

## **PodoNet**

### **Clinical Registry and Study of Genetic Risks for the Steroid Resistant Nephrotic Syndrome**

#### **Information Letter for Adolescents**

Dear .....

As you know, your kidneys do not work like those of healthy children. You are affected by a kidney disorder which is called the steroid resistant nephrotic syndrome. The kidneys' task is to filter toxic substances and water out of your body. If the filter function of the kidney is compromised, however, you will lose essential substances, the proteins, from your blood. The protein loss leads to numerous changes in your body including water retention in the tissue (edema), increased blood fat levels and a disposition for infections and spontaneous blood clotting (thrombosis). In the long-term, the kidney function will be impaired.

The majority of cases of nephrotic syndrome are caused by an imbalance of the immune system. Many patients feel better quickly with a special medication called "cortisone", "prednisone" or "steroids". These drugs can correct disorders of the immune system. If "cortisone" works, the patient recovers completely and the kidney function will always remain normal. However, 1 out of 8 children with nephrotic syndrome do not respond to the treatment with "steroids", they are "steroid resistant". In these cases, alternative drugs exist, which fight stronger against the imbalance of the immune system.

The steroid resistant nephrotic syndrome is a rare disease affecting only very few children. Actually, we do not know exactly why children and adolescents like you develop this disorder and what will eventually be the best treatment. Recently, genetic abnormalities causing steroid resistant nephrotic syndrome were identified in individual patients and their families. These genetic forms of the disease usually do not respond to any drug treatment.

In cooperation with numerous European pediatric kidney centers children and adolescents from all over Europe who suffer from the same kidney problem as you will be observed for three years. The study is meant to improve the ways we treat you and other affected children, in order to protect the proper functioning of your kidney.

#### **What exactly will be examined?**

The participation in the PodoNet Registry is voluntary. If you participate in the PodoNet project, your medical history will be recorded accurately on the occasion of a regular doctor's appointment in one of our centres. This includes the manifestation and course of the disease, the treatment modalities, the administered drugs and the family history of renal diseases. This clinical information as well as several laboratory parameters (e.g. renal function tests,

protein content of the blood, urinary protein loss) will be recorded in an Internet database (the PodoNet registry).

The duration of the study is 3 years. Once every 12 months we will obtain an additional blood (5 ml) and urine sample (20 ml) in the context of a routine clinic visit. At a single time, a genetic risk analysis will be performed in an additional blood sample of 5 to 10 ml volume. With your approval and if not performed before, we will also search for rare genetic abnormalities (mutations) of potential relevance for you and your family. In case we find a genetic change we would like to analyse a blood sample of your parents as well, provided they give their consent. Possibly, we could distinguish between a new mutation and a genetic mutation passed on by ancestors.

Blood and urine samples will only be used for the PodoNet project and will be centrally stored and analyzed in Heidelberg.

#### **How will the protection of data privacy be ensured ?**

A pseudonym will be created for all data collected during the study (that is to say no names will be recorded, all data will be assigned to codes). The data will be recorded and saved in a secure Internet database (PodoNet registry). Thus only the attending doctor of the centre in charge can relate the data to the individual patient. The blood, urine and DNA samples will be only labelled with the patient code generated by the database; therefore, no laboratory can trace the samples back to you.

The regulations of patient/physician confidentiality and all national data privacy protection laws will be respected.

You can withdraw your participation in the study at any time without specification of reasons. There will be no negative consequences concerning the medical attendance in case of a withdrawal. Upon your request, all data collected for the study will be deleted and all samples will be destroyed unless there are storage obligations imposed by law or statutes.

We would appreciate very much if you agree to participate in this study!

< Name of Principal Investigator >

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