Cardiac biomarkers in preeclampsia and eclampsia: prediction of disease and the risk of future cardiovascular events in survivors

Consent Form

Protocol Number: BUHREC014/019

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Protocol No:BUHREC014/19

PARTICIPANT INFORMATION SHEET

Title of Research: Cardiac biomarkers in preeclampsia: prediction of disease and the risk of future cardiovascular events in survivors.

The above named research is being conducted by Dr John Imaralu, a consultant Obstetrician & Gynaecologist at Babcock University Teaching Hospital (BUTH). The research is aimed to predict preeclampsia, a medical complication of pregnancy that can lead to convulsions, bleeding, reduced growth of baby and a risk of future hypertension and stroke. This study would involve the use of biomarkers; chemical substances in blood to predict preeclampsia and determine the risk of future hypertension and stroke among women who survive the condition. It will thus involve you being interviewed briefly, your blood pressure measured and a 10ml sample of blood obtained from you with a sterile needle and syringe. You or your next of kin would be contacted through phone at; 1, 2 and 5 year intervals and the interview, blood pressure measurement together with 10ml of blood sample collection repeated again. This study is being conducted in selected hospitals in the Ijebu/Remo axis of Ogun state. The findings from the study may assist healthcare workers take steps to prevent the complications of preeclampsia and the development of hypertension or stroke in women who survive preeclampsia. Your participation in this study is entirely voluntary. No immediate tangible reward, compensation or financial benefit would be given you, your questions or counselling needs would however be addressed and the blood and urine tests would be done free of charge. If you choose not to consent, all the services you receive at this clinic would be given to you as usual. You are also free to withdraw from this study at any time, the services you receive at the clinic would still continue without any consequence.

The answers you supply during the interview, your blood pressure measurements and the results of the blood biomarkers measured by our trained project staff would be recorded in the study proforma which will not bear your name, only a code. The proforma contents would be kept private and confidential. If there is a need for medical attention based on the responses, you will be appropriately referred to the doctors that are qualified to manage the problem, with your consent. Please note that at no point during the study will you or your baby be deliberately put at risk. All information relating to you will be treated with the utmost confidentiality.

We will share the knowledge that we get from this study with you before it is made available to the public. Confidential information will not be shared. Afterwards, we will publish the results so that other interested people may learn from our study.

Please bear with us as there will be no tangible reward or compensation for your participation in this research. Thank you.

If you agree with these terms, please write your name and sign the consent form(s) attached to this document.

Dr. John Osaigbovoh Imaralu MBChB, MPH, FMCOG, FWACS (Principal Investigator)

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CONSENT FORM FOR PARTICIPANTS

Project title: Cardiac biomarkers in preeclampsia: prediction of disease and the risk of future cardiovascular events in survivors.

Certificate of Consent

I have been invited to participate in the above study on cardiac biomarkers in preeclampsia: prediction of disease and the risk of future cardiovascular events in survivors. I have read the information sheet, or it has been read to me. I have had the opportunity to ask questions, and any questions that I have asked have been answered to my satisfaction. I understand that questions will be asked from me, and the personal information obtained from me would be kept confidential.

I hereby consent voluntarily to participate in this study.

Name of Participant: _____

Phone (GSM) number: __ __ __ __ __ __ __ __ __ __ __

Signature (thumb print) of participant:_ _ _ _ Date of Consent_ _/_ _/_ _ (dd/mm/yy)

Name of next of Kin: _____

Phone number of next of kin: __ __ __ __ __ __ __ __ __ __ __

Name of person that obtained consent:_____

Signature: _ _ _ _ _ Date__ __/__ __ /__ __ __ __ (dd/mm/yyyy)

Name of Witness: _____

Signature of Witness: _ _ _ _ Date__ __/ __ __/__ __ __ __ (dd/mm/yyyy)

Principal Investigator attestation:

Signature__ __ __ __ Date__ __/ __ __/__ __ __ __(dd/mm/yyyy)