INDEPENDENT INVESTIGATIONAL REVIEW BOARD INC.

SITE QUESTIONNAIRE

NON-LOCAL REVIEW

Protocol # & Complete Study Title: **(SCI-001) Test of Personal Insect Repellents**

Principal Investigator: Scott P. Carroll, Ph.D

Sub Investigator(s): None

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

Site Address: Carroll-Loye Biological Research
711 Oak Avenue
Davis, CA 951616 USA

PI's Mailing Address: _____
(If different) _____

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

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

Office Phone: 530-297-6080 24 Hour Phone: 530-297-6080

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

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

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

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

   If yes, describe procedures to be followed (if applicable): Our subjects are mainly University of California–Davis graduate and undergraduate students in life science programs with which the Principal Investigator is associated. Students in his laboratory who depend on him directly for employment or scholastically are not eligible to participate.

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

5. Indicate the approximate demographics of your site's anticipated subject population:
5 % African American 65 % Caucasian 15 % Hispanics 15 % Asian <1 % Other

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

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

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

8. Describe the setting(s) where the study will be conducted (ie, private office, clinic, hospital environment) and if the Investigator is required to seek any type of administrative or Corporate approval in order to implement the study:
Private Laboratory owned by Principal Investigator.

*If being done in a Hospital or Outpatient Surgery Center, please provide a copy of that facility's License/accreditation and/or Hospital IRB Waiver Form.

9. Distance between the nearest hospital and research site: 1.8 miles from Laboratory, within 25 miles of field sites.

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

11. How long has the PI been conducting clinical research? 17 years 1 months

12. Within the past 3 years has the FDA/OHRP audited your site/Principal Investigator? X No ☐ Yes*
**If yes, please provide a copy* of all 483's *and any applicable correspondence.*

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

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

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

Subject Compensation:

Will subject be paid for participation in this study? ☐ No X Yes*
**If yes, please specify the total amount, the amount for each visit and the timing of payment (i.e. at each visit, at the last visit, within 2 weeks of the last visit) in the draft Informed Consent Form.*

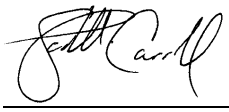
Site Specific Informed Consent Form Information

Is there any additional wording needed in the Informed Consent Form? X No X Yes*
**If yes, please specify the section and additional wording below.*
Already present in attached draft form.
_____
_____

Investigator Acknowledgment

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

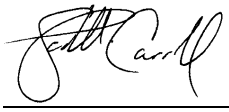
Scott P. Carroll
Print name of individual completing Site Questionnaire



Signature of individual completing Site Questionnaire

3 November 2006
Date

Scott P. Carroll
Print Name of Principal Investigator



Signature Principal Investigator

7 November 2006
Date

Please contact the Independent IRB, if you have any questions regarding this questionnaire 954.327.0778