BiopSave: Validation of a novel proteomic blood test for the diagnosis of prostate cancer

PARTICIPANT INFORMATION SHEET

USING BLOOD SAMPLES TO DIAGNOSE PROSTATE CANCER

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you.

Please take time to read the following information carefully. Talk to others about the study if you wish.

(Part 1 tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study).

Ask us if there is anything that is not clear or if you would like more information. Once you have done this please take some time to decide whether or not you wish to take part.

You do not have to take part in this study. You will be treated to the very best of our ability whether you take part or not.

PART 1

What is the purpose of the study?

This study is a research project, which is intended to assess the performance of a new blood test, 'BiopSave', which has been developed by a Newcastle-based company, Biosignatures Ltd.

A substantial number of prostate biopsy procedures are carried out each year on patients who are suspected of having prostate cancer.

The BiopSave assay is intended to be used as a screening tool prior to prostate biopsy to distinguish patients who appear to have a high likelihood of having prostate cancer from those who have a low likelihood of having prostate cancer. It is hoped that in the future this test could provide extra information to the clinical team, giving them more options in managing the care of their patients and allowing biopsy tests to be used more selectively.

The study will run for 24 months and will routinely process between 30 and 50 participants per month.

Why have I been chosen?

You have been chosen because you have been referred to a urology clinic or have been admitted to a urology ward. We need participants with a variety of conditions and also people who are healthy.

The 'population' this study is interested in is all patients that have been referred to a urology clinic for further investigation, who go on to have a prostate biopsy test carried out. Being asked to take part in this study does not mean you have a specific urological condition.

Do I have to take part?
It is up to you to decide. We will describe the study and discuss this information sheet. We will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

What will happen to me if I take part?
There will be no changes to your treatment if you take part. We would like to collect some additional information and blood samples from you.

Whilst at the clinic, all the people taking part in the research project will be asked to provide a small blood sample and asked some questions about any medications they are on and some medical history. It may be a good idea to write down your medications before your visit. Wherever possible the blood sample will be taken at the same time as any sample taken as part of the standard clinical assessment and will require no additional procedures.

The medical team will continue to access your medical records so they can look back and see if the blood sample can be used as an early warning for any condition you may have or develop. You are free to stop this access at any point without giving a reason.

This is an observational study. We gather information from lots of people and conditions and follow up the conditions they are diagnosed with to determine how accurately the new blood test is able to predict the biopsy diagnosis.

What is the study trying to assess?
This study is trying to assess the ability of a new blood test to predict prostate biopsy results. It is hoped that this will eventually lead to a reduction in the number of biopsy tests that people need to have carried out.

What are the possible disadvantages and risks of taking part?
There should be no disadvantages or risks to taking part. Your treatment will be unaffected by your taking part or not. The blood sample is a small amount and in the worst case you may experience some slight bruising from where the sample was taken. Wherever possible the sample will be taken at the same time as you provide samples during your clinical assessment and so should involve no additional risks or discomfort.

What are the possible benefits of taking part?
The trial will not help you personally but the information we get from this trial could help improve the diagnosis and treatment of urological conditions in the future.

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. The detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?
Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

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

PART 2

What will happen if I don't want to continue with the study?
You can withdraw from the study at any time and without giving a reason. If you withdraw from the study, we will destroy all your identifiable samples, but we will need to use the data collected up to your withdrawal.

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:
Research Nurse: Wendy Robson, 0191 2137322
Principal Investigator: Mr Naeem Soomro, Clinical Consultant Urologist, 0191 2336161

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure by contacting:

The Patient Advisory Service, Tel: 08000320202

In the very unlikely event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for legal action for compensation against the NHS Trust or the study sponsors but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

There is a small chance that results from this study will suggest you have a condition of which you are unaware. This will not be a diagnosis but it may suggest further standard clinical tests should be run just to be sure. In such circumstances you will be referred to the appropriate specialist in consultation with your general practitioner, if that is what you would like. Such detection has the benefit of starting treatment early but in a small number of cases may have implications for future employment and insurance.

Will my taking part in this study be kept confidential?
There are very strict rules about collecting medical research information under the 1998 Data Protection Act. We must comply with this act and keep your information safe. Any Information that leaves the hospital will have your name and address removed.

Your medical notes include details about your name, date of birth and hospital number. The information accessed for the research will be about your diagnosis and long term state of health. In order to check that the study is being carried out correctly and the information accurate the trials team may wish to see your medical records.

Your GP will not normally be notified that you are taking part in this study, but a member of the medical team would be happy to do so if you so wish.

All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the hospital will have your name and address removed so that you cannot be identified.

What will happen to the samples I give?
The blood samples will be sent anonymously to a laboratory and processed. The result of the processing is to measure relative quantities of many thousands of constituents of your blood. These measurements will be combined with information from the questionnaire and medical records and analysed to see if any of the measures can be used to diagnose specific diseases. Only the direct medical team have access to your name and records. All information leaving the clinic is not identifiable to you.

We would like to consider the samples as a ‘gift to science'. By this we mean that, if you are happy for us to do so, remaining sample not used in this study could be used in ethically approved follow on research. The same strict controls on confidentiality will be in place. An example of this may be trying to find new treatments for cancer. If you only want your samples to be used in this study then we are happy to destroy any unused samples if you would prefer. If you consent to this further use, the remaining samples will be transferred to a government licensed tissue bank where they can only be used in research that has been reviewed and received a favourable ethical opinion.

No genetic tests will be done as part of this study.

What will happen to the results of the research study?
- The results will be published in scientific journal.
- If diagnostic signatures of disease are validated they will be commercialised and put into standard clinical practice as soon as is practical
- At no time will you be identified in person.

An overview of results of the research will also be presented on the sponsor's website http://www.biosignatures.com/BiopSave_SST to allow participants to follow overall progress.

Who is organizing and funding the research?

The driving force behind this research study is a local company, Biosignatures Ltd. Biosignatures is a small team based in Newcastle and is passionate about the region and what its people can do. If successful this study would be recognised internationally and showcase the scientific abilities of the region.

This study has been designed and conceived by Biosignatures who are also providing the funding. Although it is hoped that the research will go on to benefit patients within the NHS the clinical staff have been contracted to participate in this study and did not instigate it.

The sponsor is paying the hospital to employ a full time research nurse and to have some time from the experts in the clinic. The contract is for a fixed time and there is no per patient payment or incentives for any of the clinical staff. No Biosignatures staff work in the clinic and everyone you meet will be employed, trained and managed by the hospital.

Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by the Oxford C Research Ethics Proportionate Review Sub-Committee.

The study has also been reviewed and approved by The Newcastle Upon Tyne Hospitals NHS Foundation Trust.

Thank you for reading this information leaflet. If you have problems or questions now or during your treatment, please do not hesitate to get in touch.

Please use one of the following contact numbers:

Freeman Urology clinical team:

Research Nurse: Wendy Robson, **tel:** 0191 2137322
Principal Investigator: Mr Naeeem Soomro, **tel:** 01912336161

Address: Urology Renal Medicine, Freeman Hospital, NE7 7DN

Biosignatures Ltd.,

Clinical Operations Manager: Dr Ben Chaffey
email: info@biosignatures.com
web: http://www.biosignatures.com
tel: 0191 6453645
Address: Keel House, Garth Heads, Newcastle Upon Tyne, NE1 2JE

Additional and updated information is available here:
http://www.biosignatures.com