Informed consent for human-related research involving minors: 12 up to and including 17 years that are compos mentis.

The regulations for consent declaration for participants aged 12 up to and including 17 involved in research is currently the subject of debate.
On the one hand Article 1:233 of the Civil Code (BW) states that children <18 are under parental authority. This implies that a minor (<18) is competent to perform legal acts but he/she acts with permission from his/her legal representative. This can best be achieved with written consent from the parents.
On the other hand the Civil Code (title 13, Article 234 paragraph 3) states that consent may be granted if the legal act concerned is one which is common in society for minors of this age to perform independently.

A letter from Minister Schippers dated 12 June 2014 concerning 'Progress of the amendment of the Medical Research involving Human Subjects Act' contains criteria that the research must satisfy in interpreting the term 'common in society' as mentioned in Article.1:234 paragraph 3 of the Civil Code. It states that there is little difference in the cognitive level between 16, 17 and 18 year-olds and that a 16 year old may be assumed to possess the required understanding.
The most important safeguard is the actual participant's well-considered decision: from the age of 16 a participant can be deemed capable of deciding on his or her participation, but cETO may impose further conditions such as if there are unnecessary risks involved or if the study involves an excessive load.

On this basis the cETO has decided to maintain the following guideline with regard to informed consent for research among the age group 12 up to and including 17 years that are compos mentis:

- For participants aged between 12 up to and including 15 their legal representative must also actively sign the informed consent as well as the subject, prior to the research being performed.
- Participants aged 12 up to and including 17, who are compos mentis, must always actively sign the informed consent prior to the research being performed.
- For participants aged 16-17 years it depends on the research being performed with the paricipants whether an active or passive informed consent is necessary from the legal representative or whether the legal representative is informed at all. In this situation the researcher must reason whether and if so, how the legal representative will be involved in the research and whether he or she will need to sign an informed consent prior to the research being performed.