PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM:
Pre-eclampsia Biobank

SUMMARY

Name of principal investigator: Dr Cathy Cluver
Name of research midwife: _____
Contact number of principle investigator: 082 321 0298

What is pre-eclampsia?
Pre-eclampsia is a serious condition that occurs only in pregnancy.
It is defined as high blood pressure that involves different parts of the body like the kidneys, liver and the brain.
Pre-eclampsia and its complications cause significant problems for women and their babies.

The research project: Pre-eclampsia biobank:
You are invited to participate in this project because you are pregnant, and you have been admitted to Tygerberg hospital.

Our research team is investigating pre-eclampsia so that we can try to improve care for women and their babies. To do this, we need to create a biobank (collection of information and tissue samples).

This Information and Consent leaflet explains this project. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you do not understand or want to know more about. Before deciding whether you want to participate you may want to talk about it with a relative, friend or health worker. Participation in this research is voluntary. If you do not wish to take part, you do not have to. You will receive the best possible care whether you take part or not.

If you would like to participate, you will be asked to sign the consent form. By signing this form, you are telling us that you:

- understand what you have read
- would like to take part in the research project
- consent to participate in the research processes
- consent to the use of your personal and health information as described

You will be given a copy of this form to keep. You may ask questions at any time

INVITATION TO BE INVOLVED IN THE PRE-ECLAMPSIA BIOBANK

You are being invited to participate in a research project to create a biobank (collection of information and tissue samples). The name of the study is the pre-eclampsia biobank. It is important that you read all the information provided before you decide to take part. If you have any questions you can ask your doctor, the midwives or any of the staff from the research project. You can also talk to the other women who have been invited to participate.

What is pre-eclampsia?
Pre-eclampsia is a serious medical condition that affects only pregnant women.
The first sign is high blood pressure. Pre-eclampsia can also affect other organs like the kidneys and can cause liver problems, blood clotting problems, and in severe cases eclampsia (fits) and stroke.

How do we treat pre-eclampsia?
There is no treatment apart from delivery of the baby and the placenta (afterbirth).
Blood pressure medication can control the high blood pressure, but it does not treat the pre-eclampsia.

Why are we establishing this pre-eclampsia biobank?
We want to understand why certain women develop pre-eclampsia and its complications.

What is the purpose of this biobank?
The purpose is to create a collection of information and tissue samples that can be used for research about pre-eclampsia.

How many women will be included in the biobank?
This will be an ongoing project. There is no limit to the number of women that will be involved.

Why have I been invited to be involved in this biobank?
You have been invited to be involved as you have pre-eclampsia (pre-eclampsia case) or you have an uncomplicated pregnancy (control case).

Do I have to be in the biobank?
It is your choice to be involved or not. Your treatment will not be any different either way. You can decide at any stage in the pregnancy to withdraw from the study and you will not have to give a reason for why you want to withdraw. You can also ask us to remove and discard all your information at any stage.

Will I need to do anything extra if I am in the Biobank?
Yes.

1. We will ask you some extra questions about your pregnancy, particularly more details about symptoms of complications. We may ask you questions which will help us understand how your brain is functioning (cognitive questionnaire).
2. We will collect information from your medical chart such as height, weight, medical history and blood pressure.

3. When blood samples are drawn for medical reasons, we will collect an extra sample for storage in the biobank (12 mls maximum/ less than a tablespoon). We will collect blood up to four times during your stay.
4. We may ask you to provide a small amount of stool, urine and saliva for storage in the Biobank.
5. We will collect information about your baby, including the birth weight and the condition of your baby at birth.
6. If you have a casearean section, the doctor doing the pain relief may give you spinal anaesthesia (injection through a needle in the back). If you have this, we may collect a small sample (less than a teaspoon or 0,5 mls) of this fluid that is usually thrown away.
7. After the birth of the baby, we may take samples from the placenta (afterbirth) and cord. These tissues are usually thrown away after delivery. We may collect a small sample (fingertip size) of the placenta and a sample of the blood from the cord (4 mls or 1 teaspoon).
8. We may ask you if we can do an ultrasound to measure the blood flow and to assess the function of your blood vessels. This ultrasound has no risks for you. The ultrasound takes a few minutes and a small measuring device is held over your arm . When doing the ultrasound we may inflate a blood pressure cuff around your arm for a few minutes. This may cause mild discomfort but will not cause any damage.
9. We may ask you if we can do an ultrasound to measure the blood flow in your brain. We will hold a small ultrasound probe on the side of your head for less than 10 minutes. This ultrasound is of no risk to you and will not cause you any discomfort.
10. We may ask you if we can do an ultrasound to assess your heart. A small ultrasound probe will be placed on your chest to assess how your heart is functioning. This ultrasound is of no risk to you and will not cause you any discomfort.
11. We may ask you if we can do a special scan of your brain or heart called a MRI. This scan involves lying still for a maximum of half an hour. There is no risk to you for this scan and it will not cost you any money
12. We may ask you if we can use a special machine to examine your eye. A trained scientist may take a picture of the vessels in your eyes with a special camera You will see a bright flash for less than a second, but your vision will be normal immediately afterwards.

You can choose to not have any of these investigations and still be part of the project. At any stage you can ask us to stop doing any of the extra examinations.

What will happen if I am interested in being involved?

One of our research nurses or researchers will come and speak to you about the trial. If you decide to be involved, you will then sign this consent form.
We will then open a research folder for you and collect information about your pregnancy. We will look at your antenatal card and will ask you some questions about your pregnancy. The study nurse will then come and see you every day that you are admitted in the hospital. She will spend about 15 minutes with you each day and will ask you how you are feeling and will review your medical notes. She may ask the doctors and nurses who are caring for you about how you are doing. The collection of the information and samples will not harm your

health or your baby. The research nurse may ask if we can do some extra examinations like an ultrasound or MRI described above.

For how long will I be involved in the biobank?
We will see you every day until you are discharged.
We will also phone you after you have been discharged to check that you and your baby are well.
We may invite you to a follow up visit one year after the birth of your baby. At this visit we will check your general health and measure your blood pressure. We will ask you some questions to assess your brain function (cognitive questionnaire) and may take a blood sample (less than 12 mls or a tablespoon) if you give your permission. This visit is voluntary.

What will happen to the samples?
Your information and samples will be stored in our biobank for use in future studies. Your samples may even be sent overseas for analyses if we are not able to do the tests here in South Africa. All these future studies will have to be approved by a Research Ethics Committee registered with the South African National Health Research Ethics Council (NHREC). These research projects will aim to understand what causes pre-eclampsia and how we can diagnose, prevent and treat pre-eclampsia.

Will my information be kept confidential?
Yes. All information collected in the biobank will be kept confidential. Your identifying information will only be available to people directly involved in the biobank. Your information will be given a study number and your name will not be used for identifying any of your samples in the biobank. Your samples will only be labelled with your study number. If your clinical information and samples are used for future studies only deidentified information will be given. This means that these studies will not have access to your name, phone number or address for example.

Your identifying information will be stored in an electronic database which only the biobank researchers and nurses have access to. This electronic database (REDCap) is managed by Stellenbosch University and requires two passwords to access the data. All written or printed information that contains your name (any hard copies of the research notes) will be locked in a research office and only research staff directly involved with the biobank will have access to this information. Your name will not appear on any presentations or publications relating to this study. Only your study number will be on the samples taken and none of the laboratory staff will have access to your name or contact details.

Are there any benefits for me of being involved with this biobank?
No. You will not receive any immediate benefit from participating in this project.
We hope that the information we gain from the biobank will lead to better care of women with pre-eclampsia in the future.
If you come back for a follow up visit after one year, we will pay for your transport costs.

What are the disadvantages and/or risks of being in the biobank?
There are no risks for you or your baby. The researchers and midwives will come and see you every day. You may be asked more questions and may be asked if you would be willing to have extra tests. The ultrasound tests and MRI may cause mild discomfort but will not cause any damage to you or the baby. Your involvement in the biobank is voluntary and you can decide at any time to not continue participating.

What will happen with the results of this research project?
We hope to publish the results of projects from the biobank in medical journals and present them at medical conferences. We hope to find answers that can improve the care of mothers and babies affected by preeclampsia.
The projects from this biobank will involve information and samples from many different women. For this reason, you will not receive personal feedback about the projects. Your private details will not be included in any of this work or in any articles or presentations.

How can I access my information?
You have the right to access your information at any stage. You also have the right to request that any information, with which you disagree, be corrected. Please contact one of the researchers named at the end of this document, if you would like to access your information.

Who has developed this study and who has approved the biobank?
This biobank has been developed by a team of researchers from Stellenbosch University, South Africa and Uppsala University in Sweden. This biobank has been approved by the Health Research Ethics Committee at Stellenbosch University.

Who will have access to my information and samples?
Only the principal investigator (Dr Cathy Cluver), the co-investigator (Dr Lina Bergman) and the research midwives collecting your information will have access to your identifying information. Other researchers will only have access to information and samples that contain no information that can identify you. These researchers will need separate ethics approval for their study before they are given any information.

Where will people be recruited for the biobank be conducted?
Recruitment will be at Tygerberg Hospital, in the Department of Obstetrics and Gynaecology.

Who has paid for this biobank?
This biobank has been funded by the Department of Obstetric and Gynaecology at Tygerberg Hospital. Dr Cluver's has been paid for by research bursaries from the Discovery Foundation, the South African Medical Association and the Mercy Perinatal Foundation. Dr Bergman's salary has been paid for by the Center for Clinical Research, Falun, Sweden. There is no cost for you as a participant.

Who do I contact if I have a problem or want more information on the Biobank?
If you have any concerns or problems, you will be able to speak to the researchers and research midwives involved in the study at anytime.

This study has been approved by the **Health Research Ethics Committee (HREC)** and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

You can contact Dr Cathy Cluver, Principal Investigator, at telephone number 0823210298 or email her at cathycluver@sun.ac.za if you have any further questions or any problems. You can contact the **HREC** at 021-938 9207 if you have any concerns or complaints that have not been adequately addressed by your study doctor.

What if I don't want to participate?
Your participation is completely voluntary. Should you wish to withdraw at any stage, or to withdraw your information and samples, you can do this at any time, and it will have no influence on your care as a patient at Tygerberg Hospital.

What do I do if I do not want to continue with the biobank?
If you decide to not continue with the study, you may withdraw and it will not affect the care that you are receiving in any way. You will not be asked to give us a reason for why you want to withdraw. We will ask you if it will be possible to collect information about your pregnancy and delivery and we will ask you if it is possible for us to use the samples that we have already collected. You can decide if you want us to remove all your information and samples or if you are happy for us to leave them in the biobank.

What will happen to my samples if the biobank is terminated?
If the biobank is terminated all samples will be destroyed.

How do I agree to participate?
If you would like to participate, you will be asked to sign the consent section of this document. By signing this form, you are telling us that you:

- understand what you have read
- consent to take part in the research project
- consent to participate in the research processes that are described
- consent to the use of your personal and health information as described.

Thank you for taking the time to read this information leaflet.
We hope that you will consider being involved in the biobank.

CONSENT FORM: PRE-ECLAMPSIA BIOBANK

Please ask the study staff or doctor any questions about any part of this project that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research entails and how you could be involved. Also, your participation is **entirely voluntary,** and you are free to decline to participate. You will be given as much time as you need to decide whether you would like to be involved in the study. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part.

This study has been approved by the **Health Research Ethics Committee (HREC) at Stellenbosch University** and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

You can contact Dr Cathy Cluver at telephone number 082 3210 298 if you have any further queries or encounter any problems. You can contact the **Health Research Ethics Committee** at 021-938 9207 if you have any concerns or complaints that have not been adequately addressed by your study doctor.
You will receive a copy of this information and consent form for your own records.

Declaration by participant

By signing below, I …….. agree to take part in a research study entitled: The Pre-eclampsia Biobank

I declare that:

- I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.
- I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.
- I may request that my samples be removed from the biobank at any stage.
- I understand that the samples will be stored indefinitely and that laboratory studies may be performed on the samples at a later date.
- I understand that my samples may be sent overseas for further laboratory testing.
- I understand that no genetic testing will be done on my samples.

Signed at (*place*) …….. on (*date*) ……..

…….. ……..
Signature of participant **Signature of witness**

Declaration by investigator

I *(name)* …… declare that:

- I explained the information in this document to ……..
- I encouraged her to ask questions and took adequate time to answer them.
- I am satisfied that she adequately understands all aspects of the research, as discussed above
- I did/did not use an interpreter. (*If an interpreter is used then the interpreter must sign the declaration below.*

Signed at (*place*) ..... on (*date*) ……..

…….. ……..

Signature of investigator **Signature of witness**

Declaration by interpreter

I *(name)* …… declare that:

- I assisted the investigator (*name*) ……. to explain the information in this document to (*name of participant*) …….. using the language medium of English/Afrikaans.
- We encouraged her to ask questions and took adequate time to answer them.
- I conveyed a factually correct version of what was related to me.
- I am satisfied that the participant fully understands the content of this informed consent document and has had all her question satisfactorily answered.

Signed at (*place*) ..... on (*date*) ……..

…….. ……..

Signature of interpreter **Signature of witness**