

Patient information Sheet for patients with Rare Kidney Disease

Irish Rare Kidney Disease patient outcomes study

You are being invited to take part in a research study. This information sheet will help you understand why we are undertaking the research and what we would like you to do. Please read the sheet carefully and feel free to discuss it with others if you wish. Please ask us if there is anything that is not clear to you or if you would like more information. Please take time to decide whether you wish to take part or not. Thank you for reading this.

What is the purpose of the study?

This study will establish the first patient registry for rare kidney disease in Ireland, which will be used to help increase our understanding of the disease, with the ultimate aim of understanding why certain people are affected and to develop better treatments and markers of disease. The study comprises two parts:

1. Collection of patient data in a database in which we will record data about potential disease risk factors (including genetic and environmental factors) and clinical outcomes
2. Collection of patient samples (urine, blood and use of biopsy tissue if available)

Using information gained from both parts of the study we have the potential to test for certain risk factors which may help with patient care in the future, for example by increasing medical knowledge so that the most appropriate medicines can be selected.

What does the research involve for me?

There are four types of samples that we may ask your permission to use in the laboratory: 1) samples of blood; 2) DNA samples (taken from your blood or saliva); 3) urine samples and 4) biopsy samples, which will only be used if you needed a biopsy as part of your normal care. Details of each of these samples are given below.

1) **Blood samples.** We will need approximately 40mls of blood from you, equivalent to about one or two extra tubes, when you have blood taken. We are undertaking the research over five years and may need to take up to four samples from you during this time. In virtually all cases we would take the blood at the same time as you were having your routine clinic bloods done so no extra needle pricks will normally be involved.

2) **DNA samples** will be extracted from the same blood sample or will be collected in a saliva sample. The samples will be stored in a secure locked freezer using an anonymous code and may be sent to be tested in outside labs. All the data is completely confidential and no one testing the DNA will have any of your personal details.

3) **Samples of your urine.** We will use the urine samples to see if we can detect patterns of chemicals that mirror disease activity. Every time you come to clinic you normally give a urine sample. We will then store part of this sample in a freezer and analyse the chemicals in the urine at a later date, or they may be sent to be tested in outside labs.

4) **Biopsy samples.** If you are undergoing a biopsy for clinical reasons and you consent to your biopsy sample being used for research purposes, a sample large enough to allow some tissue for research as well as diagnosis will be taken. At no stage will we be giving you any extra medications during this research. We simply need samples from you that we keep in

the laboratory. Samples may be frozen for some months as we may need to repeat laboratory tests or they may be sent to be tested in outside labs. No one working with your samples will know who you are. All the samples we take will be coded and only the principal investigators will be able to relate your clinical condition to the results of the laboratory research. The samples you give are purely for research and the results of the research will have no direct benefit for you. However, we hope that the information we obtain from this study will give a better understanding of why and how vasculitis and other rare kidney diseases occur and how we may be able to better treat them.

Why have I been invited?

You have been chosen because you or one of your family members have a certain type of rare kidney disease (which is either inherited or a type of vasculitis).

Do I have to take part?

NO. It is entirely 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 we will ask you to sign a consent form. If you do decide to take part you are still free to withdraw at any time and without giving a reason. A decision not to take part or to withdraw at any time will in no way affect the standard of clinical care you receive. Also if you decide to withdraw your consent at a later date, any study samples (blood, urine, tissue or DNA) which are held for research purposes will be destroyed.

Will taking part have any negative effects on my health?

No. Taking slightly more blood will have no adverse effect and will be done, in most cases, at the time of your routine samples for your clinic appointments. There are risks associated with having a biopsy done but this will only be done if needed for your care, and the risks will be explained by the doctor doing the biopsy. Using the tissue left over from the clinical analysis involves no added risk whatsoever as no extra tissue will be taken from you for this research.

Do I have to alter my lifestyle to take part?

No.

Will my taking part in this study be kept confidential?

Yes. All information collected about you during the research will be kept strictly confidential. Given the rarity of the conditions under study, it will be necessary to combine information across many sites, both in Ireland and abroad. Any information about you which leaves the hospital in this manner, or is published, will be anonymised so that no one from outside the hospital can identify you. Your name and address, hospital number or date of birth will not be published or passed on in any way.

What will happen to the results of the study?

The results will be used as a basis for further research. If we find things out that are deemed interesting by researchers from other hospitals and universities, the results may be published in a scientific journal. If this happens, no one will be able to identify you as having taken part in the research, as all the information about patients will be anonymous. We will also make available to you a summary of the study results when they are available.

Who is organising and funding the research?

The research is being organised by Professor Mark Little of Trinity College Dublin, at the Tallaght and St James's Hospital, in collaboration with all of the Nephrologists and other specialists with an interest in Vasculitis in Ireland. No doctor taking part in this study is getting paid extra for including you in the study. Funding for the study comes from Science Foundation Ireland and Trinity College Dublin.

Is there any payment for taking part?

No, we are not paying patients to take part in the study. However you will be reimbursed for travel expenses for any additional clinic visits you make (visits that you would not have made for your routine clinical care)

Who has reviewed this study?

The Tallaght and St James's Hospital ethics committee have reviewed and approved this study.

Information regarding consent of children in the study

If you are a parent/guardian agreeing for your child to take part in this study please be aware that if your child declines to take part it will over-ride any agreement to participate that you have agreed to.

Can I withdraw from this study if I change my mind about taking part?

Yes, you can withdraw from either or both parts of the study (entry of your data in the registry and/or collection of samples). Please contact Professor Mark Little on +353-1-896 3706 or mlittle@tcd.ie or Dr Liam Casserly, Consultant Nephrologist, Limerick University Hospital at liam.casserly@hse.ie

Future Studies.

It is possible that future studies not described in this leaflet may be performed on your blood or tissue sample. These will only be performed after review and approval by an Ethics Committee.

Who should I contact about enquiries or complaints?

Please contact Professor Mark Little on +353-1-896 3706 or mlittle@tcd.ie or Dr Liam Casserly liam.casserly@hse.ie if you have any concerns regarding the study.

You can keep this information sheet and a copy of the consent form.

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