Imperial College London

CHRONOS

TRUST LOGO

Affix patient sticker here

Version: 4.0 08th October 2019
Protocol Number: 19CX5006
IRAS Number: 257246
REC Reference: 19/LO/0712
Sponsor: Imperial College London
Principal Investigator: <<Insert Principal Investigator>>

IP 4 – CHRONOS
Comparative **H**ealth **R**esearch **O**utcomes of **NO**vel **S**urgery in prostate cancer

CHRONOS-A is a comparison of Radical Therapy to Focal therapy alone

PARTICIPANT INFORMATION SHEET

We would like to invite you to take part in a study called **CHRONOS-A**. Before you decide whether you would like to join the study, it is important for you to understand why the research is being done and what it will involve. We will go through this participant information leaflet with you and answer any questions you might have. You do not have to decide straight away.

Please take time to read the following information carefully and if you wish to, with your GP, family or other people.

PART 1 tells you the purpose of this study and what will happen if you choose to take part

PART 2 gives you more detailed information about the conduct of the study

Please ask us if there is anything that is not clear or if you would like more information. You have as long as you need to decide whether you want to take part.

PART 1

1. What is the purpose of the CHRONOS A study?

Men diagnosed with significant cancer confined to the prostate currently undergo radical therapy directed to the whole prostate (radiotherapy or prostatectomy). These provide good cancer control but can cause side effects.

Focal therapy involves targeting the cancer alone, whilst leaving healthy prostate gland alone. Case series of patients treated in the past few years have shown similar cancer control over 5 years with a better side effect profile.

However, there have been no randomised control trials (RCTs) directly comparing the success in cancer control and the quality of life in patients that undergo radical therapy compared to those that undergo focal therapy. RCT's such as these are needed to confirm the findings from the case series of patients treated over the past few years. Further, there is a need to assess the use of additional therapies that may improve the cancer control outcomes following focal therapy.

The reason this study is called **CHRONOS-A** is because another study called **CHRONOS-B** is also being run. CHRONOS-A will compare radical therapy to focal therapy, whilst CHRONOS-B will compare focal therapy alone to focal therapy with various therapies targeting the testosterone pathway that can shrink the cancer before it is treated. By having two linked RCTs (CHRONOS-A and CHRONOS-B) to answer these research questions, we think this better reflects patient and doctor preferences and choices.

Your clinical team or the research team can give you more details about **CHRONOS-B** if you wish to find out more about that study. **CHRONOS-A** is a randomised controlled trial. We will explain this later in section 5.

To improve acceptability, recruitment and compliance we also have included a study aimed at finding out about patients', doctors' and nurses' perspectives and views about our study.

2. Why have I been invited to join the CHRONOS-A study?

You have been invited to consider joining this study because you have had a diagnosis of medium risk prostate cancer or have low risk cancer that your doctors think should be treated and which is suitable for either Focal Therapy or Radical Therapy. Your medical team are not sure about which treatment will be best for you. You have been approached as your clinical team feel that you are suitable to take part in this study.

There will be two stages to the **CHRONOS-A** study.

The initial pilot stage aims to see if men are willing to take part in the study in order to make sure that a larger study with hundreds of men (the second stage) can be carried out comparing these treatments. We will aim to recruit 60 patients for the pilot in a short space of time and, if the pilot is successful, 1190 patients for the larger study. Your doctor or research nurse will let you know which stage of the study we are now in. If you take part in the pilot your results and data will still be included in the same way as those patients who participate later and you will receive the same treatments as patients in the larger study.

3. Do I have to take part?

No. It is completely up to you to decide whether or not to join the **CHRONOS A** study. If you decide to take part, you are still free to withdraw at any time without giving a reason. Whether you take part or not will not affect the standard of care you receive.

4. What will happen to me if I decide to take part?

In this study, we want to see what the long term outcomes of men who have Focal Therapy are compared to men having Radical Therapy as no one knows the answer to this question. You will have been given this information leaflet about **CHRONOS-A** when you visited your doctor at your routine clinic visit in the hospital. You can take the information leaflet away with you, to think more about joining the study.

Having undergone routine diagnostic blood tests, imaging tests and prostate biopsies, you have been considered as eligible to take part in this study. You have been given this information sheet to read about CHRONOS- A, and will have an opportunity to discuss it further with your doctor or research team. We have summarised what taking part in this study would involve in section 9 onwards.

We are also conducting an embedded study, assessing why patients accept or decline participating in trials like this. This will involve an extra visit in which an interview between a member of the research team and yourself will take place. This is an optional part of the trial, and if you are interested your team can give you a further patient information leaflet.

5. What is a randomised controlled trial?

To ensure that any results are due to the treatment differences and not due to differences in the patient groups, we want to compare similar groups of men having either type of treatment. The only way to make sure that groups of patients are as similar as possible is to have your treatment decided upon by chance: this is called randomisation. Everyone who consents to participate in this study will be randomised to one of two groups, meaning you will have an equal chance of being in either of the two treatment groups, Focal Therapy or Radical Therapy.

This process ensures that the treatments are compared fully and fairly. If you agree to take part, your hospital doctor or nurse will contact the research centre. The centre will then record your details and tell your specialist your treatment group. It is important for the study that you only agree to take part if you believe you would be prepared to accept either treatment. Whichever group you are in, you will be treated with the best possible care and will be monitored closely.

This study will see how many patients in each group remain free of needing additional treatments like surgery, radiotherapy or hormonal therapy or chemotherapy in the long term. We will also compare survival rates although the survival in men who have medium and low risk cancer at 10 years is excellent.

6. Am I eligible for this study?

You must have prostate cancer, proven on biopsy, to be eligible. The cancer will have to meet some additional criteria which your doctor will go through. The cancer must still be contained inside the prostate although if there is early involvement of the capsule (lining of the prostate) you are still eligible. You also must be at least 18 years of age and be fit to undergo radical or focal therapy and must not have had any previous prostate cancer treatments.

7. What are the different treatments in CHRONOS-A

There are two different types of treatments in **CHRONOS-A:**

Types of treatment	Treatment	Aim	What it involves	Possible advantages	Possible disadvantages
Radical	Radiotherapy/ Brachytherapy	X-ray/ radiation treatment targeting the whole prostate gland	- Radiotherapy involves regular visits to your local radiotherapy centre - Radiotherapy may require marker placement at the beginning under local or general anaesthetic - Brachytherapy involves planning visits, and placement of radioactive seeds under local/ general anaesthetic or sedation	- Well known long term cancer control and survival outcomes - Requires less invasive procedures compared to surgical options - Short planning and treatment sessions	- Considerable side effects: urine leakage/ erectile dysfunction/ bowel changes - Requires multiple hospital visits - May worsen lower urinary tract symptoms if not improved prior to radiotherapy treatment
Radical	Prostatectomy	Surgical removal of the whole prostate gland, and may include removal of nearby lymph nodes	- An overnight admission (typically 1-2 nights) - Can be performed as an open or keyhole surgery - Performed with general anaesthetic	- Well known long term cancer control and survival outcomes - Typically requires only one hospital visit for treatment	- Considerable side effects: urine leakage/ erectile dysfunction/ bowel changes - Requires general anaesthetic - Risks of surgery (including damage to nearby structures and significant bleeding) - Involves hospital admission
Focal	HIFU	Heat treatment to specific area of the prostate gland using ultrasound	- Day case procedure performed under general anaesthetic	- Better side effect profile compared to radical treatment - Comparable 5 year cancer control and survival outcomes	- Requires general anaesthetic - Long term (over 10 years) cancer control and survival outcome is not currently known - May require repeat focal treatment/ whole gland treatment in the future - May not be available at your local hospital (requirement for travel to nearest centre providing treatment)
Focal	Cryotherapy	Freezing treatment to specific area of the prostate gland using cold gas	- Day case procedure performed under spinal or general anaesthetic	- Better side effect profile compared to radical treatment - Comparable 5 year cancer control and survival outcomes - Can be performed under spinal anaesthetic	- Requires spinal/ general anaesthetic - Long term (over 10 years) cancer control and survival outcome is not currently known - May require repeat focal treatment/ whole gland treatment in the future - May not be available at your local hospital (requirement for travel to nearest centre providing treatment)

Group 1: Radical therapy (radiotherapy or prostatectomy)

If you have been allocated to the radical therapy group, you will decide on which type of radical therapy you will receive, either surgery or radiotherapy or brachytherapy, with your clinical team and be provided with full details of the procedure including written information sheets. Surgery may require a general anaesthetic whilst brachytherapy may require a general or spinal anaesthetic or sedation.

Group 2: Focal therapy (cryotherapy or HIFU)

If you have been allocated to the focal therapy group, the decision of which type of focal therapy you receive will be made between yourself and your clinical team. You can receive up to two sessions of Focal Therapy over the course of the study, although most men only receive one session. The decision about a second session will be made following any MRI and biopsy tests you undergo after Focal Therapy.

8. What happens if I want to choose which treatment I get?

At the end of the discussion, you may feel that you want to choose your treatment. Focal therapy treatment in men with prostate cancer that has not spread to other areas of the body is currently not available to everyone. For it to become available to all men we need to show there is benefit in studies like **CHRONOS-A**. If you choose not to take part you will still receive the best care that is available and will not be denied any treatment that is already approved in standard clinical care in the NHS by NICE.

9. What will happen to me in the study?

Pre-Screening:

Prior to enrolment you must have undergone standard of care investigations which include blood tests, imaging tests such as an MRI and biopsy. If you decide to take part in this study you will be recruited and randomised at your consent visit.

Consent and Screening Tests:

The consent and screening visit will start with a consultation with one of the clinical research team. You will have the opportunity to raise any questions again, which you may have about the study and if you wish, you may sign the consent form if you are happy to take part.

You may continue to take your regular medication or other over the counter drugs. Your clinical team will discuss with you if anything you are currently taking interacts with treatment given within this study. You can consider enrolling in other trials, so long as these other studies do not interfere with the treatments and follow-up in this study. You must discuss this with your research team so they can advise you.

You will then be randomised into a treatment arm. Your research nurse or your doctor will tell you which treatment you have been assigned to. If you are assigned to undergo focal therapy you will require an MRI with contrast (a medication through a vein that helps image the prostate) if not previously performed. If you are unable to undergo an MRI of this kind, the research team will review if you require a different form of prostate biopsy prior to undergoing focal therapy.

In addition to questions related to the prostate cancer you will also be asked to complete a number of questionnaires regarding your general health including lifestyle factors and diet. The reason why these assessments are performed is to see what the impacts of the different treatments are on your quality of life and urinary, sexual and bowel habits. We will ask you to continue to complete these questionnaires for 5 years after randomisation. If you have any questions about these please ask the research team or your medical team. These questionnaires may also be sent to you via post or email at your choice. You should then send them back after completion.

It is important that you attend all visits, undergo all study investigations and agree to fill in all questionnaires before and after treatment. If you think this may not be possible, then you should discuss this with your doctor. If you hold private medical insurance, you should inform you insurance company that you intend to take part in the study.

Treatment:
You will be added to the waiting list for the appropriate procedure. The details of what happens for each treatment will be explained to you by your medical team who will also give you the local hospital's written information on the procedure.

10. What happens during follow up?
Whatever group you are in, you will be under the care of your medical team and followed up regularly.

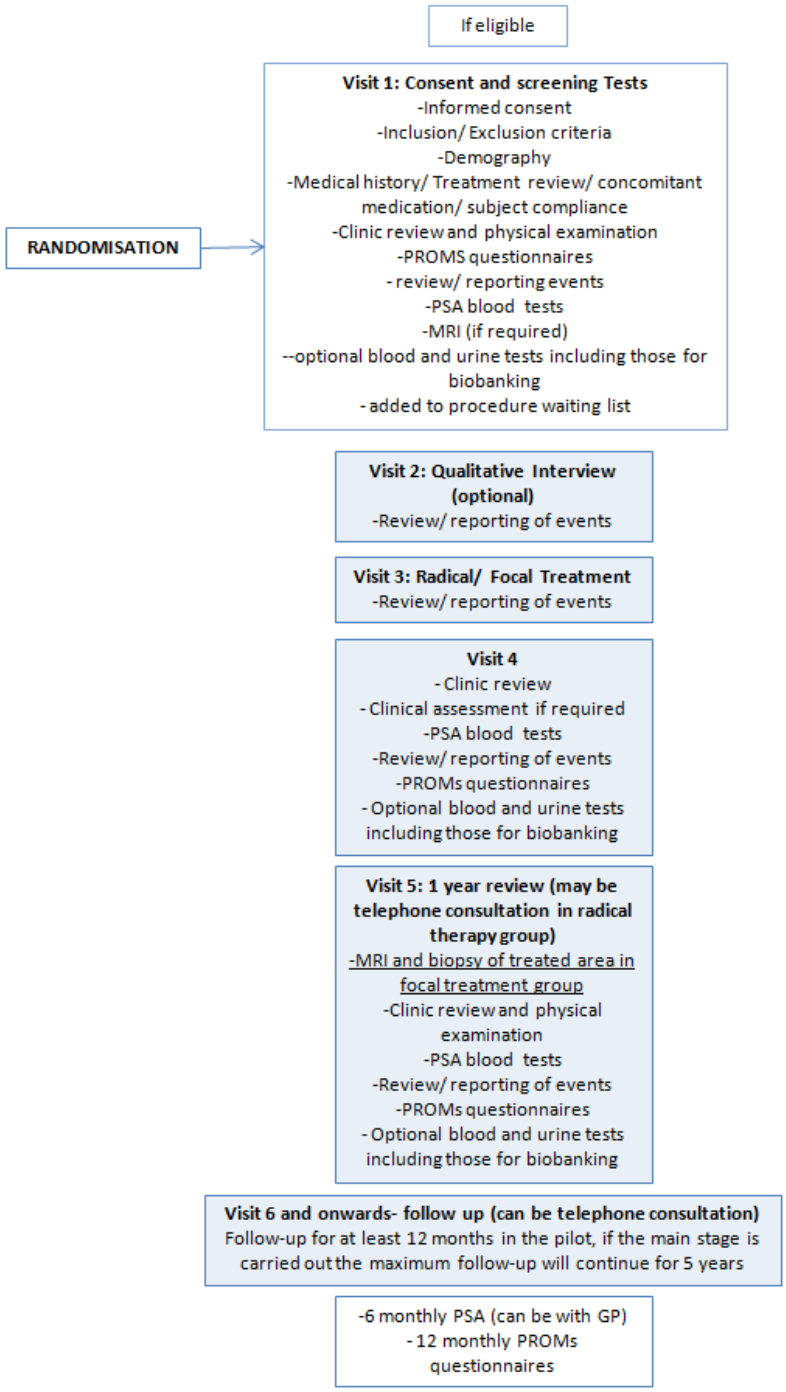
Follow-up will consist of regular clinical reviews, and patient reported outcome measures (PROMS) questionnaires in the first year, and annually for a maximum of 5 years. Prostate Specific Antigen (PSA) blood tests will be performed at 3 and 12 months, and 6-monthly thereafter. You can have the blood tests with your GP or local hospital. These visits can be done in person or you may choose to have a telephone consultation in which the team will call on the phone. You may complete the PROMS questionnaires by email to a secure NHS email account if that is acceptable for you. It is entirely up to you and your local clinical team how the visit occurs.

The visits will involve:
- Asking about any symptoms that you may be experiencing
- Completing the same questionnaires that you completed prior to therapy (if the visit is a telephone consultation, these will be posted to you with a stamped addressed envelope to return them to the trial team or emailed to you)
- Asking about any new treatments that you have undergone or started since we last saw you
- Asking you to obtain a PSA blood test at the hospital or with your GP

12 months after focal treatment
For men who have undergone Focal Therapy, we will need to do an MRI scan and prostate biopsy. We will not biopsy the untreated areas unless the MRI shows other areas in your prostate that have worrying features and were not present prior to treatment. The biopsy is done in the same way to those biopsies you had before the trial to diagnose the cancer in the first place. At this stage, if there is still significant cancer in the prostate, you will undergo another Focal Therapy session using HIFU or cryotherapy.

The standard of care provided if you enrol into the pilot study, or the larger study will be the same. Should the pilot not proceed to the larger study we will follow you up for a minimum of 3 months after your treatment, after which you will continue with routine follow up according to your local hospital policy. If the study continues into the main stage we will continue to follow you up for 5 years. Please see Figure 1 below, which shows the tests performed at each visit.

Figure 1: Diagram of Tests taken in the CHRONOS A study



11. What if the cancer recurs during the study?

You will be monitored carefully by the medical and research team, but you should always contact your GP or a member of the study team if you have any concerns. If your PSA blood test results suggest that your disease might have recurred, the doctors might organise new tests, x-rays or scans or biopsies to assess things further. Your medical team will discuss treatments with you.

If you undergo radical treatment (radiotherapy or radical prostatectomy), failure is likely to be determined according to either your symptoms, or your PSA level (or both). Further treatments may include additional medical therapy such as hormones or chemotherapy, further local treatment, or undergo a period of surveillance.

After up to two sessions of focal therapy, local failure may occur which will be picked up on MRI and / or biopsy. Further treatments may include additional medical therapy such as hormones or chemotherapy, further local treatment, or undergo a period of surveillance.

12. What else will I have to do?

There are some additional optional research requests.

Interviews
We want to find out how we might improve the study and the information we give to patients so that the study is successful. During the pilot stage of the study, we will ask you if we can audio-record your consent visit with your doctor and research nurse. This will help us to make sure that you are provided with enough information about the treatments and the study. We will ask you for written permission before this happen and would never record you without your permission. Your appointment will go ahead, whether or not you agree to it being audio-recorded. Some people will also be invited to be interviewed by one of our researchers in more detail about their experiences. This will only happen if you are willing to do this and only after you provide written permission.

Extra blood and urine samples
We will ask you to provide extra blood and urine samples to be collected and stored for research (up to 50ml of blood and up to 250 ml of urine [one cup]). If you take part in **CHRONOS-A**, we would like your permission to use these stored blood and urine samples for prostate cancer research. These research studies are not expected to benefit you, but may help to improve the diagnosis and/or the treatment of prostate cancer for future patients.

Any extra blood and urine samples that you give us for these research studies will be stored securely in Imperial College Healthcare Biobanks or a partner UK laboratory for a period of up to 10 years so that we can repeat any tests on them if necessary, and use them to look at new tests for prostate cancer. These samples will be identified using a special study number assigned to you, in such a way that the scientists analysing them will not be able to find out your identity.

Biopsy samples
We would also like your approval to store any biopsy samples that have been taken as part of your care, both prior to enrolling in the trial and during the trial itself. We may use these samples in a similar way to the blood and urine to look at new tests for prostate cancer.

Storage and analysis of optional samples
This research would be carried out only after approval from an independent research ethics committee and would involve extracting DNA and non-DNA or other chemicals from the samples to see whether the tests make it is easier to detect or monitor the effect of treatment for prostate cancer. These samples would be considered a gift from you and no personal results from these tests or studies could be provided to you. The laboratories for these tests may be based in the UK or abroad which would require us to transport your samples outside of your local hospital. All samples taken will be transferred to the Imperial College Healthcare Tissue Bank or a partner UK laboratory and will be used for histological, genomic and epigenetic analyses and for ethically approved future studies by our team or other scientists interested in prostate cancer research. Samples will not have any personal information written on them. Researchers will not be able to identify you from your samples.

You will still be eligible for **CHRONOS- A** even if you decline to provide any of the above blood, urine or biopsy samples for storage and future studies.

Imaging Scan Data
Imaging scans are performed as part of this study. We would also like to know if you are willing for us to store and use your scan data to see if new ways of looking at these scans can detect cancer better in the future.

Health Status
We will also ask you if you are happy to give consent for your health status to be followed up over time. This will be done by linking your name and NHS number with records held by the NHS and maintained by the NHS Information Centre and the NHS Central Register or any applicable NHS information system. This will allow us to see what happens after the study finishes. Results of your optional health status check will also help us in any future upcoming studies. This does not mean that that you will need to make any follow up visits.

All of the above are optional and you do not need to consent to this. If you do not wish to give this permission, you can still participate in the study.

13. What are the potential benefits of taking part in CHRONOS-A?

We cannot guarantee that participating in this study will be of direct benefit to you. The main benefit of you taking part will be the information that we can gather. This may help us improve treatment options for men with prostate cancer like you in the future.

14. What are the possible disadvantages and risks in taking part?

The potential risks and disadvantages for each treatment are listed above, in Section 7. Please read through them carefully and ask as many questions as you wish at your next appointment.

If you take part in this study you may have CT scans, PET/CT scans and bone scans. These procedures are part of your routine care. These procedures use ionising radiation to form images of your body and provide your doctor with other clinical information. If you receive radiotherapy or brachytherapy you will receive ionising radiation to treat your cancer.

Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous. The chances of this happening to you, due to the CT scans, PET/CT scans and bone scans or radiotherapy or brachytherapy are the same whether you take part in this study or not.

15. What happens when the study stops?

Once the study is completed, you will either return to your GP's care or be looked after by the clinical team in hospital. Your routine follow up would be similar to the follow-up you would expect to receive if you had chosen your treatment at the outset. We will contact you with a newsletter, at the end of the study outlining the overall results. This may be years after you complete your follow up within the study.

It would also be great for us to know how you are doing even after your participation in the study has stopped so we can follow up on your health status to help future related research. As mentioned in section 12, you may provide consent for the study team to hold your identifiable information in order to trace you and your health via the National Health Service Care Register (NHSCR) for up to 10 years after the end of the study (this is an optional part of the study).

16. Can I change my mind?

Yes, you can decide not to have any of the procedures at any time. Depending on when you change your mind, your doctor may recommend that you continue with standard treatment. If you change your mind regarding any optional part of the trial, you will still be eligible to continue within the main clinical trial.

This completes Part 1 of the information sheet. If you are considering participating in the study, please continue to read the additional information in Part 2 before making your decision.

PART 2

1. What happens if relevant new information becomes available?

Data from this study will be monitored regularly by scientists who are independent of the study. Sometimes, during the course of a research project, new information becomes available about the procedures that are being studied. If you are in the study and this happens, your study doctor will tell you about it and discuss with you whether you want to, or should, continue in the study. If you decide not to carry on, your study doctor will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign a consent form that includes new information. Also, on receiving new information your study doctor might consider it to be in your best interests to stop the medical procedures in the study. If so, they will explain the reasons and arrange for your care to continue another way. If the study is stopped for any other reason, you will be told why and your doctor will arrange for your continuing care. If any relevant new information becomes available after you have had all of your procedures and you have received your results, it will not affect you as you will no longer be in the study.

As described earlier, you can stop taking part in the study at any time without giving a reason and without your rights or care being affected in any way. If you do decide to withdraw then you should inform your doctor of your decision so that appropriate follow up can be arranged.

2. What if something goes wrong?

Every care will be taken in the course of this study. However in the unlikely event that you are injured by taking part, compensation may be available.

Imperial College London holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this

study then you should immediately inform the Chief Investigator (Professor Hashim Ahmed on 0203 311 1673 or via email chronos@imperial.ac.uk). The normal National Health Service mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College, Joint Research Compliance Office.

If you have any concerns about any aspect of the way you have been approached or treated by members of staff or about any side effects (adverse events) you may have experienced due to your participation in the clinical trial, the normal National Health Service complaints mechanisms are available to you including your local hospitals' Patient Advice and Liaison Service (PALS) who can be contacted on XXXX XXX XXXX. Please ask your study doctor if you would like more information on this. Details can also be obtained from the Department of Health website (http://www.dh.gov.uk).

In an emergency it is best to contact your local GP or go to your local Accident and Emergency department or dial 999 for an ambulance. It is important that your GP and local hospital know whom they should contact for further information. Therefore, if possible in such a situation please take the above contact details with you.

3. What will happen if I lose the capacity to consent during the study?

In the unlikely event that you lose capacity to consent during your participation in the study, you would be withdrawn from the study. Any data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected.

4. Will my participation in the study be kept confidential?

Yes. All information that is collected about you during the course of the research will be kept strictly confidential.

[Insert Site Name] will use your name, NHS number and contact details 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. Individuals from Imperial College London and regulatory organisations may look at your medical and research records to check the accuracy of the research study.

[Insert Site Name] will pass these details to Imperial College London along with the information collected from you or your medical records. The only people in Imperial College London and Cardiff University who will have access to information that identifies you will be people who need to contact you if you have consented to being contacted for the optional follow up interviews , have consented to being contacted within 10 years of enrolling into the trial in order to assess your willingness to complete a questionnaire on your health status and quality of life or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

[Insert Site Name] will keep identifiable information about you from this study for 10 years after the study has finished.

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. 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.

All data will be identified by a study number which can link to your other details. This link will be held separately from all other data collected on you. If you consent to take part in this study, we will collect information on you and your test results, and we will enter it onto a study database held at Imperial College Trials Unit, London. This is for the purposes of analysing the results. Employees of the

Imperial Clinical Trials Unit (ICTU) and staff from Imperial College London Joint Research Compliance Office may need to examine your medical records to ensure the study is being run properly, but your confidentiality will be protected at all times, and your name will not be disclosed outside the study. Your information may also be looked at by an independent quality control agency to check that the study is being carried out correctly.

Imperial College London 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. Imperial College London will keep identifiable information about you from this study 10 years after the study has finished in relation to data subject consent forms.

Further information on Imperial College London's retention periods may be found at https://www.imperial.ac.uk/media/imperial-college/administration-and-supportservices/records-and-archives/public/RetentionSchedule.pdf.

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 by contacting Professor Hashim Ahmed on 0203 311 1673 or via e-mail at Hashim.ahmed@nhs.net.

LEGAL BASIS

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

CONTACT US

If you wish to contact us regarding your treatment, or how we use your personal data, after discussing with your local site team, please contact the Chief Investigator (contact details listed on page 20). If you wish to raise a complaint on how we have handled your personal data or if you want to find out more about how we use your information, please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). The ICO does recommend that you seek to resolve matters with the data controller (us) first before involving the regulator.

As it is standard practice to inform your GP about your participation in a research study, we will ask your permission to do this. If you do not give this permission, you cannot participate in **CHRONOS-A**.

5. Who is organising and funding the study?

CHRONOS is funded by the PROSTATE CANCER UK charity through an award to Professor Ahmed and Mr Taimur Shah at Imperial College London (grant code: RIA17-ST2-012). The study is being carried out by Imperial College London in partnership with hospitals. The researchers include a team of specialised doctors, scientists, technical staff and nurses. Our team is experienced and has conducted similar research in the field.

6. Who has reviewed the study?

Patients and expert reviewers have looked at the study both before the funding was awarded and after.

This study was given a favourable ethical opinion for conduct in the NHS by the London - South East Ethics Committee. This committee is responsible for making sure that research takes place in a way that protects the patients' rights and welfare.

7. Will I get paid for taking part?

There is no payment for taking part in this study.

8. What will happen to the results of the research study?

When the study is completed the results will be analysed and presented at international meetings before being published in a medical journal. Large studies such as this take many years to complete and for the final results to appear. When the study results are concluded, they will be presented by clinicians and patient groups, and posted on our website for patients to access. Our website is: www.imperialprostate.org.uk/chronos/

9. What do I have to do now?

You will be given as much time as you feel you need to discuss any issues or questions involving this research during your appointment with the researchers and study nurses. If you have any concerns or wish to discuss the study further, please contact:

[XXX – Local Research Nurse, address, tel number]

[XXX, Local Investigator, address, phone number]

Co-Investigator
Dr Taimur Shah
Imperial College London
Charing Cross Hospital
Fulham Palace Road
W6 8RP
London

Chief Investigator
Professor Hashim U. Ahmed,
Imperial College London,
Charing Cross Hospital
Fulham Palace Road
W6 8RP
London

Clinical Trial Manager
Dr Sasikaran Thiagarajah
Imperial College London
Charing Cross Hospital
Fulham Palace Road
W6 8RP
London

Study Clinical Manager
Dr Deepika Reddy
Imperial College London
Charing Cross Hospital
Fulham Palace Road
W6 8RP
London

Tel: 0203 311 5473
Email: Chronos@imperial.ac.uk

We will give you a copy of this information and a copy of the signed consent form to keep.

Thank you for taking the time to read this information sheet