FPM-E-005-EN v4.0 08.06.2022

# 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 (*Act on Clinical Trials on Medicinal Products, 983/2021*), if the subject has reached the age of 15, however, they may independently give informed consent to a clinical trial unless, considering their age, level of development and the nature of their illness or the trial, they are incapable of understanding the significance of the trial or procedure. In such a case, their guardian or legal representative shall be informed of their participation. Study participation is voluntary and consent can be withdrawn at any time before the termination of the study without it affecting the right of your child to receive the necessary treatment.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