

**The Pre-eclampsia Intervention with
Esomeprazole (PIE) trial:
a double blind randomised, placebo-controlled
trial to treat early onset severe preeclampsia**

INFORMED CONSENT FORM

REFERENCE NUMBER:

PRINCIPAL INVESTIGATOR: Dr Catherine Anne Cluver

RESEARCH MIDWIFE: Name:

Contact number:

Email:

ADDRESS: Department of Obstetrics and Gynaecology
Tygerberg Hospital and University of Stellenbosch

You are being invited to take part in a research project. Please take some time to read the patient information leaflet given to you which will explain the details of this project.

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 082 321 0298 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 Intervention with Esomeprazole (PIE) trial: a double blind randomised, placebo-controlled trial to treat early onset preeclampsia.

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 be asked to leave the study before it has finished, if the study doctor or researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

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 Afrikaans/Xhosa.
- 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