

LETTER OF INFORMATION

Ref. Participation to the European study on familial IgA nephropathy

Dear Mr. , Ms..

You have been contacted by your relative Mr., Ms.....who is affected by IgA nephropathy. We are asking you to collaborate in a genetic study which is supported by the European Commission and approved by the local Ethical Committee. This research project is devoted to improve our knowledge of the pathogenesis of the disease and will not give immediately clinical benefits and will not improve the therapeutic management of the disease.

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 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 accepting the analysis of your urine and 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, a serum and plasma sample 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.

You are free not to participate.

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)

I declare that the information I received is clear, therefore I accept to give a sample of my blood and urine to be analysed for the study "Genetic aspects of IgA nephropathy". I know that this study, funded 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 in accordance with the national law.

I know information will be given to my family physician.
(Dr.....Tel.....)

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

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

Date.....

Signature.....

Medical investigator.....