CONSENT FORM

for

UROLOGICAL SURGERY

(Designed in compliance with DH Department of Health consent form 1)

PATIENT AGREEMENT TO INVESTIGATION OR TREATMENT

Patient Details or pre-printed label

Patient's NHS Number or Hospital number	
Patient's surname/family name	
Patient's first names	
Date of birth	
Sex	
Responsible health professional	
Job Title	
Special requirements *e.g. other language/other communication method*	

Patient identifier/label

Name of proposed procedure (Include brief explanation if medical term not clear)	ANAESTHETIC
RADICAL CYSTECTOMY AND FORMATION OF NEW BLADDER WITH BOWEL (MALE) THIS INVOLVES REMOVAL OF ENTIRE BLADDER, PROSTATE AND PELVIC LYMPH NODES AND FORMATION OF A NEW BLADDER USING BOWEL	- **GENERAL/REGIONAL** - **LOCAL** - **SEDATION**

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

TREATMENT OF BLADDER CANCER

Serious or frequently occurring risks including any extra procedures, which may become necessary during the procedure. 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. Please tick the box once explained to patient

COMMON
- ❑ TEMORARY INSERTION OF A NASAL TUBE, DRAIN, STENT
- ❑ HIGH RISK OF IMPOTENCE (LACK OF ERECTIONS)
- ❑ DRY ORGASM WITH NO SEMEN PRODUCED CAUSING INFERTILITY
- ❑ NEED TO SELF CATHETERISE IF NEW BLADDER FAILS TO FULLY EMPTY
- ❑ BLOOD TRANSFUSION REQUIRED

OCCASIONAL
- ❑ NEED TO REMOVE THE PENILE URINARY PIPE AS PART OF THE PROCEDURE
- ❑ BLOOD LOSS REQUIRING REPEAT SURGERY
- ❑ CANCER MAY NOT BE CURED WITH REMOVAL OF BLADDER ALONE
- ❑ INCONTINENCE OF URINE

RARE
- ❑ INFECTION OR HERNIA OF INCISION REQUIRING FURTHER TREATMENT
- ❑ ANAESTHETIC OR CARDIOVASCULAR PROBLEMS POSSIBLY REQUIRING INTENSIVE CARE ADMISSION (INCLUDING CHEST INFECTION, PULMONARY EMBOLUS, STROKE, DEEP VEIN THROMBOSIS, HEART ATTACK AND DEATH.)
- ❑ DECREASE RENAL FUNCTION WITH TIME

VERY RARE
- ❑ DIARRHOEA DUE TO SHORTENED BOWEL / VITAMIN DEFICIENCY REQUIRING TREATMENT
- ❑ BOWEL AND URINE LEAKAGE FROM ANASTOMOSIS REQUIRING RE-OPERATION
- ❑ SCARRING TO BOWEL OR URETERS REQUIRING OPERATION IN FUTURE
- ❑ URETHRAL RECURRENCE OF THE CANCER
- ❑ INTRAOPERATIVE RECTAL INJURY REQUIRING COLOSTOMY

ALTERNATIVE TREATMENT: RADIATION TREATMENT TO BLADDER.

A blood transfusion may be necessary during procedure and patient agrees **YES or NO (Ring)**

Signature of Health Professional	**Job Title**
Printed Name	**Date**

The following leaflet/tape has been provided Patient information leaflet Version 1.0

Contact details (if patient wishes to discuss options later) Your case worker is

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.

Signature of interpreter: **Print name:** **Date:**

Copy (i.e. page 3) accepted by patient: yes/no (please ring)

Patient identifier/label

Patient Copy

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Patient identifier/label

Statement of patient

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.
- to a blood transfusion if necessary
- That any tissue that is normally removed in this procedure could be stored and used for medical research (after the pathologist has examined it) rather than simply discarded. PLEASE TICK IF YOU AGREE ☐

I understand

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

_____

_____

Signature of Patient:		**Print please:**	**Date:**

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 DOH guidelines).

Signed_____
Date_____
Name (PRINT) _____

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.

Signature of Health Professional	**Job Title**
Printed Name	**Date**

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) ...../.....

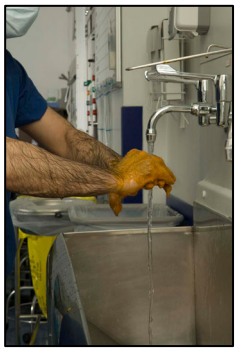
The Shrewsbury and Telford Hospital NHS Trust

RADICAL CYSTECTOMY (IN MEN) WITH BLADDER SUBSTITUTION (NEOBLADDER)

Procedure Specific Information

What is the evidence base for this information?

This publication includes advice from consensus panels, the British Association of Urological Surgeons, the Department of Health and evidence-based sources. It is, therefore, a reflection of best urological practice in the UK. It is intended to supplement any advice you may already have been given by your GP or other healthcare professionals. Alternative treatments are outlined below and can be discussed in more detail with your Urologist or Specialist Nurse.



What does the procedure involve?

This involves removal of the entire bladder, prostate and pelvic lymph nodes with formation of a bladder substitute, called a neobladder, using a segment of bowel.

What are the alternatives to this procedure?

Non-surgical options may include bladder instillations, radiotherapy and chemotherapy. If you need and agree to an operation to remove your bladder you may choose to have a permanent diversion of urine to the abdominal skin using a separated piece of bowel as a permanent urostomy stoma, an ileal conduit, rather than a neobladder. Constructing a urostomy is usually quicker and less prone to complications than a neobladder. You will have been counselled about the potential benefits and risks of having a neobladder and what to expect after the operation.

What should I expect before the procedure?

You will normally receive an appointment for pre-operative assessment to check your general fitness, to screen for the carriage of MRSA and to perform some baseline investigations.

It may be appropriate to teach you Clean Intermittent Self Catheterisation, CISC, before your operation. This technique is sometimes necessary if your new bladder fails to empty as well as expected.

You may be admitted into hospital one day pre-operatively but admission on the day of surgery to the Surgical Admissions Suite is often preferable. Your hospital stay will normally last between 14 and 21 days.

On arrival at the hospital, you will be seen by members of the nursing and medical teams which may include the Consultant, Specialist Registrar, House Officer and Urology Nurse Specialist. Your anaesthetist will also visit you before your operation.

The Urology Specialist Nurse will mark the site where your stoma will be positioned if a reconstruction of the bladder is not technically possible.

From the day before your operation you will have only fluids by mouth; you should take nothing by mouth for the 6 hours before surgery. You will be given laxatives and/or enemas to ensure that your bowel is empty prior to surgery.

You will be given a daily injection under the skin of a drug that, along with the help of elasticated stockings provided by the ward, will help prevent thrombosis (clots) in the veins. Frequently it will be advised that this drug continue for a few weeks after you leave hospital. Many patients can be taught to administer these injections themselves after discharge.

The risk of thrombosis can be further reduced by early mobilisation after the operation and you will be encouraged to sit out of bed with help as soon as possible post -operatively.

Please be sure to inform your surgeon in advance of your surgery if you have any of the following:

- an artificial heart valve
- a coronary artery stent
- a heart pacemaker or defibrillator
- an artificial joint
- an artificial blood vessel graft
- a neurosurgical shunt
- any other implanted foreign body
- a regular prescription for Warfarin, Aspirin or Clopidogrel (Plavix®)
- a previous or current MRSA infection
- a high risk of variant-CJD (if you have received a corneal transplant, a neurosurgical dural transplant or previous injections of human-derived growth hormone)

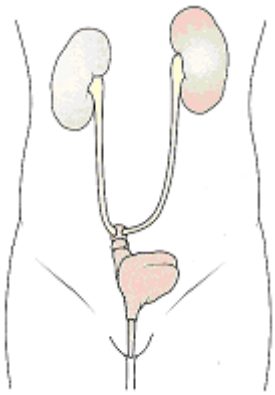
Before moving to the operating theatre you will be asked to sign the second part of the consent form giving permission for your operation to take place, showing you understand what is to be done and confirming that you wish to proceed. Make sure that you are given the opportunity to discuss any concerns and to ask any questions you may still have before signing the form.

Fact File 1 • The NHS Constitution
Same-Sex Accommodation

As a result of the new NHS constitution, the NHS is committed to providing same-sex accommodation in hospitals by April 2010. This is because feedback from patients has shown that being in mixed-sex accommodation can compromise their privacy. The NHS pledges that:

- sleeping and washing areas for men and women will be provided
- the facilities will be easy to get to and not too far from patients' beds

What happens during the procedure?



A full general anaesthetic will be used and you will be asleep throughout the procedure. In some patients, the anaesthetist may also use an epidural anaesthetic which improves or minimises post-operative pain.

In the operation, the bladder and its lymph nodes will be removed. The ureters (the tubes which drain urine from the kidneys to the bladder) are then sewn to a separated piece of small bowel which is fashioned into a bladder substitute and joined to the water pipe (urethra).

Durinhg the operation the nerves which allow you to obtain an erection are likely to be damaged. In some situations it may be possible to attempt to preserve these nerves. You may wish to ask about this before you operation.

What happens immediately after the procedure?

In general terms, you should expect to be told how the procedure went and you should:

- ask if what was planned to be done was achieved
- let the medical staff know if you are in any discomfort
- ask what you can and cannot do
- feel free to ask any questions or discuss any concerns with the ward staff and members of the surgical team
- ensure that you are clear about what has been done and what is the next move

After your operation, you may be in the Intensive Care Unit or the Special Recovery area of the operating theatre before returning to the ward; visiting times in these areas are flexible and will depend on when you return from the operating theatre. You will have at least one drip in your arm.
You will usually have a catheter in the urethra and a second catheter passing

through the abdominal wall to the bladder; these catheters are normally removed after 2 weeks once satisfactory healing has been confirmed by x-ray. Small tube drains will pass from the kidneys through the neobladder to a bag on the abdominal wall; these drains collect urine until they are removed. An additional drain is usually placed in the abdomen itself. These tubes and drains are removed sequentially as healing takes place and you recover after the operation.
You will be encouraged to mobilise as soon as possible after the operation because this encourages the bowel to begin working and helps to reduce the risk of thrombosis. Normally, we use elastic stockings to minimise the risk of a blood clot (deep vein thrombosis) in your legs. A physiotherapist will come and show you some deep breathing and leg exercises, and you will sit out in a chair for a short time soon after your operation. You will be offered fluids and food as soon as possible.

Normally, injections and elastic stockings are used to minimise the risk of a blood clot (deep vein thrombosis) in your legs. A physiotherapist will come and show you some deep breathing and leg exercises, and you will sit out in a chair for a short time soon after your operation. It will, however, take at least 3 months, and possibly longer, for you to recover fully from this surgery.

Your stay in hospital is likely to be between 14 and 21 days.

Are there any side-effects?

Most procedures have a potential for side-effects. You should be reassured that, although all these complications are well-recognised, the majority of patients do not suffer any problems after a urological procedure.

Common

- Temporary insertion of a drain and ureteric stents
- Impotence, difficulty in obtaining spontaneous erections
- Dry orgasm and infertility
- Need to self-catheterise if neo bladder fails to fully empty
- Recurrent urinary tract infection requiring antibiotic treatment and/or neobladder washing
- Passing of mucus in the urine which can cause intermittent blockage of the urinary stream

Occasional

- Blood loss requiring transfusion
- Cancer may not be cured with removal of bladder alone
- Incontinence of urine, especially at night

Rare

- Anaesthetic or cardiovascular problems possibly requiring intensive care admission (including chest infection, pulmonary embolus, stroke, deep vein thrombosis, heart attack and death)
- Infection or hernia of incision requiring further treatment
- Blood loss requiring repeat surgery

- Decreased kidney function with time

Very Rare

- Diarrhoea/vitamin deficiency due to shortened bowel requiring treatment
- Bowel and urine leakage from anastomosis requiring re-operation
- Scarring to the bowel or ureters requiring operation in future
- Urethral recurrence of the cancer
- It may not be possible to create a neobladder so that a urinary stoma, (bag), is necessary
- Intra-operative rectal injury requiring colostomy

What should I expect when I get home?

By the time of your discharge from hospital, you should:

- be given advice about your recovery at home
- ask when to resume normal activities such as work, exercise, driving, housework and sexual intimacy
- ask for a contact number if you have any concerns once you return home
- ask when your follow-up will be and who will do this (the hospital or your GP)
- ensure that you know when you will be told the results of any tests done on tissues or organs which have been removed

When you leave hospital, you will be given a “draft” discharge summary of your admission. This holds important information about your inpatient stay and your operation. If you need to call your GP for any reason or to attend another hospital, please take this summary with you to allow the doctors to see details of your treatment. This is particularly important if you need to consult another doctor within a few days of your discharge.

You will find that your energy levels are low when you get home and you will require assistance with many of the daily activities you normally take for granted. The wound clips will be removed in hospital or by the District Nurse who will also help with any other problems which may develop.

You will need to continue training your bladder substitute to increase its capacity once you get home. Initially, you will pass urine every 2 hours but this will gradually increase to 4-hourly by day and night. Bladder training may take up to 12 months to complete.

The time taken to return to normal activity is between 3 and 6 months.

What else should I look out for?

There are a number of complications which may make you feel unwell and may require consultation with your GP or contact with the Urology Department.

If you experience fever or vomiting, especially If associated with unexpected pain in the abdomen, you should contact your doctor immediately for advice.

If you are unable to pass urine and cannot pass a catheter, you should attend the Accident & Emergency Department as quickly as possible. If you have problems relating to recurrent urinary tract infection of bladder re-training, you should contact the Urology Department.

You will have to attend the outpatient clinic to see the Specialist Nurse every week for 6-8 weeks and, thereafter, at regular intervals so that your general condition can be monitored.

Occasional blocking of the urinary stream with a plug of mucus from the bowel lining is common. It usually clears on its own but you may need to carry out clean intermittent self-catheterisation for this to ensure that the bladder substitute is emptying completely.

Your blood acid content will be monitored if necessary since this can become altered with a bladder substitute. Your urologist may prescribe medication to alter the acid levels depending on the results. Symptoms of an abnormal acid level include fatigue, tiredness and weakness.

Are there any other important points?

It will be at least 14-21 days before the pathology results on the tissue removed are available. It is normal practice for the results of all biopsies to be discussed in detail at a multi-disciplinary meeting before any further treatment decisions are made. You and your GP will be informed of the results after this discussion.

You will be brought back to the Hospital for a special scan to check that the kidneys are draining into the bowel correctly and you will be seen in the outpatient clinic after 6 weeks to check your progress and to discuss the results of your surgery. If the doctors decide that further treatment is required, the necessary appointments will be made for you at this stage.

Driving after surgery

It is your responsibility to ensure that you are fit to drive following your surgery. You do not normally need to notify the DVLA unless you have a medical condition that will last for longer than 3 months after your surgery and may affect your ability to drive. You should, however, check with your insurance company before returning to driving. Your doctors will be happy to provide you with advice on request.

Is there any research being carried out in this area?

Before your operation, your surgeon or Specialist Nurse will inform you about any relevant research studies taking place, and, in particular, if any surgically-removed tissue may be stored for future study. If this is

the case, you will be asked if you wish to participate and, if you agree, to sign a special form to consent to this.

All surgical procedures, even those not currently the subject of active research, are subjected to rigorous clinical audit so that we can analyse our results and compare them with those of other surgeons. In this way, we can learn how to improve our techniques and our results; this means that our patients will get the best treatment available.

Who can I contact for more help or information?

For further information on the internet, here are some useful sites to explore:

Best Health (prepared by the British Medical Association)
NHS Clinical Knowledge Summaries (formerly known as Prodigy)
NHS Direct
Patient UK
Royal College of Anaesthetists (for information about anaesthetics)
Royal College of Surgeons (patient information section)

What should I do with this information?

Thank you for taking the trouble to read this publication. If you wish to sign it and retain a copy for your own records, please do so below.

If you would like a copy of this publication to be filed in your hospital records for future reference, please let your Urologist or Specialist Nurse know. However, if you do agree to proceed with the scheduled procedure, you will be asked to sign a separate consent form which will be filed in your hospital record. You will, if you wish, be provided with a copy of this consent form.

I have read this publication and I accept the information it provides.

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

How can I get information in alternative formats?

Please ask your local NHS Trust or PALS network if you require this information in other languages, large print, Braille or audio format.

Our hospital is smoke-free. Smoking increases the severity of some urological conditions and increases the risk of post-operative complications. For advice on quitting, contact your GP or the **NHS Smoking Helpline** free on **0800 169 0 169**

Disclaimer

Fact File 2 • The NHS Constitution
Patients' Rights & Responsibilities

The constitution, as a result of extensive discussions with staff and the public, sets out new rights for patients which will help improve their experience within the NHS. These new rights include:

- a right to choice and a right to information that will help them make that choice
- a right to drugs and treatments approved by NICE when it is considered clinically appropriate
- a right to certain services such as an NHS dentist and access to recommended vaccinations
- the right that any official complaint will be properly and efficiently investigated, and that they be told the outcome of the investigations
- the right to compensation and an apology if they have been harmed by poor treatment

The constitution also lists patient responsibilities, including:

- providing accurate information about their health
- taking positive action to keep themselves and their family healthy
- trying to keep appointments
- treating NHS staff and other patients with respect
- following the course of treatment that they are given
- giving feedback, both positive and negative, after treatment

Written by CJM Beacock, Urology Services
Version 1.0
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