

# Advice regarding the signature of parents in paediatric clinical trials

This advice was endorsed by the College Board on 20/06/2025.

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 Clinical Trials Law of 7 May 2017 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 clinical trial participation of a minor.

It is therefore ethically recommended to obtain written consent from both parents, particularly if the study may have significant implications for the child or family. In the Informed Consent Form (ICF), two signature lines should be present.

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.

However, there may be situations where obtaining written consent from both parents is not feasible or appropriate, such as when one parent is unavailable (e.g. when one parent is deceased, is in jail, in single-parent households,...), or estranged and there is no indication for the principal investigator (directly or indirectly) that the absent parent has a different opinion about the participation of the child in the study. In such cases, it may be ethically permissible to proceed with obtaining written consent from a single parent, provided that prior efforts have been made to involve and inform both parents and that the decision is made in the best interest of the child.

In that case, the parent that is present at the on-site visit should be asked if the co-parent would agree to the inclusion of the child in the study. If only one parent signs, it must be clear to that single parent that his/her written consent implies the consent of the other absent parent of the child/minor. It is good practice to document in the ICF that the single parent present then signs either in his/her own capacity, or on behalf of both parents, including the rationale behind.

If the principal investigator has knowledge of refusal of the other parent to allow the child to participate in the study, the principal investigator cannot include the child without the written consent of the other parent, even not if the single parent has signed on behalf of both parents.

It's essential to approach these situations with sensitivity and ensure that decisions are made in the best interest of the child.