Patient Information Sheet

Version 1.1 February 2007

Title

Collection of pathology and blood samples for use in kidney cancer research

Invitation

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. Ask 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.Thank you for reading this.

What is the purpose of the study?

The purpose of this study is to collect blood and surplus pathology samples from people with suspected or confirmed renal cell cancer. The samples will later be tested to find out if they contain any genetic or other abnormalities that may cause kidney cancer or affect the way the cancer responds to treatment

You may be asked to participate at one of two stages:
1. Prior to an operation to remove a suspected kidney cancer
2. After an operation to remove a kidney cancer.

If you have already had your surgery, and have been diagnosed as having a kidney cancer that has an intermediate or high risk of returning we will also ask you to consider taking part in another part of this study which is trying to find out the best way of treating kidney cancer like yours. If you are eligible for this part of the study your doctor will give you information about it.

Why have I been chosen?

When patients have surgery, samples from their cancer are often saved, as a routine, in the hospital pathology laboratory. Since you are about to have or have recently had surgery we would like to request your permission to use these samples in future scientific studies. We would also like your permission to take a 20ml blood sample for use in these studies.

We will be asking around 300 patients each year to participate in this part of the Study.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part 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.

What will happen to me if I take part?

The samples removed from your kidney cancer and normal kidney tissue and the blood sample will be tested for genetic and other abnormalities. All work carried out on the samples will have been previously approved by an ethics committee. You are free to withhold permission without affecting your future treatment or your relationship with your doctor.

All research carried out on the samples will be coded: a code number, not your name, will identify your specimens and neither you nor your relatives will be identified or contacted.

Any results from the studies carried out on your samples will only be available several years after your operation and so will not affect your future treatment. However, the research may inform future testing programs that would then be available later through the NHS and so be of benefit to many patients with kidney cancer in the future.

Please note that if any inventions resulting in commercial gain emerge from any of the above research, you will not be eligible to benefit financially from these discoveries.

What are the possible disadvantages and risks of taking part?

Participation in this study may not require any extra tests or procedures that you would not routinely have, as the blood sample may be taken during routine care. If not taken during routine care you will have one extra blood sample taken. Tissue samples are routinely taken during surgery and their removal will not impact on your wellbeing. However, if you have private medical insurance you should check that participating in this study does not affect your policy in any way.

What are the possible benefits of taking part?

Whether or not you choose to give consent for samples to be used in this research study you will still receive the same standard of care. If you do decide to participate we hope that the knowledge gained from your participation may benefit other patients with kidney cancer in the future

What if something goes wrong?

In the event that something does go wrong and you are harmed during this study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation but you may have to pay your legal costs.

If you have a concern about any aspect of the way you have been approached or treated during the course of this study, you should speak with your doctor. If you remain unhappy or would rather complain formally, you can do this through the NHS Complaints Procedure. Participation in this study does not affect your normal rights to complain about any aspect of your treatment and care. (Contact Number Details can be obtained from the hospital.)

The Medical Research Council (MRC) who are responsible for this study will give sympathetic consideration to claims for non-negligent harm suffered by a person as a result of a trial or other work supported by MRC. MRC acts as its own insurer and does not provide cover for non-negligent harm in advance for participants in MRCfunded studies.

Where studies are carried out in a hospital, the hospital continues to have a duty of care to a patient being treated within the hospital, whether or not the patient is participating in an MRC-supported study. MRC does not accept liability for any breach in the hospital's duty of care, or any negligence on the part of employees of hospitals. This applies whether the hospital is a NHS Trust or not.

Will my taking part in this study be kept confidential?

If you agree to take part in this study the MRC Clinical Trials Unit will collect the following information about you; your name, date of birth and NHS number, and then allocate you a unique number within the study. All of your personal details will be kept confidential. Your samples will be held at the Royal Marsden in Surrey and will only be identified by the unique number provided by the MRC. We will also attempt to get some details about the surgery you have had or will receive to remove your kidney cancer and some details about cancer that was removed. This information will also only be identified by the unique number provided by the MRC.

We would also like to flag your records with the Office of National Statistics or trace them via the NHS Central Register or equivalent so that if you move away or decide not to continue with the study we will still be able to find out how you are doing. You will be asked a question about this on the consent form that you will have to sign before you are entered into the study.

What will happen to the results of the research study?
After completion of the study the results will be presented at national/international scientific meetings and published in a leading medical journal. At no point in the analysis or publication will any information about the identity of individual patients be revealed. A copy of the results will be circulated to your doctor and will also be available to you or your family on request.

Who is organising and funding the research?
The study is being sponsored by the Medical Research Council (MRC), which undertakes public sector research. The study is being organised by the MRC Clinical Trials Unit, based in London and has been funded by CTAAC and TRICC (Cancer Research UK funding committees) and the MRC CTU.

Who has reviewed the study?
As well as a review by the funding bodies listed above, the study has been reviewed and approved by the National Cancer Research Institute (NCRI) Kidney Clinical Studies Group. All studies carried out on your samples will also be approved by a Research Ethics Committee.

Contacts for Further Information
If you have any further questions about your illness or this research study, please discuss them with your doctor.
You may also find it helpful to contact:
CancerBACUP, an independent patient advisory group (Freephone: 0808 800 1234; http://www.cancerbacup.org.uk/Home)
Cancer Research UK website http://www.cancerhelp.org.uk
Consumers for Ethics in Research website http://www.ceres.org.uk/index.html

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