June 1st, 2021

ID: EC/CHUK/074/2021 **INFORMED CONSENT**

Enhanced recovery after surgery program in a low and middle-income country:

Feasibility, safety, patient's acceptance, reduction of the length of hospital stay, bed turnover and cost benefits for laparoscopic cholecystectomy at CHUK

By

NYUNDO Martin. MD

Clinical Associate Professor of Surgery
Senior Consultant General Surgeon

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title of Study:

Enhanced recovery after surgery program in a low and middle-income country: ***Feasibility, safety, patient's acceptance, reduction of the length of hospital stay, bed turnover and cost benefits for laparoscopic cholecystectomy at CHUK***

Researcher's Name: Dr. NYUNDO Martin

Phone number (+ 250) 788418727

INTRODUCTION

My name is NYUNDO Martin; I am a senior consultant general surgeon interested in laparoscopic surgery. This research project is in line with the scientific development plan in minimally invasive surgery training in Rwanda.

PURPOSE OF STUDY

The puropose of our study is to test the implementation of ERAS protocol in laparoscopic cholecystectomy with the aim of decreasing of the length of hospital stay to 36 hours, turnover and assess its safety and patients' acceptance.

DESCRIPTION OF THE STUDY PROCEDURES

When you agree to participate in this study, Firstly, you will be asked to sign this consent form, then you will be explained about question, and you are thereby requested to answer to questions ask by the research assistant or any health professional involved in this research. Also you will be given a signed and dated copy of the consent form to keep, along with any other printed materials deemed necessary by the researcher.

RISKS/DISCOMFORTS OF BEING IN THIS STUDY

There are no specific risks related to this ERAS protocol even though the surgical risks remain as in normal surgical procedures. You will be closely monitored and any adverse events will be treated using standard approaches and you will be discharged using standardized criteria of safe discharge.

BENEFITS OF BEING IN THE STUDY

During this study you will benefit the follow up for 15days after discharge and a research assistant will call you regularly to know about your conditions.

CONFIDENTIALITY

The questionnaire used in this study will not be collecting or retaining any information about your identity like your name. Also the researcher will not include any information in any report he may publish that would make it possible to identify you. The questionnaires will be destroyed after the study is complete.

The records of this study will be kept strictly confidential. Research records will be kept in a Locked cupboard and all electronic information will be coded and secured using a password Protected file.

PAYMENTS

This study has academic and scientific purpose no any funds so there will be no payment to participate in this study

RIGHT TO REFUSE OR WITHDRAW

The decision to participate in this study is voluntary. If you refuse to take part in the study at any time, there will be no negative consequences for you. You have the right not to answer any single question or question you think concerns your dignity, as well as to withdraw completely from the study at any point during the process.

RIGHT TO ASK QUESTIONS AND REPORT CONCERNS

You have the right to ask questions about this research study and to have those questions answered by the research before, during or after the research. If you have any further questions about the study, at any time feel free to contact:

Contact details of researcher (for further information / reporting of study related adverse events):

Dr. Martin Nyundo Tel:(+250) 0788418727

Email: nyundomartin@gmail.com

If you have any other concerns about your rights as a research participant that has not been answered by the researcher, you may contact

1. Contact details of the research ethic committee of CHUK (for reporting of complaints / problems).

Chairperson of Ethic Committee at CHUK, Dr Rusingiza Emmanuel Tel: 0787553420

DECLARATION OF CONSENT TO PARTICIPATE IN THE RESEARCH

I hereby confirm that I understand the contents of this document and the nature of the research project, and I consent to participating voluntarily in the research project. I understand that I am at liberty to withdraw from the project at any time, should I so desire.

Participant's Signature:..... Date