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1. THE LEUKOTREAT PROJECT

LeukoTreat is an ambitious European project funded by the European Commission under the 7th Framework Programme for Research and Development.

The project aims at developing therapeutic strategies for the largest number of Leukodystrophy (LD) affected patients as well as further applications to more common white matter disorders and neurodegenerative diseases. Leukodystrophies are inherited rare neurodegenerative diseases of the white matter (WM) and its main component, the myelin, that are affecting predominantly children. Despite the achievement of remarkable advances in the past decades, there is no current curative therapy.

Launched in 2010 for 42 months, LeukoTreat gathers 24 partners from 8 different countries. The project combines the expertise of recognized European research teams in the field of WM diseases, high-technology SMEs, experts in medical ethics and LD patients and families associations.

2. ETHICS IN LEUKOTREAT

The LeukoTreat project places great emphasis on medical ethics. A dedicated independent committee and a research group conducted by the Laboratory of Medical Ethics (LEM) at the University of Paris Descartes (France) have joined their strong expertise and experience in ethics to promote and develop innovative best practices during the project.

2.1 THE ETHICS COMMITTEE

A dedicated Ethics Committee was created to deal with the ethical management and follow-up of the project. The Committee fosters discussions and awareness on ethical issues among the partners, makes recommendations and disseminates identified best practices.
The Ethics Committee includes independent experts in medical ethics, human sciences, law professionals and representatives of patients’ associations. It is chaired by Pr. Lazare Benaroyo from the University of Lausanne.

The following table details the composition of the Committee.

<table>
<thead>
<tr>
<th>Chairperson</th>
<th>Lazare Benaroyo (University of Lausanne)</th>
</tr>
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</table>
| Independent Members | - Marc Dupont (AP-HP Hôpitaux de Paris)  
- Marie-France Mamzer (AP-HP, Necker Hospital)  
- Marie-Laure Moutard (AP-HP, Trousseau Hospital)  
- Sylvie Séguret (AP-HP, Necker Hospital)  
- Roger Picard (Huntington Espoir)  
- Anne-Sophie Lapointe (VML Association)  
- Jean-Christophe Coffin (Paris Descartes University)  
- Béatrice Godard (Montreal University) |
| Invited Members | - Grégoire Moutel (Laboratoire d’Éthique Médicale)  
- Nathalie Duchange (Laboratoire d’Éthique Médicale)  
- Odile Boespflug-Tanguy (Paris 7 University)  
- Patric Aubourg (INSERM)  
- Aurora Pujol (IDIBELL)  
- Marie-Claude Blondeau (Leuko Reference Centre)  
- Marie-Louise Vendeville (Leuko Reference Centre)  
- Gaël de Miomandre (ELA Belgium)  
- Tracy Coutrix (ELA France)  
- Ella Haven (X-ALD Association, Netherlands) |
| Management members | - Ingrid Callies (Laboratoire d’Éthique Médicale)  
- Diane d’Audiffret Van Haecke (Laboratoire d’Éthique Médicale)  
- Boris Loeve (Laboratoire d’Éthique Médicale) |

### 2.2 THE ETHICS RESEARCH GROUP

The Ethics Research Group works in synergy with the Ethics Committee on ethical decisions and documents to be produced. The overall objective of the Research Group is to protect the rights of patients and their families while making data available for research purpose:

- It enriches the Ethics committee’s debates and decisions with its analysis of patients’ needs and expectations;
- It produces documents for information and consent in accordance with ethical issues from the discussions of the Ethics Committee.

The Group is composed of researchers (biologists, physicians and jurists) who are experts in practices evaluation in research and care:

- Grégoire Moutel, MCU-PH, Paris Descartes University
- Nathalie Duchange, biologist, Inserm researcher, Paris Descartes University
- Sylviane Darquy, biologist, Inserm researcher, Paris Descartes University
- Ingrid Callies, Jurist, Research Associate, Paris Descartes University
- Diane d’Audiffret Van Haecke, biologist, business school, PhD Student, Paris Descartes University
- Anne-Sophie Lapointe, PhD Student, Paris Descartes University

These ethics experts are all members of the Laboratory of Medical Ethics at Paris Descartes University.
The Laboratory of Medical Ethics (LEM) at the Faculty of Medicine of Paris Descartes University (France) has been developing ethical research on the analysis of practices and patients’ life experience for the last 15 years. Its expertise relies on patients’ rights, integration of patients’ needs in the health care system, and the protection of persons in health care and biomedical research. The laboratory is member of a network of research in medical ethics from the National Institute for Health and Medical Research (INSERM).

The laboratory favours applied ethics, using multidisciplinary evaluation expertise with national and international partners based on data collected through direct contact with health care professionals, patients, patient advocacy groups, researchers and research organisms. The founding principle is the promotion of activities which will lead medicine to reflect on its developments and the responsibilities generated, both individually and collectively.

The laboratory publishes in international peer-reviewed journals (some of them are accessible on the French public open archive www.hal.inserm.fr/LEM) and has developed one of the first European Internet sites in medical ethics (www.ethique.inserm.fr). It collaborates regularly in international studies and is involved in European Edubioethics (Bioethical education on medical progress and human rights, in a multicultural, multidisciplinary and multireligious environment).

LEM is in charge of the completion of the Work Package 5 “Ethical impacts of therapeutic challenges in leukodystrophies” whose objectives are:
- to identify patients’ expectations towards the research project and to establish appropriate answers which can be brought to them concerning their participation and communication during the research project;
- to study how patients may produce a useful knowledge for scientific purpose.

2.4 ETHICS DOCUMENTS

During the project, the Ethics team, led by LEM, produced a set of ethical documents to guide the LeukoTreat Partners in the creation and management of the patient database and in harmonizing the individual protection rules between the participating countries. While these documents have been created in the specific framework of the LeukoTreat project, they are available as models for a broader use.

The Database Charter
The Charter sets out the principles agreed upon by the members of the database project. It aims at informing participants about the data used through the project and informing members, partners and users of the database about their commitment regarding the database functioning. The Charter is based upon international reference documents on personal data protection and right of persons regarding research (international treaties and European directives).

Patient Information Forms
Two different information forms have been created: one that provides details on the nature, significance, implications and risks of taking part to a database and one that specifically deals with the use of already existing biological samples within the database.
Three versions have been developed for each form: one dedicated to major patients, another to the legal representatives of underage patients and one to legal guardians of protected major patients. Finally, one information form for patients reaching the legal age of majority has been added.

**Patient Consent Forms**

The Patient Consent Form is used to confirm whether the patient agrees to participate to the database.

As with the Information Forms, three versions have been prepared: one dedicated to major patients, another to the legal representatives of underage patients and finally one to legal guardians of protected major patients.

The following templates can be used by any project aiming at establishing a patient database and wishing to harmonize the participants’ protection rules. With these tools, compliance with the highest ethical standards for patient’s needs and health care professionals’ duties is ensured.
« Database1 Charter »

Preamble

Definitions:

Database1: means the Project database.

Database1 Committee: is the committee in charge of the management of data, samples and mutations collected.

Database1 Network: means the network in charge of documenting the Database1.

Members and Partners of the Database1 Network: entities listed in Annex I which may be amended during the course of the Project.

Database1 Charter: means the present document which sets out the principles agreed upon by the Members of the Database1 Network, created in order to bring together data from (name of the disease) patients.

Database1 Coordinator: means the person in charge of the Database1.

Participants: means persons whose data is entered into the DatabaseA.

Documenting Entity: means the persons who are entering data into the Database1.

Technical aspects of the Database1:

The Database1 is located at (localisation). The Database1 is managed by (management entity). Technical aspects concerning security, anonymisation and protection of the data are detailed in Appendix (II) to the present Charter.
**Purpose of the Charter:**

a. To ensure transparency of the Database1 functioning for the Members and Partners of the Database1 Network.

b. To inform participants about the data used through the Database1.

c. To inform Members and Partners of the Database1 Network about their commitment regarding the Database1 functioning.

The Database1 Charter is based on reference international texts concerning personal data protection and on recommendations from International Organizations. This Charter fully endorses the principles regarding personal protection data issued by the following:

- Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.


- Recommendation n° R 97 (5) on the Protection of Medical Data, Committee of Ministers, Council of Europe, 13 February 1997


- International Declaration on Human Genetic Data, UNESCO, 16 October 2003

- OECD Guidelines on the Protection of Privacy and Transborder Flows of Personal Data

In accordance with the universal principles of Dignity and Primacy of the human being, as defined in Chapter one of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Convention on Human Rights and Biomedicine, Council of Europe, Strasbourg, 4-04-1997),

<table>
<thead>
<tr>
<th>Article 1 – Purpose and object</th>
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<tbody>
<tr>
<td>Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine.</td>
</tr>
<tr>
<td>Each Party shall take in its internal law the necessary measures to give effect to the provisions of this Convention.</td>
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<table>
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<tr>
<th>Article 2 – Primacy of the human being</th>
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<tbody>
<tr>
<td>The interests and welfare of the human being shall prevail over the sole interest of society or science.</td>
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</table>

and in accordance with article 6 of International Declaration on Human Genetic Data (UNESCO, 16 October 2003),
**Article 6 – Procedures**

(a) It is ethically imperative that human genetic data and human proteomic data be collected, processed, used and stored on the basis of transparent and ethically acceptable procedures. States should endeavor to involve society at large in the decision-making process concerning broad policies for the collection, processing, use and storage of human genetic data and human proteomic data and the evaluation of their management, in particular in the case of population-based genetic studies. This decision-making process, which may benefit from international experience, should ensure the free expression of various viewpoints.

(b) Independent, multidisciplinary and pluralist ethics committees should be promoted and established at national, regional, local or institutional levels, in accordance with the provisions of Article 16 of the Universal Declaration on the Human Genome and Human Rights. Where appropriate, ethics committees at national level should be consulted with regard to the establishment of standards, regulations and guidelines for the collection, processing, use and storage of human genetic data, human proteomic data and biological samples. They should also be consulted concerning matters where there is no domestic law. Ethics committees at institutional or local levels should be consulted with regard to their application to specific research projects.

by signing this Charter, Members and Partners of the Database1 Network further undertake to comply with the following recommendations:

I/ **Data processing**

a. **Data included in the Database1**

(1) Data stored in the Database1 concerns patients suffering from *(name of the disease)*. This data includes:

- Type 1 of data
- Type 2 of data etc.

b. **Data Entry and data access issues in the Database1**

(2) Members and Partners of the Database1 Network ensure that the access to data is restricted to scientific purposes. They respect principles contained in the information given to participants, his/her representative or his/her heirs.

According to this,

(3) Prior to documenting the Database1, the Documenting Entity needs the following:

1) Permission from local data protection and ethics authorities (favourable opinion).
2) An agreement between the Database1 Coordinator and a documenting entity.
3) A password application form for each user of the Database1.
4) Signed informed Participant consent forms for each Participant containing the information listed in part 3 of the present charter.

(4) Regarding his/her own status – patient, general practitioner, clinician, researcher, clinical trial center – and the type of data – personal data, clinical data, biological data – an access right is determined for each user of the Database1.

An access right to the Database1 can also be granted to further actors of the Project. Members and partners ensure that this access will be granted in due consideration of the sensitivity of such data. Access to data from the Database1 for projects not defined in the present Project is made through a specific request sent to the Database1 Committee. If the request is accepted, an agreement with the Partners of the Project is necessary for the exploitation of these data and samples.
a. Person and data protection issues

(5) Members and Partners of the Database1 Network ensure that all Participants have a full access to their personal data, in compliance with the Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

(41) Whereas any person must be able to exercise the right of access to data relating to him which are being processed, in order to verify in particular the accuracy of the data and the lawfulness of the processing; whereas, for the same reasons, every data subject must also have the right to know the logic involved in the automatic processing of data concerning him, at least in the case of the automated decisions referred to in Article 15 (1); whereas this right must not adversely affect trade secrets or intellectual property and in particular the copyright protecting the software; whereas these considerations must not, however, result in the data subject being refused all information;

(6) Members and Partners of the Database1 Network are fully conscious of the sensitivity of the data contained in the Database1 and commit themselves to take it into account through their activities, in accordance with the International Declaration on Human Genetic Data (UNESCO, 16 October 2003).

Article 4 – Special status

(a) Human genetic data have a special status because:

(i) they can be predictive of genetic predispositions concerning individuals;

(ii) they may have a significant impact on the family, including offspring, extending over generations, and in some instances on the whole group to which the person concerned belongs;

(iii) they may contain information the significance of which is not necessarily known at the time of the collection of the biological samples;

(iv) they may have cultural significance for persons or groups.

(b) Due consideration should be given to the sensitivity of human genetic data and an appropriate level of protection for these data and biological samples should be established.

According to this:

(7) Only participant data relevant to the Project is stored and processed. It is stored and processed without the Participant’s personal data (name, address, social security number).

(8) The data that is processed is coded, which means that the data obtained from the Database1 is anonymous for researchers who analyse it, i.e. the identification of an individual Participant is not possible.

(9) Only the attending doctors can combine clinical data with personal data.

(10) Members and Partners of the Database1 Network ensure the confidentiality of the data, in accordance with the right to privacy of life, as defined by the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Convention on Human Rights and Biomedicine, Council of Europe, Strasbourg, 4-04-1997).
Chapter III – Private life and right to information

Article 10 – Private life and right to information

1. Everyone has the right to respect for private life in relation to information about his or her health.
2. Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed.
3. In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraph 2 in the interests of the patient.

According to this,

(11) The persons in charge of capture and validation of the data are bound by confidentiality rules, as defined in the Recommendation n° R 97 (5) on the Protection of Medical Data, Committee of Ministers, Council of Europe, 13 February 1997.

3. Respect for privacy:

In principle, medical data should be collected and processed only by health-care professionals, or by individuals or bodies working on behalf of health-care professionals. Individuals or bodies working on behalf of health-care professionals who collect and process medical data should be subject to the same rules of confidentiality incumbent on health-care professionals, or to comparable rules of confidentiality.

(12) Members and Partners of the Database1 Network ensure the anonymity of the Database1 data by the coding and securisation of it.

(13) Access to the Database1 shall be protected by password.

(14) No one except the Members and Partners of the Database1 Network and Participants themselves or their representatives and heirs will access to the Database1 data.

(15) Publication on the basis of the data will always be anonymous.

(16) Members and Partners of the Database1 Network ensure that each country in which data from database is shared guarantees the same level of data protection and security, in accordance with the Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

CHAPTER IV TRANSFER OF PERSONAL DATA TO THIRD COUNTRIES

Article 25

Principles

1. The Member States shall provide that the transfer to a third country of personal data which are undergoing processing or are intended for processing after transfer may take place only if, without prejudice to compliance with the national provisions adopted pursuant to the other provisions of this Directive, the third country in question ensures an adequate level of protection.

17) Members and Partners of the Database1 Network ensure that the Database1 data can never be used in order to stigmatize and/or discriminate the people concerned, in accordance with the International Declaration on Human Genetic Data (UNESCO, 16 October 2003).
**Article 7 – Non-discrimination and non-stigmatization**

(a) Every effort should be made to ensure that human genetic data and human proteomic data are not used for purposes that discriminate in a way that is intended to infringe, or has the effect of infringing human rights, fundamental freedoms or human dignity of an individual or for purposes that lead to the stigmatization of an individual, a family, a group or communities.

(b) In this regard, appropriate attention should be paid to the findings of population-based genetic studies and behavioral genetic studies and their interpretations.

(18) Members and Partners of the Database1 Network ensure the respect of the sensitive data; such data can only be shared for specific purposes, as defined in the Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

(33) Whereas data which are capable by their nature of infringing fundamental freedoms or privacy should not be processed unless the data subject gives his explicit consent; whereas, however, derogations from this prohibition must be explicitly provided for in respect of specific needs, in particular where the processing of these data is carried out for certain health-related purposes by persons subject to a legal obligation of professional secrecy or in the course of legitimate activities by certain associations or foundations the purpose of which is to permit the exercise of fundamental freedoms;

(19) Members and Partners of the Database1 Network ensure that the participant have the right to withdraw his/her consent, as granted by the International Declaration on Human Genetic Data (UNESCO, 16 October 2003).

**Article 9 – Withdrawal of consent**

(a) When human genetic data, human proteomic data or biological samples are collected for medical and scientific research purposes, consent may be withdrawn by the person concerned unless such data are irretrievably unlinked to an identifiable person. In accordance with the provisions of Article 6(d), withdrawal of consent should entail neither a disadvantage nor a penalty for the person concerned.

(b) When a person withdraws consent, the person’s genetic data, proteomic data and biological samples should no longer be used unless they are irretrievably unlinked to the person concerned.

(c) If not irretrievably unlinked, the data and biological samples should be dealt with in accordance with the wishes of the person. If the person’s wishes cannot be determined or are not feasible or are unsafe, the data and biological samples should either be irretrievably unlinked or destroyed.

According to this,

(20) In case of withdrawal of consent, the data will be irretrievably unlinked so that it is no longer possible to identify the participant concerned.

(21) Withdrawal of consent can only be requested by the Participant him/herself. His/her wishes regarding his/her personal data shall be respected by any other person.

(22) For minors and incapable persons, the right to withdraw consent lies with the representative of the Participant.
II/ Regulation of potential value of data and valorization

Considering that data stored in the Database1 is issued from biological samples,

(23) Members and Partners of the Database1 Network ensure the respect of the principle of prohibition of financial gain and disposal of a part of human body, as defined in the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Convention on Human Rights and Biomedicine, Council of Europe, Strasbourg, 4-04-1997).

Chapter VII – Prohibition of financial gain and disposal of a part of the human body

Article 21 – Prohibition of financial gain

The human body and its parts shall not, as such, give rise to financial gain.

(24) Meanwhile, it is admitted that the data issued from the samples can be valorized in an economical way. In this context, such procedure shall be led in concert with all the actors of the Project, Participants included.

(25) A subset of the data may be made available in the future to pharmaceutical companies. However, this will require a prior amendment of the present Database1 Charter as well as an express consent of the participant, his/her representative or heir, in compliance with the Additional Protocol to the Council of Europe Convention on Human Rights and Biomedicine, concerning Biomedical Research, 25 January 2005.

CHAPTER IV – Information and consent

Article 13 – Information for research participants

vi. of any foreseen potential further uses, including commercial uses, of the research results, data or biological materials;

III/ Participant information

(26) Members and Partners of the Database1 Network ensure the respect of the principle of autonomy of the human being, which is guaranteed by the respect of the information and consent procedure.


CHAPTER IV – Information and consent

Article 13 – Information for research participants

1. The persons being asked to participate in a research project shall be given adequate information in a comprehensible form. This information shall be documented.

2. The information shall cover the purpose, the overall plan and the possible risks and benefits of the research project, and include the opinion of the ethics committee. Before being asked to consent to participate in a research project, the persons concerned shall be specifically informed, according to the nature and purpose of the research (…)
According to this:

(27) Members and Partners of the Database1 Network ensure the respect of a «mutually enlightened» consent procedure: the Participant has obtained all the information he/she needs from a person in charge of the research. The Participant can reach a contact person for any further questions concerning his/her participation.

(28) Members and Partners of the Database1 Network ensure that data entered in the Database1 comes with a consent form which includes the use of data for research, properly signed by the Participant (or his/her representative) and the person in charge of the research, in compliance with the International Declaration on Human Genetic Data (UNESCO, 16 October 2003).

Article 6

(d) It is ethically imperative that clear, balanced, adequate and appropriate information shall be provided to the person whose prior, free, informed and express consent is sought. Such information shall, alongside with providing other necessary details, specify the purpose for which human genetic data and human proteomic data are being derived from biological samples, and are used and stored. This information should indicate, if necessary, risks and consequences. This information should also indicate that the person concerned can withdraw his or her consent, without coercion, and this should entail neither a disadvantage nor a penalty for the person concerned.

(29) Members and Partners of the Database1 Network ensure that the Participant or his/her representative will be informed of the results of the research all along the project, as mentioned in the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research, 25 January 2005.

CHAPTER IV – Information and consent

Article 13 – Information for research participants

2. The information shall cover the purpose, the overall plan and the possible risks and benefits of the research project, and include the opinion of the ethics committee. Before being asked to consent to participate in a research project, the persons concerned shall be specifically informed, according to the nature and purpose of the research:

v. of arrangements for access to information relevant to the participant arising from the research and to its overall results.

According to this,

(30) Participants involved in the Database1 Project shall benefit from a priority access to the information concerning therapeutic protocols possibly issued from the research.

(31) Members and Partners of the Database1 Network are invited to keep a digitized consent form in the Database1, signed by the Participant or his/her representative.

(32) Concerning the entry of participant personal data in the Database1, Members and Partners of the Database1 Network ensure that a consent form has been signed and that the Participant or his/her representative has received the following information:
A. Scientific Goal and information
- Concerns data from Participants diagnosed with *(name of the disease)*
- Mention of genetic research
- Data transfers between research teams
- Use of data for scientific research linked to *(name of the disease)* only

B. Confidentiality
- Transfer of data (between research teams, outside of the country) with the same degree of protection of the data everywhere.

C. Access to the data
- The data will be shared between the members and partners of the Project.
- The participant, his/her representative or heirs may access the data.

D. Voluntary participation and freedom to withdraw the consent

E. Validation of the consent by an Ethics Committee

(33) In addition, it is recommended that the Members and Partners of the Database1 Network accept to inform the Participant, his or her representative or heir when they see them of the following:

A. Scientific Goal and information
- The data will be used in the Project, including a description of the project
- Storage for an indefinite period of time in the Database1
- Institution in charge of hosting the Database1
- Indication of a contact person (name and address, email, telephone number)

B. Confidentiality of data
- Publication of only anonymous data
- Only Participant data relevant to the Project is stored and processed without the Participant’s nominative data (name, address, social security number).
- The data that is processed is coded, which means that the data obtained from the Database1 is anonymous for researchers who analyse it, i.e. the identification of an individual Participant is not possible.
Information sheet for major patient Participating in the Database 1

*****

You are invited to participate to the Database1 for \( (name \ of \ the \ disease) \)

\( (description \ of \ the \ database) \)

The………………………………………..Centre would like to include your data in the Database1.

Your consent is required for your participation in the Database1. This document has been validated by \( (local/ \ national/ \ project \ ethics \ committees, \ participants \ etc...) \).

I. Aim of the Database1

\( (To \ complete \ with \ the \ database \ objectives) \)

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 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 Database1 as long as needed for the research objectives.

Participation is voluntary. You are free to participate or not to the Database1. 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 Project 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 Database1 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].

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):
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, 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 Database1 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 Database1.

A Database1 Charter (available on the internet) has been elaborated in order to ensure transparency in the way the Database1 functions and to inform participants about the data used through the Database1. 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 Database1 at any time.
- **Withdraw your participation** in the Database1 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 Database1, unless irreversible anonymisation has been done before.

You can exercise your rights by contacting the resource person in charge of the Database1 in the Center that follows you, as mentioned in the header and at the end of this document.

*****
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 Database 1, you can contact the resource person (physician in charge of the Database 1 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 : |
Information sheet for the legal representative of a minor patient
Participating in the Database1

You are the legal representative of a minor who is invited to participate in a research program on *(name of the disease)*. The minor is invited to join the Database1 *(description of the database)*.

The ...................................... Reference Center would like to include, in the Database1, data from the minor you represent.

Your authorization is required so that the minor can participate in this database. The present document has been validated by the *(local/ national/ project ethics committees, participants etc…)*.

I. **Aim of the Database1**

*(To complete with the database objectives)*

II. **Participation of the minor in the Database1**

By his/her participation, you agree to the collection, storage and sharing data from his/her medical record, and from research programs. These are biological, radiological, electrophysiological, genetic and cognitive evaluations data. The name of the 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 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 the patient and his/her family members as well as gene mutations involved in the disease. All data will be stored in the Database1 as long as needed for the research objectives.

Participation of the minor in the Database1 is subject to your authorization. You are free to withdraw this authorization at any time. Refusal to participate or withdrawal will not be prejudicial to the minor, in particular regarding his/her medical follow-up.

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

III. **Data protection and confidentiality**

The Database1 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):

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. »

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, 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 Database1 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 Database1 network.

A Database1 Charter (available on internet) has been elaborated in order to ensure transparency in the way the Database1 functions and to inform participants about the data used through the Database1. 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. As a legal representative, you have the right to:

• Access and rectify minor’s data contained in the Database1 at any time.

• Withdraw his/her participation in the Database1 at any time. You may withdraw at any time without penalty, or loss of benefits to which he/she is entitled, and without affecting his/her medical follow-up. In this case, his/her data will be irreversibly and permanently anonymized, making it impossible to identify the minor.

This right may only be exercised during the lifetime of the person represented.

• In case of death, the data will be kept coded into the Database1, unless irreversible anonymisation has been done before.

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.
You can exercise your rights by contacting the resource person in charge of the Database1 in the center where the minor is followed, as mentioned in the header and at the end of this document.

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**Practical information :**

Security of the minor’s 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 the minor participation to the Database1, you can contact the resource person (physician in charge of the Database1 in the clinical center where he/she is followed). The resource person can be

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You are the legal guardian of a person ("the represented person") who is invited to participate in a research program on (name of the disease).

The represented person is invited to join the Database1, (description of the database).

The ...................................... Reference Center would like to include, in Database1, data from the person you represent.

Your authorization is required so that the represented person can participate in this Database1. The present document has been validated by (local/ national/ project ethics committees, participants etc…).

I. **Aim of the Database1**

(To complete with the database objectives)

II. **Participation of the represented person in the Database1**

By his/her participation, you agree to the collection, storage and sharing data from his/her medical record, and from research programs. These are biological, radiological, electrophysiological, genetic and cognitive evaluations data. The name of the 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 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 the patient and his/her family members as well as gene mutations involved in the disease. All data will be stored in the Database1 as long as needed for the research objectives.

Participation of the represented person in the Database1 is subject to your authorization. You are free to withdraw this authorization at any time. Refusal to participate or withdrawal will not be prejudicial to the represented person, in particular regarding his/her medical follow-up.

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

III. **Data protection and confidentiality**

The Database1 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):
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, selon les cas, incomplètes, équivoques, périmées, ou dont la collecte, l’utilisation, la communication ou la conservation est interdite.

Data registered in the Database1 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 Database1 network.

A Database1 Charter (available on internet) has been elaborated in order to ensure transparency in the way the Database1 functions and to inform participants about the data used through the Database1. 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. As a legal guardian, you have the following rights:

• Access and rectify person’s data contained in the Database1 at any time.

• Withdraw his/her participation in the Database1 at any time. You may withdraw at any time without penalty, or loss of benefits to which he/she is entitled, and without affecting his/her medical follow-up. In this case, his/her data will be irreversibly and permanently anonymized, making it impossible to identify the represented person.

This right may only be exercised during the lifetime of the person represented.

• In case of death, the data will be kept coded into the Database1, unless irreversible anonymisation has been done before.

You can exercise your rights by contacting the resource person in charge of the Database1 in the center where the minor is followed, as mentioned in the header and at the end of this document.

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Practical information:

Security of the person’s 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 the represented person’s participation to the Database1, you can contact the resource person (physician in charge of the Database1 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 the minor’s participation, at the following address:

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Information document upon BECOMING OF AGE
Participating in the Database 1

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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 Database1.

While you were a minor, your legal representative(s) authorized your participation in the Database1.

(description of the database)

The Reference Centre ...................................................... added your data while you were a minor and would like to keep them in the Database1 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 (local/ national/ project ethics committees, participants etc…).

The aim of the Database1 is to provide Project researchers with as much data as possible in order to facilitate research on (name of the disease): understanding its causes and the manifestations of its diseases (natural history), developing diagnostic and therapeutic methodologies.

The Database1 will also make it easier to recruit patients for clinical trials.

The Database1 incorporates a clinical database, a database on genetic mutations and a database for the inventory and localization of existing biological samples (biobank).

The Database1 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 Database1

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 Database1 for as long as required by the research objectives.

Participation in the Database1 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 you 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.

III. Data protection and confidentiality

The Database1 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.

Unless you object, this data will be made available to Database1 members and partners.

A charter has been developed to ensure transparency in how the Database1 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 Database1 contains on you at any time.
- **Withdrawal from participation:** you have the right to withdraw your participation in the Database1. 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 Database1, unless it was previously irreversibly anonymized.

You can exercise all these rights by contacting the contact person in charge of the Database1 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 Database1, you can contact the contact person in charge of the Database1 in the clinical centre that handles your case at any time and for any question at this address:

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Patient information sheet
Information update concerning the use of already existing samples
in research on (name of the disease)
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N.B.: - This document concerns already existing biological samples and their using in the frame of the Database1. 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 the Database1 partners only. In the case of sharing with researchers who do not belong to this 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.

In the frame of your 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.

You are invited to participate to a research project for (objectives of the project). In the frame of this research project, your biological samples are listed and located in the different storage centers of the Database1.

The storage and use of those existing biological samples by the research project members requires your consent. 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 (local/national/ project ethics committees, participants etc…).

I. Reuse of your existing biological samples for research in the Project
(secondary use of samples)

This research on (name of the disease) will involve genetic studies. These studies concern how the disease affects you and your 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 your biological samples**

The storage and use of your 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 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Information sheet for the legal representative of a minor patient

Information update concerning the use of already existing samples in research on (name of the disease)

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N.B.:
- This document concerns already existing biological samples and their using in the frame of the Database1. 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 the Database1 partners only. In the case of sharing with researchers who do not belong to this 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 (name of the disease). 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 (objectives of the project). In the frame of this research project, his/her biological samples are listed and located in the different storage centers by the Database1.

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 (local/ national/ project ethics committees, participants etc…).

I. Reuse of the minor's existing biological samples for research in the Project (secondary use of samples)

This research on (name of the disease) 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.
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: …………………………………………………………………………………

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 (name of the disease).

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

II. 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.

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

III. Your rights:

If you give your authorization to the reuse of the minor’s biological samples for research on (name of the disease), 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.
Information sheet for the legal guardian of a protected major

Information update concerning the use of already existing samples in research on *(name of the disease)*

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**N.B.:**
- This document concerns already existing biological samples and their using in the frame of the Database1. 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 the Database1 partners only. In the case of sharing with researchers who do not belong to this 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 guardian of a person (*the represented person*) who is invited to participate in a research program on *(name of the disease)*.

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 represented person is invited to participate to a research project for *(objectives of the projects)*. In the frame of this research project, his/her biological samples are listed and located in the different storage centers by the Database1. 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 *(local/ national/ project ethics committees, participants etc…)*.

**I. Reuse of the person’s existing biological samples for research in the Project (secondary use of samples)**

This research on *(name of the disease)* will involve genetic studies. These studies concern how the disease affects the represented person 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 his/her 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: ……………………………………………………………………………

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 (name of the disease).

This storage is performed under the responsibility of the physician 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.

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 person’s biological samples for research on (name of the disease), 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).
3.3 PATIENT CONSENT FORMS

"Enlightened consent form" for your participation to the Database1: data & biological sample

In order to give an enlightened and informed consent, please read the information documents here attached: “Information sheet - Participation in the Database1” and “Information update concerning the using of existing biological samples in research on (name of the disease)."

During a consultation with the physician, I have received written and oral information about:

A. The use of my data through the Database1:
   □ Yes, I have received this information
   □ No, I have not received this information

B. The use of my biological samples within the Project:
   □ Yes, I have received this information
   □ No, I have not received this information

I have understood the interests and conditions of my participation to the Database1 and its contribution to solidarity-based research.

N.B: in case of genetic tests, I have received specific information on the this test and I signed a specific consent form.

I am aware I have the following rights:

- To withdraw from the Project at any stage of it, without penalty or loss of benefits to which I am entitled, and without affecting my medical follow-up.
- To access and to rectify my data stored in the Database1.
- To access global results of the research, once scientifically validated, available on the website.
- To access research results, when relevant to my health, through the physician in charge of my follow-up.
I thereby give my consent:

A. **The collect, storage and sharing of my clinical and biological data** in the Database1:

Data collected is extracted from your medical record, and from research programs. These are biological, radiological, electrophysiological, genetic and cognitive evaluations data. This data is coded so that only a person with a specially defined responsibility (for example a physician in personal care of an individual patient) will retain the key with which the person can be identified.

[ ] Yes, I give my consent

[ ] No, I do not give my consent

B. **The storage and use of my biological samples**:

This consent concerns the use and storage, for medical research purposes, of my biological samples taken in the frame of my medical follow-up.

[ ] Yes, I give my consent

[ ] No, I do not give my consent

For further interrogations concerning my participation to the Database1, I can contact the resource person, as detailed below, at all times.

The participant:

Name, last name:
Date of birth:
Date and signature:

The physician:

Name, last name:
Official stamp:
Date and signature:

(This document is delivered in triplicate: one for the patient, one for the medical file, one for the Database1)
Consent form for legal representative of a minor

You are the legal representative of a minor who is invited to participate in a research program on *(name of the disease)*.

In order to give an enlightened and informed consent, please read the information documents here attached: « Information sheet - Participation in the Database1 » and « Information update concerning the using of existing biological samples in research on *(name of the disease)* ».

During a consultation between the participant and the physician, I have received an information sheet and we have discussed:

A. The use of his/her data through the Database1 :
   □ Yes, I have received this information
   □ No, I have not received this information

B. The use of his/her biological samples within the Project
   □ Yes, I have received this information
   □ No, I have not received this information

I have understood the interests and conditions of my participation to the Database1 and its contribution to solidarity-based research.

Minor’s rights (exercized by the legal representative) :

- To withdraw from the Project at any stage of it, without penalty or loss of benefits to which the minor is entitled, and without affecting his/her medical follow-up.
- To access and to rectify his/her data stored in the Database1.
- To access global results of the research, once scientifically validated
- To access research results, when relevant to his/her health, through the physician in charge of his/her follow-up.
I thereby give my consent:

Data collected is extracted from his/her medical record, and from research programs. These are biological, radiological, electrophysiological, genetic and cognitive evaluations data. This data is coded so that only a person with a specially defined responsibility (for example a physician in personal care of an individual patient) will retain the key with which the person can be identified

☐ Yes, I give my authorization

A. To the storage and use of the minor’s biological samples:

This consent concerns the use and storage, for medical research purposes, of his/her biological samples taken in the frame of his/her medical follow-up.

☐ Yes, I give my authorization

☐ No, I do not give my authorization

For further interrogations concerning his/her participation to the Database1, I can contact the resource person, as detailed below, at all times.

If your child is alive, he/she can sign here:

Name, Last name:
Date of birth:

Name, Last name:
Date of birth:
Date and signature:

The legal representative:
Name, Last name:
Date and signature:

Official stamp:

(This document is delivered in triplicate: one for the patient or his/her legal representative, one for the medical file, one for the Database1)
Authorization form for the legal guardian of a protected major
for his/her participation in the Database1: data and biological samples.

You are the legal guardian of a person (« the represented person ») who is invited to
take part in a research program on (name of the disease).

In order to give an enlightened and informed consent, please read the information documents here attached:
« Information sheet - Participation in the Database1 » and « Information update concerning the using of existing
biological samples in research on (name of the disease) ».

During a consultation between the represented person and the physician,
I have received written and oral information about:

A. The use of his/her data through the Database1:
☐ Yes, I have received this information
☐ No, I have not received this information

B. The use of his/her biological samples within the Project:
☐ Yes, I have received this information
☐ Non, I have not received this information

I have understood the interests and conditions of his/her participation to the Database1 and its contribution to
solidarity-based research.

Represented person’s rights (exercized by the legal guardian):

• To withdraw from the Project at any stage of it, without penalty or loss of benefits to which the minor is entitled,
  and without affecting his/her medical follow-up.
• To access and to rectify his/her data stored in the Database1.
• To access global results of the research, once scientifically validated
• To access research results, when relevant to his/her health, through the physician in charge of his/her follow-up.
I thereby give my consent:

A. To the collect, storage and sharing of clinical and biological data of the represented person in the Database 1:

Data collected is extracted from his/her medical record, and from research programs. These are biological, radiological, electrophysiological, genetic and cognitive evaluations data. This data is coded so that only a person with a specially defined responsibility (for example a physician in personal care of an individual patient) will retain the key with which the person can be identified.

☐ No, I do not give my authorization

B. To the storage and use of the represented person's biological samples:

This consent concerns the use and storage, for medical research purposes, of his/her biological samples taken in the frame of his/her medical follow-up.

☐ Yes, I give my authorization

☐ No, I do not give my authorization

For further interrogations concerning his/her participation to the Database 1, I can contact the resource person, as detailed below, at all times.

The participant:
Name, Last name: ____________________________ Date of birth: ____________________________

The physician:
Name, Last name: ____________________________ Official stamp: ____________________________
Date and signature: ____________________________

Name, Last name: ____________________________ Date of birth: ____________________________
Date and signature: ____________________________

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Laboratoire d’Ethique Médicale
Université Paris-Descartes
45 rue des Saints-Pères. Paris 75006
gregoire.moutel@parisdescartes.fr
nathalie.duchange@inserm.fr

www.leukotreat.eu