Consent Form 1

Department of Health

THE ROYAL MARSDEN NHS FOUNDATION TRUST

Robotic-assisted Laparoscopic Prostatectomy (RALP)

Patient Agreement to Investigation or Treatment

Patient's surname/family name

Patient's first names

Date of birth

Responsible health professional

Job title

NHS number (or other identifier)

☐ Male ☐ Female

Special requirements
(e.g. other language/other communication method)

Name of proposed procedure or course of treatment (include brief explanation if medical term not clear).

Robotic-assisted Laparoscopic Prostatectomy (RALP) –

removal of prostate, and associated structures (vas, seminal vesicles).

The procedure is done through six small cuts (a keyhole approach) and involves removing the prostate and then joining the bladder to the site where the prostate was connected. You will need to have a soft flexible tube in place (catheter) to drain your bladder for 10-14 days.

Intraoperative recording of the procedure

It is routine for us to record digital video images of the procedure. The recording is stored in the Urology department for the purpose of clinical audit (to review any adverse events) and for teaching. Images are totally anonymous when used for this purpose and will not be used for other applications without obtaining separate consent from you. Unfortunately personal copies of the recording are not available.

☐ I give consent to routine recording of the procedure

☐ I do not give consent to recording

To be retained in patient's notes

Statement of health professional (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)

I have explained the procedure to the patient. In particular, I have explained:

The intended benefits:

- ☐ Removal of the prostate cancer as far as possible
- ☐ To find out what stage the cancer is and to help with deciding possible treatment options
- ☐ Use of Robotic-assisted Laparoscopic Prostatectomy (RALP) rather than conventional surgery to increase speed of recovery and reduce the patient's stay in hospital (average 2 days)
- ☐ In the case that the cancer is not completely removed, there may be a need for further cancer treatment (radiotherapy or hormonal treatment) (5% risk)

Serious or frequently occurring risks: Specific to the operation

- ☐ Infertility (100% risk)
- ☐ Impotence (erectile dysfunction) (50% risk): depending on erectile function before the operation and the degree of nerve sparing performed during the operation
- ☐ Leakage of urine (stress incontinence) due to muscle weakness requiring the temporary wearing of pads for a few months (common (25% risk). 85% of all patients are pad free by one year). This may need additional treatment (less than 1% risk)
- ☐ Development of a protrusion of internal tissue through the muscle (hernia) at the site of keyhole surgery (less than 1% risk)
- ☐ Excessive bleeding requiring an open procedure or a repeat operation (less than 1% risk)
- ☐ Damage to the tubes (ureter) from the kidneys to the bladder (less than 1% risk)
- ☐ Bowel injury needing a temporary stoma/bag (less than 1% risk)
- ☐ Injury to nerves which control the muscles on the inside of the thigh (less than 1% risk)
- ☐ Damage to nerves supplying legs (neuropraxia) resulting in numbness or weakness. Usually temporary in nature. (Less than 0.5% risk)
- ☐ Blood clots: They most commonly form in the calf causing lower leg swelling and pain or in the lung causing shortness of breath or chest pain. Blood clots can be life threatening and are treated with blood thinning drugs. Please tell a doctor immediately if you are worried you may have a blood clot. Airline travel and long journeys where you have to remain seated are also associated with an increased risk. Therefore, it is important that you tell your hospital team of any plans to travel while you are on treatment. (Deep vein thrombosis (DVT) or pulmonary embolism (PE) (0.25% risk))

To be retained in patient's notes

☐ **Minor**

- Bladder spasms leading to a strong sensation of needing to pass urine. Usually lasts several hours and occurs in around 10% of patients.
- Wound infection
- Mild abdominal/penis pain, bruising of the scrotum
- Burning sensation after catheter removal – this will be temporary
- Blood in urine for a few days
- Temporary urine leak from the new join between the tubes (urethra) and bladder
- Difficulty in passing urine after your catheter has been removed needing re-catheterisation or further surgery
- Passing small plastic surgical clips in the urine weeks/months after the operation. This may need a small procedure to remove clips via a telescope passed through the urethra into the bladder (less than 5% risk)

Any other risks:

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.....

.....

Any extra procedures which may become necessary during the procedure:

☐ blood transfusion

☐ removal of draining lymph nodes

☐ other procedure (please specify) .....

.....

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

The following leaflet has been provided as part of the patient's information prescription:

☐ Prostate cancer booklet (version no_____)

This procedure will involve:

☐ general and/or regional anaesthesia ☐ local anaesthesia ☐ sedation

Signed: ..... Date .....

Name (PRINT) ..... Job title .....

Contact details (if patient wishes to discuss options later) .....

.....

.....

To be retained in patient's notes

Statement of interpreter (where appropriate)

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe s/he can understand.

Signed ..... Date .....

Name (PRINT) .....

Copy of consent form accepted by patient: yes/no (please ring)

To be retained in patient's notes

Statement of patient

Patient identifier/label

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of page 2 which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

I agree to the procedure or course of treatment described on this form.

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.

I understand that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia.)

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.

I have been told about additional procedures which may become necessary during my treatment. I have listed below any procedures **which I do not wish to be carried out** without further discussion. .....
.....
.....
.....

Patient's signature ..... Date.....

Name (PRINT) .....

A witness should sign below if the patient is unable to sign but has indicated his or her consent. Young people/children may also like a parent to sign here (see notes).

Signature ..... Date .....

Name (PRINT) .....

To be retained in patient's notes

Confirmation of consent (to be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed with the patient that s/he has no further questions and wishes the procedure to go ahead.

Signed: ..... Date .....

Name (PRINT) ..... Job title .....

Important notes: (tick if applicable)

☐ See also advance directive/living will (eg Jehovah's Witness form)

☐ Patient has withdrawn consent (ask patient to sign /date here) .....

To be retained in patient's notes

Guidance to health professionals (to be read in conjunction with consent policy)

What a consent form is for
This form documents the patient's agreement to go ahead with the investigation or treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an *aide-memoire* to health professionals and patients, by providing a check-list of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way, however, should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent
See the Department of Health's *Reference guide to consent for examination or treatment* for a comprehensive summary of the law on consent (also available at www.dh.gov.uk/consent).

Who can give consent
Everyone aged 16 or more is presumed to be competent to give consent for themselves, unless the opposite is demonstrated. If a child under the age of 16 has "sufficient understanding and intelligence to enable him or her to understand fully what is proposed", then he or she will be competent to give consent for himself or herself. Young people aged 16 and 17, and legally 'competent' younger children, may therefore sign this form for themselves, but may like a parent to countersign as well. If the child is not able to give consent for himself or herself, some-one with parental responsibility may do so on their behalf and a separate form is available for this purpose. Even where a child is able to give consent for himself or herself, you should always involve those with parental responsibility in the child's care, unless the child specifically asks you not to do so. If a patient is mentally competent to give consent but is physically unable to sign a form, you should complete this form as usual, and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form
If the patient is 18 or over and is not legally competent to give consent, you should use form 4 (form for adults who are unable to consent to investigation or treatment) instead of this form. A patient will not be legally competent to give consent if:

- they are unable to comprehend and retain information material to the decision and/or
- they are unable to weigh and use this information in coming to a decision.

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives **cannot** be asked to sign this form on behalf of an adult who is not legally competent to consent for himself or herself.

Information
Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and the alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'serious or frequently occurring' risks. In addition if patients make clear they have particular concerns about certain kinds of risk, you should make sure they are informed about these risks, even if they are very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on page 2 of the form or in the patient's notes.

To be retained in patient's notes