Informed Consent Form

Title:

Cluster Randomized Controlled Trial: Efficacy of Gravid Oviposition Sticky Trap (GOS) and Dengue NS1 Antigen Rapid Diagnostic Test for Early Surveillance of Dengue Among Adult Aedes Mosquitoes to Reduce Dengue Outbreaks in PJU10, Damansara Damai, Selangor, Malaysia

Version date: 2 January 2019

PATIENT/PARTICIPANT INFORMATION SHEET

Please read the following information carefully, do not hesitate to discuss any questions you may have with your doctor or the person-in-charge

Study Title: Combating dengue with innovative paradigm shift strategies

Introduction

Dengue infection is very common in Malaysia. Dengue infection can cause ill-effects on the health of healthy individuals in the community, including pregnant women.

Surveys have shown that during dengue outbreaks, the Ministry of Health have employed various methods to control the larvae of dengue infested mosquitoes together with educating and disseminating information about the dengue outbreak, to the community. However, when there is an outbreak, it will be devastating and life threatening to the community and it will be too late for these actions to be taken. Therefore, we are aiming to educate the public and detect infected mosquitos before a dengue outbreak happens. Now, there has been a shift in the approach as there are newer techniques employed that help to reduce death due to dengue.

What is the purpose of this study?

To determine new techniques (GOS trap and NS1 kit) in reducing dengue epidemics compared to the usual activities carried out by the Ministry of Health and to determine whether the community will be more receptive towards this new surveillance activity as they will receive information of infected mosquitoes before dengue cases are reported.

What are the procedures to be followed?

1. You would be given a questionnaire to answer.

2. With your permission/consent, we would require about 2 ml blood (less than a teaspoon) from you to test if you already have had dengue infection.

3. During the surveillance, if you and your family are nearby the area where a dengue infected mosquito is found, we would go from house-to-house, distribute flyers or set up booths to alert you and educate you to take precautionary measures.

5. A questionnaire survey will be done towards the end of the project to you and members of your community.

Who should not enter the study?

You should not enter the study if you are less than 18 years of age, if you are unable to give consent and if you not willing to participate in the blood taking.

What will be the benefits of the study:

a) To you as the subject?

   Your participation can help in identifying infected mosquito using newer methods that can help to prevent you and your family from dengue outbreak at your house and community.

b) To the investigator?

   The investigators intend to publish the study findings for the benefit of the public and the country by reducing death due to dengue outbreak.

What are the possible drawbacks?

The only drawback is the blood taking,

Can I refuse to take part in the study?

Yes. You will not be affected in any way if you decline to take part in the study.

Who should I contact if I have additional questions during the course of the study?

Prof. Datin Dr. Indra Vythilingam:	019-6501250
Dr. Wan Yusoff Wan Sulaiman:	013-3800727
Assoc. Prof. Dr Si Lay Khaing:	019-3941063
Dr. Neha Sethi A/P Neha Sethi:	017-3702555
Dr. Rafdzah Ahmad Zaki:	012-5159447
Prof. Dr. Yvonne Lim Ai Lian:	012- 2198762
Prof. Dr. Jamunarani S. Vadivelu:	012-2110463

CONSENT BY PATIENT/PARTICIPANT FOR CLINICAL RESEARCH

Please create Version No. and Version Date for this document:

Version No.: 1
Version Date: 28 May 2018

I, ……. Identity Card No……..……
(Name of Patient)
of ……...
(Address)
hereby agree to take part in the clinical research (clinical study/questionnaire study/drug trial) specified below:

Title of Study: Combating dengue with innovative, paradigm shift-strategies

the nature and purpose of which has been explained to me by Dr. ……..……..……
(Name & Designation of Doctor)

and interpreted by ……..……..…..……
(*Name & Designation of Interpreter)*

…….. to the best of his/her ability in ……..…… language/dialect.

I have been told about the nature of the clinical research in terms of methodology, possible adverse effects and complications (as per patient information sheet). After knowing and understanding all the possible advantages and disadvantages of this clinical research, I voluntarily consent of my own free will to participate in the clinical research specified above.

I understand that I can withdraw from this clinical research at any time without assigning any reason whatsoever and in such a situation shall not be denied the benefits of usual treatment by the attending doctors.

Date: ……...…….. Signature or Thumbprint ……..……
(Patient)

IN THE PRESENCE OF

Name ……..…..……..…

Identity Card No. ……..……..…… Signature

(*Witness for Signature of Patient)*

Designation ……..……

I confirm that I have explained to the patient the nature and purpose of the above-mentioned clinical research.

Date …….. Signature ……
(Attending Doctor)

CONSENT BY PATIENT FOR CLINICAL RESEARCH

R.N.
Name
Sex
Age
Unit