INFORMATION SHEET (for all participants)

Title: Impact of Peri-operative Malaria Screening and Treatment on Surgical Outcomes at the Eastern Regional Hospital, Koforidua

Principal Investigator: Forster Amponsah-Manu

Address:
FORSTER AMPONSAH-MANU
DEP'T. OF GENERAL SURGERY
EASTERN REGIONAL HOSPITAL
P.O.BOX 201.
KOFORIDUA- EASTERN REGION
GHANA
TEL: +233 24 4655108
Email: foster_amponsah@yahoo.com

This is research entitled '**Impact of Peri-operative Malaria Screening and Treatment on Surgical Outcomes at the Eastern Regional Hospital: A Single-blind Randomised Controlled Trial**'. The objective of the research is to determine impact of malaria screening and treatment on surgical outcomes of patients undergoing elective surgeries at the Eastern Regional Hospital, Koforidua. This study will help us get data to standardize surgical care and to improve surgical outcomes. Supposing screening and treating patient undergoing planned surgery for malaria provides better results following surgery, it can serve as a new way of surgical practice for better and satisfactory results to patients.

You will be asked to give informed consent to enroll in the study. A minimum of 348 persons being planned for surgery will be enrolled into this study. Enrollment into the study will take place for a period of three months. Each participant will be enrolled into one of two arms of the research. Participants in one arm will be tested for malaria, and treatment using 3 days course of antimalarial drug will be offered to those who test positive. On the other hand, participants in the 2nd arm will not be tested for malaria and will not be given antimalarial drug. The selection will be made by balloting. The research is for the whole duration of your hospital admission and up to thirty days after surgery.

Some information from your medical records will be used in filling out a questionnaire and subsequent information recorded during the course of follow-up. **It would take about 20-40 minutes during administration of questionnaire**. Blood sample (**two teaspoonful of blood maximum**) would be taken for laboratory tests, which will include malaria test in case you are enrolled into that arm of the study**. If you are enrolled in the other arm of the study which would not require malaria screening, two teaspoonful (10mls) of blood would be taken to perform routine tests prior to**

surgery but no malaria test would be performed on the sample. A tiny needle will be used to puncture a vein through the skin on your forearm to draw blood for the laboratory tests. After the tests, blood sample shall be discarded immediately. All the information collected will be confidential and your identity will be anonymous.

You will continue to receive the standard surgical care provided by the hospital. Additionally, you will be required to report to the hospital weekly after discharge until post-op day 30 during which some questions will be asked and you will be physically examined to look out for certain results. In the case where you are not able to report for follow-up, a phone call interview will be done as an alternative.
Suppose you find yourself among unscreened group, and you develop symptom(s) suggestive of malaria you will be screened and treated immediately, if it comes out positive.

The risks associated with this study are needle pricks during blood sampling and frequent than usual visits to the hospital. However, these risks are not much different outside the study or during routine surgical care. You can stop participating at any time if you feel uncomfortable. No one will be angry with you if you do not want to participate. You will not be denied treatment in the hospital in case you decide not to participate; you will receive standard surgical treatment and care anyway.

I**f screening and treatment for malaria before operation is found to have positive impact on surgical outcomes then it would have been of benefit to participants in the intervention arm of the study.** Findings of the study will be used to improve services in the facility for future care provided by health workers.

Cost of laboratory tests and antimalarial drug will be paid for with or without National Health Insurance. For each follow up visit, you will be given a fixed amount of ghc 20.0 to compensate for your cost of transport. There will be no other compensation for your participation. Cost of surgery and hospital admission(s) will not be absorbed by this study.
As stated above, your name or identity will be kept anonymous during data processing and analysis. All information taken from you for the purpose of this study shall be kept safe under a lock and key drawer. Data will be analyzed and final report will be presented to the School of Public Health, University of Ghana for the purpose of attaining master's degree. Findings will also be shared with the Eastern Regional Hospital, to help inform policy in the hospital.

The study is being funded by President's Malaria Initiative, a USAID program in collaboration with Ghana Malaria Control Program.

By signing the attached consent form, it means that you understand and know the issues concerning this study. If you do not want to participate in this study, please do not sign the consent form. You will be given a copy of the Information sheet and Consent form

after it has been signed or thumb-printed to keep.

You may contact me (as the Principal Investigator) by using the following information in case of any concern with regards to this study.

Forster Amponsah-Manu
Department of Surgery, Eastern Regional Hospital, Koforidua
Tel: 0244655108
Email address: foster_amponsah@yahoo.com

If you have any questions about your rights as a research participant or you require further clarification on ethical issues, you can contact the ERC via the under stated information.

Nana Abena Apatu
Administrator, GHS-ERC
Tel: 0503039896
Email address: ethics.research@ghsmail.org