**PATIENT INFORMATION SHEET**

**UROLE trial
(Urogenital function in RObotic vs Laparoscopic rEctal surgery trial)
IRAS ID: 211302**

Thank you for showing an interest in this study. Before you decide whether or not you wish 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 carefully and ask us if there is anything that is unclear or if you would like additional information. We will be happy to answer any queries you may have. Please take time to decide whether or not you wish to take part.

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

Unfortunately, rectal surgery can sometimes cause urological and sexual problems. These can be permanent or transient. The majority of rectal surgery is performed by the laparoscopic (commonly known as keyhole) method. However, in the past few years, some rectal surgery is also performed by the robotic method (this is another form of keyhole surgery). Currently it is not clear if there is any benefit it terms of urological and sexual function between the two methods. We want to investigate which method of surgery has the best outcomes in terms of urological and sexual function.

**Why have I been chosen?**

All male patients having elective rectal surgery in this hospital are being offered the chance to take part in this study. The type of surgery you are having falls in this category.

**Do I have to take part?**

Taking part in the research is entirely voluntary - it is up to you to decide whether or not to take part. With your permission, a member of the team at your hospital will contact you in a couple of days’ time to ask whether you would be willing to take part in the study.

If you agree, we will ask you to sign a consent form. If you choose to participate, you will be free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

You are advised to discuss the surgical options with your surgeon before agreeing to participate.

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

If you choose to take part, you will be invited to attend a nurse led clinic, where we will ask you to fill in two short questionnaires to assess your urological and sexual function. Your answers will be completely anonymised and will be kept confidential. During this clinic you will also be asked to pass urine in a specialist lavatory that measures your urine flow. For this reason, we will ask you to attend the clinic with a full bladder. After passing urine, you will have an ultrasound scan (otherwise known as jelly scan) to see how much urine is left over in your bladder. This is not invasive, will not hurt and will not take a lot of your time.

Following this, you will be randomly (like the toss of a coin) allocated to have your surgery via the laparoscopic or robotic method. Every other aspect of your care will be the same as if you did not take part in this trial. Both types of surgery will be performed by the same surgeon. Both procedures (robotic and laparoscopic) are keyhole (or otherwise known as minimally invasive) methods of surgery and the surgery performed is exactly the same. The only difference between the two methods is the instruments your surgeon will use during the operation. Since both are minimally invasive methods of surgery, you will have small scars and a quicker and less painful recovery than if receiving conventional open surgery. There will be no additional delay in receiving your surgery regardless of which method you are allocated to have - if you are a cancer patient and we are not able to provide the method of surgery you are allocated for within a safe timeframe (within 62 days of you being seen by your GP) we will not be able to include you in the trial.

We will ask you to attend the same nurse led clinic as you did before your surgery at 3, 6 and 12 months after your surgery. During these clinic appointments, you will fill in the same questionnaires and do the same urine tests as you did before your surgery. These nurse led clinic appointments will coincide with your routine surgical appointments so you won’t have to come to hospital for any extra visits for this trial.

Your participation in the study is complete once you have completed the last set of questionnaires and gone to the nurse led clinic at 12 months after your operation. We will notify your GP of your participation in the study, unless you don’t want us to do so – please tell us if this is the case.

**What are the possible disadvantages and risks of taking part?**

There are no disadvantages or risks in taking part in this study. Both surgical methods (laparoscopic and robotic) are widely used and there are no proven advantages of one method over the other that should influence your surgeon’s choice of method if you choose not to participate in this study.

**What if I do not wish to have robotic surgery?**

If you do not wish to have robotic surgery you should not take part in this trial. We will arrange for you to have laparoscopic surgery instead.

**What if I wish to have robotic surgery?**

Unfortunately, due to the limited availability of the robotic system we cannot guarantee that you can have robotic surgery whether you participate in the trial or not.

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

There may not be any immediate benefits to you for taking part in the study, but the information we collect could help improve the treatment of people having rectal surgery in the future.

**What if there is a problem?**

If you have any concerns about any aspect of this study, you should ask to speak with the researcher, Mr. Sofoklis Panteleimonitis, or your consultant, who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital’s PALS service (contact details below):

<Insert local PALS contact details>

**Will my taking part in the study be kept confidential?**

Yes - all the information about your participation in this study will be kept confidential. Any information about you provide us which will leave the hospital will have your name and address removed so that you cannot be recognised from it. All data collected from you during the study will be stored securely on an encrypted hard drive kept in a secure location at Poole Hospital NHS Trust and will be analysed by the University of Portsmouth. If you participate in this study, some parts of your medical records and the data collected for the study may be looked at by authorised people from within this hospital or the research team at Poole Hospital NHS Trust, to ensure that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and nothing that could reveal your identity will be disclosed outside the research site.

**What will happen to the results of the research study?**

We intend to publish the results of the research in peer-reviewed medical journals. You will not be identified in any of these publications.

**Who is organising and funding the research?**

The Sponsor of this research is Poole Hospital NHS Trust.

**Who has reviewed the study?**

This study was reviewed by, and given a favourable ethical opinion for conduct in the NHS, by an independent Research Ethics Committee (RES Committee East of England – Cambridgeshire and Hertfordshire).

It has been given local Trust research governance approval by the research & development department at the <Insert trust name> local trust..

**Contact Details:**

If you have any questions, or would like to speak to a member of the research team, please feel free to contact a member of the team listed below.

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| UROLE trial contact details |
| Main study team contact | < Insert name & job title> | <insert telephone number> |
| Principal Investigator | < Insert name & job title> | <insert telephone number> |
| Chief Investigator | Prof. Amjad Parvaiz | 01202 665511 |

Thank you for reading this information sheet and for considering taking part.