

Informed Consent Form

Title: Quantification of the epidemiological impact of targeted indoor residual spraying on Aedes diseases transmitted diseases

NCT Number: NCT04343521

IRB Approval Date: August 3, 2021



INFORMED CONSENT FORM HOUSING

ENROLLMENT

Project title: *"Quantification of the epidemiological impact of targeted indoor residual spraying on Aedes diseases transmitted diseases".*

Dependency or Institutions of origin: Emory University, Autonomous University of Yucatan.

Host institution: Universidad Autónoma de Yucatán.

UADY Principal Investigator: Pablo Manrique Saide (UCBE-UADY).

EMORY Principal Investigator: Gonzalo Vázquez Prokopec (Emory University).

Clinical researcher: Norma Pavía Ruz (CIR-UADY).

The Universities of Yucatan and Emory have invited me to include my home in a research study on the epidemiology and control of dengue, chikungunya and Zika that will occur in the city of Mérida. This consent explains the justification for the study, the procedures it will involve, and all the information needed to help me decide if I want to participate. If the information in this document is unclear, or I have doubts, I can ask any of the team members.

Brief description of the objective of the study:

Purpose and Justification: The *Aedes aegypti* mosquito is primarily responsible for the transmission of dengue, chikungunya and Zika. These diseases are very important because, just as they can occur without giving symptoms or only cause temporary discomfort, they can also cause serious affectations such as chronic pain in the joints, hemorrhages (bleeding), sudden drop in blood pressure (shock), problems in the nervous system of babies if their mothers became infected in pregnancy and even death, depending on the disease. In Yucatan, these diseases are a problem because the mosquito inhabits the entire region and is very difficult to control.

Currently, there is no effective vaccine against any of these viruses nor is there a specific treatment, so the application of insecticide represents one of the best measures to eliminate mosquitoes inside homes and thus prevent these diseases.

The aim of the study is **to assess whether the "Targeted Indoor Residual Spraying" technique, which consists of a low-toxicity insecticide application, lasting approximately 15 minutes and protecting the home for 6-7 months, has a measurable impact against the *Aedes aegypti* mosquito and the diseases it transmits (dengue, chikungunya and Zika).**

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In addition, we want to investigate how mosquitoes respond, especially if they were to present resistance in the presence of high-quality insecticides, in order to take appropriate measures; and to study through laboratory tests how they behave towards insecticides. All this information is very important to improve the control strategies of mosquitoes that transmit diseases in Mérida, Yucatán.

Description of the procedures to be performed

During the study, four types of activities will be carried out:

1. Initially, an "**entomological survey**" will be done, which consists of looking for and collecting mosquitoes in and around my house (rooms, backyard/back garden). A group of 2 UADY technicians will use a vacuum cleaner to collect mosquitoes inside my house, look for containers that could be or become breeding grounds for mosquitoes, identify and collect larvae, and place in my garden a device called "ovi-trap" to collect mosquito eggs.
2. In case my home has been randomly selected to be part of the houses where the "**insecticide spraying**" will be done, a project member will contact me and we will agree on a day for them to do it. For this they will apply the insecticide in the rooms (living room, rooms, bathrooms) and places where mosquitoes perch to rest (walls, under the tables, furniture). It will not be necessary to move any furniture, I will only avoid that there are food or drinks near where they are going to spray the insecticide. The application lasts about 15 minutes and requires staying outside until the insecticide is dry (about 1 hour).
3. After they apply the product, they will do a "**follow-up survey**" to get my opinion about the procedure and indicate any comments or suggestions.
4. Monthly, if my home is chosen, mosquito collections will be carried out like the one that was done initially, with the purpose of analyzing the mosquitoes in my home, regardless of whether or not the house was selected for the insecticide to be applied.

Potential risks and considerations regarding insecticide spraying: The product they will apply is used by the Yucatan Health Services for the control of dengue, chikungunya and Zika and is low toxic to humans and mammals. It is recommended by CENAPRECE and the World Health Organization for mosquito control inside homes. But **for safety, I must follow some indications and protection measures:**

- Although the application of the product only takes about 15 minutes, I will NOT have to enter the house until 1 hour after they have finished to let the product dry.
- During that time I will keep the doors and windows open to ventilate the environment and eliminate any odor due to the application of the insecticide.
- Once the product is dry there will be no odor and I will only have to clean the floor before the children or pets enter the house, if deemed necessary.
- I should not clean or wash the areas where they put the insecticide.
- If someone touches a fresh sprayed area, I will instruct them to wash that part of the body with plenty of water and avoid touching their eyes, because it can cause irritation.
- **In case I or someone in my family has any symptoms of allergic reaction or mishap that seems related to the insecticide (although I am not sure), I can call toll-free 01-800-4DENGUE or cell 9993-68-01-14 to contact a doctor of the project.**

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Benefits: During the entomological surveys, I will receive information about which places in my house serve as breeding grounds for mosquitoes and how I can prevent them from forming. In addition, every time they visit my home they will eliminate mosquitoes so we will have fewer and fewer mosquitoes in the house and could decrease mosquito bites in my home. If the insecticide is applied, I will receive an intervention that will control mosquitoes and other pests. Regardless of whether or not my home receives the intervention, routine mosquito control actions, performed by the Yucatan Health Services, will not be interrupted.

Use and protection of information: All information obtained will be handled confidentially and for exclusively academic/scientific purposes. The results of the project may be presented in academic sessions (symposia) or published in scientific journals, without personal information being disclosed or identifying me, my family members or my home address.

Cost: All project activities will be provided free of charge. We will not receive any material compensation for participating in this study and will not have to pay anything to access all of the benefits described.

I declare that it has been explained to me that **participation is completely voluntary** and that, even if I have agreed to participate, if I change my decision, I can cancel my participation at any time, without having to justify the decision and without fear of sanctions. I will be notified in the event that new information emerges that may cause me to change my mind about continuing the study.

I report that I have read (or have read) this document in its entirety, I have been informed of the objectives of the research, the justification, the risks, the benefits and I have received explanations about the procedures and what is required as part of the study. **I would like to say that the information presented seems clear to me, that all my doubts have been resolved and that I agree that my home, my family and I should be part of the investigation.**

I have received a copy of this informed consent which I can keep for reference. I am aware that I will be able to request, at any time, additional information about this study by contacting Dr. Pablo Manrique Saide, professor at UADY and main responsible for the project, with direction road Mérida-Xmatkuil Km. 15.5 Tizapán, 97100 Mérida, Yuc., at [REDACTED]; or send an email to Dr. Gonzalo Vázquez Prokopec ([REDACTED]), to obtain the information or an appointment so that it can be expanded.

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Merida, Yucatan, Mexico a _____ of _____ of the year _____

Project title: *"Quantification of the epidemiological impact of indoor directed residual spraying on diseases transmitted by Aedes".*

Housing information:

Address: Cluster ID: _____

Participant Information:

Age of participant: _____

Participant full name (*in impressa lettera*) Participant's signature

Full witness name (*in impressa lettera*) Signature of the witness

In the event that the participant cannot read or write, the presence of an adult person will be required to testify to the process of this informed consent.

Full name and signature of the person carrying out the informed
consent process (*in print*)

Date (DD/MM/YY) hour