This is the Patient Information Sheet for a Health Research Study called PROMIS

PROMIS: Prostate MRI Imaging Study

An evaluation of multi-parametric magnetic resonance imaging in the diagnosis and characterisation of prostate cancer

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REC reference number: 11/LO/0185

We are inviting you to take part in this study because your doctors are considering you for a prostate biopsy. Doctors usually recommend a prostate biopsy if you have a high or rising Prostate Specific Antigen (PSA) level in the blood, or if your doctor can feel a lump in your prostate.

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

Please ask us if there is anything that is not clear or if you would like more information, you can have as much time as you need to consider the study, but you will have at least 24 hours to decide whether you want to take part.
PART 1

1. **What is the purpose of the study?**
   The purpose of this study is to test the value of multi-parametric magnetic resonance imaging (MP-MRI) scans for men who have been recommended for a prostate biopsy. There are two possible improvements that we are looking at. Firstly, we want to know whether MP-MRI scans can be used to help advise men whether or not they might safely avoid having a biopsy at all. Secondly, we want to know whether MP-MRI scans can help us to do better biopsies for men who choose to have them.

   Standard biopsies can miss prostate cancers completely, or they may underestimate how serious the cancer is. In this study, a more thorough biopsy called Template Prostate Mapping (TPM) will be used in addition to the standard biopsy to assess the prostate as accurately as is possible. We will also give each person an MP-MRI scan, so that we can compare the results of the scans with the more accurate biopsies.

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 may help 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](image_url)
3. **What is a biopsy and how does it diagnose prostate cancer?**

We diagnose prostate cancer using a standard biopsy, which is also called a TRUS guided biopsy. This is a procedure in which a doctor uses needles to take samples from the prostate gland. The doctor places an ultrasound probe in your rectum (your “back passage”). This probe produces pictures to guide needles (usually 10 or 12) through the rectum and into the prostate. The doctor uses the ultrasound picture of the prostate to make sure the needles are spread equally around the prostate. We call this procedure a TRUS guided biopsy because TRUS stands for **Trans Rectal Ultra Sound**. We carry out standard TRUS biopsies using a local anaesthetic, and it takes around 10 to 15 minutes to complete. It can be uncomfortable and there is a small risk of side effects such as infection (see Table 1 on page 9). The samples obtained from the prostate are looked at under a microscope to see whether or not cancer is present.

TRUS biopsies, which are currently used as standard care, can miss important cancers. TRUS biopsies are also believed to sometimes pick-up cancers that may not have affected the patient during their life-time, had they never been discovered in the first place. This is known as over-diagnosis. If these cancers are treated it is likely that little or no benefit will be had. When this happens we call it ‘over-treatment’.

TRUS biopsies can also give a false impression of how much cancer there is and how aggressive the cancer looks under a microscope. This is because the biopsies may not have sampled the main part of the cancer area. As a result, men can often undergo repeat biopsies every 1 or 2 years.

TRUS biopsies are the current standard biopsy for diagnosing prostate cancer. This study will be looking at this and other procedures for diagnosing prostate cancer, shown in section 7 below.

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

We have invited you to take part because your doctor has recommended that you have a prostate biopsy. Approximately 720 men from the UK will take part in this study.

5. **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 sheet, and we will give you a copy of the information to keep. You will have as much time as you need to decide. If you decide to take part, you are free to withdraw at any time without giving a reason and without affecting the care you receive in the future. If you choose not to take part then your doctor will explain the best standard care available.
Please note, if you have a pacemaker or have had any hip replacement surgery, you will not be able to have an MRI scan and so you cannot take part in the study.

6. What is the standard care?
The standard care at the moment is to have a TRUS biopsy, as detailed in section 3.

7. What are the other procedures for diagnosing prostate cancer that are being looked at in this study?

- **MP-MRI** stands for Multi Parametric Magnetic Resonance Imaging. This type of scan does not use radiation. As in standard MRI, MP-MRI uses magnetic signal to build up a picture of your prostate. However, in addition to this, MP-MRI uses additional types of magnetic signals to build up images of the prostate tissue such as how dense the cells are and how much blood flows through different parts of the prostate. This gives an overall assessment of your prostate. It is believed the MP-MRI approach increases the accuracy of the scan result but we cannot be sure of this without doing this study.

- **TPM** – Stands for Template Prostate Mapping. This is a biopsy that involves taking samples of the prostate through the outer skin between the rectum and scrotum rather than through the inside of the rectum. The number of samples to be taken depends on the size of your prostate. Typically doctors take around 50-60 samples in order to thoroughly sample and map the entire prostate, but in some cases it can be more or less than this. We usually carry out TPM under a general or spinal anaesthetic.

The men in the study will have these extra procedures as well as the standard TRUS guided biopsy, so that we can compare all the results to see which are the most accurate for diagnosis and which are the most helpful for planning treatment.

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

Once you have talked about the study with the research team and after you have signed the consent form, we would need to assess you in order to see whether you fit the entry criteria for the study. If it has not been done already, we will take blood and urine samples and perform a digital rectal examination (see section 11b for description) at your first visit to assess your baseline details such as PSA level, which will help with your diagnosis. If you have agreed on the consent form for additional blood and urine samples to be taken, these will be taken at this point. If you fit the entry criteria, we will register you to the study (Visit 1) and invite you to have an MP-MRI scan of your prostate (Visit 2) (See Figure 2). After your scan, we will carry out one combined biopsy procedure (TPM and TRUS guided biopsy) under the same anaesthetic (Visit 3). A follow-up visit will occur...
after the biopsies where your results of all procedures will be given to you (Visit 4). At this stage your participation in the study will be over.

**Figure 2: Trial diagram**

<table>
<thead>
<tr>
<th>Visit 1</th>
<th>Visit 2</th>
<th>Visit 3</th>
<th>Visit 4</th>
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</thead>
<tbody>
<tr>
<td>Registration</td>
<td>MP-MRI Scan</td>
<td>Combined Prostate Biopsy Procedure TPM &amp; TRUS guided biopsy</td>
<td>Follow Up/Results Visit</td>
</tr>
</tbody>
</table>

**a) MP-MRI scan**
We do MP-MRI scans with you lying flat on your back on a bed that moves through a scanner. A radiographer controls the scanner, and he or she can see, hear and talk to you at all times. In order to get the best pictures of the prostate we will inject you with a contrast agent (or “dye”). We inject this contrast agent into your arm, which can sometimes make your arm feel warm. A medication called Buscopan is injected into your vein to slow bowel movements. A moving bowel can reduce the quality of the images produced by the MRI. The whole scan should take about 30 to 40 minutes. During the scan we will ask you to lie as still as you can. We can offer you music to listen to using headphones, if you wish.

If you are anxious about the scan feel free to ask any questions. We can arrange for you to visit the scanner beforehand if you wish. You can also find information about MRI scans on the website [www.macmillan.org.uk](http://www.macmillan.org.uk), or by ringing Macmillan Cancer Support on freephone 0808 808 0000.

**b) Combined prostate biopsy procedure**
The combined prostate biopsy procedure should take place within 3 months of the MP-MRI scan. To prepare you for the procedure, you will be prescribed a tablet called an alpha-blocker (such as tamsulosin or alfuzosin). This type of tablet relaxes the prostate and reduces the chance of problems passing urine after the procedure. You should continue taking these tablets for two weeks after the procedure.

We will also give you antibiotic tablets and antibiotic injections at the time of the anaesthetic (see appendix 1).

You will need to come into hospital a few hours before the biopsy procedure. You should not eat anything for 6 hours before the biopsy and you can drink only water up to 4 hours before the biopsy. The anaesthetist will see you before the procedure to discuss the anaesthetic with you.
The combined prostate biopsy procedure (TPM + TRUS) takes around 50 to 60 minutes. We do it under general or spinal anaesthetic. Once you are anaesthetised an ultrasound probe is gently inserted into your rectum. A soft flexible tube, called a catheter, is inserted through your penis into your bladder. Both the ultrasound probe and catheter are placed whilst you are under anaesthetic. After the procedure, it is likely that your doctor will keep the catheter in place for about 7 to 10 days. This is to make sure that in the period needed for your prostate to recover you are able to pass urine comfortably. The catheter does not need to be connected to a bag at all times and will not interfere with most of your daily activities. Your doctor will explain with further detail when you visit the trial team. We will arrange for you to come and have your catheter removed in hospital.

TPM involves a biopsy of the prostate done through a grid (template). The grid has holes every 5mm, which we place against the skin between the scrotum and rectum. This approach allows us to biopsy the whole of the prostate. At the beginning of the procedure we inject your skin with local anaesthetic. At the end of procedure, we place a dressing over the area. Immediately following this and whilst you are still anaesthetised we clean the back passage with an anti-septic solution and then we will do a TRUS guided biopsy.

c) After the combined prostate biopsy procedure
It is normal to spend about 20 to 30 minutes in the recovery area after an anaesthetic. Once you have fully woken up we will transfer you to the ward. Once you feel steady on your feet we will allow you to go home. You will need to be accompanied on your journey home. Most men are ready to go home within 2 to 4 hours of the procedure. Before going home we will make sure you have enough antibiotics and alpha blockers. We will also prescribe pain killers in case you experience pain or discomfort after the procedure. However, pain is unusual and most patients are comfortable either with no pain killers or with something like paracetamol or an anti-inflammatory.

Any prostate biopsy can lead to infection; this is why it is very important that you take the antibiotics that you are given. Infection that is left untreated can be a very serious complication.

If, after the biopsy, you experience a fever, or any other symptoms of concern, it is extremely important to head directly to the closest accident and emergency department. Inform them that you had prostate biopsies and show them your patient card. Then contact your study hospital (using the details at the end of this information sheet or on your patient card). You must make contact so that any complications may be treated promptly before they become serious.
You can usually return to work the day after the procedure. It may be difficult sitting down for prolonged periods for the first 2 to 3 days. Before driving, you need to check with your insurance company about your cover following a general or spinal anaesthetic. You also need to feel comfortable doing an emergency stop. If you are taking any medication, check with your pharmacist whether it is safe to drive while taking them.

Neither you, nor your study doctor, will be given the results of the MP-MRI scan until approximately 4 weeks after the biopsies, when you will get all your results at a follow-up clinic visit. At this stage your participation in the study will be over and depending on your results, you will discuss future treatment options with your clinician.

9. **What are the alternatives?**
If you choose not to take part in the study then your doctor will recommend that you have a TRUS guided biopsy, without the study procedures i.e. without the MP-MRI or the additional TPM.

10. **Can I change my mind?**
Yes, you can change your mind at any time after you consent. Depending on when you change your mind, your doctor will recommend that you continue with standard care which could be a TRUS guided biopsy, without the MP-MRI or the additional TPM. Your doctors could also recommend that you undergo the TPM biopsy.

If you choose not to enter this study and you have a prostate biopsy as your standard care, you cannot then change your mind and enter the study.

11. **What else will I have to do?**

a) **As part of the PROMIS trial**
If you choose to participate and enter the study, you will make some extra visits to hospital:

- To assess your suitability for the study, and that you wish to take part. You will be asked to sign a consent form
- For the MP-MRI scan
- For a combined TRUS guided biopsy and TPM procedure under general or spinal anaesthetic. You will also be required to attend either another visit or a telephone call with a nurse at the hospital to assess your fitness for a general or spinal anaesthetic.

b) **Additional optional research requests**
In addition to the initial blood and urine tests, we will ask you to provide extra samples to be collected and stored for research (100 ml of blood (just under half a cup) and up to 250 ml of urine (one cup). We will ask for urine samples before and after a back passage examination (also known as a digital rectal examination). The first sample before this examination can be given at any time. You will then be asked to drink more water. Once your bladder feels full, the researcher will carry out the digital rectal examination. During this, the researcher will put a gloved finger into your back passage (rectum) and gently stroke the prostate to feel your prostate gland. You will then be asked to provide a urine sample. If you take part in PROMIS, 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 for several years, so that we can repeat any tests on them if necessary, and evaluate 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.

This research would be carried out only after approval from an independent research ethics committee and would involve extracting DNA or other chemicals from the samples to see whether the tests make it is easier to detect 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.

A MP-MRI scan is performed as part of this study. A 3-dimensional Ultrasound is performed as part of the biopsy procedure. We would also like to know if you are willing for us to store and use your MP-MRI and Ultrasound imaging data to see if new ways of looking at these scans can detect cancer better in the future.

We would also like to know if you are willing for us to record and store your full postcode. This part of the study is optional. The postcode will be used to study socioeconomic status of PROMIS participants. Your postcode will be collected at study registration and kept confidential in a secure password protected database.

We will also ask if you are happy to be contacted within 5 years to see if you would be willing to fill in a questionnaire about your health status (including details of any other biopsies you have had since the study) and your quality of life. If you do decide to take part a member of the PROMIS research team may send this request to your home address.
12. What are the possible disadvantages and unwanted side effects of the study?
If you do take part in the PROMIS study, you will need to attend some extra hospital visits. There are possible side effects associated with the study procedures, which are detailed below. We will monitor you for these side effects and you may need to take additional treatment to control any that develop. For more information see Table 1 on page 9.

Possible side effects
a) MP-MRI
MRI rarely has any side effects. Some men find the scanner claustrophobic. Putting a cannula (plastic needle) in the arm (to inject the contrast agent – see Part 1 section 8a above) may cause mild discomfort and, rarely, nausea and vomiting (less than 5 in 10,000 people). Very rarely the contrast agent may cause an allergic reaction. Such reactions are usually mild. A severe allergic reaction will occur in less than 1 in 10,000 people. Staff are trained and will be on hand to deal with this if it does occur.

b) Anaesthetic
Bruising of the skin from intravenous catheters is common. Less common side effects include skin infections from intravenous catheters affects, nausea or vomiting, a dry cough and a sore throat. These side effects are temporary.

The risk of death under anaesthesia in the UK is very low (1 in 150,000 anaesthetics).

c) Combined prostate biopsy procedure
Both biopsy procedures carry risks and complications (See Table 1 on page 9). These are similar but there are two important differences:

- TPM is cleaner than TRUS guided biopsy and has a lower infection rate because the needles are going through skin rather than rectum.
- TPM takes more samples than TRUS guided biopsy, so there is more bruising and the prostate can swell resulting in difficulty passing urine because the water passage can become blocked.
- In standard care, TRUS guided biopsies are done without men being asked to empty their back passage or without any cleansing of the back passage. In the PROMIS study we ask you to empty the back passage with enemas or suppositories. In addition, we cleanse the back passage with anti-septic solution during the procedure in order to reduce the risk of infection.
If you are concerned about possible side effects you can find the 24 hour emergency contact details for your study hospital at the end of this information sheet (Part 2 section 9).

There is no evidence that having multiple biopsies raises your chances of prostate cancer spreading.

Table 1: Possible side effects of the combined biopsy procedures compared to standard TRUS guided biopsy

<table>
<thead>
<tr>
<th>Side effect</th>
<th>TRUS alone (standard care)</th>
<th>Combined biopsy: TPM +TRUS (in the PROMIS study)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain/Discomfort</td>
<td>Almost all men experience temporary discomfort in the rectum</td>
<td>Almost all men experience temporary discomfort in the rectum</td>
</tr>
<tr>
<td>Burning when passing urine</td>
<td>Almost all men</td>
<td>Almost all men</td>
</tr>
<tr>
<td>Bloody Urine</td>
<td>1 in 2 men (self-resolving, 2-3 days)</td>
<td>Almost all men (self-resolving, 2-3 days)</td>
</tr>
<tr>
<td>Bloody Sperm</td>
<td>3 in 10 men (2-3 months to resolve)</td>
<td>Almost all men (lasting up to 3 months)</td>
</tr>
<tr>
<td>Poor erections</td>
<td>3 in 10 men (self-resolving after 6-8 weeks). Rarely, tablets may be needed to help the erections improve.</td>
<td>Almost all men (self-resolving after 6-8 weeks). Rarely, tablets may be needed to help the erections improve.</td>
</tr>
<tr>
<td>Infection of skin or urine</td>
<td>1-8 in 100 men</td>
<td>1-8 in 100 men</td>
</tr>
<tr>
<td>Infection of skin or urine requiring admission and intravenous antibiotics</td>
<td>Between 1-4 in 100 men</td>
<td>Between 1-4 in 100 men</td>
</tr>
<tr>
<td>Difficulty passing urine*</td>
<td>1 in 100 men</td>
<td>1-3 in 20 men</td>
</tr>
<tr>
<td>Bruising of skin</td>
<td>None</td>
<td>Almost all men</td>
</tr>
<tr>
<td>Bruising spread to scrotum</td>
<td>None</td>
<td>Between 1 in 20 to 1 in 10 men</td>
</tr>
</tbody>
</table>

A catheter is usually placed temporarily as otherwise the urine flow may stop suddenly, requiring a visit to the A&E department. To avoid this, your doctor is likely to keep your urinary catheter in place for about seven to ten days after the procedure as explained above (Section 8.C). Most find the catheter tolerable although some discomfort can be felt. Rarely, there may be on going discomfort which is controlled by medications.
13. What are the possible benefits to me and for others of me taking part?
Because the TPM biopsy is more thorough than TRUS guided biopsy, if you do have prostate cancer, it is more likely that it will be diagnosed. The size and features of any prostate cancer can also be assessed in more detail. This makes it easier to choose the most appropriate treatment because the TPM gives more information about the risk that a particular cancer poses to an individual man.

Alternatively, if all the tests in this study come back normal, you can be reassured you do not have prostate cancer (unlike after a normal TRUS guided biopsy only). It is therefore less likely that you will need to have another prostate biopsy in the future.

If you decide not to take part in the study, and prostate cancer was found during the TRUS guided biopsy, you will receive the standard care available at your hospital. Some hospitals offer an MRI scan as standard care to those men diagnosed with prostate cancer on biopsy in order to provide a more detailed picture of how advanced a cancer is. If you do take part in the study you will undergo an MP-MRI scan before the biopsies. There are two main benefits of this. Firstly, MP-MRI scans are clearer to read before, rather than after, biopsy procedures and secondly, if you do need treatment, it may be possible to start treatment sooner.

In addition, the PROMIS trial could mean that, in the future fewer men will need to be biopsied, and that biopsies will be more accurate.

14. 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.

15. Will my taking part in the study be kept confidential?
Yes, all the information about your participation in this study will be confidential. The details are included in Part 2 section 3.

16. What happens when the study stops?
It is also important 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. For this reason, we will ask for your consent for your name to be used to gather information from records held by the NHS and maintained by the NHS Information Centre and the NHS Central Register or any applicable NHS information system (including linkage to routine hospital admission data). In order
for us to do this we provide identifiable information for us to trace you on the National Health Service Care Register (NHSCR) (this is an optional part of the study).

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. The maximum amount of time we expect participants to spend in this study is 3 to 4 months. For most it will be significantly less.

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. If you do withdraw, your doctor may still recommend that you undergo biopsies of the prostate including TPM biopsies as standard care.

We expect this study to run for two or three years, whilst we recruit the 720 volunteers, carry out all the procedures and assess all the results. 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. The aim of this study is to provide new information about the procedures involved to find the most accurate way of diagnosing prostate cancer in future, across the world.

2. What if there is a problem?

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 study doctor, please make the claim in writing to Professor Mark Emberton who is the Chief
Investigator for this study and is based at UCL. 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.

Regardless of this, if you wish to complain, or 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. 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).

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

All data will be identified by a number only 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, your disease and your results, and we will enter it onto a study database. This is for the purposes of analysing the results. Scientific and medical employees of the Medical Research Council Clinical Trials Unit (MRC CTU) and people from University College London (UCL/UCH) Joint Biomedical Research and Development Unit 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.

You will be asked to give consent to allow potential future contact so that you may be sent questionnaires on health status and quality of life. If you consent to this, a letter may be sent to your home addresses. Your name and address would be kept separately from the study database to keep the study data collected anonymous. This consent is optional and does not affect your right to take part in the rest of the study. Ethical approval would be sought for future research involving the use of questionnaires.

The MRC CTU and UCL are registered under the [UK] Data Protection Act to hold such information on a confidential basis. An independent expert committee will confidentially review the study at regular intervals. This is so that if new evidence comes to light or that evidence from within the study clearly shows that one of the procedures gives substantially better or worse diagnoses than the other, then the study could be stopped early, though your care will continue. This expert committee will also monitor the safety of the procedures within the study. No individual patients will be identified when the study results are published.
4. Involvement of your General Practitioner (GP)/family doctor
Because this study is not being carried out by your GP we would like to inform him or her of your participation. If you agree to take part and agree to us contacting your GP, we will give him or her details of the study and inform them that you have chosen to participate in it.

5. Additional Research: Health Economics
A further part of this study is to find out the cost effectiveness of having the MP-MRI scan instead of, or as well as, the other two biopsies. To help with this we will ask you to fill in a questionnaire about your health.

6. 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, although we expect to have the results from this study available in summer 2014 or possibly sooner. If you wish to receive information on these results when they are presented please ask your study doctor. We will also publish a summary of the results on the MRC CTU web site (http://www.ctu.mrc.ac.uk/).

7. Who is organising and funding the research?
The study is funded by the National Institute for Health Research, Health Technology Assessment (NIHR HTA) programme and is supported by the National Cancer Research Network (NCRN). NIHR HTA and the NCRN receive money from the government, charities and industry. The sponsor of the trial is UCL and they have delegated the study to be managed and run by the MRC.

None of the doctors or other staff conducting the research are being paid for recruiting patients to the study or for looking after patients in the study.

8. Who has reviewed the study?
The study has been reviewed by independent international experts, the National Institute for Health Research, Health Technology Assessment (NIHR HTA) and the National Cancer Research Network (NCRN). The study has been approved by the NRES Committee London – Hampstead.

Three cancer patient representatives have been involved in reviewing the study within the NRCN, two cancer patients have helped work on the design on this study, and all three cancer patient have helped write this information sheet.
9. 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.

PROMIS research staff contact details:

Principal Investigator: Mr Nick Burns-Cox
Consultant Urological Surgeon
Tel: 01823 344847
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Research Nurse: Ms Hannah Routley
Urology Nurse Specialist
Tel: 01823 342111
Email: hannah.routley@tst.nhs.uk

Urology Research Fellow: Mr Amerdip Birring
Urology Research Fellow
Tel: 01823 342111
Email: amerdip.birring@tst.nhs.uk

You may also find it useful to contact Macmillan Cancer Support, an independent patient advisory group (www.macmillan.org.uk, freephone 0808 808 0000; address: 3 Bath Place, Rivington Street, London, EC2A 3JR) or the Cancer Research UK website (www.cancerresearchuk.org). Macmillan Cancer Support includes the information and helpline formerly provided by CancerBACKUP.

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 NCRN (www.ncrmdv.org.uk) or the NHS (www.invo.org.uk)

Any prostate biopsy can lead to infection; this is why it is very important that you take the antibiotics that you are given. If infection is untreated this can be a very serious complication. If, after the biopsy, you experience a fever, or any other symptoms of concern, it is extremely important to contact your study hospital immediately (using the emergency details below). You must make contact so that any complications may be treated promptly before they become serious.

Your emergency 24 hour contact numbers are:
01823 342111
(Surgical Investigations Unit)

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 about the study.
Appendix 1

Your doctor will be giving you a prescription containing these medications after reviewing your medical history. Unless told otherwise by your trial doctor you should use the medications prescribed as follows:

• Tamsulosin or alfuzosin: (prostate relaxer) – start taking this medication one week before your biopsy and continue taking it for two weeks after your biopsy. Tamsulosin and alfuzosin can make you feel light-headed upon standing so we ask you to take it at night before you go to bed. If the feeling of light-headedness on standing up continues during the day then please stop taking the tablets and contact one of the trial team.

• Ciprofloxacin: (antibiotic) – start taking the night before your biopsy and also on the morning of the biopsy. Continue taking twice a day until you finish the course that has been given to you.

• Phosphate enema: please use this the evening before your biopsy. If you find that the enema does not help with opening your bowels or you are unable to use the enema for any reason then take one of the glycerine suppositories we have given you the night before the procedure.

• Glycerine Suppository: We will give you two of these suppositories. Use one if the enema has not worked the night before (see above). Please bring the second glycerine suppository to the hospital with you on the morning of the procedure and use it immediately when you arrive. The reason you should do this in the hospital is to avoid loose motions on your way in.