

Participant Information Leaflet**Study: The metabolic consequences of Gastrointestinal surgery (IRAS 194370)****Version 3****11th November 2016****Mr Geoffrey Roberts
Clinical Research Associate,
Honorary SpR General Surgery****Project title: The metabolic consequences of gastrointestinal surgery.**

We would like to invite you to take part in a research study. Before you decide, you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish.

Part 1 tells you the purpose of this study and what will happen to you if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. The patient advice and liaison service (PALS) at Addenbrooke's Hospital can be approached for independent advice about the research information that you have been given. Thank you for reading this information sheet.

PART 1

What is the purpose of this study? It is widely acknowledged that surgery on the gastro-intestinal tract, particularly the stomach and oesophagus (gullet), changes the way the body senses and processes food. While this can prove beneficial, in many cases we find that people suffer problematic symptoms after surgery. These particularly include the "dumping syndrome", whereby a person may feel flushed, faint or even pass out after a meal. We believe that these symptoms are caused by an overactive response of certain cells in the lining of the gut to food. These cells produce chemical signals (hormones) which would normally tell the body how much food has been eaten, and how to deal with it. When too much of one of these hormones is produced, the body can react badly and make someone unwell. This study aims to understand what hormones are altered by surgery, why this happens and how we can reduce the impact of this problem in people who have had surgery.

The same hormones and processes are most likely involved in the development of some forms of diabetes, and we would equally like to investigate whether they can be harnessed into novel treatments for diabetic patients.

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What information will be produced by this study? This study aims to produce information on patterns of eating behaviour, how the body senses and utilises food, and how these findings are affected by the function of the cells that line your intestine. We have designed a study with multiple arms and you may not be invited, or wish, to participate in all of them. However, the collated information collected from you and fellow participants over the whole study will greatly expand our understanding of how surgery changes the body's metabolism.

The questionnaire aspect of the study will be given to anyone who has undergone an operation on the stomach or gullet, and will provide information on how surgery may have changed your approach to eating. You will be sent a link and anonymous code to a secure website hosted by the University of Cambridge, where you will be able to complete the questionnaires. This will take up to two hours and can be split over several days. We will invite you to repeat the questionnaires before and at set periods after your operation. No person identifiable information will be uploaded to the internet.

Some participants will be invited to attend Addenbrooke's Hospital for a test designed to work out how their intestine senses food. We will collect blood samples, and analyse them for substances that are involved in the processing of food (e.g. insulin), as well as blood sugar levels. Within this group, we may invite some participants to undergo the test before and after their surgery, some solely after their surgery, and some several times after surgery, including after specific medications to change how the body responds to foodstuffs. We would like to see whether the substances that we test for in the blood are related to sugar levels, symptoms and hunger levels. We may also invite you to wear a continuous sugar monitor for a period of time after the visit, to monitor your sugar levels during day-to-day activities.

If you are due to undergo surgery in the near future, we would like to make use of some of the tissue that would normally be thrown away during surgery. Most operations, as a result of the techniques that we use, mean that a small segment of intestine is removed but of no use for diagnosis. This is normally less than 2cm in length, out of a total of 600cm of intestine, and is routinely discarded. We would however like your permission to take this discarded tissue and process it in the laboratory, to give us more information on the cells in your body that sense the food that you eat. This would in no way alter the course of your operation, or other clinical care, and generates no risk to you.

Some participants will be due to undergo a follow up endoscopy (camera test), or be invited to undergo an endoscopy specifically for the purposes of this study. During the endoscopy, we would collect samples of the lining of the intestine and treat them in the same way we do tissue collected during surgery. We aim to examine whether the number, or function, of cells that respond to food are altered by surgery. We would do this by comparing either directly with the results on tissue collected from you during surgery, or by comparing to the average results from the tissue collected during surgery on several other participants.

Why have I been invited? You have been invited because you are due to undergo, or have previously undergone surgery on your gastro-intestinal tract, and were treated or followed up in Addenbrooke's Hospital.

Do I have to take part? You are under no obligation to take part in this study. If you are interested, we will describe the study, give you this information sheet and answer any questions you might have. If you decide to take part in the study, we will then ask you to sign a consent form to show you have agreed to take part. Even after you sign the consent form, you are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive in the future.

Will this affect my normal medical care? Your normal medical care will not be affected by this study. However, if you are willing, we will inform your GP if you wish to participate.

What do I have to do? A doctor or nurse from the study team will talk to you and collect information relevant to our study, such as your height, weight, age and past medical history, as well as a small amount of information about your family, such as whether any of your relatives suffer from certain diseases. All the information in the questionnaire will be kept strictly confidential, and will only be available to the doctors and nurses on the researching team.

You will be asked to sign a consent form to confirm you are happy to take part in this study. The consent form signifies which aspects of the study in which you would be willing to participate. You are free to state which, if any parts of the study in which you are willing to participate or otherwise, and not all participants will be approached to join all parts of the study.

Study requirements

In the paragraphs below, you will find short descriptions of each part of this study. This information sheet is the comprehensive description of the questionnaire, and surgical tissue part of the study. If you are invited to participate in the glucose tolerance test, or endoscopy branches of the study we will provide you with more detailed information in the future.

Questionnaire: This part of the study can be undertaken from home. We will contact you by email with an online link to an eating behaviour questionnaire, and instructions on how to fill it out. This will not take longer than two hours in total and will need to be done on a computer. You will be asked specific questions about how you feel about food, hunger and meal times.

Separate to the questionnaires above, we will ask you to take part in a “real-time” questionnaire study of eating behaviour. Over a two week period, our computer system will contact you by email or text a maximum of six times a day, at random times (only during waking hours), to prompt you to log in and complete a very short questionnaire (which will take under 5 minutes). This is to assess how you think about food while living normally.

If you do not have a computer or internet access, but would still like to participate, please let the study team know and we may be able to arrange for you to attend Addenbrooke’s Hospital and use one of the study team’s computers.

Surgical tissue: If you are due to undergo surgery, we will collect any tissue that would otherwise be discarded and take it to the laboratory for analysis. There are no specific requirements for this part of the study, beyond you acknowledging your consent for us to take this tissue on your operative consent form. Your surgeon will cover this with you prior to your operation.

Glucose tolerance test studies: We may invite you to attend the Clinical Research Facility at Addenbrooke’s Hospital for a test designed to work out how your body senses and responds to food.

This would involve attending the unit after an overnight fast, taking a sugary drink or standard meal, and having some blood taken over several hours. We will also ask you to blow into the mouthpiece of a device that measures the activity of the bacteria in your intestine. We will (optionally) also ask you to provide a sample of faeces. Some participants will be invited to attend just for the breath test and monitoring of blood sugar levels. If we invite you to take part in this part of the study, we will provide you with a more detailed information sheet prior to you having to make any decisions. Most participants invited to this part of the study will be invited to have their basal metabolic rate measured by breathing into a clear plastic hood for 25 minutes, and have their body composition measured by a DEXA scan. This uses very low doses of X-rays (less radiation than that naturally received during two normal days) to measure the percentage of bone, fat and muscle in your body.

Endoscopy: We may ask your permission to collect samples of the lining of your intestine to compare the function of the food sensing cells with that in tissue collected during surgery. If you are undergoing an endoscopy for clinical reasons, we will ask your permission to take these samples during the same endoscopy, once any clinical assessment has been completed. We may also invite you to undergo an endoscopy for the specific reason of providing tissue for this research project. This will involve attending one of the endoscopy suites in Addenbrooke's Hospital, undergoing an endoscopy (camera test) through the mouth, and taking several samples of the lining of the intestine. If we invite you to provide tissue via endoscopy by either of these routes, we will provide you with a more detailed information sheet prior to you having to make any decision.

What are the possible disadvantages or risks of taking part? There are no significant risks to registering for the study. The questionnaire is unobtrusive and can be completed in your own home. Any collection of surgical tissue would not in any way alter your clinical care.

The glucose tolerance test study, and endoscopy study, both carry specific but rare risks. The glucose tolerance test study uses standard methods (an oral glucose tolerance test, or standard meal test) that are in widespread use for the diagnosis of diabetes or testing of gut hormones. The amount of blood that would be taken would be less than half a blood donation. Occasionally, participants may suffer a low blood sugar during the test, which we would monitor and treat as necessary. Some gut hormone study participants will be invited to repeat the study after being given medication to alter how the body responds to foodstuffs. These would be low risk medications that are well understood, and the participants would be given full information on the risks and benefits prior to the study.

The endoscopy study requires the participant to undergo an endoscopy with either local anaesthesia, sedation or general anaesthesia. The procedure, and anaesthesia, while in widespread use, both carry risks. These include oversedation, discomfort during the procedure, reaction to the anaesthetic, and very small risks of significant bleeding or damage (perforation) to the bowel during the biopsies. These risks would be fully explained with specific literature and consent forms prior to you agreeing to the endoscopy.

Should you wish to take part in some, but not all of this study, that is fine – we appreciate your help. Please let us know, and if we invite you to take part in a branch of the study that you would rather not be involved with, please just say and we will not contact you further about it.

There is a small risk that while analysing your blood tests, we will detect abnormalities which you were not aware of before the study. This might include, for example, a new diagnosis of diabetes. If this occurs, we will discuss the matter with you in confidence. If you are willing, we would then talk to your GP who can arrange appropriate treatment if required. While this is a risk of participation in the study, it offers you the possibility of having important conditions diagnosed early, which may be of benefit to your long-term health.

You may have previously participated in research studies led by the same study team. Where these used similar methodology to that detailed above, we would like your permission to use the results gained from these previous studies as part of this project. This will reduce the burden of investigations on you, and other participants, by avoiding repetition of previous work.

What happens if I experience side effects during or after the study? We think it is unlikely that the procedures involved in this study will cause significant side effects. However, it is possible that some participants may experience minor bruising or arm discomfort from the cannula or lightheadedness due to fasting in the gut hormone study. There are also potential risks and side-effects of endoscopy, which would be explained in detail prior to that part of the study. We will ask you to make a note of any side effects that you experience and we will discuss this with you. If you feel the side effects are more severe than expected, you should contact the investigators promptly, who will arrange for you to be reviewed. In the event of severe symptoms, you should contact the investigators as soon as possible – they are available 24 hours a day and will be able to arrange appropriate assessment and treatment. Telephone Mr Geoffrey Roberts on 01223 767176 (9am-5pm only) or 07740 782742 (24 hrs a day).

Are any devices or drugs involved? For the questionnaire, and surgical tissue arms of the study, to which you initially consent, there are no drugs or devices involved. Should we invite you to participate in the glucose tolerance test or endoscopy studies, these may involve the use of specific, well understood drugs or devices with which we are experienced. If that is the case, we will provide you with full information prior to those parts of the study.

What are the possible benefits of taking part? We cannot promise the study will help you, but the information we obtain from our experiments will help us to find out more about how surgery affects the way the body senses food. This may lead to new understanding and treatments for patients suffering with troubling symptoms after surgery, and contribute to our overall understanding of how the body works.

Will I be paid for my participation in the study?

Reasonable travel expenses and parking costs will be reimbursed, and for certain aspects of the study participants will be offered a £30 honorarium in lieu of the inconvenience of participating.

What happens if I become pregnant during the study? Pregnant women and those who are breast-feeding will not be able to take part in this study. If you are taking part in the study and become pregnant, please inform the investigators promptly. You may be able to complete the rest of the study after your child is born.

What happens when the research study stops? The blood taken for analysis will be stored until the end of the research study. The information will be used to help researchers and doctors understand

gastrointestinal diseases better and will hopefully be used to plan new treatment options for these disorders. If you wish, after the study has been completed, the investigators will send you a report explaining the results of the research.

What if there is a problem? Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information of this is given in part 2.

Will my taking part in the study be kept confidential? Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

If you have found this information interesting and you are considering participation, please read the additional information in Part 2 before making any decision.

PART 2

What if new information becomes available? We continuously review the latest scientific reports in order to plan useful and worthwhile experiments. If new evidence comes to light, we might consider amending our study design. However, if this occurred, we would explain the changes to you and give you the opportunity to withdraw if you wish.

Will video/audio tapes be used? No

What if there is a problem? If you have a concern about any aspect of this study you should ask to speak to the researchers who will do their best to answer your questions (01223 767176). The Addenbrooke's hospital Patient Advice and Liaison Service (PALS) is also available to offer advice or support and to listen to any concerns (01223 216756). If you remain unhappy and wish to complain formally you can do this through the NHS Complaints Procedure (University of Cambridge), details of which can be obtained from the hospital.

Are there any compensation arrangements if something goes wrong? If you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanism may be available to you. In the event that something does go wrong and you are harmed during the research and that is due to someone's negligence then you may have grounds for legal action for compensation against the University of Cambridge and Cambridge University Hospitals NHS Foundation Trust, but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you.

Will my taking part in this study be kept confidential? All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised.

Prof Fiona Gribble, Prof Rebecca Fitzgerald, Mr Richard Hardwick, Mr Geoffrey Roberts and the research nurse in their department, will have access to your personal data. We believe that the confidentiality of your personal data is vital. We will discuss this with you before you give consent. The study will meet the requirements of the Data Protection Act and will adhere to the NHS Code of Confidentiality.

These doctors have either honorary or full NHS hospital contracts which have the appropriate confidentiality clauses inserted. It is also possible that representatives of the University of Cambridge or Cambridge University Hospitals NHS Foundation Trust may ask to see the study files, to confirm that the research is being performed to the required high standards. All members of staff are aware of the requirement for strict confidentiality and work to appropriate confidentiality standards.

What will happen to the samples I give? Once the samples have been obtained by the researchers, they will be coded for identification, with only the Chief Investigator or Associate Investigator having access to the codes. Samples will be analysed and stored in a secure place. After the study has been completed, samples will be disposed of in accordance with the best practice for research samples.

Will any genetic tests be done? No analysis will be done to investigate mutations in genes that could determine the risk of disease. If you elect to donate tissue during surgery or endoscopy, we will examine the activity of genes within different cell types in the biopsies, using a process called RNA sequencing. This will give us information on how the different cell types work, and potentially how they respond to foods.

What will happen to the results of the research study? We plan to write scientific papers in medical journals explaining to others what we have learnt from doing these studies. Personal identities will not be revealed in any publications. Fully anonymised data will be published via the University of Cambridge Data Repository in line with research best practice.

Can I withdraw from the study if I change my mind? You will be free to withdraw from this study at any stage without explanation and without affecting your current or future treatment. Any samples taken up to the time of withdrawal will be kept and used in the study for the purposes they were taken for.

Who is organising and funding the research? This study is funded by two large grant-awarding bodies called the NIHR and the Wellcome Trust.

Who has reviewed the study? All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity.

Are there any other studies which I could participate in? We are conducting several similar studies related to the hormonal control of appetite, obesity and type 2 diabetes. If you would be interested in participating in further studies, we would be delighted to give you more information.

Local contact for information. Should you wish to discuss any issues related to this study, please use the contact details below:

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Clinical Research Associate

Prof Fiona Gribble
BA (Hons) MA BM BCh MRCP DPhil
Honorary Consultant & Senior Research Fellow

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Telephone: 01223 767176

Email: gpr25@cam.ac.uk

University of Cambridge
**Telephone: 01223 336746 (9am-5pm
only)**

Email: fmg23@cam.ac.uk

Thank you for taking the time to read this leaflet and taking part in the study. You will be given a copy of this information sheet and a signed consent form to keep.