VOLUME 1

Study Title

Protocol for Evaluating the Efficacy of Personal Repellents Against Mosquitoes in the Laboratory Including Supporting Materials Satisfying 40 CFR §26.1125
for
***Avon Skin-So-Soft SSS Bug Guard Plus Picaridin Insect* Repellent (EPA Reg. No. 806-29) and *Avon Skin-So-Soft SSS Bug Guard Plus Picaridin Insect Repellent Spray* (EPA Reg. No. 806-31)**

Data Requirement

EPA/OPPTS 810.3700 (Draft)

Authors

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ICR Principal Investigators

Materials compiled by:
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7140 Heritage Village Plaza
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Performing Laboratory

Insect Control & Research, Inc.
1330 Dillon Heights Avenue
Baltimore, MD 21228-1199

Completed On

August 8, 2007

Project ID

Protocol ID: G0590607001A117

Sponsor

Avon Products, Inc.
1251 Avenue of the Americas
New York, NY 10020

CONFIDENTIALITY STATEMENT

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA section 10(d)(1)(A), (B), or (C).

Company: Avon Products, Inc.

Company Agent: _____ Date: 8/8/07

Alan C. Katz, D.A.B.T.
Principal
toXcel, LLC
Authorized Representative of Avon Products, Inc.

Protocol ID: G0590607001A117

GOOD LABORATORY PRACTICE STATEMENT

The proposed research will be conducted according to the requirements of the Good Laboratory Practice regulations (40 CFR part 160); however, this compilation of materials was not conducted according to the requirements of the Good Laboratory Practice regulations.

Sponsor/Submitter: Alan C. Katz, D.A.B.T.
Principal
toXcel, LLC
Authorized Representative of Avon Products, Inc.
Date: 8/8/07

Study Director: William J. Gaynor
Principal Investigator,
Insect Control and Research, Inc.
Date: 8/8/07

*NOTE: Please see subsequent pages for further details and page references.

APPENDIX A

40 CFR 26.1125 Prior submission of proposed human research for EPA review
[Protocol ID: G0590607001A117]: [August 8, 2007]

Any person or institution who intends to conduct or sponsor human research covered by §26.1 1 01 (a) shall, after receiving approval from all appropriate IRBs, submit to EPA prior to initiating such research all information relevant to the proposed research specified by §26.1115(a), and the following additional information, to the extent not already included:

		Requirement	Y/N	Comments/Page Refs
The following Information, to the Extent not already included:	§1 125(a) a discussion of-	(1) The potential risks to human subjects	Y	11-14, 39-40, 78-79, 88-89
		(2) The measures proposed to minimize risks to the human subjects;	Y	11-14, 39-40, 78-79, 88-89
		(3) The nature and magnitude of all expected benefits of such research, and to whom they would accrue	Y	23, 40, 79, 89
		(4) Alternative means of obtaining information comparable to what would be collected through the proposed research; and	Y	12-14
		(5) The balance of risks and benefits of the proposed research.	Y	20-23, 39-40, 78-79, 88-89
	§1125(b): All information for subjects and written informed consent agreements as originally provided to the IRB, and as approved by the		Y	36-41, 75-80, 85-90
	§1125(c): Information about how subjects will be recruited, including any advertisements proposed to be used.		Y	17-18, 25, 36, 75, 85
	§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	17-18, 25, 36-41, 75-80, 85-90
	§1125(e): All correspondence between the IRB and the investigators or sponsors.		Y	9-95, see next page
	§1125(f): Official notification to the sponsor or investigator. ... that research involving human subjects has been reviewed and approved by an IRB.		Y	82
all information relevant to the proposed research specified by § 26.1115(a)	(1) Copies of • all research proposals reviewed by the I • scientific evaluations, if any, that accompanied the reviewed by the I RB, • approved sample consent documents, • progress reports submitted by investigators, and reports of injuries to subjects.		Y	10-34 research proposals, 85-90 consent forms
	(2) Minutes of IRB meetings ... 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	69-71, 82
	(3) Records of continuing review activities.		n/a	n/a for protocols
	(4) Copies of all correspondence between the IRB and the investigators.		Y	9-95, see next page
	(5) • A list of I RB 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, for example, full-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant.		Y	92-94
	(6) Written procedures for the I RB in the same detail as described in §26.1108(a) and §26.1108(b).		N	95, see next page
	(7) Statements of significant new findings provided to subjects, as required by §26.1116(b)(5).		n/a	n/a for protocols

Protocol for Conducting Insect Repellent Field Efficacy Testing on Mosquitoes Including Supporting Materials Satisfying 40 CFR §26.1125 for *Avon Skin-So-Soft SSS Bug Guard Plus Picaridin Insect* Repellent (EPA Reg. No. 806-29) and *Avon Skin-So-Soft SSS Bug Guard Plus Picaridin Insect Repellent Spray* (EPA Reg. No. 806-31)

Note: This summary follows the 26.1125 checklist (see p. 4)

(a) The following information, to the extent not already included (§26.1125(a)-(f)):

Note: Many of the responses to the requirements listed below refer back to their inclusion either in the study protocol on pages 10-34 or in the approved informed consent documents (ICDs) on page 85-90 of this volume. The preliminary ICD that was reviewed by Essex IRB is contained on pp. 36-41; the revised ICD reviewed by Essex IRB is contained on pp. 75-80.

(a)(1) – Characterization of potential risks posed to study subjects and measures taken to minimize those risks are described in the study protocol (pp. 11-14) and the informed consent document (pp. 39-40, 78-79, and 88-89).

(a)(2) – Characterization of potential risks posed to study subjects and measures taken to minimize those risks are described in the study protocol (pp. 11-14) and the informed consent document (pp. 39-40, 78-79, and 88-89).

(a)(3) – Details regarding expected benefits are described in the study protocol (p. 23) and in the informed consent document (pp. 40, 79, and 89).

(a)(4) – The most reliable data for insect repellent efficacy testing is derived from studies conducted in a field setting on human subjects. This rationale is justified in the study protocol (pp. 12-14).

(a)(5) – The risks and benefits of this study are addressed within the study protocol (pp. 20-23) and within the informed consent document (pp. 39-40, 78-79, and 88-89).

(b) – The informed consent document (ICD) as originally provided to the IRB is located on pp. 36-41. An updated ICD (August 2, 2007) is located on pp. 75-80. The approved ICD is located on pp. 85-90.

(c) – Details regarding test subject recruitment are presented in the protocol on pp. 17-18, 25 and pp. 36, 75, and 85 of the ICDs.

(d) – A description of presenting information to potential subjects to obtain his or her informed consent is located on p. 17-18, 25 of the protocol and on pp. 36-41, 75-80, and 85-90 of the ICDs.

(e) – All correspondence between the investigator and IRB is outlined on the Correspondence Chronology page which follows (essentially pp 9-95). All correspondence

is included in this volume including submitted documents for IRB review and IRB approval documents.

(f) – Official notification from the IRB to conduct the proposed research is provided on p. 82.

(b) All information relevant to the proposed research specified by §26.1115(a):

(1) – The study protocol (research proposal) is included on pp. 10-34. The approved sample consent document is provided on pp. 85-90.

(2) – Information fulfilling this requirement is provided on pages 69-71 and 82.

(3) – Not applicable for protocols.

(4) – Please refer to 11.25(e) above.

(5) – Information fulfilling this requirement is provided on pages 92-94.

(6) – Essex IRB asserts its position that copies of its written procedures and standard operating procedures are available to USEPA for review only on the premises of Essex IRB. A statement of compliance is included on p. 95.

(7) – Not applicable for protocols.

Correspondence Chronology between the Investigator and the IRB

Date — Page

July 25, 2007

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Study Protocol for Insect Repellent Efficacy Testing Against Mosquitoes in the Laboratory

ICR
Independent Laboratory
Pesticide Efficacy Testing
Regulatory Services

July 25, 2007

Chairman
Essex Institutional Review Board, Inc.
121 Main Street
Lebanon, NJ 08833-2162

Protocol # G0590607001A117 ICR Project # 0607-059-0157

Dear Dr. Lambert:

Please find enclosed our complete document package for your review and approval. We are requesting a full board review for this project. The proposed date that the study will be submitted to the EPA is **August 8, 2007**, so we respectfully request that we receive your approval prior to this date. We would like these documents sent to us by **Federal Express Overnight**, so please charge the delivery to our FedEx account number 1028-0348-5.

We also request a copy of the minutes of any followup meeting that the IRB has that pertain to this study, so that we submit them to EPA's HSRB as required by the Common Rule.

We enclose the following documents to support our request:

We are enclosing the following documentation to support this request:

-Protocol (6 copies) (please return **one approved copy** to us)
-Informed Consent Form (6 copies)
-MSDS' for each of the 2 test samples
-**Three** signed copies of the indemnification from Avon for Essex IRB (please return **two** signed copies to us)
-**One** signed copy of the indemnification from Avon for ICR, Inc. (please keep for your files)
Memo regarding ongoing training for investigators and staff in clinical research procedures
-CV's for the ICR personnel participating in this study are on file at Essex IRB

Thank you for your attention, and please do not hesitate to contact me by telephone at 410-747-4500, by fax at 410-747-4928, or email address nspero@icrlab.com if you have any questions.

Sincerely,

Niketas C. Spero
Principal Investigator

Enclosures

1330 Dillon Heights Avenue, Baltimore, MD 21228-1199 | tel 410.747.4500 | fax 410.747.4928 | web www.icrlab.com

PROTOCOL NUMBER: G0590607001A117

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PROJECT NUMBER:
0607-059-0157

PROTOCOL TITLE:
EVALUATION OF THE EFFICACY OF PERSONAL REPELLENTS AGAINST MOSQUITOES IN THE LABORATORY

PROTOCOL VERSION DATE
June 12, 2007

PROPOSED Laboratory INITIATION DATE
TBD

PROPOSED Laboratory CONDUCT COMPLETION DATE
TBD

STUDY DIRECTOR
Niketas C. Spero

STUDY ASSOCIATES
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Mosquitoes make enjoyment of outdoor activities unpleasant in many parts of the U.S.A. There are few effective, registered active ingredients available as insect repellents. These two factors provide the impetus for the current search for new effective repellents.

HYPOTHESIS

The repellent samples are expected to provide 8 hours of personal protection from *Culex quinquefasciatus* mosquitoes, a West Nile virus vectors, in the laboratory.

OBJECTIVE

The objective of the study is to determine the mean protection time from bites provided by the test articles under laboratory conditions to confirm the hypothesis. Therefore ICR will conduct a laboratory study to assess repellency of these test articles against *Culex quinquefasciatus* mosquitoes.

STUDY RATIONALE

This laboratory cage study is intended to evaluate the efficacy of two currently EPA registered picaridin-containing insect repellent products (EPA Reg. No. 806-29 and 806-31) against laboratory raised Culex quinquefasciatus. It is well documented that Culex sp. are known as primary vectors of West Nile virus (WNV) in the wild. This is in contrast to the lab, where disease transmission is not possible since laboratory raised mosquitoes have never been exposed to any arboviruses. Based on this reasoning, the EPA has recommended that laboratory data with uninfected mosquitoes can be used to support the addition of WNV product label claims.Therefore, this laboratory cage study (utilizing disease free mosquitoes) is being specifically conducted to support additional label claims that the above EPA registered products repel mosquitoes that may transmit West Nile virus.

Presently there are 15 picaridin-based insect repellent products registered under FIFRA. The products range from 5% picaridin to 20% picaridin and include pump spray, aerosol, lotion, and towelete applicator products. ICR has previously evaluated Picaridin-based repellents in both the laboratory and in the field for efficacy. We have found these types of repellents to be efficacious against other species of mosquitoes in the laboratory as well as in field studies for up to and beyond 8 hours. In previous studies we have seen no indication of any type of reaction from these repellents, or cause for concern regarding safety issues.

Laboratory studies, such as the one proposed, have been considered by regulatory authorities and the scientific community to be a reliable method for testing the performance of a topically applied insect repellent product. Under FIFRA, EPA requires submission of such human efficacy study data (EPA/OPPTS Guideline 810.3700) in support of insect repellent product registration. Each new insect repellent formulation must have performance studies conducted on human subjects to substantiate the product label claims.

Each product is unique and will provide different protection times for different pests depending on both its percent active ingredient and formula composition. The incorporation of film formers, fragrances, and other ingredients may significantly influence the duration of repellency against target pests.

The prominent risks associated with the proposed laboratory study to assess the performance of these insect repellents are the potential for allergic or irritation responses to the test material and mosquito bites. These laboratory colonies of mosquitoes have been raised in the laboratory for many generations and have not been exposed to outside blood sources of the West Nile virus or other mosquito borne diseases. Therefore the potential risk of contracting a mosquito or other insect borne disease will be minimal. The risk of skin reactions and the disease threat were significant factors that were considered in detail and addressed in the development of the proposed study design.

With regard to the potential for irritation or allergic reactions to the test material, this risk has been greatly reduced by careful consideration of the components of the test material and avoidance of the use of known sensitizers and irritants. As an added precaution, subjects with a history of reaction to insect bites, insect repellents, and skin care products will be excluded from the study. Further, the subjects will be closely monitored during the study for signs of significant skin reactions and prompt medical attention will be obtained should an adverse reaction be experienced.

While the above risks are a concern to the study sponsor and the conducting laboratory, there are currently no viable alternatives to such human studies for determination of the performance characteristics of insect repellents. As indicated above, it is unlawful to distribute unregistered pesticide products, which include insect repellents. EPA requires that efficacy data collected from human studies be submitted for EPA review in order to obtain approval for an insect repellent registration. These data must substantiate the public health protection claims made on the product's labeling. Specifically, data are required to both substantiate the repellency of specific insect pests and provide the user realistic expectations of the protection time provided from each of those pests by the product.

While there is obviously an economic incentive to the sponsor of the study to offer a new insect repellent alternative to consumers, such products must offer a recognized benefit to consumers or they will simply not be purchased or used. It is important to bring new insect repellent products to market so that consumers have alternatives that they find personally acceptable and convenient to use to protect themselves and family members from irritating and potential disease-carrying insect bites. New products, such as the proposed test samples, have been formulated to provide protection from insect bites in combination with other benefits that promote consumer acceptance and use of the product (i.e., convenience of product form or method of application, fragrance preferences, preference for, or avoidance of, a specific active ingredient, etc.).

ICR prefers to evaluate repellency based on protection from bites rather than landings while conducting laboratory studies. Disease transmitted by laboratory raised mosquitoes that have not been exposed to any arboviruses is not possible. Therefore there is no risk of disease transmission to any of the test subjects.

In this study efficacy is defined as the Protection Time (PT). The PT is the time interval between the application of the repellent and the First Confirmed Bite (FCB). A bite is defined as the ingestion of blood by a mosquito while it is on a repellent-treated area of skin, as evidenced by an enlarged, blood filled abdomen of the mosquito. The FCB is a bite which is followed by another bite within 30 minutes.

This study may be submitted to EPA to support an insect repellent label claim. The efficacy study will test the repellent formulations in controlled laboratory conditions, exposing test subjects to only disease-free mosquitoes.

According to the EPA OPPTS Guideline No. 810.3700 " Product Performance of Skin-Applied Repellents of Insect and Other Arthropods", there exists no alterative to evaluating topical repellents on human subjects; therefore, field or laboratory testing of repellents is necessary.

STUDY OVERVIEW

- *ICR will randomly recruit from our database of test subjects.*
- *During the recruitment process, potential test subjects will have an ICD mailed to them. They will be instructed to contact the P.I. with any ICD or study related questions.*
- *When 13 subjects have committed, recruitment will cease.*
- *Randomization and selection of test, control, and alternate test subjects will be done prior to the test initiation.*
- *All test subjects will meet at the ICR laboratory on the designated test day.*
  - *All females test subjects will take an OTC pregnancy test.*
  - *The pregnancy tests will be read by a female ICR staff member to verify that no pregnant test subjects are present.*
  - *At this meeting unscented soap will be provided to each test subject.*
  - *The study parameters will be explained to everyone.*
  - *Any subjects found to be ineligible for any reason or who decline to participate will be allowed to leave at this time. They will be compensated for the time used at the hourly rate.*
  - *Treated and control test subjects will be identified.*
  - *Treated and control subjects will wash their arms.*

- *ICR staff will measure, and establish the treatment area and untreated control area on test subjects' arms.*
- *Treatment and control areas will be bandaged and taped.*
- *Test subjects will proceed to the insectary to be tested for attractancy to mosquitoes. When completed the test subjects will return to the laboratory for treatment.*
- *Test articles will be applied to the test subjects.*
- *All test subjects return to the insectary for repellent testing.*
- *ICR staff verifies adequate mosquito activity using the control subject.*
- *Exposure begins for the treated test subjects.*
- *Treatment exposure ends either through breakdown or end of study duration*
- *ICR staff helps subjects remove bandages, clean off repellent and treat bites.*

MATERIALS

TEST ARTICLE NOMENCLATURE

	Product Name	Specific Gravity	Application Rate	Application/250cm^2
A.	TA# 1001108-030 (A)	0.96	1.67 mg/cm^2	417.5 mg.
	Currently marketed EPA registered product		(EPA Reg. No. 806-29)	
B.	TA# 1004024-010 (B)	0.96	1.67 mg/cm^2	417.5 mg.
	Currently marketed EPA registered product		(EPA Reg. No. 806-31)	

A Material Safety Data Sheet (MSDS) shall be provided for each test, control, and/or reference sample, which will include any hazardous information of the samples. The percentage of all active ingredients and any hazardous constituents must be included in all MSDSs.

A chain of custody letter must accompany all test, control, and/or reference samples.

NOTICE: Sample characterization is a key GLP (Good Laboratory Practices) requirement detailed in 40 CFR Part 160. The sponsor is solely responsible for conducting the complete test article, control sample, and any reference sample characterizations according to GLPs, and for providing ICR with this characterization data prior to the experimental start date of this study. This characterization must define the identity, strength, purity, and composition of the batch(es) or lot(s) of test articles. If any of the test, control and/or reference samples are

currently available for consumer use and/or purchased in the marketplace, ICR will need the same characterization information provided by the sponsor prior to the experimental start date of this study. If documentation of this characterization is not provided prior to the experimental start date, this will be noted as a non-compliance item in the GLP compliance statement. This sample characterization information will be retained in the ICR archives, and a statement identifying this location will be included in the final report.

According to GLP, the study sponsor shall provide the ICR Study Director with the confidential disclosure of the entire compositions of the test articles prior to the experimental start date. These insect repellent formulations use the active ingredient, Picaridin®, which was first registered by the US EPA under FIFRA on December 7, 2000. As required under FIFRA, registration of Picaridin® as an active ingredient is supported by an extensive data package that includes toxicity test data that demonstrate low acute and chronic toxicity. This active ingredient has been successfully used without significant incident by the study sponsor and other insect repellent formulators (and millions of consumers).

For currently registered products containing the same concentration of Picaridin® as the active ingredient (a.i.), in the test articles, the US EPA risk assessment assumes that each application of insect repellent products is applied to a skin surface area of 4,538 cm^2 for adults. In the proposed tests for mosquito repellent efficacy, the formulated product is applied once to adults on the test day over a surface area of only 500 cm^2 (*i.e.*, two patch areas of 250 cm^2 each). Consequently, the test subjects in this study will only be exposed over an area of approximately 11 percent of that previously reviewed and approved by EPA for products with the same a.i. concentration. Further, the label directions of these registered products allow for up to two applications per day, while the efficacy study will employ only one. A 100-fold margin of exposure (MOE) is considered to be the target for the determination of acceptable risk from systemic exposure. The MOE is based on the No Observed Adverse Effect Level (NOAEL) for systemic effects, the concentration of active ingredient in the formulation, frequency and rate of application, skin surface area and body weight, and dermal absorption. The MOE for the test subjects in this efficacy study will substantially exceed the minimum 100-fold target and is, therefore, considered acceptable under widely recognized scientific standards.

The stability of the test, control, and/or reference samples shall be determined by the sponsor prior to the experimental start date. When relevant to the conduct of this study, the **solubility** of each test, control, and/or reference sample shall be determined prior to the experimental start date.

Methods of synthesis, fabrication, or derivation of the test, control, and/or reference samples shall be documented by the sponsor, and the location of such documentation shall be specified by the sponsor in a letter to the Study Director.

The stability of test, control, and/or reference samples stored under the test site conditions shall be known for all studies.

All unused test articles will be returned to the sponsor within 30 days after the final report is sent to the sponsor. The sponsor will be responsible for all costs for the return of the samples, including any costs associated with hazardous materials shipping.

TEST ORGANISM

One hundred (100) female *Culex quinquefasciatus*, (3-8 days of age) will be released into each test cage. These test mosquitoes will have been deprived of their normal diet of 10% sucrose twelve hours prior to their utilization in the study and will never have received a blood meal.

TEST CAGES

There will be six test cages, two subjects per cage. The aluminum test cage measures 2 x 2 x 2 feet with two sleeved entry ports on each of two opposite sides of the cage (4 entry ports/cage). The sides and top of the cage are screened. The bottom is equipped with a mirror to facilitate observations, and a hand rest is in the center of the cage.

SUBJECTS

Human subjects are required for this study because they represent the feeding target of the mosquitoes. The purpose of these repellents is to prevent mosquitoes from biting humans. There are no satisfactory substitute models for testing repellency to mosquitoes. While there has been experimental work on product repellency accomplished using mice or guinea pigs, the data did not give reliable results when compared to data gathered from human subjects.[1]
ICR, Inc., (ICR) policy complies with the final rule by adhering to 40 C.F.R. Part 26 Subparts K and L, when human volunteers are used. Thus, ICR submits all necessary documentation to an independent institutional review board (IRB) for their review. The IRB will grant approval of the

[1] Busvine, James R. 1971, A Critical Review of the Techniques for Testing Insecticides, Commonwealth Agricultural Bureaux, England, p 233-245

study protocol and the ICD if the rights and welfare of the participants are protected and the study will be carried out in an ethical manner.

ICR uses the following IRB for this service:

Essex Institutional Review Board, Inc.
121 Main Street
Lebanon, NJ 08833

This IRB is accredited by PHRP (Partnership for Human Research Protection Inc.), and is currently in the process of obtaining accreditation from AAHRPP (Association for the Accreditation of Human Research Protection Programs).

Approval of all documentation for human subject testing must be obtained before such testing can occur.

ICR has developed a pool of male and female test subjects. The test subjects we recruit represent a diverse group including professionals such as working teachers, business owners and engineers, as well as students, housewives and others.

ICR will exclude pregnant and breastfeeding women from this study due to ethical concerns. We will also exclude children under the age of 18 for the same reason. Individuals unable to read, speak, and understand English will be excluded to ensure comprehension and understanding of the ICD and test parameters. Employees or relatives of employees of either ICR, Inc., the sponsor, or other interested parties will be excluded to ensure that coercion is not an issue. Individuals sensitive to either mosquito bites, insect repellents, or skin care products will be excluded to avoid placing them at risk. Although the groups of people that ICR would exclude s test subjects would certainly represent individuals that could use repellents, we feel justified for not including them for the reasons that are mentioned above.

The database of potential test subjects that we select our subjects from, is as representative of potential repellent users as we are able to make it in terms of both practical and ethical considerations. Our test subjects need to be in good health to withstand the rigors of testing. We will accept individuals between the ages of 18 to 55. This age group represents a large portion of the population who through their diverse activities would both encounter mosquitoes and could have a need to use insect repellents.

ICR will select individuals from our database of potential test subjects. This will be accomplished by drawing numbers that correspond to a particular test subject. We will attempt to select even numbers of male and female test subject to eliminate any gender bias in this test.

REMUNERATION

The subjects will be paid $11/hour for a typical 9-hour test day, for a total payment of $99 for the day. Payment will be mailed to the subjects on the 15th or 30th of the month.

All subjects will sign "Informed Consent Statements" prior to acceptance as a study participant. The Informed Consent Document will be formally explained to all of the test subjects before the study is scheduled to begin. If any test subject refuses to sign after learning the details of the document, they will not be allowed to participate in the study. To try to avoid this inconvenience, the informed consent will be explained to each test subject, either in person, on the telephone, and by mailing ICDs prior to the study, to try to eliminate any potential test subject not interested in the project. The "Informed Consent Document" will have been approved by an Institutional Review Board before it is presented to the test subjects.

NEGATIVE CONTROL

One untreated arm of the control subject will serve as a negative control. The control will be selected from the total pool of test subjects by drawing a name. The control landing rates will serve to establish the aggressiveness of the mosquitoes. No comparison will be made between the control landing rate and the treated subjects.

The control test subject will expose his/her untreated forearm in the test cages to confirm the aggressiveness of the mosquitoes prior to each exposure period. The acceptable level of aggressiveness will be at least 5 landings in 60 seconds. If fewer than 5 mosquitoes land in 60 seconds, a new group of 100 mosquitoes will be released into all of the cages. Mosquitoes will not be allowed to bite. The control will vigorously shake his arm as mosquitoes land. ICR staff will count the landings as they occur.

The negative controls will not be exposed to any compound related risk.

POSITIVE CONTROLS

Sufficient biting pressure (i.e., mosquito landing rates of at least 5 landings in 60 seconds in a 250 cm^2 area on an exposed untreated control arm) will be confirmed at the commencement of the study and throughout the study at the beginning of each exposure period. A positive control is intentionally excluded from the proposed study protocol for several reasons. Data on a positive control group serves no purpose in this study to confirm the mosquito repellency of the test product and determine

a reliable protection period under laboratory conditions. Putting additional subjects at risk, however minimal, to include a positive control group is not necessary.

SUPPORT STAFF

Additional ICR staff members will support the Study Director and test subjects in their activities These ICR staff members, along with the study director, will record all test data. Test subjects will not record any data. The study results would be difficult to defend in an EPA audit or in a court of law if a test subject records data.

MISCELLANEOUS

Syringe, (minus the needle), micropipette and tips, Q-tip®s, latex or vinyl gloves, clip boards, data record forms, scissors, elastic bandages, Elastikon® tape, pencils, marking pens (e.g. Sharpie®), hygrothermograph, unscented Neutrogena® soap, paper towels and a stop watch.

RECORDS TO BE MAINTAINED

All study notes, data collection sheets (true copies), SOPs (originals), Chain of Custody letters (true copies), Sample Log and Sample Record of Use Forms (true copies), the protocol (true copy) and signed Informed Consent documents will be maintained in the ICR archives. Original documents will be provided to the sponsor for archiving with the exception of SOPs, Master Schedules, signed Informed Consent documents, test article characterization, and personnel files.

RISK CHARACTERIZATION AND MINIMIZATION

The subjects will be exposed to three types of risk:

1. Test articles.

The active ingredient, Picaridin® demonstrates a low acute oral, dermal and inhalation toxicity. It is classed as Category IV for acute inhalation toxicity and primary dermal irritation. It is not a dermal sensitizer. The EPA "New Pesticide Fact Sheet" indicates that the toxicology data base for the active ingredient is complete and no additional studies are required.

There is minimal risk for subjects to experience an adverse reaction to the insect repellents being tested. The study sponsor that developed the test materials has over 120 years of experience

formulating and producing a wide variety of cosmetics with worldwide sales. This company is strongly protective of its reputation, which it knowingly stakes on every product that it puts into commerce; that is, extreme care is taken in the development and production of safe and reliable products that are intended for direct application to the skin.

The test articles are an extension of a well known and highly regarded product line of bath and body products for skin smoothing and skin care that has evolved to include insect repellents. These proposed insect repellents use the active ingredient, Picaridin®, which was first registered by the US EPA under FIFRA on December 7, 2000. As required under FIFRA, registration of Picaridin® as an active ingredient is supported by an extensive data package that includes toxicity test data that demonstrate low acute and chronic toxicity. This active ingredient has been successfully used without significant incident by the study sponsor and other insect repellent formulators (and millions of consumers). All of the inert ingredients used in the finished insect repellent products have a long history of safe use in various cosmetics. The sponsor has used these ingredients safely in numerous cosmetic products applied directly to the skin.

Insect repellents that are part of this product line of bath and body products use one of three active ingredients, including Picaridin®. The sponsor's first insect repellent in this product line was first registered in 1997 and their first insect repellent utilizing Picaridin® was registered in 2005. The inert ingredients in the formulation were selected because they are widely used in cosmetic formulations, and are non-sensitizers. To expedite product registration under FIFRA, the sponsor has confirmed that the inert ingredients have been previously reviewed and approved by EPA for use in FIFRA registered products.

While there is low concern for the toxicity potential for the test samples to induce an adverse reaction in the test subjects, they will be monitored throughout the study and prompt medical attention will be obtained if any adverse reaction is observed among the subjects on test. Those individuals who are known to have allergies to mosquito bites, insect repellents, or skin care products will be excluded from participation in the study.

2. Bites from target mosquitoes.

The typical reaction to a bite from a mosquito can vary from person to person. Most people will experience a small area of redness, swelling and itching that usually goes away within 24 hours. In more sensitive individuals, the area of swelling and itching can be much larger and last for several days. In extremely rare cases, a serious reaction to a bite results in swelling of the throat, hives and wheezing. This condition (anaphylaxis) could be life-threatening and requires immediate medical attention.

All subjects known to have severe reactions to mosquito bites will be excluded from this study.

All subjects will be issued latex or vinyl gloves. Only a small portion (250 cm^2) of bare skin on each arm will be exposed. All other parts of the body will be covered with the subject's personal clothing. Immediately upon receiving a FCB on an arm, that arm will be withdrawn from the test and not be exposed to the caged mosquitoes again. Caladryl® or Calamine® lotion and rubbing alcohol will be available for use to mitigate any reaction to mosquito bites.

There will be First Aid qualified staff members on site, and First Aid supplies will be available at the test site at all times. A selected local hospital will receive prior notification of this study and on-site staff will have cell phones to make emergency calls if necessary. In the case of medical emergency, people will be transported to the selected local hospital, St. Agnes Hospital, by either ICR staff or professional ambulance. The hospital is 7 miles from the laboratory and is located at 900 S. Caton Ave., Baltimore, MD. 21229. The telephone number is 410-368-2389. If any test subjects need medical attention, their medical care will be paid by ICR.

3. Arthropod-borne diseases

There will be no risk for arthropod-borne diseases. The mosquitoes being used in this test are commonly called the southern house mosquito, which is one of the most common species throughout the southeastern United Sates, ranging as far north as the District of Columbia, and west to Missouri, Utah, New Mexico and California. This species can carry the West Nile virus, St. Louis encephalitis, and both Western and Venezuelan equine encephalitis.

This strain of mosquito has been laboratory colonized for many years and has not been exposed to outside blood sources. None of the mosquitoes used in this test will have had a blood meal prior to their introduction into the test cages. All mosquitoes used in the study will be destroyed either through starvation, freezing or exposure to carbon dioxide. Once a group of mosquitoes has been used in a study, it will not be re-used in another study. Therefore, transmission of a blood borne disease by these mosquitoes is not possible.

All of the above factors combined will minimize disease and bite risks. Also the subjects will only need to receive two bites within 30 minutes to confirm breakdown, after which the test arm will not exposed to the mosquitoes again.

DISCOMFORT AND HAZARD

Although the mosquitoes being used in this test are capable of transmitting the diseases listed above, in the wild, this strain of mosquito has been laboratory colonized for many years and has

not been exposed to outside blood sources. None of the mosquitoes used in this test will have had a blood meal prior to their introduction into the test cages. All mosquitoes used in the study will be destroyed either through starvation, freezing. Once a group of mosquitoes has been used in a study, it will not be re-used in another study. Transmission of a blood borne disease by these strains of mosquitoes is not possible.

In the event that study related injury or illness should occur, test subjects would be instructed to seek medical attention through a health care provider, at ICR's expense. Test subjects would be instructed to submit study related bills to ICR. ICR will incur the cost of any study related bills. The principle investigator will contact all test subjects by telephone, two weeks after the conclusion of the study to enquire if they have experienced any adverse effects.

BENEFITS

While the sponsor gains the most direct benefit from the conduction of this study through knowledge gained on the performance of its repellent products, ICR and the sponsor also acknowledge that greater benefits exist to society at large. Insects continue to have a substantial impact on outdoor activities of many people. As the EPA registration requires efficacy data, the protocol in discussion is the only path toward development of alternative and perhaps more effective insect repellent products. Societal benefits from additional repellents becoming available in the market place would include:

1. New novel insect repellent formulas demonstrating increased effectiveness against mosquitoes would be available to consumers.
2. New repellent products would allow more choices to consumers.
3. New repellent products containing a DEET-alternative active ingredient would allow consumers a choice between DEET and non DEET repellent products.

TEST SUBJECTS

Inclusion Criteria:

Sex:	Male/Female
Age:	*18 to 55*
Race:	No exclusions
Literacy:	Must be able to read, speak, and understand English

Exclusion Criteria:

1. Test subjects can not participate if they are pregnant or breastfeeding.
2. Test subjects can not be an employee or a relative of an employee of ICR Inc., the sponsor, or any interested party.
3. Test subjects must follow the requirements of the study as explained to them.
4. Test subjects must not be sensitive to mosquito bites.
5. Test subjects must have no known sensitivity to insect repellents or skin care products.
6. Test subjects must be attractive to mosquitoes, as evidenced by previous being bitten by mosquitoes.
7. Test subjects must not smoke or drink alcoholic beverages 12 hours prior to the test.
8. Test subjects must not use perfumed cosmetics, skin creams, shaving lotions, etc. after 12 AM before the test, and during the test.
9. Test subjects must wear proper protective clothing during the test, such as their own blue jeans, heavy socks, long sleeve shirts, and gloves provided by ICR.

Number of Subjects and Rationale for Sample Size

The EPA Guideline (EPA/OPPTS Guideline 810.3700) recommends at least six test subjects be used. Because of the cost of doing repellent studies, it is prudent to ensure data collected will give a good representation of the repellency of the test formulations. In a published paper[2] the number of subjects required to achieve an estimated among-subjects standard deviation for specific times of 0.5 hours to 2.0 hours was calculated for protection times from 1 hour to 8 hours. The number of subjects required to achieve an estimated among-subjects standard deviation of 2.0 hours at a 95% confidence level for an 8 hour protection time was calculated to be between 10 and 11 subjects. This study, therefore, will use ten treated test subjects. There will be an additional control subject, plus two additional treated test subjects to replace anyone that either drops out or is ineligible to participate due to a positive pregnancy test or other unforeseen circumstances. These additional two treated test subjects will help to ensure a minimum "n" of ten and will aid in protecting the privacy of any dropouts.

[2] L.C. Rutledge and R. K. Gupta, 1999, Variation in The Protection Periods of Repellents on Individual Human Subjects: An Analytical Review, Journal of the American Mosquito Control Association, 15(3):348-355

Test Subject Recruitment
ICR has been conducting repellent studies for over twenty years. During this time ICR has amassed a large list of potential study subjects. These subjects also refer friends and colleagues to us. When a repellent study date has been established, ICR will contact potential study subjects by telephone and briefly discuss the study, the date of the study, and location if different than ICR. Any study specific inclusion/exclusion requirements will also be mentioned at this time. When the number of interested subjects required for a particular study has been met, ICR will stop recruitment.

ICR uses the following initial telephone script to recruit test subjects:

"ICR will be conducting a repellent project on these dates, (Month, Day(s), Year), at (exact study site) would you be available to participate in this study?"
If the potential test subject is available, the inclusion/exclusion criteria will be discussed in detail and verified whether the subject qualifies to participate. The ICD will also be discussed with the test subject at this time. In addition, ICR will mail a copy of the ICD to each interested test subject for their review. They will be instructed to contact the P.I. to verify receipt of the ICD and to ask any ICD or study related questions they may have.

The P.I. will contact all interested subjects by phone several days after receipt of the ICD to fully explain the ICD with them. All contacted people that show interest will be offered the opportunity to come to ICR to go through the consent process in person.

ICR has been fully compliant with 40 CFR 26.1125 in obtaining written approval for all repellent studies from an independent Institutional Review Board

In the event that an interested subject declines to sign an informed consent document, they will not be permitted to participate in the study.

There is no coercion for any subject to participate. The inclusion/exclusion criteria are clear, the payment is clear, the subjects are informed of the conditions they will likely encounter and what is expected of them. Each consenting test subject will be informed that they may drop out of the study at any time. Further, they may leave as soon as practical after early withdrawal from the test.

METHODS

Experimental Design
This is a subject-blinded study. The delineated areas on the arms of subjects will be treated and used as test areas. Only arms are being treated in this study, since arms are quite easy to monitor for mosquito activity. Therefore there will be twelve test arms for each treatment. Each test

subject will have one arm treated with one of the two test products and the other arm will be treated with the other test product.

Test location:
This test will be conducted in the insectary at ICR. The insectary is maintained at 70% RH ± 15% RH and 70° F ± 15°F.

Dose
The Standard application rate of 1.67 mg/cm^2 for this study. This is the dose currently recommended in the EPA guidelines for mosquito efficacy testing and the dose that was used when the efficacy field tests were conducted on these two EPA registered products.

Blinding of the Study
The test articles will be coded as "A" and "B". During the test these codes will be the only test article designation referred to or that the test subjects will see. The Study Director and members of the ICR staff will know the actual test articles, but will refrain from such identifications in the presence of test subjects.

Treatment Groups
There will be two groups: a treated group of twelve (two more than required to allow for drop outs) subjects whose arms will be treated, and one untreated (control) test subject whose arms will be untreated. Subjects will be given a subject number. They will be assigned to the groups by lottery selection of the subject number.

Personnel preparation
All test subjects will complete and will sign an "Informed Consent Document" prior to acceptance as a test participant.

Females will be required to perform an over the counter pregnancy test that will be supplied by ICR. They will do this the morning of the test. The results will be verified by a female ICR staff member. They may not participate if they are pregnant or breastfeeding. The results of this pregnancy test will be kept confidential and will not be disclosed to anyone other than the test subject and the P. I.

All test subjects will wash their arms with unscented Neutrogena® soap. The test subject's arms will then be measured in the following manner for the demarcation of the 250 cm^{2}test area:

For Arms:
The subject's elbow will be placed on a flat rigid surface with the forearm held perpendicular to that surface. A mark will be made on the upper forearm 3" from the flat surface. A second mark will be made on the lower forearm at a point just below the wrist bone. The circumference of the

arm will be measured at each of these points. The average of the two circumferences will be calculated. This represents the approximate circumference at the center point between the two marks. A third mark will be made at the center point between the two marks. The average circumference will be divided into 250cm^2, the total exposed surface area required for the test. This will yield the length of arm required to be exposed. The end points of this length of exposure area will be marked on the forearm so that each end point is equidistant from the center point. The endpoint measurements from the center point will be recorded so that they may be duplicated in the laboratory. The distance from the tip of the little finger to the center point will be measured and also recorded so that the center point may be duplicated at another time.

The above mentioned measurements will be recorded on a repellent measurement form. If a test subject has been previously measured, the existing measurements will be used.

The test subjects and the control subject will have 250 cm^2 areas delineated around their forearms and these arms will be prepared for treatment. The skin above and below the target area will be protected with elastic bandages and or Velcro® straps held in place with Elastikon® tape. Arms will be protected by shirt sleeves. Latex or vinyl gloves will be given to the subjects to protect their hands. The control test subject will be randomly selected by flipping a coin.

Determination of Attractancy to Mosquitoes
Test subjects will then be taken to the insectary. They will then place their right forearm into their test cage and the number of mosquitoes landing on their arms will be counted. The required landings will be at least 5 mosquitoes in 60 seconds to qualify a subject as being attractive to the mosquitoes. Volunteers will repeat the qualifying exposure as above using the left arm. The procedure will be repeated if the subject fails to qualify. If a subject again fails to qualify after repeated exposure, that subject may be replaced.

After qualification the test subjects will return to the laboratory for the application of the test repellent.

Treatment Application
The repellents will be coded as "A" or "B", and each arm will be labeled on the protective wrap with the code corresponding to the repellent applied. Each test subject will be treated on the right arm with repellent "A" and on their left arm with repellent "B".

The test articles will be applied to the test subjects using a syringe (minus needle). The amount of test article applied will be determined in the dose range finding. The hands will be protected with gloves. The control subject will receive no treatment.

Subjects will be treated in pairs. Both members of a pair will be treated with one test article and then they will be treated with the other test sample. The time of treatment will be the time when

the application of the second test article begins. This time will represent the starting time used for calculation of the protection times afforded by the test samples.

Testing
The aggressiveness of the caged mosquitoes during the test day will be determined from the landing rate on the control's arm before each test exposure. Once the landing rate has been confirmed (5 landings in 60 seconds) the counts will cease. The landing rate verification will be conducted before each exposure of the treated test subjects. If fewer than the required number of mosquitoes land in 60 seconds, a new group of 100 mosquitoes will be released into all of the cages.

The study director or technician will assist the test subjects in inserting their arms into the test cages, taking care not to rub them on the cloth sleeve. The test subjects will expose their treated forearms to the mosquitoes in these test cages for 5 minutes. The subjects will then remove their arms from the cages with assistance from an ICR staff. Exposures to the mosquitoes will be repeated every 30 minutes until the formulation on any given forearm is determined to be no longer effective or until 8 hours have elapsed, whichever occurs first.

The test data to be recorded will be bites (blood is ingested, as evidenced by abdominal swelling and color change). Test data will be recorded on a Repellency Test Data Sheet

Criteria for Test End Point
Efficacy will be evaluated by intermittent exposure of the test subjects' arms. The treated test subjects will expose their treated arms to the caged mosquitoes for 5 minutes at approximately 30 minute intervals. The test subjects will expose treated arms until the FCB (when two bites occur on the same arm in the same exposure period, or one bite occurs in each of two consecutive exposure periods, the first bite being the confirmed bite) or until 8 hours have elapsed, whichever occurs first. For the purposes of this test, a bite is defined as a mosquito penetrating the skin with its proboscis and taking sufficient blood to cause its abdomen to swell. When the two bites have occurred as noted above, the test will terminate on that arm.

When the testing is terminated for an arm, test subjects will then roll down their sleeves to cover such discontinued arms. The test will be terminated on a treated arm when a bite is followed by one additional bite (the initial bite and one confirming bite). If the bites do not occur within the specified time, the number of bites required will begin anew.

Once a confirmed bite occurs, the test subjects will stop exposing that arm to mosquitoes. They will then be able to remove the bandages and tape, scratch and wash that arm. If they want to, they can use rubbing alcohol to help stop the itching from the bites they may have received. Caladryl® or Calamine® lotion may also be used.

CONFIDENTIALITY

The information obtained from test subjects taking part in this test may be used by ICR and its sponsor and may become part of a report. This report will be kept as confidential as possible under local, state and federal law. The test subjects' first and last initial and their dedicated identity number only may be referenced. ICR cannot guarantee that their identity will be kept confidential. Essex Institutional Review Board has the right to review their records.

DATA ANALYSIS:

The purpose of this study is to examine the effective duration of an insect repellant. Ideally, it is expected that there will be no significant breakdown in efficacy of the product over a 8 hour interval. Given the small sample size ($N = 10$) and the dichotomous nature of the data (effective vs. non-effective), nonparametric statistics will be used to analyze the data. Data will be analyzed using SPSS for Windows version 12.

Subjects will be evaluated each half hour over the 8 hour window of the study to determine whether or not the product continued to prevent insect bites. For each 30 minute assessment interval, the proportion of subjects not having insect bites will be identified. A basic degradation curve can then be plotted. These data will then be subjected to a Cochran Q test, which is particularly useful for measuring changes in frequencies (proportions) across time. A significant effect would indicate that there was a systematic degradation in the product's efficacy over the 8 hour testing interval. If such an effect is found with the Q test, then a series of 2 (baseline vs. assessment interval) X 2 (protected vs. non-protected) cross-tabulations will be created and the resulting proportions will be analyzed using a Fischer's Exact Test (employing a 1-tailed alpha level) to determine the specific time point at which efficacy became significantly impaired.

Data also to be collected from subjects will be the length of time before a significant number of bites were noted. These data will be aggregated and basic descriptive statistics determined (e.g., mean, standard deviation, confidence intervals). If this distribution is non-normal, appropriate transformations will be applied and statistics recalculated. In the case of negative skewness (which is expected), the data will be reflected and a logarithmic transformation will be employed. In the case of significantly skewed distributions, the median will be used as the measure of central tendency. Confidence intervals will be calculated on the basis of percentile ranks rather than standardized scores.

QAU AND DATA ARCHIVING

Good Laboratory Practices, as outlined in 40 CFR §160 will be followed throughout the study. The QAU representative will observe and write phase report(s) for this study. All data will be archived.

SCHEDULE OF EVENTS

DATE	PROCEDURE
Time Zero	Test Conducted
At End of Test	Verbal Report
After The Laboratory Test Conduct	Written Report
After Final Report Has Been Issued	Samples Returned

STATEMENT OF AMENDMENT OR DEVIATION

Any amendments to this protocol must be discussed with and approved by the Sponsor. Any amendments to, or deviations from, this protocol will be documented in the final report.

Director, ICR, Inc. Date 7/25/07 QAU Representative Date 7/25/07

7-25-07 NCS WE

SPONSOR'S REPRESENTATIVE ~~Study Director~~ Date 7/24/07

STUDY DIRECTOR ~~Sponsor's Representative~~ WE NCS 7-25-07 Date 7-25-07

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APPENDIX I: DATA COLLECTION SHEETS

CONTROL RAW DATA COLLECTION SHEET

DATE:_____ START TIME:_____ A.M./P.M.
TEST SUBJECT INT/#:_____ STUDY DIRECTOR: NICK C. SPERO
STUDY ASSOCIATES: T. FOARD W. GAYNOR J .SHARPE C. JOHNSON F. ZGIDOU

Time (hrs)	# of Landings on Arm	Time Required to Verify Landing Rate
0		
0.5		
1		
1.5		
2		
2.5		
3		
3.5		
4		
4.5		
5		
5.5		
6		
6.5		
7		
7.5		
8		

Signatures of Study Associates
Recording data on this sheet/date:

_____
_____
_____
_____

Study Director's Signature/Date

_____

Test Subject's Signature/Date

_____

RAW DATA COLLECTION SHEET

SPONSOR: 059 DATE: START TIME:

S D/TECH: Nick C Spero SPECIES: *C. quinquefasciatus* FORMULATION APPLIED BY: N.C.S

COMP	SUBJ		SUBJ		CONTROL INITIALS:_____	
TIME	RIGHT	LEFT	RIGHT	LEFT	LAND	TIME
	BITE	BITE	BITE	BITE		
0.5						
1.0						
1.5						
2.0						
2.5						
3.0						
3.5						
4.0						
4.5						
5.0						
5.5						
6.0						
6.5						
7.0						
7.5						
8.0						
Fail Time						

Signatures of Study Associates Recording data on this sheet/date:

_____

_____

_____

Study Director's Signature/Date _____

Test Subject's Initials/Date _____

Repellent Measurements–Arm

SUBJECT: _____

DATE: _____

LEFT ARM

LOWER ARM = _____

AVG = _____ $\frac{250\text{ cm}}{2}$ = ____ = ____ ____

UPPER ARM = _____

CENTER POINT = DISTANCE FROM LARGE TO SMALL CIRCUMFERENCE $\frac{\text{____ cm.}}{2}$ = _____

DISTANCE FROM CENTER POINT TO TIP OF LITTLE FINGER _____

DISTANCE FROM EITHER SIDE OF CENTER POINT _____

RIGHT ARM

LOWER ARM = _____

AVG = _____ $\frac{250\text{ cm}}{2}$ = ____ = ____ ____

UPPER ARM = _____

CENTER POINT = DISTANCE FROM LARGE TO SMALL CIRCUMFERENCE $\frac{\text{____ cm.}}{2}$ = _____

DISTANCE FROM CENTER POINT TO TIP OF LITTLE FINGER _____

DISTANCE FROM EITHER SIDE OF CENTER POINT _____

DATA TRANSFER VERIFIED BY:_____DATE:_____

Informed Consent Document
for Review by Essex Institutional Review Board

PROTOCOL: EVALUATION OF THE EFFICACY OF PERSONAL REPELLENTS AGAINST MOSQUITOES IN THE LABORATORY

INFORMED CONSENT AUTHORIZATION TO PARTICIPATE IN AN ICR, INC. MOSQUITO REPELLENT EVALUATION IN THE LABORATORY

Principal Investigator: Niketas C Spero
Address: ICR, Inc. 1330 Dillon Heights Ave. Baltimore, MD
Telephone Number: 410-747-4500
24 Hour Emergency Number: 410-371-7223

Purpose of Study

We (ICR, Inc.) have been contracted by an outside company ("Sponsor") to conduct a research study on two mosquito repellent products, to find out how well these products repel one species of laboratory-reared mosquitoes. This study will occur in the ICR, Inc. lab. where the mosquito repellent testing will occur in cages. Your participation will be strictly voluntary. We have prepared this Informed Consent Document (ICD) to explain this study to you. We will go over the ICD with you to ensure that you fully understand what would be expected of you if you participate, and explain any risks you may face through your participation. We will also use the following suitability checklist to determine if you qualify to participate in the study. Please ask us about anything you do not understand before deciding whether to participate in this study. Your signing of the ICD indicates your willingness to participate in this study, but if you are selected to participate, you would still be able to withdraw from the study at any time. If you have come into our office to review the ICD, you may take the ICD home with you if you need more time to think about whether to participate. If you decide to participate, sign the ICD in the presence of the person administering the ICD or other ICR study personnel, after which you will receive a signed copy.

Suitability Checklist for the Study

To be suitable to participate in this study you must meet the following conditions:

1. You must be between 18 and 55 years of age and consider yourself to be in good health.
2. You must be able to read, speak and understand English so you can follow directions.
3. You must not be pregnant or breastfeeding. Women will be required to perform an over-the-counter urine pregnancy test on the morning of the study. We will provide the test kit. A female ICR staff member will verify the results. ICR will keep the results of the pregnancy test confidential from everyone except you and the P.I..
4. You must not be an employee or a relative of an employee of ICR, Inc, the Sponsor, or

Test subject's initials:.....

Date:.....

any other interested party.

5. You must be willing to follow the requirements of the study as will be explained to you below.
6. You must have no known sensitivity to insect repellents or skin care products.
7. You must have been bitten by at least one mosquito in the past five years.
8. You must not be bothered with your reaction to that mosquito bite(s).
9. You must not smoke or drink alcoholic beverages within 12 hours prior to the study.
10. You must not use perfumed cosmetics, skin creams, shaving lotions, etc. after midnight the day of the study until after that day's testing is completed.
11. You must be willing to wear proper protective clothing, as explained below, during the study.
12. You must be willing to provide your own transportation to the ICR lab.
13. You must be available to participate in the study for its maximum duration of one day.

Laboratory Repellent Phase Volunteers

There will be a total of 13 of you who will participate in the one-day laboratory study. One of you will be the control subject who will receive no treatment. You will place one untreated arm in each test cage for up to one minute every one-half hour exposure period to monitor mosquito activity; at least five mosquitoes must land on your arm within 60 seconds. The laboratory study will take one day. If you are chosen to participate in this study, you will be paid for a total of one day as discussed below.

Procedures

Study Schedule Overview

Prior to the test:

1. We will discuss with you every line of the ICD. If you visit our Baltimore office, you may voluntarily sign the ICD at that time if you wish to be considered for participation in the study. If you do not want to visit our Baltimore office, we will mail the ICD to you, and fully discuss it with you via phone. You may subsequently sign the ICD but it must be in the presence of one of our study personnel.
2. We will notify you within one week whether we have selected you for participation.

If selected to participate in the laboratory study:

On the morning of the laboratory study at the ICR lab:

1. You will wash your arms with unscented Neutrogena® soap.
2. We will measure and treat a 3 - 5 inch wide test area around both of your forearms as described below.

Test subject's initials:.....

Date:.....

Laboratory Study Details

1. We will select one of you as a control subject, and the other 12 of you as treated test subjects.
2. We will use a felt tip pen to mark a 3 - 5 inch wide band around one of your forearms if you are a control subject and two forearms if you will be treated.
   We will determine the exact location of this band by measuring the distance around two locations of your forearm, i.e. a location near the wrist and another just below the elbow of the forearm.
3. We will protect the skin above and below this band from mosquito bites by using multiple layers of elastic bandages and or Velcro© straps held in place with adhesive tape.
4. If we have selected you as a treated test subject, we will cover the band on your forearms with the repellents using a syringe without the needle with an amount of repellent product similar to that which would normally be applied by consumers.
5. We will then put on a latex or vinyl glove, and using a finger tip, spread the repellent evenly over the treatment areas.
   Once we treat your arms, you must not rub them against anything, as this could rub off some of the test repellent and change the results.
6. We will mark your bandages with a letter identifying the repellent on that arm.
   We will not identify the repellents to you.
7. If we have selected you as a control test subject, you will receive no treatment.
8. You will all then go into the test laboratory and wait for your repellents to dry for one-half hour before you put on your gloves to begin the first five-minute exposure period of the day's study.
   Treated subjects: we will pair you with another treated test subject and tell you which cage to use. You will assist your partner in alerting him/her to mosquito landings on hard to see parts of his/her arms. When you see a mosquito land on you or your partner, you will notify ICR study personnel.
9. Control subjects: you will sequentially insert your untreated arm in each of the five test cages before the beginning of each five-minute exposure period. We will count how long it takes for five mosquitoes to land on your untreated arm. If five mosquitoes do not land within 60 seconds, we will add more mosquitoes to the cage. When you reach the required landing rate (5 landings within one minute), you will remove your arm from that cage.
   We will try to brush the mosquitoes away before they can probe or bite you.
10. Treated subjects: we will count the number of mosquitoes (up to two) which bite the treated skin of either of your two arms during the five-minute exposure periods which occur every 30 minutes. When you receive two bites on the same arm in the same exposure period, or one bite in each of two consecutive exposure periods, you will remove that arm from the cage and cover with your sleeve. This is called

Test subject's initials:.....

Date:.....

"breakdown". You will no longer expose that arm for the rest of the day's study. You will then be able to remove the bandages and tape, and scratch that arm. If you wish, you may use Caladryl®, Calamine® lotion or rubbing alcohol to help stop the itching from the bites you received. When you reach breakdown on both arms, you will have finished your part in the study and may go home.

11. At the end of each five-minute exposure period you will remain in the lab except for trips to the restroom or study-director lead breaks every few hours.
12. The day's study will consist of five-minute exposure periods every half hour for up to 8 hours or until all treated test subjects have reached breakdown on both arms.

The study duration could be 9 hours: preparing your arms for the test, along with preparing the other test subjects, will take about one hour; exposures to mosquitoes will go on for up to 8 hours.

Discomfort and Hazard

In addition to sitting in a room maintained at 80° ± 15°F and 70% ± 15% relative humidity, conditions that can be uncomfortably warm, you may be exposed to two types of study-related hazards by participating in this study:

1. Mosquito bites or probes

   A bite occurs when a mosquito pierces your skin and takes blood. A probe is the same except it doesn't take blood. The irritation from a mosquito bite or probe may cause itching, redness or swelling that will usually disappear within a couple of days, or in severe cases may cause the development of large bumps on your skin, difficulty breathing, sweating and/or a rapid pulse.

   Although we will remove your arm from the cage if it receives two bites in one exposure period, or one bite in two successive exposure periods, it is possible you may receive more than two bites during the test. A bite which is not followed by another bite in the same or a succeeding exposure period will be disregarded. You will still need to receive two additional bites.

   If you are a treated test subject, we will only expose you to mosquitoes for five minutes every half hour. If you are a control test subject, we will only expose you to mosquitoes until five land on your arm within 60 seconds. We will also minimize the irritation from bites or probes you receive by making Caladryl® or Calamine® lotion or rubbing alcohol available at the study site for your use after the study is completed. The mosquitoes we us in this test are laboratory reared and there is no possibility that they can carry disease.

Test subject's initials:.....

Date:.....

2. Reaction to the test repellents

You may have a reaction to the test repellents.

The Sponsor has minimized this possibility by choosing an active ingredient (picaridin) which has demonstrated low acute oral, skin, and inhalation toxicity. The Environmental Protection Agency (EPA) has classified it as Toxicity Category IV, low toxicity for acute inhalation toxicity and primary skin irritation. The EPA has classified it as Toxicity Category III, mild toxicity for ocular irritation. The Sponsor has selected the inert ingredients in the formulation because these inerts are widely used in cosmetic formulations, and have a long history of safe use.

Should you have any medical problems, we will have First Aid qualified staff members, as well as First Aid supplies, present on site. We will have cell phones to make emergency calls if necessary. In the case of medical emergency, we will transport you to a selected local hospital at our expense. We will pay all of your medical bills for study-related illnesses and injuries. The principal investigator will contact you by telephone, two weeks after the conclusion of the study to enquire if you have experienced any adverse effects. You should contact the P.I. if you experience any study-related adverse effects after this follow-up call.

Financial Consideration

We will pay you $99/day for an anticipated 9- hour work day. This payment will be mailed to you on the 15th or end of the month. If we ask you to drop out of the test, and you have complied with all of our requests, we will still give you full payment. If we ask you to drop out of the test because you have not followed all of our directions, or if you choose to drop out of the test, we will compensate you for time up to that point.

Benefits

While you will get no personal benefit from this study, the results of the study may help bring a new repellent to the market and thus provide consumers with a greater choice of repellents.

Your Rights

We will give you an opportunity to discuss with us any aspects of this ICD that are not clear to you so that you can fully understand the nature of the study, its purpose, and the procedures to be used, together with the discomforts, risks or other adverse effects you may experience during or after the study. Your participation is voluntary. You may refuse to take part in this study or quit at any time without penalty or loss of benefits to which you may be otherwise entitled. If after reading this ICD you sign it to signify your agreement, we will give you a copy for your files.

Test subject's initials:.....

Date:.....

Alternative
Your only alternative to participating is to not do so.

Questions
If you have any questions about this study or suffer a reaction potentially associated with the study, call us at 410-747-4500. If you have any questions about your rights as a research participant, or related concerns, you may contact the Essex Institutional Review Board (IRB), 121 Main Street, Lebanon, NJ 08833, and its telephone is 908-236-7735. Essex IRB is a committee that has reviewed this research project to help ensure that the rights and welfare of the participants are protected and that the study is carried out in an ethical manner. Review of this study by Essex IRB is not an endorsement of the study or its outcome.

Confidentiality
We and our sponsor may use the information obtained from your taking part in this test, and this information may become part of a report. We will keep this report as confidential as possible under local, state and federal law. We will reference only your first and last initials and your dedicated identity number in the report. However, we cannot guarantee that your identity will be kept confidential; the sponsor, personnel associated with the study, a regulatory agency such as the Environmental Protection Agency (EPA), and the Essex Institutional Review Board (EIRB) have a right to review your records.

Consent
I voluntarily agree to participate in this study. I will be given a copy of this signed form.
I am 18 to 55 years of age. By signing this form I have not given up my legal rights.

_____
Signature of Subject Date

_____
Signature of Witness Date

_____
Printed Name of Subject Date

_____
Signature of Principal Investigator Date

Additional Materials:

Site Application Letter
Resumes/CVs of investigator and sub-investigators
Material Safety Data Sheets for Test Materials
Indemnification Form
Investigator Attestation
Investigator Conflict of Interest Declaration
Memo regarding ongoing training for investigators and staff

SITE APPLICATION LETTER

Date 7-25, 2007

Chairman
Essex Institutional Review Board, Inc.
121 Main Street
Lebanon, NJ 08833-2162

In connection with the **[Sponsor]** Avon Products, Incorporated clinical research project, entitled:

[Protocol Title] EVALUATION OF THE EFFICACY OF PERSONAL REPELLENTS AGAINST MOSQUITOES IN THE LABORATORY

and **[Protocol number]** G0590607001A117

application is being made to the Essex Institutional Review Board for review under the provisions of 21 CFR 50, 21 CFR 56, 45 CFR 46, and 40 CRF 26.

The following information will assist the Essex IRB review of your request. All questions must be answered completely.

You must transmit this letter for each site requesting review and approval.

1. ☐ A Form 1572 (if applicable to this study) listing each research site is attached.

   ☑ A Form 1572 is not applicable to this study. A copy of the Investigator Attestation Form is attached.

   ☐ A copy of a valid IND, when one is required. A copy of the Form 1572 or a copy of the Investigator Attestation Form is attached.

   ☐ For device study, attach IDE letter from the FDA or statement supporting non-significant risks or why exempt from IDE requirements under 21 CFR 812.2 or otherwise exempt. A copy of the Investigator Attestation Form is attached.

2a. **Research Site: (Complete a separate letter for each site seeking approval.)**

Name: ICR Inc.

Address: 1330 Dillon Heights Avenue
Baltimore, Maryland 21228

Office Phone: 410-747-4500 Fax: 410-747-4928 24 Hour Emergency Number 410-371-7223

How many clinical research studies are currently underway at this site? None

SITE APPLICATION LETTER

2b. A site should ensure that adequate medical care is provided to subjects for any adverse events. Does the site have a policy and provisions for handling adverse reactions, including abnormal lab results related to the trial?

☑ **Yes**

☐ **No (Please explain)**_____

3. Can the principal investigator be reached 24-hours a day? (**NOTE**: Answering machines not acceptable)

☑ **Yes**

☐ **No (Please explain)**_____

4. **Hospital to be used in an emergency:** **Distance from site:** 10 miles

Name: St. Agnes Hospital

Address: 900 South Caton Ave
Baltimore, Md. 21229

Phone: 410-368-2389

Is this hospital equipped to handle adverse reactions?

☑ **Yes**

☐ **No**

5. The research site listed in question 2a is [check all boxes that apply]:

a) ☐ Independent private practice(s).

b) ☐ Private practice(s) located within a hospital or teaching institution.

c) ☐ Hospital(s) or teaching institution(s) **without** a local IRB.

d) ☑ Other [specify]: Contract Testing Laboratory

[if only 5a, 5b, 5c and/or 5d are selected, skip to question 7]

e) ☐ Hospital(s) or teaching institution(s) with a local IRB.

6. The local IRB could have jurisdiction over this study. ☐ **Yes** *[if yes, attach local IRB waiver letter]* ☑ **No**

SITE APPLICATION LETTER

7. The local IRB has restrictions on independent IRB approval of this study for the listed site. ☐ **Yes** *[if yes, attach listing of restrictions]* ☑ **No**

8. Has this protocol been submitted to, reviewed by, disapproved, terminated and/or withdrawn from another IRB? ☐ **Yes** [if yes, attach IRB findings] ☑ **No**

9. Is there a local community attitude that could impact on the manner in which your study will be conducted? ☐ **Yes** [if yes, attach listing of attitudes] ☑ **No**

10. Please provide the names of the sub-investigators in this study. **If none, please write "NONE".** (This includes any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial –related decisions.) (If necessary, please attach an addendum providing the names of the sub-investigators)

    NOTE: These names must be listed on the 1572 form [Box 6], if required by this study type.

    Include resume(s) and current license(s)/certification.

    Timothy Foard, William Gaynor, John Sharpe, and Fouad Zgidou

    CVs on file at Essex IRB

11. Do you personally attend to research participants at this site? ☑ **Yes** ☐ **No**

    If "**No**", list the names of those who attend the participants: _____

    Include resume(s) and current license(s)/certification.

12. In your absence, research-related medical emergencies are handled by which healthcare giver?

    Timothy Foard and John Sharpe are both CPR and First Aid Trained and certified

    Include resume(s) and current license(s)/certification.

13. **a.** How will you identify and recruit potential subjects? _____

    From a list of past study participants

    b. Will there be any bonus payment for recruiting participants? ☐ **Yes** ☑ **No**

    If yes, please explain and submit amounts:

SITE APPLICATION LETTER

14. Will subjects be eligible to participate in any additional studies during this trial?

☐ **Yes (Please explain)** ☑ **No**

15. Please provide information about the planned methods for obtaining informed consent.

I. When will the consent process take place? Before the test begins

II. Where will the consent process take place? At the test site

III. How will you verify whether the subject understands or has the capacity to comprehend what has been explained the consent process?

Subjects will have time to ask questions, and decline to participate if they choose. The principal investigator will ask if the informed consent document is understood, and if subjects will sign to verify comprehension and acceptance.

IV. Will you provide the opportunity for the prospective subjects to consider whether or not to participate? ☑ **Yes** ☐ **No (Please explain)**

V. For studies of greater than one year duration, will you be reviewing the consent form again with the subject? ☐ **Yes** ☐ ☑ **No (Please explain)**

ICR's studies with human subjects do not last that long.

16. Please list the individuals other than the principal investigator and sub-investigator(s) as requested below. If none, please write "NONE". **Include resume(s) and current license(s)/certification.**

a. Individual(s) who will administer the consent form at this site:

None

b. Individual(s) involved with this study (include responsibility):

None

17. **a.** Will a non-English consent form be required for your study population? ☐ **Yes** ☑ **No (skip to Q. 18)**

b. If so, what language(s)? _____

Would you like Essex IRB to contract for this service? ☐ **Yes** ☐ **No**

If **"Yes"**, consult the Essex IRB Fee Schedule for estimated fees.
If **"No"**, consult the "submission guidelines" for translation certification required.

SITE APPLICATION LETTER

18.	Has the Food and Drug Administration inspected this site and/or investigators?	☐ **Yes** (Continue with next question)	☑ **No (Skip to Q. 19)**
	If inspected, was a Form 483 issued at the end of the inspection?	☐ **Yes** (if yes, attach copy of the Form 483 & related correspondence for Board review)	☐ **No** (if no, attach any related correspondence with the FDA for verification)
	Was a Warning Letter subsequently issued?	☐ **Yes** (If yes, attach copy(ies) of all correspondence for Board review)	☐ **No**
19.	Has the FDA, OHRP or any regulatory agency, a Sponsor, or an IRB ever terminated a study at this site?	☐ **Yes** (If yes, attach explanation for Board review)	☑ **No**
20.	Does this site have established, written standard operating procedures?	☑ **Yes**	☐ **No**
21.	**a.** Does this site have ongoing training for investigators and staff in clinical research procedures in addition to any professional licenses and/or certifications? If yes, please provide a memo stating the type of training (i.e. ACRP, NIH, in-house training, seminars, literature, staff meetings, etc.). Provide any certificates, letters, etc. if applicable.	☑ **Yes**	☐ **No**
	b. Does anyone plan to become certified?	☑ **Yes**	☐ **No**
	c. May we assist anyone in obtaining certification?	☐ **Yes**	☑ **No**

22. We need to know if you or anyone involved with this research has any financial or nonfinancial conflict of interest (COI) that could compromise or lessen the safety and welfare of subjects who enroll in the study. Please complete the separate Investigator Conflict of Interest Form and submit with this form.

The threshold amount is $50,000 or more equity in the sponsor. If you qualify for a COI, please attach a separate sheet to describe how it will be managed and who will have the authority to impose those measures, how subjects and others will be informed and whether you have a COI Committee or equivalent backed by policies and procedures.

SITE APPLICATION LETTER

23. CERTIFICATION –

Your signature below certifies that:

a) Selection of participants for the above research study will be on an equitable basis and that all participants will be treated fairly;

b) informed consent will be sought from each prospective participant or the participant's legally authorized representative;

c) the research site listed in question 2a is appropriately equipped to handle adverse reactions should they occur;

d) adverse reactions and unexpected events will be reported to the Sponsor (for notification to the FDA and other investigators), with a copy forwarded to the IRB within 15 working days after the event;

e) any FDA site audits leading to a Form 483 or Warning Letter will be promptly reported to Essex IRB for its review and determination of adequacy of responses and corrective actions;

f) any participant recruitment material (which includes but is not limited to printed media; video and audio tape; and Web site pages and information) will be submitted to the IRB for review and approval prior to its release to the study population;

g) you shall provide a periodic, continuing review report prior to the expiration date of the approval and a final report no later than 90 days after completion of your participation in the study (last study participant contact); and,

h) you have examined this application letter and any accompanying documentation, and to the best of your knowledge and belief, they are true, correct and complete.

i) State laws shall be observed during the conduct of the study.

j) You will not commence any research activity until you have received approval to do so by Essex IRB.

SIGNATURE:

Niketas Spero 7-25-07

[Principal Investigator's Signature] [Date]

Niketas C. Spero B.S.

[Printed Name and Degrees]

DOCUMENT MAILING ADDRESS:

ICR, Inc. 1330 Dillon Heights Avenue

[office street address 1]

[office street address 2]

Baltimore, Maryland 21228

[city, state, ZIP code]

410-747-4500 / 410-747-4928

[phone number] [fax number]

NSpero@icrlab.com Niketas C. Spero

e-mail address and name of Study Contact Person

March 28, 2007

NIKETAS C. SPERO
ICR, Inc. Baltimore, MD
Tel: 410-747-4500

EDUCATION:

Allegheny Community College		1975-1976	Forestry
Penn State University State College, PA		1977-1978	Forestry
Towson State University Towson, MD	B.S.	1978-1981	Biology/Field & Natural Sci

CERTIFICATIONS

Pest Control Certification No 165-19757	1997-2007

SHORT COURSES/CONFERENCES:

Society of Quality Assurance Annual Meeting	2006
American Mosquito Control Association Annual Meeting	2006
American Mosquito Control Association Annual Meeting	2005
National Safety Councils Adult CPR and First Aid Training and certification	2005
Society of Quality Assurance Annual Meeting	2004
MDA Pesticide Safety Course	2002
Hazardous Material Course	2002
American Red Cross Adult CPR and First Aid Training and certification	2002
GLP Essentials For Technical Staff and Quality Assurance	2002
Training On Proper Wearing of The Respirator	2002

Basic Rules and Procedures For Working With Chemicals	2002
Workers Right To Know and Chemical Hazard Inventory and MSDS Information	2002
Hazardous Materials Training	2002
Society of Quality Assurance Annual Meeting	2001
MDA Pesticide Safety Course	2001
MDA Pesticide Safety Course	2000
MDA Pesticide Safety Course	1999
Fed Ex Dangerous Goods Seminar	1999
MDA Pesticide Safety Course	1998
Society of Quality Assurance Annual Meeting	1998
NCARSQA, Quality Assurance and Data Mgmt Forming an Alliance	1996
Society of Quality Assurance Annual Meeting	1996
Society of Quality Assurrance Annual Meeting	1994
CSMA GLP Seminar	1992

PROFESSIONAL EXPERIENCE:

2006-Present	Associate Director of Operations, ICR, Inc.
1983-2006	Laboratory Manager, Insect Control and Research, Inc., Baltimore, MD. Served as study director, managed personnel, supervised the rearing of approximately 48 species of insects.
1978-1983	Spero's Salads, Lexington Market, Baltimore, MD Managed operations and personnel while attending Towson State University.
1976	Koogle and Pouls Engineering, Albuquerque, NM. Worked as Surveyor's Aid.

Niketas C. Spero 3-28-07

Niketas C. Spero Date

February 12, 2007

WILLIAM GAYNOR

Baltimore, MD 21220

EDUCATION:

Rutgers University New Brunswick, NJ	MS	1972	Environmental Science
Loyola College Baltimore, MD	B.S.	1971	Biology

OTHER EDUCATION:

Attended Pest Control Applicator Training, 2007.

Received Pest Control Applicator Certificate, 2006.

Good Laboratory Practices for Scientists and Staff and Advance Compliance Issues, 2006.

Training on the Operation of *Aedes aegypti* Pupal Separator, 2005.

Training on Proper Aliquot Sampling of *Aedes aegypti,* 2005.

United Parcel Service - Hazardous Materials Customer Training Seminar, 2004

Training on the Care and Maintenance of the Cat Colony, 2002.

Training for Proper Wearing of the Respirator and its Cleaning, Inspection and Maintenance, 2002.

GLP Essentials For Technical Staff and Quality Assurance Personnel, 2002, ICR, Inc.

Basic Rules and Procedures For Working With Chemicals, 2002, ICR, Inc.

Workers Right To Know, Chemical Hazard, Inventory and MSDS's, 2002, ICR, Inc.

Hazardous Materials Training, 2002, ICR, Inc.

Training for Shipping of Hazardous Materials, 2002

GLP Training - Data Recording and Corrections, 1998

Aug. 8. 2007 2:59PM No. 1864 P. 2

NCARSQA, Quality Assurance and Data Mgmt: Forming an Alliance, 1996

Society of Quality Assurance annual Meeting, 1996

CSMA, Good Laboratory Practices Seminar, Washington, DC., 1993

Assertiveness Skills Workshop, pre1993,

Time Management Workshop, pre 1993,

Creative Thinking Workshop, pre 1993,.

Total Quality Awareness, pre 1993,

Effective Technical Presentation Workshop, pre 1993.

AWARD, HONORS:

Fellowship	Rutgers University	1971

EMPLOYMENT AND PROFESSIONAL EXPERIENCE:

1993-Present	Biologist, Regulatory/Efficacy Specialist and Quality Assurance Unit staff, Insect Control and Research, Inc., Baltimore, MD.
1981-1993	Computer Analyst/Programmer, Westinghouse Electric Corporation, Baltimore, MD.
1974-1981	Sanitarian, Environmental Specialist and Computer Programmer/Analyst, State of Maryland, Department of Health and Mental Hygiene, Baltimore, MD.
1973-1974	Environmental Writer for Environmental Assessment Reports, Princeton Aqua Science, New Brunswick, NJ.

William J. Gaynor 2/12/07

William J. Gaynor Date

March 28, 2007

TIMOTHY FOARD

EDUCATION:

M.S. - Entomology (1995), The University of Georgia, Athens, Georgia

B.S. - Biology (1984), Armstrong Atlantic State University, Savannah, Georgia

CERTIFICATIONS:

Pest Control Applicator Certification No 165-50614	2001 - Present
Adult CPR and Standard First Aid	2003 - Present

EMPLOYMENT:

3/2000 - Present	Entomologist, Insect Control and Research, Inc., Baltimore, Maryland
10/97 - 12/99	Agricultural Research Assistant II, Department of Crop and Soil Sciences, University of Georgia, Athens
2/94 - 9/96	Biological Laboratory Technician, U.S. Department of Agriculture, Russell Research Center, Athens, Georgia
3/87 - 12/92	Biological Laboratory Technician, U.S. Department of Agriculture, Stored Products Insects Research and Development Laboratory, Savannah, Georgia
6/82 - 3/87	Archaeological Field Supervisor/Laboratory Technician, Center for Low Country Studies, Armstrong Atlantic State University, Savannah, Georgia
3/81 - 3/82	Young Adult Conservation Corps (YACC) Worker, Oatland Island Education Center, Savannah, Georgia

TRAINING AND WORKSHOPS:

Entomological Society Of America Annual Meeting	2006
Entomological Society Of America Annual Meeting	2004
Entomological Society Of America Annual Meeting	2003
Entomological Society Of America Annual Meeting	2002
Entomological Society Of America Annual Meeting	2000
GLP Essentials For Technical Staff and Quality Assurance	
GLP Essentials For Technical Staff and Quality Assurance	2006
Training On Proper Wearing of The Respirator	2002
Basic Rules and Procedures For Working With Chemicals	2002
Workers Right To Know and Chemical Hazard Inventory and MSDS Information	2002
Hazardous Materials Training	2002
Hazardous Materials Training	2004
	2002

PROFESSIONAL MEMBERSHIP

Entomological Society of America
Entomological Society of Washington
Maryland Entomological Society

PUBLICATIONS

D. MICHAEL JACKSON, S. F. NOTTINGHAM, W. S. SCHLOTZHAUER, R. J. HORVAT, V. A. SISSON, M. G. STEPHENSON, T. FOARD, AND R. M. McPHERSON, 1996. Abundance of *Cardiochiles nigriceps* (Hymenoptera: Braconidae) on *Nicotiana* Species (Solanaceae). Journal of Environmental Entomology 25 (5): 1248-1255

T. FOARD, 1992. Occurrence of the Acanthocephalan, *Eocollis arcanus* Van Cleave, in Georgia. Journal of Parasitology 78 (4): 734

T. FOARD, AND D. L. AUTH, 1990. Food Habits and Gut Parasites of the Salamander, *Stereochilus marginatus*, in Georgia. Journal of Herpetology 24 (4): 428-431

Timothy Foard 3/28/07
Date

John W. Sharpe II
Parkville MD 21234

EDUCATION:

Institution	Year degree earned	Major and/or degree
University of Wisconsin, Madison	1997	B.S. Entomology

OTHER EDUCATION: Training, Short Course, Conference, Presentations, Etc.

West Coast Training Institute	GLP Training Seminar	February 2006
Maryland Dept of Agriculture	Pesticide Applicators License	February 2006
CPR Certification	Baltimore FD	2006

AWARDS, HONORS, CERTIFICATIONS:

EMPLOYMENT AND PROFESSIONAL EXPERIENCE:

2005-Present	Entomologist	ICR, Inc., Baltimore MD 21228
2004-2005	Science Teacher	NOVA High School, Milwaukee WI 53209
2004	Vector Control Specialist	Winnebago County Health Dept., Rockford IL 61104
2003-2004	Operations Manager	$^2DX_2$ Geothermal Systems Inc., Franklin WI 53132
1998-2003	Co-Owner	Breakaway Bicycle Courier LLC, Milwaukee WI 53203

PUBLICATIONS

3-28-2007

Name Date

February 6, 2007

Fouad Zgidou
Baltimore, MD

EDUCATION:

Elementary and High School Kenitra, Morocco	1966 - 1979
Vocational School For Carpentry Kenitra, Morocco	1979 - 1985

OTHER EDUCATION:

Pacific Rim Consulting	GLP Training	February 22, 2006
Pacific Rim Consulting	GLP Training	October 29, 2002
UPS - Hazardous Materials Shipping Training Course		2002
On The Job Training - GLP Training		April 8, 1998
Purdue Pest Control Course		1995
On The Job Training - Insect Rearing		1993
English Language Course		1990

Arabic - Fluent
French - Fluent
Spanish - Fluent

EMPLOYMENT AND PROFESSIONAL EXPERIENCE:

1993 - Present	Technician	Insect Control and Research, Inc. Baltimore, MD 21228
1990 - 1993	Cabinet Maker	Prostamen Cabinet Maker, Baltimore, MD
1989		Emigrated To The USA
1985 - 1989	Laborer	Italian Company (Name Unknown), Kenitra, Morocco

Fouad Zgidou 4-5-07
Fouad Zgidou

Date Prepared: July 24, 2007
EPA Reg. No. 806-29
TA# 1001108-030

MATERIAL SAFETY DATA SHEET

I. PRODUCT NAME
TA# 1001108-030

II. INGREDIENTS
HAZARDOUS INGREDIENT(S) (as defined by OSHA Hazard Communication Standard, 29 CFR 1910.1200)

NAME	CAS#	HAZARD DATA
SD Alcohol 40B (denatured with Bitrex® [denatonium benzoate])	64-17-5	Flammable; CNS depressant TLV:TWA=1000ppm
Picaridin	119515-38-7	Eye Irritant
Isobutane	75-28-5	Highly Flammable; Irritant/ Asphyxiant
Propane	74-98-6	Highly Flammable

Ingredients not precisely identified are proprietary or non-hazardous.

PRECAUTIONARY LABEL STATEMENT(S)
Hazards to Humans: Caution: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes and do not spray on face. Wash thoroughly with soap and water after handling, returning indoors, and before eating, drinking, chewing gum, or using tobacco. Wash treated clothing before wearing again. Discontinue use and consult a doctor if irritation or rash occurs.
PHYSICAL HAZARDS - Flammable. Contents under pressure. Keep away from heat, sparks and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting. Keep treated surface area away from fire or flame until dry. Intentional misuse by deliberately concentrating and inhaling contents may be harmful or fatal. Will not harm most plastics or synthetic fabrics. May damage painted or varnished surfaces, including nail polish.

NA= Not Applicable

MATERIAL SAFETY DATA SHEET

III. HEALTH HAZARD DATA

EFFECTS OF OVER EXPOSURE

SKIN: None expected. Use as directed.

EYES: This material may cause eye irritation. In accordance with good worker health and safety practices, avoid contact with the eye. Rinse immediately with water if product comes in contact with the eye.

INHALATION: Avoid inhaling concentrated vapors. Use only as directed.

INGESTION: Ingestion of this product may cause temporary gastric distress.

IV. FIRST AID PROCEDURES

SKIN: This material is not expected to irritate skin. However, if redness, itching, or a burning sensation should develop, wash material off the skin with soap and water. If irritation persists, seek medical attention.

EYES: Immediately flush with copious amount of water for at least 15 minutes. If redness, itching, or a burning sensation develops, have eyes examined and treated by medical personnel.

INHALATION: This material is not expected to present an inhalation hazard or exposure at ambient conditions.

INGESTION: Give one or two glasses of water to drink. If gastrointestinal symptoms develop, consult medical personnel. (Never give anything by mouth to an unconscious person.)

V. SPECIAL PROTECTION INFORMATION:

SKIN: N/A. Use only as directed.

EYES: Avoid direct contact with eyes.

INHALATION: Avoid inhaling concentrated vapors. Use only as directed.

VI. FIRE AND EXPLOSION HAZARD DATA

Flash Point and Method: ~75°F

Autoignition Temperature: No data

Flammable Limits: No data

Extinguishing Media: Use water fog, foam, carbon dioxide, dry chemical, alcohol-type or universal-type foams applied by manufacturer's recommended technique to extinguish fire.

Special Fire Fighting Procedure: Keep all unprotected and unnecessary people away.

Unusual Fire and Explosion Hazards: Flammable. Keep away from all sources of ignition.

VII. SPILL, LEAK, AND DISPOSAL PROCEDURES

Collect spilled material with vermiculite or other absorbent material. Sweep up and shovel into appropriate waste container.

Do not reuse empty container. Dispose of waste and container in compliance with all federal, state, and local laws concerning health and environmental regulations.

NA= Not Applicable

MATERIAL SAFETY DATA SHEET

VIII. REACTIVITY DATA

Stability: Stable

Incompatibility (Materials to Avoid): Avoid contact with plastics, such as eyeglass frames, plastic watch crystals, costume jewelry, leather, and synthetic fabrics such as acetate, rayon, spandex, and dynel. May damage painted or varnished surfaces, including nail polish.

Hazardous Decomposition: Thermal decomposition in presence of air may yield carbon monoxide, carbon dioxide, and water vapor.

IX. PHYSICAL DATA

Boiling Point: NA

Vapor Pressure (mm Hg at 20°C): No data

Solubility in Water: Miscible

Viscosity @ 25°C (Cps): NA

pH: 7.5 to 8.5 (liquid component without propellant)

Specific Gravity (H_2O=1): 0.87 to 0.93 (liquid component without propellant)

Appearance and Odor: A water-white to straw-colored liquid, lightly fragranced.

The information provided in this Material Safety Data Sheet has been compiled from our experience and data with similar, commercially available materials and is believed to be accurate. No guarantee of accuracy is made. It is the user's responsibility to determine the suitability of this information for the adoption of necessary safety precautions.

NA= Not Applicable

Date Prepared: July 24, 2007
EPA. Reg. No. 806-31
TA# 1004024-010

MATERIAL SAFETY DATA SHEET

I. PRODUCT NAME
TA# 1004024-010

II. INGREDIENTS
HAZARDOUS INGREDIENT(S) (as defined by OSHA Hazard Communication Standard, 29 CFR 1910.1200)

NAME	CAS#	HAZARD DATA
SD Alcohol 40B (denatured with Bitrex® [denatonium benzoate])	64-17-5	Flammable; CNS depressant
Picaridin	119515-38-7	Eye Irritant

Ingredients not precisely identified are proprietary or non-hazardous.

PRECAUTIONARY LABEL STATEMENT(S):
Hazards to Humans. Warning: Causes substantial but temporary eye injury. Harmful if swallowed. Do not get in eyes. Wash thoroughly with soap and water after handling, returning indoors, and before eating, drinking, chewing gum, or using tobacco. Wash treated clothing before wearing again. Discontinue use and consult a doctor if irritation or rash occurs.
PHYSICAL HAZARDS - Flammable. Keep away from heat and open flame. May damage painted or varnished surfaces, including nail polish.

III. HEALTH HAZARD DATA
EFFECTS OF OVER EXPOSURE
SKIN: None expected. Use only as directed.
EYES: Direct contact in the eye with this product may cause brief, temporary eye irritation. Avoid direct contact with the eye
INHALATION: Excessive inhalation can cause respiratory irritation, headache, and dizziness.
INGESTION: Ingestion of this product may cause nausea, vomiting, mental excitement or depression, drowsiness, impaired perception, uncoordination, or stupor.

MATERIAL SAFETY DATA SHEET

IV. FIRST AID PROCEDURES

SKIN: This material is not expected to irritate skin. However, if redness, itching, or a burning sensation should develop, wash material off the skin with soap and water. If irritation persists, seek medical attention.

EYES: For direct contact, flush the affected eye(s) with copious amounts of clean water for at least fifteen minutes. Seek medical attention if redness persists.

INHALATION: Remove affected individual to fresh air. If symptoms persist seek medical attention.

INGESTION: Give one or two glasses of water to drink. If gastrointestinal symptoms develop, consult medical personnel. (Never give anything by mouth to an unconscious person.)

V. SPECIAL PROTECTION INFORMATION:

SKIN: Not applicable Use only as directed.

EYES: Avoid contact with eyes.

INHALATION: Use only as directed. Avoid inhaling concentrated vapors.

VI. FIRE AND EXPLOSION HAZARD DATA

Flash Point and Method: <100°F

Autoignition Temperature: No data

Flammable Limits: No data

Extinguishing Media: Use water fog, foam, carbon dioxide, dry chemical, alcohol-type or universal-type foams applied by manufacturer's recommended technique to extinguish fire.

Special Fire Fighting Procedure: Keep all unprotected and unnecessary people away.

Unusual Fire and Explosion Hazards: Flammable. Keep away from all sources of ignition.

VII. SPILL, LEAK, AND DISPOSAL PROCEDURES

Collect spilled material with vermiculite or other absorbent material. Sweep up and shovel into appropriate waste container.

Do not reuse empty container. Dispose of waste and container in compliance with all federal, state, and local laws concerning health and environmental regulations.

VIII. REACTIVITY DATA

Stability: Stable

Incompatibility (Materials to Avoid): Avoid contact with plastics, such as eyeglass frames, plastic watch crystals, costume jewelry, leather, and synthetic fabrics such as acetate, rayon, spandex, and dynel. May damage painted or varnished surfaces, including nail polish.

Hazardous Decomposition: Thermal decomposition in presence of air may yield carbon monoxide, carbon dioxide, and water vapor.

MATERIAL SAFETY DATA SHEET

IX. PHYSICAL DATA

Boiling Point: Not applicable
Vapor Pressure (mm Hg at 20°C): No data
Solubility in Water: Miscible
pH: 6.75 to 7.75
Specific Gravity (H_2O=1): 0.8700 to 0.9300
Viscosity @ 25°C (Cps): Not applicable
Appearance and Odor: Slightly hazy liquid free of foreign matter.with a faint, pleasant odor.

The information provided in this Material Safety Data Sheet has been compiled from our experience and data with similar, commercially available materials and is believed to be accurate. No guarantee of accuracy is made. It is the user's responsibility to determine the suitability of this information for the adoption of necessary safety precautions.

Indemnification Agreement
Between
Avon Products, Incorporated
and
ICR, INC.

Avon Products , Incorporated (" **Avon** ") agrees to hold harmless **ICR, Inc. ("ICR")** from any claims of injury or illness resulting from the development, evaluation and implementation of Protocol No.G0590607001A117, entitled EVALUATION OF THE EFFICACY OF PERSONAL REPELLENTS AGAINST MOSQUITOES IN THE LABORATORY only under the following circumstances:

If any undesirable side effect or reaction occurs following the administration of the test product(s), and if ICR has employed reasonable care in the development of the protocol and has not violated any local, state or federal laws pertaining to the administration of chemical substances, medical devices, drugs or biological agents, including but not limited to the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, and the Federal Food, Drug and Cosmetic Act of 1938, as amended, and the regulations promulgated pursuant thereto, Avon shall indemnify and hold harmless ICR against any and all claims, lawsuits and judgements thereon (including reasonable attorney's fees through the appellate level) which may be brought against it as a result of the development or implementation of the protocol.

In the event any such claim is made or lawsuit is initiated, ICR shall give prompt written notice thereof to Avon , shall permit Avon or its insurance carrier to defend such claim or lawsuit, and shall cooperate fully in any such defense.

ICR, Inc.
Accepted By:

Name: Robin G. Todd, PhD, BCE

Title: Director

Date: 7/25/07

Avon Products, Incorporated
Accepted By:

Name: Romez dr

Title: Toxicology Manager

Date: 7/24/07

INDEMNIFICATION AGREEMENT

Between

Avon Products, Incorporated

[Company Name]

and

ESSEX INSTITUTIONAL REVIEW BOARD, INC.

Avon Products, Incorporated (hereafter "Avon") agrees to hold harmless, Essex Institutional Review Board, its principals, agents and board members ("EIRB") from any claims of injury or illness resulting from the evaluation and implementation of Protocol, # G0590607001A117, entitled "

- EVALUATION OF THE EFFICACY OF PERSONAL REPELLENTS AGAINST MOSQUITOES IN THE
- LABORATORY

",

under the following circumstances:

If any undesirable side effect or reaction occurs following the administration of the product and if EIRB has employed reasonable care in the evaluation of the protocol, and has not violated any local, state, or federal laws, pertaining to medical devices, drugs or biological agents, including but not limited to, the Federal Food, Drug and Cosmetic Act of 1938, as amended, and the regulations promulgated pursuant thereto, Avon shall indemnify and hold harmless EIRB against any and all claims, lawsuits, and judgments thereon (including reasonable attorney fees through the appellate level), which may be brought against them as a result of the evaluation or implementation of the protocol.

In the event any such claim is made or lawsuit is initiated, EIRB shall give prompt written notice thereof to Avon, shall permit Avon, or its insurance carrier, to defend such claim or lawsuit and shall cooperate fully in any such defense.

Essex Institutional Review Board Accepted By:	[Company Name] By:
[Signature of person authorized to legally bind]	[Signature of Company person authorized to to legally bind]
[Printed Name of person authorized to to legally bind]	Ramez Labib [Printed Name of Company person authorized to legally bind]
Date	7/24/07 Date

Version Date: January 31, 2007

ESSEX INSTITUTIONAL REVIEW BOARD, INC.

Investigator Attestation

Qualifications: I am qualified by education, training and experience to assume responsibility for the proper conduct of the following research study:

Sponsor name: Avon Products, Incorporated

Protocol name: EVALUATION OF THE EFFICACY OF PERSONAL REPELLENTS AGAINST MOSQUITOES IN THE LABORATORY

Protocol number: G0590607001A117

- Any patients and participants involved in the research shall be informed of the procedures related to the research study, ensuring that consent has been obtained in accordance with 21 CFR 50, as it relates to IRB review and approval.

- Essex IRB is in compliance with 21 CFR 50 and 56 and 45 CFR 46, and is responsible for the initial and continuing review of all changes, recruitment procedures, safety reporting and annual review of the research site(s). The investigator shall promptly report to the Essex IRB any changes in research activity and all unanticipated (adverse) events involving risks to human subjects or others.

- Changes to the research plan and/or participant consent form shall not be made without the approval of Essex IRB, with the exception of the elimination of apparent immediate hazards to human subjects.

- Past performance as an investigator where the Food & Drug Administration (FDA) and/or the Office of Human Research Protection (OHRP) inspection(s) or audit(s) led to recommendations for corrective actions, sanctions, or disqualification (FDA Form 483, FDA Warning Letter, etc.) will be submitted to the Essex IRB, along with documentation of resolution of the issue(s).

- Resources to conduct the research study in a manner providing protection to human participants in the study will be employed, including, but not limited to: adequate qualified staff and facilities; providing information and necessary training with regard to the protocol, the test product, and duties and functions. It is the obligation of the Principal Investigator to oversee all aspects of the study, providing adequate medical (or dental) care, as indicated.

- The Principal Investigator certifies compliance with 21 CFR 54 regulations regarding financial interest in the outcome of the research and to minimize bias in the design, conduct, reporting and analysis of the study. Disclosure of certain financial arrangement with the Sponsor will be made available to the Essex IRB upon request or at site inspection.

Attestation: I will comply with applicable regulatory requirements, ICH Guidelines and Good Clinical Practices. I understand my responsibilities as Principal Investigator in conducting research. I am familiar with human research protection regulations and will strictly adhere to these regulations.

Niketas C. Spero		7-25, 2007
Printed Name of Principal Investigator	Signature of Principal Investigator	Date

Version Date: January 31, 2007

ESSEX IRB

INVESTIGATOR CONFLICT OF INTEREST DECLARATION

Study title and number: EVALUATION OF THE EFFICACY OF PERSONAL REPELLENTS AGAINST MOSQUITOES IN THE LABORATORY
G0590607001A117

Sponsor: Avon Products, Incorporated

Financial relationships of investigators (or institutions/sites) to sponsors have the potential to adversely affect the rights and welfare of human subjects involved in research. In order to help ensure that such issues do not compromise the results or create hazards for the subjects, Essex IRB requests you to make a declaration regarding any conflict of interest (COI) in the conduct or outcome of the trial. To achieve this, we ask you to answer the following questions and submit a response to any that have a "Yes" reply in a separate letter.

- Do you have any relationship with the sponsor or institution that could cause potential or actual conflict of interest? Yes [ ] No [✓]
  If yes, describe the degree of conflict and with which parties.
- Is there any compensation that your institutional ethics/COI committee has deemed to be a conflict or could affect the outcome of the trial?
  Yes [ ] No [✓] If yes, describe.
- Does anyone involved with the research have proprietary interests in the product, drug or device, including patents, trademarks, copyright and licensing agreements? Yes [ ] No [✓] If yes, describe.
- Does anyone have an equity interest in the research sponsor?
  Yes [ ] No [✓] Describe, if yes.
- Do you receive significant payments, equipment, retainers, incentives, grants or honoraria from the sponsor? Yes [ ] No [✓] If yes, describe.
- Are the payments or incentives you receive per participant considered to be outside the norm? Yes [ ] No [✓] If yes, describe.

You may submit a letter from your institution's COI Committee regarding their determination of any COI in this study. Any recommendations you or they make to reduce or eliminate any COI will be appreciated. Examples of these are: describing any COI in the informed consent form, having an impartial third party obtain consent, reduction or elimination of the financial interest or equity ($50000 or greater), monitoring by an impartial party (independent data and safety committee), or separation of duties or roles (e.g., change of principal investigator). Violation of this declaration may result in it being reported to the FDA or OHRP (Office for Human Research Protection), as well as, our terminating approval for you to conduct this research study.

We thank you for indulgence in completing this document. If you have any questions, please contact us.

Principal Investigator's Printed Name: Niketas C. Spero

Signature: [signature] Date: 7-25, 2007

Version Date: January 31, 2007

ICR | *Independent Laboratory*
Pesticide Efficacy Testing
Regulatory Services

July 13, 2007

Essex Institutional Review Board, Inc.
121 Main Street
Lebanon, NJ 08833-2162

Subject: Memo regarding ongoing training for investigators and staff in clinical research procedures

Dear Dr. Lambert:

ICR, Inc. provides ongoing training for all investigators and staff for compliance with Good Laboratory Practices, comprehension of and adherence to internal SOPs, and any necessary continuing education. In addition to this training, two of our investigators are currently enrolled in a self-paced Web course entitled "RAN 9002 Informed Consent Process Training without CE Curriculum. All of our potential investigators will be encouraged to enroll in and complete the above online course.

Please do not hesitate to contact me with any questions.

Sincerely,

Ellen Quinn
Associate Director, Administration

1330 Dillon Heights Avenue, Baltimore, MD 21228-1199 | tel 410.747.4500 | fax 410.747.4928 | web www.icrlab.com

Initial Essex IRB Review of Submitted Materials

Essex IRB Response to ICR and Meeting Minutes

Meeting Minutes

Avon Products, Inc.
G0590607001A117

On **July 30, 2007** the Board met and reviewed the Avon Products, Inc. clinical research project, "Evaluation of the Efficacy of Personal Repellents Against Mosquitoes in the Laboratory" (G0590607001A117, 6/12/07).

On **July 30, 2007** the Board met at 121 Main Street, Lebanon, NJ 08833 at 4:00 p.m. Board members present: Glenn P. Lambert, MD, FAAP (Chairman) Loretta P. Szczepanski, RN and Deborah A. Timmerman. Alternate Board Members: Jorshinelle T. Sonza, PhD (alternate for Philip B. Carr-Jones, M Div) and Sandra S. Sullivan, OTR (Alternate for Tom Ollis, R Ph). The following individuals were also present to take minutes: Karen Radcliffe. Glenn Lambert, MD chaired the meeting.

The **Protocol** (dated 6/12/07) reviewed by a full board, was conditionally approved pending the following modifications recommended by the board:

Page 3:
- Under section **HYPOTHESIS**, line 2 – Please delete the word "a" after the word "mosquitoes".

Page 6:
- **Bullet 3**, line 2 – Please verify what is completed before the test subjects return to the laboratory.

Page 10:
- Under section **RENUMERATION**, 2nd paragraph, line 5 – Please replace the words "on the telephone, **and**" with the words "on the telephone, **or**".
- Under section **NEGATIVE CONTROL**, 1st paragraph – Please verify that the test subjects will be selected "**by drawing a name**" as opposed to "**a flip of a coin**" as stated on page 18 of the protocol.
- Under section **NEGATIVE CONTROL**, 2nd paragraph, line 4 – Please verify the manner in which the "mosquitoes will not be allowed to bite."

Page 11:
- Section title **MISCELLANEOUS** – Please add the word "**SUPPLIES**" after the words "MISCELLANEOUS".

Page 18:
- 3rd paragraph, line 5 - Please verify that the test subjects will be selected by "**a flip of a coin**" as opposed to "**by drawing a name**" as stated on page 10 of the protocol (See comment for page 10, section NEGATIVE CONTROL).

NOTE: When making the revisions to the Protocol, please remember to update the version date before re-submitting.

The **Consent Form** (dated 7/17/07) reviewed by a full board, was conditionally approved pending the following modifications recommended by the board:

Page 1:

- Under section **Suitability Checklist for the Study**. Item 3, line 4 – Please replace the initial "P.I." with the words "Principal Investigator (P.I.)".

Page 2:

- Item 8, top of page – Please delete the word "that" after the words "your reaction to".
- Under section **Laboratory Repellent Phase Volunteers**, line 2 – Please replace the words "will receive no **treatment. You will** place" with the words "will receive no **treatment and will** place"
- Under section **Laboratory Repellent Phase Volunteers**, line 4 – Please replace the words "must land **on your arm**" with the words "must land **on the exposed arm**".
- Under section **Laboratory Repellent Phase Volunteers**, - Please verify what 12 of the 13 subjects will be doing while the one control subject has the exposed arm in the test cage.
- Under section **Laboratory Repellent Phase Volunteers**, line 5 – Please replace the words "**one day**." with the words "**one day, approximately 9 hours**."

Page 3:

- Under section **Laboratory Study Details** – Please verify that lunch will be provided to the test subjects and breaks during the day are allowed.
- Under section **Laboratory Study Details**, Item 9, line 1 – Please replace the words "Control subjects: you will sequentially insert your untreated arm" with the words "Control subject will insert an untreated arm".
- Under section **Laboratory Study Details**, Item 9, line 2 – Please replace the words "**five-minute exposure period**." With the words "**five-minute exposure period for one minute, every half hour**."
- Under section **Laboratory Study Details**, Item 9, line 4 – Please replace the words "we will **add more** mosquitoes" with the words "we will **add 100 more** mosquitoes".

Page 4:

- Under section **Discomfort and Hazard**, Item 1, 1st paragraph, line 6 – After the words "and/or a rapid pulse." please add the sentence "This could be life-threatening."
- Under section **Discomfort and Hazard**, Item 1, 3rd paragraph, line 2 – Please replace the words "If you are **a**" with the words "If you are **the**".
- Under section **Discomfort and Hazard**, Item 1, 3rd paragraph, line 6 – Please replace the words "The mosquitoes we **us**" with the words "The mosquitoes we **use**".

Page 5:

- Under **Item 2**, top of page, 2nd paragraph, line 3 – Please delete the words "Toxicity Category IV" after the words "classified it as".
- Under **Item 2**, top of page, 2nd paragraph, line 5 – Please delete the words "Toxicity Category III" after the words "classified it as". Also, please replace the words "for **ocular** irritation." with the words "for **eye** irritation."

Page 5 (continued):

- Under section **Financial Consideration,** line 5 – Please replace the words "**up to that point.**" with the words "**up to that point at the rate of $11 per hour.**"
- After the section **Financial Consideration** – Please add a new section titled "**Costs**" and verify that they are no costs to the participants.

NOTE: When making the revisions to the Consent, please remember to update the version date before re-submitting.

Glenn P. Lambert, MD, FAAP is authorized to review the protocol and consent form and issue letters of approval, provided the returned documentation is in order specified by the Board. All meeting votes were unanimous with a vote of 5:0. There were no controverted issues and there was no conflict of interest for any of the Board members in attendance. Approvals will be for one year from date of site notification.

Please be reminded that the study may not commence any research activity (including scheduling) until formal, written approval and a stamped consent form is received by the research site.

Glenn P. Lambert, MD, FAAP
Chairman

8-2-07
8/2/07

August 2, 2007

Follow-up Submission to Essex IRB by ICR, Inc.

Protocol Amendments 1-8

Revised Informed Consent Documents
(Version Date August 2, 2007)

ICR, INCORPORATED
1330 Dillon Heights Avenue
Baltimore, MD 21228
Telephone: (410) 747-4500
Fax: (410) 747-4928

Protocol Amendments

Project Number:	0607-059-0157
Protocol Number:	G0590607001A117
Sponsor:	Avon Products, Inc.
Test Article(s):	TA# 1001108-030 and TA# 1004024-010
GLP Compliance:	40 CFR 160
Amendment #1:	The PROTOCOL VERSION DATE becomes August 02, 2007.
Amendment #2:	Page 2; Under the section TABLE OF CONTENTS, line 11 becomes "Miscellaneous Supplies".
Amendment #3	Page 3; Under section HYPOTHESIS, line 2, the word "a" after the word "mosquitoes" is deleted.
Amendment #4:	Page 6 Bullet 3 Line 2; the words "the test for attractancy is" follow the word "When".
Amendment #5:	Page 10; Under the section REMUNERATION, 2nd paragraph, line 5, the words "on the telephone, and" become "on the telephone, or".
Amendment #6:	Page 10; Under the section NEGATIVE CONTROL, 2nd paragraph, line 5, the words "to prevent these landings from turning into bites" are inserted after the words "as mosquitoes land".
Amendment #7:	Page 11; Section title MISCELLANEOUS becomes "MISCELLANEOUS SUPPLIES".
Amendment #8:	Page 18, line 5; the words "a flip of a coin" become "by drawing a name".

Aug. 8. 2007 3:00PM No. 1864 P. 4

Impact On The Study: These amendments change wording to clarify the intent of the protocol.

Submitted by: William J. Gaynor 8/3/07
Date

Acknowledged by QA: 8/3/07
Date

Acknowledged by:
Sponsor Representative 8/2/07
Date

Aug. 8. 2007 3:00PM No. 1864 P. 5

PROTOCOL: EVALUATION OF THE EFFICACY OF PERSONAL REPELLENTS AGAINST MOSQUITOES IN THE LABORATORY

INFORMED CONSENT AUTHORIZATION TO PARTICIPATE IN AN ICR, INC. MOSQUITO REPELLENT EVALUATION IN THE LABORATORY

Principal Investigator: Niketas C Spero
Address: ICR, Inc. 1330 Dillon Heights Ave. Baltimore, MD
Telephone Number: 410-747-4500
24 Hour Emergency Number: 410-371-7223

Purpose of Study
We (ICR, Inc.) have been contracted by an outside company ("Sponsor") to conduct a research study on two mosquito repellent products, to find out how well these products repel one species of laboratory-reared mosquitoes. This study will occur in the ICR, Inc. lab. where the mosquito repellent testing will occur in cages. Your participation will be strictly voluntary. We have prepared this Informed Consent Document (ICD) to explain this study to you. We will go over the ICD with you to ensure that you fully understand what would be expected of you if you participate, and explain any risks you may face through your participation. We will also use the following suitability checklist to determine if you qualify to participate in the study. Please ask us about anything you do not understand before deciding whether to participate in this study. Your signing of the ICD indicates your willingness to participate in this study, but if you are selected to participate, you would still be able to withdraw from the study at any time. If you have come into our office to review the ICD, you may take the ICD home with you if you need more time to think about whether to participate. If you decide to participate, sign the ICD in the presence of the person administering the ICD or other ICR study personnel, after which you will receive a signed copy.

Suitability Checklist for the Study
To be suitable to participate in this study you must meet the following conditions:

1. You must be between 18 and 55 years of age and consider yourself to be in good health.
2. You must be able to read, speak and understand English so you can follow directions.
3. You must not be pregnant or breastfeeding. Women will be required to perform an over-the-counter urine pregnancy test on the morning of the study. ICR will provide the test kit. A female ICR staff member will verify the results. ICR will keep the results of the pregnancy test confidential from everyone except you and the Principal Investigator (P.I.).

Test subject's initials:.....

Date:.....

4. You must not be an employee or a relative of an employee of ICR, Inc, the Sponsor, or any other interested party.
5. You must be willing to follow the requirements of the study as will be explained to you below.
6. You must have no known sensitivity to insect repellents or skin care products.
7. You must have been bitten by at least one mosquito in the past five years.
8. You must not be bothered with your reaction to mosquito bite(s).
9. You must not smoke or drink alcoholic beverages within 12 hours prior to the study.
10. You must not use perfumed cosmetics, skin creams, shaving lotions, etc. after midnight the day of the study until after that day's testing is completed.
11. You must be willing to wear proper protective clothing, as explained below, during the study.
12. You must be willing to provide your own transportation to the ICR lab.
13. You must be available to participate in the study for its maximum duration of one day.

Laboratory Repellent Phase Volunteers
There will be a total of 13 of you who will participate in the one-day laboratory study. One of you will be the control subject who will receive no treatment and will place one untreated arm in each test cage for up to one minute every one-half hour exposure period to monitor mosquito activity; at least five mosquitoes must land on the exposed arm within 60 seconds. After the control subject has verified that there was a satisfactory landing rate, the other 12 of you will place your treated arms in the cage with mosquitoes for five minutes every half hour until you receive two bites in one five-minute exposure period, or one bite in each of two successive exposure periods. The laboratory study will take one day, approximately 9 hours. If you are chosen to participate in this study, you will be paid for a total of one day as discussed below.

Procedures
Study Schedule Overview

Prior to the test:

1. We will discuss with you every line of the ICD. If you visit our Baltimore office, you may voluntarily sign the ICD at that time if you wish to be considered for participation in the study. If you do not want to visit our Baltimore office, we will mail the ICD to you, and fully discuss it with you via phone. You may subsequently sign the ICD but it must be in the presence of one of our study personnel.
2. We will notify you within one week whether we have selected you for participation.

If selected to participate in the laboratory study:

On the morning of the laboratory study at the ICR lab:

Test subject's initials:.....

Date:.....

1. You will wash your arms with unscented Neutrogena® soap.
2. We will measure and treat a 3 - 5 inch wide test area around both of your forearms as described below.

Laboratory Study Details

1. We will select one of you as a control subject, and the other 12 of you as treated test subjects.
2. We will use a felt tip pen to mark a 3 - 5 inch wide band around one of your forearms if you are a control subject and two forearms if you will be treated.
   We will determine the exact location of this band by measuring the distance around two locations of your forearm, i.e. a location near the wrist and another just below the elbow of the forearm.
3. We will protect the skin above and below this band from mosquito bites by using multiple layers of elastic bandages and or Velcro© straps held in place with adhesive tape.
4. If we have selected you as a treated test subject, we will cover the band on your forearms with the repellents using a syringe without the needle with an amount of repellent product similar to that which would normally be applied by consumers.
5. We will then put on a latex or vinyl glove, and using a finger tip, spread the repellent evenly over the treatment areas.
   Once we treat your arms, you must not rub them against anything, as this could rub off some of the test repellent and change the results.
6. We will mark your bandages with a letter identifying the repellent on that arm.
   We will not identify the repellents to you.
7. If we have selected you as a control test subject, you will receive no treatment.
8. You will all then go into the test laboratory and wait for your repellents to dry for one-half hour before you put on your gloves to begin the first five-minute exposure period of the day's study.
   Treated subjects: we will pair you with another treated test subject and tell you which cage to use. You will assist your partner in alerting him/her to mosquito landings on hard to see parts of his/her arms. When you see a mosquito land on you or your partner, you will notify ICR study personnel.
9. Control subjects will insert an untreated arm in each of the five test cages before the beginning of each five-minute exposure period for one minute, every half hour. We will count how long it takes for five mosquitoes to land on your untreated arm. If five mosquitoes do not land within 60 seconds, we will add 100 more mosquitoes to the cage. When you reach the required landing rate (5 landings within one minute), you will remove your arm from that cage.
   We will try to brush the mosquitoes away before they can probe or bite you.
10. Treated subjects: we will count the number of mosquitoes (up to two) which bite the

treated skin of either of your two arms during the five-minute exposure periods which occur every 30 minutes. When you receive two bites on the same arm in the same exposure period, or one bite in each of two consecutive exposure periods, you will remove that arm from the cage and cover that arm with your sleeve. This is called "breakdown". You will no longer expose that arm for the rest of the day's study. You will then be able to remove the bandages and tape, and scratch that arm. If you wish, you may use Caladryl®, Calamine® lotion or rubbing alcohol to help stop the itching from the bites you received. When you reach breakdown on both arms, you will have finished your part in the study and may go home.

11. At the end of each five-minute exposure period you will remain in the lab except for trips to the restroom or study director-lead breaks every few hours. You may either bring your own lunch or pay to have your lunch ordered.
12. The day's study will consist of five-minute exposure periods every half hour for up to 8 hours or until all treated test subjects have reached breakdown on both arms.

The study duration could be 9 hours: preparing your arms for the test, along with preparing the other test subjects, will take about one hour; exposures to mosquitoes will go on for up to 8 hours.

Discomfort and Hazard

In addition to sitting in a room maintained at 80° ± 15°F and 70% ± 15% relative humidity, conditions that can be uncomfortably warm, you may be exposed to two types of study-related hazards by participating in this study:

1. Mosquito bites or probes

   A bite occurs when a mosquito pierces your skin and takes blood. A probe is the same except it doesn't take blood. The irritation from a mosquito bite or probe may cause itching, redness or swelling that will usually disappear within a couple of days, or in severe cases may cause the development of large bumps on your skin, difficulty breathing, sweating and/or a rapid pulse. This could be life threatening.

   Although we will remove your arm from the cage if it receives two bites in one exposure period, or one bite in two successive exposure periods, it is possible you may receive more than two bites during the test. A bite which is not followed by another bite in the same or a succeeding exposure period will be disregarded. You will still need to receive two additional bites.

   If you are a treated test subject, we will only expose you to mosquitoes for five minutes every half hour. If you are the control test subject, we will only expose you to mosquitoes until five land on your arm within 60 seconds. We will also minimize the irritation from bites or probes you receive by making Caladryl® or Calamine®

lotion or rubbing alcohol available at the study site for your use after the study is completed. The mosquitoes we use in this test are laboratory reared and there is no possibility that they can carry disease.

2. Reaction to the test repellents

You may have a reaction to the test repellents.

The Sponsor has minimized this possibility by choosing an active ingredient (picaridin) which has demonstrated low acute oral, skin, and inhalation toxicity. The Environmental Protection Agency (EPA) has classified it as low toxicity for acute inhalation toxicity and primary skin irritation. The EPA has classified it as mild toxicity for eye irritation. The Sponsor has selected the inert ingredients in the formulation because these inerts are widely used in cosmetic formulations, and have a long history of safe use

Should you have any medical problems, we will have First Aid qualified staff members, as well as First Aid supplies, present on site. We will have cell phones to make emergency calls if necessary. In the case of medical emergency, we will transport you to a selected local hospital at our expense. We will pay all of your medical bills for study-related illnesses and injuries. The principal investigator will contact you by telephone, two weeks after the conclusion of the study to enquire if you have experienced any adverse effects. You should contact the P.I. if you experience any study-related adverse effects after this follow-up call.

Financial Consideration

We will pay you $99/day for an anticipated 9- hour work day. This payment will be mailed to you on the 15th or end of the month. If we ask you to drop out of the test, and you have complied with all of our requests, we will still give you full payment. If we ask you to drop out of the test because you have not followed all of our directions, or if you choose to drop out of the test, we will compensate you for time up to that point at the rate of $11 per hour.

Costs

There are no financial costs to you for participating in this study.

Benefits

While you will get no personal benefit from this study, the results of the study may help bring a new repellent to the market and thus provide consumers with a greater choice of repellents.

Your Rights

We will give you an opportunity to discuss with us any aspects of this ICD that are not clear to you

Test subject's initials:.....

Date:.....

so that you can fully understand the nature of the study, its purpose, and the procedures to be used, together with the discomforts, risks or other adverse effects you may experience during or after the study. Your participation is voluntary. You may refuse to take part in this study or quit at any time without penalty or loss of benefits to which you may be otherwise entitled. If after reading this ICD you sign it to signify your agreement, we will give you a copy for your files.

Alternative
Your only alternative to participating is to not do so.

Questions
If you have any questions about this study or suffer a reaction potentially associated with the study, call us at 410-747-4500. If you have any questions about your rights as a research participant, or related concerns, you may contact the Essex Institutional Review Board (IRB), 121 Main Street, Lebanon, NJ 08833, and its telephone is 908-236-7735. Essex IRB is a committee that has reviewed this research project to help ensure that the rights and welfare of the participants are protected and that the study is carried out in an ethical manner. Review of this study by Essex IRB is not an endorsement of the study or its outcome.

Confidentiality
We and our sponsor may use the information obtained from your taking part in this test, and this information may become part of a report. We will keep this report as confidential as possible under local, state and federal law. We will reference only your first and last initials and your dedicated identity number in the report. However, we cannot guarantee that your identity will be kept confidential; the sponsor, personnel associated with the study, a regulatory agency such as the Environmental Protection Agency (EPA), and the Essex Institutional Review Board (EIRB) have a right to review your records.

Consent
I voluntarily agree to participate in this study. I will be given a copy of this signed form.
I am 18 to 55 years of age. By signing this form I have not given up my legal rights.

Signature of Subject	Date	Signature of Witness	Date
Printed Name of Subject	Date		
Signature of Principal Investigator	Date		

IRB Approval Documentation

eirb

Essex Institutional Review Board, Inc.
121 Main Street • Lebanon, New Jersey 08833
Telephone (908) 236-7735 • Fax (908) 236-2027
www.essexirb.com

August 7, 2007

Niketas C. Spero,
Insect Control & Research, Inc.
1330 Dillon Heights Avenue
Baltimore, MD 21228

Dear Dr. Spero:

The Essex Institutional Review Board, Inc. reviewed the Avon Products, Inc. clinical research project, "Evaluation of the Efficacy of Personal Repellents Against Mosquitoes in the Laboratory" (G0590607001A117, 6/12/07, Amends. #1-8, 8/2/07).

The Protocol (dated 6/12/07) reviewed by a full board, was conditionally approved on July 30, 2007. The Amendments to the Protocol, #1-8 (dated 8/2/07) were approved on August 6, 2007. The Essex Institutional Review Board, Inc. has determined that the proposal meets the IRB requirements for safety and ethical standards. Approval to conduct the study expires on August 6, 2008 based on the degree of risk.

Your Informed Consent (dated 8/2/07) reviewed by a full board, and Research Site located at 1330 Dillon Heights Avenue, , Baltimore, MD were approved on August 7, 2007. Approval for this site expires on August 7, 2008.

Risks to subjects were determined to be reasonable and minimized, based on review of the study design, anticipated results, Investigator's Brochure (if it was submitted), reports of any data and safety monitoring (if available) and balancing research versus therapeutic activities and potential benefits to the participants.

Essex requests that you forward a study summary, including adverse reactions, within 90 days of study termination. In any event, reports must be made at intervals not exceeding one year. Any serious or unexpected experiences must be reported to the Board promptly. Enclosed is our brochure detailing your responsibilities associated with this research study.

The Essex Institutional Review Board is in compliance with the federal regulations of the National Institute of Health and Office of Human Research Protection (OHRP) effective August 19, 1991 (45 CFR 46). The Board is also in compliance with the federal regulations of the Food and Drug Administration effective July 27, 1981, and with all amendments thereto, contained in Title 21 of the Code of Federal Regulations, Parts 50 and 56. The OHRP Assurance Number is 1742. A Statement of Compliance and Board Member listing are attached for your files.

Sincerely,

Loretta P. Szczepanski, RN

Loretta P. Szczepanski, RN
Vice-Chairperson

klr

ICR, INCORPORATED
1330 Dillon Heights Avenue
Baltimore, MD 21228
Telephone: (410) 747-4500
Fax: (410) 747-4928

RECEIVED
AUG 0 6 2007
Essex Institutional Review Board, Inc.

Protocol Amendments

APPROVED
AUG 0 6 2007
Essex Institutional Review Board, Inc.

Project Number:	0607-059-0157
Protocol Number:	G0590607001A117
Sponsor:	Avon Products, Inc.
Test Article(s):	TA# 1001108-030 and TA# 1004024-010
GLP Compliance:	40 CFR 160
Amendment #1:	The PROTOCOL VERSION DATE becomes August 02, 2007.
Amendment #2:	Page 2; Under the section TABLE OF CONTENTS, line 11 becomes "Miscellaneous Supplies".
Amendment #3	Page 3; Under section HYPOTHESIS, line 2, the word "a" after the word "mosquitoes" is deleted.
Amendment #4:	Page 6 Bullet 3 Line 2; the words "the test for attractancy is" follow the word "When".
Amendment #5:	Page 10; Under the section REMUNERATION, 2nd paragraph, line 5, the words "on the telephone, and" become "on the telephone, or".
Amendment #6:	Page 10; Under the section NEGATIVE CONTROL, 2nd paragraph, line 5, the words "to prevent these landings from turning into bites" are inserted after the words "as mosquitoes land".
Amendment #7:	Page 11; Section title MISCELLANEOUS becomes "MISCELLANEOUS SUPPLIES".
Amendment #8:	Page 18, line 5; the words "a flip of a coin" become "by drawing a name".

Impact On The Study: These amendments change wording to clarify the intent of the protocol.

Submitted by: William J. Gaynor 8/3/07
Date

Acknowledged by QA: 8/3/07
Date

Acknowledged by:
Sponsor Representative 8/2/07
Date

APPROVED
Essex Institutional Review Board, Inc.

PROTOCOL: EVALUATION OF THE EFFICACY OF PERSONAL REPELLENTS AGAINST MOSQUITOES IN THE LABORATORY

INFORMED CONSENT AUTHORIZATION TO PARTICIPATE IN AN ICR, INC. MOSQUITO REPELLENT EVALUATION IN THE LABORATORY

Principal Investigator: Niketas C Spero
Address: ICR, Inc. 1330 Dillon Heights Ave. Baltimore, MD
Telephone Number: 410-747-4500
24 Hour Emergency Number: 410-371-7223

APPROVED
ESSEX I.R.B.
AUG 07 2008
SITE APPROVAL EXPIRES ON ABOVE DATE

Purpose of Study

We (ICR, Inc.) have been contracted by an outside company ("Sponsor") to conduct a research study on two mosquito repellent products, to find out how well these products repel one species of laboratory-reared mosquitoes. This study will occur in the ICR, Inc. lab. where the mosquito repellent testing will occur in cages. Your participation will be strictly voluntary. We have prepared this Informed Consent Document (ICD) to explain this study to you. We will go over the ICD with you to ensure that you fully understand what would be expected of you if you participate, and explain any risks you may face through your participation. We will also use the following suitability checklist to determine if you qualify to participate in the study. Please ask us about anything you do not understand before deciding whether to participate in this study. Your signing of the ICD indicates your willingness to participate in this study, but if you are selected to participate, you would still be able to withdraw from the study at any time. If you have come into our office to review the ICD, you may take the ICD home with you if you need more time to think about whether to participate. If you decide to participate, sign the ICD in the presence of the person administering the ICD or other ICR study personnel, after which you will receive a signed copy.

Suitability Checklist for the Study

To be suitable to participate in this study you must meet the following conditions:

1. You must be between 18 and 55 years of age and consider yourself to be in good health.
2. You must be able to read, speak and understand English so you can follow directions.
3. You must not be pregnant or breastfeeding. Women will be required to perform an over-the-counter urine pregnancy test on the morning of the study. ICR will provide the test kit. A female ICR staff member will verify the results. ICR will keep the results of the pregnancy test confidential from everyone except you and the Principal Investigator (P.I.).

Test subject's initials:.....

Date:.....

4. You must not be an employee or a relative of an employee of ICR, Inc, the Sponsor, or any other interested party.
5. You must be willing to follow the requirements of the study as will be explained to you below.
6. You must have no known sensitivity to insect repellents or skin care products.
7. You must have been bitten by at least one mosquito in the past five years.
8. You must not be bothered with your reaction to mosquito bite(s).
9. You must not smoke or drink alcoholic beverages within 12 hours prior to the study.
10. You must not use perfumed cosmetics, skin creams, shaving lotions, etc. after midnight the day of the study until after that day's testing is completed.
11. You must be willing to wear proper protective clothing, as explained below, during the study.
12. You must be willing to provide your own transportation to the ICR lab.
13. You must be available to participate in the study for its maximum duration of one day.

Laboratory Repellent Phase Volunteers

There will be a total of 13 of you who will participate in the one-day laboratory study. One of you will be the control subject who will receive no treatment and will place one untreated arm in each test cage for up to one minute every one-half hour exposure period to monitor mosquito activity; at least five mosquitoes must land on the exposed arm within 60 seconds. After the control subject has verified that there was a satisfactory landing rate, the other 12 of you will place your treated arms in the cage with mosquitoes for five minutes every half hour until you receive two bites in one five-minute exposure period, or one bite in each of two successive exposure periods. The laboratory study will take one day, approximately 9 hours. If you are chosen to participate in this study, you will be paid for a total of one day as discussed below.

Procedures

Study Schedule Overview

Prior to the test:

1. We will discuss with you every line of the ICD. If you visit our Baltimore office, you may voluntarily sign the ICD at that time if you wish to be considered for participation in the study. If you do not want to visit our Baltimore office, we will mail the ICD to you, and fully discuss it with you via phone. You may subsequently sign the ICD but it must be in the presence of one of our study personnel.
2. We will notify you within one week whether we have selected you for participation.

If selected to participate in the laboratory study:

On the morning of the laboratory study at the ICR lab:

Test subject's initials:.....

Date:.....

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Essex Institutional Review Board, Inc.

1. You will wash your arms with unscented Neutrogena® soap.
2. We will measure and treat a 3 - 5 inch wide test area around both of your forearms as described below.

Laboratory Study Details

1. We will select one of you as a control subject, and the other 12 of you as treated test subjects.
2. We will use a felt tip pen to mark a 3 - 5 inch wide band around one of your forearms if you are a control subject and two forearms if you will be treated.
   We will determine the exact location of this band by measuring the distance around two locations of your forearm, i.e. a location near the wrist and another just below the elbow of the forearm.
3. We will protect the skin above and below this band from mosquito bites by using multiple layers of elastic bandages and or Velcro© straps held in place with adhesive tape.
4. If we have selected you as a treated test subject, we will cover the band on your forearms with the repellents using a syringe without the needle with an amount of repellent product similar to that which would normally be applied by consumers.
5. We will then put on a latex or vinyl glove, and using a finger tip, spread the repellent evenly over the treatment areas.
   Once we treat your arms, you must not rub them against anything, as this could rub off some of the test repellent and change the results.
6. We will mark your bandages with a letter identifying the repellent on that arm.
   We will not identify the repellents to you.
7. If we have selected you as a control test subject, you will receive no treatment.
8. You will all then go into the test laboratory and wait for your repellents to dry for one-half hour before you put on your gloves to begin the first five-minute exposure period of the day's study.
   Treated subjects: we will pair you with another treated test subject and tell you which cage to use. You will assist your partner in alerting him/her to mosquito landings on hard to see parts of his/her arms. When you see a mosquito land on you or your partner, you will notify ICR study personnel.
9. Control subjects will insert an untreated arm in each of the five test cages before the beginning of each five-minute exposure period for one minute, every half hour. We will count how long it takes for five mosquitoes to land on your untreated arm. If five mosquitoes do not land within 60 seconds, we will add 100 more mosquitoes to the cage. When you reach the required landing rate (5 landings within one minute), you will remove your arm from that cage.
   We will try to brush the mosquitoes away before they can probe or bite you.
10. Treated subjects: we will count the number of mosquitoes (up to two) which bite the

Test subject's initials:.....

Date:.....

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Essex Institutional Review Board, Inc.

treated skin of either of your two arms during the five-minute exposure periods which occur every 30 minutes. When you receive two bites on the same arm in the same exposure period, or one bite in each of two consecutive exposure periods, you will remove that arm from the cage and cover that arm with your sleeve. This is called "breakdown". You will no longer expose that arm for the rest of the day's study. You will then be able to remove the bandages and tape, and scratch that arm. If you wish, you may use Caladryl®, Calamine® lotion or rubbing alcohol to help stop the itching from the bites you received. When you reach breakdown on both arms, you will have finished your part in the study and may go home.

11. At the end of each five-minute exposure period you will remain in the lab except for trips to the restroom or study director-lead breaks every few hours. You may either bring your own lunch or pay to have your lunch ordered.
12. The day's study will consist of five-minute exposure periods every half hour for up to 8 hours or until all treated test subjects have reached breakdown on both arms.

The study duration could be 9 hours: preparing your arms for the test, along with preparing the other test subjects, will take about one hour; exposures to mosquitoes will go on for up to 8 hours.

Discomfort and Hazard

In addition to sitting in a room maintained at 80° ± 15°F and 70% ± 15% relative humidity, conditions that can be uncomfortably warm, you may be exposed to two types of study-related hazards by participating in this study:

1. Mosquito bites or probes

   A bite occurs when a mosquito pierces your skin and takes blood. A probe is the same except it doesn't take blood. The irritation from a mosquito bite or probe may cause itching, redness or swelling that will usually disappear within a couple of days, or in severe cases may cause the development of large bumps on your skin, difficulty breathing, sweating and/or a rapid pulse. This could be life threatening.

   Although we will remove your arm from the cage if it receives two bites in one exposure period, or one bite in two successive exposure periods, it is possible you may receive more than two bites during the test. A bite which is not followed by another bite in the same or a succeeding exposure period will be disregarded. You will still need to receive two additional bites.

   If you are a treated test subject, we will only expose you to mosquitoes for five minutes every half hour. If you are the control test subject, we will only expose you to mosquitoes until five land on your arm within 60 seconds. We will also minimize the irritation from bites or probes you receive by making Caladryl® or Calamine®

Test subject's initials:.....

Date:.....

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lotion or rubbing alcohol available at the study site for your use after the study is completed. The mosquitoes we use in this test are laboratory reared and there is no possibility that they can carry disease.

2. Reaction to the test repellents
   You may have a reaction to the test repellents.

   The Sponsor has minimized this possibility by choosing an active ingredient (picaridin) which has demonstrated low acute oral, skin, and inhalation toxicity. The Environmental Protection Agency (EPA) has classified it as low toxicity for acute inhalation toxicity and primary skin irritation. The EPA has classified it as mild toxicity for eye irritation. The Sponsor has selected the inert ingredients in the formulation because these inerts are widely used in cosmetic formulations, and have a long history of safe use

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Costs
There are no financial costs to you for participating in this study.

Benefits
While you will get no personal benefit from this study, the results of the study may help bring a new repellent to the market and thus provide consumers with a greater choice of repellents.

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Consent
I voluntarily agree to participate in this study. I will be given a copy of this signed form.
I am 18 to 55 years of age. By signing this form I have not given up my legal rights.

Signature of Subject Date

Signature of Witness Date

Printed Name of Subject Date

Signature of Principal Investigator Date

APPROVED
Essex Institutional Review Board, Inc.

Supplemental IRB Information

eirb

Essex Institutional Review Board, Inc.
121 Main Street • Lebanon, New Jersey 08833
Telephone (908) 236-7735 • Fax (908) 236-2027
www.essexirb.com

MEMBERS

Philip B. Carr-Jones, M Div
Episcopal Priest

Loretta P. Szczepanski, RN
EIRB Vice-Chairperson
Registered Nurse

Glenn P. Lambert, MD, FAAP
EIRB Chairman
Pediatrician

Tom Ollis, R Ph
EIRB Vice-Chairman
Pharmacist

Thomas G. McElrath, MD
Obstetrician/Gynecologist

Deborah A. Timmerman
Office Administrator

Nancy Maulding
Mathematician

ALTERNATE MEMBERS

John Castro
Engineer/Airline Pilot

Sandra S. Sullivan, OTR
Occupational Therapist

Louise M. Dougherty, RN
Registered Nurse

Jorshinelle T. Sonza, PhD
Playwright/Writer

Vassie C. Ware, PhD
Molecular Biologist

Harry M. Woske, MD
Cardiologist

William C. Waggoner, PhD
FAACT (Ex Officio)
Medical Ethicist

James L. Harris
Chemist/Business Manager

10/2006

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Essex Institutional Review Board, Inc.
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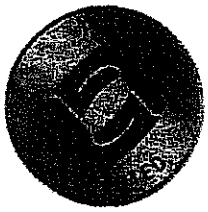

Ellen Quinn
Associate Director, Administration
Insect Control & Research, Inc.
1330 Dillon Heights Avenue
Baltimore, MD 21228

Re: Essex IRB Members

Dear Ellen:

Per your request for the profiles of the members of the Essex IRB, I enclose the following information:

Members:

Glenn P. Lambert, MD, FAAP: BS; Chairman; Board-Certified in Pediatrics, 29 years of IRB experience, full-time employee for 7 years

Loretta P. Szczepanski, RN; Vice-Chairperson; BSN, MA/Administration, CNA, Registered Nurse; retired Director of Patient Care Services Hunterdon Medical Center; 5 years on Board

Philip B. Carr-Jones, BA, M Div; Episcopal Priest; 14 years on Board

Deborah A. Timmerman: HS degree; homemaker, bookkeeper/secretary/office manager; 13 years on Board

Tom Ollis, R Ph; BS, MA of Administrative Science; hospital pharmacist; 5 years on Board

Thomas G. McElrath, MD, FACOG; Ob/Gyn specialist; 3 years on Board

Nancy Maulding, BS, MAT; Professor of Mathematics; 2 years on Board

Alternate Members:

Louise M. Dougherty, RN, BSN, MS in Education; Public Health Nurse; 5 years on Board

~~John Castro, BS Engineering; Airline Pilot; 2 years on Board~~

Sandra S. Sullivan, OTR, BS; Occupational Therapist; 2 years on Baord

Jorshinelle T. Sonza, PhD; Playwright and author; BA, MA, PhD in English and Comparative Literature; 4 years on Board

Vassie C. Ware, PhD, BA, MPhil; Professor of Molecular Biology, Lehigh University; 6 years on Board

Harry M. Woske, MD; FACC, FACP; AB; Cardiologist; 5 years on Board

James L. Harris, BS, MBA; Chemist/Business Manager; 1 year on Board

William C. Waggoner, PhD, FAACT, AB, MS; Toxicologist, medical ethicist, CEO/President of Essex IRB; Board chairman from 1981 to 1999; on Board as an ex officio member for 3 years

Other than the Chairman and Dr. Waggoner, no Board member is an employee of Essex IRB. Dr. Waggoner is the principal stockholder/ owner of Essex IRB and does not participate in the review and approval of any studies. One member has an equity holding in one pharmaceutical company that requires her to be recused from any deliberations concerning trials submitted by that sponsor.

Essex IRB has established and follows written procedures for conducting its initial and continuing review of research and for reporting its findings, recommendations and actions to the investigator and the institution.

If there is any additional information you need, please let me know.

Thank you for using Essex IRB for your studies.

Sincerely,

Glenn P. Lambert, MD

Glenn P. Lambert, MD, FAAP
Chairman

Sponsor: Avon Products, Inc.
Protocol #: G0590607001A117

STATEMENT OF COMPLIANCE
(USA)

Name of IRB: **The Essex Institutional Review Board**
Address: **121 Main Street**
Lebanon, NJ 08833

The Essex Institutional Review Board is duly constituted (fulfilling FDA and OHRP requirements for diversity), allows only those IRB/IEC members who are independent of the investigator and sponsor of the trial to vote/provide opinion on the trial, has written procedures for initial and continuing review of clinical trials, prepares written minutes of convened meetings, and retains records pertaining to the review and approval process; all in compliance with the requirements defined in 21 CFR (Code of Federal Regulations) parts 50, 56 and 312, 45 CFR 46 and the International Conference on Harmonisation (ICH) guidance relating to Good Clinical Practice (GCP).

Loretta P. Szczepanski, RN.
Signature of IRB Chairperson or Designee

August 7, 2007
Date of Signature

Loretta P. Szczepanski, RN, Vice-Chairperson
Printed Name