

Resource person to be contacted :
Institution :

phone :
Email :

Information sheet
for the legal representative of a minor patient

information update concerning the use of already existing samples in research on leukodystrophies

N.B.:

- This document concerns already existing biological samples and their using in the frame of the LeukoDB database. In the case of new biological samples, a specific procedure is necessary and this document is not sufficient.
- This document concerns the sharing of biological samples between LeukoDB partners only. In the case of sharing with researchers who do not belong to the LeukoDB network, another consent is required and this document is not sufficient.
- In case of genetic studies, a specific document from your center will be given to the patient.

You are the legal representative of a minor who is invited to participate in a research program on leukodystrophies.

In the frame of his/her medical follow-up, biological samples have been collected. Those biological samples represent a precious resource since they are necessary for establishing diagnosis and adapting the treatment that he/she may receive. Therefore they have been stored in a specific center.

The minor is invited to participate to a research project for the development of methods of diagnosis and treatment for leukodystrophies and other genetic diseases affecting the brain white matter. It has received financial support from the European Commission. In the frame of this research project, his/her biological samples are listed and located in the different storage centers by the database called "LeukoDB".

The storage and use of those existing biological samples by the research project members requires your authorization. The present document aims at giving you clear and precise information, in order to update your consent to:

- The reuse of existing samples for research in the project (secondary use of samples).
- The storage of the biological samples (duration, storage conditions, post-mortem storage).
- The commercial use and valorization of the samples.

This document has been validated by the LeukoTreat Ethics Committee. Biological samples storage conditions have been validated by national authorities in each country.

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I. Reuse of the minor’s existing biological samples for research in the LeukoTreat project (secondary use of samples)

This research on leukodystrophies and other genetic diseases affecting the brain white matter will involve genetic studies. These studies concern how the disease affects the minor and his/her family members as well as gene mutations involved in the disease. With your authorization, the remaining part of these samples (if existing) may be used for medical research including genetic studies.

You can withdraw your consent to the future reuse of those biological samples at any time. In this case, biological samples and data are irreversibly anonymised.

II. Storage of the minor’s biological samples

The storage and use of his/her biological samples by the research teams is made in the strictest confidentiality, in respect of personal rights.

If biological samples have not been used in totality by researchers, the remaining samples are stored in the following location:.....

Please indicate the storage location

With your consent, some of these samples will be stored indefinitely, even after death, with the goal of further use for medical or scientific research on leukodystrophies and other white matter diseases.

This storage is performed under the responsibility of the physician in charge of the biobank:
.....
.....

Please indicate the name of the person in charge of the biobank

III. Commercial use and valorization of the biological samples

This is an altruistic donation; therefore, once your authorization given, no economic compensation will be awarded to the donor. However, we expect that results obtained by the use of his/her samples will enable us to improve the knowledge on this kind of disorders and finally may result in useful benefits for society as a whole.

If the donated biological samples are made available for commercial research with financial benefit or gain to third parties, it will take into account, as far as possible, the common interest of the patient community, notably in regard to the return of financial benefits.

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You can oppose to the commercial use and valorization of his/her samples, and/or withdraw your consent at any time.

IV. Your rights :

If you give your authorization to the reuse of the minor's biological samples for research on Leukodystrophies, the following rights are granted.

You have the right to:

- Withdraw your consent to the storage and reuse of his/her biological samples at any time, without penalty or loss of benefits to which he/she is entitled, and without affecting his/her medical follow-up (irreversible anonymization).
- Withdraw your consent to the commercial use and valorization of his/her samples at any time.

You can exercise your rights by contacting at any time the resource person in charge of the biobank (mentioned in the header of this document).

When the minor comes of age, he/she (or his/her guardian) will receive new information sheet and will be asked to sign a new consent (or authorization) form.