AFRICAN SURGICAL OUTCOMES-2 (ASOS-2) TRIAL IN TANZANIA
PARTICIPANT INFORMATION SHEET AND CONSENT FORM

A: INFORMATION SHEET

This is the information sheet that gives information to the participants (patients). The patient must be in the facility that appear eligible and to be recruited and participate in the study titled African Surgical OutcomeS-2 (ASOS-2) Trial. The form should be read by the participants before allowing his or her information to be used for research.

STUDY TITLE: A cluster randomised trial to determine whether increased postoperative surveillance of adult African surgical patients reduces postoperative mortality

You are asked to participate in a research study conducted by Dr Mpoki Ulisubisya from the Ministry of Foreign Affairs of the United Republic of Tanzania, Dr Bernard Mbwele and Dr Lazaro Mboma from the University of Dar es Salaam - Mbeya College of Health and Allied Sciences (UDSM-MCHAS). The investigators have an intention to use the results for writing reports to the united republic of Tanzania and publications into a research paper. You were selected as a possible participant in this study because the investigators are succinctly intending to gather data. As you are the participant who have been identified by our protocol you eligible to participate.

1. BACKGROUND

Recently, the African Surgical Outcomes Study (ASOS) demonstrated, that despite a patient low risk profile and low complication rates, patients in Africa were twice as likely to die following surgery when compared to the global average. ASOS provides the most comprehensive data on surgical outcomes in Africa, comprising 25 countries, 247 hospitals, and data from over 11 000 patients. Importantly, 95% of the deaths in ASOS occurred in the postoperative period, suggesting that many lives could be saved by effective surveillance for physiological deterioration amongst the patients who developed complications. In ASOS, the median number of combined anaesthesia, surgical and obstetric specialists was 0·7 (IQR 0·2-1·9) per 100,000 population, which is well below the documented inflection point of 20 to 40 specialists per 100,000 population necessary to significantly decrease surgical mortality.

It is likely that a major contributor to the high mortality in ASOS was 'failure to rescue' after a postoperative complication partly due to an inadequacy of sufficient human resources necessary to identify postoperative surgical patients at risk. A potential solution to improving surgical outcomes in Africa is identification of the high-risk surgical patient prior to further physiological deterioration.

2. PURPOSE OF THE STUDY

The objective of this trial is to assess whether increased postoperative surveillance of surgical patients at increased risk of postoperative morbidity or mortality is associated with improved survival.

3. PROCEDURES

If you will agree to volunteer to participate in this study, we will record all of your medical information related to surgery before and after surgery.

As a patient the team of researchers and health care workers will increase postoperative follow up that may include any of the following; i) admission to a higher care ward than had been planned at the time of surgery, ii) an increase in the frequency of nursing observations in the postoperative period, iii) ensuring that you are assigned to a bed in view of the nursing station, and not in a remote location in the postoperative ward, or iv) allowing family members to stay with you in the ward in the postoperative period.

More than one of the increased postoperative follow up intervention may be noticed in some hospitals. The healthcare providers will also require more information from you regarding the surgical site infections, presence of any bloodstream infection and presence of acute respiratory distress syndrome, presence of pneumonia, acute kidney injury, postoperative bleeding, and cardiac arrest. This will be known as the 'Postoperative surveillance bedside guide' and will be placed at the bedside of every patient flagged as high-risk by the ASOS Surgical Risk Calculator. This will be placed in a visible position at the patient's bedside e.g. posted on the wall above the patient's bed.

The following will be the procedures;

a) Your clinical data described above will be recorded for research purposes.
b) Some of the information from your medical file might be taken for further research purposes and they will be kept with strict confidentiality with anonymity.
c) You will not be asked to draw any sample like blood, urine, stool, saliva or sputum

If possible, the nurses or doctor might ask additional questions to help health services for improving surgical outcomes in Tanzania.
Depending on the situation, a photograph of some other documents from your medical file copied and filed as well.

You will then be free to find a

a) The suitable place in the hospital environment for reading this information package
b) The suitable place in filling the consent forms after agreeing to participate

4. POTENTIAL RISKS AND DISCOMFORTS

The study will not have any anticipated risks or harms to your health outcomes. You are not required to donate any sample

5. POTENTIAL BENEFITS TO SUBJECTS AND/OR TO SOCIETY

The following are the benefits of participating in the s African Surgical OutcomeS-2 (ASOS-2) Trial.

- You will be having an additional advantage of health care as a volunteer participant
- Your Participation in this study will contribute to the general knowledge on methods to reduce deaths due to poor post-operative care
- Your Participation in this study will contribute to the reduction of mortalities and morbidities attributed by surgical interventions.

6. PAYMENT FOR PARTICIPATION

There is no payment or any financial benefit for participation in this study.

7. CONFIDENTIALITY

All information collected about your provision of care in your facility during the study for African Surgical OutcomeS-2 (ASOS-2) Trial will be kept strictly as confidential information. Confidentiality

will be maintained by means of coding procedures in the database and plans to safeguard data, including where data will be kept, who will have access to it.

- Coding procedures will hide your name and your facility name and therefore by only study identification number and hospital registration number, your initials will be used in the data collection procedure (no name).
- Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law.
- The information obtained will be used for research analysis. If information will be released to any other party for any reason, we will state the person/agency to whom the information will be furnished, the nature of the information, and the purpose of the disclosure.
- The interview will be audio taped for research, once the information will be used for educational purpose you will have a right to review/edit the tapes, and when they will be erased.
- The information obtained might be published and the confidentiality will be maintained in publication by using the codes for the participants and the facility involved.

8. PARTICIPATION AND WITHDRAWAL

You can choose whether to be in this study or not. If you volunteer to be in this study, you may withdraw at any time without consequences of any kind. You may also refuse to answer any questions you don't want to answer and still remain in the study. The investigator may withdraw you from this research if circumstances arise which warrant doing so.

One of the circumstances is to use the abusive language to the supervisors of managers of the health care system or the use of any language that might rise into conflicts and misunderstandings with the interviewers or the investigator.

9. IDENTIFICATION OF INVESTIGATORS

If you have any questions or concerns about the research or if there is anything you don't understand or if you would like more information, please feel free to contact us.

If you have any questions about the study, please contact Dr Mpoki Ulisubisya through contact +1 787 488 4227, Dr Bernard Mbwele available through +255 755 513 858 and Dr Lazaro Mboma available through +255 767 505 089

10. RIGHTS OF RESEARCH SUBJECTS

You may withdraw your consent at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding your rights as a research subject, contact Dr Bernard Mbwele available through +255 755 513 858 and Dr Lazaro Mboma available through +255 767 505 089.

Thank you for taking time to consider participation in this study.

B: SIGNATURE OF RESEARCH SUBJECT OR LEGAL REPRESENTATIVE

The information above was described to _____ [name of the participant] by _____ [name of relevant person] in [English/Swahili/other] and I am the participant in command of this language or it was satisfactorily translated to [me/him/her]. I was given the opportunity to ask questions and these questions were answered to my and his/her satisfaction. I hereby consent voluntarily to participate in African Surgical OutcomeS-2 (ASOS-2) Trial that will help to reduce deaths due to poor post-operative care. I am hereby consent that as a participant I will participate in this study that does not involve sample collection but rather clinical data from my medical file. I have been given a copy of this form for my personal records.

_____

Name of Participant

_____

Name of Legal Representative (if applicable)

_____ _____

Signature of Subject/Participant or Legal Representative Date

C: SIGNATURE OF INVESTIGATORS

I declare that I explained the information given in this document to _____ [name of the patient/participant] and/or [his/her] representative _____ [name of the representative]. [He/she] was encouraged and given ample time to ask me any questions. This conversation was conducted in [English/Swahili] and there was /No/ translator used in this conversation who translated _____ into_____ by _____.

Name_____ Signature_____ Date_____

Name_____ Signature_____ Date _____