PARTICIPANT INFORMATION SHEET/CONSENT FORM

PROJECT TITLE: ASSESSING THE DIAGNOSTIC ACCURACY OF AN EPIGENETIC-BASED TEST IN THE EARLY DETECTION OF ENDOMETRIAL CANCER IN AFRICAN WOMEN PRESENTING WITH ABNORMAL VAGINAL BLEEDING

PRINCIPAL INVESTIGATOR: Dr. Sebastian Ken-Amoah
SUPPORTED BY: UCL and EUTOPS

INVITATION TO BE PART OF A RESEARCH STUDY

You are invited to be part of a research study. This consent form will help you choose whether or not to participate in the study. Feel free to ask if anything is not clear in this consent form.

IMPORTANT INFORMATION ABOUT THIS RESEARCH
Things you should know:

- The purpose of the study is to assess a simple, cost-effective and diagnostic tool designed for early detection of endometrial cancer in African women

-To participate in this study, you must be 40 years old and above and currently, not pregnant. Your womb must be intact and you must not have been diagnosed with any form of cancer, currently.

- If you choose to participate in this study, you will be asked to (a) fill out a questionnaire and (b) go through the standard protocol for the evaluation of your condition. Additionally, a cervical smear will be taken from you. This will take about 90 minutes to complete.

- There is no direct risk associated with this study, other than what is associated with the established protocol for the investigation of your condition

- The possible benefits of this study include getting to know about your health status, whether you have endometrial cancer or not.

- Taking part in this research study is voluntary. You do not have to participate and you can stop at any time.

WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

If you agree to take part in this study, you will be asked to be part of an intervention study. Your other details (socio-demographic, clinical history, etc.) will be extracted from your hospital folder.

HOW LONG WILL I BE IN THIS STUDY AND HOW MANY PEOPLE WILL BE IN THE STUDY?

Participation in this study will last the usual time it takes for anyone with such clinical presentation to go through the hospital system, if not faster. 200 women are expected to be in this study.

WHAT ARE THE RISKS OF TAKING PART IN THIS RESEARCH STUDY?

Participation in this study does not put you at any specific risk, other than the ones inherent in the standard investigations for anyone with such clinical presentation. You may feel some discomfort, when the samples are being taken and during the ultrasound scan.

ARE THERE ANY BENEFITS FROM BEING IN THIS RESEARCH STUDY?

You may learn a little more about your condition and your participation will help develop a more efficient, cost-effective and less invasive method for the early detection of endometrial cancer.

WHAT IF YOU LEARN SOMETHING ABOUT MY HEALTH THAT I DID NOT KNOW ABOUT?

Although this is a study, the investigations you will undertake are the recommended investigations for anyone with such a clinical presentation. It is possible that we may notice something that could be important to your health. If so, we will contact you to explain what was noticed and manage you appropriately, if necessary. It will be your choice whether to proceed with additional tests and/or treatments to evaluate what was found; you or your insurer will be responsible for any associated costs.

HOW WILL YOU PROTECT MY INFORMATION?

We will keep the records of this study confidential by keeping them securely stored in locked file cabinets in locked offices and in password-protected documents on password-protected computers and secure servers. We will make every effort to keep your records confidential. However, there are times when the laws of the nation require the disclosure of your records.

The results of this study may also be used for teaching, publications, or presentations at professional meetings. If your individual results are discussed, your identity will be protected by using a code number or pseudonym rather than your name or other identifying information.

WILL I BE COMPENSATED FOR BEING PART OF THE STUDY?

If we ever need you to be seen for this study at a time outside your usual clinic visit, your transportation cost will be covered.

WHO CAN PROFIT FROM STUDY RESULTS?

Your samples will not be used for commercial purposes, as such no monetary gain is expected.

YOUR PARTICIPATION IN THIS STUDY IS VOLUNTARY

Taking part in this study is entirely voluntary. You are free not to take part or to withdraw at any time for any reason known to yourself; you will owe no one no explanation. No matter what you decide, there will be no penalty or loss of benefit to which you are entitled. If you decide to withdraw from this study, the

information that you have already provided will be kept confidential. You will not be offered or receive any special consideration if you take part in this research study.

CONTACT INFORMATION FOR THE STUDY TEAM AND QUESTIONS ABOUT THE RESEARCH

Dr Sebastian Ken-Amoah
Cell phone: 0244361223
Email: kenamoah@gmail.com

Prof. Dorcas Obiri-Yeboah
Cell phone: 024-452-7387
Email: d.obiri-yeboah@uccsms.edu.gh

Mr. Bright K. S. Domson
Cell phone: 0542808931
Email: brightdomson@gmail.com

CONTACT INFORMATION FOR QUESTIONS ABOUT YOUR RIGHTS AS A RESEARCH PARTICIPANT

If you have questions about your rights as a research participant or wish to obtain information, ask questions or discuss any concerns about this study with someone, other than the researcher(s), please contact the following:

The Ethical Review Committee, Cape Coast Teaching Hospital.
ccthresearch@gmail.com

YOUR CONSENT

By signing this form, you agree that the researchers have explained the purpose of the research and that you understand the nature of the study and how your identity will be protected. Your signature indicates that you grant permission to voluntarily participate in this study.

I have read the information sheet. I understand what the study requires of me and all my questions have been duly answered. I do not feel that I have been forced to take part in this study and I am doing so of my own free will. I know I can withdraw at any time, if I so wish and that will have no negative consequences in my care.

Signed/Thumbprint: _____

Participant ID: _____ Date: _____

Witness signature: _____ Date: _____ (In cases where the participant cannot read).