Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Clinical Research Ethics Committee of The Cork Teaching Hospitals

CONSENT BY SUBJECT FOR PARTICIPATION IN RESEARCH PROTOCOL

Section A

Protocol Number:_____ Patient Name:_____

Title of Protocol: **Irish Rare Kidney Disease Registry and Bioresource**

Doctor(s) Directing Research:

Dr Michael Clarkson	Phone: 021 4922000	email: michael.clarkson@hse.ie
Dr Sarah Moran	Phone: 021 4922000	email: sarahmoran@physicians.ie
Prof Mark Little	Phone: 01 8963706	email: mlittle@tcd.ie

You are being asked to participate in a research study. The doctors at University College Cork study the nature of disease and attempt to develop improved methods of diagnosis and treatment. In order to decide whether or not you want to be a part of this research study, you should understand enough about its risks and benefits to make an informed judgment. This process is known as informed consent. This consent form gives detailed information about the research study, which will be discussed with you. Once you understand the study, you will be asked to sign this form if you wish to participate.

Section B

I. **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

Section C

AGREEMENT TO CONSENT

The research project and the treatment procedures associated with it have been fully explained to me. All experimental procedures have been identified and no guarantee has been given about the possible results. I have had the opportunity to ask questions concerning any and all aspects of the project and any procedures involved. I am aware that participation is voluntary and that I may withdraw my consent at any time. I am aware that my decision not to participate or to withdraw will not restrict my access to health care services normally available to me. Confidentiality of records concerning my involvement in this project will be maintained in an appropriate manner. When required by law, the records of this research may be reviewed by government agencies and sponsors of the research.
I understand that the sponsors and investigators have such insurance as is required by law in the event of injury resulting from this research.
I, the undersigned, hereby consent to participate as a subject in the above described project conducted at the Cork Teaching Hospitals. I have received a copy of this consent form for my records. I understand that if I have any questions concerning this research, I can contact the doctor(s) listed above. If I have further queries concerning my rights in connection with the research, I can contact the Clinical Research Ethics Committee of the Cork Teaching Hospitals, Lancaster Hall, 6 Little Hanover Street, Cork.

After reading the entire consent form, if you have no further questions about giving consent, please sign where indicated.

Doctor: _____ Signature of Subject: _____

Witness: _____ Date:

Time:_____AM

(Circle) PM