




## Appendix



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Head of Department  
Research & Programs  
KNH

**RE: LETTER OF SUPPORT FROM KNH DEPARTMENT OF MEDICINE**

We are writing this letter in support of Dr. Linda Gathara she is an employee of Kenyatta National Hospital, Medicine Department working at Endoscopy Unit. She is intending to conduct a study entitled "Gastroesophageal reflux disease and its association with body mass Index" at Kenyatta National Hospital.

This is a departmental research in Medicine Department and we are in support of this study and will facilitate its implementation. The findings from this study will go a long way in helping to change policy and management guidelines for the overall improvement of patient care in the wards.

Any assistance accorded to her will be highly appreciated.

  
Dr. KINOTI NDEGE  
HOD - MEDICINE

*Vision: A world class patient-centered specialized care hospital*



ISO 9001: 2015 CERTIFIED

**Appendix I:** Authorization Letter from KNH Department of Medicine.

## Appendix II: Consent Form

Patient Study Number - \_\_\_\_\_

### Introduction

Good day, my name is Dr. Linda Gathara (A WGO Fellow at the Nairobi Gastroenterology Training Center) I am doing a research study on GERD and its association with BMI in patients undergoing upper GI Endoscopy at the Kenyatta National Hospital.

This is a request to participate in the study above for medical research. The principal investigator / assistants will explain this research to you. Please take your time to make your decision about participating. If you have any question, you may ask the researcher. The following are the details about the research

## Part 1: Information Sheet

### Aim of Study

This study entails looking at gastroesophageal reflux disease (GERD) and its association with body mass index (BMI) in patients undergoing upper GI Endoscopy at the Kenyatta National Hospital. After enrollment into this study, information assessing for dyspepsia and reflux symptoms, your weight, your age, and your gender will be collected. Based on the findings, you will then be subjected to an endoscopy to further assess any conditions and establish a diagnosis. Plan of treatment will then be discussed.

### Participation in this Study

Participation in this study is voluntary and you can withdraw your participation at any time. Refusal to participate in this study will not result in any penalty or loss of rights. You can ask any other questions appertaining to assessment and treatment and this will be availed to you at any time.

### Purpose of Study

Dyspepsia and reflux disease are common occurrences in our population. Common symptoms include heartburn and regurgitation. The association between the disease and risk factors e.g., body mass index is yet to be established in our population. Establishing these links may be important in guiding management and treatment. The results of this study will be published as a book (theses) or in a Medical Journal. It will also serve as information for teaching purposes. Results will be made available to the community for better understanding of this illness. We assure you that we will NOT use your name anywhere in the presentation of these results.

### Cost

Participation will be entirely on a voluntary basis and there will be no financial compensation. No additional costs will be incurred by the patient.

### Duration of Participation

Every participant will be enrolled only once but the study will take place over a 3-month period at the Endoscopy Unit, KNH. Data will be collected within the time approved by Kenyatta National Hospital/ University of Nairobi Ethics and Research committee (KNH/UON-ERC).

### Risks and Benefits

While participating in this study, you will not be exposed to any extra risks and you will not incur any losses.

### Confidentiality

The identities of the subjects will be concealed by the use of case numbers and no information concerning them will be published except that which is directly related to the research.

This research has been approved by the ethics committee at the Kenyatta National Hospital/ University of Nairobi. This committee helps to ensure the research participants are protected from harm. If you have any questions about the rights of the participants, or complaints about the study, please contact the following person

### The Secretary

Kenyatta National Hospital Ethics and Research committee

Tel: (020) 2726300 ext.43791 or 44102

Thank you ..... Dr. Linda Gathara

### Part II: Certificate of Consent

I the undersigned have been explained to and have understood the above and willingly accept to let the subject participate in the research study.

Name of participant.....

Signature/ thumb print ..... Date .....

Certificate of consent for illiterate participant

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely to participate in the research.

Name of witness.....

Signature of witness..... Date.....

Statement by the Researcher/ person taking consent

I the investigator, having explained in detail the purpose of this study, hereby submit that confidentiality of the data collected will be maintained and only the details relevant to the study revealed.

Signature ..... Date ..... Telephone: .....

### Investigator

Dr. Linda Gathara

Email: lindagathara@gmail.com

Phone: 0722689741

### Supervisors:

1. Sign ..... Date .....

Insert Name and Addresses

2. Sign ..... Date .....

Name and Addresses

Sign ..... Date .....

**Appendix III: F.S.S.G (Frequency Scale for Symptoms of GERD)****F-Scale**

Do you have any of the following symptoms?  
If not, please circle the appropriate response?

<b>Patient ID</b>	<b>Weight (Kg)</b>
Age	Height(M)
Gender	BMI

Questions	Fillinspace				
	Never	Occasionally	Sometimes	Often	Always
1. Do yougetheartburn?	0	1	2	3	4
2. Doesyourstomachgetbloated?	0	1	2	3	4
3. Doesyourstomacheverfeelheavyaftermeals?	0	1	2	3	4
4. Do yousometimessubconsciouslyrubyourchestwithyourhand?	0	1	2	3	4
5. Do youeverfeelsickaftermeals?	0	1	2	3	4
6. Do yougetheartburnaftermeals?	0	1	2	3	4
7. Do youhaveanunusual (e.gburning) sensationinyourthroat?	0	1	2	3	4
8. Do youfeelfullwhileeatingmeals?	0	1	2	3	4
9. Do somethingsgetstuckwhenyouswallow?	0	1	2	3	4
10. Do yougetbitterliquid (acid) comingupintoyourthroat?	0	1	2	3	4
11. Do youburp a lot?	0	1	2	3	4
12. Do yougetheartburnifyoubendover?	0	1	2	3	4

**Please describe any other symptoms you experience**

Sum points \_\_\_+\_\_\_+\_\_\_+\_\_\_=\_\_\_

Acid reflux related symptoms= \_\_\_ Points

Dyspeptic symptoms = \_\_\_ Points

**Appendix IV: Endoscopy Findings**

Esophagitis

Present..... Absent.....

1. Grade A
2. Grade B
3. Grade C
4. Grade D

Hiatus Hernia

Present ..... Absent.....

Length ..... (cm)

Biopsies taken

Yes..... No.....

If yes, histology report....