The Centre for Sexual Health and HIV AIDS Research Zimbabwe (CeSHHAR Zimbabwe)
4 Bath Road, Belgravia
Harare, Zimbabwe
Phone: +263-4-304583, +263-4-308042, +263-4-333393. +263-4-332074

Appendix 41

HOUSEHOLD TEMPERATURE MONITORING CONSENT AMONG 50 HOUSEHOLDS OF PREGNANT WOMEN PARTICIPATING IN THE PRE-INTERVENTION SURVEY

Willing and interested household head and pregnant woman participating in the Pre-Intervention survey selected for household thermal monitoring must BOTH sign this household thermal monitoring consent form personally. The Houshold head can designate a proxy to sign this form on his/her behalf, prior to installation of the thermal monitor.

Where the pregnant woman is the household head, please indicate this on the Informed Consent.

Study Title: HAPI study: Influence of household, health facility and environmental heat exposure on the health of pregnant women and neonates for the formulation of intervention opportunities

Study Name: HAPI

Sponsor: Wellcome Trust Grant number: 226758/Z/22/Z

Co-Principal Investigator: Fortunate Machingura

Institution: CeSHHAR Zimbabwe

Contact number: 0772 971 481

Hello, my name is_____(*study staff name and surname*). I am a part of the research team working at _____Health Facility, on the heat adaptation for pregnant women project being conducted by CESHHAR Zimbabwe. I am speaking to you because _____ (*name of participant*) is participating in the pre-intervention survey with 399 other pregnant women in Mt Darwin District. As part of the study we are kindly requesting to monitor temperature in your household. This will enable us to get a better understanding of her heat health experiences.

Temperature monitoring is being conducted in 50 of the 400 womens households and your household has been selected. The monitoring will begin today _____(date of recruitment). The device will be removed within 5

days of our last interview.

As the head of your household, it is important for us to tell you about the study as well and get your permission to have your household monitored. The information we give you here is to help you to decide if you would like to give your permission for the temperature monitoring to be conducted in your home.

We will tell you:

- why we are doing this study,
- what will happen during this study, and
- how this study could be of benefit to you and the disadvantages.
- It is also important to know that you can stop being in the study at any time. There will be NO negative consequences, and this will not affect the care that _____ gets at the clinic.
- If you have any questions, please feel free to ask me. You should not give permission unless you are satisfied about everything involved in the study.
- If you decide to take part in the study, you will be asked to complete a consent form where you will sign your name or make your mark.

In the absence of the household head a proxy as delegated by the household head will be contacted.

_____ (*name of household head*) told us that he/she has spoken to you already and asked you to sign this consent form on his/her behalf as he/she is not available to sign when we are available.

WHAT IS THIS STUDY ABOUT AND WHY IS IT IMPORTANT?

There is research that has shown that experiencing very hot weather during pregnancy and in the time after childbirth may be harmful for both mother and baby. In this part of our study, we will be implementing some interventions to test if they work to cool pregnant women and their babies down. This part of the study is an important step in understanding local experiences.

WHY ARE YOU BEING ASKED FOR PERMISSION

We are asking for your permission because you are the household head and part of this study involves us doing interviews with _____at the clinic or your home. She is part of the main study. She is interested in taking part in this smaller study and has given us your contact details and permission to ask you if she can take part in this smaller study and include her household as well. We will be monitoring the temperature in your home. This is important for understanding how comfortable it is. By allowing the temperature monitoring device to be installed in your home you give important information around heat in your home.

As the Household Head we want to know if you are ok with us installing the temperature monitoring device .

WHAT WILL HAPPEN DURING THIS PHASE OF THE STUDY

In addition to the **interviews, urine tests and temperature monitoring as well as extraction of clinical data from the woman's maternal case record we would like to conduct HOUSEHOLD TEMPERATURE MONITORING**: this is to measure how hot your house gets. To do this we will need to install devices that measure the heat in your home. This device will be attached to the wall where you sleep or in your bedroom and maybe where you cook and eat or outside of your sleeping area if you have a living room. This device does not have a camera and can't "see" or "hear" what you are doing. Be rest assured these devices are completely safe and do not make any noises. They will not harm you or the baby or other people around you. The devices do not record voices or take photos, and do not track your movements from one place to another. We will need to come to your house every month to collect the information from the devices.

If you agree to be part of the study, these devices will be removed from your home after the study is complete. We will do this within five days of the last interview. If you have any questions or concerns about the monitor in your home, please feel free to ask for further clarity. If you are not comfortable with this part of the study, then we will not install the device in your home.

IS THERE ANY RISK TO TAKING PART IN THE STUDY ?

The risks of participating in this study for your household are low. We are installing temperature monitors and collecting temperature data **only**. One risk is a possible breach of confidentiality. We feel this risk is low as we will use strict security measures to ensure no personal information about your household and its occupants is collected unnecessarily.

ARE THERE ANY BENEFITS FOR TAKING PART?

There are some direct benefits to taking part in this study:

- _____and your family will benefit from knowing the temperature in your home which makes you and your family think more about how heat can affects your family and your baby which in turn helps you do more to protect herself and your family from the heat.
- You will not need to pay anything to take part in the study.

WILL YOU GET ANY MONEY OR GIFTS FOR BEING PART OF THIS STUDY?

_____will be given $ 10 (USD) for each study visit. This will be for her time and inconvenience. She will not need to travel for the interviews as these will be done at her clinic visit while she is waiting to be seen by the Nurse or we will come to your home. The money will

be given to her in cash.

IS PARTICIPATION IN THIS STUDY VOLUNTARY?

It is your decision to allow the temperature monitoring device to be installed in your home. Taking part in this study is completely voluntary. You may stop participation in the study at any time without giving a reason.

WILL THE INFORMATION COLLECTED BE KEPT CONFIDENTIAL?

When you decide to participate we will give your household a study number. The study number will be written on our records. We will only use this number on all information we collect. We will not reveal the names and addresses of the participants under any circumstances.

We must know your address to enable us to collect information from the monitors. Your contact information will be kept in strict confidence by the research team at CeSHHAR.

Your privacy and confidentiality will be protected throughout. No personal identifying information will be collected on anyone in this study. No names will be collected (except for the signing of the consent form). So, no names will be in our presentations, reports or academic articles.

Your data will be collected, processed, and stored according to the Data Protection Act in Zimbabwe. All your data will be protected by security access codes. Any written information will be kept locked in a cabinet. The information will be kept separate from any information that identifies you (such as the consent form). After the study is completed, all information will be kept securely in the project office for up to 10 years. This is after all analysis and publications are done for this study. After this the information will be destroyed. Your de-identified data may be stored electronically for longer than 10 years for use in other studies if you agree.

WILL ANYONE ELSE BE TOLD ABOUT YOUR PARTICIPATION?

The research team will not tell anyone about your participation in the study. However, the researchers will come to your home and other members of your community may see them arrive and be curious about why they are visiting your home. We can talk about any concerns you might have about others in your community knowing you are taking part in research.

DOES THIS STUDY HAVE ETHICAL APPROVAL?

This study has ethical approval from the Medical research Council Of Zimbabwe.

WHO DO YOU CONTACT FOR ANY STUDY QUESTIONS OR ISSUES?

If you have any questions about your household's participation in this study, the contact details will be
Dr Fortunate Machingura
The Centre for Sexual Health and HIV AIDS Research
4 Bath Road, Belgravia, Harare

0772 971 481
Fortunate.machingura@ceshhar.org

If you have any questions concerning this study or consent form beyond those answered by the researcher, including questions about the research, your rights as a research participant or research-related injuries; or if you feel that you have been treated unfairly and would like to talk to someone other than a member of the research team, please feel free to contact the Medical Research Council of Zimbabwe (MRCZ) on telephone +2638644073772 or the MRCZ Offices located at 20 Cambridge Road in Avondale, Harare. Please feel free to contact these people with your concerns.

Do you have any questions or concerns?

State questions asked and responses below.

INFORMED CONSENT FORM – HOUSEHOLD HEADS AND PREGNANT WOMEN

WRITTEN PERMISSION FROM HOUSEHOLD HEAD AND PARTICIPANT FOR HOUSEHOLD TEMPERATURE MONITORING IN THE PRE-INTERVENTION SURVEY

For Study Staff:

Who is signing this written consent?

	Household Head	*Continue with completion of this page of the written consent*
	Designated Proxy	*DO NOT complete this page. Proceed to signature page*
	Research Participant	*Co- sign with the Household head*

The Household Head must **initial (or put thumbprint)** in the chosen response next to each statement.

Statement	**YES**	**NO**
I confirm that I have read and understood the information given to me.		
I have had time to think about the information. I have asked questions, and I am happy with the answers I received.		
I agree for the study team to visit my home and install temperature monitors in my home. These will be removed after the last interview with _____(Participant name).		
I agree for the study team to visit my home monthly to collect data from the temperature monitors installed in my home.		
I understand that all the information collected during the study will be treated with confidentiality. The information will only be used for scientific research.		
I agree my household to be video recorded and picture taken during the study. I understand that this material will be used on other platforms, publications, and websites as part of the study and information dissemination.		
I agree to be audio and video recorded and to have my picture taken during the study. I understand that this material will be used on other platforms, publications, and websites as part of the study and information dissemination.		
I understand that I may, at any stage, withdraw consent. This means I can stop taking part in the study without any consequences.		

If ALL are signed "Yes", proceed with consent.

☐ **NO** (please tick), I **DO NOT** agree for my household to be part of this study.

If NO, please stop all permission and enrolment processes for this participant. Staff member to sign

below

☐ **YES** (please tick), I **DO** agree for my household to be part of this study.

Signature/Mark/Thumbprint of household head/designated proxy:

Signature/mark or thumbprint		Date of signature			
			DD	**MMM**	**YYYY**
Print name		Time of signature	: *(24 hour clock)*		

If the Study Participant is the Household head they will sign on both the Household head and Participant Sections.

Signature of Study Participant:

Signature		Date of signature			
			DD	**MMM**	**YYYY**
Print name		Time of signature	: *(24 hour clock)*		

Signature of witness
(If applicable: when verbal consent is required for household head/proxy unable to write):

Signature		Date of signature			
			DD	**MMM**	**YYYY**
Print name		Time of signature	: *(24 hour clock)*		

Signature of witness
(If applicable: when verbal consent is required for household head/proxy unable to write):

Signature		Date of signature			
			DD	**MMM**	**YYYY**
Print name		Time of signature	: *(24 hour clock)*		