

## 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. 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 and therapeutic benefits.

Before asking you to participate, let me introduce some information on the disease which was described for the first time by professor Berger (Paris, France) more than 30 years ago. IgA nephropathy is a disease characterized by the presence of 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 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 a family.

For this study we need to collect DNA from healthy subjects and for this reason we are asking for your collaboration which consists in the analysis of your urine and the collection of a small sample of your blood which contains white cells. The 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.

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.

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) .....

I declare that the information I received is clear, therefore I accept to give a sample of my blood and urine. I accept that these samples will be analysed for the study "Genetic aspects of IgA nephropathy". I know that this study, supported by The European Commission, has been approved by the local Ethical Committee.

I know I am free to participate or not.

I have 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 my name will be included in the database of the European IgA nephropathy registry which will be encrypted to protect my privacy according to the national law.

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

Date.....

Signature.....

Medical investigator.....