PARTICIPANT INFORMATION LEAFLET

Non-invasive diagnostic testing for Gastro-intestinal disease

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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. Take time to decide whether or not you wish to participate. Thank you for reading this information sheet.

What is the purpose of the study?
We are trying to develop a new way to diagnose cancer of the oesophagus, stomach, colon and rectum in a way that doesn’t involve having an endoscopy. To do this we are collecting breath and urine samples. These samples contain metabolites, chemicals produced by cancer cells that 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 without the need for an endoscopy 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 an endoscopy to diagnose the cause of your gastrointestinal symptoms. We want to see if new non-invasive tests on your breath and urine can also help to diagnose the cause of your symptoms and possibly replace the need for some endoscopies in the future.

Do I have to take part?
Participation in this research study is entirely voluntary. It remains your decision at all times whether or not to take part. If you choose to take part, you will be provided with a copy of this information sheet to keep and 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. A reason for withdrawal need not be given. A decision not to take part or to withdraw at any time shall not affect the standard of care you receive throughout your treatment.

What do I have to do?
You are not required to do anything specific. In accordance with endoscopy and theatre protocol, we request for you not to eat or drink anything for at least 6 hours prior to attending the hospital. You shall undergo your investigations and treatment as planned. The collection of breath and urine will not interfere with your planned treatment nor shall it result in any change to your planned treatment. No additional invasive procedures will be undertaken for the purposes of the research study. We also request your permission to access your hospital records for the purpose of the research study only, including blood tests, radiology and pathology results. All your hospital records shall be handled with strict confidentiality in accordance with the Data Protection Act 1998.

How much of my breath and urine will be taken?
Before your procedure, you will be asked to blow twice in a special device which stores this breath in a plastic bag for analysis later. You will also be asked to pass a small quantity of urine (20mL) into a container for analysis later. No extra needle pricks or vein punctures are required. The sample shall undergo analysis via our mass spectrometry instrument.

What will happen to the samples?
All breath and urine samples shall be discarded after completion of analysis.

**Will I be contacted again in the future?**
You shall need to indicate on the consent form whether or not you would like to be contacted again. We shall only contact you to obtain an update on your condition and to inform you of the results of any research carried out on your samples. Whether or not you chose to be contacted shall not impact in any way on the standard of care that you receive; this information may be discussed with you by your Hospital Consultant.

**What if something goes wrong?**
We do not believe that you would be harmed by donating breath or urine samples during this study. Your treatment pathway shall remain the same irrespective if you choose to participate in this research study. If you wish to complain, or have any concerns about the way you have been approached or treated during the course of this study, the standard National Health Service complaints procedure is available to you.

**Will I receive payment for the samples that I donate to the study?**
There shall be no payment or remuneration for any sample provided. We shall treat your samples as a gift to the St. Mary’s Hospital Upper GI Research Group, London and you would therefore relinquish any interest in the samples provided.

**Who is organising and funding body of the tissue bank and the study?**
Division of Surgery, Department of Surgery & Cancer, Imperial College London, St. Mary’s Hospital, Praed Street, London, W2 1NY.

**Who has reviewed the ethical considerations of the study?**
This study has been reviewed and given favourable ethical opinion for conduct in the NHS by Camden & Islington REC.

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?

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Alternatively, you can seek impartial advice from the Patient Advice and Liaison Service (PALS), at PALS, Ground Floor QEQM, St Mary’s Hospital, 41 Praed Street, London W2 1NY, Tel: +44(0)2078867777, Fax: +44(0)2078861753

Lastly, the trust R&D provide a third point of contact: Ms Christine Buicke AHSC Joint Research Compliance Office, 510B, 5th Floor Lab Block, Charing Cross Hospital, Fulham Palace Road, London, W6 8RF Tel: +44 (0) 203 311 0212 Fax: +44 (0) 203 311 0203 c.buicke@imperial.ac.uk