Paediatric clinical trials: single parent or both parents signature needed

History table		
Prepared by: BAREC & College Board Approved by : College Board Date of endorsement : 10/07/2026		
Previous version	Adopted version	Summary of changes
Version 2 (04/07/2025)	Version 3 (05/08/2026)	Change in the order of paragraphs Clarification on the minor's assent and involvement in the consent process.

Recommendation

Under the EU Clinical Trials Regulation, the informed consent of a singular legally designated representative is sufficient for enrolling a minor in a clinical trial. Belgian law, through the Law of 7 May 2017 on clinical trials with medicinal products for human use and the Law of 22 August 2002 on Patients' Rights, clarifies that this representative must be someone who exercises parental authority or is the child's legal guardian.

According to Articles 373 and 374 of the Belgian Civil Code, parental authority is typically exercised jointly by both parents, regardless of whether they live together. In practice, each parent is presumed to act with the consent of the other, unless a court has ruled otherwise. While this legal presumption facilitates everyday decisions, it may not be appropriate for high-stake matters such as the participation of a minor in a clinical trial.

It is therefore ethically recommended, and in some cases legally required, to obtain written consent from both parents, particularly if the study may have significant implications for the child or family. This may include important healthcare decisions, such as the administration of an experimental medicinal product, or organisational implications affecting both parents, such as frequent study visits. Accordingly, the Informed Consent Form (ICF) should include two signature lines.

Simultaneous signing is not required. The parent that is present at the on-site visit can take the ICF home which gives the other parent the opportunity to sign it too. Sufficient time should be given to participants and parents to consider before signing the ICF, allowing for both signatures to be obtained at a later time. The ethical principle of respect for autonomy thus suggests that efforts should be made to obtain consent from all relevant parties whenever possible, including involvement of the minor concerned. By analogy with the Belgian Patient Rights Law, minors should be involved in decision-making to the extent that they are capable of understanding the information and forming a reasoned opinion. The treating physician or principal investigator should assess this on a case-by-case basis, taking into account the minor's age, maturity, and other relevant factors, including the scope and impact of the intervention or research, as well as the minor's personality, mental state, family and social environment, and level of education.

This implies that, in the context of clinical trials, the principal investigator should explicitly evaluate the minor's capacity for discernment and adapt the information provided to the minor's level of understanding. The minor's assent (or dissent) should be actively sought and appropriately documented. The minor's own wish to participate must therefore be considered.

As stated above, in the context of clinical trials, it may be legally required or ethically recommended to obtain written consent from both parents. This can be facilitated by including two signature lines in the ICF and allowing sufficient time for each parent to sign, even if not simultaneously.

However, there may be situations where obtaining written consent from both parents is not feasible or appropriate, such as when one parent is genuinely unavailable (for example deceased, incarcerated, or otherwise unreachable), or estranged, and there is no indication for the principal investigator, directly or indirectly, that the absent parent holds a different view on the child's participation in the study. This exception applies only in cases of true absence and does not apply where one parent is merely not present at the consultation or where parents are separated or divorced. In such cases, both parents must still agree on important decisions concerning the child.

In exceptional circumstances, it may be ethically permissible to proceed with written consent from a single parent, provided that reasonable efforts have been made to inform and involve both parents and that participation is considered to be in the best interest of the child. In such cases, the parent present at the on-site visit should be asked whether the co-parent consents to the child's participation in the study. Where only one parent provides written consent, it must be made explicit that this consent is given on the assumption that it reflects the agreement of the other parent.

It is recommended to document in the ICF whether the parent signs in their own capacity or on behalf of both parents, together with the underlying justification. In principle it applies that if the principal investigator has knowledge that the other parent refuses consent, the child may not be included in the study without that parent's written consent, notwithstanding the signature of the present parent on behalf of both. But, it is essential to approach this situation with sensitivity and ensure that decisions are made in the best interest of the child, taking into account not only parental authority, but also the evolving autonomy and discernment of the minor.