PROJECT NO:
472-0031

STUDY TITLE
EVALUATION OF THE EFFICACY OF TWO MATTRESS COVERING FABRICS FOR PREVENTION OF BITING BY BED BUGS

PROTOCOL NO:
N4720910031A333

IN-LIFE COMPLETION DATE:
September 17, 2010

STUDY COORDINATOR:
William J. Gaynor

PERFORMED FOR:
Mission: Allergy, Inc.
28 Hawleyville Road
Hawleyville CT 064407

PERFORMED BY:
ICR, Inc.
1330 Dillon Heights Avenue
Baltimore, MD 21228

EXECUTIVE SUMMARY

Two human subjects took part in this test of two Mission: Allergy, Inc. bedding coverings: Mission: Allergy Premium Microfiber and Mission: Allergy Barrier II. Single adult or early instar bed bugs were placed in 4-dram vials. The vials were covered with one of the test fabrics. The vials were inverted on each forearm of a human subject, with the fabric-covered mouth against the skin. The vials remained in place for 5 minutes while ICR staff observed for bed bugs biting through the fabric (as evidenced by the ingestion of blood or penetration of the skin by the proboscis).

Both Mission: Allergy Premium Microfiber and Mission: Allergy Barrier II prevented any biting by either adult or nymphal bed bugs. Therefore, none of the bed bugs bit through either of the test fabrics. For every bed bug failing to bite through the test fabric, the procedure was repeated with the same insects, but using a control screen, which bed bugs are known to feed through. All bed bugs bit through this control screen. This confirmed that they were eager to feed and only the test fabrics had prevented them from doing so.

William J. Gaynor 9/23/10

William J. Gaynor Date
Study Coordinator

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OBJECTIVE:

To test the ability of two mattress covers in preventing bed bugs from biting a human forearm in a laboratory setting.

This is not a GLP (Good Laboratory Practices, as defined by 40 CFR part 160) protocol, and the final report is not intended to be submitted to any regulatory agency as part of a GLP study or to support product registration.

MATERIALS AND METHODS:

The following test samples were provided by Mission: Allergy, Inc.:

1. Mission: Allergy Premium Microfiber
2. Mission: Allergy Barrier II

All test materials and methods were as per Protocol No. N4720910031A333 (APPENDIX I).

RESULTS:

Single adult or early instar bed bugs were placed in 4-dram vials. Each of the vials was covered with one of the test fabrics. Each test subject tested one of the fabrics. One or two such vials were inverted on each pre-washed forearm of one of two human subjects with the fabric-covered mouth against the skin. The vials remained in place for 5 minutes while ICR staff monitored the bed bugs for any biting through the fabric (as evidenced by the ingestion of blood or penetration of the skin by the proboscis). Five adult bed bugs and 5 nymphal bed bugs were tested on each of the two test subjects.

Both Mission: Allergy Premium Microfiber and Mission: Allergy Barrier II prevented feeding by either adult or nymphal bed bugs. Therefore, none of the bed bugs were able to bite through either of the test fabrics. In each case, the procedure was then repeated with the same insects, but using a control screen, which bed bugs are known to feed through. The bed bugs bit through this control screen confirming that they were eager to feed and only the test fabrics had prevented them from doing so.

CONCLUSIONS:

Both mattress covering fabrics, Mission: Allergy Premium Microfiber and Mission: Allergy Barrier II, were completely effective in preventing early instar and adult bed bugs from biting human forearms.

APPENDIX I: PROTOCOL

PROTOCOL NUMBER:
N4720910031A333

PROJECT NUMBER:
472-0031

PROTOCOL TITLE:
EVALUATION OF THE EFFICACY OF TWO MATTRESS COVERING FABRICS FOR PREVENTION OF BITING BY BED BUGS

PROTOCOL VERSION DATE:
September 1, 2010

PROPOSED START DATE:
September 2010

PROPOSED COMPLETION DATE:
September 2010

PRINCIPAL INVESTIGATOR:
William J. Gaynor

SPONSOR:
Mission: Allergy, Inc.
28 Hawleyville Road
Hawleyville, CT 06440

TESTING FACILITY:
ICR, Inc.
1330 Dillon Heights Avenue
Baltimore, MD 21228-1199

OBJECTIVE:

To test the ability of two mattress covers in preventing bed bugs from biting a human forearm in a laboratory setting.

This is not a GLP (Good Laboratory Practices) study or protocol.

MATERIALS:

TEST FABRIC:	The Sponsor will provide the fabric sample as ready-to-use. The sample identity will be documented in the final report.
CONTROL SCREEN:	Fine screen used by ICR to maintain its bed bug colony; these insects can bite through this screen when placed against the skin
TEST ORGANISMS:	Early instar and adult bed bugs from the ICR colony *(Cimex lectularius)* reared at ambient indoor temperatures and humidities. This colony was obtained from the USDA Gainesville lab in July 1983.
HUMAN SUBJECT:	Will sign an Informed Consent Agreement prior to participation. Two test subjects will be utilized. One test subject will be needed for testing each fabric. Two fabrics will be tested. Test subjects will not be replaced even if bed bugs do not bite them. Test subjects must avoid alcohol and fragranced products (e.g., soap, perfume, cologne, hair spray, lotion, antiperspirant/deodorant, etc.) for 8 hours before the test as well as, during the test. Female subjects must not be pregnant or breastfeeding, this will be based solely on self-reporting as part of the informed consent.
CONTAINERS:	Vials (5.5 x 2.5 cm ext. diam.) with lids cut to leave only the threaded collars (these allow the fabric or screen to be secured over the vial mouths by screwing them down over it).
MISCELLANEOUS:	Forceps, rubber bands/tape, source of CO_2, screen used in rearing bed bugs at ICR- (bed bugs can easily bite through it).

METHODS:

Summary

Test subjects will wash their forearms with unscented Neutrogena® soap. No treatment will be applied to these forearms. Single adult bed bugs will be placed in 4-dram vials. The vials will be covered with the test fabric. One or two such vials will be inverted on each forearm of a human volunteer with the fabric-covered mouth against the skin. The vials will remain there until the bed bugs bite or for 5 minutes, whichever occurs first. In the case of any bed bugs which do not bite, the procedure will then be repeated with the same insects, but using a control screen which bed bugs are known to bite through. Biting through this control screen will confirm that the bed bugs were eager to bite but the test fabric prevented biting. Those bed bugs which bite through the test fabric or the control screen are called positive responders. This method of exposure will be repeated until five positive responders have been tested.

The forgoing procedure will be repeated with early instar bed bug nymphs.

Sample Handling and Storage

The samples will be logged in when received and stored in a locked cabinet at ambient temperature and humidity until the study date.

Replication

Sufficient adult and nymphal bed bugs will be exposed to the test subject to yield five positive responders of each life stage. When the second fabric is tested, the forgoing procedure will be repeated with a different test subject.

Handling of Bed Bugs

The bed bugs will not have received a blood meal within 2 weeks prior to the test to ensure that they are hungry. The date of the most recent blood meal will be noted. Bed bugs will be anesthetized with CO_2 and then placed individually into vials. The mouths of the vials will be covered with sections of test fabric.

Test Exposures

One or two bed bugs will be tested on each arm simultaneously. ICR staff will invert one or two 4-dram vials, each containing a bedbug onto both forearms of the volunteer. The vials will be held in place with sufficient pressure to ensure contact of the fabric with the skin. The vials will be held in place for 5 minutes, or until the bed bugs bite (as evidenced by the ingestion of blood or penetration of the skin by the proboscis), whichever occurs first.

Control Exposures

Any bed bugs which do not bite through the test fabric will be given the opportunity to bite

bite, it will confirm that they would have fed through the test fabric cover had they been able to penetrate it.

DATA ANALYSIS:

The numbers of bed bugs biting through the test fabric and through the screen will be compared. These data may be subjected to statistical analysis if appropriate. If one or more bedbugs can bite through the test fabric it will be considered a failure of the product.

SCHEDULE OF EVENTS:

DATE	PROCEDURE
Day 0	Test Conducted
End of Study	Telephone Report
Within following 30 days	Written Report
After the Written Report	Samples returned

STATEMENT OF DEVIATION OR AMENDMENT

All amendments to this protocol must be discussed with and approved by the Sponsor and Institutional Review Board (IRB). All amendments to, or deviations from, this protocol will be documented in the final report.

William J Gaynor 9/7/10
William J. Gaynor Date
Principal Investigator
ICR, Inc.

9/2/10
Dr. Jeffrey Miller Date
President
Mission: Allergy, Inc.

APPENDIX I
RAW DATA SHEET: BED BUGS BITING (BITEING) THROUGH FABRIC / SCREEN

Test Date: Date of Last Blood Meal:

Test Fabric Name:

Life Stage: Early instar nymphs OR **Adults** (circle one)

Volunteer identity (code number only to protect privacy):

Test Replicate I bed bug/rep.	**FED THROUGH TEST FABRIC (YES/NO)**	**Control Replicate** 1 bed bug/rep	**FED THROUGH** CONTROL **SCREEN (YES/NO)**
1		**1**	
2		**2**	
3		**3**	
4		**4**	
5		**5**	
6		**6**	
7		**7**	
8		**8**	
9		**9**	
10*		**10**	
Total		**Total**	

*Sufficient bed bugs will be tested to yield five positive responders per life stage

Principal Investigator/Date:

Recording Technician/Date:

APPENDIX II: INFORMED CONSENT DOCUMENT AND ADDENDUM

PROTOCOL: "EVALUATION OF THE EFFICACY OF TWO MATTRESS COVERING FABRICS FOR PREVENTION OF BITING BY BED BUGS"

CONSENT INFORMATION FOR PARTICIPATION IN AN ICR, INC. BED BUG BITE PREVENTION TEST IN THE LABORATORY

Principal Investigator: William J. Gaynor
Address: 1330 Dillon Heights Avenue, Baltimore, MD 21228
Telephone # 410-747-4500 (7:00AM to 5:00PM Eastern Time)
24 Hour Emergency number: (414) 704-6821

Introduction

You are being asked to participate in a research study. Before agreeing to participate in this study, it is important that you read this form. This form, called an informed consent document, describes the purpose, procedures, benefits, financial payment, if any, risks and discomforts of the study. It also describes the alternative procedures that are available to you and your right not to participate or to withdraw from the study at any time. Please ask as many questions as you need to so that you can decide whether you want to be in the study. After reading this form and having all your questions answered, if you decide to participate, you will return this consent form to the principal investigator's office, sign this form in the presence of the study staff, on the last page and initial and date each prior page. You may refuse to participate in this study and this decision will not be held against you.

Study Duration and Number of Volunteers

Preparing your forearms for the test, along with one other volunteer, will take only a few minutes. The exposures to bed bugs will go on for up to two (2) hours for each of the two fabrics tested. You will not be replaced with another test subject regardless of whether bed bugs bite you or not.

Purpose of Study

ICR, Inc. wishes to conduct a research project (also known as a test or study) on two untreated mattress covering fabrics. A small piece of this untreated fabric will be used to cover a vial containing a bed bug that has not been fed. This vial will be inverted and placed against your bare forearm. The purpose of this study is to determine if the bed bug is able to bite through the fabric.

Your Suitability for the Study

Before beginning the study you will be questioned about allergies to insect bites and about any skin conditions that you may have. In addition, if you are female, you may not participate if you are pregnant or breastfeeding. You must avoid alcohol and fragranced products (e.g., soap,

perfume, cologne, hair spray, lotion, antiperspirant/deodorant, etc.) for 8 hours before the test as well as, during the test. If ICR decides that you should not take part in this test because of any of the answers which you give, you will not take part in it. If this happens it is no reflection upon you.

Treatment of Forearms
Before the test begins you will wash your forearms with unscented Neutrogena® soap. There will be no other treatment.

Bites
An ICR staff member will invert ten vials (one or two at a time) onto each of your forearms for up to five minutes each. Each of these vials will be covered with a small piece of the untreated test fabric, and each will contain one adult bed bug which has not received a blood meal in at least two weeks. At the end of the five-minute period, the staff member will record which bed bugs bit and which did not. A bed bug will be recorded as having bitten if it has ingested blood or has obviously penetrated the fabric with its mouth parts. The fabric covering the vials containing the bed bugs which did not bite will be replaced with a porous control fabric through which bed bugs can bite. These vials will again be inverted over your forearm to determine if the bed bugs will now bite. This is done to determine if the test fabric had previously prevented the bed bug from biting or if the bed bug just did not want to bite. This adult portion of the test will continue until five bed bugs either bit through the test fabric or bit through the control fabric.

This test will be repeated on your other arm following the same procedures, but using more vials, each containing one baby bed bug. This will complete the testing of one test fabric. This process will be repeated for the other fabric using the other test subject. You will receive five bites from adult bed bugs and five from baby bed bugs (also called nymphs) in testing one of the test fabrics. The test will take no more than four hours, probably considerably less.

At the end of the test, you may use Caladryl® or Calamine® lotion, or rubbing alcohol to help stop any itching from the bites.

Discomfort and Hazard
Bed bugs are not known to carry any diseases since there has been no conclusive evidence that they have done so. There are no records of bed bugs transmitting disease to humans. The bed bugs used in this test have been colonized at ICR since 1983, and have been kept in the laboratory, away from possible infection from infected people. A bite from one of these bed bugs will usually only be irritating, and will not give you any diseases.

Reactions to bed bug bites vary greatly with the individual. The bite of bed bugs is painless, however you may develop some allergic reaction to the saliva the bed bug injects as it bites. If

you react to the bite, it will probably become a red welt, the size of which varies with the individual. The welt may not appear for a few days after the bite occurs and will usually fade shortly after that. The irritation from the welt may itch, become red and/or swell. The skin of some individuals is more easily irritated than that of others. The irritation will usually disappear within a couple of days. However, if you develop a severe reaction to the bite, the test supervisor will refer you to a physician for treatment at ICR's expense.

The test will be conducted in a room kept at comfortable temperature and humidity conditions. The test will keep you steadily occupied but you may leave the room to go to the rest room or to make or receive phone calls.

Financial Consideration
You will be paid $100.00 for participating in this test that will last for up to two hours per fabric tested (maximum 9-hour working day). This payment will be mailed to you on the 15th or at the end of the month.

Although you may drop out of the test, if you do you will be paid only for the amount of time that you participated in the test at a rate of $11/hour, because little useful information can be obtained unless the test is completed. If on the other hand, ICR asks you to drop out of the test, and you have complied with all of their requests, full payment will be made. If ICR asks you to drop out of the test because you have not followed all their directions, you will only be paid for the time that you followed directions during the test.

Benefits
You will probably get no personal benefit from this study, but people in general may benefit by the development of a mattress covering through which bed bugs cannot bite.

Your Rights
You have been given an opportunity to discuss with ICR personnel any aspects of this document which are not clear to you. Your consent must be freely given after you are certain that you understand the nature of the test, its purpose, and the procedure to be used together with the discomforts, risks or other adverse effects you may experience during or after the test. 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. After you read, and sign to signify agreement, you will receive a copy of the signed consent form for your files.

New Information
You will be informed verbally or in writing of any significant new findings discovered during the course of this demonstration which may influence your continued participation.

Alternative

Your only alternative to participating is to not do so.

Questions

If you have any questions about this study or suffer a reaction, call ICR at 410-747-4500. If you have any questions concerning your rights as a research subject or related concerns or complaints, you may contact the Essex Institutional Review Board (IRB), 121 Main Street, Lebanon, NJ 08833, telephone (908) 236-7735, fax (908) 236-2027 or e-mail glambert@essexirb.com. Essex Institutional Review Board (IRB) is a committee that has reviewed this study to help ensure that your rights and welfare as a research participant are protected and that the study is carried out in an ethical manner. Review and approval of this study by Essex Institutional Review Board is not an endorsement of this study or its outcome.

Research Participation Information

You can obtain information about participating in research studies from a number of sources. A few are:

- Center for Information and Study on Clinical Research Participation (CISCRP): www.ciscrp.org
- Food and Drug Administration (FDA): www.fda.gov
- Office for Human Research Protections (OHRP)" www.hhs.gov/ohrp
- National Institutes of Health: www.nih.gov
- National Cancer Institute: www.nci.nih.gov
- Center Watch: www.centerwatch.com
- Various large university websites
- Various associations and societies concerned with specific diseases websites.

Confidentiality

The information obtained from your taking part in this test will be used by ICR and its client and will become part of a report. This report will be kept as confidential as possible under local, state and Federal law. ICR cannot guarantee that your identity will be kept confidential. Federal regulatory agencies and the Essex Institutional Review Board have the 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 years of age or over. By signing this form I have not given up my legal rights.

Subject's signature	Date	Person Obtaining Consent's Signature	Date
Printed name of subject	Date		
Principal Investigator's signature	Date		

TEST SUBJECT SELECTION CHECKLIST		
YES	**NO**	**DESCRIPTION**
		Is the subject in good health with no problematic skin conditions?
		Is the subject free of significant skin disease, skin problems or a known sensitivity or allergy to bed bug bites?
		Is the subject free of taking any medications or of any concurrent illness which, in the opinion of the study coordinator, may interfere with the study or its results?
		Has the subject voluntarily signed an informed consent form and is willing to follow the study protocol as explained?
		Is the test subject currently pregnant or a breast-feeding mother?

All answers must be "Yes", except for the last question which must be "No" (females only), in order for the subject to be considered for inclusion in the study. If one or more "No" answers are given, or the last answer is "Yes", exclude the subject and save this form for documentation of reason(s) that the subject was excluded from the study. If a test subject is concerned about any of the above questions they should discuss them with the study coordinator.

If subject is to be enrolled in the study, file this completed form with other evaluation forms completed by the investigator on the subjects.

_____ _____

PRINCIPAL INVESTIGATOR'S SIGNATURE DATE TEST SUBJECT'S NAME

APPENDIX III: RAW DATA SHEETS

APPENDIX I
RAW DATA SHEET: BED BUGS BITING (BITEING) THROUGH FABRIC / SCREEN

Test Date: 9-17-10 Date of Last Blood Meal: AUGUST 31, 2010

Test Fabric Name: MISSION: ALLERGY PREMIUM MICROFIBER

Life Stage: (Early instar nymphs) OR **Adults** (circle one)

Volunteer identity (code number only to protect privacy): 41

Test Replicate I bed bug/rep.	**FED THROUGH TEST FABRIC (YES/NO)**	**Control Replicate** 1 bed bug/rep	**FED THROUGH CONTROL SCREEN (YES/NO)**
1	NO	1	YES
2	NO	2	YES
3	NO	3	YES
4	NO	4	YES
5	NO	5	YES
6		6	
7		7	
8		8	
9		9	
10*		10	
Total		**Total**	

*Sufficient bed bugs will be tested to yield five positive responders per life stage

Principal Investigator/Date: William J Gaynor 9/17/10

Recording Technician/Date: NCyn 9-17-10

APPENDIX I
RAW DATA SHEET: BED BUGS BITING (BITEING) THROUGH FABRIC / SCREEN

Test Date: 9/17/10 Date of Last Blood Meal: August 31, 2010

Test Fabric Name: Mission: Allergy Premium Microfiber

Life Stage: Early instar nymphs OR (**Adults**) (circle one)

Volunteer identity (code number only to protect privacy): 4/1

Test Replicate I bed bug/rep.	**FED THROUGH TEST FABRIC (YES/NO)**	**Control Replicate** 1 bed bug/rep	**FED THROUGH CONTROL SCREEN (YES/NO)**
1	NO	**1**	YES
2	NO	**2**	YES
3	NO	**3**	YES
4	NO	**4**	YES
5	NO	**5**	YES
6		**6**	
7		**7**	
8		**8**	
9		**9**	
10*		**10**	
Total		**Total**	

*Sufficient bed bugs will be tested to yield five positive responders per life stage

Principal Investigator/Date: William J. Gaynor 9/17/10

Recording Technician/Date: NCho 9-17-10

APPENDIX I
RAW DATA SHEET: BED BUGS BITING (BITEING) THROUGH FABRIC / SCREEN

Test Date: 9/17/10 Date of Last Blood Meal: August 31, 2010

Test Fabric Name: Mission: Allergy Barrier II

Life Stage: (Early instar nymphs) OR **Adults** (circle one)

Volunteer identity (code number only to protect privacy): 4/2

Test Replicate I bed bug/rep.	**FED THROUGH TEST FABRIC (YES/NO)**	**Control Replicate** 1 bed bug/rep	**FED THROUGH** CONTROL **SCREEN (YES/NO)**
1	NO	**1**	Yes
2	NO	**2**	Yes
3	NO	**3**	Yes
4	NO	**4**	Yes
5	NO	**5**	Yes
6		**6**	
7		**7**	
8		**8**	
9		**9**	
10*		**10**	
Total		**Total**	

*Sufficient bed bugs will be tested to yield five positive responders per life stage

Principal Investigator/Date: William J Grayson 9/17/10

Recording Technician/Date: WJG 9/17/10

APPENDIX I
RAW DATA SHEET: BED BUGS BITING (BITEING) THROUGH FABRIC / SCREEN

Test Date: 9/17/10 Date of Last Blood Meal: August 31, 2010

Test Fabric Name: Mission: Allergy Barrier II

Life Stage: Early instar nymphs OR (**Adults**) (circle one)

Volunteer identity (code number only to protect privacy): 42

Test Replicate I bed bug/rep.	**FED THROUGH TEST FABRIC (YES/NO)**	**Control Replicate** 1 bed bug/rep	**FED THROUGH CONTROL SCREEN (YES/NO)**
1	NO	**1**	Yes
2	NO	**2**	yes
3	NO	**3**	Yes
4	NO	**4**	Yes
5	NO	**5**	Yes
6		**6**	
7		**7**	
8		**8**	
9		**9**	
10*		**10**	
Total		**Total**	

*Sufficient bed bugs will be tested to yield five positive responders per life stage

Principal Investigator/Date: William J Gaynor 9/17/10

Recording Technician/Date: MJB 9/17/10