



Feidhmeannacht na Seirbhíse Sláinte  
Health Service Executive

## 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.

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 Dr Michael Clarkson of University College Cork and Professor Mark Little of Trinity College Dublin, 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 Clinical Research Ethics Committee of the Cork Teaching Hospitals have reviewed and approved this study.

**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 Dr Sarah Moran on +353 21 4922000 or sarahmoran@physicians.ie or Dr Michael Clarkson on +353 21 4922000 or Michael.clarkson@hse.ie or Professor Mark Little on +353-1-896 3706 or mlittle@tcd.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 Dr Sarah Moran on +353 21 4922000 or sarahmoran@physicians.ie or Dr Michael Clarkson on +353 21 4922000 or michael.clarkson@hse.ie or Professor Mark Little on +353-1-896 3706 or mlittle@tcd.ie if you have any concerns regarding the study.

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