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**PaRTICIPANT Information Leaflet**

**(Endotracheal aspirate group)**

**A diagnostic accuracy study of a Point of Care Lipase pH test strip to confirm the correct nasogastric tube position**

IRAS Study Number: 192968

Principal Investigator:

Professor George Hanna PhD FRCS

Professor of Surgical Sciences / Consultant Surgeon

Imperial College, St Mary’s Hospital, London

Co-investigator:

Sophie Doran

Clinical Research Fellow

Imperial College London

 Date: 23/10/2016

**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 a member of the research team, one of whom will introduce themselves to you when they ask for your consent to take part in the study. Contact details are also provided at the bottom of this information sheet. 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?

The purpose of this study is to investigate the use of a new bedside test that has been designed to recognise gastric (stomach) fluid by detecting lipase and an acidic environment in body fluids. Lipase is a chemical produced in the stomach that helps with the absorption of food. Neither lipase nor an acidic environment should be present in the lungs of patients. The purpose of this study is to confirm that our new test correctly identifies that neither are present in fluid samples taken from the lungs of patients.

Why have I been chosen?

You have been chosen to participate because of the **endotracheal tube** that you will have placed during your operation as a part of your clinical care. This is the tube that the anaesthetist will place while you are asleep to help you breath during your operation. This tube provides a means for us to collect a sample of fluid from the lungs.

**Do I have to take part?**

Participation in this research study is entirely voluntary. It is your decision whether you want to take part or not on the study. If you choose to take part, a copy of the participation information sheet will be provided to keep and you will be asked to sign a consent form.

In the event you decide not to continue in the study, you are free to withdraw anytime without providing any reasons and it will not affect the standard of care you receive throughout your treatment.

**What do I have to do?**

There will be no change to the usual clinical care you will have as part of your operation. While you are asleep the anaesthetist will suck a small amount of fluid from the lung that we will use to test the new test strip. This is safe and painless. 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 aspiration from the endotracheal tube is needed to test the pH?

Aspiration of 0.5-1.0 ml of lung fluid from the endotracheal tube is needed for the pH test.

**What will happen to the samples?**

All lung fluid samples will be discarded immediately after pH test has been performed.

**Where and for how long will study data be stored?**

All study data will be kept anonymously by allocating each participant a participant study number. A key to match participant study number to hospital patient identification number will be kept in a locked document cupboard within a locked university office in the Department of Surgery & Cancer, St Mary’s Hospital, Praed Street, London, W2 1NY. Consent forms will be stored in the same way. This is so that the study data can be linked to participants’ medication use and chest x-rays (when undertaken) if required.

**What are the advantages of participating?**

There will be no direct advantage to participating in the study as your care and treatment will not be affected. However, you will be contributing to the development of a novel test that may improve future patient care.

**What are the disadvantages of participating?**

The disadvantage of participating is undergoing the aspiration of fluid from your lung. However, this is a painless safe procedure.

# Will I be contacted again in the future?

The study is planned to continue until the end of 2017. If you would like to see the results of the study when it is completed, we would be happy to send you a summary of the results and details of any publications that have resulted from the study. A member of the research team will ask if you would like this information to be sent to you.

**What if something goes wrong?**

We do not believe that you would be harmed by donating these samples during this study. Your treatment pathway shall remain the same irrespective if you choose to participate in this research study.

Imperial College London holds insurance policies which apply to this study.  If you experience serious and enduring harm or injury as a result of taking part in this study, you may be eligible to claim compensation without having to prove that Imperial College is at fault.  This does not affect your legal rights to seek compensation.

If you are harmed due to someone’s negligence, then you may have grounds for a legal action.  Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (Sophie Doran Email: s.doran@imperial.ac.uk or Frances Domingo Email: f.domingo@imperial.ac.uk ).  The normal National Health Service complaints mechanisms are also available to you.  If you are still not satisfied with the response, you may contact the Imperial AHSC Joint Research Compliance Office.

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

There shall be no payment for any sample provided and you would hand over any interest in the samples provided.

**Who is organising and funding body of the tissue bank and the study?**

The study is organised by the NIHR Diagnostic Evidence Co-operative London that is based at Imperial College. Innovate UK has paid for the study. The study is being sponsored by Imperial College London.

W**ho has reviewed the ethical considerations of the study?**

This study has received ethical approval from the London - Chelsea Research Ethics Committee (Reference 16/LO/0998).

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

In the first instance, please direct any questions, queries or concerns to the co-investigators for this study:

Ms Sophie Doran email: s.doran@imperial.ac.uk

Ms Frances Domingo email: f.domingo@imperial.ac.uk

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 Ruth Nicholson 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 r.nicholson@imperial.ac.uk

*Thank you again for taking time to read this information leaflet. Your participation in this research is most appreciated.*