Clinical trial informed consent for a guardian of a minor (age under 15)

I have received and read the trial information sheet and received verbal information regarding this trial and I have understood this information. I have had enough time to consider my child's participation in the trial. This information was provided by _____. I have also been able to ask questions about the trial. My child has been informed about the trial and his/her agreement has been accepted, taking into account his/her developmental stage.

I have been informed that the data about my child, which is relevant to this trial, can be demanded from health care clinics _____ which store my child's patient records. For this purpose I give permission to record my child's social security number and use it to obtain the necessary data. This data will be collected in _____ study register.

I am aware that Finnish medicinal regulatory authorities, and with my consent, also medicinal regulatory authorities evaluating this medicine and representatives of sponsors in other countries have the right to check and verify the authenticity of the research data during and after the trial by comparing my child's patient records to the research data. This verification done by other than Finnish medicinal regulatory authorities happens under the supervision and responsibility of an investigator involved in this trial. All parties are under obligation to maintain confidentiality. The research data is handled confidentially so that it is coded in a way that will not reveal my child's identity without consulting the investigator involved in this trial who is responsible for the key-code. If necessary, this coded research data can also be handled within the European Union and outside it, as well as be handed over to a company which is involved in the development of this medicine under investigation. I also give my consent to use the research data mentioned above regarding my child in other trials investigating this medicine.

I understand that my child's participation in this trial is entirely voluntary and I can withdraw my consent and discontinue his/her participation in the trial at any given moment before the completion of the trial. I am also aware that the data collected up to the withdrawal will be used as part of the research data and safety evaluation of the medicine. Withdrawal from the trial does not, however, affect my child's right to receive any possible treatment. I have seen and read the informed consent form signed by my child and heard his/her agreement to participation in the trial.

☐ I have discussed my child's participation in this trial with his/her other guardian and his/her consent has been taken into account (if not the person who has signed this form).

☐ A DNA-sample study is conducted as a part of this trial. Taking part in this sub-study requires a separate informed consent form signed by a guardian(s). My child is participating in this sub-study and I / we have signed the DNA-study informed consent form. Date of consent: _____

I give my consent to my child's participation in this trial;

_____ _____
Child's name *Child's date of birth*

_____
Child's address

_____ _____
Guardian's (1) signature *Guardian's (2) signature*

_____ _____ _____ _____
Name in block letters *Date* *Name in block letters* *Date*

I have informed the child and his/her guardian (s) about this trial according to protocol and accept this consent form;

_____ _____
Investigator's (M.D.) signature *Date and place*

_____
Name in block letters

Two copies of this informed consent form have been made; one of which is given to the guardian(s) and the other one is filed in the Investigator's Trial File.