



INFORMED CONSENT FORM FOR PARENTS/LEGAL GUARDIANS

Version 2 of 15/12/2022

Title of the study: Newborn screening for the diagnosis of Metachromatic Leukodystrophy (MLD)

Protocol code: NBSMLS2020

Promoter: Prof. Giancarlo la Marca, U.O. Newborn Screening Laboratory, Biochemistry and Pharmacology, AOU Meyer

Local Principal Investigator(at the Birth Centre): *indicate the name, surname, affiliation of the birth centre*

I, the undersigned, (mother/guardian) _____
born on ___/___/___ residing at _____ street/square _____
Tel. _____ domicile (if different from residence) _____

I, the undersigned, (father/guardian) _____
born on ___/___/___ residing at _____ street/square _____
Tel. _____ domicile (if different from residence) _____

of the newborn _____ born on ___/___/___
residing at _____ street/square _____

DECLARE that

- I have received from Doctor _____ exhaustive explanations regarding the request for participation in the project in question, as reported in the information sheet, of which I was given a copy on _____ at _____ (indicate date and time of delivery) .
- I have been clearly explained the nature, the purposes and the potential implications for the health of our child in this study.

I also **DECLARE** that:

1. I have read and understood the provided information sheet, that is part of this content, about the research project;
2. I had the opportunity to ask any questions to the trial investigator and I received satisfactory answers;
3. I had sufficient time to reflect on the information received and to discuss it with third parties;
4. I have been informed that the trial protocol and all modules used have received the favourable opinion by the competent Ethics Committee;
5. It has been clearly explained to me that I can decide that the minor does not participate in the trial, without providing any justification, and that these decisions will not in any way change the relations with the treating physician and with the structure where the child is being treated;
6. I have been informed on how they will communicate the results of this trial;



- 7. I have been informed that the results of the study, as aggregated data, will be made known to the scientific community, protecting the child's identity according to the current privacy legislation;
- 8. The signing of this document expresses my consent to Our son/daughter's participation in the trial, to the collection of the sample and its use together with his/her personal data, as described in the Information Sheet; in case of purposes and use other than those described, such consent will lose its validity and we will need to be contacted again;
- 9. I understand that Our son/daughter's personal data may be transferred to the San Raffaele Hospital under the responsibility of the Promoter and the trial Manager; for this reason all the security measures provided for by current legislation will be implemented.

I therefore **declare** that:

I consent Do not consent - REQUIRED -

- to the child's participation in the trial

I consent Do not consent - REQUIRED -

- to be informed about the results of the analysis

I consent Do not consent

- to the transfer of our son/ daughter's personal data to the San Raffaele Hospital, Milan

_____ / / _____
 Mother/legal guardian's Date Time Signature
 full name

_____ / / _____
 Father/legal guardian's Date Time Signature
 full name

By signing this form I consent to the processing of my child's personal data for the purposes of research within the limits and in the manner indicated in the information provided to me with this document, pursuant to provisions of the UE Regulation 2016/679 and the Legislative Decree 196/2003 s.m.i., I read the information on the processing of personal data from the paragraph "How personal data relating to your child's identity will be protected".

_____ / / _____
 Full name of Date Time Signature
 the parent/legal guardian



Regione Toscana



_____ / / _____
 Full name of _____ Date _____ Time _____ Signature _____
 the parent/legal guardian

I, the undersigned Prof./Dr. _____ (Surname) _____ (Name)

I declare that the parents/legal guardians of the Patient have voluntarily signed the participation in the trial

I also declare that:

- I have provided full explanations regarding the purpose of the trial, the procedures, the possible risks and benefits and possible alternatives;
- I have verified that the parents/legal guardian have sufficiently understood the information provided;
- I have given the parents/legal guardian the necessary time and the opportunity to ask questions about the trial;
- I have not exercised any coercion or undue influence in requesting the Consent

_____ / / _____
 Full name of the doctor _____ Date _____ Time _____ Signature _____
 who provided the information and
 obtained the informed consent