

LETTER OF INFORMATION

Ref. Participation to the European study on familial IgA nephropathy

Dear Ms., Mr.....

We are involved in studying the genetic aspects of the IgA nephropathy or Berger's disease by performing the analysis of urine and collecting the DNA from blood of patients and family members. This project is supported by the European Commission and approved by the local Ethical Committee. This research project is devoted to improve our knowledge in the pathogenesis of the disease and will not give immediate clinical benefits and will not improve the therapeutic management of the disease.

Before asking you to participate, let me introduce some information on your disease which was described for the first time by professor Berger (Paris, France) more than 30 years ago. IgA nephropathy is a disease which presents blood in the urine coinciding with episodes of upper respiratory tract infection. Blood in the urine gives the characteristic red or coca-cola colour when present in large quantities (macrohematuria). In other cases the presence of blood in the urine is revealed microscopically by urinalysis (microhematuria). Hematuria may be associated with proteinuria and/or high blood pressure.

This disease is characterised by the deposition of the immunoglobulin A in the kidneys. Factors responsible for this deposition are unknown. The disease may involve one or more members of the family.

The aim of our study is to understand the genetic factors which may be responsible for the disease.

If you wish to participate in the study your collaboration consists in giving a small sample of your blood which contains white blood cells. Your DNA present in these cells will be stored in the genetic laboratory and will be used only for this study. In addition, serum and plasma samples will be collected and used for biochemical and immunological parameter measurements. After the blood sample is taken you may have a small hematoma which disappears within 1 week. We would also like you to promote the participation of your family members in this study.

If you do not wish to participate in the study we will continue to assist you in the disease and your decision will not affect our support in no way. Please do not hesitate to contact us for further information.

All data obtained during the study will be enclosed in a database which will be encrypted for preventing the access to third persons. In this manner your privacy will be completely protected. This study will not provide immediate clinical benefits for patients and relatives, however if gene(s) will be identified at the end of the study we will inform your family physician on the final results if you are interested. You can contact us for additional information.

Thank you very much for your kind collaboration.

Yours sincerely.

LETTER OF INFORMED CONSENT

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Doctor (surname).....(name).....

(Hospital).....

informed me that I am affected by IgA nephropathy. He asked me to participate in the European Study "Genetic aspects of IgA nephropathy". The European Commission has funded this study which has been approved by the local Ethical Committee. The physician underlined that I am free to participate or not.

I have been informed on the disease and on the participation in the study. I accept to give a sample of my blood and urine. I accept that these samples will be analysed for the study in the established conditions.

I have also been informed that I do not have to pay for this genetic research. I know that this study will not benefit single participants nor will it improve the clinical course of the disease nor the therapeutic management.

I accept that medical data concerning my case will be included in the database of the European IgA nephropathy registry. I know that measures will be taken in order to protect my privacy according to the national law.

Only my family physician (Dr.....Tel.....) could receive medical information.

After discussing the aspects of the study and receiving all information requested, I accept to participate in this study.

I know that I can withdraw my participation at any time without damaging my relationship with Dr.

Date.....

Signature.....

Medical investigator Dr.....