STUDY NAME

Participant Information Sheet

**Cover page overview**

Title of the research:

Name and affiliation of Principal Investigator and co-investigators [Name/contact info]

Sponsor of research:

Organizations involved:

Purpose of research:

We are inviting you to take part in the [NAME OF STUDY], which aims to investigate [INSERT PURPOSE OF STUDY], which we suspect may predict problems later in pregnancy such as preeclampsia or preterm birth, and could lead to the development of new treatments for moms and newborns that may be at higher risk.

Before you decide, we would like you to understand why the research is being done and what is required of each participant.

Please read this information sheet carefully. One of our team will go through it with you and answer any questions you have. We suggest this should take about 15 minutes.

Talk to others about the study if you wish.

Please ask us if anything is not clear.

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**Purpose of our study**

As you know, many babies are born too soon, too small, or too sick to survive, and many pregnant women become ill during their pregnancy. It is a huge problem in this part of the world and we need to find ways to stop this from happening. We know that malnutrition and infections are two conditions that can lead to these problems. Because not all babies exposed to the same conditions are affected the same way, we believe that some are at higher risk than others. If we can discover a way to know in advance which moms and babies are at high risk for getting sick, then we may be able to make a medicine that we can give to all women that will keep them healthy during their pregnancy, help their babies develop normally in the womb, and stop babies from being born too soon or getting sick soon after they are born.

**Why we ask you to participate**

In our study we want to know if we can identify important clues during early pregnancy that will help us predict the health of the mom and baby later in pregnancy and early in his/her childhood. Gaining a better understanding of these clues may allow the development of new treatments for moms and newborns who are at higher risk for poor outcomes such as preterm birth, stillbirth, preeclampsia and intrauterine growth restriction (IUGR).

This study will take place in [INSERT NUMBER] countries and we hope to recruit around [INSERT NUMBER] volunteers, (INSERT TARGET ENROLLMENT NUMBER FOR LOCAL SITE] of whom will come from (INSERT NAME OF STUDY SITE).

**What we are asking of you**

We are inviting all women who are [INSERT INCLUSION CRITERIA PER PROTOCOL] to take part in our study. We would like your permission to do the following things:

1. Collect information on forms and by means of a simple interview on aspects of family history and medical background. This interview should take approximately 20 minutes.
2. We also wish to perform certain *laboratory tests* to look at genes, which we suspect might be associated with poor pregnancy outcomes. What we are asking to do is to take a sample of [INSERT TYPE OF BIOSPECIMEN] from you to study the genetic material it contains, and we would like to explain to you what that genetic material is. The genetic material is found in blood, urine, saliva and tissues and is what makes everyone different from birth – in our height, in our looks, and in many other ways, including whether a baby is born on time or too soon. We are studying the genetic material from moms and babies who have problems and from those who do not have any problems, to try to discover the exact part of the genetic material that can inform us about the health of the developing baby. Samples will be requested from both parents.

**What will happen to me if I take part in the study?**

If you agree to take part in the study, you would be offered [INSERT THE NUMBER OF VISITS AND WHEN THEY OCCUR-BEFORE, DURING OR AFTER PREGNANCY, PER YOUR PROTOCOL]: For Example:

1. within the first 14 weeks of your pregnancy
2. in the second trimester of your pregnancy
3. in the third trimester of your pregnancy
4. at 42 days from the day you deliver your baby

We would ask you to donate a [INSERT TYPE AND AMOUNT OF BIOSPECIMENS YOU EXPECT TO COLLECT] at the first visit.

We would also ask you to donate [INSERT TYPE AND AMOUNT OF BIOSPECIMENS YOU EXPECT TO COLLECT] at your second antenatal visit.

At the time of delivery, we would ask to take a 10cc blood sample from the umbilical cord and collect samples of your placenta [INSERT NUMBER AND SIZE OF SAMPLES PER YOUR PROTOCOL] after your baby has been delivered.

Lastly, we would also like to collect a final [INSERT TYPE AND AMOUNT OF BIOSPECIMENS YOU EXPECT TO COLLECT] on day 42 after delivery.

We will also collect some information about your pregnancy and about your baby’s health from his/her delivery up to day 42.

We would also ask your baby’s father to provide a [INSERT TYPE AND AMOUNT OF BIOSPECIMENS YOU EXPECT TO COLLECT] at one of the 4 visits.

**Are there any costs or payments involved?**

There is no payment for donating samples to our study or to the local [NAME OF STUDY] Biobank for future approved studies. Sometimes research may result in findings or medicines that have value if they are made or sold. But you would not receive any financial benefit.

**What are the possible risks of taking part?**

Taking a blood sample may cause some discomfort, but the study will not damage you or your baby in any way.

**What are the possible benefits of taking part?**

Taking part in this study will not benefit you or your baby directly but we hope that it will benefit future women and babies everywhere by helping us learn more about pregnancy and newborn outcomes. However, you must realize that we are trying to tackle a very difficult problem and that it may be many years before we achieve our goals.

**What will happen to the sample?**

We will take the samples back to our laboratory in [INSERT LOCATION] where we will extract the genetic material. We will keep some of this genetic material in [INSERT LOCATION] and we will send some of it to researchers in [INSERT OTHER STUDY SITES, IF APPLICABLE] who are working with us on this project.

We will do some tests on this sample immediately but other tests will take many years to develop. We are asking permission to store the samples in the [INSERT NAME OF STUDY] Biobank in [INSERT LOCATION] until we have finished all of the genetic tests and for future approved studies into the causes of problems in pregnancy.

**What will happen to the information?**

Once we take your samples, we will assign it a code number and we will separate your name from the sample. Only the principal researcher or a research assistant authorized by him or her will be able to link the sample back to you or your baby. We will be very careful about the information that we have collected about you and your baby and we will make absolutely sure that when we tell people about our findings on the genetic material, no one will be able to discover that this genetic material came from you or your baby.

**Do I have to take Part?**

It is up to you to decide whether or not you wish to take part. Your decision will not affect the care you receive in any way. We will describe the study and go through this information sheet with you. If you agree to take part, we will then ask you to sign a consent form. If you have any questions or concerns after reading this leaflet, our study coordinator will be happy to answer them. You can also call her on the number on the front of this information leaflet.

**What will happen if I don’t want to carry on with the study?**

Your participation in this study is entirely voluntary—it is up to you. If you don’t want your samples to be taken, then this will in no way affect the help you or your baby will get now or in the future. You are free to withdraw from the study at any time, without giving a reason. If at any time in the future you change your mind and decider that you don’t want your samples to be used, please tell us and the sample will be destroyed. This will have no consequences for you. It will not affect the care you receive in any way. Any stored data that identifies you, and any samples that you have donated would be destroyed.

**Will my taking part in this study be kept confidential?**

Any information that is collected about you during the course of the research will be kept strictly confidential. Our research coordinator, who has duty of confidentiality to you and your baby as research participants, is the only person able to identify you and your baby. If you choose to continue with the study, you and your baby’s medical information and samples will be held anonymously in a secure database to which only the research team will have access.

Authorized representatives of the [INSERT NAME OF STUDY] may look at anonymized results to check that the study is being performed correctly. No individual participants will be identified when the results of the study are published. Any information that leaves the (INSERT NAME OF FACILITY) will have your name removed so that you cannot be identified.

The data will be retained for [INSERT THE NUMBER OF YEARS YOU WILL STORE DATA/SPECIMENS, PER YOUR PROTOCOL] after the end of the study in the event that future discussions about pregnancy and newborn outcomes require the data to be reanalyzed. After X years, the data will be disposed of securely. You have the right to check the accuracy of the data held about you and your baby, to correct any errors.

**What will happen to any samples I give?**

For confidentiality reasons, your name will be removed by the principal investigator or authorized research coordinator from all biological samples and replaced by a code number. The samples will either be used as soon as possible to study the genetic material or stored in the [INSERT STUDY NAME] Biobank for future, approved research. The results from any tests carried out on these samples will not benefit you or your baby but we hope that it will benefit future generations of women and newborns.

**What will happen to the results of the research study?**

The results will be prepared for publication in scientific journals and presentation at international meetings. We can provide you with a copy of the papers after publication if you wish. Your name will not appear in any report or publication. Your identity will be protected at all times.

**What are my rights as a participant?**

You may choose not to have your samples stored for future research and still be part of this study. Also, you may agree to have your sample stored and later decide that you want to withdraw it from storage. If so, you should contact the principal investigator or study coordinator and tell him or her to discard your sample. He or she will discard your sample but any data from testing your sample until that point will remain part of the research.

**Whom do I call if I have questions or problems?**

If you have any questions about how this study works, contact [INSERT NAME/CONTACT INFORMATION OF STUDY COORDINATOR]. If you have any concerns about your rights in this study, contact [INSERT NAME/CONTACT INFORMATION OF PRINCIPAL INVESTIGATOR]. If you think that being in this study injures you, contact [INSERT NAME/CONTACT INFORMATION OF LOCAL ETHICS BOARD]

**What will happen if I don’t want to carry on with the study?**

You may withdraw from the study at any time. It would not affect the care you receive in any way. If you withdraw from the study, any stored data that identifies you would be destroyed. If you withdraw after you have donated biological samples, you will be asked if you are happy for the samples to be used and, if not, all samples remaining in the biobank will be destroyed. Analyses that have already been completed on your data and or samples prior to withdrawing will not be destroyed or removed from datasets.

**Who is organizing and funding the research?**

The research is being carried out by (INSERT LOCAL SITE), and it is being coordinated by the [INSERT COORDINATING INSTITUTION] with funding from [INSERT SOURCE OF FUNDING]. The people involved in the research are not being paid to include you in the study and have no conflicts of interest with regards to the study.

**Who has reviewed the study?**

Research is reviewed by an independent group of people called a Research Ethics Committee to protect your interests, safety, rights, well-being and dignity. This study has been reviewed and given favorable opinion by the [INSERT NAME OF COORDINATING INSTITUTION].

**Further information and contact details**

If you have any further questions, please do not hesitate to contact (INSERT NAME/CONTACT INFORMATION OF STUDY COORDINATOR] and she/he will be able to explain better to you what our study is about. You should also contact this person if you would like to withdraw from the study, or if you have any worries regarding your participation in this study.

You can find our website at:

You may keep this information leaflet for your records.

If you have any questions, please contact us per above.

If you wish to take part in the study we will ask you to sign a consent form.

We will give you a signed copy to keep for your records.