

EXPRESSION OF INFORMED CONSENT FOR THE PARENT(S) OR LEGAL GUARDIAN TO INCLUDE A MINOR IN A CLINICAL TRIAL

(Project title: *Newborn Screening for the Early Diagnosis of Metachromatic Leukodystrophy - MLD*)

(Notes: 1 copy for the participant, 1 copy for the person in charge of the trial)

Name, place and date of birth of the minor _____

Title of the trial: Newborn screening for the early diagnosis of Metachromatic Leukodystrophy

Protocol Code, version and date: version 1.0 of 30th May 2023

Trial promoter/sponsor/funding body: ASST Fatebenefratelli Sacco/Telethon

Main Investigator (NAME, AFFILIATION, REFERENCES): _____

I, the undersigned, _____

born in _____ on ___/___/_____

as mother/legal guardian of the minor named in the epigraph;

I, the undersigned, _____

born in----- on ___/___/_____

as father/legal guardian of the minor named in the epigraph;

HEREBY DECLARE

- that I/we have received from Dr. _____ exhaustive explanations regarding the request to participate in the research in question, according to the information sheet, which is part of this consent, a copy of which was delivered to me on _____ at _____ (*specify date and time of delivery*);
- that I/we have been clearly told about, and that I/we have understood the nature, purpose, procedures, expected benefits, possible risks and inconveniences, and alternative treatment modalities with respect to the proposed clinical trial;
- that I/we have had the opportunity to ask any questions to the trial investigator and have received satisfactory answers;
- that I/we have had sufficient time to reflect on the information received;
- that I/we have had sufficient time to discuss the information with third parties;
- that I/we have been informed that the relevant Ethics Committee has favourably approved the trial protocol and all forms used;
- that I/we am/are aware that the trial may be terminated at any time if so decided by the person in charge of the trial;
- that I/we have been informed that I/we will be given any new information that may compromise the safety of the research and that I/we may refer to the doctors who are treating my/our child/the minor in case of any problems or further questions;
- that, to best protect the health of our child/the minor, I/we am/are aware of the importance (and my/our responsibility) of informing the family doctor/paediatrician about the trial in which we agree to have our

ENTITY'S LETTERHEAD

that the father and mother/the legal guardian have/has voluntarily consented to the minor's participation in the trial.

I further declare that:

- I have given full explanation of the purpose, procedures, possible risks and benefits, and possible alternatives to the trial;
- I have verified that the parents/legal guardian have/has sufficiently understood the provided information;
- I have allowed the parents/legal guardian the necessary time and the opportunity to ask questions about the trial;
- I have clearly explained the possibility of withdrawing from the trial at any time or changing the choices made;
- I have not exercised any coercion or undue influence in requesting this consent;
- I have provided the parents/legal guardian with information on how the trial results will be made known;
- I have provided the parents/legal guardian with a simplified information sheet intended for minors aged between 7 and 11 and have emphasised the desirability of informing them – in an age-appropriate manner – about the characteristics of the trial in which they will participate.

First name Surname (in block letters) of the doctor who provided the information and who collected the consent

Signature (and stamp)

This form is an integral part of the informed consent form for the minor's parents/legal guardian