Esophageal Squamous Cell Carcinoma African Prevention Research (ESCCAPE) Cytosponge™ Feasibility Study

Cytosponge™ Feasibility Study in Tanzania (CytoSCCAPE)



Consent Form

Date: 03 March 2019





ESCCAPE Cytosponge™ Feasibility Study – CytoSCCAPE

Kilimanjaro Clinical Research Institute & International Agency for Research on Cancer

Instructions for completing this form: Please confirm that the participant meets all of the inclusion and exclusion criteria by completing the form on the back of this sheet, before asking the participant to complete and sign the consent form below.

Consent Form

I confirm that I have been informed by the interviewer, about the study in a language that I understand. I have also received, read and understood the **Participant Information Sheet.** I understand that I do not have to participate and can withdraw at any time. I have been given the opportunity to ask questions and they have been answered satisfactorily.

Please tick to confirm:	
I understand that participation involves answering a questionnaire on lifestyle factors.	
I understand that I will be asked to provide a sample of cells collected using a swallowed device. I understand that these cells will undergo analyses for possible cell changes, DNA damage and genetic testing.	
I understand that I will be contacted in the event of an abnormal finding in my samples, but that the test is not 100% sensitive.	
I understand that my samples will leave Tanzania to undergo analysis.	
I hereby agree to take part in this study. I furthermore data and samples to be used in health research. Participant's name:	
Participant's signature (or thumbprint):	
Interviewer or nurse's signature:	Date:
STICK CONSENT FORM LABEL HERE	STICK SUCCESSFUL DEVICE SECURITAINER LABEL HERE*

^{*}If sample collection was not successful, please place the label intended for the Cytosponge™ sample here instead, and attach the securitainer labels of all failed devices to the failed devices log.

Inclusion criteria Please tick <u>all</u> boxes to confirm the participant met <u>all</u> of the inclusion criteria. Yes No	
30 years of age or above	
Resident of Kilimanjaro Region for 10 years or more	
Exclusion criteria	
Please tick <u>all</u> boxes to confirm the participant <u>does not</u> meet <u>any</u> of the exclusion criteria. Yes No	
Eaten or drank within the last 4 hours	
☐ ☐ Known current pregnancy	
Objection to CytoSCCAPE data collection	
Symptoms of dysphagia (difficulty swallowing)	
Recorded history of oropharyngeal, oesophageal or gastric cancer	
Received prior surgical intervention to the oesophagus	
Oesophageal varices, stricture or requiring oesophageal dilation	
Recorded cirrhosis of the liver	
Swallowing difficulty due to cerebrovascular accident or neurological disorder	
Recent history of vomiting blood	
Recent use of anticoagulation therapy/medication	
Myocardial infarction or any cardiac event within the last 6 months	
Lacking capacity to provide informed consent	

Unwilling to swallow beef gelatine capsule due to dietary preferences