Participant Information Sheet

Research Study Title: Perianal Fistula Research
Researcher Name: Professor Charles Knowles

We would like to invite you to take part in a research study. Please take time to read the following information carefully. Talk to others about the study if you wish. We will give you at least a day to make your decision, but please take as much time as you like.

PART 1: About the research

What is the purpose of this study?

This research is looking into **perianal fistulas**, which are abnormal connections between the back passage and the nearby skin. We still do not know why many fistulas form and why they do not heal on their own. This research aims to understand more about the **biology of fistulas** and why some are more difficult to cure than others. This could lead to better treatments for some patients in the future.

We also do not have accurate ways of *measuring* the symptoms caused by perianal fistulas. Therefore this research will also aim to develop a **questionnaire tool** to measure these symptoms. In the future, this questionnaire will help us to assess how well certain treatments work.

Why have I been invited?

You have been asked to participate because you have attended this hospital for diagnosis and/or treatment of a **perianal fistula**.

Do I have to take part?

Participation is entirely **voluntary**. It is up to you to decide to join the study. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

What will happen if I take part?

You will be asked to complete a 10-minute symptom questionnaire up to four times in total, before, during and after your care. This can be done by post or online or during one of your hospital visits. You may also be invited to a 60-minute interview, if convenient, to explore your symptoms in more depth. We may ask to audio tape this interview if you are happy with this.

If you need a MRI scan, it will routinely involve an injection of contrast agent into your veins via a plastic cannula. For the purposes of this research, we will use a special setting on the machine to take pictures that allows us to measure the blood flow in the fistula.

If you need surgery, whilst you are asleep under general anaesthetic, we will take four tiny biopsy samples from your fistula and the lining of your back passage. This would take us about 5 minutes to do.

During your follow-up we will examine you to record how successful your treatment has been. You may also be invited to a 20-minute interview, if convenient, to ask about

your views on this research. Your participation in the research will end when you are discharged from outpatient follow-up, which will be approximately within 6 to 12 months.

How will participating affect me?

We will give you a minimum of 24 hours to decide whether you wish to participate in the study or not.

There will be little that affects you other than giving your time as detailed above. Your tests and **treatment will not be different** and will proceed as planned with your clinical team. There will also be no delays to your treatment as a result of participating in this research.

For those having an MRI scan, the special setting we will use is already done routinely for some types of brain scans in the NHS. There are no known side effects to MRI scanning. If you need surgery, the tiny biopsy samples will be done whilst you are asleep under the same general anaesthetic. There is a small risk of pain, bleeding and infection afterwards.

Will my taking part in this study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in the **strictest confidence**. Electronic data and paper files containing details that could identify you, such as your name, date of birth and hospital number, and any audio tapings, will be destroyed 1 year after the study has ended. Data collected for the research will be stripped of your personal details so you cannot be identified. This anonymous data will be used for analysis and to report our findings. It will then be encrypted and kept secure for 10 years, and we may use it for other related research. Only members of the research team will have access to the data. The data will not be used or transferred to commercial organisations.

Will my biopsy samples be stored?

Your biopsy samples will be stored until the project ends in October 2016. They will be stored in a secure freezer at our research facilities and will be linked to the anonymous data, but not to your personal details. If we have made some discoveries that suggest further testing on these samples would be useful, we will apply for ethical approval for this further research to be done. If we don't apply by the end of the project, the samples will be destroyed safely.

PART 2: Information if you participate

What will happen if I don't want to carry on with the study?

You are free to drop out at any time. This would not affect your care. If you wish any unused specimens to be discarded please let us know.

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. The main research fellow, **Mr James Haddow**, can be contacted on 020 7882 8755 or jameshaddow@nhs.net. If you remain unhappy and wish to complain the normal NHS complaints mechanisms will be available to you through the hospital's **Patient Advice and Liaison Service (PALS)** on 020 3594 2040 or pals@bartshealth.nhs.uk.

We do not expect you to suffer any harm or injury as a result of this research. In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the sponsor Queen Mary University of London, but you may have to pay your legal costs.

What will happen to the results of this study?

We aim to publish our work in scientific journals and present at meetings and conferences. Patient identifiable information **will not be divulged**.

How can I be kept informed?

As the information from this research will not be directly relevant to your treatment we will not be routinely feeding back this information to you. However it is possible for you to know more about the research and what has happened to any specimens collected:

- You are welcome to **visit** our research office and talk to us about our research
- We have a **web page** http://blizard.qmul.ac.uk/centres/digestive-diseases.html for information on our other research
- Mr Haddow maintains a **log of the specimens** and what has happened to them and this can been seen on request
- You can sign up to an **emailing list** by going to http://eepurl.com/Gxghn

Who is organising and funding this research?

We are a collaboration involving surgeons, gastroenterologists, immunologists, radiologists and nurses. There are both hospital and university staff from Bart's Health, North West London Hospitals, and Queen Mary University of London. The Sponsor, who is overall responsible for this research, is Queen Mary University of London.

We are funded by the NHS (through the National Institute for Health Research) and Department of Health (through the Healthcare Technology Co-operative, Enteric). If further funding is secured, this will be from charitable or commercial sources. At all times, our autonomy will be preserved, meaning that none of the funders will be able to influence the conduct, analysis or results of this research.

Who has reviewed this 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. This study has been reviewed and approved by Queen's Square Research Ethics Committee.

Further information and contact details

The research team is based at the National Centre for Bowel Research and Surgical Innovation, Blizard Institute, 1st Floor Abernethy Building, 2 Newark St, Whitechapel, London E1 2AT.

The chief investigator is **Professor Charles Knowles**. The hospital's research fellow is **Mr James Haddow** and can be contacted on 020 7882 8755 or jameshaddow@nhs.net

The office that oversees all research at Queen Mary University of London is the **Joint Research Management Office**, Queen Mary Innovation Centre, Lower Ground Floor 5 Walden St, London E1 2EF. The Director is Gerry Leonard and can be contacted on 020 7882 7250 or sponsorsrep@bartshealth.nhs.uk.

Consent Form for Participation in Research

Research Study Title: Perianal Fistula Research
Name of Researcher: Professor Charles Knowles

Participant Details *(or please affix sticker)*

Surname		Hospital No	
First name			

Statement of Participant *Please initial each box*

I confirm that I have read and understood the **information sheet** (version 2.3). I have had the opportunity to consider the information ask questions and have had these answered satisfactorily.	
I understand that my **participation is voluntary** and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	
I understand that relevant sections of any of my medical notes and data collected during the study, may be looked at by responsible individuals from Queen Mary University of London, or from regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have **access to my records**.	
I understand that the Sponsor research administrators at Queen Mary University of London may also access my data for **monitoring and audit** purposes.	
If I am invited to a 60-minute interview, I understand that this may be **audio taped** and transcribed. I am aware that I can decline this at the time.	
If I undergo surgery I give permission for **biopsy samples** to be taken, stored and used for research purposes and potential future studies that will be ethically approved.	
I agree to take part in this research.	

Name of participant	Signature	Date
Name of person taking consent	Signature	Date

When completed: 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes.