



CERPed's recommendations regarding the drafting of the acceptance document and the proposed signature of minors proposed for biomedical research

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Reminder of the texts:

Article 32 of REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014.

"Clinical Trials on Minors

1. A clinical trial may be conducted on minors only if, in addition to the conditions laid down in Article 28, all of the following conditions are met:

- (a) The informed consent of their legally appointed representative has been obtained;
- (b) The minors have received the information referred to in Article 29(2) from the investigators or from members of the investigator team trained and experienced in working with children, in a manner appropriate to their age and mental maturity;

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- (c) The explicit wish of a minor, who is capable of forming an opinion and assessing this information referred to in Article 29(2), to refuse participation or to be withdrawn from the clinical trial at any time is considered by the investigator or where appropriate the principle investigator".

Art 1122-2 of the Public Health Code (CSP)

Modified by LAW n°2012-300 of 5 March 2012 - art. 1 (V)

"Unemancipated minors, protected adults or adults who are incapable of giving their consent and who are not subject to a legal protection measure shall, when their participation in research involving the human person is envisaged, receive the information provided for in Article L. 1122-1 appropriate to their capacity to understand, both from the investigator and from the persons, bodies or authorities responsible for assisting them, representing them or authorizing the research, who themselves shall be informed by the investigator. They shall be consulted insofar as their condition permits. Their personal consent to participate in research involving the human person shall be sought. In any event, their refusal or revocation of their acceptance may not be disregarded. »

Comment: Respect for the possible refusal of the child to participate in research: in 2014, the European regulation joined the French CSP on this point, which had already specified this provision in the Huriet-Sérusclat Law in 1988.

It should be noted that under no circumstances can the signature of minors be required. In view of the difficulties encountered by promoters and investigators in formalizing the drafting of these specific paragraphs, CERPed proposes models intended for parents and the different age groups of minors. Children's information should be "adapted to their ability to understand".

Parents

"I have noted that after being informed by his doctor, my child is free to accept or refuse to participate in the study and that I cannot object to his possible refusal. He is free to stop participating at any time without giving reasons and without any consequence on the quality of his medical follow-up.

He will then be offered the usual treatment for the pathology he suffers from.

My child's signature is optional. »

Children

"You just spoke with the doctor. He explained that you can participate in a research study. You can say yes or no, even if your parents agree to participate. You can ask all the questions you want.

If you say no, no one will be angry. You will be treated just as well.

If you say yes, you'll participate in the research and you can change your mind if you want to."

Comment: No signature proposed

Tweens

"You just spoke with the doctor. He explained that you can participate in a research study. No one can force you to do it, you can accept or refuse even if your parents agree. Before you decide, ask all the questions you want.

If you don't want to participate, tell your parents and the doctor. You will be treated in the usual way.

If you accept, tell your parents and the doctor. If you want, you can change your mind afterwards.

No signature is required, but you can sign this document if you wish."

Teenagers

"The doctor who is following you has just explained that you can participate in research. Even if your parents agree, you can agree or refuse to participate, after asking all the questions you want.

If you do not want to participate, you will be treated in the usual way.

If you agree, you can change your mind at any time, without changing your relationship with the doctors and their teams.

Tell your parents and the doctor about your decision.

If you wish, you can sign this document.

If you become of legal age during the course of this study, you will then receive the adult information leaflet and you will have to sign a consent form to continue participating."