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 22

PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT PRE-INTERVENTION EVALUATION COHORT WITH PREGNANT WOMEN

Study Title: HAPI: 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: Dr Fortunate Machingura

Institution: The Centre for Sexual Health and HIV AIDS Research Zimbabwe (CeSHHAR Zimbabwe)

Contact number: 0772 971 481

Hello, my name is_____ (*STUDY STAFF FIRST NAME AND SURNAME*). I am a _____ *(INSERT DESIGNATION*). I am part of a team of researchers working at CeSHHAR Zimbabwe doing research on Climate and Health, together with the Ministry of Health and Child Care. We are doing a research study to find ways to help protect pregnant women and their babies from harm during very hot weather. We are inviting you to take part in a research study.

The information we give you here is to help you to decide if you would like to be part of the study. Before you decide if you want to be part of this study, it is important that you know:

- why we are doing this study,
- what will happen during this study, and
- how this study could be good or bad for you.

It is also important to know that you can stop being in the study at any time.

If you have any questions, please feel free to ask me. You should not agree to take part unless you are satisfied with everything involved in the study.

Before you agree to take part, we will give you information about the study. This information is in this participant information sheet and consent form. You may read about why we are doing this study. We also explain the study to you. We will tell you about the risks and benefits of being in this study.

WHAT YOU SHOULD KNOW ABOUT THIS RESEARCH STUDY:

- Before agreeing to participate, we are giving you this participant information sheet and consent form so that you may read about the purpose, risks, and benefits of this research study.
- Your participation is voluntary, you do not have to participate if you do not want to.
- You also have the right to agree to take part now and change your mind later.
- Whatever you decide, there will be no negative consequences.
- Please review this consent form carefully. If there is anything that is unclear or if you have any questions about this study, please do not hesitate to ask. We want to make sure you fully understand the study before making your decision.
- If you decide to take part in the study, you will be asked to complete this consent form where you will sign your name or make your mark.
- You will be offered a copy of this information sheet and consent form to keep.

WHAT IS THIS STUDY ABOUT AND WHY IS IT IMPORTANT?

Many parts of the world – including Zimbabwe – are experiencing climate changes. 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. We are interested to know what would work well to protect pregnant women and women who have given birth in the hottest times of the year. The results of this study can also help the government and other partners when they are planning how to deal with heat in communities and clinics as the climate continues

to change.

The first part of the study started last year where we looked at how pregnant and postpartum women feel in the heat, and deal with the heat. We also asked women what would work best in their homes and the community, to help protect pregnant women and babies when it is hot. We also spoke to household heads, community leaders and clinic managers to find out what could work in the community and clinic to help pregnant women and babies feel cooler in the heat.

In this part of our study, we will be making some changes in the community and facility and in a small number of people's homes. This study is an important step to see how best to implement these interventions. We want to see what works and what doesn't work and what people like and don't like. To see if these interventions work, we will collect information from about 400 pregnant women before we make the changes and from another 400 pregnant women after we make the changes. This will help us see if our changes helped pregnant and postpartum women in the heat.

WHY ARE YOU BEING INVITED TO PARTICIPATE IN THIS STUDY?

We are inviting you to take part in this study because you are 16 years old or older, you are currently pregnant, and you are also client at a health facility in Mt Darwin District.

STUDY PROCEDURES AND DURATION

We are inviting you to take part in this study. There are 3 parts to the study

INTERVIEWS

This means we will collect information from you during an interview, where we will ask you questions. These interviews will happen today (enrolment) and then at 2 other times during your pregnancy (at 4 week intervals from enrollment), when you give birth and at your Day 3 postpartum clinic visit (this can happen anytime from 3-10 days after you give birth). In total we will interview you 5 times to see how things change in your pregnancy and after having your baby. All interviews will be done while you are at the clinic for your normal clinic visits. You will be one of 400 pregnant women invited to participate. The first interview will last about an hour. Follow-up interviews will be shorter (around 30 minutes). In the interviews we will ask about you, your home, water and electricity access, and knowledge and use of cultural coping strategies. We will

also ask what you know about heat, how heat affects you, what you do when its hot and what other people say you must do when it's hot. We will also ask about how you are feeling. These interviews will be conducted in the language you feel most comfortable. Remember, there are no right or wrong answers. We just want to hear about your experiences and opinions. If for some reason we cannot interview you at the clinic we will ask you if you are willing for a study staff member to see you at home. We will not do this unless you give us permission.

URINE TESTS AND TEMPERATURE MONITORING

We would also like to see if the heat is causing dehydration or thirstiness. To do this, we will need to collect a urine sample from you at enrolment and at all your follow-up visits. We will share your urine test results with you as soon as we have the results. We will also explain what these results mean. The test takes 20 minutes and will be done in a safe and private space. We would like to know how hot you are feeling by measuring your body temperature. We will do this at the enrolment visit and at each follow-up visit. We will use a digital, infrared, no-contact thermometer and take your temperature at your forehead. The thermometer will not touch your skin. 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 heat health experiences. Temperature monitoring is being conducted in 50 of the 400 women's households and your household has been randomly selected. The monitoring will begin today _____(date of recruitment). The temperature monitoring device will be removed within 5 days of our last interview.

COLLECTING INFORMATION FROM YOUR CLINIC RECORD

This part of the study will not take up any of your time. We will need to look at your clinic file and the birth register at the clinic/hospital where your baby is born to see what the nurse and doctor have written. We may take a picture of your file with the study phone and enter the information into a database afterwards so that we don't take up more of your time. We will delete the picture as soon as we have captured the data we need. The information we will look at and put into our database includes your clinic visit dates, previous pregnancies, your medical records and information about your baby as he/she is growing and when he/she is born.

Being part of this study means that you will need to consent to all 3 things. That is, being part of the interviews, urine tests and temperature monitoring, and allowing us to capture information

from your medical records.

SUB-STUDY INFORMATION

Of the 400 pregnant women who take part in this study, we will invite about 30 to take part in another part of the study called Action Research. This Action Research will be used to test and improve the selected interventions at individual and household level. For this part of the study, we will select pregnant women based on maternal age at enrolment (16-24 and >25 years), housing type and area of residence. You may be asked if you are interested in taking part in this more intensive part of the study where your household will be involved in testing out some of the interventions.

At the end of this consent, if you agree to be part of the main cohort study of 400 women, we will ask if you are interested in taking part in this Action Research. If you are interested and you are selected to take part, we will contact you. A different consent will be done to take part in the Action Research.

IS THERE ANY RISK TO TAKING PART IN THE STUDY?

The risks of taking part in this study are low. Besides the urine test, there are no medical procedures or treatments involved. One risk is a possible breach of confidentiality. We feel this risk is low as we will use security measures to protect the information collected. We are not collecting any personal information, such as your name (except for signing the consent form), address, or phone number.

The interviewer may ask you some sensitive questions, such as those about yourself, how you are feeling and your childbirth experience. If you find that there is any question that you don't want to answer, you can say so. You can also stop the interview if you feel uncomfortable or find any aspects of the interview stressful to discuss. If necessary, and with your permission, the interviewer can refer you to counselling services at any participating health facility in Mt Darwin District.

ARE THERE ANY BENEFITS FOR TAKING PART?

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

- When you are part of this study, the temperature and dehydration monitoring will possibly make

you think more about how heat can affect you and your baby. When you know this, you could do more to protect yourself and your family from the heat.

- This may not be a direct benefit, but the valuable information you provide will help us design practical and acceptable ways to improve the wellbeing of pregnant women and newborn babies, as well as the staff who serve them in health facilities when the weather is hot.

REIMBURSEMENT

You will be given **USD 10** at each interview. This compensation is for your time and inconvenience. You will not need to travel for the interviews; they will be done at your clinic visit while you are waiting to be seen by the Nurse or we will come to your home. The money will be given to you in cash.

IS PARTICIPATION IN THIS STUDY VOLUNTARY?

It is your decision whether to take part in this study or not. Taking part in this study is completely voluntary. You may stop your participation in the study at any time without penalty. You are free to leave the study at any time without giving a reason. This will not affect you or the healthcare services you get from the clinic.

WILL THE INFORMATION COLLECTED BE KEPT CONFIDENTIAL?

If you decide to be in this study, we will allocate you a unique participant identification number. This participant identification number will be written on your study file and will only be used on all the information we collect. We will not reveal the names and addresses of the participants under any circumstances. Your contact information will be kept in strict confidence by the research team at CeSHHAR Zimbabwe. We need this information so that we can contact you for your other study interviews.

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). Your data will be collected, processed, and stored according to the Data Protection Act of Zimbabwe (2021). 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.

WHO WILL HAVE ACCESS TO THE INFORMATION COLLECTED DURING THIS STUDY?

The researchers who are involved in this study have access to this information. There are other organizations that we work with who may want to look at the information we collect. The Ministry of Health and Childcare, Medical Research Council of Zimbabwe and the Research Council of Zimbabwe might check the information that we collect. This is to make sure that we have done the study correctly. If you are a part of this study, you give us permission to show your study records to these mentioned organizations.

The WITS RHI in South Africa is our study partner. We may join the information we collect, to the information they collect in South Africa. They may also be involved in analysing the data and preparing reports and publications. To do this work they may look at and/or copy the information from the study. Only your Participant Identification number will be with the information we share with them. No names or other identifying information will be shared.

We may also share your anonymous information with researchers for use in other research studies if you agree to this. The information will be labelled with a study number and the date of observation, and we will not share your name. At the end of this form, you will be able to mark your decision on whether we can share this information for use in other research studies or not.

DOES THIS STUDY HAVE ETHICAL APPROVAL?

This study has ethical approval from the Medical Research Council of Zimbabwe (MRCZ).

WHO DO YOU CONTACT FOR ANY STUDY QUESTIONS OR ISSUES?

If you have any questions about your participation in this study, please contact:

Dr Fortunate Machingura

The Centre for Sexual Health and HIV AIDS Research

4 Bath Road, Belgravia, Harare

Fortunate.machingura@ceshhar.org

+263772971481

If you have any questions concerning this study or consent form beyond those answered by the investigator, 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.

YOU WILL HAVE A COPY OF THIS INFORMATION SHEET TO KEEP. Thank you for taking the time to consider taking part in this study. Do you have any questions that you would like to ask?

INFORMED CONSENT FORM – PREGNANT WOMEN PRE-INTERVENTION COHORT

WRITTEN PERMISSION FOR PARTICIPATION IN THE HAPI STUDY: PRE-INTERVENTION COHORT

Please ask eligible women to **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 sheet.		
I have had time to think about the information. I have asked questions and I am happy with the answers I received.		
I agree to take part in interviews at all study visits, to talk about my experience of the effects of heat on me during and after my pregnancy		
I agree to provide a urine sample at all study visits and share Maternal Case Records		
I agree to allow the research team to look at my medical records and capture my information into a secure database		
I agree to personal body temperature measurement at each study visit using a digital, infrared, no-contact thermometer with readings taken from my forehead		
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 understand that I may, at any stage, withdraw my consent. This means I can stop taking part in the study without any consequences.		
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 agree for my contact details to be stored so that the research team may contact me to set up interviews.		
According to the rules of the **Data Protection Act of Zimbabwe (2021),** I agree to my personal information (which is also called 'data') being collected, processed, shared and stored. This will be done according to the research protocol that has been approved by the MRCZ.		

If ALL boxes have a signature or thumbprint for "Yes", proceed with enrolment.

☐ **NO** (please tick), I **DO NOT** agree to take part in this study.

If NO, please stop all enrolment processes at this point.

☐ **YES** (please tick), I **DO** agree to take part in this study.

Please continue to next page ///

Additional consents (Initial/thumbprint next to choice)	**YES**	**NO**
I agree for my contact details to be stored. This is so that the research team can contact me later to take part in future research related to this study.		
I agree that my anonymous information to be shared and processed with other researchers. The data can also be placed in trusted data repositories (like a bank for data). These repositories may be outside of Zimbabwe.		
I agree for my anonymised data to be used for other research studies, subject to CESHHAR approval, including studies on a different topic.		

Enrolment may proceed if any of the above additional consents are ticked "No"

Signature/Mark/Thumbprint of participant:

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

Signature of study staff taking consent:

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

Signature of witness (If applicable: when verbal consent is required for participants unable to write):

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

Interest in taking part in Action Research

☐ **Yes** (please tick), I am interested in taking part in the Action Research study where my household will be involved in testing out some of the interventions. I understand that if I am selected to take part, the research team will contact me to sign another consent for the Action Research.

☐ **NO** (please tick), I am NOT interested in taking part in the Action Research

For study staff only:

Study PTID: _____