

National Study of Nephrotic Syndrome (NephroS)

Information Sheet for Adolescent Patients

You are being invited to participate in a research study. Please read this information sheet which explains why the research is being done and what it will involve for you. If anything is not clear, talk to your mum/ dad/ person who looks after you or to your doctor/ nurse.

The purpose of this study

Your doctor has made a diagnosis of Nephrotic Syndrome (NS). This can be a nasty illness and can be difficult for the doctors treat, as it often keeps coming back. Researchers in Bristol want to find out why some people get NS and others don't. They are asking both children and adults with NS to help out with the research.

Do I have to take part?

It is up to you - if you don't want to take part this will not affect the treatment you receive. If you decide to take part you can change your mind and withdraw from the study at any time, without giving a reason.

What will happen if I agree to take part?

- 1) A little extra blood (about 2-3 tablespoons) will be taken when you visit the hospital for your routine appointments, if your disease comes back (relapse) or you undergo a kidney transplantation (only some patients will). This extra blood will be taken when you normally visit the hospital, but you may be asked (if convenient) to visit the hospital when you relapse. Visiting the hospital outside of routine appointments for research purposes is optional and you can choose whether to consider visiting the hospital at these times. Any expense you incur as a result of so doing will not be reimbursed.
- 2) Urine samples may be collected when you visit the hospital for routine appointments or if your disease come back.
- 3) Your medical details will be reviewed from the online secure Database called RaDaR
- 4) 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.

- 5) A few patients may undergo a treatment called 'plasma exchange'. During this treatment your plasma is exchanged for new plasma and the original plasma is discarded. Instead of throwing the old plasma away, it would be saved for testing.
- 6) You may also be invited to participate in other research studies but you can decide whether or not to take part. This will include the NIHR-BioResource study which will analyse your genes (the 'instructions' that make you), to see if there is an 'error' in one of the instructions that causes your NS.
- 7) Cells within in some of your samples may be used to generate cell lines which allow cells to continue to grow. Most cells die once they have been removed but by generating cells lines, scientists in the lab can continue to work on the cells for longer.
- 8) You/Your parents may be given a questionnaire to complete about your quality of life at various time points throughout your disease course. This will not have your name on it, just your unique study number. There will be help available to complete this form if needed.

What will happen to any information about me?

The information collected by the RaDaR study is stored on a secure web server. Certain members of the NephroS research group have permission to access your information until the study finishes. After this time, the RaDaR group will continue to store this information securely. Other researchers who are interested in your condition can view your anonymized data and that of others will the same condition.

What will happen to my samples?

Site Instructions - Please delete one of the options below depending on whether you are a Site Type A (NephroS) or Site-Type B (NURTuRE)

[Site-type A: Your samples will be sent to the laboratory where a variety of tests will be run. Your samples will be stored for further studies. Some samples may be made available to researchers in other organisations bot in the UK and Overseas, to develop discoveries that benefit patients with NS.

The samples you donate are given as gifts i.e. without payment. You will not receive any financial benefits if the research leads to new treatments or tests.]

[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, in 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 these 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. The samples you donate are given as gifts i.e. without payment. You will not receive any financial benefits if the research leads to new treatments or tests.]

How will I know the outcome of the research?

The research group will send genetic results to your kidney specialist who will talk to you about the results (unless you don't want them to). Other results will be made available through scientific publications, reports or websites but you will not be identified personally.

Will my GP know about this research?

If you would like your GP to know about this research, your specialist can let them know you are participating and inform them of any results from the study.

Can I have more time to decide?

Yes, there is no time limit. Please discuss this study with anyone you choose.

What are the risks/benefits of taking part?

Most samples for this study will be collected when you attend hospital for your routine appointments. However, at times of relapse, we may ask you to visit the hospital to donate some samples, including a blood sample. This comes with 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 normal management of your NS.

The research group hopes that the information gained will help provide better treatment for NS in the future.

What if I wish to stop participating?

You may stop at any stage, without saying why - just tell your kidney doctor. At that time you can decide if you are happy for us to use your samples collected or would like these to be destroyed.

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

If you have any concerns or questions, you should contact your kidney specialist. You can also contact the PALS service of the hospital where you are being treated.

Has this research been approved by an ethics committee?

This research has been approved by the South West Central Bristol Research Ethics Committee – 09/H0106/80.

Thank you for reading this – please ask any questions you may have.

Chief investigator: Professor Moin Saleem, University of Bristol

Local Investigator: