CONSENT FORM

Participant ID: _____

Protocol Title:
Principal Investigator: Faculty Advisor (if PI is a student):
Description of Study Population:
Version Date:

INSTRUCTIONS: This template was adapted from Harvard with permission. To use this template, complete all required sections (substituting appropriate language for any italicized wording) and any applicable additional sections (marked "if applicable"), then **delete all shaded instruction boxes, italicized instructions, brackets and/or omitted sections prior to submitting this form**. It may be required to have various translations if necessary.

About this consent form

Please read this form carefully. This form provides important information about participating in research. You have the right to take your time in making decisions about participating in this research. You may discuss your decision with your family, your friends and/or your doctor. If you have any questions about the research or any portion of this form, please ask us. If you decide to participate in this research you will be asked to sign this form. A copy of the signed form will be provided to you for your record.

Participation is voluntary

You are invited to take part in this research because *[fill in the circumstance/condition that makes the participant eligible]*. It is your choice whether or not to participate. If you choose to participate, you may change your mind and leave the study at any time. Refusal to participate or stopping your participation will involve no penalty or loss of benefits to which you are otherwise entitled.

What you should know about a research study

- Someone will explain this research study to you.
- A research study is something you volunteer for.
- Whether or not you take part is up to you.
- You can choose not to take part in the research study.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- Feel free to ask all the questions you want before you decide.

What is the purpose of this research?

The purpose of this research is to *[fill in the purpose]*.

How many people will take part in this research?

About *[fill in number]* people will take part in this research.

How long will I take part in this research?

INSTRUCTIONS: Include the following information in this section:

- Expected time commitment to complete the study, e.g., "We expect that you will be in this research for _____." Or, "It will take you about 14 months to complete the study. During this time, you will be asked to make 14 study visits."

What can I expect if I take part in this research?

As a participant, you will be expected to complete the following *[describe all study procedures, study visits, etc.]*

[What are my responsibilities? *if applicable***]**

As a participant, you are responsible for *[list responsibilities]*.

What are the risks and possible discomforts?

INSTRUCTIONS: Describe the reasonably foreseeable risks or discomforts (whether physical, psychological, privacy, legal, social or economic) that may result from study procedures, (e.g., answering study questions, participating in focus group, using investigational products). Do not understate risk and/or discomfort.

Are there any benefits from being in this research study?

INSTRUCTIONS: Unless there are benefits, say: "There are no direct benefits to you from your taking part in this research." If there may be benefits, say: "We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include *[fill in possible benefits including benefits to a particular population or society at large]*

What are my alternatives to participating in this research?

INSTRUCTIONS: Unless this is a treatment study, say: "The alternative to participating in this research study is not to participate." If it is a treatment study, include the following information:

- Alternative procedures, tests, evaluations, or courses of treatment for the disease/medical condition. Be specific and name at least some other drugs, tests, or procedures.
- Palliative care or no treatment, when appropriate.

Can I still get medical care at <insert facility> if I choose not to participate in this research*? Delete this section if not applicable*

Yes, you may still get medical care if you choose not to participate in this study. Your decision will not change the care you receive now or in the future. Taking part in this research is your choice. If you decide to take part in this study, you may leave/stop the study at any time. There will be no penalty to you and your medical care will not be affected. If you would like to stop participating in this research you should let us know. We will make sure that you stop the study safely.

It is possible that the investigator may ask you to stop the study before it is finished. If this happens we will tell you why and arrange for other care for you if needed.

Will I be compensated for participating in this research?

INSTRUCTIONS: Include the following information in this section:

- Money or other forms of compensation or reimbursement, e.g., gift certificate, meal voucher, parking voucher, and travel expenses
- Include the method and timing of the compensation
- Include how the amount of compensation is calculated if the participant does not complete the entire study for any reason, e.g., "If you do not complete all of the study visits, we will give you 500 KSh for each study visit you completed."

If participants will not be paid or will not receive other forms of compensation for participation, say: "You will not be compensated for participating in this research".

What will I have to pay for if I participate in this research?

INSTRUCTIONS: Describe any costs the participant may incur. If participants will not incur any costs, say: "It will not cost you anything to participate in this research".

What happens if I am injured as a result of participating in this research study?

INSTRUCTIONS: Include this section heading and the wording below in all consent forms. This section will be deleted by the IRB if it is found to be not applicable.

If physical injury resulting from participation in this research should occur, although Tenwek's policy is not to provide compensation, medical treatment will be available including first aid, emergency treatment and follow-up care as needed, and your insurance carrier may be billed for the cost of such treatment. In making such medical treatment available, or providing it, the persons conducting this research project are not admitting that your injury was their fault.

Can my taking part in the research end early?

INSTRUCTIONS: Unless there are adverse consequences to withdrawing from the research, say: "You may decide not to continue in the research at any time without it being held against you. The person in charge of the research *[*or the sponsor – *if applicable]* can remove you from the research at any time without your approval for any reason." *If appropriate, include:* "Possible reasons for removal include *(reasons why the participant may be withdrawn, such as "if it is in your best interest" or "if you do not follow study directions")*."

If there are adverse consequences, say: "You may decide not to continue in the research at any time without it being held against you. If you decide to leave the research (describe adverse consequences). If you decide to leave the research, contact the investigator

If I take part in this research, how will my privacy be protected? What happens to the information you collect?

INSTRUCTIONS: Describe confidentiality protections. Participants should be told when data containing any identifiers (including audio and video) will be destroyed. Include any plans for future use of data, data sharing, i.e., required of NIH-funded studies using/generating large-scale human genomic data, or future open access, i.e., free availability and unrestricted use, of data, e.g., as a requirement of publication (PLoS). Include also how data would be shared under those circumstances. Include the following language at the end.

Data collected, including your identifiable information, may be seen by the Tenwek Hospital Institutional Ethics Review Committee (IERC) that oversees the research *[add if applicable:* and/or the Quality Improvement Program*.] If applicable, include the sentence:* We may also share your information related to this study with other parties including *(translators, transcribers, thesis committee, FDA, and/or other federal agencies as applicable.)*

If I have any questions, concerns or complaints about this research study, who can I talk to?

INSTRUCTIONS: Include the following information in this section:

- Name and academic degree(s) of the person(s) in charge of this research study
- When person is available, e.g., M-F 9am-5pm or 24 hours and what telephone numbers or email addresses (office phone, hospital page) to contact
- Name and contact telephone number of person responsible for scheduling appointments and study visits, if applicable
- General contact information (e.g., phone, email address, etc.) for investigator (for student investigators, include this information for faculty sponsors)

The Principal Investigator of this study: *[Insert Investigator Name]*. S/He can be reached at *[Insert Investigator Contact information.]*:

- If you have questions, concerns, or complaints,
- If you would like to talk to the research team,
- If you think the research has hurt you, or
- If you wish to withdraw from the study.

This research has been reviewed by the Tenwek Hospital Institutional Ethics Review Committee. If you wish to speak with someone from the ISERC, please contact the Research Manager via email at ierc@tenwekhosp.org or by phone at 0728 091 900 extension 1680.

- If your questions, concerns, or complaints are not being answered by the research team,
- If you cannot reach the research team,
- If you want to talk to someone besides the research team,
- If you have questions about your rights as a research participant, or
- If you want to get information or provide input about this research.

Statement of Consent

I have read the information in this consent form including risks and possible benefits. All my questions about the research have been answered to my satisfaction. I understand that I am free to withdraw at any time without penalty or loss of benefits to which I am otherwise entitled.

I consent to participate in the study.

SIGNATURE [please list all required signature(s)]

Your signature below indicates your permission to take part in this research

Name of participant

Signature of participant Date

Signature of person obtaining consent Date

Printed name of person obtaining consent