CONSENT FORM for UROLOGICAL SURGERY

(Designed in compliance with OH) Department 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	

Name of proposed procedure

(Include brief explanation if medical term not clear)

ANAESTHETIC

RADICAL CYSTECTOMY AND ILEAL CONDUIT (FEMALE)

THIS INVOLVES REMOVAL OF BLADDER, PELVIC LYMPH NODES & REMAINING FEMALE ORGANS (I.E. OVARIES AND UTERUS INCLUDING A PORTION OF VAGINA) AND PERMANENT DIVERSION OF URINE TO ABDOMINAL SKIN USING A LOOP OF BOWEL AS A STOMA

- GENERAL/REGIONAL
- LOCAL
- SEDATION

<u>Statement of health professional</u> (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

<u>Serious or frequently occurring risks</u> 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 PAIN OR DIFFICULTY WITH SEXUAL INTERCOURSE DUE TO NARROWING OR SHORTENING OF VAGINA IN EVENT OF OVARY REMOVAL MENOPAUSE MAY OCCUR BLOOD TRANSFUSION REQUIRED	
OCCASIONAL BLOOD LOSS REQUIRING REPEAT SURGERY CANCER MAY NOT BE CURED WITH REMOVAL OF BLADDER ALONE	
RARE INFECTION OR HERNIA OF INCISION REQUIRING FURTHER TREATMENT ANAESTHETIC OR CARDIOVASCULAR PROBLEMS POSSIBLY REQUIRING INTENSIVE CARE ADMISSION (INCLUDIN CHEST INFECTION, PULMONARY EMBOLUS, STROKE, DEEP VEIN THROMBOSIS, HEART ATTACK AND DEATH.) DECREASE IN RENAL FUNCTION WITH TIME	IG
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 SCARRING, NARROWING OR HERNIA FORMATION AROUND STOMAL OPENING REQUIRING REVISION INTRAOPERATIVE RECTAL INJURY REQUIRING COLOSTOMY	
ALTERNATIVE TREATMENT: RADIATION TREATMENT TO BLADDER, CONTINENT DIVERSION OF URINE WAS DISCUSSED	D.

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

Signature of	Job Title	
Health Professional		
Printed Name	Date	
The following leaflet/tape has been provided	BAUS information lo	eaflet (21/024)
Contact details (if patient wishes to discuss options lat	er) <u>Your case worker is</u>)
Statement of interpreter (where appropriate) and in a way in which	'	
Signature of	Print name:	Date:

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

interpreter:

Name of proposed procedure ANAESTHETIC (Include brief explanation if medical term not clear) RADICAL CYSTECTOMY AND ILEAL CONDUIT (FEMALE) - GENERAL/REGIONAL THIS INVOLVES REMOVAL OF BLADDER, PELVIC LYMPH NODES & REMAINING FEMALE ORGANS (I.E. OVARIES AND UTERUS INCLUDING A PORTION OF VAGINA) AND PERMANENT DIVERSION OF URINE TO ABDOMINAL SKIN USING A LOOP OF BOWEL AS A STOMA - 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

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VEF	PY 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 SCARRING, NARROWING OR HERNIA FORMATION AROUND STOMAL OPENING REQUIRING REVISION INTRAOPERATIVE RECTAL INJURY REQUIRING COLOSTOMY
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A blood transtusion may be necessary during pro	ocedure	e and patient agrees y	ES or NO (Ring)
Signature of		Job Title	
Health Professional			
Printed Name		Date	
The following leaflet/tape has been provided BAUS information leaflet (21/024)			
Contact details (if patient wishes to discuss options later) Your case worker is			
Statement of interpreter (where appropriate) and in a way in which		•	
Signature of interpreter:	F	Print name:	Date:

Radical cystectomy and ileal conduit formation under General Anaesthesia (removal of bladder, uterus, ovaries, fallopian tubes and cuff of vagina and formation of permanent stoma)

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 I understand	 to a blood transfusion in That any tissue that is and used for medical rethan simply discarded. If that you cannot give me procedure. The person in that I will have the opperances the sist before the prevents this. (This only anaesthesia.) that any procedure in a carried out if it is neces health. about additional procedure. 	normally removed in this presearch (after the pathologic PLEASE TICK IF YOU AGRICE a guarantee that a particul will, however, have appropried that the detail of the procedure, unless the urgoy applies to patients having addition to those described assary to save my life or to planes which may become need below any procedures which	ocedure could be stored ist has examined it) rather EE lar person will perform the late experience. ails of anaesthesia with an ency of my situation general or regional on this form will only be prevent serious harm to my dessary during my
Signature of Patient:		Print please:	Date:
her consent. You	should sign below if the patiening people/children may also like a signed Date Name (PRINT)	parent to sign here. (See Do	
Confirmation	on of consent (to be complete	ed by a health professional	when the patient

<u>Confirmation of consent</u> (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.

Job Title
Date

Important notes:	(tick if	applica	able

See also advance directive/living	will (eg Jehovah's Witness form)
Patient has withdrawn consent	(ask patient to sign/date here)



RADICAL CYSTECTOMY WITH FORMATION OF AN ILEAL CONDUIT (IN WOMEN)

Information about your procedure from The British Association of Urological Surgeons (BAUS)

This leaflet contains evidence-based information about your proposed urological procedure. We have consulted specialist surgeons during its preparation, so that it represents best practice in UK urology. You should use it in addition to any advice already given to you.

To view the online version of this leaflet, type the text below into your web browser:

http://www.baus.org.uk/_userfiles/pages/files/Patients/Leaflets/Rad cyst female conduit.pdf

Key Points

- The aim of cystectomy is to remove your bladder and the cancer that it contains
- This usually involves removal of your uterus (womb), ovaries, part of your vagina and local lymph glands to give us the best chance of removing all the cancer
- Once we have removed your bladder, we divert your urine, using an isolated section of bowel, on to your abdominal (tummy) wall as a urostomy (ileal conduit)
- This procedure can be done using an open or keyhole approach (often with robotic assistance)

What does this procedure involve?

Removal of your bladder, uterus, ovaries, upper part of your vagina and local lymph nodes. Your urine is then diverted into a section of bowel which is brought to the skin surface as a stoma (usually an ileal conduit, also known as a urostomy).

Most of your vagina is left in place and, for women who are still sexually active, intercourse should be possible. Your surgeon can give you more details about this.

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What are the alternatives?

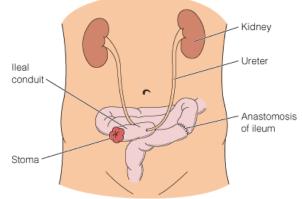
- Radical radiotherapy if, for any reason, a decision has been made that you should not undergo surgery
- **BCG instillation into the bladder** only indicated for high-grade non-muscle invasive cancer; not for muscle-invasive disease
- Radical cystectomy with formation of a neobladder or construction of a catheterisable pouch – radical bladder removal but without an external urostomy
- Systemic chemotherapy drugs given by mouth or into your bloodstream; sometimes used before radiotherapy or radical cystectomy

What happens on the day of the procedure?

Your urologist (or a member of their team) will briefly review your history and medications, and will discuss the surgery again with you to confirm your consent.

An anaesthetist will see you to discuss the options of a general anaesthetic or spinal anaesthetic. The anaesthetist will also discuss pain relief after the procedure with you.

We may provide you with a pair of TED stockings to wear, and we may give you a heparin injection to thin your blood. These help to prevent blood clots from developing and passing into your lungs. Your medical team will decide whether you need to continue these after you go home.



Some urology units admit you the day before your procedure to administer laxatives to clear your bowel; others will admit you on the day of surgery and will not use laxatives. Your urologist will advise on which protocol will be used.

Will I have any say in where my urostomy is sited?

Before your procedure we will arrange for you to see a **Stoma Nurse Specialist**. Their job is to help you decide on the ideal site for your stoma. They will then mark this on the skin of your abdomen. The surgeon needs to see this mark during the procedure, so it is important not to wash it off. If you wish, we will give you the opportunity to meet someone who already has a urostomy.

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Details of the procedure

- we normally use a general anaesthetic for the procedure
- your anaesthetist may also use an epidural or spinal anaesthetic to minimise any post-operative pain
- you will usually be given an injection of antibiotics before the procedure, after you have been checked for any allergies
- we normally perform the procedure through an incision in your lower abdomen (tummy) or using a laparoscopic (keyhole) approach with or without robotic assistance
- we will remove your bladder, uterus, both ovaries and the upper part of your vagina
- we may be able to preserve the nerves which control sexual function but this is not always possible; you should discuss this with your urologist before the procedure
- we stitch the ureters (the tubes which drain urine from the kidneys to the bladder) to a separated piece of small bowel and bring this out on the surface of the abdomen as a urostomy (usually an ileal conduit)
- we re-join the ends of the small bowel from which the urostomy has been made
- Completed ileal conduit
- we close the wound with stitches or staples
- we normally place one or more drains where the bladder has been removed and leave two small splints in the ureters, protruding from the end of your urostomy (pictured)
- we attach a drainage bag to your urostomy
- the procedure can take anything from two to six hours to perform, depending on how complex the procedure is and what approach (open or keyhole) is used
- you should expect to be in hospital for seven to 14 days.

Following radical cystectomy, some urology units have introduced Enhanced Recovery Pathways. These actually start before you are admitted to hospital. After your surgery, they are designed to speed your recovery, shorten your time in hospital and reduce your risk of re-admission.

We will encourage you to get up and about as soon as possible. This reduces the risk of blood clots in your legs and helps your bowel to start

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working again. You will sit out in a chair shortly after the procedure and be shown deep breathing/leg exercises. We will encourage you to start drinking and eating as soon as possible.

We normally remove your drains when they have stopped draining. The splints in your stoma will be removed 10 to 14 days after the procedure, sometimes after an X-ray along the splints shows that the ureters and bowel have been joined securely.

Are there any after-effects?

The possible after-effects and your risk of getting them are shown below. Some are self-limiting or reversible, but others are not. We have not listed very rare after-effects (occurring in less than 1 in 250 patients) individually. The impact of these after-effects can vary a lot from patient to patient; you should ask your surgeon's advice about the risks and their impact on you as an individual:

After-effect	Risk
Discomfort or difficulty with sexual intercourse due to narrowing or shortening of your vagina	Almost all patients
Menopausal symptoms because your ovaries have been removed	Almost all patients
Your cancer may not be cured by the procedure (this possibility will have been discussed with you before the operation)	Between 1 in 2 & 1 in 10 patients
Blood transfusion	Between 1 in 2 & 1 in 10 patients
Paralytic ileus (failure of your bowel to work) for several days causing nausea, bloating & vomiting, and requiring an intravenous drip and stomach drainage tube through your nose until it recovers	Between 1 in 2 & 1 in 10 patients
Infection in your wound or an abscess in your abdominal (tummy) cavity	Between 1 in 10 & 1 in 50 patients

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Anaesthetic or cardiovascular problems possibly requiring intensive care (including chest infection, pulmonary embolus, stroke, deep vein thrombosis, heart attack and death)	Between 1 in 10 & 1 in 50 patients (your anaesthetist can estimate your individual risk)
Decrease in kidney function over time	Between 1 in 10 & 1 in 50 patients
Need to abandon a keyhole procedure and convert to open surgery because of operative difficulties	Between 1 in 10 & 1 in 50 patients
Need to remove your urethra (waterpipe) as part of the procedure	Between 1 in 10 & 1 in 50 patients
Need for return to theatres for re-operation due to bleeding, bowel leakage, urine leakage or bowel obstruction	Between 1 in 50 & 1 in 250 patients
Hernia of the incision (or keyhole ports) requiring further surgical repair	Between 1 in 50 & 1 in 250 patients
Scarring, narrowing or hernia formation around your urostomy requiring revision	Between 1 in 50 & 1 in 250 patients
Diarrhoea/vitamin deficiency due to shortened bowel requiring specific dietary supplements or other treatment	Between 1 in 50 & 1 in 250 patients
Late stricturing (scarring) of the bowel or ureters requiring further surgery	Between 1 in 50 & 1 in 250 patients
Rectal injury at the time of surgery requiring a temporary colostomy (bowel opening on your abdomen)	Between 1 in 50 & 1 in 250 patients

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What is my risk of a hospital-acquired infection?

Your risk of getting an infection in hospital is between 4 & 6%; this includes getting *MRSA* or a *Clostridium difficile* bowel infection. This figure is higher if you are in a "high-risk" group of patients such as patients who have had:

- long-term drainage tubes (e.g. catheters);
- bladder removal;
- long hospital stays; or
- multiple hospital admissions.

What can I expect when I get home?

- you will be given advice about your recovery at home
- you will be given a copy of your discharge summary and a copy will also be sent to your GP
- any antibiotics or other tablets you may need will be arranged & dispensed from the hospital pharmacy
- by the time you get home, you should be able to perform "daily living" activities such as making a cup of tea, preparing food and emptying your stoma bag
- you will feel tired for several weeks and may need to take regular "cat naps" during the day
- we will arrange for the stitches or clips in your wound to be removed after 10 to 12 days
- if you get a fever or start vomiting, especially if associated with unexpected pain in your abdomen, you should contact your GP immediately
- a follow-up appointment will be made for you six to 12 weeks after your surgery

General information about surgical procedures

Before your procedure

Please tell a member of the medical team if you have:

- an implanted foreign body (stent, joint replacement, pacemaker, heart valve, blood vessel graft);
- a regular prescription for a blood thinning agent (e.g. warfarin, aspirin, clopidogrel, rivaroxaban, dabigatran);
- a present or previous MRSA infection; or
- a high risk of variant-CJD (e.g. if you have had a corneal transplant, a neurosurgical dural transplant or human growth hormone treatment).

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Questions you may wish to ask

If you wish to learn more about what will happen, you can find a list of suggested questions called "Having An Operation" on the website of the Royal College of Surgeons of England. You may also wish to ask your surgeon for his/her personal results and experience with this procedure.

For several years, BAUS has collected data from urologists undertaking this surgery. You can view these data, by unit and by Consultant, in the <u>Surgical</u> Outcomes Audit section of the BAUS website.

Before you go home

We will tell you how the procedure went and you should:

- make sure you understand what has been done;
- ask the surgeon if everything went as planned;
- let the staff know if you have any discomfort;
- ask what you can (and cannot) do at home;
- make sure you know what happens next; and
- ask when you can return to normal activities.

We will give you advice about what to look out for when you get home. Your surgeon or nurse will also give you details of who to contact, and how to contact them, in the event of problems.

Smoking and surgery

Ideally, we would prefer you to stop smoking before any procedure. Smoking can cause bladder cancer, increase the risk of cancer recurrence and make complications more likely after surgery. We strongly advise anyone with bladder cancer to stop smoking. For advice on stopping, you can:

- contact your GP;
- access your local NHS Smoking Help Online; or
- ring the free NHS Smoking Helpline on 0300 123 1044

Driving after surgery

It is your responsibility to make sure you are fit to drive after any surgical procedure. You only need to <u>contact the DVLA</u> if your ability to drive is likely to be affected for more than three months. If it is, you should check with your insurance company before driving again.

What should I do with this information?

Thank you for taking the trouble to read this information. Please let your urologist (or specialist nurse) know if you would like to have a copy for

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your own records. If you wish, the medical or nursing staff can also arrange to file a copy in your hospital notes.

What sources have we used to prepare this leaflet?

This leaflet uses information from consensus panels and other evidence-based sources including:

- the Department of Health (England);
- the Cochrane Collaboration; and
- the National Institute for Health and Care Excellence (NICE).

It also follows style guidelines from:

- the Royal National Institute for Blind People (RNIB);
- the Information Standard;
- the Patient Information Forum; and
- the <u>Plain English Campaign</u>.

Disclaimer

We have made every effort to give accurate information but there may still be errors or omissions in this leaflet. BAUS cannot accept responsibility for any loss from action taken (or not taken) as a result of this information.

PLEASE NOTE

The staff at BAUS are not medically trained, and are unable to answer questions about the information provided in this leaflet. If you do have any questions, you should contact your urologist, specialist nurse or GP.

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