



FPM-E-005-EN v3.0 30.03.2021

Notification to the Guardian of a 15-17-year-old child Participating in a Clinical Trial

Dear guardian of _____,

We would like to inform you that your child has agreed to participate in a clinical _____ trial.

Title of the trial is: _____

This trial aims to find out _____

Your child has given their consent on _____. The trial starts on _____ and ends on _____. In this research unit, the physician responsible for the study is _____

The principal investigator responsible for this trial in Finland is _____

For more information about this trial, please contact _____

According to Finnish law (*Medical Research Act, April 9, 1999/488 and its amendments 295/2004 and 794/2010*), a minor who is 15 years or older can decide themselves if they want to participate in a clinical trial, if they are capable of understanding the importance of the study, and the study is likely to be of direct benefit to the minor's health. The guardian shall be informed of this decision, however. Study participation is voluntary and consent can be withdrawn at any time before the termination of the study without it affecting the right of your child to receive the necessary treatment. We have discussed issues related to this study with the adolescent before giving consent and they have had enough time to consider their participation.

Sending of this notification has been recorded in the consent form of the study subject.

Name and title of the sender of the notification: _____

Signature of sender: _____

Date and place: _____

More information on paediatric clinical trials:

Finnish Investigators Network for Pediatric Medicines (FINPEDMED): www.finpedmed.fi and www.finpedmed.com