Imperial College London

Joint Research Compliance Office

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PARTICIPANT INFORMATION LEAFLET

Title: Exploring patient perception of Quality of Surgery in Clinical trials – Focus Group

You are being invited to take part in a research study. Before you decide whether or not to take part 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 leaflet carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. A copy of this information sheet in addition to your signed consent form if you choose to partake will be given to you to keep.

Thank you for reading this information leaflet

What is the purpose of this study?

This study has been designed to assess patient perspective on quality of surgery, concerns/perception of challenges regarding quality of surgery and to explore patient's ideas relating to possible solutions to challenges to quality of surgery in Upper GI trials.

Why have I been chosen?

You have been chosen to take part in this study, as you are member of the Oesophageal Patient Association who has previously been a patient with oesophageal cancer and had surgery. You may or may not have previously been involved in a clinical trial. We have chosen you as would like to study and learn from

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your insight into quality of surgery in Upper GI trials and your perception of challenges in this area and possible solutions to those challenges.

Do I have to take part?

Your participation in this study is completely voluntary. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and will be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without having to give a reason. A decision to withdraw at any time, or a decision not to take part, will have no future implications. We will routinely keep participant data following their withdrawal from the study for further analysis. However if you have withdrawn from the study and wish to have your data removed from the study please simply inform one of the investigators using the contact information below and we will remove all your data from the study.

What do I have to do?

If you choose to take part in this study you will be contacted by a member of the research team to arrange a convenient time for you to partake in a focus group. In this focus group that will be conducted either in person, a researcher will facilitate a group discussion relating to patient perspective on quality of surgery, concerns/perception of challenges regarding quality of surgery and to explore patient's ideas relating to possible solutions to challenges to quality of surgery in Upper GI trials. You may be asked your opinion relating to the above subject. Prompts will be used to guide the focus group discussion if required. The focus group is expected to last approximately 60-90 minutes in duration. The focus group discussion will be recorded and then transcribed verbatim. The data will then be analysed by two independent researchers using qualitative tools to identify themes.

What are the possible disadvantages and risks of taking part?

There are no disadvantages we are aware of from taking part in this study.

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What if something goes wrong?

We are not aware of any risks involved in taking part in this study. If you are harmed by taking part in this research project, there are no special compensation arrangements. 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 (Professor G B Hanna, g.hanna@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 my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential. Any information that leaves the primary research group will be pseudonymised such that your name and other personal details are removed in order that you cannot be recognised from it.
Imperial College London is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Imperial College London will keep identifiable information about you.

- For 10 years after the study has finished in relation to data subject consent forms.
- For 10 years after the study has completed in relation to primary research data.

Further information on Imperial College London's retention periods may be found at https://www.imperial.ac.uk/media/imperial-college/administration-and-support-services/records-and-archives/public/RetentionSchedule.pdf.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you

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that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.
You can find out more about how we use your information by contacting the Principle Researcher James Butterworth at: james.butterworth12@imperial.ac.uk
LEGAL BASIS
As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study.
Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

What will happen to the results of the research study?

The results of this study will be analysed and published in a scientific journal, which will be made available to yourself and the public on-line. If you would like help in locating and viewing the published results please contact us using our details below. Study data will be stored for 10 years post end of study in-keeping with Imperial College London research policy.

What are the possible benefits of taking part in the study?

Through taking part in this study you may have the benefit of reflecting on and discussing on your previous experiences of surgery and participating in research.

Who is organising and funding the research?

This study is being organised and sponsored by Imperial College London. This is an unfunded study.

Who has reviewed this study?

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This study was reviewed by the HoD and the Joint Research And Compliance Office

Contact information:
Should you have any questions in regard to this study, please contact the research team using the details provided below.

Chief Investigator: Professor George B Hanna
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Research Ethics Committee
Email: researchethicscommittee@imperial.ac.uk