Clinical trial informed consent for children aged 15 to 17 years

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 taking part in the trial. This information was provided by _____. I have also been able to ask questions about the trial.

I have been informed that data about me, which is relevant to this trial, can be demanded from health care clinics ---Other optional text----- , which store my patient information. For this purpose I give permission to record my social security number and use it to obtain the necessary data. This data will be collected in ---Other optional text----- 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 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 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 in other trials investigating this medicine.

I understand that participation in this trial is entirely voluntary and I can withdraw my consent and discontinue participation in the trial at any given moment before the completion of the trial. I am also aware that the data collected up to 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 right to receive any possible treatment.

☐ The guardian(s) have been notified about the participation in this trial [by mail: *Notification of participation in a clinical trial to the guardian of a 15 to 17-year-old child*, or by phone].
Date of notification: _____

☐ 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 the participant. I am participating in this sub-study and I have signed the DNA-study informed consent form. Date of consent: _____

I give my consent to participation in this trial;

_____ _____ _____
Signature *Date of birth* *Date*

_____ _____
Name in block letters *Address*

I have informed the participant about this trial according to protocol and accept this consent form;

_____ _____
Doctor's 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 participant and the other one is filed in the Investigator's Trial File.