**Patient Information Sheet**

**Version 1.1 Date: 11th November 2013 REC Number: 13/YH/0371**

**Study Title: I**nternational **S**urgical **O**utcomes **S**tudy(ISOS Study)

**Principal Investigator: Insert local details**

**Introduction**

You are being invited to take part in a research study which aims to help improve the care of patients who undergo surgery in the future. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information.

**What is the purpose of this study?**

ISOS is a study which is simply recording information about patients undergoing surgery and the care they receive. This information will help us to understand how surgical patients are treated across different healthcare systems worldwide.

**Why have I been invited?**

This study is taking place in hundreds of hospitals around the world for one week during the spring of 2014. We have chosen you because you are having surgery and will stay in hospital overnight during that week. In the United Kingdom more than 150 hospitals have registered to take part.

**Do I have to take part?**

No. It is up to you to decide to join the study and your participation is voluntary. You will be asked to sign a consent form if you decide to participate. If you change your mind afterwards you may leave the study at any time.

**What will happen to me if I take part?**

You will not receive any additional treatments or medicines as part of this study. The study simply involves collecting a small amount of information about your treatment during and after surgery. Patients will be followed up until they leave hospital. We will then follow your health status for one year using an NHS database called the Health and Social Care Information Centre (HSCIC).

**Will being in this study affect my care?**

No. The care you receive will be exactly the same as if the study was not taking place.

**What information is collected?**

We will record details including your name, age and hospital number, which will allow us to find your information in the NHS database. We will also collect information about your surgery, anaesthesia and your treatment afterwards.

**Who collects this information?**

A trained member of NHS staff will collect the information. They are required to adhere to strict codes of confidentiality.

**How is this information used?**

The information collected about you will be stored on a secure database. Statisticians will analyse the information to understand the care of patients having surgery around the world.

**How secure is this information?**

The information is held on a secure computer system and the study has been approved under the Data Protection Act by the lead site, Barts Health NHS Trust.

**What are the benefits of taking part?**

You will not benefit directly from the study but your participation will help patients undergoing surgery in the future.

**What are the disadvantages or risks of taking part?**

No. There are no disadvantages of taking part and no changes to your treatment.

**Who has reviewed the study?**

This study was reviewed by the Yorkshire & The Humber - Humber Bridge Research Ethics Committee (REC). This committee are a group of people who oversee the ethical conduct of research studies. These people are not part of the study team.

**Questions about the study**

If you have any questions, concerns or would like to speak to the study team for any reason, please call the principal investigator; (insert local details) or another member of the research team on Tel: (insert local details).