

## 16.5. Information Leaflet for IGR Households

### Insect Growth Regulators to Control Jiggers

**Principal Investigator:** Dr Ulrike Fillinger, icipe

You and your family are being asked to take part in a study. The box below tells you important things you should think about before deciding to join the study. We will provide more detailed information below the box. Please ask questions about any of the information before you decide to participate. You may also wish to talk to others (for example, your family, friends) about this study, before agreeing to join.

#### Key Information for You to Consider

- **Voluntary Consent.** You and your family are being asked to volunteer for a research study. You can choose whether you would like to participate or not. If you do agree you can change your mind at any time and withdraw from the research. Any member of the family can withdraw at anytime.
- **Purpose.** We are doing this research to find out if a solution prepared from an insecticide called pyriproxifen or from neem oil can control jiggers in the floor of people's houses before they infect people
- **Duration.** Your participation in this study will last 1 month.
- **Procedures and Activities.** To start with we will need to quickly check everyone's feet for jiggers, ask a few questions of you, make observations of your house. If your house is found to be eligible to join the study, we would wish to spray the floor of the house every 5 days with a water-based solution and after 25 days we would need to take a soil sample from your house
- **Risks or disadvantages.** There is a possibility that we will disrupt your normal daily routine on the days we visit you and that your neighbours will become aware that your family have jiggers.
- **Benefits.** The spray we put on the floor may control the jiggers and reduce the infection of your family. Everyone who is infected will be referred for treatment at the health facility which we will provide with medicine. We hope the research will show an affordable way for people to use themselves to control jiggers in their homes.

#### Introduction

Jiggers are fleas which burrow into the skin of people's feet and grow rapidly causing much pain and itching. The jiggers spend some of their life in the floor of houses.

#### Who is implementing this study?

This study is being carried out by *icipe*. *icipe* is an international organization based in Kenya to study insects that are harmful or useful to humans.

### **What is this study about?**

The study is trying to find out if spraying the house floor with insecticides that affect the development of insects, can control the off-host stages of jiggers.

### **Procedures**

To find out if your family is eligible to participate we will check the feet of all your family members for jiggers and would like to get an idea of the size of your house. We will then select those families living in a house with a soil floor, having at least 2 people with more than 5 jiggers in their feet and a house that is no larger than 72 m<sup>2</sup>.

If your household is eligible, it will be assigned to one of three study groups through a system that gives you equal chance to be assigned to any group. One group will have their floor sprayed with pyriproxyfen, the second group will have their floor sprayed with neem oil, the third group will have their floor sprayed with water only. We will return every 5 days to spray the floor for 5 rounds. At the end of the spraying activity, we will collect soil samples from your house. We will then examine the feet of all household members and count the total number of fleas. All family members with jiggers will be referred to the nearest health facility for treatment which we will provide.

### **Are there any risks or disadvantages to taking part?**

While we do our work we will cause some disruption of your daily routine.

- We will conduct observations of your house which will take about 20 minutes
- Rapid examinations of feet for jiggers will take about 1 minute for each person.
- On spray dates will need you to remove items from the floor and allow us to enter to spray the floor.
- We will return to spray the floor every 5 days and will take soil samples at the end of the study.
- If you normally apply something to the floor or elsewhere in the house, we request that you do not do so during the 1 month of this study.

- Another risk from participating is that your neighbours may find out that your family have jiggers. We will do everything we can to reduce the chance of this and will not talk to others about it.

### **Are there any advantages to taking part?**

- All infected individuals identified during the study will be referred to the nearest health facility for treatment and we will provide them with the medicine.
- The spray we apply may control the jiggers in your house.
- In talking to us, you will contribute to knowledge of jiggers that may help other people in Kenya and elsewhere in the future, for example through developing new health policies.

### **What happens to the soil samples?**

- Your privacy is important so your names will not be on the soil.
- The soil samples will be sent to laboratories at *icipi* in Muhaka.
- Any insects found in the soil samples will be stored at *icipi* for exact identification.

### **Who will have access to the information you give?**

- All of our documents will be stored securely in locked cabinets and on password protected computers. The knowledge gained from this research will be shared in summary form, without your identity, with the Ministry of Health.
- In future, information collected or generated during this study may be used to support new research by other researchers in Kenya and other countries. In all cases, we will only share information with other researchers without including your identity and where you live and will replace this information with number codes.
- When the study is finished, we will need to share the results and the information we collected with other scientists around the world and health officers in Kenya. This will only be done in a way that does not share your identity. We could request to take a few pictures of the floors of the households as well as of the feet of the infected only after you have permitted for us to do so and after receiving verbal consent from the persons photographed for every photo taken.

### **Who has allowed this research to take place?**

This research was approved by the National Ethics Review committee located at KEMRI.

**What will happen if I refuse to participate?**

All participation in research is voluntary. You are free to decide if you want to take part or not. If you do agree you can change your mind at any time without any consequences. Even if you agree, any member of the family can refuse for us to screen their feet.

**What if I have any questions?**

You are free to ask any question about this research. At any time, you can also contact:  
Dr. Ulrike Fillinger, International Centre of Insect Physiology and Ecology, Kenya (*icipe*),  
Duduville Campus, Nairobi 00100. [ufillinger@icipe.org](mailto:ufillinger@icipe.org), mobile: 0791845259

**If you want to ask someone independent anything about this research, please contact:**

The Head, KEMRI Scientific and Ethics Review Unit, P. O. Box 54840-00200, Nairobi;  
Telephone numbers: 0717 719477; 0776 399979 Email address: [seru@kemri.org](mailto:seru@kemri.org)

## 16.6. Household's Consent Form for Baseline Survey

### Insect Growth Regulators to Control Jiggers

Village \_\_\_\_\_ County \_\_\_\_\_

**Head of Household Name:** \_\_\_\_\_

**Study ID no.** \_\_\_\_\_ **Date:** \_\_\_\_\_ **Time:** \_\_\_\_\_

I have had the study explained to me. I have understood all that has been read/explained and had my questions answered satisfactorily.

- ☐ **Yes please tick I agree for myself and my family to take part in this research.**
- ☐ **Yes please tick I agree for the soil samples from my house and anything found inside them to be shipped to icipe-Muhaka**
- ☐ **Yes please tick I agree for photos and videos be taken in and around my house; if these include people – prior verbal consent has to be sought from the individual captured.**

I understand that I can change my mind at any stage and it will not affect me or my family in any way.

**Head of household's Signature/thumb print:** \_\_\_\_\_

Other Adults' name	I agree for my feet to be examined (tick)	Adult's Signature/thumb print

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***Where the adults cannot read, a witness\* may observe consent process and sign below if needed:***

I attest that the information concerning this research was accurately explained to and apparently understood by the subjects and that informed consent was freely given by the subjects.

**Witness' signature:** \_\_\_\_\_ **Date** \_\_\_\_\_

**Witness' name:** \_\_\_\_\_ **Time** \_\_\_\_\_

*\*A witness is a person who is independent from the trial or a member of staff who was not involved in gaining the consent.*

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I have followed the study SOP to obtain consent from the Household head. S/he apparently understood the nature and the purpose of the study and consents to the participation (of the child) in the study. S/he has been given opportunity to ask questions which have been answered satisfactorily.

**Designee/investigator's signature:** \_\_\_\_\_ **Date** \_\_\_\_\_

**Designee/investigator's name:** \_\_\_\_\_ **Time** \_\_\_\_\_  
(Please print name)

**THE INTERVIEWEE SHOULD NOW BE GIVEN A SIGNED COPY TO KEEP**

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## 16.7. Household's Consent Form for Endline Survey

### Insect Growth Regulators to Control Jiggers

Village \_\_\_\_\_ County \_\_\_\_\_

**Head of Household Name:** \_\_\_\_\_

**Study ID no.** \_\_\_\_\_ **Date:** \_\_\_\_\_ **Time:** \_\_\_\_\_

I have had the study explained to me. I have understood all that has been read/explained and had my questions answered satisfactorily.

- ☐ **Yes please tick I agree for myself and my family to take part in this research.**
- ☐ **Yes please tick I agree for the soil samples from my house and anything found inside them to be shipped to icipe-Muhaka.**
- ☐ **Yes please tick I agree for photos and videos be taken in and around my house; if these include people – prior verbal consent has to be sought from the individual captured.**
- ☐ **Yes please tick I agree for my feet to be screened for jiggers and for data to be recorded.**

I understand that I can change my mind at any stage and it will not affect me or my family in any way.

**Head of household's Signature/thumb print:** \_\_\_\_\_

Other Adults' name	I agree for my feet to be examined (tick)	Adult's Signature/thumb print

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***Where the adults cannot read, a witness\* may observe consent process and sign below if needed:***

I attest that the information concerning this research was accurately explained to and apparently understood by the subjects and that informed consent was freely given by the subjects.

**Witness' signature:** \_\_\_\_\_ **Date** \_\_\_\_\_

**Witness' name:** \_\_\_\_\_ **Time** \_\_\_\_\_

*\*A witness is a person who is independent from the trial or a member of staff who was not involved in gaining the consent.*

I have followed the study SOP to obtain consent from the Household head. S/he apparently understood the nature and the purpose of the study and consents to the participation (of the child) in the study. S/he has been given opportunity to ask questions which have been answered satisfactorily.

**Designee/investigator's signature:** \_\_\_\_\_ **Date** \_\_\_\_\_

**Designee/investigator's name:** \_\_\_\_\_ **Time** \_\_\_\_\_  
(Please print name)

**THE INTERVIEWEE SHOULD NOW BE GIVEN A SIGNED COPY TO KEEP**

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## 16.8. Information Leaflet for Control Households

### Insect Growth Regulators to Control Jiggers

Principal Investigator: Dr Ulrike Fillinger, icipe

You and your family are being asked to take part in a study. The box below tells you important things you should think about before deciding to join the study. We will provide more detailed information below the box. Please ask questions about any of the information before you decide to participate. You may also wish to talk to others (for example, your family, friends) about this study, before agreeing to join.

#### Key Information for You to Consider

- **Voluntary Consent.** You and your family are being asked to volunteer for a research study. You can choose whether you would like to participate or not. If you do agree you can change your mind at any time and withdraw from the research. Any member of the family can withdraw at anytime.
- **Purpose.** We are doing research to find out if insecticides can kill jiggers in the floor of people's houses before they infect people. Your house has been selected as a control household, meaning we will not test the insecticide in your house but request to check for jiggers on the floor, only this one time.
- **Procedures and Activities.** To start with we will need to quickly check everyone's feet for jiggers, ask a few questions of you, make observations of your house. If your house is found to be eligible to join the study, we would need to take a soil sample from your house, thereafter you will be given treatment for the infection and if you like we will spray your floor with the insecticide next week.
- **Risks or disadvantages.** There is a possibility that we will disrupt your normal day and that your neighbours will become aware that your family has jiggers.
- **Benefits.** Everyone who is infected will be referred for treatment at the health facility which we will provide with medicine. We hope the research will show an affordable way for people to use themselves to control jiggers in their homes.

#### Introduction

Jiggers are fleas which burrow into the skin of people's feet and grow rapidly causing much pain and itching. The jiggers spend some of their life in the floor of houses.

#### Who is carrying out this study?

This study is being carried out by *icipe*. *icipe* is an international organization based in Kenya to study insects that are harmful or useful to humans.

### **What is this study about?**

The study is trying to find out if spraying the house floor with insecticides that affect the development of insects, can control the off-host stages of jiggers.

### **Procedures**

Your family has been found to be eligible to participate in the study as a control household. A control household does not receive the test treatment. It helps us to study the difference that the test treatment might make. We have already treated different households over the past one months with insecticides. Now we are collecting soil samples from these houses and from control houses like yours for comparison. We also request to examine the feet of all people in your house and to count the total number of jiggers of those infected. All family members with jiggers will be referred to the nearest health facility for treatment which we will provide. If you wish, we will also return next week to treat the floor of your house with the insecticide we found most useful.

### **Are there any risks or disadvantages to taking part?**

While we do our work we will cause some disruption of your day:

- We will conduct observations of your house which will take about 20 minutes
- Rapid examinations of feet for jiggers will take about 1 minute for each person.
- Another risk from participating is that your neighbours may find out that your family have jiggers. We will do everything we can to reduce the chance of this and will not talk to others about it.

### **Are there any advantages to taking part?**

- All infected individuals identified during the study will be referred to the nearest health facility for treatment and we will provide them with the medicine.
- In talking to us, you will contribute to knowledge of jiggers that may help other people in Kenya and elsewhere in the future, for example through developing new health policies.

### **What happens to the soil samples?**

- Your privacy is important so your names will not be on the soil samples only codes.

- The soil samples will be sent to laboratories at *icipe* in Muhaka.
- Insects found in the soil samples will be stored at *icipe* for exact identification.

**Who will have access to the information you give?**

- All of our documents will be stored securely in locked cabinets and on password protected computers. The knowledge gained from this research will be shared in summary form, without your identity, with the Ministry of Health.
- In future, information collected or generated during this study may be used to support new research by other researchers in Kenya and other countries. In all cases, we will only share information with other researchers without including your identity and where you live and will replace this information with number codes.
- When the study is finished, we will need to share the results and the information we collected with other scientists around the world and health officers in Kenya. This will only be done in a way that does not share your identity. We could request to take a few pictures of the floors of the households as well as of the feet of the infected only after you have permitted for us to do so and after receiving verbal consent from the persons photographed for every photo taken.

**Who has allowed this research to take place?**

This research was approved by the National Ethics Review committee located at KEMRI.

**What will happen if I refuse to participate?**

All participation in research is voluntary. You are free to decide if you want to take part or not at any time. We only need to visit you once for this survey.

**What if I have any questions?**

You are free to ask any question about this research. At any time, you can also contact:

Dr. Ulrike Fillinger, International Centre of Insect Physiology and Ecology, Kenya (*icipe*),  
Duduville Campus, Nairobi 00100. [ufillinger@icipe.org](mailto:ufillinger@icipe.org), mobile: 0791845259

**If you want to ask someone independent anything about this research, please contact:**

Initial submission to SERU: Control of off-host stages of Tunga penetrans – version  
1pis\_igr\_randomisedcontrolledfieldtrial.docx

The Head, KEMRI Scientific and Ethics Review Unit, P. O. Box 54840-00200, Nairobi;  
Telephone numbers: 0717 719477; 0776 399979 Email address: [seru@kemri.org](mailto:seru@kemri.org)

## 16.9. Household's Consent Form for Control Households

### Insect Growth Regulators to Control Jiggers

Village \_\_\_\_\_ County \_\_\_\_\_

**Head of Household Name:** \_\_\_\_\_

**Study ID no.** \_\_\_\_\_ **Date:** \_\_\_\_\_ **Time:** \_\_\_\_\_

I have had the study explained to me. I have understood all that has been read/explained and had my questions answered satisfactorily.

- ☐ **Yes please tick I agree for myself and my family to take part in this research.**
- ☐ **Yes please tick I agree for the soil samples from my house and anything found inside them to be shipped to icipe-Muhaka**
- ☐ **Yes please tick I agree for photos and videos be taken in and around my house; if these include people – prior verbal consent has to be sought from the individual captured.**
- ☐ **Yes please tick I agree for my feet to be screened for jiggers and for data to be recorded.**

I understand that I can change my mind at any stage and it will not affect me or my family in any way.

**Head of household's Signature/thumb print:** \_\_\_\_\_

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**Witness' signature:** \_\_\_\_\_ **Date** \_\_\_\_\_

**Witness' name:** \_\_\_\_\_ **Time** \_\_\_\_\_

*\*A witness is a person who is independent from the trial or a member of staff who was not involved in gaining the consent.*

I have followed the study SOP to obtain consent from the Household head. S/he apparently understood the nature and the purpose of the study and consents to the participation (of the child) in the study. S/he has been given opportunity to ask questions which have been answered satisfactorily.

**Designee/investigator's signature:** \_\_\_\_\_ **Date** \_\_\_\_\_

**Designee/investigator's name:** \_\_\_\_\_ **Time** \_\_\_\_\_  
(Please print name)

**THE INTERVIEWEE SHOULD NOW BE GIVEN A SIGNED COPY TO KEEP**

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Initial submission to SERU: Control of off-host stages of Tunga penetrans – version  
1pis\_igr\_randomisedcontrolledfieldtrial.docx