A minor´s (under 15 years) Guardian's Informed Consent Form template for a Clinical Trial

My child _____ whose legal guardian I am, has been asked to participate in the above mentioned medican device trial that aims to _____.

I have received verbal information regarding this trial, and I have received a written Trial Information Sheet. I have read and understood the received information on the objective and implementation of the trial, benefits and risks of the trial and my rights. My child has been told about this trial, and the child's positive attitude towards participation has been confirmed, taking into account the child's developmental level (maturity) and health status. I have been able to ask questions which have been answered, and I have had enough time to consider my child's participation. Me or my child have not been pressured to participate in this trial. Information about the trial was given by _____.

I understand that my child's participation in this trial is voluntary and I know that I have the right to refuse the child's participation. I can withdraw my consent and discontinue the child's participation at any time before the end of the trial and without giving a reason. I am also aware that the child's data collected up to early termination of the trial or withdrawal of consent may be used as part of the research data and safety evaluation of the medican device. Early termination of the trial or withdrawal of consent does not in any way affect the care the child might need or the way the child is treated.

I have received sufficient information about collection, processing, storage and disclosure of my child's personal data in connection with this trial. I am aware that the child's information is processed confidentially and is not disclosed to third parties. The sponsor of the trial will store my child's research data for at least _____ years, after which the data is appropriately destroyed. I am aware that travel expenses and/or loss of earnings caused by participation in the trial will free text space.

[Add when applicable] I consent to the collection of my child's gene sample and analysis of the samples for genetic studies described in the information leaflet. I also consent to the storage of the samples until the end of the genetic studies, but not exceeding [xx] years, before they are destroyed. I may request that my child's samples are destroyed earlier, during year [xx].

To be filled in when necessary:

☐ I have seen and read the informed consent signed by my child or heard the child express his/her own positive opinion on participation.

☐ I have discussed the participation with my child's legal guardian(s) and the positive view of the guardian(s) has been taken into account (if not present at the time of consent*).

By signing this form, I consent to my child's participation in this trial and confirm that the child's participation is voluntary

Child's name	*Child's date of birth or Social security number*
Child's home address	
Signature of guardian (1)	*Signature of guardian (2) (if present*).*
Name in block letters / *Date*	*Name in block letters* / *Date*

Confirmation of the person obtaining the consent;

- The guardian(s) of the child invited to participate in the study have been told about this study and they have received a written study information leaflet.
- The guardian(s) of the child invited to participate in this study have been given the opportunity to ask questions which have been answered.
- The guardian(s) of the child invited to participate in this study have been given enough time to consider and decide on the child's participation.
- It has been verified that the guardian(s) of the child invited to participate in this study has/have the right to sign the consent.
- The guardian(s) of the child invited to participate in the study have been told what happens to the biological samples collected during the study. (add when applicable)

_____ _____

Signature of study physician/study nurse *Place and date*

_____

Name in block letters

This consent form is prepared in two copies, one for the guardian(s), and the other is archived in a study file of the study physician.

