

**Department of Surgery & Cancer
Imperial College London**

Level 7, VOC lab
Commonwealth building
Hammersmith campus
London SW7 2AZ

Professor George Hanna PhD FRCS
Professor of Surgical Sciences
g.hanna@imperial.ac.uk

PARTICIPANT INFORMATION LEAFLET

Breath Analysis for Diagnosis of Oesophageal Squamous Cell Carcinoma

Chief Investigator:

Professor George Hanna
Head of Department of Surgery and Cancer
Imperial College London

Co-investigators:

Ms Sameera Sharma
Clinical Research fellow
Imperial College London

Dear Sir/Madam

You are being invited to take part in the above titled research study. This information sheet explains the nature of the research being undertaken and what the process involves. Please take your time to read the following information and discuss with others if you wish. Should you require any further information or have any questions, please ask us.

What is the purpose of the study?

We are trying to develop a new way to detect cancer of the oesophagus. To do this we are collecting breath samples. Our breath contains numerous metabolites, called volatile organic compounds (VOCs) that are chemicals produced by cancer cells. These metabolites can be analysed and may show whether cancer is present. If this analysis is successful, we hope to develop a test that can detect cancer at an early stage when treatment is likely to be more successful.

Why have I been chosen?

You have been chosen for this research project because you are having or have had an endoscopy to diagnose the cause of your gastrointestinal symptoms. We want to see if new non-invasive tests on your breath can help to diagnose the cause of your symptoms and possibly replace the need for multiple endoscopies in the future.

Do I have to take part?

Participation in this research study is entirely voluntary. It always remains your decision whether to take part in the study. If you choose to take part, you will be provided with a copy of this information sheet and you will be requested to sign a consent form. Should you decide at any point that you do not wish to continue with your participation in this research study, you are free to withdraw at any time without it affecting the standard of care you receive. You are not expected to give a reason for withdrawal.

What do I have to do?

You are not required to do anything specific. We request you not to eat or drink anything for at least 6 hours prior to attending the hospital. The collection of breath will not interfere with your planned treatment, nor shall it result in any change to your planned treatment. We also request your permission to access your hospital records for the purpose of the research study only. No further procedures will be undertaken for the purposes of the research study.

How will my breath be collected?

Your breath sample will be collected using a bag. The breath from the bag will be transferred to a special breath sampling tube using a novel pump, specific for breath transfer. The pump will be assessed for its accuracy and efficiency of breath sample transfer.

How much of my breath will be taken?

You will be asked to provide two breath samples. The sampling requires you to give multiple exhalations in a breath sampling bag until a defined volume (no more than 2 Litres) has been collected. The pump we use will transfer your breath sample onto adsorbent breath sampling tubes. We expect this to take no longer than 5 minutes. No other procedures are required. The sample shall undergo analysis via our mass spectrometry instruments.

What will happen to the samples?

The machine which we will use to analyse your breath samples will destroy them once the analysis is complete. Therefore, no breath material will remain. Any breath samples we have not looked at will be discarded.

Will I be contacted again in the future?

You will have the opportunity to indicate on the consent form whether you would like to be contacted again. Whether or not you chose to be contacted will not impact in any way on the standard of care you receive. You will be asked at the time of consent if you wish to receive information about the results of the study following analysis and presentation for publication. If you register your interest, you will be provided with a summary sheet explaining our results.

What if something goes wrong?

We do not believe that you would be harmed by donating breath samples during this study. Your treatment pathway shall remain the same irrespective of whether you choose to participate in this research study or not. If you wish to complain or have any concerns about the way you have been approached or treated during this study, please contact the co-investigator.

Will I receive payment for the samples that I donate to the study?

There will be no payment or remuneration for any sample provided. We will treat your samples as a gift to Imperial College London Upper GI Research Group and you would therefore relinquish any interest in the samples provided.

Who is the organising and funding body of the study?

Division of Surgery, Department of Surgery & Cancer, Imperial College London, 7th Floor, Commonwealth building, hammersmith hospital campus, London - SW7 2AZ

What happens if I lose capacity during the study?

If you lose capacity after consenting to participate in the study, you will be withdrawn from the study. Identifiable data breath that is already collected with consent would be retained and used in the study. No further data or breath will be collected, or any other research procedures carried out on or in relation to the participant.

Who has reviewed the ethical considerations of the study?

This study is under review for ethical approval.

THANK YOU AGAIN FOR TAKING THE TIME TO READ THIS INFORMATION LEAFLET. YOUR PARTICIPATION IN THIS RESEARCH IS MOST APPRECIATED.

I have some more questions, with whom may I get in contact?

Professor George B Hanna PhD FRCS

Head of the Department of Surgery & Cancer
Imperial College London
VOC lab, Level 7
Commonwealth building, Hammersmith campus
London SW7 2AZ
E-mail: g.hanna@imperial.ac.uk

Ms Sameera Sharma

Clinical Research Fellow
Department of Surgery & Cancer
VOC lab, Level 7
Commonwealth building, Hammersmith campus
London SW7 2AZ
E-mail: ssharma@ic.ac.uk