

UBOMI BUHLE - Pregnancy Exposure Registry, South Africa:

INFORMED CONSENT FOR ADULTS 18 YEARS AND OLDER

UBOMI BUHLE PROJECT: Understanding Birth Outcomes from Mothers and Infants, Building Healthcare by Linking Exposures - the South African pregnancy exposure registry

Protocol Version 6.0 dated 23 September 2022

SPONSOR: President's Emergency Plan for AIDS Relief (PEPFAR) through the Centers for Disease Control and Prevention (CDC), under the terms of Cooperative Agreement Number GH001934 through Wits Health Consortium (FWA 00000715) and The Bill and Melinda Gates Foundation (BMGF) INV-004508

NATIONAL PRINCIPAL INVESTIGATORS: Dr Ushma Mehta and Prof Lee Fairlie

SITE INVESTIGATOR: DR FAEZAH PATEL

INSTITUTION: WITS RHI SHANDUKANI RESEARCH CENTRE

Daytime and after-hours contact TELEPHONE NUMBER(S): 072 630 7892

Good Day,

My name is _____ and I am a _____ at Wits RHI Shandukani Research Centre

We would like to invite you to be part of this project called UBOMI BUHLE. UBOMI BUHLE stands for Understanding Birth Outcomes from Mothers and Infants, Building Healthcare by Linking Exposures. Please read this information sheet so that you understand what being part of this project means.

Goal of the UBOMI BUHLE project

The goal of the UBOMI BUHLE project is to look at different things that may affect women who are pregnant. It will also let us see what happens to them and their babies after their baby is born. This is called a Pregnancy Exposure Registry. We want to use this information to care for pregnant women and their babies better.

Who will be asked to take part in this project?

All pregnant women attending antenatal care at this facility will be invited to take part in this project.

UBOMI BUHLE project

Sheet and consent form (Adults 18 years and older), Version 1.4 dated 23 September 2022

Investigator's names: Dr Faezah Patel

Approved by Wits IEC (HREC)

Date approved: 11 October 2022

Information

Participant Initials: ____ ____ ____

What will it mean to take part in the project?

When you come to the clinic, information about you and your pregnancy will be written on your clinic maternity case record (MCR) or patient card, as usual. Your MCR will also have information about medicines that you take, your medical conditions and any other pregnancies you had. Clinic nurses will also write in the MCR what happens in this pregnancy, at birth and about your baby after birth.

If you decide to be part of this project, we will put all this information into a safe information system called a database. The nurses and doctors at the clinic and hospital where you have your baby will be able to see this information. Project staff might also look at the information in the database. For your information to be added to the database, we might use your MCR, or the copy of your MCR that the clinic keeps. If your clinic doesn't keep paper copies of your MCR, the study team may take a photograph or make a copy of your MCR. This is to make sure that all information is captured onto the database. We will make sure these photographs are stored in a safe, secure, password-protected and access-controlled database. Only study staff will have access to this data base. All photographs will be deleted off the tablets or phones that were used to take them, as soon as they are safely stored in the database.

Some information from this database will later be added to a bigger central database. This is so that we have more information about what is happening with pregnant women and their babies in South Africa.

If you agree to take part, you are free to change your mind at any time and stop participating in the project. This will not affect your care or the care of your baby.

Data Storage and sharing.

Your information will be stored in a password-protected database. All your information will be stored on safe servers to make sure that it is secure and protected. Your data will be collected, processed and stored according to the South African Protection of Personal Information (POPI) Act of 2013.

When your information is shared with other researchers or people working on the study, any information that can identify you or your baby will not be shared. So, we will remove your name

and other personal details before we share the information. We will also use a special code so that no one knows who the information belongs to. This is called de-identification and encryption. This means that there will be no names, surnames, dates of birth or file numbers on the database we share. These details will also not appear in any information that we or our partners publish from this project.

Is there any risk to taking part in the project?

There is no risk to you or your baby if you take part in this project. The information we collect is routine information that you would give to the clinic on paper. We will not ask you for extra information. The only difference is that it will now be put into a computer database.

Are there benefits of this project?

There may be no direct benefits to you by being in the project, but the results of this project will make health care for mothers and babies across the country better. Your treatment in any of the health facilities will not change if you do or do not take part in the study. You will not be paid to contribute data for this project.

Ethical approval of this project

This project has been submitted to the University of the Witwatersrand, Human Research Ethics Committee. An Ethics Committee is a group of experts who make sure your rights are protected.

This committee has approved the project. If you want any information regarding your rights in this project, or complaints about it, you may contact Prof. Penny. His contact information is in the block below.

Prof. Penny
 Chairperson of the University of the Witwatersrand, Human Research Ethics Committee (HREC)
 University of the Witwatersrand
 Tel: 011 717 2301
 The HREC is an independent committee established to help protect the rights of research participants

Confidentiality

We will do everything we can to protect your confidentiality. Only clinic and project staff will see information that says who you are. They need this to make sure they have the right

information for you. The information in the database will have strong passwords. This means that only people who should see the information can see it.

The UBOMI BUHLE project is paid for by CDC (Centers for Disease Control and Prevention) and the Bill and Melinda Gates Foundation. Staff from either organization, or from the ethics committee, may monitor or check on project activities to make sure that the project is being done properly. This is also to protect your rights. Your and your baby's personal medical information may be seen by them during this check but will be kept private.

Your information that is collected may be shared with other researchers, who study pregnancy and babies. We will first get approval from the University of the Witwatersrand, Human Research Ethics Committee (HREC) before sharing any information with other researchers. Your and your baby's personal identifying details will not be included when we share this information.

Statement of Acceptance

I have read and/or had this form read to me. I have been asked to participate in the UBOMI BUHLE project. I have been given a chance to ask questions and my questions have been answered.

☐ **YES** I freely agree to participate in the UBOMI BUHLE project

☐ **NO** I do not agree to participate in the UBOMI BUHLE project

Signature/Mark/Thumbprint of participant:

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

Signature of study staff taking consent:

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

Signature of witness (if applicable):

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

Permission for UBOMI BUHLE staff to contact me:

☐ **YES** I agree that UBOMI BUHLE staff may contact me if they need more information, such as to find out what happened to my pregnancy or my baby

☐ **NO** I do not agree that UBOMI BUHLE staff may contact me

Signature/Mark/Thumbprint of participant:

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

Signature of study staff taking consent:

Signature		Date of signature			
			DD	MMM	YYYY

Print name		Time of signature	:
			(24-hour clock)

Signature of witness (if applicable):

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