PARTICIPANT INFORMATION SHEET

A. Antenatal clinic appointment visitors v1.1

Study Title: Comparative evaluation of standard and dual-treated LLIN efficacy in Sud Ubangi, Democratic Republic of Congo

DRC Principal Investigator: Prof. Paul Mansiangi, University of Kinshasha School of Public Health

Sponsor: Liverpool School of Tropical Medicine

What is the purpose of the study?
The Liverpool School of Tropical Medicine (UK), President's Malaria Initiative (USA) and University of Kinshasa School of Public Health have formed a partnership to investigate how well the insecticide bednets distributed throughout Sud Ubangi at the end of 2019 may be protecting you and your communities from malaria. They are investigating this by assessing how rates of malaria parasite infection change in different areas of Sud Ubangi receiving nets. Recent studies in DRC and elsewhere show that malaria parasite infection rates in pregnant women tested at antenatal clincs provide a good indicator for the community.

Why have I been chosen?
You have been asked today to consider joining this study because you are attending your first antenatal clinic appointment.

How can I join the study?
After considering the information in this sheet you will be asked to give your written agreement to be included in the study.

Do I have to take part?
Your participation is entirely voluntary. It is up to you to decide whether to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. Your decision to take part or not, will affect the test procedure but will not affect the care given at the clinic.

What will happen to me if I take part?
The standard care procedure recommended by the Ministry of Health for pregnant women visiting antenatal clinics is to give the anti-malaria drug called SP, without a malaria test, or if you are showing malaria symptoms to take a malaria rapid diagnostic test. If this test does not show you have malaria, SP is prescribed but if the test is positive artemisinin-based drugs are prescribed.
For this study we will ask you to take a malaria rapid diagnostic test whether you show symptoms of malaria or not, and we will also ask you to answer some questions during the time you wait for the result. These are the only the differences from the standard Ministry of Health procedure that the study requests; all other parts of your appointment will follow standard guidelines.

Procedures
You will be asked to take a malaria rapid diagnostic test today which involves a finger prick to take a drop of blood which is applied to a test kit. The procedure usually takes no more than a couple of minutes with results usually available after about 15 minutes. You will be asked to complete or give answers to some questions during this time. You will only be asked to do each of these at this appointment.

What are the possible risks and disadvantages of taking part?
There will not be any additional risks to you if you take part in the study. Sometimes the finger-prick for the rapid diagnostic test can sting for a few moments but often you won't notice very much. A possible disadvantage is that the appointments may take slightly longer than they would otherwise, but the extra time required will be short.

What are the possible benefits of taking part?
There is no direct benefit to taking part and we will not be providing compensation because we are not asking you to attend any extra appointments or take extra medications. You will only attend your usual appointment today. Information we get from this study will help us to understand how well insecticide treated bednets are protecting people in Sud Ubangi, and will help us to understand which bednets provide the best protection, which will inform future distributions.

What will happen to the results?
The findings of this study will be made available to the providers of the bednets, the National Malaria Control Programme and the Ministry of Health and to the wider community by publication in an international journal. No information which will allow your identification will be used in reports or publications.

What if I <u>do not</u> want to take part in the study?
There is no obligation to take part in the study and you will not be persuaded to do so: this is entirely your decision. If you choose not to take part, you will simply receive the standard antenatal clinic procedures and treatment and you can withdraw your consent at any time. Whether you are part of the study or not will have no effect on the care of bednets your house receives at any time.

What if I <u>do</u> want to take part in the study?
If you wish to take part in the study, after you have asked any questions, we will ask you to sign a consent form to indicate that you understand what the study is about and what will be required from you. If you are between 15 and 18 years old and are attending your appointment with your parent, guardian or husband (if he is 18 years old or over) we will also ask them to read this sheet and to sign the consent form if you are both in agreement.

Further information or concerns
Please feel free to ask the clinic staff about anything that you feel you have not understood or any concerns you may have. You can also contact the study team leader on the telephone number below:

Professor Paul Mansiangi tel: 0998903346

Thank you for taking the time to read this sheet and for considering joining the study.

SIGNATURE PAGE FOR CONSENT TO PARTICIPATE IN THE STUDY

Study Title: Comparative evaluation of standard and dual-treated LLIN efficacy in Sud Ubangi, Democratic Republic of Congo

DRC Principal Investigator: Prof. Paul Mansiangi, University of Kinshasha School of Public Health Sponsor: Liverpool School of Tropical Medicine

I have read /been read the information sheet concerning the study and understand what will be required of me if I take part and I have had the opportunity to ask questions about the study and what will be required of me.

I understand that I am free to refuse to take part and at any time may withdraw from inclusion in this study without giving a reason and without affecting my normal healthcare or that of my family. I voluntarily agree to take part in the study.

PARTICIPANT'S CONSENT

My signature (or thumbprint) below confirms that I freely agree to take part in the study or for a parent/ guardian that I confirm my assent for my daughter's participation.		
		|___|___|/|___|___|/|___|___|___|___|
Participant's Name	**Participant's Signature/Thumbprint**	**Date**
		|___|___|/|___|___|/|___|___|___|___|
Parent/guardian/husband (over 18 years) name (if participant aged <18 and accompanied)	**Parent/ guardian Signature/Thumbprint**	**Date**

IMPARTIAL WITNESS in the event the participant is unable to read

I confirm that I saw the participant being informed about the study and that he/she freely consented verbally and by marking this form confirms to this consent.		
		|___|___|/|___|___|/|___|___|___|___|
Witness Name	**Signature**	**Date**

DESIGNEE

As an individual properly delegated by the principal investigator, I have fully informed the participant of all relevant aspects of the study, that I have answered any questions arising.		
		|___|___|/|___|___|/|___|___|___|___|
Designee Name	**Signature**	**Date**

PARTICIPANT INFORMATION SHEET

B. Household mosquito collections v1.1

Study Title: Comparative evaluation of standard and dual-treated LLIN efficacy in Sud Ubangi, Democratic Republic of Congo

DRC Principal Investigator: Prof. Paul Mansiangi, University of Kinshasha School of Public Health Sponsor: Liverpool School of Tropical Medicine

What is the purpose of the study?
The Liverpool School of Tropical Medicine (UK), President's Malaria Initiative (USA) and University of Kinshasa School of Public Health have formed a partnership to investigate how well the insecticide bednets distributed throughout Sud Ubangi at the end of 2019 may be protecting you and your communities from malaria. They are investigating this by assessing how rates of malaria parasite infection change in different areas of Sud Ubangi receiving nets. Part of the assessment involves determining how the bednets affect the numbers of mosquitoes in your homes, whether they are carrying malaria parasites and how sensitive they are to the insecticide on the bednets.

Why has my house been chosen?
You have been asked today to consider joining this study because your village is within of the areas we have identified for mosquito collections as part of the study. There is no specific reason why your house within the village has been chosen.

How can I join the study?
After considering the information in this sheet you will be asked to give your written agreement to allow mosquito collections from your property and to be included in the study.

Do I have to take part?
Your participation is entirely voluntary. It is up to you to decide whether to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. Your decision to take take part or not, will affect any form of healthcare you receive.

What will happen if I agree to my household to take part?
If you agree to take part we will request permission to collect mosquitoes in your house in the near future and again at 6 month intervals for a total of 6 collections, each of which should take no more than 20 minutes. We will ask you to sign the consent form and will ask again for your verbal consent on any occasion we visit for collections. We will also record a few basic structural details of your house such as wall construction material and roofing type, number of rooms, and will ask you how many people sleep there and how many bednets are used.

Procedures
On the morning of collection we request that you keep windows and doors closed as much as possible until we have visited to prevent exit of any mosquitoes present. It would be helpful if residents could vacate the property during our collection but one or more of your household members are welcome to remain to observe. Mosquitoes will be collected from rooms in your house using a mechanical suction device which we will demonstrate to you. Collections will take no more than 20 minutes and are planned to occur between 6am and 9am (or by 10am at the latest). Mosquitoes collected will be stored in tubes and later identified, counted, and parasites and insecticide resistance genes within them identified if present. Some mosquitoes may also be transported live to out laboratory in Gemena and used to test their insecticide sensitivity and how many are killed by exposure to bednets.

What are the possible risks and disadvantages of taking part?
There are no risks to you or your household if you take part in the study. The only disadvantage is the possible inconvenience of keeping your house closed until we visit, and the request for most of the members to vacate the property if possible during the collection period. If sick or infirm people live in your house who could not easily vacate the property at the time of collection we advise that you do not agree to take part to avoid their inconvenience.

What are the possible benefits of taking part?
There is no direct benefit to taking part and we cannot offer to provide payment. Information we get from this study will help us to understand how well insecticide treated bednets are protecting people in Sud Ubangi, and will help us to understand which bednets provide the best protection, which will inform future distributions.

What will happen to the results?
The findings of this study will be made available to the providers of the bednets, the National Malaria Control Programme and the Ministry of Health and to the wider community by publication in an international journal. No information which will allow identification of your house will be used in reports or publications.

What if I <u>do not</u> want to take part in the study?
Your participation is entirely voluntary. It is up to you to decide whether to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. Your decision to take part or not, will not affect any form of healthcare you receive. You are free to refuse entry to collect on any occasion if you have signed the written consent form.

What if I <u>do</u> want to take part in the study?
If you wish to take part in the study, after you have asked any questions, we will ask you to sign a consent form to indicate that you understand what the study is about and what will be required from you. We ask you to explain to any members of your household who are not present at the time of our initial visit. We will arrange a date for the visit to your house for the collection or if the collection will not occur for any reason we will also notify you of this. You are free to refuse entry to collect on any occasion if you have signed the written consent form.

Further information or concerns
Please feel free to ask the collection team staff about anything that you feel you have not understood or any concerns you may have. You can also contact the study team leader on the telephone number below:

Professor Paul Mansiangi tel: 0998903346

Thank you for taking the time to read this sheet and for considering joining the study.

SIGNATURE PAGE FOR CONSENT TO PARTICIPATE IN THE STUDY

Study Title: Comparative evaluation of standard and dual-treated LLIN efficacy in Sud Ubangi, Democratic Republic of Congo

DRC Principal Investigator: Prof. Paul Mansiangi, University of Kinshasha School of Public Health Sponsor: Liverpool School of Tropical Medicine

I have read /been read the information sheet concerning the study and understand what will be required of me and my household if I take part and I have had the opportunity to ask questions about the study and what will be required of me and my household.

I understand that I am free to refuse to take part and at any time may withdraw from inclusion in this study without giving a reason and without affecting my normal healthcare or that of my family. I voluntarily agree to take part in the study.

PARTICIPANT'S CONSENT

My signature (or thumbprint) below confirms that I freely agree to take part in the study.		
		|___|___|/|___|___|/|___|___|___|___|
Participant's Name	**Participant's Signature/Thumbprint**	**Date**

IMPARTIAL WITNESS in the event the participant is unable to read

I confirm that I saw the participant being informed about the study and that he/she freely consented verbally and by marking this form confirms to this consent.		
		|___|___|/|___|___|/|___|___|___|___|
Witness Name	**Signature**	**Date**

Study team member

As an individual properly delegated by the principal investigator, I have fully informed the participant of all relevant aspects of the study, that I have answered any questions arising.		
		|___|___|/|___|___|/|___|___|___|___|
Team member name	**Signature**	**Date**

PARTICIPANT INFORMATION SHEET

C. Net durability assessments v1.1

Study Title: Comparative evaluation of standard and dual-treated LLIN efficacy in Sud Ubangi, Democratic Republic of Congo

DRC Principal Investigator: Prof. Paul Mansiangi, University of Kinshasha School of Public Health Sponsor: Liverpool School of Tropical Medicine

What is the purpose of the study?
The Liverpool School of Tropical Medicine (UK), President's Malaria Initiative (USA) and University of Kinshasa School of Public Health have formed a partnership to investigate how well the insecticide bednets distributed throughout Sud Ubangi at the end of 2019 may be protecting you and your communities from malaria. They are investigating this by assessing how rates of malaria parasite infection change in different areas of Sud Ubangi receiving nets. Part of the assessment involves determining the durability of the bednets by examining how they change physically and chemically over time.

Why has my house been chosen?
You have been asked today to consider joining this study because your village is within of the areas we have identified for bednet durability assessment as part of the study. There is no specific reason why your house within the village has been chosen.

How can I join the study?
After considering the information in this sheet you will be asked to give your written agreement to allow examination of the bednets hanging within your property and collection of one net for further analysis from your property and to be included in the study.

Do I have to take part?
Your participation is entirely voluntary. It is up to you to decide whether to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. Your decision to take part or not, will not affect any form of healthcare you receive.

What will happen if I agree to take part?
If you agree to take part we will request permission to enter your house to examine bednets and take measurements of their condition and remove and replace one net with a new LLIN of the same type. We will ask you to sign the consent form and will ask again for your verbal consent when we visit. We will also record a few basic structural details of your house such as wall construction material and roofing type, number of rooms, and will ask you how many people sleep there and how many bednets are used. We only request to visit you once.

Procedures
When we visit we will follow a standard procedure to document the condition of each net in your house. We will then choose one bednet at random to remove and replace. The bednet will be returned to our laboratory in Gemena. Some sections will be used to test how well mosquitoes are killed by exposure to the net. Sections will also be transported to the Liverpool School of Tropical Medicine (UK) for chemical analysis to determine the amount of insecticide present in the net material.

What are the possible risks and disadvantages of taking part?
There are no risks to you or your household if you take part in the study. The only disadvantage is the minor inconvenience of allowing our study team members into your house for a short time period. If sick or infirm people live in your house who would be sleeping under nets at the time of our visit we advise that you do not agree to take part to avoid their inconvenience.

What are the possible benefits of taking part?
There is no direct benefit to taking part and we cannot offer to provide payment. Information we get from this study will help us to understand how well insecticide treated bednets are protecting people in Sud Ubangi, and will help us to understand which bednets provide the best protection, which will inform future distributions.

What will happen to the results?
The findings of this study will be made available to the providers of the bednets, the National Malaria Control Programme and the Ministry of Health and to the wider community by publication in an international journal. No information which will allow identification of your house will be used in reports or publications.

What if I <u>do not</u> want to take part in the study?
There is no obligation to take part in the study and you will not be persuaded to do so: this is entirely your decision. Whether you are part of the study or not will have no effect on any provision of healthcare or of the bednets your house receives at any time. You are free to refuse entry to collect on any occasion if you have signed the written consent form.

What if I <u>do</u> want to take part in the study?
If you wish to take part in the study, after you have asked any questions, we will ask you to sign a consent form to indicate that you understand what the study is about and what will be required from you. We ask you to explain to any members of your household who are not present at the time of our initial visit. We will arrange a date for the visit to your house or if the visit will not occur for any reason we will also notify you of this. You are free to refuse entry to collect on any occasion if you have signed the written consent form.

Further information or concerns
Please feel free to ask the collection team staff about anything that you feel you have not understood or any concerns you may have. You can also contact the study team leader on the telephone number below:

Professor Paul Mansiangi tel: 0998903346

Thank you for taking the time to read this sheet and for considering joining the study.

SIGNATURE PAGE FOR CONSENT TO PARTICIPATE IN THE STUDY

Study Title: Comparative evaluation of standard and dual-treated LLIN efficacy in Sud Ubangi, Democratic Republic of Congo

DRC Principal Investigator: Prof. Paul Mansiangi, University of Kinshasha School of Public Health Sponsor: Liverpool School of Tropical Medicine

I have read /been read the information sheet concerning the study and understand what will be required of me and my household if I take part and I have had the opportunity to ask questions about the study and what will be required of me and my household.

I understand that I am free to refuse to take part and at any time may withdraw from inclusion in this study without giving a reason and without affecting my normal healthcare or that of my family. I voluntarily agree to take part in the study.

PARTICIPANT'S CONSENT

My signature (or thumbprint) below confirms that I freely agree to take part in the study.		
		|___|___|/|___|___|/|___|___|___|___|
Participant's Name	**Participant's Signature/Thumbprint**	**Date**

IMPARTIAL WITNESS in the event the participant is unable to read

I confirm that I saw the participant being informed about the study and that he/she freely consented verbally and by marking this form confirms to this consent.		
		|___|___|/|___|___|/|___|___|___|___|
Witness Name	**Signature**	**Date**

Study team member

As an individual properly delegated by the principal investigator, I have fully informed the participant of all relevant aspects of the study, that I have answered any questions arising.		
		|___|___|/|___|___|/|___|___|___|___|
Team member name	**Signature**	**Date**

QUESTIONNAIRE TO BE ADMINISTERED TO PREGNANT WOMEN DURING THEIR FIRST ANTENATAL CLINIC VISIT IF CONSENT TO STUDY PARTICIPATION v1.0

Questionnaire number : …….

Corresponding ANC sheet number : ……

Line number in the ANC register : ……..

Visit date : /……../……../…….

Question number	Questions	Items	Answer code
Section 1 : Participant details *Note : questions marked * are to be completed by the staff member, rather than being asked*			
Q1.1	Date of birth	/……/……./……..	
Q1.2	Age	…… years	
Q1.3	Occupation		
Q1.4	In which village do you live?		
Q1.5*	Is your village inside this health area or in another health area?	1. This area 2. Another area	
Q1.6*	If in another – which health area?		
Q1.7*	Approximate distance from the village to this clinic?		
Q1.8	How many months pregnant are you?		
Q1.9	How many children have you had previously?		
Section 2 : Prevention and risk behavior relating to malaria in the household			
Q2.1	Do you use insecticide-treated bednets in the household?	1. Yes 2. No	
Q2.2	If no, ask why?	a. Bednets not delivered to house during distribution campaign b. Bednets available are damaged c. Bednets given to others d. Other reason (please specify) ……. ……	
Q2.3	How many LLINs are present in your household?		
Q2.4	Among these LLINs, do you use one regularly?	1. Yes 2. No	
Q2.5	Did you spend last night under an LLIN ?	1. Yes 2. No	

Q2.6	If no – ask why?		
Q2.7	Other than bednets do you use any other method of mosquito control in your home ?	1. Yes 2. No	
Q2.8	If yes, why ?		
Q2.9	Which additional methods do you use?		
Q2.10	What time do you usually go to bed?		
Q2.11	How many people live in your house ?		
Section 3: RDT RESULT			
Q3.1*	What is the result of the RDT?	1. Positive 2. Négative	