Consent Form

Point-of-care ultrasound abnormalities in eclampsia - prevalence and association between pulmonary interstitial syndrome and cardiac dysfunction, brain natriuretic peptide, and serum albumin

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Co-investigators:

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International Collaborator: Dr. Clemens M. Ortner, MD, MSc, DESA

1. Purpose of the study

We are asking for you to be in this study because you are an otherwise healthy pregnant woman admitted to Groote Schuur Hospital labour and delivery unit, and you now have a diagnosis of "eclampsia", a disease with high blood pressure in pregnancy, complicated by one or more seizures. We want to see how results of a type of blood test and of ultrasound examinations of your chest and eyes compare to the outcome of your delivery. The blood test is a marker of heart function in the blood that may be off-balance in patients with eclampsia. The ultrasound examination is similar to examinations you might have had during your pregnancy, where pictures of your baby were taken with a device called ultrasound machine. An ultrasound machine makes sound that you or your baby do not hear or feel to make a picture. This "ultrasound" has also no known side effects. In a similar way, we are now making pictures of your heart, lung and eye. This study is important as it will help us to better understand and manage this disease in the future.

2. Study procedures

If you choose to be in this study, your participation in the study will take place during your stay in the hospital before and/or after delivery. The following research procedures will take place in addition to the treatment you would have normally received:

<u>Collection of blood from the vein:</u>

We will collect a small amount of blood from you one time for this study. For standard clinical care, blood will also be collected from your vein. If possible, we will try to collect extra blood from the clinical draws (blood samples routinely taken for your condition). With the blood draw we will collect 2-3 teaspoons of blood, which will take less than 3 minutes to complete. This is necessary for this study, as some information cannot be obtained from the routine blood draw (serum brain natriuretic peptide, serum albumin level, soluble tyrosine kinase, placental growth factor and Kisspeptin). We will try our best to draw blood from you only once.

<u>Ultrasound examination of your heart, lung and eye nerve:</u>

For the study purpose we will perform an ultrasound examination of your heart, lungs and eye within 24 hours of your admission, at a time when the doctors looking after you regard it as safe. Ultrasound is a non-invasive method, using a probe placed on the surface of your body which will not be uncomfortable for you, to make images of your heart, lung and eye nerve. The ultrasound examination of your eye can

give us important information about the pressure behind your eye. For that purpose, ultrasound gel will be applied on a small ultrasound probe (stick) that will be gently positioned on your chest and eye lids. The ultrasound examination on your chest will take 30-35 minutes and the examination of your eye will take 5 minutes. So, in total the ultrasound examinations will take approximately 35-40 minutes.

Collection of data from the medical record: We will collect information about you and your newborn baby from the Groote Schuur Maternity Hospital record. We will collect information about your pregnancy, delivery, and medications from your health history until one-day after delivery. We will collect information about your baby such as birth weight, placental weight, Apgar score, and overall health.

3. How could these measurements help your treatment?

If there are any abnormal findings on ultrasound examination, the doctors looking after you will be informed, and treat you accordingly.

4. What are the possible risks?

The risk of the taking of a blood sample from your vein is very low. The ultrasound examination causes very little discomfort to you, and the ultrasound examination is safe and there is no or very little risk to you and your baby. We can assure you that study procedures will only be done when all routine or emergency care is completed, and your doctor says it is safe.

5. What if something goes wrong?

This research study is covered by an insurance policy taken out by the University of Cape Town if you suffer a bodily injury because you are taking part in the study.

The insurer will pay for all reasonable medical costs required to treat your bodily injury, according to the SA Good Clinical Practice Guidelines 2020, which are based on the Association of the British Pharmaceutical Industry Guidelines. The insurer will pay without you having to prove that the research was responsible for your bodily injury. You may ask the study doctor for a copy of these guidelines.

The insurer will *not* pay for harm if, during the study, you:

- Use medicines or other substances that are not allowed
- Do not follow the study doctor's instructions

If you are harmed and the insurer pays for the necessary medical costs, usually you will be asked to accept that insurance payment as full settlement of the claim for medical costs. However, accepting this offer of insurance cover does not mean you give up your right to make a separate claim for other losses based on negligence, in a South African court.

Will any of your blood be stored for research in the future?

Yes, with your permission, we will store some of the blood to use in future research. We would like to collect one 10 mL (2 teaspoons) sample for future research.
The research will be related to eclampsia, and the samples will be anonymized (i.e., no one will know that they are your samples).
All future research will be approved by the research ethics committee.

6. Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you choose to not participate, this will not affect your treatment, care or relationship with this hospital.

If you decide to take part and later change your mind, you are free to withdraw from the project at a later stage.

7. How will I be informed of the final results of this research project?

If you desire, you can be sent the results of this research in the form of a summary document or publication arising from the research.

8. What will happen to information about me?

We will record health information about you and your baby that will include your age, gender, ethnicity, weight, height, blood pressure, pulse rate and a history of existing disease. We will also record how far along your pregnancy is and if you've been pregnant before. We will further record how you deliver and the health status of your baby.
This is information that is usually routinely recorded as part of your pregnancy care.
You will receive a code number and all information will be stored anonymously in a secured area in the Department of Anaesthesia using only this code number.
The list that matches your name with the code number will be kept in a locked file in the Department of Anaesthesia.

On completion of this study the data will be presented for review by the University of Cape Town and also for possible publication in a medical journal. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared. Data will only be shared with the international partner as mentioned on this protocol (Dr. C Ortner) and only for the purpose of data analysis.
We will keep your participation in this research study confidential to the extent permitted by law. In accordance with regulatory guidelines, the information collected in this research project will be kept for at least 5 years.
However, it is possible that other people may become aware of your participation in this study. For example, the following people/groups may inspect and copy records pertaining to this research in order to ensure that the research complies with ethical and clinical requirements.

- Human Research Ethics Committee
  E 52, Room 24, Old Main Building, Groote Schuur Hospital, Observatory
  Telephone: 021 406 6338

- Professor Robert Dyer

  D23 Department of Anaesthesia and Perioperative Medicine, University of Cape Town
  Telephone: 0836002095

9. Can I access research information kept about me?

In accordance with relevant laws, you have the right to access the information collected and stored by the researchers about you. Please contact Professor RA Dyer, (D23 Department of Anaesthesia, telephone 0214045142) if you would like to access your information or have further study related questions.

10. Is this research project approved?

The ethics aspects of this research project have been approved by the Human Research Ethics Committee of the University of Cape Town. If you want any information regarding your rights as a research participant, or complaints regarding this research study, you may contact Professor Marc Blockman at the University of Cape Town Faculty of Health Sciences Human Research Ethics

Committee which is an independent Committee established to help protect the rights of research participants on telephone number 021 4066492.

11. Consent

Your signature below means that you have received and understood the information regarding this study, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

By signing below, you indicate that you give permission to take part in this research.

_____	_____	_____ _____
Signature of Participant	Date	Printed Name
_____	_____	_____ _____
Signature of witness 1	Date	Printed Name

Person Explaining the Research: Your signature below means that you have explained the research to the participant/participant representative and have answered any questions he/she has about the research.

_____	_____	_____
Signature of person who explained this research	Date	Printed Name

Interpreter (where applicable)

_____	_____	_____
Signature of interpreter	Date	Printed Name

I _____(Full name of participant), hereby consent that anonymised samples of my blood or the results of tests on these samples may be used for scientific research, the purpose of which is to improve understanding of eclampsia. I understand that my data and sample(s) will be securely stored and be identified only by a code.

Participant _____ Date: _____ Signature_____