

PATIENT INFORMATION SHEET

“HIGH INTENSITY  
FOCUSED ULTRASOUND  
*FOCAL ABLATION* OF  
LOCALISED PROSTATE  
CANCER”

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## PATIENT INFORMATION SHEET

### Part 1

#### High Intensity Focused Ultrasound Focal Ablation of Localised Prostate Cancer

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. 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. Take time to decide whether or not you wish to take part.

### 1. What is the purpose of the study?

#### **Main Aim of the Project**

The procedure we are testing is destruction of only areas of the prostate gland with prostate cancer using a device called the Sonablate® 500 HIFU machine. It uses a high energy focused ultrasound beam, which is directed across the wall of the back passage into the prostate to heat and destroy a very precise volume of tissue at its focus. This study will help us to find out just how safe and well tolerated HIFU is in destroying only discrete areas of the gland.

#### **Why is trial needed?**

At the time of diagnosis, prostate cancer may be confined to the prostate itself, or may have spread to other sites within the body. If prostate cancer is confined to the prostate, there are a number of treatments available.

Men with localised prostate cancer have to choose between two extremes of care - active surveillance versus radical therapy. Active surveillance involves monitoring the disease with regular 3 monthly blood tests (a PSA test), examination of your prostate in clinic, and 2 or 3 yearly biopsies: if these show signs that the disease is progressing, then treatment will be recommended. Radical therapy involves treatment that aims to destroy the whole prostate. These include surgery (radical prostatectomy), external beam radiotherapy, brachytherapy (small implanted radioactive seeds), cryosurgery (freezing) or HIFU. The best evidence we have shows that the difference between these two very different approaches is not large in terms of preventing an individual from dying of prostate cancer within a 10 year period - 14% of men died within ten years whilst on active surveillance, compared to a rate of 9% for men who had surgery. On the other hand, we know that the side effects of radical treatments are high - they include, amongst others, deterioration in urinary, sexual and bowel function. It is these harms of therapy that many men are keen to avoid. These harms arise because when the whole gland is treated, there is damage to surrounding areas such as the muscle that controls urine flow and the nerve bundles that control erections.

Could there be some way in which the benefits of treatment for cancer control could be obtained without exposure to the harms traditionally associated with radical therapies? Our focal-ablation (destruction of cancer areas only) study using high intensity focused ultrasound (HIFU) addresses this precise point. In other words, if we are as sure as we can be that cancer is confined to certain areas in the gland, then why not treat just those areas and monitor the untreated areas? This will allow us to avoid or reduce the damage to surrounding structures such as the muscle controlling urine flow and the nerves controlling erections. If we can do this, can

we control the cancer and keep the side effects to a low level? This trial will assess whether we are correct in this theory.

## 2. What is High-intensity Focused Ultrasound?

HIFU works by generating sound waves which make the prostate tissue heat up and die. The treatment areas can be carefully located within the prostate and avoid the delicate organs that lie next to the prostate gland. It does not involve any needles into the prostate or any cuts to the skin.

HIFU therapy for prostate cancer has been in use for about 5 years. Studies are either under way or have been completed in the United States, Europe and Japan. Over 3000 patients have been treated so far. Studies have shown that HIFU therapy is at least as safe as other treatments for early prostate cancer and may have fewer side effects. It also appears to be effective at controlling prostate cancer, though the studies that show this are relatively new. This means that the longest period of time between HIFU therapy and assessment of side effects and cancer control is 5 years. Whilst this may sound like quite a long time it is generally agreed that 10 to 15 years needs to pass before we can be reasonably sure that any one prostate cancer treatment is as effective as any other. These studies show that HIFU, in the short term, appears to be a promising treatment. Depending on the study, and exactly how success was measured, reports have shown that HIFU therapy was effective at controlling prostate cancer in 80% to 95% of men treated, up to five years after the patient received the treatment.

### **Am I eligible for HIFU in this study?**

We look at the following characteristics of your individual case before making a decision about whether HIFU is suitable for you:

- i. You have localised prostate cancer with a Gleason score of 7 or less
- ii. Your PSA is 15ng/ml or less
- iii. The prostate gland is either 40cc or less in volume or the height of the prostate (measured with ultrasound) is 4.5cm or less.
- iv. Calcium in the gland can make the HIFU ineffective by stopping the sound waves. If the prostate has 1cm or more of calcium (as shown on ultrasound) then you will be ineligible for HIFU.
- v. If the gland has fluid-filled areas (cysts) larger than 1cm then this can also affect the ultrasound beam.
- vi. Latex allergies make you ineligible for HIFU as the probe is covered with a latex sheath before we insert it into the back passage.
- vii. If there is clinical or tissue evidence of bladder cancer, or if you have a narrowing in your water passage (urethral stricture) or have any metal implants or stents in the urethra you will be ineligible.

In addition, patients with the following criteria will not be treated with the Sonablate® 500:

- i. Men who have had previous prostate surgery (including TURP);
- ii. Men who have had previous radiation therapy for prostate cancer;
- iii. Men with evidence of metastatic disease;
- iv. Men with an inability to tolerate a transrectal ultrasound;
- v. Men with active urinary tract infection;
- vi. Men with functional bladder problems; and
- vii. Men who have undergone prior significant rectal surgery (this depends on the type of surgery and an individual decision will be made).

## 3. Why have I been chosen?

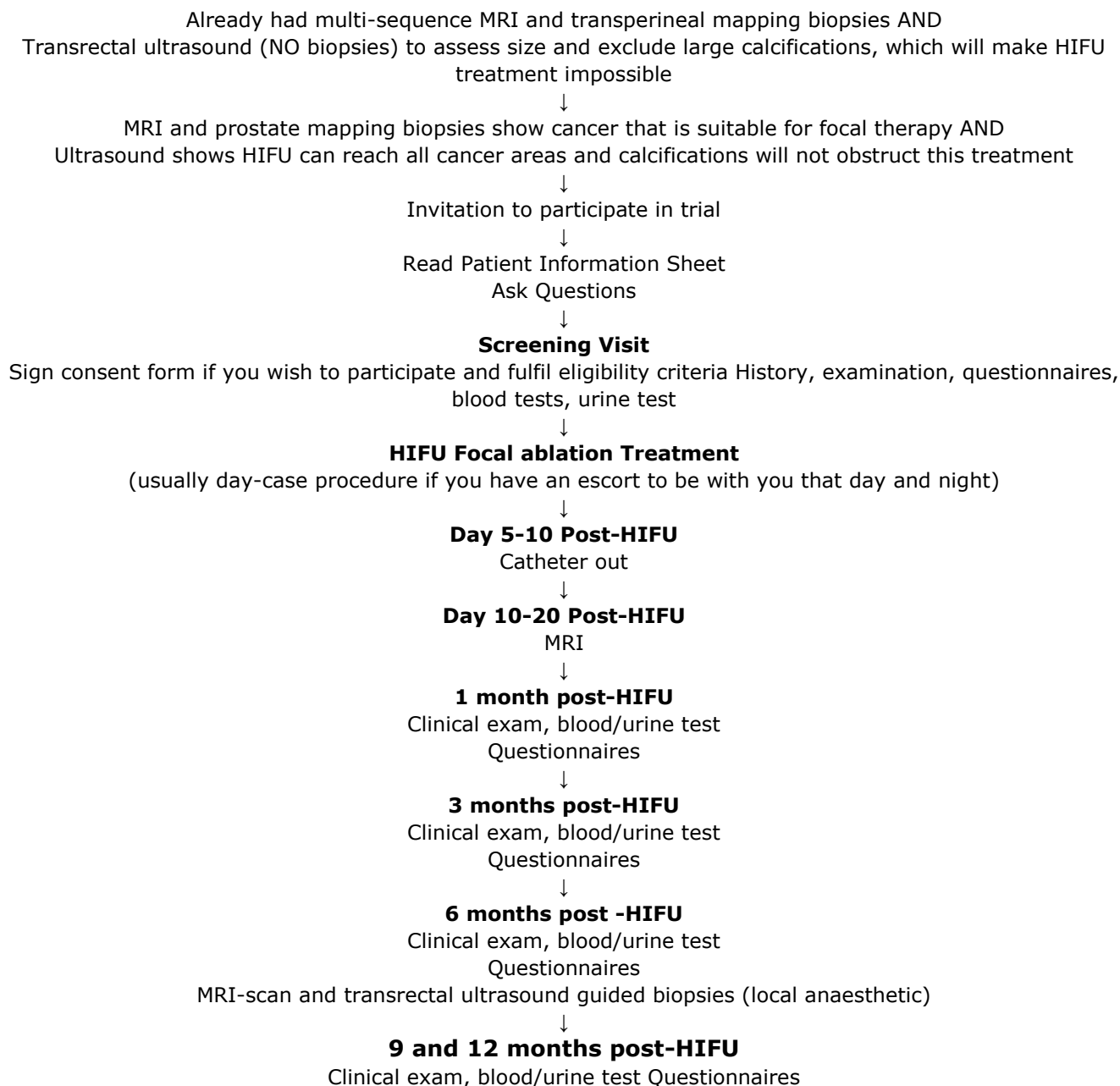
You have been chosen because you have had a diagnosis of prostate cancer. The cancer seems to not have spread outside the prostate and it seems to be localised to only areas of the prostate gland that have been mapped by an MRI scan and prostate mapping biopsies under general anaesthesia. The research team, upon looking at your results, think they can destroy only those areas of the prostate with cancer and leave non-diseased areas alone. Also, they believe they can preserve at least one of the nerves that run alongside the prostate that supplies the penis for erection function. In radical treatments both nerves are usually damaged.

#### 4. Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep and be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

#### 5. What will happen to me if I take part?

The flowchart gives a summary of what this study involves.



If you decide to take part in the trial, you will be asked to attend in trial visits over the course of the next one year. The precise commitment this will involve is laid out below. After this period, your care will continue in the same way as if you had not taken part in the study. Your progress and condition will be monitored by your

doctors in the urology or oncology clinic in the same way that it would have been if you had not decided to take part in the trial.

## **6. What happens exactly at each visit is outlined below**

### **Visit 1: Screening Visit**

Your research doctor will see you as an outpatient, explain the procedure to you, and answer any further questions that you might have. You will be asked to sign a consent form before we carry out anything further as part of the study. Once you have done this, you will have your full medical history taken and a physical examination carried out of your chest, heart and abdomen.

We will ask for the following things as well:

- 4 questionnaires to complete. These will include questions of a personal nature relating to erectile/sexual function, urinary flow/continence and your quality of life. You will be free to complete these in privacy.
- Blood sample for baseline tests and for anaesthetic pre-assessment [prostate specific antigen (PSA), full blood count (FBC), kidney function test (urea, creatinine, electrolytes)]. The amount of blood taken will be 10mls. This is about the same as a tablespoon of blood.
- A chest x-ray and a heart tracing (ECG) may also be required.

### **Visit 2: HIFU Focal Ablation Treatment**

- You will be asked to not eat anything for at least 6 hours before the procedure. You should NOT drink anything for at least 4 hours before the procedure. On the morning of the procedure you will be given an enema to clear your rectum. This allows us to have clearer ultrasound pictures during HIFU treatment.
- An anaesthetist will explain the anaesthetic options available to you and make sure that your preferred option is both appropriate and safe. The anaesthetic will usually be a general anaesthetic (which puts you into a deep sleep during which you cannot feel anything. This is so that you do not move during the procedure so that the HIFU treatment is effective. The HIFU focal ablation will use a probe, slightly larger in size to the one used when you had your very first prostate biopsies taken, that is placed into the rectum. The treatment normally takes between 1<sup>1/2</sup> to 2 hours.
- After the treatment, a urinary catheter (a tube that drains urine from the bladder) is placed in the bladder. This is usually placed through the skin directly into the bladder rather than through your penis. Once this has been done your anaesthetist will wake you up. Most men will be able to have their treatment and go home about three hours later, provided there is someone else at home and suitable transport can be arranged. Occasionally, there will be the need for an overnight stay after treatment if your medical team think it is safer.
- You will be taught all about your catheter and how to look after it. Mild pain killers and a course of antibiotics and a contact number if you have any problems at home are given.

### **Visit 2 and 3: Removal of Catheter (5-10 days) and MRI scan (10-20 days) after HIFU Treatment**

The MRI scan will allow us to see how successful the destruction of prostate tissue was. Your catheter will be removed. This is a simple procedure that is usually not painful. Once the catheter has been removed you will be encouraged to drink and asked to try and pass urine. If you are unable to pass urine, a new catheter will be placed and you will be invited back a week later to have it removed. If at the second attempt at catheter removal, you are still unable to pass urine two things may happen. The first would involve teaching you the technique of Clean Intermittent Self Catheterisation (CISC). Although this may sound difficult to perform, most people learn it very quickly. It involves you passing a small slippery catheter into the bladder to empty it. You would only do this when you needed to. With time your bladder would start to work again and your need for CISC would become less and less.

If you cannot re-establish normal bladder emptying a cystoscopy (using a telescope to look into the bladder) will be carried out to investigate the cause. Some men, about 10-20%, may need this to be done. At the time a small procedure may be performed in order to promote normal bladder emptying. This might involve releasing some scar tissue in the prostate (formed as a result of the HIFU therapy) or cutting through the bladder neck in order to allow more efficient bladder emptying. Very occasionally some dead tissue or debris within the prostate would have to be removed. These procedures can be done using a telescope and should require no more than a one night stay in hospital.

### **Visits 4 and 5: 1 and 3 months after HIFU treatment**

- Blood tests to measure PSA, kidney function and haemoglobin level, white cell count and platelet count
- Urine test
- You will be asked about any symptoms that you experienced following the therapy.
- Complete the same 4 questionnaires that you completed prior to the HIFU therapy.

### **Visit 6: 6 months post treatment**

The only difference between this visit and visits 4 and 5 is that we will need to take further biopsies of the prostate as well as other items done in visits 6 and 7. Biopsies are taken to be as sure as we can that no cancer cells remain in the treated parts of the prostate. We will not biopsy the untreated areas unless the MRI shows a suspicious lesion that was not seen in your pre-treatment biopsy. It is done under local anaesthetic using a transrectal probe in a similar fashion to those biopsies you had before the trial to diagnose the cancer. You will not normally need to stay in hospital overnight. The procedure lasts for 15-20 minutes and you will be given a course of antibiotics to ensure infection does not develop.

### **Visits 9 and 10: 9 and 12 months after HIFU Treatment.**

These visits would be identical to visits 4 and 5.

### **7. What will happen once the trial finishes?**

Longer-term follow up will be carried out in the form of routine clinical appointments. This would be similar to the follow-up that you would expect to receive if you had chosen active surveillance at the outset.

### **8. What will happen to me if the treatment fails?**

The HIFU therapy will be assumed to have been effective unless one or both of the following occur. Firstly, if prostate biopsies (scheduled at 6 months) show prostate cancer cells in the treated areas. Secondly, if rises in PSA occur which indicate there may be cancer. If the PSA level rises in a way to suggest a recurrence you will be offered further prostate biopsies, even if previous biopsies did not reveal cancer at 6 months. If any biopsies show prostate cancer cells the HIFU focal ablation treatment will be deemed to have failed. Further treatments might include: surgery, radiotherapy, cryotherapy, hormonal treatment, photodynamic therapy or further HIFU treatment. You will be given detailed information on this.

### **9. What data will be collected?**

We will hold information about you without anything that could identify you to that data. You will be given a study number and this will be used on all your study records. The code for this number will be known to Mr Mark Emberton and Mr Hashim Uddin Ahmed so that the link between your name and the data we hold on you is not completely broken. All clinic visit information including questionnaires, scans, biopsy results and blood results will be kept in study records so that we can analyse how this HIFU treatment has performed.

### **10. What do I have to do?**

You may continue to take your regular medication or other prescribed over-the-counter drugs. You should not be involved in any other studies that involve the prostate gland. Normally, you should not be involved in any other type of study using drugs or medical devices. Please discuss this with your research doctors and they will advise you. It is important that you attend all visits, undergo all study investigations and agree to fill in all questionnaires before and after the treatment.

### **11. What is the device or procedure that is being tested?**

The procedure we are testing is destruction of only areas of the prostate gland with prostate cancer using a device called the Sonablate® 500 HIFU machine. It uses a high energy focused ultrasound beam, which is directed across the wall of the back passage into the prostate to heat and destroy a very precise volume of tissue at its focus. This study will help us to find out just how safe and well tolerated HIFU is in destroying only discrete areas of the gland.

### **12. What are the alternatives for diagnosis or treatment?**

At the time of diagnosis, prostate cancer may be confined to the prostate itself, or may have spread to other sites within the body. If prostate cancer is confined to the prostate, there are a number of treatments available. The types of treatment that aim to destroy the whole prostate include surgery (radical prostatectomy), external beam radiotherapy, brachytherapy (small implanted radioactive seeds), cryosurgery (freezing) or HIFU. All these treatments can fail to cure prostate cancer. There are two main reasons why this may happen. First, the cancer within the prostate was not properly treated. In other words, some of the cancer cells survived. Second, although the prostate cancer was thought to be confined to the prostate this was not the case: some cancerous cells had spread to other areas and were therefore unaffected by the surgery, radiotherapy, or HIFU. The best result shows that radical prostatectomy reduces the risk of dying from prostate cancer in 10 years by 5% compared to watchful waiting (where no treatment is given).

### **13. What are the side effects of any treatment received when taking part?**

#### Complications from HIFU using the Sonablate® 500 HIFU

Most patients report temporary urinary symptoms (frequency, urgency, difficulty in urination) during the first 2-3 months after treatment. Other complications are listed with the chances of them happening in brackets:

- Urinary tract infection (5 in 100)
- Urethral stricture (narrowing in the urine passage) (1 in 10)
- No semen produced during ejaculation (dry ejaculation) (most men)
- Epididymitis (infection of the tubes surrounding the testicles) (3 in 100)
- Urinary retention requiring surgery (2 in 100)
- Impotence (2 in 5)
- Urinary Incontinence (temporary) (0-2 in 100)
- Recto-urethral fistula (an abnormal connection between the rectum and urinary passage) (0-1 in 200)

These complications are from published results using HIFU to treat the whole gland. We believe that using HIFU to treat only some parts of the gland may mean less complications and this is what we want to prove. However, this is a theory and we will only know the true extent of complications after the study results have been analysed.

### **14. What are the other possible disadvantages and risks of taking part?**

#### Complications from the Contrast-agent Gadolinium during the MRI Scan

The use of gadolinium is very safe and widely used in clinical practice and not just for this study. Some complications occur and include:

- nausea and vomiting (less than 5 in 10,000)
- mild allergic reaction (e.g., rash, itching) (less than 4 in 1,000)
- moderate allergic reaction (less than 5 in 10,000)
- severe allergic reactions (breathing problems, face swelling) (less than 1 in 10,000)

#### Complications from General Anaesthetic

There are risks associated with undergoing any anaesthetic procedure.

- Nausea/vomiting after anaesthetic (less than 1 in 10).
- Most men will have a dry cough for an hour or two and may experience a sore throat for 24 hours. This occurs because a mask and /or tube are placed in the throat during the anaesthetic.
- Minor bruises from intravenous catheters (drips) are common.

- Occasionally extensive bruising, temporary hardening of the vein (phlebitis) or infection can occur from intravenous catheters (1 in 20).
- The known risk of death under anaesthesia in the UK is 1 in 150,000 anaesthetics. To put this in perspective, if we anaesthetised a volunteer every day for 400 years there would be one death.

#### Complications from Transrectal Prostate Biopsies

These include:

- bloody urine and semen (less than 1 in 100)
- retention of urine requiring a temporary catheter (2 in 100)
- prostatitis (inflammation or infection of the prostate, less than 1 in 100)
- temporary pain in anal area (less than 1 in 200)
- infection (requiring admission and intravenous antibiotics, 0-1 in 100)

If, during the course of this trial, we were to discover a condition of which you were unaware, we will inform you, and if necessary, refer you to the relevant medical practitioner. If you have private medical insurance you should check with the company, before agreeing to take part in the trial, whether participation is considered a 'material fact' that should be reported. You will need to do this to ensure that your participation will not affect their medical insurance.

Please share this information with your partner if it is appropriate: it is not known if the study device will affect sperm or semen. It is possible that the sperm quality could be affected by participation in the study. You should not assume that you will be infertile as the majority will not be affected. We are hoping that ejaculation will be maintained.

### **15. What are the possible benefits of taking part?**

The possible benefits from this treatment are that we can treat the prostate cancer and reduce the side-effects traditionally associated with other forms of prostate cancer treatment which affect your urinary, rectal and erectile function. We hope that you will personally benefit from HIFU therapy. However, this cannot be guaranteed. The information provided in this information sheet should help you to decide whether you wish to undergo this experimental form of HIFU treatment.

### **16. What happens when the research study stops?**

When the research study is completed, the results will be analysed. If the treatment has been shown to be useful, the next step would be to compare the longer-term results of HIFU focal ablation treatment directly with surgery and radiotherapy. Your own care will continue regularly as it would with any other form of managing your disease.

It is also important for us to know how you are doing even after the period of the study has elapsed. For various reasons, we may be unable to contact you. For this reason, we will also obtain your consent for us to obtain information from the Office for National Statistics General Register Office in the event that we are unable to contact you after the study period (this is called 'ONS flagging'). 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 means that when a person's entry is flagged, we can be notified when any of the following occurs to you:

- exits from and re-entries to the NHS. This means we will be informed each time you have been seen in the NHS
- Any other cancers that you may have developed and been treated in the NHS (this includes cancer site, type of cancer, cancer registry, registration year and number of years from diagnosis of cancer)
- Death. ONS Flagging will give us a copy of the death certificate which will include date and place of death, occupation, usual address and cause of death.

### **17. 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 have suffered will be addressed. The detailed information on this is given in Part 2. A contact number for complaints is given in Part 2.

### **18. Will my taking part in the study be kept confidential?**

Yes. All the information about your participation in this study will be kept confidential. The details are included in Part 2.

### **19. Contact Details**

In the first instance, for further information or any concerns during the study, please contact

Mr Hashim Uddin Ahmed

Mobile: 07980 551 297

E-mail: hashim\_uddin\_ahmed@hotmail.com

You may also contact Mr Mark Emberton via his office on

Tel: 020 7380 9194

*In an emergency it is best to contact your local GP or go to your local Casualty department or dial 999 for an ambulance.*

**This completes Part 1 of the Information Sheet. If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.**

## Part 2

### 20. What if relevant new information becomes available?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your research doctor will tell you about it and discuss whether you want to or should continue in the study. If you decide not to carry on, your research doctor will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.

Also, on receiving new information your research doctor might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons and arrange for your care to continue.

If the study is stopped for any other reason, you will be told why and your continuing care will be arranged.

### 21. What will happen if I don't want to carry on with the study?

Your participation in the trial is entirely voluntary. You are free to decline to enter or to withdraw from the study any time without having to give a reason. If you choose not to enter the trial, or to withdraw once entered, this will in no way affect your future medical care. All information regarding your medical records will be treated as strictly confidential and will only be used for medical purposes. Your medical records may be inspected by competent authorities and properly authorised persons, but if any information is released this will be done in a coded form so that confidentiality is strictly maintained. Participation in this study will in no way affect your legal rights.

### 22. What if there is a problem?

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about this study, the normal National Health Service complaints mechanisms should be available to you.

If you have any comments or concerns you may discuss these with the investigator. If you wish to go further and complain about any aspect of the way you have been approached or treated during the course of the study, you should write or get in touch with the Complaints Manager, UCL hospitals. Please quote the UCLH project number at the top of this consent form.

Governance Department, UCL Hospitals  
2nd Floor West  
250 Euston Road  
London  
NW1 2PQ  
Fax: 020 7380 9595

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

Our procedures for handling, processing, storage and destruction of their data are compliant with the Data Protection Act 1998.

- Your data will be collected at each visit. Blood and biopsy results will be collected from UCLH NHS Trust computer database and your medical notes. The data will be held in paper form in one site and also held on secured laptop computers
- The data will be stored securely, in a coded manner so that no information that could identify you is held in study records. The controller for this data is UCLH NHS Trust. The custodian of this data who is responsible for the safety and security of the data is Mr Mark Emberton (Chief Investigator).
- The data will be analysed and any results may be published in medical journals. The data will also help us plan larger trials using this form of HIFU treatment if it is successful. If the data is to be used in any other way in future studies then approval will be sought from the local Research Ethics Committee.

- The following persons will have authority to view identifiable data:
  - Mr Mark Emberton (Chief Investigator)
  - Mr Hashim Uddin Ahmed (Clinical Research Fellow)
  - Miss Rebecca Scott (Research Nurse)
  - Dr Dean Barratt (Senior Research Fellow, UCL)
  - Professor David Hawkes (Professor of Computer Science, UCL)
  - Mr Dominic Morgan (PhD Student)
  - Mr Enrico deVita (Medical Physics Department, UCL)
  - Mr Alan Bainbridge (Medical Physics Department, UCL)
  - Dr Jan van der Meulen (Clinical Trial Monitor, Royal College of Surgeons)

The data will be retained for 2 years after the end of the study. All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital/surgery will have your name and address removed so that you cannot be recognised from it.

#### **24. Involvement of your General Practitioner/Family doctor (GP)/Other Doctors**

With your consent, your GP and other doctors not involved in the research but looking after you in this or another hospital will be notified of your participation in this study. If you will not consent for this then we cannot enter you into the trial as it is important these doctors are aware what treatment you have had for the prostate.

#### **25. What will happen to any samples I give?**

All blood samples will be processed in UCLH laboratories as part of routine anaesthetic work-up or for follow-up after treatment. Samples are not kept for more than 2 days in the laboratory and no further tests are carried out on them. All these blood tests would occur if you were to undergo surgery or radiotherapy and are not extra samples taken just for this study.

The prostate biopsies you have taken will be processed and reported by the Department of Histopathology at UCLH. After they are reported by a Consultant Histopathologist, this study will make no further use of the samples. We view your samples as a 'gift' which are stored in the Histopathology department with your hospital number, name and date of birth. This means that your samples may be used in other research in the future, but this will only be carried out with Research Ethical Approval by an Ethics Committee.

Future studies can only be carried out on the samples with approval from the Research Ethics Committee. If such approval is gained the Ethics Committee may insist on those future researchers seeking your permission if the committee considers that the study is likely to substantially affect your interests.

#### **26. Will any genetic tests be done?**

No genetic studies will be carried out.

#### **27. What will happen to the results of the research study?**

The results of the study will be analysed and presented as publications for medical journals and at scientific meetings around the world. There will be no identifiable data in these publications. A summary of these results will be available for you and copies of full publications will also be available if you wish to have them.

#### **28. Who is organising and funding the research?**

The University College London Hospitals NHS Trust is sponsoring the study and is responsible for making sure it runs according to best research practice and relevant laws of the United Kingdom.

The study is funded by a charity organisation. This is the Pelican Cancer Foundation (Basingstoke, UK).

## 29. Who has reviewed the study?

This study was given a favourable ethical opinion for conduct in the NHS by the UCLH Research Ethics Committee A.

A copy of this Information Sheet will be given to you and if you decide to participate, a copy of the signed consent form will also be given. Please feel free to ask any questions to the Research Staff. Many thanks for taking the time to read this Information Sheet and considering taking part in our Study.

### Contact Details

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Clinical Research Fellow

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E-mail: hashim\_uddin\_ahmed@hotmail.com

Mr Mark Emberton

Reader in Interventional Oncology

Consultant Urological Surgeon

Tel: 020 7380 9194