Single Site Study Submission Form

1. Submission requirements: Visit the Submit Study page of the Schulman website for detailed submission requirements.

2. Submission instructions: Submit via Secure eSubmission or email to Submissions@sairb.com

3. Canadian Studies: Visit the Research in Canada page of the Schulman website for provincial review restrictions.

SECTION 1.0: General Information

1. Protocol Number: 18/011

2. Acronym: **3. Indication:** Pesticide

4. Sponsor: Pulcra Chemicals

5. CRO (if applicable)**:**

6. This study is classified as: More than Minimal Risk ☐ Phase 1 ☐ Phase 2 ☐ Phase 3 ☐ Phase 4 ☑ N/A

a. Does this study involve first-time administration of investigational new drug/biologic in human subjects?

7. Qualifying studies will be reviewed in an expedited manner by Minimal Risk Review (MRR) rather than by the full Board. If this study qualifies, may Schulman review by MRR? Yes

8. Please provide the protocol number(s) of any similar/related protocols previously reviewed by Schulman:

16/231, 17/460

9. Principal/Qualified Investigator (PI/QI) Name:

First: Timothy **Middle:** **Last:** Foard **Credentials:** M.S.

10. Primary Site:

Site Name: i2LResearch USA, Inc.
Address: 1430 Joh Avenue Suite M
City: Baltimore
State/Province: MD **Zip/Postal Code:** 21227 **Country:** United States
Site Phone: 410-747-4500
Email: timothy@i2lresearch.com

a. How would you like the Office Phone Number to appear on IC (Optional) ?

410-747-4500

b. How would you like the 24-hour Phone Number to appear on IC (Required) ?

202-905-1401

11. Will the research or study-related procedures be conducted at additional locations under the same PI/QI ? No

If Yes **>>>** Submit an Additional Site Location Form for each additional location.

SECTION 2.0: Site Contact Information

Single Site Study Submission Form

1. Primary Site Contact:

Name: Jennifer Hostetler
Title: Study Director, QAU, and Technical Writer
Company: i2LResearch USA, Inc.
Address: 1430 Joh Avenue Suite M **City:** Baltimore
State/Province: MD **Zip/Postal Code:** 21227 **Country:** US
Phone: 4107474500
Email: jen@i2lresearch.com

2. Secondary Site Contact (optional):

Name:
Title:
Company:
Address: **City:**
State/Province: **Zip/Postal Code:** **Country:**
Phone:
Email:

NOTE: Site contacts receive Schulman SiteAccess in order to download IRB documents and review status information.

SECTION 3.0: Study Contact & Billing Information

1. Sponsor Contact:

Name: Luther Dasher
Title: Sponsor Representative
Company: Pulcra Chemicals
Address: 474 Bryant Blvd. **City:** Rock Hill
State/Province: SC **Zip/Postal Code:** 29732 **Country:** US
Phone: 803-325-8533
Email: ldasher@pulcrachem.com

2. CRO Contact

Name: Kristine Styer
Title: Executive Director
Company: i2LResearch USA, Inc.
Address: 1430 Joh Avenue Suite M **City:** Baltimore
State/Province: MD **Zip/Postal Code:** 21227 **Country:** US
Phone: 4107474500
Email: Kristine@i2lresearch.com

NOTE: Study contacts receive Schulman SiteAccess or WebPortal™3D access to review status information and download IRB documents.

3. *Party responsible for Schulman service fees:

Name: Cheryl Tinelli
Title: Bookkeeper
Company: i2LResearch USA, Inc.
Address: 1430 Joh Avenue Suite M **City:** Baltimore
State/Province: MD **Zip/Postal Code:** 21227 **Country:** US
Phone: 4107474500
Email: Cheryl@i2lresearch.com

4. Please send invoices via: ☑ Email OR ☐ Hard Copy **Purchase Order Number** (if applicable): 18/011

*If there are additional contacts for US studies or separate contacts for Canadian studies, attach the additional contact information.

SECTION 4.0: Study Information

1. What is the source of funding for this study? Check all that apply:

☐ Pharmaceutical or Medical Device Company

☐ Not-for-Profit Sponsor

☐ US Government >>> Please Complete a. through b.:

☑ Other: Pesticide-treated fabric formulator

a. Please specify the funding agency:

b. Has the IRB reviewed the grant application for the version of the protocol being submitted?

If No >>> Submit the grant for review by Schulman IRB.

2. Does this study involve an investigational new drug or biologic OR the investigational use of a marketed drug or biologic? No -

If Yes >>> Please complete **a.** through **c.** for US studies or **d.** and **e.** for Canadian studies:

US study: a. What is the IND number?

b. If this is a Phase 1 or 2 study, please provide the date of the IND submission to the FDA:

**** IND has NOT been submitted to the FDA:** ☐

☐ By checking here, the sponsor/CRO/site agrees to comply with FDA guidelines and control release of the study drug so it is not available to study sites until day 31 after the IND submission or release by the FDA and any questions from the FDA have been answered (if applicable).

Note: sponsors have responsibilities to submit to the FDA protocols that will be conducted under an existing IND as noted in 21 CFR 312.30.

c. Does this study include an off-label use of an FDA approved drug?

If yes, indicate whether the off-label is subject to the IND regulations or whether it is exempt from the IND regulations because such use satisfies all criteria of 21 CFR 312.2. Please provide copies of all relevant FDA documentation.

Canadian study: d. What is the CTA Control Number?

e. If this is a Phase 1, 2, or 3 study, please provide:

☐ A copy of the No Object Letter (NOL) **OR** The date of submission to Health Canada:

NOTE: Schulman will review Canadian studies at any time, however final approval cannot be granted until the NOL letter is provided.

3. Is this study under the jurisdiction of the U.S. Environmental Protection Agency (EPA)? Yes

4. Does this study involve the use of an investigational device? No

If Yes, complete **a.** through **c.**

a. Does the study involve an investigational in vitro diagnostic device (IVD)?

b. Select one of the following and attach the applicable documentation:

- ○ FDA letter granting an Investigational Device Exemption (IDE) for the proposed use;
- ○ Letter from the Sponsor stating that the test article is a non-significant risk device; or
- ○ *Letter explaining why the investigation is exempt from the IDE requirements under 21 CFR 812.2 (c).
- ○ Letter stating that the IVD is a Laboratory Developed Test (LDT) meaning that it is designed, manufactured, and used within a single laboratory. (FDA has exercised enforcement discretion with respect to LDTs.)

* This letter must be provided for your study to qualify for expedited review (MRR).

c. Will subject-specific results from the test be reported from the laboratory, and will or could the results be used for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, individual subjects?

If Yes **>>>** Does the laboratory have a CLIA certification that covers the tes

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****Does this study involve a Study Product other than a drug, biologic, or device?** Yes

Pesticide-treated fabric

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5. Does this study involve the dispensing of a controlled substance which comes under the jurisdiction of federal/state/provincial laws regulating its manufacture, sale, distribution, use, and disposal? No

If Yes **>>>** Please complete **a.** through **c.** for US studies or **d.** and **e.** for Canadian studies:

US study: a. What is the generic name of the controlled substance?

b. The controlled substance is Class:

c. Attached is a copy of the DEA registration or controlled substance license for each investigator prescribing and/or dispensing the controlled substance.

Canadian study: d. What is the generic name of the controlled substance?

e. Attached are copies of the Letter of Exemption under the Controlled Drugs and Substances Act and Regulations and Letter of Authorization permitting the controlled substance to be shipped to the QI.

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6. Does this study involve the use of a placebo control? No

If Yes **>>>** Please complete **a.** through **d.**:

a. Is there standard treatment for the indication(s) being studied? No

b. Is the targeted population refractory to standard treatment AND there exists no standard second-line treatment for this targeted population? No

c. Is the study testing add-on treatment to standard therapy such that all subjects will receive all treatments that would normally be prescribed? No

d. Does the informed consent document (IC) fully inform subjects of the reasons why a placebo-controlled study design is necessary? No

NOTE: Responses must be substantiated by protocol text and, where applicable, informed consent text.

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7. Does this study involve infectious disease explicitly required by the protocol or at the Investigator's discretion

☐ By checking here, the site agrees to comply with local laws and regulations regarding infectious disease. No

NOTE: Schulman recommends that sites consult with local health officials and/or legal counsel for assistance with local laws and regulations pertaining to infectious disease.

8. Does this study involve a sub-study and/or additional research activities that affect a subset of subjects? No

If Yes >>> Refer to the Sub-Study/Additional Research Submission Form at the end of this form.

9. Does this study involve a Data Safety Monitoring Board or Committee? No

If Yes >>> Please complete **a.** through **b.**:

a. Attach the data monitoring plan or indicate the protocol section(s) where this information is located:

☐ Data monitoring plan attached **OR** ☐ This information is located in protocol section(s)

b. ☐ By checking here, the site agrees to submit to Schulman routine data and safety monitoring reports within ten (10) days of availability and urgent data and safety monitoring reports within twenty-four (24) hours of availability.

SECTION 5.0: Research Site Information

1. Describe the primary site facility:

☑ Dedicated Research Facility
☐ Surgery Center >>> Submit a Research Oversight Jurisdiction Form
☐ Private Practice
☐ Nursing Care Facility >>> Submit a Research Oversight Jurisdiction Form
☐ Free-standing Psychiatric Facility
☐ Hospice >>> Submit a Research Oversight Jurisdiction Form
☐ Public Health Clinic
☐ Hospital or Hospital System Owned or Affiliated >>> Submit a Research Oversight Jurisdiction Form
If checked, provide the name of the hospital system or parent organization:

☐ University/Academic Medical Center Owned or Affiliated >>> Submit a Research Oversight Jurisdiction Form
If checked, provide the name of the university/academic medical center or parent organization:

☐ Other:

2. Is the primary site under the jurisdiction of or affiliated with another IRB/REB or human research protection program (HRPP)? No

If Yes >>> Please submit a Research Oversight Jurisdiction Form if not previously completed.

3. In additional to access to 911, what resources are available at the primary site for subjects in need of emergency ? Check all that apply:

☑ ACLS certified staff
☐ Automatic external defibrillator
☐ Crash cart with emergency medications
☐ Other (specify):
☑ CPR certified staff
☐ On-Site paramedics
☐ None

4. How far is the nearest hospital from the primary site?

Distance: 1.5 miles **Or** Travel Time: **Or** ☐ Site is a hospital or located on hospital campus

5. Has the site or PI/QI previously submitted to another IRB/REB for review of this study? No

If Yes >>> Please complete **a.** and **b.**:

a. Was it disapproved or withdrawn? No

If Yes **>>>** Submit written documentation of the disapproval or withdrawal.

b. Was it approved and closed by another IRB? No

If Yes **>>>** Submit written documentation/explanation of closure

c. Are you requesting transfer of IRB oversight? No

If Yes **>>>** Submit a Transfer of IRB Form.

6. Are there any state, provincial or local laws governing research at the site which extend requirements for this study beyond those established by federal regulations and/or Schulman IRB? No

If Yes **>>>** Provide an explanation:

NOTE: If unsure, please contact a healthcare attorney or your local, state or provincial government.

7. Are there negative attitudes in the community (e.g. religious, ethical or economic) that affect the conduct of research at the site? No

If Yes **>>>** Provide an explanation:

8. Does the site agree to use the following precautions to maintain confidentiality and security of records, as they apply to this study?

☑ Paper records are kept in a secure location and will be accessible only to authorized personnel involved in this study

☑ Computer records are accessible only to authorized personnel involved in the study through access privileges and passwords

☐ Site staff members sign agreements to protect the security and confidentiality of identifiable health information

☑ Whenever feasible, identifiers will be removed from study-related information

Provide an explanation:

9. Does the site agree to use the following precautions to maintain subject privacy, as they apply to this study?

☑ Discussion of health-related information in a private room

☐ Adherence to applicable privacy laws (e.g., HIPAA/Omnibus Rules, PIPEDA)

☐ Consideration of parental inclusion in the visits if the study involves children

☐ Consideration of parental absence in the visits if the study involves teens

Provide an explanation:

10. Is this study conducted under an FWA (Federalwide Assurance) at the primary or any additional site location? No

If Yes **>>>** Complete **a**. and **b**.:

a. Submit an IRB Authorization Agreement or equivalent

b. In Section 6.0 include all key study personnel working on the project in addition to the PI/QI and Sub-Is.

NOTE: Consider all sites that may be involved in the conduct of the research where an FWA may apply. Refer to the Submit FWA Study page of the Schulman website for additional submission requirements.

SECTION 6.0: Research Experience, Education & Training

Please list the PI/QI and all Sub-Is for this study and indicate the clinical research experience (in years) and human researc subject protection education and training for each. For federally funded studies and/or research under an FWA, also list key personnel working on the project. Submit supplement sheets if necessary to list all individuals.

* Curriculum Vitae (CV) must reflect experience, be signed and dated within the past 2 years.

Role	Name (First Last)	*Experience CV is:	Education & Training

PI/QI	Timothy Foard	Upload Now	☐ Reviewed FDA Information Sheets, TCPS Tutorial(CAN), GCP Guidelines and the Belmont Report ☐ Attended educational seminar(s) or received training on human subject protection provided by the sponsor/CRO/research site or other entity ☑ Completed formal education/training in human subject protection via web-based or published modules (e.g NIH, OHRP video training series or CITI) ☐ Human subject protection training has not yet been completed, but is scheduled to be completed prior to study initiation at the site ☐ Other:

SECTION 7.0: Informed Consent

**** Does your study design involve a Request for Waiver of Informed Consent?** No

**** Does your study design involve the collection of Protected Health Information (PHI)?**

1. Will compensation for study participation or reimbursement for expenses be provided? Yes

If Yes **>>>** Provide the details to be included in the IC by completing **a.** through **c.**:

a. Who will receive compensation / reimbursement? Check all that apply:

☑ Adult Subjects ☐ Minor Subjects and/or their Parents/Guardians ☐ Caregivers ☐ Other:

b. Attach or describe the visit compensation/reimbursement schedule Describe

Examples of visit types that should be addressed are:

•Screening	•Completed	•Inpatient/Confinement	•Telephone
•Unscheduled	•Optional	•Sub-study	•Subjects serving as alternates

NOTE: To avoid delays in processing, refer to the visit schedule in the study protocol to ensure all visits are addressed.

Please describe:

$30 for each training session attended. $104 for test subject participation up to 8 hours, $19.50/hour thereafter. $50 a day for alternates not needed to replace a test subject.

** Specify any visits for which subjects will **NOT** be compensated/reimbursed:

n/a

c. Compensation/reimbursement must be prorated across study visits. When will compensation/reimbursement be provided to subjects?

other

15th and last day of the month

Note: Compensation/reimbursement must be provided at least annually for participation lasting longer than 1 year.

2. In addition to the PI/QI, which individuals at the site are delegated to conduct the informed consent discussion with subjects? Check all that apply:

☐ Sub-Is ☐ Research Coordinator/Study Nurse ☐ None ☑ Other: Staff familiar with the protocol

3. In addition to knowledge of the protocol, what education related to informed consent discussion has been provided to these individuals? Check all that apply:

☐ Job Orientation ☑ In-house education ☐ Education provided by a professional association

☐ Role Play ☐ Education provided by sponsor/CRO ☐ Other:

4. Will this study use an electronic IC (eIC) to obtain consent? No

If Yes **>>>** Complete **a.** through **c.** below and reference Schulman's eIC Guidance and FDA Guidance.

Note: Electronic informed consent refers to the use of electronic systems and processes that may employ multiple electronic media, including text, graphics, audio, video, podcasts, passive and interactive Web sites, biological recognition devices, and card readers, to convey information related to the study and to obtain and document informed consent.

a. Will subjects be consented in-person at the research site?

If no, please explain:

b. Is the eIC compliant with 21 CFR Part 11?

If no, please explain:

c. Describe the process for providing new information to subjects during the study. Check all that appl

- ☐ update the eIC
- ☐ create a new paper consent
- ☐ update paper IC
- ☐ Other:

5. Does the site agree to use the following informed consent processes, as they apply to this study?

- ☑ Informed consent discussions with subjects will take place in a private area.
- ☑ Potential subjects will be allowed as long as needed to review the IC to decide study participation, including at home or overnight.
- ☑ The PI/QI will be available to answer subject questions during the informed consent process.
- ☑ A copy of the signed IC will be provided to the subjects.
- ☑ Information during the consent process will be provided in a language understandable to the subjects.
- ☑ Subjects will be informed of alternative treatments, therapies, or procedures prior to participation in this research study.
- ☑ No information will be presented to a subject that waives or appears to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the organization, or its agents from liability for negligence.
- ☑ Subject understanding of the study will be assessed following the consenting process and before being enrolled into the study.
- ☑ Coercion and undue influence will be minimized by thoroughly explaining the IC and allowing for subjects to ask questions.

NOTE: Please attach or provide a written explanation.

SECTION 8.0: Vulnerable Groups

The site must review and comply with the appropriate safeguards for enrolling subjects from vulnerable groups. Visit the Safeguards for Vulnerable Subjects page of the Schulman website to review this information.

1. Does the site plan to enroll non-English speaking subjects in the study? No

If Yes **>>>** Please complete **a.** and **b.**

a. Who will be responsible for obtaining translations? Choose one:

If Site or Sponsor/CRO **>>** Please reference the Schulman *Translations Guidance.*

If Schulman **>>** List authorized language(s) and dialect(s):

b. Is there someone at your site fluent in the language(s) of the non-English speaking subject(s) who is capable of explaining the study and answering questions throughout the participation in the study (i.e. employee, member of the study staff, professional [impartial] translator)?

If No **>>>** Provide an explanation

NOTE: Translated study documents may be used only if enrollment of non-English speaking subjects is permitted by the protocol and authorized by the Sponsor/CRO. All translations of study documents and materials approved in English must be approved by Schulman. You must comply with the safeguards pertaining to enrollment of subjects from the vulnerable group of non-English speaking subjects. For further information, please reference the *Translations Guidance*.

2. Does the site plan to enroll adults with diminshed decision-making capacity? No

If Yes **>>>** Please complete **a.** through **c.**:

*An LAR may consent on behalf of an adult subject only if the Board has determined that an LAR is appropriate for the study.

a. Please provide a description of the method(s) (e.g. interview, cognitive assessment, review of medical records, etc.) by which the PI will assess the subject's cognitive ability to provide consent and/or assent.

b. How will you verify who may act as an LAR in the site's state/province? Check all that apply:

☐ Legal Counsel ☐ Sponsor/CRO ☐ Other:

c. Which individuals will you allow to give consent/permission? For example, durable power of attorney for health care, spouse, guardian etc.:

NOTE: Who can serve as a legally authorized representative (LAR) is determined by state or province. If uncertain, Schulman recommends the PI/QI seek legal/regulatory advice to determine their state or provincial requirement.

3. Does the site plan to enroll children/minors for the study? No

NOTE: The PI/QI is responsible for confirming the legal age of majority under the applicable law where the study will be conducted and informing all study staff to ensure children/minors are not enrolled in studies targeting only adult subjects.

4. Does the study *specifically target* the recruitment/enrollment or data collection of vulnerable groups? No

☐ Economically Disadvantaged ☐ Physically Impaired ☐ Nursing Home Residents

☐ Educationally Disadvantaged ☐ Pregnant Women ☐ Employees/Family Members of Employees

☐ Life-Threatening Condition/Seriously Debilitating Illness

☐ ** Non-English Speaking ☐ ** Adults with Diminished Decision-Making Capacity ☐ ** Children/Minors

NOTE: Schulman does not review studies in which prisoners and/or wards of the state/province are the targeted population. Submit a description of any additional safeguard(s) for vulnerable groups used at your site beyond those described on the Schulman

SECTION 9.0: Financial Interest

1. Each investigator* is required to disclose any of the following financial interests when those financial interests are related to the research. During the past calendar year, has any investigator involved in this study:**

• Held a position as an officer or member of the Board of Directors of the sponsor or CRO of this study;	No
•Held ownership interest (equity or stock options) related to the research whose value when aggregated for the immediate family is greater than $5,000 or 5% interest in any single publicly traded company;	No
• Held ownership interest related to the research of any value held in a non-publicly traded company;	No
• Had any proprietary interest related to the research;	No
• Received, or made any arrangement to receive, any significant payments of other sorts related to the research to support activities of the investigator (exclusive of the costs of conducting the research study);	No
• Entered into any financial arrangement related to the research whereby the value of compensation paid or of equity owned could be affected by the outcome of this study?	No

If Yes **>>>** Submit a Conflict of Interest Disclosure for each investigator with a financial interest related to the research.

***Investigator:** Includes the PI/QI, all Sub-Is and research staff involved in this research study, as well as spouses and dependent children of the PI/QI, Sub-Is and research staff.
****Related to the Research:** A financial interest is related to the research when financial interest is in the sponsor, product or service being tested, or competitor of the sponsor, product or service being tested in this research study.
NOTE: Visit the Conflict of Interest page of the Schulman website for additional information and definitions.

SECTION 10.0: Regulatory History

1. Within the last 5 years, has the site or any investigator associated with this study been audited by a regulatory authority (e.g. FDA, OHRP, HPFB or EPA)? Yes

If Yes **>>>** Please complete **a.**:

a. Provide the information for all audits within the last 5 years (submit additional sheets if necessary):

Regulatory Authority	Investigator	Audit Dates	Was a 483 or Inspection Exit Notice, or other agency's equivalent	Audit Correspondence
EPA	Niketas Spero	05/15/2015	Yes	Upload Now

2. Has any investigator involved with this study :

- Had a sponsor, CRO, or an IRB/REB terminate, suspend, impose restrictions or sanctions on a protocol? No
- Has an IRB/REB refuse to review a protocol? No
- Had a regulatory authority terminate a study? No
- Had the hospital/healthcare facility take an adverse action against his/her clinical privileges/medical staff membership, e.g., suspension, revocation, or restriction? No
- Resigned his/her medical staff membership or surrendered clinical privileges while under investigation by the medical staff or its designee? No
- Been convicted or charged with a felony? No
- Had a state/provincial medical board taken a disciplinary action against his/her license, or is currently under investigation? No
- Had a state/provincial medical board notify him/her that complaints and/or charges are currently pending investigation? No

If Yes **>>>** Submit copies of all relevant documents and/or provide an explanation.

Please explain:

SECTION 11.0: Study Management

1. **By what date are approval documents needed in order to meet the goal for consenting the first study subject?**
   02/27/2018
2. **Would you like to review Board revisions to the IC before the IC is given final approval and issued?** Yes
3. **Schulman requests an Indemnity Agreement from the sponsor for all protocols reviewed. The study contact will be notified and provided a template if an Indemnity Agreement is not already in place for this study.**

SECTION 12.0: Investigator Certification

Single Site Study Submission Form

As the individual responsible for completing this form, my submission certifies that:

1. I am the Principal Investigator (PI) or Qualified Investigator (QI) or the PI/QI's designee authorized to submit on behalf of the PI/QI;
2. The PI/QI and all study personnel are aware of their responsibilities for conducting research as defined by the applicable federal, state,provincial and local law, ICH GCP guidelines and as set forth on the Schulman IRB website at www.sairb.com;
3. If utilizing eIC, the investigator is aware of relevant laws pertaining to electronic signatures in the jurisdiction where the research is going to be conducted;
4. No subject related study activities will occur prior to receiving the approval letter and informed consent from Schulman;
5. The research site has and will maintain adequate facilities, including equipment and appropriate levels of trained staff, to conduct the proposed research safely;
6. Responses to the financial interest questions are accurate and complete and constitute a full disclosure of any conflicting interests and activities of any investigator or staff involved in this research at this site. The requirements to disclose any potential conflict of interest have been discussed with these individuals and any conflicts of interest that arise during the course of the study will be disclosed to Schulman;
7. The protocol, clinical trial agreement or other contract with the sponsor/CRO of this study states: the responsible party who will provide medical care in case of study-related injury and who will pay for the care (e.g., sponsor, site, subject, insurance provider); the sponsor/CRO is required to promptly report any findings of study monitors that could affect the safety of participants or influence the conduct of the study at this site, and will be promptly forwarded to Schulman; the sponsor/CRO is required to send routine and urgent data and safety monitoring reports to the site, and will be promptly forwarded to Schulman; and the sponsor/CRO is required to report to the site any study results uncovered within two (2) years of study closure that could directly affect subject safety, and will be promptly forwarded to Schulman;
8. The PI/QI and all study personnel have reviewed the information regarding safeguards for vulnerable group(s) and agree to the appropriate safeguards;
9. If a potential subject is eligible for multiple research studies being conducted at this site, study personnel will collaborate with the potential subject to decide in which study the subject will enroll;
10. Recruitment bonuses and referral fees (Schulman agrees with the AMA Code of Ethics and CMA Code of Ethics Policy 13) will not be accepted by or paid to physicians/healthcare providers or others without prior explicit Board approval; and
11. All information provided in this form is true and accurate, has been reviewed by the PI/QI and communicated to all study personnel.

☑ **I agree**

Jennifer Hostetler, Study Director	February 6, 2018 1:32 pm
Principal Investigator [US] / Qualified Investigator [CAN] or Designee Name & Title	**Date (EST)**

Submitted By: Client Submitted Initial eSubmission 2.0 (jen@i2lresearch.com)

Name:	Jennifer Hostetler	**Email:**	jen@i2lresearch.com
Company:	i2LResearch USA, Inc.	**Phone:**	410-747-4500
Address:	1330 Dillon Heights Avenue	**Country:**	US
City:	Baltimore	**State/Province:**	MD
		Zip/Postal Code:	21228

Form: **Single Site Study** **Submission ID:** **SS1800060** **Date Submitted:** **February 6, 2018 1:32 pm**

Submission comments:

Documents Uploaded:

File Type	File Name	File Description	Date Uploaded
Regulatory History Detail Documentation	Cover letter.pdf		02/06/2018
Regulatory History Detail Documentation	Inspection Observations.pdf		02/06/2018
Regulatory History Detail Documentation	Response to EPA Audit_20150519.pdf		02/06/2018
PI Education, Experience and Training Documentation	TF CV 2017.pdf		02/06/2018
Protocol	18-011 protocol.docx		02/06/2018
Informed Consent	18-011 Informed Consent Document.docx		02/06/2018
Product Information	Skintex MRIII Hang Tag generic 12-2017.pdf		02/06/2018
Product Information	Skintex MRIII Insect Repellent Apparel generic sew in label 2-5-18.pdf		02/06/2018
Product Information	Skintex MRIII Treated Article SDS.pdf		02/06/2018

APPROVED: 02/13/2018
EXPIRATION DATE: 02/12/2019

February 22, 2018

FROM:	Schulman IRB
TO:	Timothy Foard, MS
SUBJECT:	Initial Approval Documents
SPONSOR:	Pulcra Chemicals
PROTOCOL NO:	18/011
PROTOCOL TITLE:	Laboratory evaluation of mosquito bite protection from permethrin-treated clothing after 0, 50, 75, and 100 washings

The following protocol items were reviewed and approved on the dates listed below:	**Review Type**	**Approval Date**	**IC Finalized**
• Study Protocol Version Number 1.2 dated 01/27/2018:	Full Board	02/13/2018	N/A
The following information is specific to the investigator referenced above:			
• Site(s) approval to conduct this study:	Full Board	02/13/2018	N/A
• Site specific Consent Information for Participation in an i2LResearch USA, Inc. Mosquito Repellent Study (Schulman Version 1.0):	Full Board	02/13/2018	02/21/2018

The Board approved the items listed above. You must use only the "Schulman Approved" informed consent(s).

Please note: Effective for new studies submitted on or after 05/02/2016, Schulman has an updated informed consent versioning process. For more information, please refer to the memo available at http://www.sairb.com/ICversioncontrolmemo.

This approval will last 12 months.

If the study is expected to last beyond the approval period, you must request and receive re-approval prior to the expiration date noted above. A report to the Board on the status of this study is due prior to the expiration date or at the time the study closes, whichever is earlier. It is recommended that you submit status reports at least 4 weeks prior to your expiration date to avoid any additional fees or lapses in approval. You can find the Study Status Report Form at www.sairb.com.

Approved investigators and sites are required to submit to Schulman for review, and await a response prior to implementing, any amendments or changes in: the protocol; advertisements or recruitment materials ("study-related materials"); Principal/Qualified investigators; or sites (primary and additional). Refer to www.sairb.com for comprehensive submission requirements.

Approved investigators and sites are required to notify Schulman of the following reportable events, including, but not limited to: unanticipated problems involving risks to subjects or others; unanticipated adverse device effects; protocol violations that may affect the subjects' rights, safety, or well-being and/or the completeness, accuracy and reliability of the study data; subject death; suspension of enrollment; or termination of the study. Refer to the "Event(s) That Investigators Have to Report to Schulman" guidance document available on the Schulman WebPortal/SiteAccess and at www.sairb.com.

Schulman IRB is in compliance with Part C Division 5 of the Canadian Food and Drug Regulations, the Tri-Council Policy Statement (TCPS), the International Conference on Harmonization Good Clinical Practice Guidelines, the regulations of the United States Food and Drug Administration as described in 21 CFR parts 50 and 56, and the United States Department of Health and Human Services regulations 45 CFR part 46, and the Environmental Protection Agency 40 CFR 26.

The current Board Membership List is available to download at the link on SiteAccess at www.sairb.com. Please maintain the appropriate Board Membership List with your study binder.

PLEASE REFERENCE IRB # 201800994 ON ALL CORRESPONDENCE FOR THIS STUDY.

Arling, Michelle

From: Anna Montag <AMontag@sairb.com>
Sent: Tuesday, February 13, 2018 10:20 AM
To: Jen Hostetler
Cc: Amanda Bailey; Kristine Styer; ldasher@pulcrachem.com
Subject: Protocol: 18/011 IRB # 201800993 Study Status Notification I and Draft 1 IC
Attachments: SSN I.PDF; DRAFT 1 IC TO CLIENT.DOCX

Good morning Jennifer,

Please confirm receipt of this message.

Attached please find Study Status Notification I which communicates to you the outcome of the review of the above-noted protocol and informed consent at today's board meeting.

Attached please find the DRAFT of the informed consent (IC), with the board's required revisions and comments. For your convenience, these are marked in tracked revisions. Should the sponsor/Investigator have any feedback on the Board directed revisions, please make the changes directly within the document or convey the feedback by inserting comments and return the revised document to me for review. The track changes feature of Word is activated. Please provide rationale or protocol reference in support of any significant IC revisions to facilitate the review of your request.

Please note, that any new information not previously reviewed by the board will require subsequent board review.

If you agree with the board's revisions, please leave the language as is and we will accept all revisions.

Please call or e-mail me with any questions about these documents.

Kind Regards,

Anna Montag| **Board Liaison**
Schulman IRB
Office 513-761-4100 Ext.5217| amontag@sairb.com
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Study Status Notification I

DATE: 2/13/2018

TO: Timothy Foard, MS

FROM: Anna Montag, Board Liaison
Schulman IRB

RE: **Protocol#:** 18/011
Sponsor: Pulcra Chemicals
IRB#: 201800993
Title: Laboratory evaluation of mosquito bite protection from permethrin-treated clothing after 0, 50, 75, and 100 washings

The Board reviewed the above-referenced protocol version 1.2 (dated 1/27/2018) and informed consent at the 2/13/2018 meeting and identified issues to be addressed by the Sponsor/Investigator. The study status is ***Conditionally Approved*** pending response to the following ***conditions of approval:***

1) The informed consent form template requires modifications. Board comments regarding the informed consent template are currently being consolidated. Upon completion, you will receive a draft of the informed consent for your review and acceptance of Board mandated revisions. Please note any changes made outside of the Board's edits will require additional review. As a reminder, client-preference edits to the informed consent, including formatting, client version dates and other special requirements, should be applied prior to finalizing the document.

The Board requests your response to this Study Status Notification. Your response will be reviewed to determine whether the condition of approval is met. You will be contacted if further information is necessary.

You may submit your response to via e-mail: amontag@sairb.com

The Board reviewed the above-referenced Principal Investigator and site at the 02/13/2018 meeting. The site status is **Approved**.

Thank you for your assistance with the above-referenced study. You may contact me at 513-761-4100 Ext. 5217 if you have concerns or questions.

Please note: This is not an approval letter. The Schulman IRB approval letter will be sent under separate cover.

Arling, Michelle

From: Anna Montag <Anna.Montag@sairb.com>
Sent: Thursday, February 22, 2018 5:31 PM
To: Jen Hostetler
Cc: Amanda Bailey; Kristine Styer; ldasher@pulcrachem.com; Timothy Foard
Subject: RE: Protocol: 18/011 IRB # 201800993 Study Status Notification II
Attachments: SSN II.PDF

Good afternoon Jen,

Attached please find Study Status Notification II, which communicates to you the outcome of the Board review of your responses to the conditions of approval as outlined in Study Status Notification I (dated 02/13/18). We will now begin preparation of your IRB documents.

After your approval documents have been prepared, management of this study within Schulman will be transitioned from me to the Submission team who will serve as your primary Schulman contact for this study. For any questions or assistance during the conduct of this study, please feel free to contact the Submissions team at Submissions@sairb.com

Kind Regards,

Anna Montag| Board Liaison
Schulman IRB
Office 513-761-4100 Ext.5217| amontag@sairb.com
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From: Jen Hostetler [mailto:jen@i2lresearch.com]
Sent: Thursday, February 22, 2018 1:44 PM
To: Anna Montag
Cc: Amanda Bailey ; Kristine Styer ; ldasher@pulcrachem.com; Timothy Foard
Subject: RE: Protocol: 18/011 IRB # 201800993 Draft 2 and Sign-Off

Hi Anna,

Please find my signature below.

Jen

From: Anna Montag [mailto:Anna.Montag@sairb.com]
Sent: 21 February 2018 16:07
To: Jen Hostetler <jen@i2lresearch.com>
Cc: Amanda Bailey <Amanda.Bailey@sairb.com>; Kristine Styer <Kristine@i2lresearch.com>; ldasher@pulcrachem.com;

Timothy Foard <Timothy@i2lresearch.com>
Subject: RE: Protocol: 18/011 IRB # 201800993 Draft 2 and Sign-Off

RE: Informed Consent (IC) Approval
NUMBER OF ICs: 1 **DRAFT # 2**
Protocol #: 18/011
Sponsor: Pulcra Chemicals
IRB#: 201800993
Title: Laboratory evaluation of mosquito bite protection from permethrin-treated clothing after 0, 50, 75, and 100 washings

Dear Jen,

I have added 'non-alcoholic' to the description of drinks on page 4. Attached please find the latest draft of the informed consent for this study. If you agree that the draft informed consent is complete and accurate as written, please indicate this by typing your name and date in the space below. A Study Status Notification will be forwarded to you indicating all conditions of approval are met once your acceptance of this version has been received and we will move forward with a final review and finalization of the approval documents. If not, please forward your requested changes to me for review. *Please ensure Sponsor/CRO edits to the informed consent, including your versioning (if applicable), formatting, and other special requirements are completed prior to submitting your acceptance.*

Please note that any revisions after your sign off may be subject to subsequent board reviews and considered an amendment/revisions to informed consent subject to additional charge.

FOR SPONSOR/CRO USE:

Sponsor/CRO (or authorized designee) reviewed the draft informed consent(s) and agrees they are complete and accurate as written.

Jennifer Hostetler February 22, 2018
Typed Name of Sponsor/CRO Representative or Designee Date

FOR SCHULMAN INTERNAL PURPOSES ONLY:

Date/ Staff Member Initials: AM 02/22/18

Kind Regards,

Anna Montag| Board Liaison
Schulman IRB
Office 513-761-4100 Ext.5217| amontag@sairb.com
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Follow Schulman on Twitter: **@SchulmanIRB**
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From: Jen Hostetler [mailto:jen@i2lresearch.com]
Sent: Wednesday, February 21, 2018 3:45 PM
To: Anna Montag <Anna.Montag@sairb.com>
Cc: Amanda Bailey <Amanda.Bailey@sairb.com>; Kristine Styer <Kristine@i2lresearch.com>; ldasher@pulcrachem.com; Timothy Foard <Timothy@i2lresearch.com>
Subject: RE: Protocol: 18/011 IRB # 201800993 Study Status Notification I and Draft 1 IC

Good afternoon Anna,

We have reviewed the draft IC and agree with the Board's changes. The only comment the Study Director had was that any mention of drinks in the IC should specify that they are non-alcoholic. Otherwise we accept all the revisions.

Jen

From: Anna Montag [mailto:AMontag@sairb.com]
Sent: 13 February 2018 10:20
To: Jen Hostetler <jen@i2lresearch.com>
Cc: Amanda Bailey <ABailey@sairb.com>; Kristine Styer <Kristine@i2lresearch.com>; ldasher@pulcrachem.com
Subject: Protocol: 18/011 IRB # 201800993 Study Status Notification I and Draft 1 IC

Good morning Jennifer,

Please confirm receipt of this message.

Attached please find Study Status Notification I which communicates to you the outcome of the review of the above-noted protocol and informed consent at today's board meeting.

Attached please find the DRAFT of the informed consent (IC), with the board's required revisions and comments. For your convenience, these are marked in tracked revisions. Should the sponsor/Investigator have any feedback on the Board directed revisions, please make the changes directly within the document or convey the feedback by inserting comments and return the revised document to me for review. The track changes feature of Word is activated. Please provide rationale or protocol reference in support of any significant IC revisions to facilitate the review of your request.

Please note, that any new information not previously reviewed by the board will require subsequent board review.

If you agree with the board's revisions, please leave the language as is and we will accept all revisions.

Please call or e-mail me with any questions about these documents.

Kind Regards,

Anna Montag| Board Liaison
Schulman IRB
Office 513-761-4100 Ext.5217| amontag@sairb.com
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Total Control Panel Login

To: amontag@sairb.com
From: jen@i2lresearch.com

Message Score: 50
My Spam Blocking Level: Custom

Block this sender
Block i2lresearch.com

High (60): Pass
Medium (75): Pass
Low (90): Pass
Custom (55): Pass

This message was delivered because the content filter score did not exceed your filter level.

Total Control Panel Login

To: anna.montag@sairb.com
From: jen@i2lresearch.com

Message Score: 50
My Spam Blocking Level: Custom

Block this sender
Block i2lresearch.com

High (60): Pass
Medium (75): Pass
Low (90): Pass
Custom (55): Pass

This message was delivered because the content filter score did not exceed your filter level.

Study Status Notification II

DATE: 2/22/2018

TO: Timothy Foard, MS

FROM: Anna Montag, Board Liaison
Schulman IRB

RE: **Protocol#:** 18/011
Sponsor: Pulcra Chemicals
IRB#: 201800993
Title: Laboratory evaluation of mosquito bite protection from permethrin-treated clothing after 0, 50, 75, and 100 washings

The above-referenced item was *Conditionally Approved* at the 2/13/2018 Board meeting. On 2/21/2018, the submitted responses to the Study Status Notification I dated 2/13/2018 were reviewed and the conditions of approval were met.

The purpose of this memo is to inform you that the response satisfies the conditions of approval.

Thank you for your assistance with the above-referenced study. You may contact me at 513-761-4100 Ext. 5217 if you have concerns or questions.

Please note: This is not an approval letter. The Schulman approval letter will be sent under separate cover.

May 04, 2018

FROM : Schulman IRB ("Schulman" or the "Board")
TO: Timothy Foard, MS
SUBJECT: Recruitment/Study-Related Material
IRB NO.: 201800994;
SPONSOR : Pulcra Chemicals
PROTOCOL NO.: 18/011

The following item was reviewed by Expedited Review, as referenced below, and received a decision of

Approved for use ONLY in its entirety

Material Type : Other
Description : 18-011 Recruitment Script 1
Material Item# : MA1805995-0
Review Date : 05/04/2018

Approved and/or Acknowledged Recruitment/Study-Related materials should not be used or distributed to study subjects until you have received an approval letter from Schulman to conduct this study.

Acknowledged material includes, but is not limited to, copyrighted documents, some subject instructions, standardized questionnaires, etc.

Any variation of approved or acknowledged materials must be resubmitted as outlined in the Recruitment Guidance available at www.sairb.com .

PLEASE REFERENCE MATERIAL ITEM NUMBER **MA1805995-0** ON ALL CORRESPONDENCE

WebPortal/Paperless

60-MA1805995-1-7

All dates in mm/dd/yyyy format

[Procedure for Initial Contact in Recruiting Test Subjects over the telephone for Mosquito Bite Protection Studies.] (Words in parenthesis will not be spoken)

(Initial Contact Script- Read to recruits to determine if recruit is interested in participating). (Phone Call- The initial phone call will be placed by employee of i2LResearch USA, Inc. or by a recruitment firm).

"Hello (Potential Test Subject's name), this is (enter name) from i2LResearch USA, Inc. (i2L).

I'm calling because you expressed interest in participating in our upcoming insect repellent research study.

"This study will be conducted at the i2LResearch USA, Inc. laboratory in Halethorpe, MD. The study will evaluate various permethrin treated fabrics to see if they prevent bites from mosquitoes. The test is scheduled to begin during the month of (enter month) and the purpose of this study is to determine how much protection the treated fabrics provide from mosquito bites after being washed a different numbers of times.

"Are you interested in learning more about this study?"

(If they respond "No") "Ok, thank you for your time today."

(If they respond "Yes") "May I ask if you are between the ages of 18 and 55?"

(If "No") "Unfortunately we do require subjects to be between the ages of 18 and 55, but I do thank you for your time today."

(If "Yes"):

"Okay, great. I'm now going to go over the basics of this study, as I go through this, if you have any questions feel free to ask them, and I will answer to the best of my ability."

"If chosen to be a Test Subject you would participate in a test day that would last potentially up to eight hours. If chosen to be an Alternate you will be asked to come to the lab on the day of the test but will only participate if a Test Subject is absent or withdraws. An Alternate who is not needed to replace a Test Subject would be at the laboratory for about two hours."

"We will need five test subjects and 4 alternate subjects for each of the test days. We are recruiting more than the subjects needed for each day of the study to create a pool of subjects to choose from. Subjects will have to attend a training and information session at i2L prior to testing. This training session will take about 2 hours, and you will be paid for your time. If at the end of the session, you are qualified and still interested in participating in the study, you will be assigned a code number. For privacy reasons, your name will not appear anywhere on the data sheets or in the study reports; instead, we'll use the code number. When subjects are needed for a test day we will randomly select females and males from the pool to participate. If you have been randomly selected to participate in the test day you will then be notified."

"The following will occur during a testing day:

- You will be required to wear short sleeves, with all other clothing choices up to you.

- While wearing gloves, a member of the study staff will fasten the untreated and treated fabrics around your forearms in the shape of a sleeve.

• You will then insert your forearms with the untreated fabric into a cage containing approximately 200 mosquitoes for fifteen minutes. During this time the mosquitoes will land on the fabric, probe through it to your skin, and then bite or feed. If 20 mosquitoes successfully feed through the untreated fabric, you will be considered attractive, and may continue to participate. You will then insert your forearms with the treated fabrics into the mosquito cages for 15 minutes, and this process will be repeated until all fabrics have been tested.

•The fabrics are treated with a pesticide called permethrin. Permethrin is registered by the U.S. Environmental Protection Agency (EPA) to kill a variety of insect pests such as products to treat fleas, mites, and other pests on house pets. Permethrin is also used to control mosquitos, including being impregnated into clothing for this purpose.

•The fabrics being tested in this study will contain around 0.52% permethrin, but it may be slightly higher or lower depending on the type of fabric tested, and they have not yet been registered by the U.S. EPA. The data collected in this study will be used to support their registration. Other permethrin impregnated fabric products have been registered and are already being marketed to consumers.

• The study will be conducted with two mosquito species. You may participate in multiple test days. You will be notified in advance if you are randomly selected to participate in any of the test days, and whether you would be a test subject or an alternate. Alternates will only participate in the study if a chosen test subject doesn't show up or drops out."

"You will be paid for your participation as follows:

• $30 for participating in a training session, which lasts about two hours.

• If assigned as a Test Subject you will be paid $104 (which is equal to $13 per hour) for any length of participation up to 8 hours on a test day, and $19.50 for each additional hour after the first 8 hours, rounded up to the nearest hour.

• If you are assigned as an Alternate and come to the lab on the day of the test but are not needed to replace an absent or withdrawn test subject, you will be paid $50 for your time and inconvenience. You would be at the laboratory for about two hours in this case. If, as an alternate, you're needed to replace a test subject, you will be paid the same as a Test Subject ($104 for any length of participation up to 8 hours, and $19.50 for each additional hour after the first 8 hours, rounded up to the nearest hour)."

"Payment is provided by check on the 15th or on the last day of the month. Checks can be mailed or held at the lab for you to pick up.

"If this sounds like something you might be interested in participating in, I will call you (enter month and week) to discuss the inclusion and exclusion criteria for Test Subjects and answer any further questions you may have about the study. The phone discussion will take about 15 to 20 minutes."

"Are you interested in moving forward in the screening process?" (If they respond

"No") "Ok, thank you for your time today."

(If they respond "Yes") "Great, I do want to state upfront that you have the freedom to quit or withdraw from the study at any point in time and you will still be paid for the hours worked.

"What would be the best time of day to have someone from our staff call you back to further

discuss the study with you? (Enter Contact Time if you don’t already have it) Please remember that this phone conversation could take up to 20 minutes."

"Great, and what would be the best number to reach you?" (Write down information if you don’t already have it)

“Thank you so much for your interest in the study. You can expect a call back from us around (Estimated date). Have a great rest of your day.”

May 04, 2018

FROM : Schulman IRB ("Schulman" or the "Board")
TO: Timothy Foard, MS
SUBJECT: Recruitment/Study-Related Material
IRB NO.: 201800994;
SPONSOR : Pulcra Chemicals
PROTOCOL NO.: 18/011

The following item was reviewed by Expedited Review, as referenced below, and received a decision of

Approved for use ONLY in its entirety

Material Type : Other
Description : 18-011 Recruitment Script 2
Material Item# : MA1805996-0
Review Date : 05/04/2018

Approved and/or Acknowledged Recruitment/Study-Related materials should not be used or distributed to study subjects until you have received an approval letter from Schulman to conduct this study.

Acknowledged material includes, but is not limited to, copyrighted documents, some subject instructions, standardized questionnaires, etc.

Any variation of approved or acknowledged materials must be resubmitted as outlined in the Recruitment Guidance available at www.sairb.com .

PLEASE REFERENCE MATERIAL ITEM NUMBER **MA1805996-0** ON ALL CORRESPONDENCE

WebPortal/Paperless

60-MA1805996-1-7

All dates in mm/dd/yyyy format

[Procedure for Follow-Up Contact in Recruiting Test Subjects over the telephone for Mosquito Bite Protection Studies] (Words in parenthesis will not be spoken)

(Follow-Up Contact Script- Read to individuals who have indicated, based on the initial telephone contact, that they are interested in learning more about the study to determine if the recruit is still interested in participating).

(These individuals will be contacted by phone by a designated member of the i2L staff, at the time scheduled in the initial contact.)

(The i2L staff member will go over in more detail the study and the potential subject's role).

"Hello, my name is (enter name), and I am with i2LResearch USA, Inc. You indicated in a previous phone call that you are interested in participating in a treated fabric mosquito protection research study with us. I'm calling to follow up and give you more information about the study.

"Are you still interested in learning more about the study?"

(If "No") Thank you for your time today.'

(If "Yes") "Thank you for your interest in the study and taking time to talk with me today. I'm going to be repeating some of the information I gave to you during the previous phone call, but I have to repeat it to make sure you have all the information needed to make an informed decision about your participation.

"The purpose of this research study is to determine how well various permethrin treated fabrics prevent bites from two different species of mosquitoes. The study will be conducted in a laboratory located in Halethorpe, MD. Human Test Subjects will expose their forearms to mosquitoes for fifteen minute intervals throughout the test day, which will potentially last up to 8 hours."

"Let me go over in more detail what this study entails. Please ask any questions at any time.

"If you choose to potentially participate in and qualify for the study...

(Read for all):

You will attend a training and information session at I2L prior to participating in each study. During this training, which will last approximately 2 hours, study staff will describe the study in detail, demonstrate the procedures that participating subjects will follow during each 15 minute exposure to mosquitoes, briefly discuss the pesticide that the fabric is treated with, review the inclusion and exclusion criteria, and thoroughly go over the Informed Consent form with you. They will also answer any questions you have. You will need to bring in two forms of identification such as a driver's license, social security card, or birth certificate, or just a passport. This will let us both confirm your age and put you on our payroll. If after this, you would still like to participate in the study, you would sign the Informed Consent document.

"If you do, you will then be assigned a code number, which would be subject to a random drawing with the other subjects, to determine if you will be chosen to participate in a test day. For privacy reasons, names of subjects will not appear anywhere on the data sheets or in the study reports; instead, we'll use the code numbers. If you are selected, the study staff will notify you of your scheduled test day and review the restrictions you must adhere to during your participation."

"Five test subjects and four alternates will be needed for each of the test days."

"The testing is scheduled to begin (enter time, date month, year) at the i2L laboratory in the Halethorpe area. You would need to be available to stay at the lab from 8 a.m. to 5 p.m. and must refrain from alcohol for 24 hours before the test, and refrain from using nicotine and fragrance products (e.g. scented soap, perfume, cologne, hair spray, scented lotion, antiperspirant/deodorant, etc.) for 24 hours before the test, as well as during the test."

"On your scheduled test days, you would need to wear short sleeves. By advance random selection, five subjects will be assigned to have untreated and treated fabrics applied to their forearms for each test day, and another four subjects will be assigned as alternates for each test day. If you are assigned as an alternate, you will be asked to remain at the laboratory for about two hours, until it is determined if you are needed to replace a test subject. If this doesn't happen, you will be allowed to leave the laboratory."

"If you are selected to wear the untreated and treated fabrics, the study staff will fasten the untreated fabrics to both forearms. You will place your arms into cages with approximately 200 mosquitoes for fifteen minutes. The mosquitoes will be allowed to land on the fabric, probe to the skin and feed on or bite the skin. After the fifteen minutes have passed and your arms are removed from the cages, a staff member will collect the mosquitoes to count how many have blood-fed. If more than 20 have blood-fed on your skin, you are considered attractive to the mosquitoes and may continue participating in the study with the treated fabrics. Otherwise, you are considered unattractive to the mosquitoes, and will be replaced in the study but still paid the full amount for your time. Once your attractiveness to mosquitoes is confirmed, the study will continue by replacing the untreated fabrics with treated fabrics and placing your arms in the cages for another fifteen minutes. This process will repeat until all fabrics have been tested."

“You have the freedom to quit or withdraw from the study at any point in time. You will be paid for the hours worked. Once you leave, you will not be able to re-join the test at a later time.

"Now that I have further explained the training session and test days, are you still interested in potentially volunteering as a test subject for this study?"

(If the person is not interested): "Thank you for your time today."

(If the potential test subject is still interested the staff member will proceed with the following):

"To see if you qualify to participate in the study, I need to go over the criteria for test subjects. Some of the questions may be sensitive, such as questions about medical conditions. You only have to answer YES or NO to the questions, or you do not have to answer any of the questions you do not want to answer. I will not be documenting any of the answers you give me during this conversation. Do I have your permission to proceed?"

(If they give permission to proceed, the following yes/no questions will be asked:)

1. Are you within the ages of 18-55 and can provide proof of age by a driver's license, passport, or other valid identification? (MUST SAY YES)

2. Can you read and speak English fluently? (MUST SAY YES)

3. Are you an employee of i2L or of Pulcra Chemicals or an immediate family member of an employee of i2L or of Pulcra Chemicals? Are you related to employees or owners of either company?(MUST SAY NO TO BOTH)

4. Do you have a reliable form of transportation to get to and from the test location? (MUST SAY YES)

5. Are you willing to be exposed to and bitten by mosquitoes on your forearms? (MUST SAY YES)

6. Are you sensitive or allergic to mosquito bites? (MUST SAY NO)

7. Are you highly sensitive or allergic to latex, insect repellents, pesticide-treated fabrics, or skin care products? (MUST SAY NO)

8. Do you have any known skin diseases or problems such as eczema, psoriasis, or atopic dermatitis? (MUST SAY NO)

9. Do you have any open cuts or scrapes on your forearm? (MUST SAY NO)

10. Do you feel you are healthy enough to participate in the study and do not have any health conditions that would make you unable to sit in a chair for up to 15 minutes, with breaks for limb stretching and movement at reasonable intervals?
(MUST SAY YES)
11. Do you have any health conditions that could become worse by wearing insecticide-treated fabrics? (MUST SAY NO)

12. Are you willing to refrain from using alcohol, nicotine, and fragrance products for 24 hours before the test, and refrain from using nicotine and fragrance products (e.g. scented soap, perfume, cologne, hair spray, scented lotion, antiperspirant/deodorant, etc.) during the test? (MUST SAY YES)
13. Are you willing to follow the study procedures as explained? (MUST SAY YES)

14. Are you male or female?

(If female):

15. Do you know if you are currently pregnant? (MUST NOT BE PREGNANT)

16. Are you currently breastfeeding? (MUST SAY NO)

17. Are you willing to perform an over the counter pregnancy test in private that will be supplied by the lab on each testing day before you participate? You will only need to disclose the results if they are negative and you still wish to participate in the testing, in which case you would share them with a female member of study staff. The results themselves will not be recorded. (MUST SAY YES)

(If the person does not qualify for the study):

"Unfortunately, you do not meet all of the test subject criteria for this study. You will not be able to volunteer as a test subject for this study and we will not store any information collected at the conclusion of this call. Thank you for your interest and for taking the time to answer these questions."

(If the person qualifies for the study based on this initial discussion):

"You meet the criteria to participate. Are you still interested in potentially participating in this study?"

(If the person is not interested): "Thank you for your time today; we will not store any information collected at the conclusion of this call."

(If the person is still interested):

“Great, thank you. The compensation for the study will be as follows:

- You will be paid $30 for participating in each training session
- Assigned Test Subjects will be paid $104 for any length of participation up to 8 hours on a test day, and $19.50 for each additional hour after the first 8 hours, rounded up to the nearest hour.
- Assigned Alternates who are not needed to replace an absent or withdrawn test subject will be paid $50 for their time and inconvenience. It is expected they would be at the laboratory for about two hours in this case. If an alternate is needed to replace a test subject, they will be paid the same as an Assigned Test Subject ($104 for any length of participation up to 8 hours, and $19.50 for each additional hour after the first 8 hours, rounded up to the nearest hour.)
- Payment is provided by check on the 15th or on the last day of the month. Checks will be mailed or you can pick them up here.”

"Training and information sessions will be held on (enter dates and times) at the following location: 1430 Joh Avenue, Suite L-M, Baltimore, MD 21227. Which training session should I schedule you for? (Write response down. If no preference, choose closest date). If you have any questions or need to contact the study staff the phone number is (410-747-4500). Please bring two forms of ID to the training session. This can be your driver’s license or state ID along with your social security card or birth certificate. If you have a passport you can just bring that in.

"If you have an email or mailing address you are willing to provide, I can send you the informed consent document to review prior to the testing day. Although we encourage you to read the consent form in advance, it is not required that you read the document ahead of the training session. We will completely review it with you at that session, so if you don't get a chance to read it ahead of time, that is okay.”

"Thank you for your time today. We will give you a reminder call about the training session a day or two before. Have a great rest of your day.”