National Study of Nephrotic Syndrome (NephroS)

Information Sheet for Adult Patients

You are being invited to participate 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 for you.

Please take time to read the following information carefully and discuss it with others if you wish.

Your kidney specialist or research team will explain 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 taking the time to read this.

The purpose of this study

Your kidney specialist has made a diagnosis of Nephrotic Syndrome (NS). This can be described as either Steroid Sensitive Nephrotic Syndrome (SSNS), Steroid Resistant Nephrotic Syndrome (SRNS) or Focal Segmental GlomeruloSclerosis (FSGS). SSNS is usually a milder disease, and most cases respond to steroids. However, this occasionally becomes resistant to steroids and is then termed SRNS. Unfortunately, some patients with SRNS/FSGS go onto develop kidney failure and require a kidney transplant. After transplant there is a chance that the disease can return to affect the transplanted kidney.

For this reason the Kidney Research Unit in Bristol has developed a special interest in NS/FSGS and what happens to the kidney in this disease. They want to find out:

- If some patients are likely to develop the disease because of gene mutations. Our genes sit in all the cells of the body and hold the information to develop and maintain our cells. If the programming of the gene is slightly altered this results in a 'gene mutation' which can result in a disease. We know that there are some gene mutations which cause NS but we don't know how often this occurs in the UK.

- How the disease actually affects the kidney.

- Whether NS causes a pattern of changes in the kidney cells which is the same in every patient.

Why have I been chosen?

The research team are approaching all patients with Nephrotic Syndrome or FSGS, at hospitals running this study in the United Kingdom.

Do I have to take part?

It is up to you to decide whether you take part. If you do decide to take part you will be asked to sign a consent form. You are still free to change your mind and withdraw at any time without giving a reason. If you decide not to take part or to withdraw from the study, this will not affect the treatment you receive.

What will happen if I agree to take part?

There are several parts to this study:

1) During routine blood tests, a little extra blood will be taken. The amount of extra blood to be taken is about 5 tablespoonfuls (70mls).

2) Your medical details will be reviewed from the Rare Kidney Disease Database, RaDaR. You may have previously consented to the details being placed onto this, if not, consent for the RaDaR study will be done at the same time as consenting for this study.

3) Should you suffer from a disease relapse, remission, or undergo kidney transplantation, a little extra blood would be taken during routine blood tests to be sent to the research group. If you are willing, we may ask to you visit the hospital to donate samples at times outside of your routine appointments. These visits are optional and you can choose whether you wish to consider visiting the hospital at these times. Any expense you incur as a result of so doing will not be reimbursed.

4) Urine samples may be also be collected during routine appointments and at times of relapse, remission and transplantation.

5) If you had/have a kidney biopsy as part of your routine care, we ask your permission to collect any surplus tissue for research purposes. You will not be asked to have another kidney biopsy as part of the research. If however, in the future your doctor feels a biopsy is needed for routine clinical care, we will ask your consent to collect an additional tissue sample for research use.

6) If you have a transplantation and the disease returns in the transplanted kidney, it is possible you will undergo a treatment called 'plasma exchange'. During this treatment your plasma is exchanged for new plasma and the original plasma is discarded. In this study, the discarded plasma would be sent to the research group.

7) You may be given some questionnaires to complete about your quality of life and asked additional questions so we can understand the demographics of those with Nephrotic Syndrome. This will either be given to you in clinic or sent to you. These will not have your name on it, just your unique study number. There will be help available to complete these forms if needed.

Your samples will be used in a variety of tests in the laboratory, which may include looking at your genetic material. Cells within some of your samples may be used to generate cell lines. This means that the cells can continue to divide in the laboratory indefinitely. Most cells die once they have been removed but by generating these cells lines, researchers can continue to work on the cells for longer.

You may also be invited to participate in other medical research studies. This will include the chance to have a comprehensive DNA analysis as part of the BioResource – Rare Diseases study. Your DNA will be sequenced and analysed for changes in the DNA code that may be responsible for your NS. You will be provided with full information regarding these studies and are free to decide whether or not to take part.

What will happen to any information about me?

The information that has been or will be collected by the RaDaR study is stored on a secure web server. Researchers who are interested in your condition can view your anonymized data and that of others will the same condition.

The research group leading this research has signed a confidentiality agreement with the RaDaR group. A restricted number of NephroS researchers can see your personal information, e.g. to invite you to studies such as the BioResource study. These researchers have been carefully selected and are only given access appropriate to their roles. At the end of the study the research group will no longer have access to this information, and the RaDaR group will continue to store it securely.

What will happen to my samples?

<u>Instructions for sites: Please delete one of the below options and these instructions depending on whether you are a Site Type A (NephroS) or Site-Type B (NURTuRE-NephroS) centre</u>

[Site Type A: Your samples will be sent to the lab for use in medical research. Some samples may be made available to researchers in other organisations in the public and private sector

(eg. pharmaceutical and biotechnology industry) both in the UK and Overseas. This will help develop discoveries that benefit patients with NS. At the end of the study the samples will continue to be stored pending further study.]

[Site Type B: Your samples will be collected for use in medical research both in the UK and Overseas. These samples will be used in academic research, commercial research and some of your samples will be stored for future use in a central Biobank, where they will be stored anonymously, identified by a barcode linked to your unique study number. Access to your stored samples will be controlled by an Independent Committee to make sure your samples are used in the best way possible to develop discoveries that benefit patients with NS.]

How will I know the outcome of the research?

We expect that about 10% of adults tested will have a gene mutation identified which may not have been known about previously. Any results on genetic testing will be fed back to your kidney specialist who will talk to you about the result. On the RareRenal website (rarerenal.org), information on each of the genes being tested will be uploaded and kept up to date as new information is found.

The data and other tests will be collated and published and your specialist will explain the findings to you. Results of studies will be made available to the public through scientific publications, reports, websites or publications but you will not be identified personally in these.

Will my GP know about this research?

If you would like your GP to know about this research, your specialist can send an information sheet about the study to your family doctor and inform him or her of any results from the study. Your GP will only be contacted if you consent to them being informed.

Can I have more time to decide?

Yes. There is no time limit. You can discuss this research proposal with anyone you choose.

What if I wish to withdraw?

A patient may withdraw at any stage without having to give an explanation. You can do this in writing to your local kidney doctor or to the research team directly if you wish. At that

time you can decide if you are happy for us to use samples collected or you would like these to be destroyed.

What are the risks/benefits in participating in this study?

The majority of samples collected in this study do not require you to attend hospital more frequently or for you to undergo extra procedures, only to have more blood taken and to give urine samples at routine appointments. We may ask you to visit the hospital to have a blood sample taken and donate urine at other times. This would be an additional procedure, and blood sample collection carries the small risk of bruising, inflammation or fainting. Biopsy samples would only be requested from procedures that have already taken place, or take place during routine care. No extra biopsy operations would be performed, although we ask your consent to take an extra sample of kidney tissue during future routine procedures.

The benefits are to increase the medical knowledge about this disease and the research group hope that the information we obtain will help provide better treatment for NS in the future.

What happens if a discovery is made using my donated samples?

The samples donated are given as a gift i.e. without payment. You will not receive any financial benefit if the research leads to new treatments or tests.

What do I do if I have concerns about the study?

If you have any concerns or further questions about this study or the way it is carried out, you should contact your kidney specialist in the first instance. You can also contact the PALS service of the hospital where you are being treated.

Has this research study been approved by an ethics committee?

This study has been approved by the South West- Central Bristol Research Ethics Committee, reference number 09/H0106/80.

Chief investigator:
Professor Moin Saleem, University of Bristol

Local Investigator: