LSU REPELLENT STUDY 4370

Field Evaluation of Two Topically Applied Insect Repellent Products Containing IR3535 Against Mosquitos in Louisiana

COVER PAGE:

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Study Consent Form: (Approved May 17, 2021)

RESEARCH STUDY CONSENT FORM

INTRODUCTION

Name of person seeking your consent: _____

Place of employment & position: _____

Please read this form, which describes the study in some detail. A member of the research team will describe this study to you and answer all of your questions. Your participation is entirely voluntary. If you choose to participate, you can change your mind at any time and withdraw from the study. You will not be penalized in any way or lose any benefits to which you would otherwise be entitled if you choose not to participate in this study or to withdraw. If you have questions about your rights as a research subject, please call the University of Louisiana Office of Research and Economic Development at 225-578-5833.

GENERAL INFORMATION ABOUT THIS STUDY

1. **Name of Participant ("Study Subject")**

   _____

2. **What is the Study Number and Title of this research study?**
   Study Number: 1215 Livful, (4370 LSU)
   Title: Field Evaluation of two topically applied insect repellent products containing IR3535 against mosquitos in Louisiana

3. **Who do you call if you have questions about this research study?**
   Study Director: Kristen Healy, PhD. Phone 225-578-7386

4. **Who is paying for this research study?**
   LivFul Inc.
   c/o RegWest Company, LLC
   8209 West 20th St., Suite B
   Greeley, CO 80634-4699

5. **Why is this research study being done?**
   The purpose of this research is to evaluate how long new insect repellents applied to the skin protect against mosquito bites. The results of this study will be used to register the repellents with the U.S. Environmental Protection Agency (EPA) so they can be made available for consumer use.

   You are being asked to be in this research study because mosquitos bite people and animals and transmit diseases. The purpose of this research is to test how well new products stop or repel mosquitos from biting people.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. **What substances will you be exposed to as a result of your participation in the study?**
   The products being tested contain IR3535 (ethyl butylacetylaminopropionate), a pesticide registered by the U.S. EPA under the pesticide law, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), to repel a variety of insect pests. IR3535 can be used as an insect repellent against mosquitos, deer ticks, body lice, and biting flies. Products containing this active ingredient are applied to exposed human skin. Both products being tested in this study contain 20% IR3535. The products containing IR3535 that are being tested in this study have not yet been registered by the U.S. EPA under FIFRA. The data collected in this study will be used to support registration of the products being tested. Other products containing IR3535 have already been registered and are already being marketed to consumers.

7. **What will be done as part of your normal clinical care (even if you did not participate in this research study)**
   Participation in this study will not affect your routine clinical care.

8. **What will be done only because you are in this research study?**
   You will be asked to test an insect repellent containing IR3535 for its ability to stop mosquitos from biting. There are two products to be tested: a lotion (which contains 20% IR3535) and a wipe (which contains 20% IR3535). Each is applied directly to the skin. Although the product is not EPA registered yet, many products containing the active ingredient IR3535 have been approved to date.

   There are three main components to your involvement in the study:
   1. A screening and consenting session, which will take place over the phone or via video conference, and which is expected to take no more than one hour
   2. A training session, in which we will test your attractiveness to mosquitoes, give you training in mosquito collection, and measure the dimensions of your lower leg in preparation for the field test days. This is expected to last no more than two hours.
   3. One or two field test visits, which will involve a repellent product being applied to your lower leg. You will be transported to the field site, and will expose your leg to wild mosquitoes for 5 minutes every half hour. If you are randomly selected to be a control subject, you will not have any repellent on your leg. The field test days may take up to 14 hours.

   You will be asked to adhere to these rules for 24 hours before the experiment:
   - No alcohol to be consumed prior to experiments
   - No excessive exercise
   - Wash using hot water and non-scented soap (provided) only
   - No scented soaps, shampoo, deodorant, perfumes, cosmetics, etc.
   - No smoking (cigarettes, cigars, pipes etc.) or chewing tobacco.

   Phone call or video conference: Screening and paperwork
   We will arrange phone call or video conference, in which you will complete a questionnaire that will verify your suitability to take part in the study. We will also check a government-issued photo identification to ensure that you are at least 18 years old.

During this call, the staff member leading the discussion will briefly outline the study, its purpose, your potential role in the study, the potential duration of testing, the identity and function of the repellent to be used, potential hazards associated with the study, and steps taken to mitigate these hazards. They will talk through the inclusion/exclusion criteria, and the procedures for reporting adverse events. They will also describe the test procedures, including a visit to the Test Facility at the Life Sciences Building at LSU, Baton Rouge, LA, for mosquito collection training, product application and testing in the field.

This session is expected to take no more than one hour.

Visit 1: Mosquito attractiveness test and training
You will be invited to the Test Facility at the Life Sciences Building, Louisiana State University in Baton Rouge. For this visit, you will need to wear long sleeved shirts and pants because you will be exposed to mosquitos. If you are a female then you will be required to take a pregnancy test at this visit to confirm that you are not pregnant.

Pregnancy test
You will perform the pregnancy test yourself and initially only you will see the results. After completion of the pregnancy test, a female employee associated with the study will ask you, in a private setting, if you still want to participate in the study. If you do, the employee will verify the negative test result. She will also share the result with the Study Director, unless the Study Director checked the test results. The results will be kept confidential, and will not be disclosed to anyone other than the test subject, the verifying employee, and/or the Study Director. We will provide opaque plastic bags in the private area for disposing of the test in a private, discrete manner. However, you may keep the test if you wish to do so.

If you are not eligible to move forward in the study (due to your answers to the questionnaire or test results), or do not wish to do so, you will still be compensated for your participation in the current and any previous sessions.

Mosquito attractiveness test
If you choose to proceed, you will be tested for attractiveness to mosquitos. You will be required to place one arm in a 45 x 45 x 45 cm cage of approximately 78 *Aedes* mosquitos. The mosquitos will not be permitted to bite; they will be blown off or captured after they land on your arm. If you receive fewer than five landings in one minute, you will be allowed to repeat the test up to two more times (each time with a new cage of mosquitos). If you still receive fewer than five landings in one minute then you will be considered not sufficiently attractive to mosquitos and you will not be allowed to continue with the study or finish the training. The mosquitos we use in this test will be free of disease. The colony has been bred in the laboratory for at least 10 years.

Mosquito collection training
After the mosquito attractiveness test, you will be trained to identify mosquito landing behavior and to use a device called an aspirator to collect landing insects before they have time to probe or bite. Again, the mosquitos we use in this training will be free of disease. The colony has been bred in the laboratory for at least 10 years.

For this step, you will be provided with a new set of gloves and a new head net, and will go into a screened free-flight cage to observe mosquitoes landing. You will be paired with one other person and will have a chance to practice collecting mosquitoes from the lower legs of each other, to simulate what will happen on a test day, where you will be doing the same thing but with wild mosquitos.

Leg measurement
The study will require some participants to have the repellent product applied to their lower leg on field test visits, so your lower leg measurements will be taken in order for the right amount of product to be applied. You will be shown how the products will be applied.

This session is expected to take no more than two yours. If you are not eligible to move forward in the study (due to the results), or do not wish to do so, you will still be compensated for your participation in the current and any previous sessions.

Visits 2-3: Field testing
This kind of test allows us to estimate the amount of time that the repellent chemicals protect you and is known as an "assessment of median complete protection time" (CPT).

You will be asked to wear light-colored, loose-fitting long pants and long-sleeved shirt on the test days, and to arrive at the Test Facility at a certain time 3-4 hours before testing begins at the test site. If you are a female, you will be required to take a pregnancy test as before, and will only be able to continue if a negative result is verified by a female member of staff. At the start of the day, we will select, through a randomization process, 13 people to get treated with the repellent, and 2 people to serve as untreated controls. For all subjects, one leg (knee to ankle) will be prepared for the test by washing the lower leg with unscented soap and carefully rinsing and drying. Throughout the study day, you will be asked to avoid strenuous exercise and sweating (as much as possible). If you receive a treatment with the repellent, you will be asked to avoid rubbing, touching, or wetting the treated area.

A dose of topically applied insect repellent containing IR3535 will be applied to the exposed area of the treatment leg. The dose rate will be based on EPA's recommendations for standard dosing. The total amount we will apply to your lower leg will be calculated based on the surface area of your lower leg. The amount of repellent applied will not exceed the recommended daily dose.

After we apply the repellents, you will wait at our facility and then be transported to the field site to allow testing in the field to begin 2 hours after the product is applied to the test subjects. However, if you choose, you may transport yourself from the facility to the test site in your own vehicle.

The field site will be determined based on a presence of mosquitos but absence of eastern equine encephalitis virus (EEEV), St. Louis encephalitis virus (SLEV), Zika virus and West Nile virus. We will trap mosquitos for the two months prior to the field testing and make sure that the mosquitos in the area do not carry these viruses. The location is expected to be Cameron Parish, Plaquemines Parish, Calcaseau Parish Mosquito Control, or Grande Isle (approximately 110-160 miles from the Test Facility in Baton Rouge).

You will travel to the field site with the Study Director, her study staff, and the rest of the volunteers (15 subjects in total) or on your own if prefer to drive yourself. You will be paired with the another untreated person or another treated person, depending upon if you are untreated or treated. As there

is an uneven number of people, one person will be paired with a member of the study staff. Each pair will be at least 3 meters from another pair. You will be provided with the appropriate protective clothing to prevent bites (head net, gloves) and a chair. You will also be provided with a data recording sheet, clipboard, timer and pencil for recording landings, and a mosquito aspirator.

You will test the repellent effectiveness every 30 minutes for 5 minutes each and then rest in a screened enclosure with fans until the next test period as described below. You will alternate with your partner to test or monitor and aspirate. The monitor will count and aspirate mosquitos as they land on the test participant's leg. Once the repellent fails (one landing on the treated leg in the 5-minute test period followed by a second confirmatory landing during the same test period or the next test period) you will stop testing. When you finish your testing, you may still need to continue in the test. You may not be able to leave the study site until your partner has finished testing if all study staff are occupied. Once both of you have performed your five-minute tests you will return to a screened enclosure where you can rest until your next test.

You will have the repellent on for a maximum of 14 hours for each test day (the lotion is being tested for up to 14 hours, and the wipe is being tested for up to 13 hours). In the first two hours you will not perform any tests. To determine the duration of protection time, the repellent will be left on the leg and tested for 5 minutes every 30 minutes for up to 14 hours or until the Complete Protection Time (CPT) has been determined. CPT is defined as one landing on the treated leg in a 5-minute test period followed by a second confirmatory landing during the same test period or the next test period.

Some individuals may be randomly selected to be untreated control participants. These people will be protected from mosquito bites with appropriate clothing, but will expose one untreated lower leg during 5-minute test intervals every 30 minutes. Once 5 mosquitos land on each untreated control participant's exposed lower leg, they may roll down their pant legs until the next 5-minute test interval.

We will provide a screened area for you to rest for the period between the 5-minute test intervals. In addition, we will provide cold drinks (water, soft drinks, etc.) to keep you hydrated, as well as snacks to maintain your blood sugar. We recommend that you bring your own form of entertainment to enjoy during the periods between the 5-minute intervals. In addition, we recommend that you bring lunch if you would like to eat a meal during the test day. We will provide a cooler to keep your food cold.

If you are not eligible to move forward in the study (due to your adherence to the pre-test procedures or test results), or you were selected as an alternate, or you do not wish to do so, you will still be compensated for your participation in the current and any previous sessions.

Once you and the participant you are paired with have completed your tests you will be free to leave. If you have your own transport, you can leave immediately, or you can wait until one of the staff vehicles is available to return you to the Test Facility.

After the test day, will contact you within 72 hours to check on your wellbeing following your participation in the experiment.

If you have any questions now or at any time during the study, please contact the Study Director, listed in question 3 of this form.

Alternate subjects
On each test day, 13 individuals will be treated with the repellent on their lower leg and 2 individuals will be control subjects without a treatment. In case some participants fail to turn up on a test day, we will invite an extra 5 participants. These 'alternates' may not be needed; if there are enough participants, they will be free to leave within two hours.

9. How long will you be in the research study?
The study will involve a screening call, a training visit, and then up to 2 visits (2 products). You are not obliged to participate in all 2 tests. If you participate in more than one test day, they will be spaced at least 72 hours apart. By signing this consent form you are expressing your willingness to participate in at least one of these tests in completion (screening, training, and field test). If you participate in all 2 tests, we estimate a maximum duration of 4 days over a period of approximately one month.

10. How many people are expected to take part in this research study?
We are aiming to enrol 80 people in the study. This is to ensure that we get a wide range of ages, and ethnicities, for our research. After you are enrolled, we will randomly select 20 people and invite them to take part in a test day. Of those 20 people, 5 will be "alternates". Alternates are reserve candidates for participants that have been invited but do not turn up or are ineligible on the day. If not required, they are able to return to their normal activities after a maximum of 2 hours at the Test Facility.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY, AND WHAT ARE YOUR OPTIONS?

11. What are the possible discomforts and risks from taking part in this research study?
You will be exposed to biting insects. Efforts will be taken to avoid the risk of bites, such as training on aspirator use, instructions from the study team, providing a head net and gloves, and working in pairs. However, there is a slight risk that you will receive one or more mosquito bites, and if bitten may experience some irritation and itching.

As this is a field study, efforts will be taken to minimize the risk of infection from vector-borne illness as follows:

- Mosquito sampling will occur in the two test sites weekly for two months prior to the tests using two trap types. All mosquitos captured will be identified and a subset will tested to see whether they carry disease.
- This is a landing study and mosquitos will be captured before they have a chance to bite.
- You will be trained in aspirating mosquitos and spotting mosquito landing behavior.
- You will be asked to wear light, loose fitting clothing that fully covers the rest of your body. You will also be provided with a head net and gloves.
- All mosquitos that land on the exposed lower leg will be captured, identified and a subset will be tested to see whether they carry disease.
- Mosquitos will be tested to see whether they carry West Nile virus (WNV), St. Louis encephalitis virus (SLEV), Eastern equine encephalitis virus (EEEV), and Zika virus (ZIKV).

Mosquito bites

If you are bitten by mosquitos, you may experience some irritation and itching. The study sponsor will provide topical, over-the-counter anti-itch cream at the conclusion of a test day upon request to you if you are experiencing irritation and/or itching as a result of your participation in the study.

Mosquito-borne illness
There is a very slight risk of contracting mosquito-borne illnesses, such as Eastern equine encephalitis virus. Many precautions are being taken to avoid this, such as training you on how to catch mosquitos before they probe or bite, limiting exposure periods to no more than 5 minutes per 30-minute period, providing head nets and gloves to protect skin that could be exposed to bites during the test period, and providing a screened enclosure for you to rest between exposure periods. We are also monitoring the potential test sites to ensure no mosquitos carrying diseases have been present where the testing will occur. Information about diseases that can be transmitted by mosquitos is available at https://www.cdc.gov/niosh/topics/outdoor/mosquito-borne/default.html.

Irritation from the insect repellent
Both products contain IR3535, which is moderately irritating to the eyes, but is not irritating to the skin. It may also produce an allergic reaction or irritation of the respiratory tract. Correct handling by the researcher will avoid risks associated with the eyes or respiratory tract. You will be excluded from the study if you have a known allergy or sensitivity to the test product or any of its ingredients, or any insect repellent products, or have any skin condition which may affect your reaction to the product. If new findings are developed during the course of the research that may relate to your willingness to continue participation, you will be provided with this information.

Discomfort from being outside
Other risks associated with participation in this trial include the risks associated with being outside in a hot humid climate, such as sunburn, heat stroke. In addition, there is a risk of fatigue due to the length of the test day.

Precautions will be taken to prevent sunburn, such as exposing only minimal skin, wearing a hat, and limiting the exposure period. You will be directed to spend the time between test periods in a screened enclosure with fans.

- Water and other drinks will be provided to prevent dehydration and snacks will be provided to maintain blood sugar levels if necessary. You will be told at the consent meeting and reminded at the training to bring snacks, lunch, and entertainment to occupy your time during breaks between test periods.
- You will be provided with breaks as needed between the test periods. Chairs and a shaded and screened area will be provided for relief from the sun. You will have an opportunity to eat meals and snacks, and will have opportunities to use the restroom as necessary.
- In addition, any time remaining immediately following an exposure period and before the start of the following exposure period, you will be encouraged to stretch and walk around as needed to try to minimize the discomfort from the length of the testing period, as well as to remain inside the shaded, screened area to avoid heat-related illnesses.
- If you choose to participate in more than one test day, at least 72 hours will lapse between each test day to allow you to rest and recover.

Release of confidential information

A potential risk of participation is unintentional release of confidential information. Researchers will take appropriate steps to protect any information they collect about you. However, there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information, such a release could upset or embarrass you, or possibly affect your insurability or employability. Questions 17-21 in this form discuss what information about you will be collected, used, protected, and shared.

Pregnancy testing
There can be psychological stress relating to pregnancy testing. In order to minimize the psychological stress, women will be given a private place to take the test, a female member of the study team will verify a negative test result, and the study director will ensure confidentiality of any test result. Positive test results will not be recorded. The results of the test will not be discussed with or released to anyone besides the subject. The confidentiality of the pregnancy testing will be discussed during the consent process.

General risk mitigation
General risks to participants associated with involvement in this study will be addressed by adhering to ICH Good Clinical Practices, the Declaration of Helsinki, the Data Protection Act and all applicable regulatory requirements.

There will be no direct benefit to you or other participants. Indirect benefits to society will be improved products for prevention of mosquito biting and pathogen transmission. The results of this study will inform the product labelling. This study may include risks that are unknown at this time.

Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another research study, please inform one of the research team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

Throughout the study, the researchers will notify you of new information that may become available and might affect your decision to remain in the study.

COVID-19
As a precaution against COVID-19, you will be required to wear a face mask for visits to the Test Facility and throughout test days, except when you are aspirating mosquitos. You will also be required to keep a social distance of 6 feet from other participants and staff as far as possible. You will also have your temperature taken on each visit, and a staff member will contact you ahead of ach visit to assess your health and potential exposures to COVID-19. Those that do not meet the CDC's screening criteria will be excluded. If you fail to abide by social distancing and mask wearing provisions you will be asked to leave.

If you wish to discuss the information above or any discomforts you may experience, please ask questions during the consent call, or phone one of the research team members listed in question 3 in this form.

12. What are the potential benefits to you for taking part in this research study?
You will not personally benefit from participating in this study. Significant new findings developed during the course of the research will be provided to you.

13. How could others possibly benefit from this study?

The discovery of new insect repellents is a possible benefit of this research. The chemicals we test may help prevent bites from mosquitos that transmit certain diseases. The study sponsor will benefit from data to support registration and sale of repellent products. Society may benefit from more accurate information about how long the repellent provides protection.

14. How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, the Study Director listed in question 3 of this form may benefit if the results of this study are presented at scientific meetings or in scientific journals.

15. What other choices do you have if you do not want to be in this study?

The alternative option is to not take part in this study. If you do not want to take part, tell the Study Director and do not sign the Informed Consent Form.

16. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled.

If you decide to withdraw your consent to participate in this study for any reason, please contact one of the research team members listed in question 3 of this form. They will tell you how to stop your participation safely.

If you have any questions regarding your rights as a research subject, please call the University of Louisiana Office of Research and Economic Development at 225-578-7386.

17. If you withdraw, can information about you still be used and/or collected?

That data that were collected as a result of your participation are still valuable and will be reported for this study, even if you do not complete the study. You have the option to request that your data not be used if you decide to withdraw from the study or if you are withdrawn.

18. Can the Study Director withdraw you from this study?

You may be withdrawn from the study without your consent for the following reasons:

- The Study Director decides that continuing the study would be harmful to you.
- You are not following directions necessary for the study to proceed.
- Participation in the study has a bad effect on you.
- The study is cancelled.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

19. If you choose to take part in this research study, will it cost you anything?

Study Services: The Sponsor will pay for or provide the study services/activities required as part of your participation in this study as described above in the question "What Will Be Done Only Because You Are In This Research Study". If you receive a bill for these services, please contact Dr Kristen Healy, on 225-578-7386

If requested, we will provide standard over-the-counter first aid items such as bandages, antiseptics, and hydrocortisone cream immediately upon completion of the test at no cost to you.

Items/Services Not Paid for by the Sponsor: Any other medical services provided to you that are not directly related to participation in this study will be billed to you or your insurance company in the usual manner.

20. Will you be paid for taking part in this study?

You will receive compensation for participating in this study. The amount of compensation will depend the duration of your involvement but will equate to approximately $10 per hour. You will receive $10 for attending the remote consent session, and $40 for attending the mosquito attractiveness test/mosquito capture training session. On test days, you will receive $10 per hour for the first 8 hours, and $15 per hour for your participation beyond the first 8 hours.

An alternate who shows up to the test site and who is not needed to replace a test subject will be paid $20. The decision as to whether an alternate is needed will occur within the first two hours of the test, before all the treatments have been finished, at which point they can leave. If you are an alternate that is asked to replace another participant, you will be paid at the same rate as other test participants, as described above. All payments will be made in cash or pre-paid card in person at the end of each event.

If you are paid more than $75 for taking part in this study, your name and social security number will be reported to the appropriate University employees for purposes of making and recording the payment as required by law. You are responsible for paying income taxes on any payments provided by the study. Payments to nonresident aliens must be processed through the University's Payroll and Tax Services department.

If you have any problems regarding your payment contact the Study Director. The approximate amount of compensation is as follows, assuming participation in both test days, with the test days lasting the maximum amount of time (14 hours for the lotion and of 13 hours for the wipe)

Visit	Reason		Compensation
1	Consenting appointment	$	10.00
2	Mosquito attractiveness and training	$	40.00
3	Lotion test visit	$	170.00
4	Spray test visit	$	155.00
	Total	$	375.00

If you have participated in any of the pre-test sessions, but then choose to withdraw or are asked to withdraw from or during the session, you will still be paid for all sessions you have participated in.

Subjects may decline to participate at any time during the training session or test day without penalty. You will be compensated for your time up until the decision to withdraw.

If the Study Director or other study staff ask you to withdraw from the test and you have complied with all of their requests, or if you need to withdraw early because of a health or emergency reason, full payment will still be made for the entire 13 hour (spray) or 14 hour (lotion) test day. This will not affect payment for any previous test days that you have completed.

All payments to volunteers will be made by cash or pre-paid card at the end of each visit.

21. What if you are injured because of the study?

If you are injured or made ill as a direct result of your participation in this study, the Sponsor will pay for any required medical treatment required to treat your injury or illness, as long as:

1. The injury or illness occurs as a result of your participation in the study.
2. The injury or illness results directly from an intervention that you would not have received if you were not enrolled in the Study.
3. The injury is not a result of the negligence or misconduct of the study staff.

In the event of an injury as a result of the study the Study Director will immediately inform the Clinical Trials Office (CTO) at 318 675-8306, the Study Sponsor, and the Self-Insurance Program (SIP)

The Sponsor, medical monitor, and the Study Director will determine whether the injury is related to the subject's participation in this study. To do this, they may request to consult with the person/facility that provided medical treatment following an adverse effect, which could require your consent. Apart for paying for any necessary medical treatment, no additional compensation for injuries or illnesses sustained due to your participation in the research is routinely offered.

A CTO liaison will assist the Study Director with the process for ordering and tracking of services for you (the subject) to prevent you from receiving bills for medical treatment of the study related injury or illness, and assist with billing of these medical services to the sponsor.

The Study Director and others involved in this study may be University of Louisiana employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact Dr. Kristen Healy on 225-578-7386 if you experience an injury or have questions about any discomforts that you experience while participating in this study.

22. How will your health information be collected, used and shared?

If you agree to participate in this study, the Study Director will collect, and use private information about you and your health. This information is called protected health information or PHI. In order to do this, the Study Director needs your authorization. The following section describes what PHI will be collected, used and shared, how it will be collected, used, and shared, who will collect, use or share it, who will have access to it, how it will be secured, and what your rights are to revoke this authorization.

Your protected health information may be collected, used, and shared with others to determine if you can participate in the study. This information will be gathered from you via a health questionnaire. More specifically, the following information may be collected, used, and shared with others:

- Your name will be collected and assigned a coded subject identifier based on your gender, such as Subject M1, F2, F3, M4, etc.
- Your age will be requested because participation of those under the age of 18 is prohibited for this study.
- Your gender may be reported with the data as the coded identifier above, where M is for male and F is for female.
- Information about your health including: general health, allergies, pregnancy (if applicable), insect bite history, and participation in other studies.
- Your phone number and email address will be requested so we can follow up with you within 72 hours of your participation in a test day. We will also ask for the contact details of someone who can reach you if contact tracing is necessary.

This information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices.

The information collected from you as part of this research will not be used or distributed for future research studies.

23. For what study-related purposes will your protected health information be collected, used, and shared with others?

Your PHI may be collected, used, and shared with others to make sure you can participate in the research, through your participation in the research, and to evaluate the results of the research study. More specifically, your PHI may be collected, used, and shared with others for the following study-related purpose(s):

- The purpose of this study is to evaluate the repellency of novel and commercial repellents against mosquitos that bite humans and other animals. Some of the results from these studies will be averaged and reported and published in scientific journals. Some results from these studies may be kept confidential so that only the Study Director, her staff and the repellent manufacturer are aware of the results.

Once this information is collected, it becomes part of the research record for this study.

24. Who will be allowed to collect, use, and share your protected health information?

Only certain people have the legal right to collect, use and share your research records, and they will protect the privacy and security of these records to the extent the law allows. These people include:

- The Study Director (listed in question 3 of this form) and research staff associated with this project.
- The University of Louisiana Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research).
- In the event of a medical emergency, medical professionals at the University of Louisiana Hospital.

25. Once collected or used, who may your protected health information be shared with?

Your PHI may be shared with:

- The study Quality Assurance Unit (Compliance Services International)

- ARCTEC, London School of Hygiene & Tropical Medicine, UK, contract research organization (study monitor).
- The Study Sponsor (listed in Question 4 of this form).
- United States agencies who are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, the Environmental Protection Agency, and the Office of Human Research Protections.

Government agencies who are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.

Otherwise, your research records will not be released without your permission unless required by law or a court order. It is possible that once this information is shared with authorized persons, it could be shared by the persons or agencies who receive it and it would no longer be protected by the federal medical privacy law.

26. If you agree to take part in this research study, how long will your protected health information be used and shared with others?

Your PHI will be used and shared with others until the end of the study.

You are not required to sign this consent and authorization or allow researchers to collect, use and share your PHI. Your refusal to sign will not affect your treatment, payment, enrollment, or eligibility for any benefits outside this research study. However, you cannot participate in this research unless you allow the collection, use and sharing of your protected health information by signing this consent and authorization.

You have the right to review and copy your protected health information. However, we can make this available only after the study is finished.

You can revoke your authorization at any time before, during, or after your participation in this study. If you revoke it, no new information will be collected about you. However, information that was already collected may still be used and shared with others if the researchers have relied on it to complete the research. You can revoke your authorization by giving a written request with your signature on it to the Study Director.

SIGNATURES

As the Study Director, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

_____ _____

Signature of Person Obtaining Consent and Authorization Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used

and shared with others. You have received a copy of this form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described in sections 21-26 above. By signing this form, you are not waiving any of your legal rights.

_____ _____

Signature of Person Consenting and Authorizing Date