

Contact person in charge of the database at your clinical centre: Institution:

Telephone: E-mail:

Information document

Upon BECOMING OF AGE

Participating in the European LeukoDataBase

You have just reached the age of 18, which is the legal age of majority. As such, you are now able to decide for yourself whether or not to continue participating in the European database on leucodystrophies: the LeukoDataBase.

While you were a minor, your legal representative(s) authorized your participation in the LeukoDataBase.

The LeukoDataBase (LeukoDB) is a European database for research on leucodystrophies and other genetic diseases that attack the white substance in the brain. The LeukoDB was set up thanks to funding from the European Commission.

The Reference Centre added your data while you were a minor and would like to keep them in the database now that you are of age.

To that end, your consent is requested: you will need to sign a specific consent form.

This information document has been validated by the LeukoDB Ethics Committee and by the local ethics committees of each partner country.

I. Purpose of the LeukoDB database

The aim of the LeukoDB is to provide project researchers with as much data as possible in order to facilitate research on leucodystrophies: understanding its causes and the manifestations of its diseases (natural history), developing diagnostic and therapeutic methodologies.

The LeukoDB will also make it easier to recruit patients for clinical trials.

The LeukoDB incorporates a clinical database, a database on genetic mutations and a database for the inventory and localization of existing biological samples (biobank).

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The LeukoDB operates based on collaborative participation of the project partner clinical and research centres. The data is anonymized and secure and will be made available to partner research teams.

II. You participation in the database

By participating, you authorize data from your medical file and the research programmes to be collected, stored and shared. The data in question is biological, radiological, electrophysiological and genetic, as well as data from behavioural assessments. All this data will be encoded so as to make it impossible for a third party to identify you; only a manager will have the ability to securely recover a patient's identity.

The genetic information enables characterization of the way the disease affects the patients and their family members and makes it possible to determine the mutations involved in their disease. All the data will be stored in the LeukoDB for as long as required by the research objectives.

Participation in the LeukoDB is entirely voluntary. You are free to withdraw your consent at any time. Refusing to participate or withdrawing consent will in no way be prejudicial to you, in particular as regards your medical care.

All the scientific results produced by the research will be available on the Internet once they have been validated. When the research results provide information on your health (individual results), they will be relayed to the physician in charge of your case, who will contact you and give you this information if you so desire.

Leucodystrophies are rare diseases, and having a large number of patients is a decisive factor.

III. Data protection and confidentiality

The LeukoDB has been authorized by the various different data protection authorities in the participating countries.

The data will be shared in encoded and secure form among the project research teams of the participating countries. These teams ensure that your data is handled with the same level of protection. In the context of scientific publications and presentations, this data will be entirely anonymized.

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Unless you object, this data will be made available to LeukoDB members and partners.

A charter has been developed to ensure transparency in how the LeukoDB operates and for participant information regarding the data included (available through search engines). The project member and partners have agreed to comply with the ethical standards set out in the charter: protecting data and respecting individual rights in a strictly confidential manner.

IV. Your rights:

- Access and modification: you have the right to access and modify the data the LeukoDB contains on you at any time.
- Withdrawal from participation: you have the right to withdraw your participation in the LeukoDB. You may exercise this right at anytime without prejudice or loss of opportunity and without affecting your medical care. In this project, withdrawal means that your data is definitively, entirely and irreversibly anonymized, making it impossible to connect it to an identity.
- In case of death, the data is kept in encoded form in the LeukoDB, unless it was previously irreversibly anonymized.

You can exercise all these rights by contacting the contact person in charge of the database in the clinical centre that handles your case. This contact person is mentioned in the header and at the end of this document.

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Practical information

The security of your data follows the rules established by the relevant national authority on the protection of personal data (the CNIL: national commission on computer technologies and liberties), which has validated the project.

If you would like more information on your participation in the LeukoDB, you can contact the contact person in charge of the database in the clinical centre that handles your case at any time and for any question at this address:

Surname:

Forename:

Institution:

Telephone:

E-mail: