



**Contraception and Pregnancy in Minors Participating in Biomedical
Research regarding health products
April 2017**

In many research protocols including minors, contraception and follow-up of a possible pregnancy are considered.

In biomedical research regarding health products, pregnancy is medically contraindicated. Effective contraception according protocol modality concerned must be prescribed to any minor of childbearing age. Refusal of this contraception is a non-inclusion criterion.

The interview concerning contraception must take place face to face with the minor in the absence of the holders of parental authority, in order to respect the professional secrecy that minors have the right to oppose their parents or guardians.

Likewise, if a pregnancy test carried out as part of the protocol proves positive, the result must be announced to the minor directly; it is up to her to decide whether or not to inform her parents or guardians.

PROFESSIONAL SECRECY AND THE LAW

Public Health Code - Article L.1110-4:

"Any person under the care of a professional, an establishment, a health network or any other organization involved in prevention and care is entitled to respect for his private life and the secrecy of information concerning him.

Public Health Code - Article R.4127-4:

Professional secrecy, instituted in the interest of patients, is imposed on all physicians under the conditions established by law.

Secrecy covers everything that has come to the knowledge of the physician in the exercise of his profession, i.e. not only what has been entrusted to him, but also what he has seen, heard or understood.

The right of the minor to oppose medical secrecy to his parents:

Article L1111-5 of the CSP amended by LAW n°2016-41 of 26 January 2016 - art. 7

"By way of derogation from Article 371-1 of the Civil Code, the doctor or midwife may dispense with obtaining the consent of the holder(s) of parental authority for medical decisions to be taken when preventive action, screening, diagnosis or intervention is necessary to safeguard the health of a minor, where the latter expressly opposes consultation of the holder(s) of parental authority in order to keep his or her state of health secret. However, the doctor or midwife must first strive to obtain the minor's consent to such consultation. If the minor maintains his or her opposition, the doctor or midwife may implement the preventive action, screening, diagnosis or intervention. In this case, the minor shall be accompanied by an adult of his or her choice.

Contraception does not require parental permission

Article L5134-1 of the CSP

"I.-The consent of the holders of parental authority or, where applicable, of the legal representative is not / isn't required for the prescription, delivery or administration of contraceptives to minors. The delivery of contraceptives, the performance of medical biology tests with a view to prescribing contraception, the prescription of such tests or of a contraceptive, as well as their care, are protected by secrecy for minors."

Drafting proposal for information notice where the protocol calls for the inclusion of minors of childbearing age.

Parents' information Notice: "Pregnancy is contraindicated in this biomedical research. Your daughter will therefore be prescribed contraception according to the terms of the protocol, during a face-to-face interview outside your presence. If a pregnancy test is positive during the research, the investigating physician will announce the result directly to your minor daughter. He will endeavour to obtain her consent so that you are informed. She may object. In any case, she will be referred to a competent service for the follow-up of this early pregnancy, whether she decides to continue it or not. »

Minor Information Notice: "Pregnancy is contraindicated in this biomedical research. You will therefore be prescribed contraception during a face-to-face interview without your parents. If a pregnancy test is positive during the course of the research, the study doctor will announce the result to you personally. He will ask for your consent to share this information with your parents. You can object to this. In any case, he will refer you to a competent service for the follow-up of this early pregnancy, whether you decide to continue it or not. »