To be presented on local headed paper

Additional Research Patient Information Sheet

STAMPEDE

We are inviting you to take part in a clinical study called STAMPEDE

- This information leaflet includes information about four additional research projects
- These projects are optional so you can still participate in STAMPEDE even if you choose not to take part.
- Please take your time to read this carefully, you can discuss this information with your family and friends if you wish
- Please let your doctor or research nurse know if you have any questions or if anything is unclear
- Thank you for taking part in STAMPEDE

What do you need to know?

We want to find out whether we can improve prostate cancer treatment by adding new treatments to the current standard approach or by modifying the type of hormone therapy given

We want to know how well each treatment controls your cancer and how your quality of life is affected

We want to look at how much value for money each treatment offers

We will look for genetic markers that may predict whether some people are more likely to benefit from a specific treatment or more likely to get side-effects

We want to develop approaches to identify genetic changes present in prostate cancers that may predict which treatments work best

We will look for genetic changes in the cancer that may explain why treatments stop working

We hope this knowledge will mean that in the future we can choose the right treatment at the right time for each patient

How to contact us

If you have any questions about this study, please talk to your doctor or nurse:

Name of doctor or nurse
Hospital Department
Hospital
Address
Address
Tel: 01234 XXX XXX

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Project 1: Quality of life and value for money

1 How do we work out which treatment is best?

STAMPEDE collects a lot of information about how well each treatment controls prostate cancer. To determine which treatment is best, we think it is equally important to find out how each treatment makes you feel and the impact on your quality of life. We will also look at how much value for money each treatment provides.

When we share the results of this study, we will provide all of this information to help guide men with prostate cancer and their doctors in choosing which treatment is best.

2 What information do we require?

If you choose to take part in this research project, we will ask you to fill in some questionnaires that ask you about your physical and emotional feelings and wellbeing. We are also interested in any side-effects you may be experiencing from treatment. We will use this to assess the impact treatment is having on your quality of life.

We are also looking at how much value for money each treatment offers and so we will ask if you have required any extra medications, or visits to your hospital or GP.

3 What will this involve?

You will be asked to fill in a questionnaire when you first come to clinic after joining the study. **Table 1** shows how often we would like you to complete one throughout the study.

If your cancer grows and you stop trial treatment and start additional cancer treatment, you will no longer need to complete this questionnaire.

Table 1: Questionnaire schedule

TIME FROM STARTING THE STUDY	HOW OFTEN WE WILL ASK YOU TO COMPLETE A QUESTIONNAIRE
First 6 months	Every 6 weeks
6 months - 2 years	Every 3 months
2 – 5 years	Every 6 months
After 5 years	Each year

If possible, you should complete the questionnaires on your own. Please make sure the correct date is written at the top of the questionnaire before you start. Try to answer all the questions but do not spend too much time thinking about each answer, as your first response is likely to be more accurate. If a question is not applicable to you, please write "not applicable" or "N/A" instead, but please do not leave any answers blank.

We ask about lots of different symptoms as the questionnaires are used in many different areas of research, not just prostate cancer studies. If you are not given a questionnaire to complete, please remind your doctor.

You can, of course, decline to complete a questionnaire at any time without affecting your relationship with your doctor or your participation in the study.

4 Will the information I provide be kept confidential?

Yes, your answers are treated in confidence. Your doctor should not see the questionnaires once you have filled them in. This is to ensure that you are not influenced by what you think your study doctor may think about your responses.

However, it is important that you share any concerns and tell your doctor or research nurse about any new side-effects.

Your questionnaires will be sent directly to the MRC Clinical Trials Unit at UCL where they will be treated in confidence and analysed together with questionnaires from men treated in other hospitals.

Project 2: Looking for genetic markers to help make better treatment decisions

5 Why are we doing this project?

Many men are affected by prostate cancer but not all men will respond to treatment in the same way. We want to look for genetic markers that help explain why some men benefit from a particular treatment when others do not. We are interested to learn more about the causes of prostate cancer and identify men with aggressive disease. We will also look for markers that may predict who is most likely to get side-effects from treatment.

6 What would I need to do?

If you choose to take part, we would like to ask you to provide a blood and saliva sample when you first join the study. We have recently started collecting saliva so if you did not provide a sample when you first joined the study we are asking if you would mind providing a sample now.

7 How would my samples be used?

We will store your blood and saliva samples at your hospital and then transfer them to Institute for Cancer Research in London where they will be analysed. We will use them to look at your genetic material (DNA and proteins). We hope that this information will help us predict who will respond to which treatment and who is most likely to get side effects. We hope this will mean we can make better treatment decisions in the future.

Project 3: Exploring why treatments stop working

8 Why are we doing this project?

We want to explore why treatments often stop working (treatment resistance). To do this we would like to collect samples of genetic material (DNA) from cancer cells that are shed into the blood stream. We can

do this by taking a blood sample from you. By doing this over time we can look for the genetic changes that occur in the cancer cells that may explain how the cancer becomes resistant to treatment.

9 What would I need to do?

If you choose to take part we would like to ask you to provide extra blood samples. This would mean an extra 20ml (around 4 teaspoons) of blood per sample. We will aim to take this sample at the same time as your routine blood tests, where possible, so no extra needle pricks are needed.

The number of extra blood tests we ask for depends on how far your cancer has spread. If your cancer has spread to other parts of the body (metastatic prostate cancer) then we ask for a total of up to 9 extra blood samples (a total of 180ml) over about 18 months. If your cancer is confined to the prostate or nearby lymph nodes in the pelvis (locally advanced) then we ask for up to 6 extra blood tests (total of 120ml) over about 18 months.

The blood samples are taken at the point when we think your treatment is beginning to stop working and again when you stop your research treatment. This provides us with information about the changes in the cancer that may help explain why the treatment is no longer effective.

Table 2: Timing of extra blood samples

TIME FROM STUDY ENTRY	LOCALLY ADVANCED	METASTATIC
At study entry	20ml	20ml
48 weeks	None	20ml
72 weeks	None	20ml
84 weeks	None	20ml
If the cancer starts to grow again	Up to 60ml (Up to three samples taken at different times)	Up to 60ml (Up to three samples taken at different times)
When the treatment is stopped	20ml	20ml
Before you start a new treatment	20ml	20ml

Project 4: Donating stored tumour tissue to research

At the time you were diagnosed with prostate cancer, you will have undergone a procedure to obtain a sample of tumour tissue. This sample is usually taken from the prostate during a biopsy or operation e.g. TURP but may have been taken from another metastatic site e.g. lymph node. These samples were analysed in the pathology laboratory at your local hospital and helped confirm the diagnosis of cancer. We would like your permission to collect and use some of this stored remaining material for future research.

10 How would my samples be used?

They will be stored in research organisations and will be accessible by researchers from academic and commercial organisations that are granted access by the committees that oversee STAMPEDE. The samples may be transferred outside the UK or Europe to be analysed. The researchers will not be able to identify the sample as belonging to you and your confidentiality will be protected at all times.

We will look at genetic markers that predict who will benefit from which treatment as well as markers that help identify men with aggressive disease. In the future the samples may also be used in research that involves animals where this helps answer important questions about how best to improve prostate cancer treatment.

You will not financially benefit from any developments made but we hope that this research will help develop better treatments and better tests for men with prostate cancer.

11 What would I need to do?

You do not need to have any extra tests to take part in this project, we will only use any remaining tumour tissue from samples that you have already had taken. You will need to sign on the consent form that you agree we can collect, store and analyse your samples.

Project 5: Participating in a biomarker-screening pilot

12 Why are we doing this project?

We want to develop approaches to identify genetic changes present in prostate cancers that may predict which treatments work best.

These genetic changes are referred to as a type of "biomarker". In this pilot we will test different approaches that aim to identify biomarkers in men with newly diagnosed prostate cancer.

This pilot is being run in a selected number of hospitals participating in STAMPEDE and will help the trial prepare to test a treatment predicted to work in a proportion of cancers with a specific genetic fault, "biomarker-positive" cancers.

This will not apply to you if your hospital is not participating in this pilot.

13 What would I need to do?

Only some hospitals are taking part in the biomarker-screening pilot. If you are asked to participate we would ask for your permission to analyse all three types of samples described in this information sheet:

- A saliva sample to analyse your genetic material (DNA)
- An extra blood test to detect genetic material shed from the cancer cells
- Stored tumour tissue to detect genetic changes present in the cancer cells

We will compare the results of biomarker-screening using these different approaches.

The results of this research will help in the planning of the trial but will not affect which treatment group you are allocated to in STAMPEDE.

Important general information

14 Will I be told of any genetic results?

If you choose to provide or donate additional saliva, blood or stored tumour tissue for additional research, your samples may undergo genetic testing.

You will be asked to indicate on the consent form whether or not you would like to receive any results from the genetic analysis.

This would include testing for genes that are known to increase prostate cancer risk. Some of these genes that we test for are known to *increase the chances of developing other diseases*. Where these genetic changes are found to be in your germline (ie present in every cell in your body and not just in your tumour) this means they can also be passed on to or inherited from your family members, so can have implications for their cancer risk as well.

If we find any of this type of genetic change, we will inform you and your treating doctor who can refer you to a specialist genetics clinic who can discuss the implications for you and your family. The only results reported back to you will be those which have known medical implications and for which testing would be available under standard NHS genetic testing guidelines.

We will periodically review this data to ensure that we report to you any results that are newly included in updated guidelines in the future.

Any results that arise from this research will not change your current treatment and will not alter which treatment group you are allocated to in the trial.

It is possible that if specific genetic changes are detected, this knowledge could have implications on which treatments you might receive in future.

The results of this research analysis may not be available immediately and does not replace any genetic screening that your doctor may recommend as part of standard clinical care.

You can opt not to receive any information arising from this genetic analysis and still take part in these projects. If you chose not to receive the results, neither you, your treating doctor or your family would be made aware of these.

You can always change your mind at a later date.

15 Do I have to take part in these projects?

You can choose if you wish to take part in these additional projects. If you choose not to, you can still take part in STAMPEDE. All samples are given voluntarily and you can always change your mind and not provide a sample if you do not want to. This will not affect your relationship with your doctor or your participation in the study.

16 Will I be identified?

No, the researchers taking part in these projects will not be told your name and the samples will be identified by a code number only.

17 How is my personal information protected?

Your personal information will be stored confidentially and will only be accessible to staff who have a duty of confidentiality to you as the donor of the sample, in accordance with the Data Protection Act 1998. We will make every effort to protect the confidentiality of your information and make sure your personal identity does not become known.

18 Who will have access to my samples?

The Medical Research Council (MRC), who organise this study, will oversee who accesses the samples and this will only be granted for research projects that are expected to provide answers to important questions that will help improve prostate cancer care. All projects will need to be approved by an independent ethics committee.

Researchers may belong to academic institutions e.g. universities or a commercial company but no one commercial company will be given exclusive rights of access. You will not financially benefit from any results from work with commercial companies but it is hoped that this research will help improve care for example through developing better tests to be used in the care of men with prostate cancer.

If we find anything important during our research on prostate cancer it will be published in a well-recognised scientific journal so it will be available to the whole medical and scientific community. Your personal details will not be identified in any way in any publication.

19 What will happen to these results?

The results of these projects are unlikely to benefit you directly but we hope that the information gained will help improve treatments for men with prostate cancer in the future. We will share the results in several ways but your personal details will never be identified in any way.

Important results will be presented at scientific conferences, published in well-respected scientific journals and shared with prostate cancer support networks and all the hospitals taking part.

For more information, please contact your doctor:

< Principal Investigator Names >

More information is also available on our website **www.stampedetrial.org**

Thank you for taking the time to read this information and for considering taking part.