Participant Information Sheet
(To be presented on local headed paper)

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Study Title: A prospective cohort study in men with a suspicion of prostate cancer investigated using an MRI-based diagnostic pathway with donation of tissue, blood and urine for biomarker analyses. (ReIMAGINE Prostate Cancer Risk)

This is the Participant Information Sheet for a Health Research Study called ReIMAGINE Prostate Cancer Risk

We are approaching you to take part in this study because you have been referred to have an MRI scan of your prostate, or you have already had an MRI scan and your doctor has advised you to have a prostate biopsy.

Before you decide whether or not to take part in this study, it is important for you to understand why the study is being done and what it will involve. Please take time to read the following information carefully. Talk with your GP, family or other people about the study if you wish.

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.

If you agree to participate we will ask you to donate blood, urine and tissue (3 additional prostate tissue samples). The blood and urine samples can be taken before or at the time of your standard of care prostate biopsy that will be arranged by your hospital. The prostate tissue samples will be taken at the time of the biopsy. Donated samples will then be analysed along with your medical data to assess existing methods of detecting and monitoring prostate cancer (if cancer is found). We will also try to develop and assess new methods of detecting and monitoring prostate cancer.

There will be no direct benefit in your care by taking part in this study but your participation will help with our understanding of prostate cancer diagnosis and risk to better inform the care of future men (e.g. friends, sons or grandsons).

Please ask questions if there is anything that is not clear or if you would like any more information.

You are free to decide whether or not to take part in this research. Please remember that your medical care will not be affected if you decide to not take part in this study.

PART 1

1. What is the purpose of the study?

The purpose of this study is to carry out very detailed testing on prostate tissue (whether it contains cancer or not) as well as on blood and urine. The reason to do this is because we do not fully understand

- How prostate cancer develops
- Why some prostate cancers spread to other parts of the body and others do not
- Why some prostate cancers respond to treatment and others do not

We know that 1 in 3 of the male population over the age of 50 have cancer cells in their prostate. However, most of these men will never know they have cancer and it will not affect their quality of life or their life expectancy. However, some cancers can be aggressive. These are more likely to spread outside of the prostate and cause problems. We do not currently have a good way to tell the difference between aggressive cancers and those that will not cause any problems. Men can have multiple tumours in their prostate and some of these tumours can be aggressive and others do not cause a problem during the lifetime of a man. This project will try to find out more about what makes different tumours aggressive or harmless.

It is important to find out what makes some cancer cells spread to other parts of the body and other cancer cells stay within the prostate. This might help us develop better ways of finding aggressive cancers of the prostate and in future develop new treatments. For us to do this we need to collect fresh biopsies (or samples) of cancer tissue from the prostate and from different areas of the prostate.

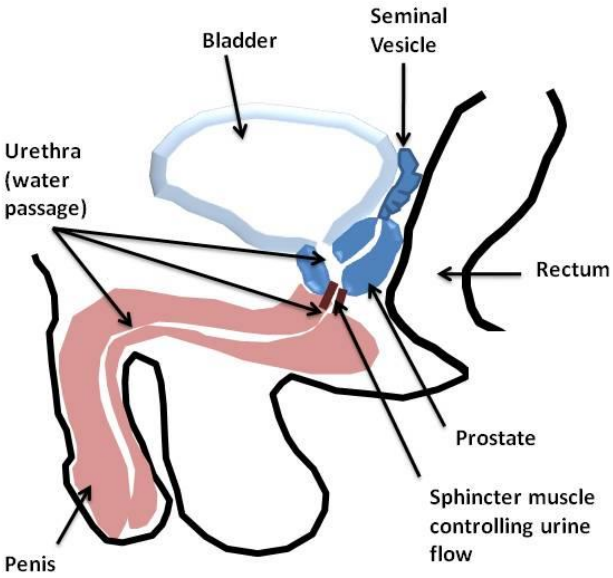
We are asking men who are undergoing prostate biopsies as part of their normal care to kindly allow us to take additional biopsies for this study. We will also ask men to donate some blood and urine so that we can look at whether anything in the blood and urine can help us develop better tests for prostate cancer detection and monitoring.

Should you wish, you can view videos from patients and researchers on the study website discussing different aspects of the research at https://www.reimagine-pca.org

2. What is the prostate?

The prostate is a male gland that sits just below the bladder (See Figure 1). The prostate produces fluid that forms part of the semen and helps nourish sperm. When you empty your bladder, urine flows through a tube (the urethra) that passes through the prostate before reaching the penis.

Figure 1: Location of the prostate



3. What is a biopsy and how does it diagnose prostate cancer?

We diagnose prostate cancer using an MRI scan and biopsy. MRI shows us where the abnormal areas are in the prostate and these areas are targeted in a procedure that uses needles to take tissue samples (biopsies). The samples obtained are looked at under a microscope to see whether or not cancer is present. An abnormal MRI scan does not mean that cancer is present.

4. Why have we invited you to take part in this study?

We have approached you and provided you this information sheet because your doctor has recommended you undergo further tests to see if you have cancer in your prostate. You may have been approached at one of the time points below:

- Following referral to the hospital by your GP (usually after a PSA test but before your MRI).
- On the day of your Prostate MRI.
- After your MRI has been reported and you have been advised to have a prostate biopsy.

You will only be invited to take part in the study if your MRI reports suspicious area(s) which indicate the need for a prostate biopsy, and you choose to have this biopsy.

5. What will happen to me if I take part in the study?

Once you have discussed the study with the research team we will ask you to sign a consent form. This initial discussion may be over the telephone. We will note your consent in your medical records and ask you to sign a paper consent form when you next visit the hospital.

After the consent form is signed, we will ask you to provide urine into a small container (up to 4 table spoons), and we will take a blood sample. We will ask you to donate a minimum of 50ml of blood

(approximately 4 tablespoons), up to a maximum volume of 100ml (7 tablespoons). However, men who provide over 10mls (approximately two thirds of a tablespoon) can still participate.

You will then have your prostate biopsy (which could be on the same day), where we would like to take some additional samples of tissue. Normally, men can have between 10 to 20 samples of tissue taken from the prostate and we would like to take up to 3 extra samples of tissue from the prostate. The risk of taking these additional biopsies is low and we will explain them in detail below.

Images from your MRI scan and scanned images of your prostate biopsy tissue will be uploaded to the study database. Small sections will be cut from the tissue collected for your standard of care biopsy, then returned to the hospital.

We will also require your permission to use identifiable information such as your name, address, date of birth and NHS number so that we can collect healthcare information on you from national records, such as the Office for National Statistics, NHS Digital, Public Health England, and other applicable NHS information system, or national database. The information we receive will be related to both your prostate and general healthcare (for example: cancer diagnosis, prostate cancer treatment details). Rigorous safeguards are in place so that we send, receive, store and handle your data safely and securely. For this you will not have to attend the hospital but we do need your permission to receive and hold this information on you securely.

We will collect healthcare information on you during the study and three years after your prostate biopsy. Further funding will be explored for life-long collection of this data.

6. Do I have to take part?

No. It is up to you to decide whether or not to take part. If you decide to take part we will ask you to sign the consent form attached to this information sheet, and give you a copy of the information sheet to keep. You will have adequate time to decide whether to take part (normally at least 24 hours) and you are free to withdraw at any time without giving a reason and without affecting any future care you receive.

7. What are the alternatives?

If you choose not to take part in the study, you will not need to provide additional urine and blood samples and you will have the standard number of biopsies.

8. Can I change my mind?

Yes, at any time you can decide not to have any of the procedures.

9. What will happen with the samples taken for research purposes?

Analyses on samples (including stored images from your MRI scan and biopsy) will be performed by academic and commercial partners both within and outside the EU.
You may also have been asked to take part in other studies with ethics approval which also involve scanning tissue from your prostate biopsy. If you choose to consent to both studies, your prostate biopsy tissue would be scanned once, and the scans used by both study groups. This would happen with your specific consent, and no sharing of any other information or material would occur.

We will use your blood, urine and tissue specimens to extract DNA and RNA (genetic material), proteins and other chemicals. We will use molecular tests such as DNA and RNA sequencing to check how cancerous samples differ from normal samples such as blood. If you have any cancerous cells, we may keep some of them for growing in the laboratory to test how changes in the DNA and the RNA have on the behaviour of cancer cells. We will also use some existing commercial tests on these

samples to see how good they are at predicting the presence of aggressive cancer and monitoring it after a diagnosis of cancer.

DNA testing will be performed on the samples you provide. It is therefore possible that the research could produce findings of clinical significance for you or your relatives. Some tests on the samples you donate (blood, urine, tissue) could suggest that genetically you or a family member may be more likely to develop certain diseases. In such situations we will inform you and your GP, but as these tests are performed in a research setting any results would need to be repeated using additional existing tests.

Once we have completed the analyses which are planned to answer our research questions, we will store any remaining samples or substances extracted from them securely for future research, so that we can repeat any tests on them if necessary, and evaluate new academic or commercial tests for prostate cancer care, if you consent to it. Your samples would be considered a gift from you and no personal results from these tests or studies will be provided to you.

10. What are the possible disadvantages and unwanted side effects of the study?

If you take part there are possible side effects associated with the study procedures, which are detailed below. Your clinical team will give you detailed information about how the biopsy is done. The table below gives the side-effects that could occur with biopsies under normal practice. As we are only taking a few additional biopsies from the prostate these risks will not be significantly higher than the rates we quote in the table. However, there may be small increases in the risk of temporary bleeding in the urine and sperm as well as a small increase in the amount of bruising of the skin. There is no evidence that having multiple biopsies raises your chances of prostate cancer spreading, if it is present.

Side effect	**Prostate Biopsy**	
	Proportion of men	**Duration**
Pain/Discomfort in back passage	Almost all	Temporary for 1-2 days
Burning when passing urine	Almost all men	Self-resolving, 1-3 days
Bloody Urine	Almost all	Self-resolving, 1-7 days
Bloody Sperm	Almost all	Lasting up to 3 months
Poor erections	1-2 in 100	Temporary for 1-6 weeks
Infection of skin/urine	1-2 in 100	7 days with treatment with antibiotics
Infection of skin/urine needing admission and intravenous antibiotics	Less than 1 in 500	7-14 days with treatment with antibiotics. Rarely up to 28 days of antibiotics after leaving hospital.
Difficulty passing urine requiring catheter placement for up to a week. A catheter is a soft plastic tube placed into the bladder to drain urine.	1 in 100	3-7 days
Bruising of skin	Almost all	Self-resolving, 7-14 days
Bruising spread to scrotum	1 in 100	Self-resolving, 7-28 days

11. What are the possible benefits to me and for others like me in taking part in this study?

The study will not benefit you directly. However, it could mean that, in the future new tests and treatments could be developed for identifying and treating aggressive prostate cancer.

12. What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed individually. You can find more detailed information on this in Part 2 section 2 of this information sheet.

13. What data will be collected and use of data?

University College London (UCL) 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. UCL will keep identifiable information about you until the end of the study.

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.

UCL will work in partnership with Philips to create a data warehouse to collect, store and process pseudonymised data for research purposes specific to the study. The data warehouse, which is hosted and managed securely in the EU, will be safeguarded against unauthorised access with established security procedures. Philips or other ReIMAGINE partners will not have access to any identifiable information about you, this will be stored and managed by UCL only.

You can find out more about how we use your information by contacting the ReIMAGINE trial coordinator on reimagine@ucl.ac.uk. Our Data Protection Officer is [insert name here] and you can contact them at data-protection@ucl.ac.uk.

To be acquainted with what data is actually shared with ReIMAGINE partners please consult the privacy notice which can be accessed via our website, **Insert URL here**. If you would prefer a paper copy please contact the study team using the details listed in Part 2, section 8.

Your local NHS Trust will collect information from you and your medical records for this research study in accordance with our instructions.

Your local NHS trust 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 UCL and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Your local NHS trust will pass these details to UCL along with the information collected from you and your medical records. The only people in UCL who will have access to information that identifies you will be people who process 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.

Your local NHS trust will keep identifiable information about you from this study for 25 years after the study has finished.

14. What happens when the study stops?

Once you have completed the study, your care will be as normal standard practice. The type of care will depend on your individual circumstances and clinical details. Your doctors will explain this further to you. We would also like to tell you that if during the study you lose the capacity to make informed consent, you would be withdrawn from the study. However, identifiable data or tissue already collected with consent would be retained and used in the study. As previously described we will also ask your permission to check your health status through national UK NHS databases.

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?

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. If any relevant new information becomes available after you have had all of your procedures, 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.

We expect this study to run for three years. We are not aware of any similar studies being carried out anywhere else in the world, and so it is unlikely that new information will come available that will affect this study.

2. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions, contact details are at the end of the document. If you remain unhappy and wish to complain formally, you can do this via the hospital's Patient Advisory Liaison Service (PALS).

Site/Hospital to insert local details

Tel: Site/Hospital to insert local details

http://www.nhs.uk/chq/pages/1082.aspx?CategoryID=68

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. If you suspect that the injury is the result of the Sponsor's (University College London) or the hospital's negligence, then you may be able to claim compensation. After discussing with your research doctor, please make the claim in writing to Professor Hashim Ahmed is the Chief Investigator for the research and is based at the Imperial College London (Charing Cross Campus, Laboratory Block, 5th Floor, Imperial Prostate office, Hammersmith, London W6 8RP). The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

3. Will my taking part in this study be kept confidential?

Yes. All personal information we collect is strictly confidential and is covered by the Data Protection Act 2018 and General Data Protection Regulations and any subsequent legislation.

4. Involvement of your General Practitioner (GP)/family doctor

Your GP will be informed in writing of your participation in this study. We may ask them for medical information about you in the future if we cannot obtain this from your hospital records. We will ask for your permission to do so at the time we ask you to sign the study consent form.

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

The results of this study will be published in scientific or medical journals and may be presented at scientific or medical meetings. Please be assured it will not be possible to identify you in any report or publication. Results from the study will also be published on the study website at, https://www.reimagine-pca.org.

6. Who is organising and funding the research?

ReIMAGINE is conducted by University College London (UCL) (Chief Investigator(s): Professors Hashim Ahmed Mark Emberton) and co-ordinated by The UCL NCITA Imaging Clinical Trials Unit. The study is funded by the Medical Research Council (UK) and Cancer Research UK. Both of these organisations are charities and are supported only by public donations and invested funds.

7. Who has reviewed the study?

All research in the NHS is reviewed by an independent group of people, called a UK National Research Ethics Committee, which is there to protect your safety, rights, wellbeing and dignity. The study has been reviewed and approved by the London-Stanmore Research Ethics Committee Research Ethics Committee). It has also been reviewed by patient representatives and independent international experts for the funders.

8. Contacts for further information

If you would like further information or have any questions about this study, please discuss them with the research staff or your study doctor.

Re-IMAGINE study contact details:

Insert local study team details here

You can also view the study website at https://www.reimagine-pca.org/ that includes videos from both patients and researchers discussing the ReIMAGINE consortium and its goals.

If you would like some independent advice, you can contact either of the following:
Macmillan Cancer Support is a useful source for further information. They can provide information on prostate health care and clinical trials. You can find this at www.macmillan.org.uk
Alternatively, you can call them on 0808 808 0000 (Freephone), and they will send you information leaflets in the post free of charge.

If you would like to know more about how patients help initiate, design, support and monitor research, you will find information on the websites for the NIHR (www.crncc.nihr.ac.uk), the NCRI (https://www.ncri.org.uk/patient-and-public-involvement/) or the NHS (www.invo.org.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 the information about the study.