To be printed on local hospital headed paper

Peri**O**perative chemotherapy or s**U**rveillance in upper **T**ract urothelial cancer

PATIENT INFORMATION SHEET

We would like to invite you to take part in a research study called "POUT". Before you decide whether to participate, 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 discuss it with friends, relatives and your GP if you wish. Ask us if there is anything that is not clear or if you would like more information – the contact details for your local POUT specialist can be found on page 10. Please take as much time as you need to decide whether or not you wish to take part in the POUT study.

Your doctor has found a cancer that has grown into the wall of your ureter, which is the tube draining from the kidney into the bladder. It may also have grown into part of your kidney called the renal pelvis, or into some of the surrounding lymph glands. This is called muscle invasive upper tract urothelial cancer and your doctor has treated it with surgery to remove your kidney and ureter (nephro-ureterectomy). Although you have had this treatment, there is still a considerable risk that the cancer may return. We do not know whether further treatment using drugs (chemotherapy) given to you after you have recovered from the operation, may help to prevent this type of cancer from returning.

WHAT IS THE PURPOSE OF THE POUT STUDY?

We need to find out about the best way of treating cancer like yours.

In the past, people with muscle invasive upper tract urothelial cancer have been treated with surgery followed by close observation (surveillance/frequent check-ups), so that if the cancer comes back, it can be treated. After surgery, patients are usually offered chemotherapy only if the cancer comes back. At this stage, the treatment is often intended to relieve symptoms rather than cure the cancer. The POUT study has been set up to try to find out whether chemotherapy should be given within a few months after surgery to help to prevent the cancer from returning, or whether close observation following surgery is the best approach.

The POUT study is investigating whether people with upper tract urothelial cancer will benefit from further treatment after surgery. There is evidence that chemotherapy reduces the risk of the cancer coming back after surgery for breast and bowel cancer. POUT is the first study that could establish whether chemotherapy works for upper tract urothelial cancer.

WHAT IS BEING STUDIED?

We are trying to identify the best treatment for patients with muscle invasive upper tract urothelial cancer by comparing the long-term results of the two different options – close observation (with the option of chemotherapy being given if the cancer comes back) or immediate chemotherapy. There is currently no evidence to show whether or not immediate chemotherapy has any benefits for people with upper tract urothelial cancer like yours, and we need to carry out this study to find out if it would be helpful. One of the reasons why there is currently no evidence is that few studies have been carried out in this type of cancer.

WHY AM I BEING INVITED TO TAKE PART?

You are being invited to take part because you have been diagnosed with upper tract urothelial cancer and have had a nephro-ureterectomy. Your doctor feels that you are suitable for either close observation or immediate chemotherapy and therefore could participate in this study. Hospitals all over the UK are taking part and 345 people like you will be included in this study.

DO I HAVE TO TAKE PART?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are free to withdraw from the study at any time and do not have to give a reason. This will not affect the standard of care you receive.

WHAT WILL HAPPEN TO ME IF I TAKE PART?

In this study we will compare two groups of people. One group will be kept under close observation after their operation with frequent check ups (surveillance) and may be given chemotherapy in the future if their cancer returns. The other group will start chemotherapy treatment in the first three months after their operation.

Randomisation

There are advantages and disadvantages to both close observation and chemotherapy. The best way to compare them is to have similar groups of patients having each of the treatments. This allows us to be sure that if one group fares better than the other group, it is because of the treatment, and not because the patients in the groups are different from each other in some way.

Everyone who agrees to take part in this research study will be allocated to one of two groups of patients. The only way to make sure that the groups of patients are as similar as possible is to have your treatment decided upon by chance: a process called randomisation. This process ensures that surveillance and chemotherapy are compared fully and fairly. You will have an equal chance of being in either group. If you agree to take part, your POUT trial specialist (this could be your doctor or nurse) will ring the research centre. The centre will then record your details and tell your specialist your treatment. You will be told which group you are in straight away.

It is important for the study that you only agree to be randomised if you believe you would be willing to accept either close observation or chemotherapy, as follow-up care. This is important because only data from patients who receive their randomised treatment can be used in the most important analyses to determine future policy for patients with upper tract urothelial cancer. You should continue to discuss randomisation and the treatments with your doctor or nurse until you are sure all your questions have been answered. You will be given time to ask all the questions you want. It is important to remember that you are considered to be suitable to receive either close observation or chemotherapy.

It is best for the study that as many patients as possible agree to be randomised and accept the treatment allocated to them. However, if you are not sure when you are told your treatment allocation that you can accept it straight away, you will be able to discuss the treatment further with your POUT specialist. If you do not want to have your treatment decided by randomisation, you will be able to discuss your options with your doctor.

If you chose to enter the study you will not chose whether you have close observation or chemotherapy and will have an equal chance of receiving either treatment.

Whichever group you are allocated to you will be treated with the best possible care and will be monitored closely. The two groups that you may be in are described below.

Group 1: Close-observation/surveillance

If you are in the surveillance group you will be kept under close observation with frequent check-ups by your medical team for the cancer returning in your bladder or elsewhere. You will only receive further cancer treatment (which may include chemotherapy), if your cancer returns. If this happens, your medical team will discuss with you the best treatment for your circumstances. The timing of your appointments will be similar to timings if you did not participate in POUT, and what each appointment will involve is described in the section ‘How many times will I need to visit the hospital’ below.

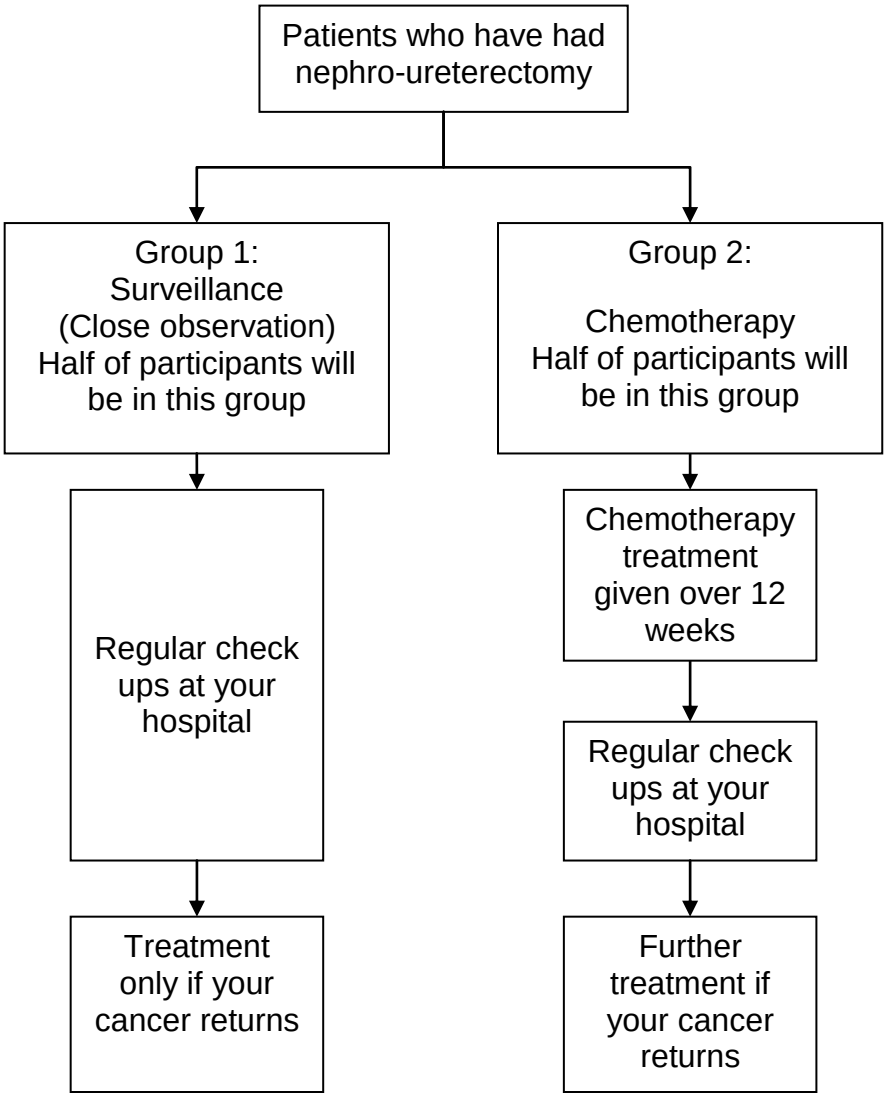
Group 2: Immediate Chemotherapy

If you are in the chemotherapy group you will receive a combination of chemotherapy drugs given over 12 weeks. The chemotherapy treatment will start as soon as possible after you have recovered from your surgery. This could be up to 90 days after your operation. The chemotherapy course will be split into four cycles, which last three weeks each. Each cycle includes the time when you have your chemotherapy treatment and then a break before the next treatment begins.

You will receive a combination of two drugs (gemcitabine and cisplatin or gemcitabine and carboplatin) on the first day of each cycle. Whether you are given cisplatin or carboplatin will depend on how well your kidney is working at the time. You will then be

given gemcitabine on its own on the eighth day. The next cycle of treatment will begin two weeks after this.

Figure 1. POUT Trial diagram



What are the side effects of chemotherapy?

The chemotherapy is likely to have some side effects. If you receive chemotherapy, you may experience some of the side effects listed below, but no-one can predict before you begin treatment whether you will have any of these, or how serious they might be. Your oncologist will support you through the treatment and prescribe additional medications if you experience problems with the chemotherapy.

It is important that you tell your hospital doctor or research nurses about any problems you have at each visit. Their telephone numbers are at the end of this information sheet

(p10). There is also 24 hour support available from your hospital for patients experiencing side effects.

The common side effects of the chemotherapy you could receive as part of POUT are listed below. Many go away shortly after the drugs are stopped and experiences vary very much from one patient to another.

Very likely

- Nausea: some people feel sick, or are sick, but this usually only lasts for a few hours. You will be given anti-sickness medication at the same time as your chemotherapy treatment to help prevent this (called anti-emetics).
- Hearing changes: cisplatin can cause loss of the ability to hear some high-pitched sounds.
- Flu like symptoms
- Feeling tired
- Increase in the risk of getting an infection.
- Shortness of breath (usually mild and doesn't need treatment)
- Sore mouth
- Itchy skin rash
- Fluid retention
- Some hair loss (less common compared to other chemotherapy regimens)

Less likely

- Diarrhoea or constipation. These can be easily controlled with medicines that your doctor can give you but remember to drink plenty of fluids if you have diarrhoea.
- Lung inflammation
- Kidney problems: cisplatin can cause kidney problems, so you will only be given it if your kidney is working well. It is given with fluids through a vein to reduce the chance of any kidney damage occurring.
- Tingling or numbness in your hands or feet

<u>How many times will I need to visit the hospital?</u>
Whichever group you are in, you will have exactly the same close follow up and you will be seen regularly by your Cancer Specialist and/or nurse after you join the study. Each visit will involve having medical investigations to check on your state of health. These will include chest x-rays, CT scans and cystoscopies (an internal examination of the bladder using a small viewing tube). You will be seen every 3 weeks up to 3 months after you join the study, then at 6 and 9 months in year one, every six months from year one to year three, and yearly after that.

During the first 3 months after you join the study, if you are receiving chemotherapy you will have regular blood tests and assessments of any side effects or symptoms you are experiencing. These will take place at the end of each of your first three 3 week cycles of treatment to make sure that you are well enough to receive your next cycle. If you

are in the surveillance group, you will also have 3 assessments every 3 weeks during the first 3 months, to collect information about any symptoms you may be experiencing.

Details of the investigations involved in each later visit are shown in the table below.

Time from joining study (months)	**3**	**6**	**9**	**12**	**18**	**24**	**30**	**Year 3**	**Year 4**	**Year 5**
Physical examination	✓									
Chest X-ray or CT scan	✓*	✓	✓	✓	✓	✓	✓	✓	✓	✓
Cystoscopy		✓		✓	✓	✓		✓	✓	✓
CT scan of pelvis	✓	✓		✓	✓	✓		✓	✓	✓
Symptom assessment	✓	✓		✓	✓	✓				
Blood sample	✓	✓	✓	✓	✓	✓				

*CT scan at this visit

Chemotherapy group - pregnancy, contraception and the POUT study

Barrier method contraception (intra-uterine device (IUD) and condom, diaphragm with spermicide and condom) should be used if you or your partner are likely to become pregnant, while taking part in the POUT study. If you have any questions about what type of contraception to use, please speak to your doctor.

Women: You should inform your doctor immediately if you are pregnant or become pregnant when taking part in the POUT study.

Men: if your partner becomes pregnant during the study or within 1 year of you stopping treatment, you should inform your doctor immediately as chemotherapy affects the normal formation of sperm.

WHAT DO I HAVE TO DO NOW?

If you agree to take part in the POUT study you will be asked to sign a consent form. You will also be asked if you would like to take part in the sub-studies which are detailed in pages 11-13.

Your treatment will be decided using the randomisation method described above and will either receive surveillance or chemotherapy. You will be closely monitored and you will be seen regularly by your doctor at the hospital. These visits are part of standard care and there is no additional funding to pay for travelling or other expenses.

WHAT ARE THE ALTERNATIVES FOR TREATMENT?

Most hospitals in the UK will offer surveillance following surgery for people who have your type of cancer. If you decide not to take part in this study your doctor will discuss with you what treatments your hospital offers and the best option for your circumstances.

WHAT ARE THE POSSIBLE RISKS OF TAKING PART?

This study requires you to receive regular chest x-rays and CT scans. Before you join the study, and if you receive chemotherapy, your kidney function will be assessed to check you are suitable for this treatment. This assessment may be done using a radioisotope test.

You will have an extra CT scan of the chest, abdomen and pelvis 3 months after joining the study that you may not otherwise have. All other CT scans are according to European guidelines. Some hospitals in the UK conduct a different number of scans for patients who are not in POUT. If you are being treated at one of these hospitals, your scans will be as shown in the table on page 6 of this leaflet. If you are concerned about this at all, please discuss it with your local POUT specialist.

Chest x-rays, CT scans and radioisotope tests all use ionising radiation. Ionising radiation may cause cell damage which can, after many years or decades, cause cancer. Due to the amount of time it would take for any cancer to develop as a result of the extra CT scan, it is highly unlikely that you will notice any changes to your health because of participation in this study.

If you have private medical insurance and/or life insurance you should contact your insurers before agreeing to take part in the study. This is to ensure that your participation will not affect your insurance cover.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

Your doctors feel that your participation in this study will give you at least as good a chance as you might expect from other available options. We hope that your allocated treatment will help you but this cannot be guaranteed. The information learned from this study may help us to improve treatments for future patients with upper tract tumours.

WHAT IF SOMETHING GOES WRONG?

Every care will be taken in the course of this clinical trial. If you are not happy with the general care and treatment you receive during the study, please speak first to your study doctor, who will try to resolve the problem. If you remain unhappy and wish to complain formally about the care and treatment received during the study, you may do so under the standard NHS complaints procedure which is available to you from your study doctor's hospital.

If you suffer any side effects or injury, please notify your doctor immediately so you can obtain appropriate medical attention.

In the unlikely event that you are injured by taking part, compensation may be available.

If you are harmed due to the negligence of someone treating you, then you may have grounds for legal action for compensation. NHS Trusts are responsible for clinical negligence and other negligent harm to individuals that are under their care and covered under the NHS Indemnity Scheme.

If you suffer adverse side effects of the trial medication or harm caused by procedures you have undergone specifically for the trial you may be able to claim compensation from The Institute of Cancer Research. In deciding the level of compensation to be awarded, consideration will be given to the likelihood of side effects and any warnings that were given.

Concerns should be raised by speaking to a member of staff at your hospital or by talking to your local Patient Advice and Liaison Service (PALS). **[NOTE TO CENTRES: PLEASE DELETE THESE PARENTHESES WHEN ADAPTING PIS TO CENTRE SPECIFIC DOCUMENT AND REPLACE PALS INFORMATION WITH EQUIVALENT LOCAL ORGANISATION IF CENTRE IS OUTSIDE ENGLAND]**.

WILL MY TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?

Your medical notes will be seen by authorised members of the research team at your hospital, so that they can collect information needed for the POUT study. When you join the study, your name, date of birth, postcode, hospital number and NHS or Community Health Index (CHI) number will be passed to the Institute of Cancer Research Clinical Trials and Statistics Unit (ICR-CTSU) where the study is being coordinated. You will be given a unique registration number, which will be used together with your initials and date of birth on forms that the research staff will send to the trials office. All information about you will be coded with the registration number and will be stored securely. It will be treated as strictly confidential and nothing that might identify you will be revealed to any third party.

Scientific and medical employees of ICR-CTSU, and those conducting the study with them or members of regulatory bodies, may need to examine your medical records to ensure the study is being run properly and that the information collected on the forms is correct, but your confidentiality will be protected at all times.

We will contact your hospital over the years to find out how you are getting on. Ideally we would like to do this for life, but patients often change address and/or GP or lose touch with their hospital, so we would also like to ask your permission to collect information about your diagnosis and future health from national electronic records which are kept on everyone's health status. One of these is held at the General Register Office (GRO). We will need to give them enough information to identify you. This is usually your name, date of birth and NHS number (or Community Health Index and/or hospital number in Scotland). Any details we receive from any source are confidential

and will only be used for the purposes of the POUT study. Please initial the consent form to show that we have your permission to do this.

All the information that is sent to the ICR-CTSU will be kept until 15 years after the POUT study has ended.

Data sharing

The organisers of this study would like to be able to combine information we collect about patients in this study with information collected for other studies, if in the future it is a useful way of advancing our knowledge of the treatment of cancer. If this happens, information about you may be passed to other researchers, but they would not be able to identify you from the information provided.

WHAT IF NEW INFORMATION RELATING TO THE STUDY BECOMES AVAILABLE?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw your doctor will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form. Also, on receiving new information your doctor might consider it to be in your best interests to withdraw you from the study. If this happens, he/she will explain the reasons and arrange for your care to continue.

WHAT IF I DO NOT WANT TO TAKE PART IN THIS STUDY?

Participation in this trial is entirely voluntary. If you decide not to take part you do not need to give reasons for your decision and it will not affect your future treatment in any way. Your legal rights are not affected by participating in this study.

WHAT HAPPENS IF I CHANGE MY MIND DURING THE STUDY?

You are free to withdraw from the study at any time. You do not have to give a reason and your future treatment will not be affected. Your doctor will discuss your treatment with you and will offer the most suitable treatment available. However, if you were to withdraw, we would like your permission to continue to collect information on your progress that is routinely recorded in your medical records. This is so that the overall quality of the study is not impaired.

WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?

Independent experts will review the progress of the research, and the results will be published in a respected journal as soon as there is enough information to be sure the results are reliable. You will not be identified in any report or publication. The results will help to decide how to treat upper urinary tract cancer in the future. Studies like these are often used in cancer research.

Your hospital will write to you when the results are known to ask if you would like to see them. The letter will explain how to get a copy. The results of this study are not likely to be available for at least 5 years.

WHO IS ORGANISING AND FUNDING THE RESEARCH?
This research study is being carried out by The Institute of Cancer Research (Chief Investigator Dr Alison Birtle). The study is approved and funded by Cancer Research UK.

WHO HAS REVIEWED THE STUDY?
The protocol has been approved by the National Research Ethics Service Committee North West - Greater Manchester South. This committee is responsible for making sure that research with patients is appropriate and that the participant's rights and welfare are protected.

WHAT DO I HAVE TO DO NOW?
You will have some time to think about the trial and make your decision. You may wish to discuss it with your family, friends, GP or research nurse. If, at any time, you have any questions about the study you should contact your POUT specialist.

WHAT IF I HAVE OTHER CONCERNS?
If you have any questions you would like to ask about this study please contact your local POUT specialist.

Your local POUT specialist is:
Address:
Telephone:
24-Hour Contact Number:
Email:

Information on all aspects of cancer care is also available on MacMillan Cancer Support's patient website http://www.macmillan.org.uk/Home.aspx.

If you agree to participate in the main trial, you will be invited to take part in one or more of the following sub-studies.

1. Looking at Quality of Life
2. Looking at surgical samples and scans

IF I WANT TO BE PART OF THE POUT STUDY, DO I HAVE TO TAKE PART IN THE SUB-STUDIES?
No. Taking part in POUT does not mean you have to take part in the sub-studies. You will be given the chance to discuss POUT and you can then decide whether you want to take part.

The following pages of this information sheet give further information about these sub-studies.

Optional components to the study:

1. Looking at Quality of Life
It is important to look at how chemotherapy treatment or surveillance might affect your life and general well-being ('quality of life'), so we would like to find out about any side effects you have and the way you feel, both physically and emotionally.

If you agree to take part in the Quality of Life study, you will be asked to fill in some short quality of life forms asking about your quality of life and general health.

What are quality of life forms?
These are standard questionnaires, which we would like you to complete, in order that we can learn how the treatment in this study might affect your quality of life. Some of the questions may seem a little repetitive, but we would ask you to be patient and complete all the sections as best as you can.

When do I have to fill them in?
This part of the study is voluntary, but we hope that most people will be willing to complete these questionnaires. We would like you to complete the questionnaires at the beginning of the study, 7 weeks after joining the study and then 3, 6, 12 and 24 months after you joined the study.

The first questionnaires will be given to you by your hospital. From 6 months onwards questionnaires will be posted to you at your home address by the Clinical Trials & Statistics Unit at The Institute of Cancer Research (ICR-CTSU).

Before sending you the questionnaire ICR-CTSU will contact your hospital or GP to check how you are; therefore we would like to ask for your permission to give ICR-CTSU your full name and address as well as your GP's name and address. If you agree to this please initial the consent form to show that we have your permission.

2. Looking at tissue, blood and urine samples

Upper tract urothelial cancer is an unusual type of cancer and we still have a lot to learn about it: how it develops and how it behaves. We would like to ask you to donate samples to help researchers learn more. If you decide to do this, you would be consenting to:

a) Give medical researchers a sample of tissue removed during your surgery (nephro-ureterectomy), so they can complete their analysis.
b) Give 4 extra blood samples before you join the study, 6 months after you join and if you have a recurrence of your cancer (about 10 mls each)
c) Give one first morning urine sample before you join the study, 6 months after you join and if you have a recurrence of your cancer

Your hospital may or may not be collecting all of these samples. For more information please discuss this further with your local POUT specialist.

If you agree to donate to our sample collection, researchers at the University of Birmingham and University of Sheffield will have access to your biological samples. They will not have access to your personal details. We are also asking for your consent so that researchers in the future may be able to re-analyse these samples, without the need to contact you further about this. Please read below for further details about this optional study.

We would like to use the samples from your surgery to find out more about the changes in DNA and genes that may cause upper tract urothelial cancer, and the knock-on effects that these changes have on the tumour cells themselves. This could lead to the development of new ways to treat this cancer.

We would also like to identify biological markers that would help us to predict how each person's tumour will behave, or whether some treatments may be better than others for some people.

Some of these markers may also be found in blood or urine, which could help us to develop accurate new tests for finding out whether treatment is being successful or for finding out very early if the disease is returning.

POUT gives us the opportunity to ask many people with cancer similar to yours whether we can collect samples that will aid this type of research, and other research into this type of cancer in the future.

Following your surgery, your hospital will have kept a sample of what your surgeon removed. We are asking for your permission to collect this, so that we can look at it in combination with samples from other people who have joined the study. This will allow us to test for genetic differences in the make-up of individuals and their cancer that may indicate why they develop cancer and predict how they react to treatment. If we show that genetic differences do explain why some patients develop this cancer or react to their treatment differently, this knowledge could help many patients in the future. Any

genetic analysis would be for research purposes only and will not affect any insurance you may hold.

In a similar way, we would also like to take samples of blood and urine before your surgery and again 6 months later (if your centre is participating in this aspect of the study). Samples will be taken routinely at these visits anyway by the doctors and nurses looking after you - we would like to take an extra 4 small tubes of blood and a tube of urine on each of these two occasions. Unfortunately, for some patients we know that the cancer does come back many months or years after surgery. If this happens, samples will be taken routinely by the doctors and nurses looking after you, and we would like to take an extra 4 small tubes of blood and a tube of urine for this study at the same time.

What will happen to the samples taken as part of this study?
Samples will be transferred to a central facility at the University of Birmingham. The samples will be stored securely and will be given a code, so that researchers receiving the samples do not know your name or any other personal details. This code will be used to link your samples to the information we collect about your treatment.

The samples collected will be used, first and foremost, for the research described above as part of the POUT study. This research will be carried out at the University of Birmingham and the University of Sheffield.

It is possible that in the future other research may be carried out on the samples collected within this trial. You may grant advance authorisation for possible future research, with the understanding that your personal details will not be shared and that prior approval of an ethics committee will be obtained. We may in the future share the information we gain from the samples you provide, including genetic details, with other researchers investigating this type of cancer. You will not be identifiable from this information. Please initial the consent form if you are happy for this information to be shared.

On the other hand, you can refuse consent to storage and future research on your samples except for the needs of the research described above.

What do I have to do?
Please initial the consent form if you agree to the donation of these samples. Donation is voluntary and if you decide against it, it will not affect your treatment in any way and you can still take part in the main POUT study.

Looking at scans
We would also like to ask your permission to collect a copy of the CT scan which you had before your surgery. If you agree, this will be compared with the scans of everyone else who agrees to allow us to collect their scan, to try and find out if these pre-operative scans provide an indication of how well people do after receiving treatment.

If you decide to take part in this study, you are agreeing for researchers to have access to this scan for research purposes. This scan will be taken anyway – it is up to you to decide whether or not you are willing for it to be used for research purposes.

POUT

Peri**O**perative chemotherapy or s**U**rveillance in upper **T**ract urothelial cancer

Consent Form

MREC Study No: 11/NW/0782 Patient Trial ID:

Name of Clinician: ……

Please initial box

1.	I confirm that I have read and understand the patient information sheet version 4.1 dated 11/03/2014 for the above study and have had the opportunity to ask questions.	☐
2.	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.	☐
3.	If I withdraw from the study, I consent to my doctor providing authorised researchers with basic clinical information that would be routinely collected and written in my medical records.	☐
4.	I understand that sections of any of my medical notes may be looked at by responsible individuals from the research team or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.	☐
5.	I agree to my GP being informed about my participation in this study.	☐
6.	I consent to the Institute of Cancer Research using information held by the NHS and the General Register Office (GRO) to keep in touch with me and follow up my health status.	☐
7.	I agree to participate in the above study.	☐
8.	Data sharing: I grant advance authorisation for the possible future sharing of information collected about me with other organisations, with the understanding that I will not be identifiable from this information *(optional)*.	☐
9.	I consent to a copy of the CT scan taken before my surgery being sent to the Institute of Cancer Research *(optional)*.	☐
10.	I consent to the gifting of tissue left over from surgery to be sent to the University of Birmingham for research in this study *(optional)*.	☐
11.	I consent to the gifting of blood and urine samples to be sent to the University of Birmingham for research in this study *(as applicable / optional)*.	☐
12.	I grant advance authorisation for possible future research on my stored samples with the understanding that I will not be identifiable from these samples and that prior approval of an ethics committee will be obtained *(optional).*	☐

Name of Patient	Date	Signature
Name of person taking consent (if different from researcher)	Date	Signature
Researcher (PI)	Date	Signature

POUT

Peri**O**perative chemotherapy or s**U**rveillance in upper **T**ract urothelial cancer

Quality of Life Study Consent Form

MREC Study No: 11/NW/0782 Patient Trial ID:

Name of Clinician: ……

Please initial box

1. I confirm that I have read and understand the patient information sheet version 4.1 dated 11/03/2014 for the above study and have had the opportunity to ask questions. ☐

2. 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. ☐

3. I consent to researchers from The Institute of Cancer Research being sent my address and GP contact details. ☐

4. I consent to researchers from The Institute of Cancer Research contacting my GP to confirm I am fit and well to receive questionnaire booklets to be sent out by post. ☐

5. I consent to my GP disclosing my health status to researchers from The Institute of Cancer Research. ☐

6. I consent to a copy of this form being sent to my GP, and to the Quality of Life Study Coordinator based at The Institute of Cancer Research. ☐

Name of Patient	Date	Signature
Name of person taking consent (if different from researcher)	Date	Signature
Researcher (PI)	Date	Signature