

**STUDY TITLE:**

**INCIDENCE OF AND FACTORS ASSOCIATED WITH POST-OPERATIVE  
NAUSEA AND VOMITING FOLLOWING SURGERY UNDER REGIONAL  
ANAESTHESIA**

**NCT NUMBER:**

**NCT03835234**

**DOCUMENT DATE:**

**1/08/2018**

## **CONSENT FORM**

### **STUDY TITLE: INCIDENCE OF AND FACTORS ASSOCIATED WITH POST-OPERATIVE NAUSEA AND VOMITING FOLLOWING SURGERY UNDER REGIONAL ANAESTHESIA**

**STUDY NUMBER:** \_\_\_\_\_

**PRINCIPAL INVESTIGATOR:** Dr. Dorothy Turitwenka, a doctor in the department of Anaesthesia and Critical care, pursuing a master's degree in Anaesthesiology and Critical Care at Makerere University College of Health Sciences, in Mulago.

**INTRODUCTION:** I am Dr. Dorothy Turitwenka, currently pursuing a Master's degree in anaesthesia and critical care at Makerere University College of Health Sciences. I am doing a research to determine the magnitude of post-operative nausea and vomiting occurring following surgery done under regional anaesthesia in Mulago hospital and the factors that may be associated with this.

**PURPOSE OF THE STUDY:** Post-operative nausea and vomiting commonly occurs among patients undergoing surgery. The incidence and factors associated with PONV in our setting have not been documented. In this study, Dr. Dorothy Turitwenka will collect data and document the number of patients with post-operative nausea and vomiting following surgery done under regional anaesthesia in Mulago hospital and the factors that may be associated with this. These findings will help to inform policy and guide future anaesthetic practice.

**DURATION OF INVOLVEMENT:** The participant in this study will be enrolled into the study before the start of the operation following consent and will be observed throughout the period of the operation. After the operation he/she will be followed up at 24 hours to assess whether he/she develops any nausea or vomiting during this time period.

**YOUR RIGHTS AS A RESEARCH VOLUNTEER:** This form gives you information about the purpose and the details of the study you are about to consent to. Once you understand the study, and agree to participate in it, you will be asked to sign this consent form. You may also be given a copy of the form to keep. Your participation in this research is entirely voluntary. You may decide to withdraw from the study at any time. Such a decision will not affect the medical care you receive or possible participation in future research studies in any way.

**PROCEDURE:** In this study, patients who are going to have surgery under regional anaesthesia and have consented will be enrolled from the operating room waiting area. Consent to participate in the study will be sought from the patient using a consent form that will be

administered by the principal investigator or the research assistants in English, Luganda, French or Kiswahili. Further information about nausea and vomiting will be obtained from the anaesthesia provider. The patient will be followed up during recovery and at 24 hours after surgery.

**RISKS:** There are minimal risks to you once you consent to be part of the study.

**BENEFITS:** You will not be paid for taking part in this study. While you may not benefit directly from this study, your participation in this research may benefit others in the future by helping us learn more about the magnitude of post-operative nausea and vomiting in regional anaesthesia.

**CONFIDENTIALITY:** The information you provide will remain confidential. Nobody except the principal investigator and her research assistants will have access to it. A study number known to you and the study personnel will be used instead of your name. The data may be seen by the ethical review committee and may be published in (a) journal(s) and elsewhere without revealing your name or disclosing your identity. Data will be stored securely.

**QUESTIONS:** In case of questions or problems related to the study, you can contact:

Dr. Dorothy Turitwenka at the Department of Anaesthesia, Mulago Hospital or on mobile phone number +256 759 889087 at any time during the study.

If you have any further questions concerning ethical issues or related to your rights while you participate in this study, you may contact the School of Medicine Research and Ethics Committee Chairman Prof. Ponsiano Ocama on Telephone +256 772 421190.

**INFORMED CONSENT:** I have been informed that Dr. Dorothy Turitwenka is carrying out a study to determine the magnitude of post-operative nausea and vomiting occurring following surgery done under regional anaesthesia in Mulago hospital and the factors that may be associated with this.

This study is being conducted as a partial fulfillment for the award of a degree in Masters of Medicine in Anaesthesiology and Critical Care of Makerere University. By this form a written consent is being sought for my participation in the study.

**STATEMENT OF CONSENT:** I have been informed by \_\_\_\_\_  
about the research intended to document the INCIDENCE OF AND ASSOCIATED  
FACTORS OF POST-OPERATIVE NAUSEA AND VOMITING OCCURRING  
FOLLOWING SURGERY DONE UNDER REGIONAL ANAESTHESIA IN MULAGO

HOSPITAL, its purpose and benefits. I understand that by signing this consent form I accept to participate voluntarily in the study and that I do not waive any of my legal rights; neither do I accept liability for anything.

Participant's name: \_\_\_\_\_

Participant's Signature/ thumb print: \_\_\_\_\_

Date: \_\_\_\_\_

Witness Signature: \_\_\_\_\_

Date: \_\_\_\_\_