includes WOCBP but Protocol does not describes BC: **Note in ICF and approval letter required!**

Pregnancy Testing

☑ pregnancy testing for all female at least prior to dosing

☐ pregnancy testing for WOCBP only at least prior to dosing

☐ **Note in approval letter required because protocol does not require medical documentation of** PM status/Surg Sterilization status

Drug Alcohol Screening prior to dosing?

At least prior to dosing: ☐ Drug screening ☐ alcohol screening

☑ No drug/alcohol screening **Note in approval letter required!**

Committee Findings: Drug/alcohol screening not needed. preg testing appropriate 1 day duration No BC req

Risk-Benefit Assessment

What is the benefit of the research? Benefit for additional insect repellent

What is the nature of the risks/were risks minimized? Risks minimized nature of risks not significant training of staff

Type of subject vulnerability/appropriate safeguards? subjects not vulnerable site questionnaire

Pediatrics being enrolled? ☑ No ☐ Yes* * If yes complete Section 3 of this form ,if no leave Section 3 blank

NA **Blood Volume:** ☐ w/in Blood Bank Standard ☐ documentation of volume w/in protocol ☐ see notes

Overall conclusion regarding study merit: ☑ Justified ☐ Requires Additional Information

STATUS ☑ Approved ☐ Tabled

Committee Findings: approved 1 yr based on risks & nature

Signature [signature]

Section 3: REVIEW OF RESEARCH THAT INCLUDES MINORS*

*States with exception to the 18 years of age for emancipation for research participation:
*IIRB does not approve research that involve minors that are the ward of the State or any other agency, institution or entity

APPROVAL ELEMENTS

Research involves:

- ☐ Neonates: (birth to 1 month)
- ☐ Infants (1 month to 2 years)
- ☐ Children (2 years to 12 years)
- ☐ Adolescent (12 years to 17 years)

NA

CATEGORY OF RESEARCH

- ☐ Research that involves no more than minimal risk
- ☐ Research involves more than minimal risk but provides direct benefit to the child (the risk must be justified by the anticipated benefit and be at least as favorable as the alternative treatment).
- ☐ Research involves more than minimal risk, does not provide direct benefit to the child, but is likely to yield generalizable knowledge about minor's disorder or condition
- ☐ Research involves more than minimal risk, does not provide direct benefit to the child, but is likely to yield generalizable knowledge about a disorder or condition (i.e., Phase I research)

SIGNATURE REQUIREMENTS

- ☐ one parent (or legally authorized individual)
- ☐ both parents (or legally authorized individual) or documentation of sole custody
- ☐ Assent required: ☐ not required:_____

FINDINGS

- ☐ Risks have been minimized
- ☐ Research not justified
- ☐ Placebo design justified ☐ Not Applicable
- ☐ generalizable knowledge anticipated to be significant
- ☐ Approval of research not justified based on available documentation: _____

_____

_____

INFORMED CONSENT REQUIREMENTS

- ☐ Assent documented: ☐ not required: _____
- ☐ Introduction Statement (informing minor and parent that both must sign icf)
  ☐ not required:_____
- ☐ PI can withdraw the minor if the minor indicates that they do not wish to be in the study or by display or behavior or verbalization (particularly in research involving young children)
  ☐ not required: _____
- ☐ Signature lines present for Parent/Legal Guardian/Assent

Attachment 4 p1

INDEPENDENT INVESTIGATIONAL REVIEW BOARD INC.

MEMBERSHIP ROSTER

- The following lists the 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.
- No member of the Independent Investigational Review Board, Inc has employment or other relationship (for example, full-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant) of Carroll-Loye Biological Research, EMD Chemicals, Inc., or otherwise involved with the research.

Chairman, Kim Lerner, B.S.
Ms. Lerner is co-founder of the Independent Investigational Review Board and has acted as Chairman for the past 16 years. She has transformed her experience as Director of the IRB at a large teaching hospital into directing a large and diverse independent IRB. Her experience serving as the Director of a Hospital Quality Assurance Program provides the foundation for implementation of the Independent IRB's continuous quality improvement and regulatory compliance programs

Vice Chairman, Anita Mc Sharry, RN (scientific)
Ms Mc Sharry is co-founder of the Independent Investigational Review Board and has acted as President for the past 16 years. She has extensive knowledge of principles of medical research, regulatory compliance and clinical safety. Previous experience included development of Research Study budgets, liaison between the Pharmaceutical Sponsor and the Principal Investigator at the University of Miami, Department of Clinical Pharmacology.

David D. Wells, MD (physician/scientific)
Dr. Wells graduated from the University of Havana, is English-Spanish bilingual and brings this international experience to the IRB. He has served as the Emergency Medicine Department Chairman at a local hospital, has health care Clinic experience working with financially disadvantaged patients and is presently volunteering as a Family Practice Physician serving migrant farm workers. This hands-on experience enables him to clearly assess overall research risks and benefits and understand vulnerable population issues.

Rabbi Akiva D. Mann, M.A. (non-scientific)
Rabbi Mann is presently the Spiritual Leader of the Hallandale Jewish Center and is the Director of the Institute of Jewish Knowledge and Learning. He has served on Mayorial Commissions addressing the issues of Medical Ethics and Geriatric Care, as well as having served on Hospital Ethics Committees.

Edward Wiederhorn (non-scientific)
Mr. Wiederhorn is the community representative to the IIRB and is a member of the American Association of Retired Persons (AARP). Mr. Wiederhorn has longstanding experience as a Civic Activist and has been a member of Fraternal and Charitable Organizations, at present he is actively involved in support of the City of Hope.

Attachment 4 p2

INDEPENDENT INVESTIGATIONAL REVIEW BOARD INC.

MEMBERSHIP ROSTER

Shari Somerstein, B.S., R. Ph. (scientific)
Ms. Somerstein has served as a member of the Independent IRB for more than 6 years and has extensive experience in the interpretation and assessment of clinical research findings and study design. She brings extensive clinical pharmacy experience in a Hospital setting and in the community. She has broad administrative experience in IRB activities including, protocol review, assessment of adverse drug experiences and informed consent form development.

George J. Garbarino (non-scientific)
Mr. Garbarino has been an advocate for Labor Union members and brings a wide range of experience in the area of worker's rights and contract negotiations. He is the Business Manager of the Tile, Marble and Stone Workers Local 121 and is associated with the School Board of Broward County.

Glenn K. Moran, DO, FACOFP (Alternate for: physican/scientific)
Dr. Moran is Board Certified in Family Practice and is presently in private practice. He maintains privileges at local hospitals and is active in the areas of Medical Quality Assurance and Peer Review and other community organizations. He is an Assistant Clinical Professor at Nova Southeastern College of Osteopathic Medicine and is familiar with current medical research requirements.

Marcos Rejtman, DO, (Alternate for: physican/scientific)
Dr. Rejtman is Board Certified in Family Practice, Geriatric Medicine and Hospice &Palliative Medicine and is presently the Medical and Team Director for VITAS Innovative Health Care (Hospice) and provides in hospital patient management for a multi-specialty group. He also has recent experience in Emergency Department Medicine. He maintains privileges at local hospitals and is active in the areas of Medical Quality Assurance and Peer Review and other community organizations. He is English-Spanish bilingual.

Maria L. Rodriguez, MS, CCRC,RHIT (Alternate for: non-scientific)
Ms Rodriguez brings to the Board extensive experience in the clinical research field and knowledge of regulatory requirements, policy and procedure development, and the implementation of the quality assurance function. Her educational background focuses on education and training in the clinical research field. She is English-Spanish bilingual.

Elsie P. Remy, MSN, ARNP-c (Alternate for: scientific)
Ms Remy has an extensive background in nursing as an educator and clinical nurse manager. Her experience includes acute and primary care. She is an Assistant Professor in the Nursing Department at Miami Dade Community College. Her responsibilities include curriculum development and she serves as an Academic Adviser and Adviser to student organizations.

Robert Lettman, Esq. (non-scientific)
Mr. Lettman is a practicing Attorney in South Florida with extensive experience in civil litigation and serves as a resource in the consideration of the legal aspects of the informed consent process. Having been in the community for 30 years he brings insights and knowledge of the needs of the community.

Attachment 5

INDEPENDENT INVESTIGATIONAL REVIEW BOARD INC.

SITE QUESTIONNAIRE

NON-LOCAL REVIEW

Protocol # & Complete Study Title: (EMD-004) Test of Personal Insect Repellents

Principal Investigator: Scott P. Carroll, Ph.D

Sub Investigator(s): None

Please indicate the location where study activities will be performed (where patients will be seen excluding Diagnostics) If more than on location is being used you may attach additional pages.

Site #1 Address: Gray Lodge State Wildlife Refuge
3207 Rutherford Rd
Gridley, CA 95948 USA

PI's Mailing Address: (If different) Carroll-Loye Biological Research
711 Oak Avenue
Davis, CA 95616

If the study is being conducted at more than one location and information requested differs for each location, please provide separate information for each location.

Regulatory/Study Coordinator: Scott Carroll Phone: 530-297-6080 Fax Number: 530-297-6080

Office Phone: 530-297-6080 24 Hour Phone: 530-297-6080 or 530-902-8267

Please complete the following: You may attach copies of relevant procedures.

1. Is this study federally funded requiring review under HSS standards? X No ☐ Yes

2. How will Study Participants be recruited?
   - ☐ Principal Investigator's Clinical Practice
   - X Data base of potential Volunteers
   - ☐ Referrals from other clinical Practices
   - ☐ Advertising in the community* (*advertisements Must be approved by the IIRB)
   - X Other *(please specify)*: Word of mouth via Volunteers in data base

3. Will you recruit volunteers from vulnerable study populations? X No ☐ Yes *(please specify below)*
   - ☐ Persons kept in detention
   - ☐ Nursing Home Resident/Elderly
   - ☐ Patients in emergency situations
   - ☐ Persons of limited capacity
   - ☐ Minors
   - ☐ Pregnant women
   - ☐ Illiterate
   - ☐ Other:
   - ☐ Members of the Armed Forces
   - ☐ Patients with incurable disease
   - ☐ Unemployed/on Public Assistance
   - ☐ Homeless
   - ☐ Employees (Site or Sponsor, etc)
   - ☐ Disabled

   If yes, describe procedures to be followed (if applicable): Note: Our subjects are mainly University of California–Davis graduate and undergraduate students in life science programs with which the Principal Investigator is associated. Students in his laboratory who depend on him directly for employment or scholastically are not eligible to participate. Other participants are technicians employed in mosquito control for state or regional agencies (principally at Site #2, below).

4. Do the subjects that you intend to enroll in this study come from any type of ethnic background or cultural environment that might have an impact on their ability to understand that participation in the study is voluntary and refusal to participate or discontinuing their participation will not have any adverse impact on the care that they will receive? No

5. Indicate the approximate demographics of your site's anticipated subject population:
__5__% African American __65__% Caucasian __15__% Hispanics __15__% Asian
__<1__% Other

6. Will you be enrolling only subjects who speak English in this study? X Yes ☐ No
If No, Is a "local dialect" or translation needed? Translation needed: ☐ Spanish ☐ Other

7. Who will discuss the research study with the volunteer and obtain informed consent (signed informed consent)? *(Check all that apply)*

X Principal Investigator ☐ Sub Investigator ☐ Study Coordinator
Explain consenting procedures: We contact subjects who participated in previous Carroll-Loye repellent efficacy tests by selecting them from our Volunteer Database. At that time interested individuals often ask if one or more of their lab mates or acquaintances can participate as well. All such potential participants are screened or re-screened for suitability for each test in a private, one-on-one conversation held at the office of the Principal Investigator (PI). The Exclusion Criteria (section 9.1.2) are exercised by asking each candidate to address them in the interview with the PI. It is explained that pregnancy will be assessed directly in on the test day. The PI encourages candidates to ask questions and ask for clarification at any time during the interview and in all activities that follow. To candidates that pass screening the PI describes the test purpose in plain language (in English), and the procedures and comportment to be followed are described in detail. Candidates are then asked if they would like to retire from consideration at that point. If they wish to remain in consideration, it is explained and emphasized that they may withdraw from the test at any time during the test without penalty to their compensation. Candidates are given copies of the State of California Department of Pesticide Regulation 'Experimental Subjects' Bill of Rights' to read as the PI reads it aloud. They are also given a copy of the IRB-approved consent form to read as the PI reads it aloud. The amount and form of compensation is described. They are again encouraged to ask any questions they have about the test, which may include understanding its purpose more fully, understanding risks and discomforts more fully, and understanding treatment and compensation for injury more fully. While the majority of our subjects have worked with us on an occasional basis for a number of years, we encourage them to personally evaluate their interests and concerns about participation seriously each time. We ask them not to sign on immediately but to give the situation due consideration (normally at least one day, sometimes less for those who have participated in multiple prior studies). Because most of the volunteers are researchers and/or have advanced degrees in life sciences, we regard their motivations and decisions to participate as being unusually well considered and well informed. Accordingly, we normally accept their decisions to participate if they so choose following due consideration. Nonetheless, the PI retains the final right to refuse participation to any candidate.

8. Describe the setting(s) where the study will be conducted (ie, private office, clinic, hospital environment) and if the Investigator is required to seek any type of administrative or Corporate approval in order to implement the study:
The site is a California State Wildlife Refuge. The refuge manager grants access to the site. The site is 150 meters from a parking/picnic area. The terrain is level with short grass and large shade trees.

9. Distance between the nearest hospital and research site: 22 road miles

10. Describe the on-site emergency equipment available for the subjects: First aid kit, skin washing soap and mild dermal detergent, eye wash.

11. How long has the PI been conducting clinical research? 16 years 6 months

12. Within the past 3 years has the FDA/OHRP audited your site/Principal Investigator?
X No ☐ Yes*

13. Has the FDA/OHRP or any State Medical Board ever sanctioned the Principal Investigator? XNo ☐Yes*
**If yes, please provide a summary of the action and applicable correspondence.*

14. Are subject files adequately stored and protected to ensure subject confidentiality, i.e. HIPAA, HIV,
etc.? ☐ No* X Yes
**If no, please explain:*

15. Does the Principal Investigator, Sub Investigator(s) or any immediate family member have a conflict of interest with the study sponsor, sponsor representatives or other study related entities? X No ☐Yes*
**If yes, please provide explanation:*

INDEPENDENT INVESTIGATIONAL REVIEW BOARD INC.

SITE QUESTIONNAIRE

NON-LOCAL REVIEW

Protocol # & Complete Study Title: (EMD-004) Test of Personal Insect Repellents

Principal Investigator: Scott P. Carroll, Ph.D

Sub Investigator(s): None

Please indicate the location where study activities will be performed (where patients will be seen excluding Diagnostics) If more than on location is being used you may attach additional pages.

Site #2 Address: Lower Florida Keys
Stock Island to Big Pine Key
Near Key West and Marathon, Florida

PI's Mailing Address: Carroll-Loye Biological Research
(If different) 711 Oak Avenue
Davis, CA 95616

If the study is being conducted at more than one location and information requested differs for each location, please provide separate information for each location.

Regulatory/Study Coordinator: Scott Carroll Phone: 530-297-6080 Fax Number: 530-297-6080

Office Phone: 530-297-6080 24 Hour Phone: 530-297-6080 or 530-902-8267

Please complete the following: You may attach copies of relevant procedures.

1-4. As above.

5. Indicate the approximate demographics of your site's anticipated subject population:
<5 % African American 80 % Caucasian 15 % Hispanics <5 % Asian <1 % Other

6-7. As above.

8. Describe the setting(s) where the study will be conducted (ie, private office, clinic, hospital environment) and if the Investigator is required to seek any type of administrative or Corporate approval in order to implement the study:
The sites are adjacent to Florida Bay and Key Deer National Wildlife Refuges, accessed under the auspices of the Manager of the Florida Keys Mosquito Control District. The terrain is level, covered by herbaceous vegetation, with shade trees.

9. Distance between the nearest hospital and research site: 10-24 road miles

10-15. As above.

Subject Compensation:

Will subject be paid for participation in this study? ☐ No X Yes*

**If yes, please specify the total amount, the amount for each visit and the timing of payment (i.e. at each visit, at the last visit, within 2 weeks of the last visit) in the draft Informed Consent Form.*

Site Specific Informed Consent Form Information

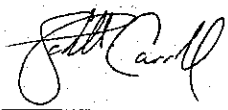
Is there any additional wording needed in the Informed Consent Form? X No ☐ Yes*

**If yes, please specify the section and additional wording below.*

Investigator Acknowledgment

On behalf of all of the investigators listed on page1, I agree that the responses provided on the Site Questionnaire are true and accurate and I agree to notify the Independent Investigational Review Board, Inc. of any changes in the research activities and to report any unanticipated problems involving risk to the research subjects. In addition, I agree not to make any changes in the research without IRB approval. I confirm that study personnel are familiar with the study and that either an Investigator or a study coordinator acting as my designee will orally explain the Informed Consent Form to all prospective subjects before obtaining their signed informed consent. Furthermore, by signing this form I confirm that I agree to conduct the study in accordance with the requirements of the protocol, for which I am seeking approval.

Scott P. Carroll
Print name of individual completing Site Questionnaire



Signature of individual completing Site Questionnaire

4-13-06
Date