

Person in charge of the database :
Institution :

phone :
Email :

## **Information sheet for major patient**

### **Participation to the European database on leukodystrophies : LeukoDataBase**

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You are invited to participate to the LeukoDataBase (called “LeukoDB”), a European database for leukodystrophies and other genetic diseases affecting the brain white matter. The LeukoDB has received financial support from the European Commission.

The.....Centre would like to include your data in the LeukoDB.

Your consent is required for your participation in the LeukoDB. This document has been validated by the LeukoTreat Ethics Committee and by the local research ethics committees of the countries participating in the project.

#### **I. Aim of the LeukoDB database**

The objective is to connect, enlarge and improve at a European level the already existing databases for leukodystrophies and other genetic diseases affecting the brain white matter, by organizing the collection and the management of several data: clinical, medical imaging, biological data including genetic information. The LeukoDB is established in collaboration with research and clinical centres which participate in the project. Anonymised and secured data included in the LeukoDB will be made available to research teams in every participating European country.

The LeukoDB includes a clinical database, a genetic mutation database and a database allowing to list and to locate existing samples (biobank).

Since leukodystrophies are rare disorders, having a significant number of patients is crucial to gain insight into the natural course of these diseases. The information collected and stored in the LeukoDB will promote research for a better knowledge and understanding of these pathologies and, hopefully, help the development of methods of diagnosis and treatment, as well as better identifying patients who can participate in a clinical trial.

#### **II. Your participation**

By your participation, you agree to the collection, storage and sharing data from your medical record, and from research programs. These are biological, radiological, electrophysiological, genetic and cognitive evaluations data. The name of a person is coded in a way that does not allow third-party persons to detect the identification of the person. However, someone with a specially

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defined responsibility (for example a physician in personal care of an individual patient) will retain the key with which the person can be identified.

The genetic information concerns how the disease affects you and your family members as well as gene mutations involved in the disease. All data will be stored in the LeukoDB as long as needed for the research objectives.

Participation is voluntary. You are free to participate or not to the LeukoDB. You are also free to withdraw at any time. Refusal to participate or withdrawal will not be prejudicial to you, in particular regarding your medical follow-up.

Global results of the research, once scientifically validated, will be made available on the LeukoTreat website. When the research results will be relevant to your health, this information will be transmitted to the physician in charge of your follow-up, who will give it to you.

**III. Data protection and confidentiality**

The LeukoDB has received permission from the respective data protection authorities in participating countries.

[Hereby, each country has to specify the name and authorization from the concerned authorities].

Pour la France, la CNIL (Commission Nationale de l'Informatique et des Libertés) a autorisé la mise en place de la base de données à la suite d'un avis favorable du CCTIRS (Comité Consultatif sur le Traitement de l'Information en matière de Recherche dans le domaine de la Santé) en accord avec l'article 54 de la loi du 6 janvier 1978.

Mention obligatoire (CNIL):

« Les informations recueillies font l'objet d'un traitement informatique destiné à ..... (Veuillez préciser la finalité). Les destinataires des données sont :..... (précisez).

Conformément à la loi « informatique et libertés » du 6 janvier 1978 modifiée notamment en 2004, vous bénéficiez d'un droit d'accès et de rectification aux informations qui vous concernent, que vous pouvez exercer en vous adressant à ..... (Veuillez préciser le service et l'adresse).

Vous pouvez également, pour des motifs légitimes, vous opposer au traitement des données vous concernant. »

«En outre, le participant (ou son représentant) accepte que les données enregistrées à l'occasion de cette recherche comportant notamment des données génétiques puissent faire l'objet d'un traitement informatisé par le responsable de la recherche ou pour son compte. Il a bien noté que le droit d'accès prévu par la loi du 6 janvier 1978 relative à l'informatique, aux fichiers et aux libertés (article 39) s'exerce à tout moment auprès du médecin qui le suit dans le cadre de la recherche et qui connaît son identité. Il pourra exercer son droit de rectification et d'opposition auprès de ce même médecin qui contactera le responsable légal de la recherche ».

Article 40 : Toute personne physique justifiant de son identité peut exiger du responsable d'un traitement que soient,

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selon les cas, rectifiées, complétées, mises à jour, verrouillées ou effacées les données à caractère personnel la concernant, qui sont inexactes, incomplètes, équivoques, périmées, ou dont la collecte, l'utilisation, la communication ou la conservation est interdite.

Data registered in the LeukoDB is shared between research teams of the different countries participating in the project, in coded and secured form. Those teams will guarantee the same protection level to your data. This data, once anonymized, might be used in scientific publications. Subject to your objection, your data is available in coded and secured form to Members and Partners of the LeukoDB network (listed at: <http://leukotreat.eu/pages/Partners>).

A LeukoDB Charter (available on the internet) has been elaborated in order to ensure transparency in the way the LeukoDB functions and to inform participants about the data used through the LeukoDB. Members and Partners of the network committed themselves to the ethical standards set in the Charter concerning the protection of your data and the respect of your rights in the strictest confidentiality.

#### **IV. Your rights :**

- Access and rectify your data contained in the LeukoDB at any time.
- Withdraw your participation in the LeukoDB at any time. You may withdraw at any time without penalty, or loss of benefits to which you are entitled, and without affecting your medical follow-up. In this case, your data will be irreversibly and permanently anonymized, making it impossible to identify you.
- In case of death, the data will be kept coded into the LeukoDB database, unless irreversible anonymisation has been done before.

You can exercise your rights by contacting the resource person in charge of the database in the Center that follows you, as mentioned in the header and at the end of this document.

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**Practical information:**

Security of your data has been validated and follows the rules established by the National authority in charge of personal data protection in your country.

For further interrogations concerning your participation to the LeukoDB database, you can contact the resource person (physician in charge of the database in the clinical center where he/she is followed). The resource person can be contacted at all times and for any question or information concerning your participation, at the following address:

Name :
First name :
Institution :
Phone number :
Email :