PARTICIPANT INFORMATION SHEET

Version 3.0 Date 27/05/2019

Study title: An observational Cohort study of heat strain and fetal wellbeing in pregnant farmers in The Gambia.

SCC:	16405	Protocol:	

Sponsor & Funder: London School of Hygiene and Tropical Medicine (LSHTM), funded by the Wellcome Trust.

What is informed consent?

You are invited to take part in a research study. Participating in a research study is not the same as getting regular medical care. The purpose of normal medical care is to improve one's health. The purpose of a research study is to gather information that may be useful in the future for the whole population. Your choice to participate or not will be respected. It is your decision and you can stop any time without giving any reason.

Before you decide you need to understand all about the study and what will happen in it. Please take time to read the following information or get the information explained to you in your language. Listen carefully. You can ask questions if there is anything that you do not understand. Ask for it to be explained until you understand it. You may also wish to discuss with your husband/wife, family members or others before deciding to take part in the study.

If you decide to join the study, you will need to sign or thumbprint a consent form saying you agree to be in the study. You will receive a copy of the consent form.

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Why is this study being done?

The world is getting hotter. Over the next 60-80 years, The Gambia and West Kiang district are predicted to suffer with extreme levels of heat for most of the year. Unfortunately, currently there is little being done to reduce the risk of this happening.

When people work outside in the heat it can cause stress to the body. In pregnancy that stress may also stress the baby in the womb and could cause problems for the baby.

There is no work being done on this at the moment and so there are many things that we do not know or understand.

From this study, we hope to understand how working in different hot/humid conditions during pregnancy effects the pregnant women and the unborn child. We also hope to understand how pregnant women loose heat so that we can begin to think of ways to help reduce the stress on the body when working in these conditions.

This study may also help us understand which people are at more risk of stress when working in the heat.

We will share the results of this study with you and your community when they are available.

What does this study involve?

This study involves pregnant women. If you meet all the eligibility criteria for the study and provide consent you will be invited to MRC Keneba for the first study visit.

At the first study visit you will be brought to the MRC compound in the early morning. On this visit:

- We will ask about your pregnancy, and details of your current health and details of previous pregnancies
- We will measure your height, weight and skin-fold thickness
- We will measure your blood pressure, heart rate and oxygen levels in the blood
- We will measure the water content in your body by bioimpedence
- We will perform an ultrasound scan of your baby
- We will ask you to wear a soft chest strap under your clothes to monitor your heart rate during the day, and if available a wrist sensor (similar to a watch)
- We will ask you to walk for 6 minutes to assess your level of fitness
- We will ask you to provide a urine sample
- We will ask to take 5ml of blood (about 1 teaspoons) from one of your veins to collect information on how much water you have in your body, and look for substances that increase when the body is under heat stress.

The visit will take approximately one hour and will be followed by breakfast?

You will then be observed over the course of the day doing your normal activities (including working in the fields), whilst wearing the portable sensors. During the day the study staff will regularly measure the temperature of the air, and humidity surrounding you. They will also perform a few additional tests:

- Temperature readings from your ear and skin
- Thermal pictures to understand which part of the body is hottest
- Assess your baby's heart rate and blood flow to your baby, if available,

At the end of the day the study staff will remove the sensors from you and do a few final checks in situ:

- Final assessment of your baby
- Final assessment of how much water is in your body – we will ask you to provide a urine sample and measure your bioimpedence
- We will ask to take 5ml of blood (about 1 teaspoons) from one of your veins to look for changes in the substances that increase when the body is under heat stress

You will be invited to join for another day 8 weeks later and every 8 weeks until the baby is delivered.

Once the baby is delivered we will collect data on baby's birth, birth weight and gestational age.

If at any stage of the study we find that you are not feeling well or there are indications that you or the baby are not well, we will assess you and if we think it is necessary, we will offer to take you to the Keneba clinic for further treatment.

What will happen to the samples taken in this study?

We will analyse the markers of heat stress in your blood at the laboratory in MRC Keneba. We will store any remaining blood in The Gambia for future related studies which may require plasma / serum (the watery parts of the blood), or genetic material (DNA). Your stored samples may be sent abroad for analysis if we require tests that cannot take place in Keneba.

What harm or discomfort can you expect in the study?

With the blood tests, there may be slight discomfort, bruising, bleeding and other symptoms (e.g. light-headedness) associated with blood draws. The amount of blood we will take is less than one hundredth of your blood volume and will have no adverse effects on you.

The measurements of weight, height, blood pressure, oxygen saturations are all painless and safe.

Bioimpedence measures the water, fat and muscle content of your body. It involves standing on a metal plate and holding a sensor in each hand. A tiny electrical current is passed through your body, which you cannot feel, is painless and is safe for you and your baby.

The ultrasound scan and doppler scan will be performed by a trained midwife and is no different from a routine scan that are performed during pregnancy. It is painless and safe.

The wearable sensors are designed specially to be worn in active/working conditions. It is made of lightweight breathable material and should be very comfortable. Should it need adjusting to ensure a proper fit, that can be done at any time.

What benefits can you expect in the study?

You will have close contact with the study staff and so will provide you with the opportunity to address any health concerns you have during the time of the study. Additionally, if during the preliminary measurements or at any time during the study, we identify anything concerning, we will take you to the antenatal clinic for a thorough investigation.

Will you be compensated for your child's/ward's participation in the study?

You will not get paid by the study, but MRC will provide transport or give you back the money for your transport.

What happens if you refuse to participate in the study or change your mind later?

You are free to join or not join in the study and you are free to stop taking part at any time without giving a reason. You will still get the normal medical care.

If you do not want to continue in the study, we will use only the samples and information already collected from you.

If we find new information during the study that may change if you can be in the study, we will tell you as soon as possible.

How will personal records remain confidential and who will have access to it?

All information that is collected about you in the study will be kept strictly confidential. Your personal information will only be seen by the study team members, the sponsor and if necessary the Ethics Committee and Government authorities.

At the end of the study, once all personal information is removed from the data and there is no means of identifying you, the data will be made available in a public repository, for future research projects.

Who should you contact if you have questions?

If you have any questions or are worried you can call Dr Ana Bonell on …. and you can also call the personal numbers of the MRC workers given to you.

Please feel free to ask any question you might have about the study.

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Who has reviewed this study?

This study has been checked by scientists at MRC and by the Gambia Government/MRC Joint Ethics Committee and by the LSHTM ethics committee. The Ethics Committees protects your rights and wellbeing, and have given permission for it to take place.

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CONSENT / ASSENT FORM

Participant's Name _____

Participant's Identification Number: |__|__|__|__|__|__|__|__|__|__|

_____ **OR** _____
(Printed name of parent) (Printed name of guardian)

☐ I have read the written information **OR**

☐ I have had the information explained to me by study personnel in a language that I understand,

and I

- confirm that my choice to participate is entirely voluntarily,
- confirm that I have had the opportunity to ask questions about this study and I am happy with the answers that have been provided,
- understand that I allow access to the information about me by the persons described in the information sheet,
- had enough time to think about whether I want to take part in this study,
- agree to take part in this study.

Tick as appropriate

I agree for my samples to be shipped outside the Gambia Yes ☐ No☐

I agree to further research on my samples including genetic testing Yes ☐ No ☐

Participant's signature/thumbprint* ☐

_____
Date (dd/mmm/yyyy) Time (24hr)

Printed name of witness* _____

Signature of impartial witness* _____
Date (dd/mmm/yyyy) Time(24hr)

Printed Name of Person obtaining consent _____

I attest that I have explained the study information accurately in _____ to, and was understood to the best of my knowledge by, the participant. She has freely given consent to participate *in the presence of the above named witness (where applicable).

Signature of Person obtaining consent _____ _____
Date (dd/mmm/yyyy) Time (24hr)

** Only required if the participant is unable to read or write.*