# PROTOCOL

Title:

Introduction:

Problem Statement:

Study Justification:

Objectives:

Research Question:

Institution(s) where study to be done (Approval required from the institution(s) where it will be conducted):

Background/Significance:

Methodology

Study Design:

Study Area and Population (including 1-- what department involved; 2-- are any of the population considered vulnerable such as children, minors, pregnant women, economically and educationally disadvantaged, prisoners, etc.):

Inclusion and Exclusion Criteria:

How Subjects Will Be Recruited (include any flyers or other types of promotion):

Sampling Method (check if randomization used \_\_\_\_):

Sample Size Determination:

Data Collection Method:

Data Entry:

Data Analysis:

Dissemination of Findings:

Study Period:

Explain the Safety Monitoring Plan for the Study:

Ethical Issues Addressed (including informed voluntary consent, attach any form used):

o Consent form in plain (Grade 5) English and simple Kiswahili, including:

 - Title of the research study

 - Name of researcher (PI) with contact info

 - Contact information for the KH ISERC Office (if the subject has questions about the subject’s rights as a research subject or to report research-related problems)

 - Purpose of data collection/research and its general value and individual benefits for the participant

 - Explanation of all procedures used in the research and why

 - Participant's part in the research including the amount of time and energy the research/data collection will take.

 - Any possible risk/pain/discomfort/stress or loss of dignity that the participant may experience.

 - How privacy, confidentiality, and anonymity will be guarded.

 - Manner in which the results will be used

 - Participant’s right to refuse to take part and their right to withdraw without any penalty at any point during the process.

o Any questionnaires used (required!) to be attached

o Conflicts of interest—Do any investigators have conflicts of interest (personal or financial)? \_\_\_\_\_\_ No \_\_\_\_\_\_\_ Yes.

 If Yes, please explain in detail any financial or personal relationships with the sponsor, product (drug, device, etc.) or institution such as receiving financial compensation for conducting the research or an investigator or their close family member having a financial interest in the product. Attach the explanation to the research request form.

What Benefit Do You Anticipate to the Hospital or Patient Care?

How Will Confidentiality and Anonymity Be Maintained?

Work Plan:

Source of Funding/Budget:

References

Study Tools (Attach)

Principal Investigator’s Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_

Date

Attach any other relevant item as appendix