

# **InPACT**

## **Patient Information Sheet**

### **InPACT-pelvis**

International Penile Advanced Cancer Trial  
(International Rare Cancers Initiative study)

An international study looking at the treatment of cancer of the penis  
that has spread to pelvic lymph nodes.

This study forms part of the National Cancer Research Network's  
portfolio of approved studies. This research is funded by Cancer  
Research UK.



# InPACT Study Patient Information Sheet

## **We are inviting you to take part in a clinical study**

- Before you decide whether 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. Discuss it with friends and relatives if you wish. Take time to decide if you wish to take part.
- You are free to decide if you want to take part in this research study. If you choose not to take part, this will not affect the care you get from your own doctors in any way.
- You can decide to stop taking part in the study at any time without giving a reason.
- This information is designed to be read together with discussions with your doctors. Ask your study doctor if anything is not clear or if you would like more information.

## **Why am I being invited to take part?**

- You have been diagnosed with cancer of the penis which has spread to your lymph nodes ("glands") and have already participated in the first part of the InPACT trial – InPACT-neoadjuvant.
- This patient information sheet contains detail relating to the second part of the InPACT-trial – InPACT-pelvis.
- You have been given this information sheet to read because you have recently had an operation to remove lymph nodes from one or both groins as part of InPACT-neoadjuvant. Your doctor will have told you that some of these lymph nodes contained cancer that has spread to them from the cancer that started in your penis. If cancer cells appear in the lymph node next to your cancer then this means that the cancer has spread from where it first developed and may be ready to travel around the lymphatic system to other parts of the body. It is very important therefore that we try very hard to stop this happening.
- We hope that all the cancer has been removed from your operation, but we know that there is chance that it could return.

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## **How to contact us**

If you have any questions about this study, please talk to your doctor at  
Hospital Department  
Hospital  
Address  
Address  
Tel: 01234 XXX XXX

# PART 1

***Please read part 1 of the information sheet fully. If you are interested in the study and wish to know more, please continue to read part 2 prior to making your final decision to take part in this trial.***

***You have already participated in InPACT-neoadjuvant and received a patient information sheet prior to taking part in the trial with information relating to the entire InPACT trial, anatomy of your type of cancer and how randomisation works. Please refer back to the InPACT-neoadjuvant information sheet if you wish to do so.***

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## 1 What is the purpose of InPACT-pelvis?

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We want to see if we can improve the treatment of patient with penis cancer like yours. The InPACT trial is examining the combination and sequence of four common treatments for men in this situation across two separate randomisations, InPACT-neoadjuvant and InPACT-pelvis. You will have already participated in InPACT-neoadjuvant. InPACT-pelvis, the second randomisation, is studying extra treatment that we can give at this stage (after your inguinal lymph node surgery 'ILND'). It is possible that this treatment might reduce the chance of your cancer returning or spreading elsewhere in the body.

It is not uncommon to have a range of possible treatments for a given illness and for doctors not to know which is best. InPACT-pelvis will help us to determine if having additional surgery to remove the lymph nodes deeper in the pelvis is better than not having this additional surgery. It is not known if there are benefits of the additional surgery and this study will help to determine this for patients in the future.

We hope that this information sheet will help you to understand all of the options.

This study is taking part in a number of hospitals across the UK together with hospitals in North America, Canada and Europe. Approximately 200 men will take part in this study.

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## 2 What are the treatments being tested in InPACT-pelvis?

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Each treatment being tested in the study is described below. InPACT-pelvis is the second part of the InPACT study. You have already taken part in InPACT-neoadjuvant which involved treatments numbered 1-3. Treatment 3, chemoradiotherapy, is also given as part of InPACT-pelvis but only if it was **NOT** received previously in InPACT-neoadjuvant before your ILND surgery.

### **Treatment No. 3: Chemoradiotherapy**

Where applicable, patients in this part of the trial attend the radiotherapy department each working day for 5 weeks. Each visit involves 5 minutes of treatment with very high energy X-rays (radiotherapy). The treatment is delivered by a large machine (a bit like having a scan) and it is painless. Patients in this part of the study will also spend one day per week (approximately 5 hours) having chemotherapy (cisplatin) via a drip into a vein in your arm or back of your hand; the purpose of this is to help the radiotherapy to work better.

### **Treatment No. 4: Surgery to the lymph nodes in the pelvis (“Pelvic Lymph Node Dissection” or “PLND”).**

The lymph nodes in the groins are linked to lymph nodes deeper in the pelvis. Those lymph nodes may also become involved by the cancer, and this operation is intended to remove the pelvic lymph nodes on the affected side (or sides).

The operation to remove pelvic lymph nodes ("pelvic lymph node dissection" or “PLND”) is performed either by cutting through the front of the abdomen or sometimes as a keyhole surgery operation. Your surgeon will advise on which operation is appropriate for you. You will be in hospital for several days, and it will take a few weeks to recover from it.

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## 3 Summary of possible side effects and risks

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It is important to understand that it is the treatments themselves that contain the side effects, and that these are treatments that are all in regular use. The side effects and risks described in this section would, therefore, apply equally whether you received your treatment as part of the trial or as part of routine (ie non-trial) treatment.

A summary of the risks and side effects associated with each treatment are summarised in the table below. Where applicable, further detail on the listed side effects is provided below the table.

For chemotherapy related side effects the table lists how ‘common’ they are:

- **Very common:** approximately 1 in 10 people will experience this side effect
- **Common:** approximately 1 in 10 to 1 in 100 people will experience this side effect
- **Less common:** less than 1 in 1000 people will experience this side effect

| <b><u>Possible risk/side effect</u></b>  | <b><u>Treatment</u></b>                              |                                     |
|--|--|-------------------------------------|
|  | <b><u>Chemoradiotherapy<br/>(treatment no.3)</u></b> | <b><u>PLND (treatment no.4)</u></b> |
| May cause leakage of fluid from the groin  | ✗  | ✓                                   |
| Collection of fluid in surgical wound  | ✗  | ✓                                   |
| Swelling of leg, groin or genitalia (lymphoedema)  | ✓  | ✓                                   |
| Surgical wound infection   | ✗  | ✓                                   |
| Localised collection of blood outside blood vessels due to surgery (haematoma or bruise) | ✗  | ✓                                   |
| Blood clots forming in the veins (venous thromboembolism)                                | ✓<br><i>Common</i>                                   | ✗                                   |
| Edges of the wound may degenerate (necrosis).  | ✗  | ✓                                   |
| Decrease in the number of white blood cells (neutropenia)                                | ✓  | ✗                                   |
| A decrease in platelets in the blood (thrombocytopenia)                                  | ✓<br><i>Very common</i>                              | ✗                                   |
| A decrease in the number of red blood cells (anaemia)                                    | ✓<br><i>Very common</i>                              | ✗                                   |
| Allergic reaction  | ✓<br><i>Less common</i>                              | ✗                                   |
| Fatigue  | ✓<br><i>Common</i>                                   | ✗                                   |
| Damage to nerves or kidneys  | ✓<br><i>Less common</i>                              | ✗                                   |
| Loss of hearing or persistent ringing in the ears (tinnitus)                             | ✓<br><i>Less common</i>                              | ✗                                   |
| Radiation skin reaction/sore skin in the groins or scrotum                               | ✓<br><i>Very common</i>                              | ✗                                   |
| Damage to the bones of the pelvis  | ✓  | ✗                                   |
| Bowel changes  | ✓  | ✗                                   |
| Bladder inflammation   | ✓  | ✗                                   |
| Diarrhoea  | ✓  | ✗                                   |
| Constipation   | ✓  | ✗                                   |

|   |   |   |
|---|---|---|
| Sickness/vomiting                                 | ✓ | ✗ |
| Inflammation/soreness of mouth or gut (mucositis) | ✗ | ✗ |

Almost all patients undergoing cancer treatment have CT Scans to see what is happening to their cancer, and you will, therefore, have scans as part of your participation in this study. You may, however, receive one extra CT scan compared to routine (non-trial) care, so that we can follow the response of your cancer more closely.

Exposure to any radiation could lead to another cancer much later in life, usually after a delay of somewhere between a few years and several decades. The additional risk to you, however, is very small, partly because of your existing condition, and partly because the risk from an extra scan is much smaller than the potential benefit of the treatment.

### **Treatment No. 3 (Chemoradiotherapy): possible risks**

You will receive radiotherapy as part of your treatment in this study. You will experience a radiation skin reaction, a bit like sunburn, to the skin in the groins by the end of the radiotherapy treatment. This is often quite uncomfortable, and may require creams and pain killers. This radiotherapy treatment may cause some scarring to the tissues in the groin in the long term, and it can cause some permanent damage to the bowel if the radiotherapy passes through the pelvis (the pelvis is the lower part of your trunk).

While the chemotherapy drugs are acting on the cancer in your body they also temporarily affect your blood. This can cause:

- A decrease in the number of white blood cells (neutropenia). White blood cells are the part of the blood that protects us against infection, so if these are low, this can increase the risk of infection.
- A decrease in platelets in the blood (thrombocytopenia). Platelets are one of the things in the blood that help it to clot. You may notice that you bruise more easily if the platelets are low.
- A decrease in the number of red blood cells (anaemia). Patients may feel tired or look pale, and some patients need a blood transfusion during or just after chemotherapy.

CT scans are used to plan and guide the radiotherapy so that it is delivered as accurately as possible – in fact we have tried to ensure that radiotherapy given in this trial is delivered to the highest international standards. The planning CT scans do involve a very small additional amount of radiation, but this is minimal compared to the radiation actually being used to treat the cancer.

There are other less common reactions, including allergic reactions, fatigue, damage to nerves or kidneys, and loss of hearing or a persistent ringing in the ears (tinnitus). Long term side effects from this treatment are relatively rare.

### **Treatment No. 4 (PLND): possible risks**

The complications include infections and swelling of leg or groin or genitals.

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## 4 What will happen if I take part in the study?

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If you are interested in taking part you will want to speak to someone to make sure that you fully understand what will happen in this study. Your hospital doctor will give you this opportunity and if you agree to take part in this study you will be asked to sign a consent form.

***This completes Part 1 of the Information Sheet.***

***If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making a decision.***

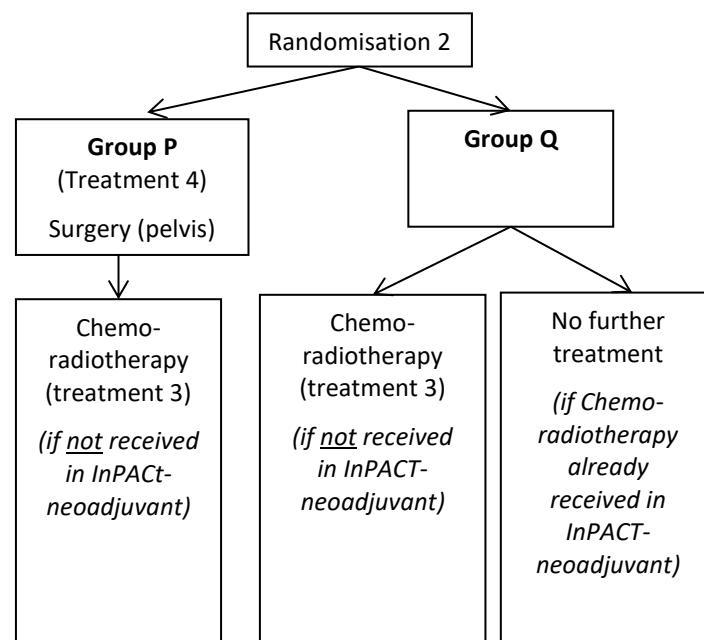
# PART 2

## 1 What will happen if I take part in the study? (continued)

You will have had surgery to remove groin lymph nodes. Those lymph nodes have been examined by a pathologist to see how many are actually involved by the cancer. This has shown that there is a high risk of the cancer spreading further and InPACT-pelvis is being discussed with you. Your doctor will discuss the alternative treatment options with you if you chose not to enter InPACT-pelvis.

**InPACT-pelvis:** compares two different options for treatment.

The treatment you receive is not decided by you, your doctor or any other person: the choice is made at random (by a computer) at the time you enter the trial, the equivalent of tossing a coin. This is the best way to make sure that the patients in the two groups are as similar as possible. If one group fares better than the other group, it is more likely to be because of the treatment, rather than because the patients in one group are somehow different from those in the other group. You will be randomly allocated to one of the following two options:



**Group P:** Treatment No. 4: immediate removal of the pelvic lymph nodes at an extra operation. Patients should then have chemoradiotherapy after Treatment No. 4 if not already received in InPACT-neoadjuvant.



**Group Q:** Surveillance: if required patients will receive Chemoradiotherapy (treatment no.3). If not required (chemoradiotherapy previously given), you will receive no further treatment at this time.

**After treatment:** You will be asked to return to the outpatient clinic at various time-points after treatment, for up to 5 years following the commencement of study treatment. These visits are considered part of standard care and they are not just because you are taking part in this study. Your doctor will decide which tests need to be done at or between these visits to monitor your cancer.

The set-up for the treatment of penile cancer nationally means you may be required to travel to different hospitals for your different treatments. You may, for example, have to a specialist hospital for your surgery, but it may be possible for chemoradiotherapy to be administered at a hospital more local to you. Your doctor will discuss with you where your treatment will be delivered.

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## 2 How to decide whether to take part in this study

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### **What are the benefits and risks of taking part?**

There is no guarantee that you as an individual will benefit directly. The options for treatment in this study have been very carefully considered by a group of experts from around the world. We hope that we can improve the treatment of penis cancer, but we cannot guarantee that everyone who takes part will benefit.

We hope the information we get from this study will help us to improve treatment for future patients with cancer of the penis.

There are risks involved when taking part in a research study. You may have side effects from the study treatment or feel discomfort from some of the study procedures. It is not possible to predict all of the risks and side effects that might happen if you take part in this study.

You will be asked to attend for extra tests, monitoring, and checks. You may also experience the side effects of treatment without the precise benefits of the treatment being known. You must also accept that you will be allocated to one of the different GROUPS of the study by a computer: you will not be able to choose which treatment you receive, you can only choose whether or not you wish to take part in the trial. This is essential to make the results of the study as reliable as possible.

If you have private medical insurance please check with the company before agreeing to take part to ensure that your medical insurance cover will not be affected.

### **What are the possible advantages and disadvantages of each option?**

**Group P** starts off with surgical treatment to the pelvis followed by chemoradiotherapy (if required).

Possible advantage: Removing the pelvic lymph nodes gives more information about how far the cancer has spread, which enables us to decide whether you should have extra treatment

Possible disadvantage: You may end up having both extra surgery *and* chemoradiotherapy – two treatments instead of one.

**Group Q** involves possible chemoradiotherapy to both the groin and the pelvis (if you have not received this in InPACT-neoadjuvant).

Possible advantage: the simplicity of having only one extra treatment - you avoid having an extra operation to remove the pelvic lymph nodes.

Possible disadvantage: You will definitely receive chemoradiotherapy to the pelvic region as well as to the groin. The side effects of this larger treatment could be worse than when chemoradiotherapy is only used on the groin.

### **Do I have to take part?**

No, it is up to you to decide whether or not to take part. If you agree to join then change your mind you can still withdraw without giving a reason. If you withdraw from the study you will still receive the best available standard treatment. It is routine for your GP to be told if you are taking part in this research.

### **Will I be asked to do anything else?**

If you agree to take part we will ask you whether you would like to take part in a Quality of Life study and Tissue collection. These optional substudies are explained fully in Part 2 of this information sheet.

You should use double barrier contraception (e.g. condom plus spermicide in combination with a diaphragm, cervical cap or intrauterine device) during your treatment and for 6 months following the last dose of your study treatment.

### **What are the alternatives for treatment?**

You and your hospital doctor should have discussed the treatment options available to you. Make sure you discuss all the available treatment options with your hospital doctor before deciding if you want to take part in this study. If you decide not to participate in the study, but your hospital doctor still feels that the treatment options in this study would be beneficial, it may be that you receive a combination of these.

### **What if there is a problem?**

Any complaint about the way you have been dealt with during this study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2 of this information sheet.

### **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 may 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.

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

Yes. All the information about your participation in this study will be kept confidential. The details are included in Part 2 of this information sheet.

**Contact Details**

If, at any time, you have any questions about the study you should contact your hospital team:

Local Consultants name: Address, Telephone [details to add]

Local Nurse name: Address, Telephone [details to add]

24 Hour Contact Number, 7 days a week [details to add]

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## 3 Quality of life sub study

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If you decide to take part in the InPACT study, we would like you to complete questionnaires as 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 questionnaires asking about your quality of life and general health. We will ask you to fill in a questionnaire before you are randomised, after pre-surgery chemotherapy or chemoradiotherapy (if receiving either treatment), after ILND surgery and then 12,18,24 and 36 months after your treatment commenced.

A member of your medical team will explain the questionnaire and answer any questions that you have. Some of the questions may seem to be a bit repetitive but these are standard questionnaires and we would ask you to bear with us and answer them as best you can.

You will be given all your questionnaires in the clinic and they should take about 20 minutes to complete. The information you provide in the Quality of Life study will be treated in the strictest confidence. If you subsequently change your mind and do not want to take part in the Quality of Life study you can still take part in the main InPACT study.

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## 4 Tissue collection

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Part of your cancer will have been removed before this study has been discussed with you, either a biopsy (removal of a small part of the cancer) to establish the diagnosis, or some or all of your penis as part of your treatment so far (partial or total penectomy). These samples are routinely stored (in a block of paraffin wax) in the pathology department of your hospital, even after it has been examined to give the diagnosis. You will not need to undergo any more surgery for this – we are just aiming to use what has already been taken. We would like you to agree to the donation of some of this stored tissue for future research. If you agree, the identification number of the sample and the hospital at which it is stored will be recorded. Tissue will not be collected

at this stage, until the trial organisers have been successful in obtaining funding, we are only asking for your consent at this stage.

It is expected that future studies may collect a small amount of the sample for use in research. This research will not benefit you directly, but may help doctors give a more personalised approach to future patients with penis cancer. This donation is optional, and your treatment will not be affected if you choose not to give these samples.

Any samples collected in this study will be stored indefinitely at the Orchid Research Tissue Bank, Barts Cancer Institute. Future research will be conducted on the samples collected within this study. This may include tests for genetic differences that may indicate why some people develop penis cancer and how they react to treatment. If we show that genetic differences do explain why some patients develop penis cancer or, react to their treatment differently, this knowledge could help many patients in the future. You are being asked to grant advance authorisation for possible future research, with the understanding that their confidential nature will be fully protected and that prior approval of an ethics committee will be obtained.

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## 5 Confidentiality

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### **Who will have access to my data?**

The Institute of Cancer Research is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly.

The Institute of Cancer Research will keep identifiable information about you for at least 5 years after the study has finished.

The Institute of Cancer Research's lawful basis for processing your information is for the performance of a task carried out in the public interest and it is necessary to process sensitive health and genetic information for the purposes of scientific research with appropriate safeguards in place to protect personal information, as required by the United Kingdom General Data Protection Regulation (UKGDPR).

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at [www.icr.ac.uk/our-research/centres-and-collaborations/centres-at-the-icr/clinical-trials-and-statistics-unit/transparency](http://www.icr.ac.uk/our-research/centres-and-collaborations/centres-at-the-icr/clinical-trials-and-statistics-unit/transparency).

**[Insert appropriate name for NHS site]** will collect information from you and your medical records for this research study in accordance with our instructions.

**[Insert appropriate name for NHS site]** will use your full name, hospital number, date of birth, postcode and NHS number (or Community Health Index (CHI) and/or hospital number in Scotland) to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study.

### **Will my taking part in this study be kept confidential?**

All information which is collected about you during the study will be kept strictly confidential. When you join the trial, your full name, hospital number, date of birth, postcode and NHS/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 trial ID number, which will be used together with your initials and date of birth on forms that the research staff at your hospital will send to ICR-CTSU. All information about you will be stored securely. It will be treated as strictly confidential and nothing that might identify you will be revealed to any third party. Only members of the research teams at your hospital and the ICR-CTSU will have access to the information that could allow this trial ID number to be linked to you.

From time to time, we would like to know how you are getting on. Ideally we would like to do this for life, and we would like to use national records, which are kept on everyone's health status to find this out. 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 postcode and NHS number (or Community Health Index (CHI) 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 trial. Please initial the consent form to show that we have your permission to do this.

Representatives from the ICR-CTSU, the NHS Trust relevant to your taking part in research, the Medicines and Healthcare products Regulatory Agency (MHRA), the ethics committee approving the trial, and third parties approved by ICR-CTSU (and which may have offices outside of the UK/EU) may need to see your hospital or clinic records to the extent permitted by applicable laws and regulations to make sure the information received is correct. All information will be kept confidential.

**[Insert appropriate name for NHS site]** will keep identifiable information about you from this study for at least 5 years after the study has finished.

If you receive radiotherapy in this study a copy of the imaging (such as CT, MRI and PSMA PET-CT) used to design your treatment plan will be sent to the Radiotherapy Quality Assurance team. The data is sent electronically by an NHS secure file transfer system and your name will not be included in any of the files sent. We need to send this information to the Quality Assurance team to make sure that radiotherapy given to patients is consistent across the different hospitals taking part. The organisers of this study may use the information and images (including any future imaging) for future research into radiotherapy treatment, but the information stored for future research will not contain your name.

**Will information about me be shared with other researchers?** When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations now or in the future. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and

researchers to conduct research in accordance with the [UK Policy Framework for Health and Social Care Research](#).

Your information could be used for research in any aspect of health or care, and could be combined with information about you from other sources held by researchers, the NHS or government. Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance.

Where there is a risk that you can be identified your data will only be used in research that has been independently reviewed by an ethics committee.

Our main privacy policy can be found at <https://www.icr.ac.uk/legal/privacy>. If you have any questions about your rights under the UKGDPR or how we use your information please contact our Data Protection Officer at [dataprotectionofficer@icr.ac.uk](mailto:dataprotectionofficer@icr.ac.uk).

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## 6 Further information

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### **What if something goes wrong?**

It is unlikely that anything will go wrong with your treatment or care, but if you wish to complain about any aspect of the way you have been treated during the course of the study you can do so using the normal NHS complaints procedure.

Healthcare professionals working on Clinical Trials are covered by NHS Indemnity and if you are harmed by taking part in this study you may have grounds for a legal action but you may have to pay for it.

If you do wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you. Concerns should be raised by speaking to a member of staff at your hospital or by talking to the local Patient Advice and Liaison Service (PALS) which has been established in every NHS Trust and Primary Care Trust (PCT).

Your progress will be watched closely and you will be offered whatever help is available to cope with any side effects. Occasionally some patients need a short stay in hospital for side effects to be treated, and on rare occasions these can be serious. If this were to happen, full details of what has happened will be reviewed carefully by the oncologist with overall responsibility for the InPACT study. These details will also be sent to the Medicines and Health Care Products Regulatory Agency (MHRA) who oversee the safety of people who take part in any research involving drugs within the UK. We are required by law to do this.

### **What happens if I don't want to carry on with 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 you the most suitable treatment available.

However, if you were to withdraw from treatment, we would like your permission for your hospital doctor to send us information on your progress and any further treatment that you receive to the Clinical Trials & Statistics Unit at The Institute of Cancer Research. This is to build up as complete a picture as possible of how patients with cancer of the penis are treated in the UK. We believe that it is important to know how individual teams manage their patients, placing our knowledge of penis cancer on a par with our knowledge of how doctors treat the much commoner cancers.

### **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 medical 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 penis cancer in the future. Studies like these are often used in cancer research.

The results of this study are not likely to be available for at least 5 years. If deemed appropriate at the time that the results are available, your hospital will write to you when the results are known to ask if you or a family member would like to see them. The letter will explain how to get a copy.

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

The research study is being carried out by a network of doctors across the UK. The trial is co-ordinated by the Institute of Cancer Research. The research is approved and funded by Cancer Research UK.

Your doctor will not receive any payments for including you in this research study. As the follow up visits in this study are considered part of your standard care there is no additional funding to reimburse any travelling or other expenses which may occur as a result of your taking part in this study.

### **Who has reviewed the study?**

The study has been approved by the London - Riverside Research Ethics Committee.

### **What do I have to do now?**

You will have some time to think about the study and make your decision. You may wish to discuss it with your family or friends. Please keep this information sheet and copies of the signed consent form. If, at any time, you have any questions about the study you should contact your consultant.

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## **7 Contacts for support**

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Healthtalk.org ([www.healthtalk.org](http://www.healthtalk.org)) is a registered charity where you can find out about what it's like to live with a health condition, by watching other people share their stories. You can look on their internet website to find out more about penis cancer. To do this, go to <https://healthtalk.org/penile-cancer/overview>.

ORCHID is a registered charity specialising in male cancer, providing information, support and advice. You can look on their internet website to find out more about penis cancer. To do this, go to <https://orchid-cancer.org.uk/> and select penile cancer. ORCHID also provide a national male cancer helpline to contact one of the ORCHID nurses on 0808 802 0010.

You can learn more about clinical trials on the Cancer Research UK's patient website ([www.cancerhelp.org.uk](http://www.cancerhelp.org.uk)).

Further information: Macmillan Cancer Support ([www.macmillan.org.uk](http://www.macmillan.org.uk)) is a registered charity providing information, emotional support and publications about all aspects of cancer for cancer patients and their families. You can contact one of their Cancer Information Nurse Specialists on the Macmillan Support Line; Freephone 0808 808 00 00, (8am – 8pm, 7 days a week). In addition to their nurses, the Macmillan Support Line also has other specialist teams that can provide advice and information relating to welfare benefits, financial issues and everyday practical concerns.

***Thank you for interest in our research.***



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## 8 Glossary

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|---------|--|
| CT scan | Computerized Tomography scan                         |
| GP      | General Practitioner                                 |
| ILND    | Inguinal Lymph Node Dissection                       |
| InPACT  | International Penile Advanced Cancer Trial           |
| MHRA    | Medicines and Health Care Products Regulatory Agency |
| NHS     | National Health Service                              |
| PALS    | Patient Advice and Liaison Service                   |
| PCT     | Primary Care Trust                                   |
| PLND    | Pelvic Lymph Node Dissection                         |