



NATIONAL ASSEMBLY

FIRST SESSION

FORTIETH LEGISLATURE

Bill 30

(2013, chapter 17)

An Act to amend the Civil Code and other legislative provisions with respect to research

**Introduced 28 March 2013
Passed in principle 30 May 2013
Passed 14 June 2013
Assented to 14 June 2013**

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EXPLANATORY NOTES

This Act amends certain provisions of the Civil Code of Québec that pertain to research. The term “experiment” is replaced by the term “research that could interfere with the integrity” and a new obligation is introduced whereby any research project in which a person of full age capable of giving consent participates must be approved and monitored by a research ethics committee.

The prohibition against submitting a minor or a person of full age incapable of giving consent to an experiment that involves a serious risk to their health is replaced by the possibility for them to participate in research that could interfere with the integrity of their person provided the risk incurred, taking into account their state of health and personal condition, is not disproportionate to the benefit that may reasonably be anticipated.

Various changes are also made with regard to the consent required to participate in research. Thus, a minor 14 years of age or over may give consent alone to research if, in the opinion of a competent research ethics committee, the research involves only a minimal health risk and the circumstances justify it. In addition, in the case of a person of full age incapable of giving consent who is not represented by a mandatary, tutor or curator, consent may be given by the person qualified to consent to the person’s care if a competent research ethics committee is of the opinion that the research involves only a minimal health risk for the person of full age.

Moreover, giving consent to research otherwise than in writing is authorized if, in the opinion of a research ethics committee, it is justified in the circumstances. The committee is empowered to determine the proper manner, for evidential purposes, of obtaining consent in such cases.

The rules governing consent for the use, for research purposes, of a body part removed as part of the care received by a person who has since died are also specified. In such cases, consent may be given by the person who could give or could have given consent to the care the deceased person required.

Lastly, the Act respecting health services and social services is amended by introducing a requirement that the complaint examination procedure of an institution that carries on research activities must enable any person, whether or not a user, who participates in research, as well as the heirs or the legal representatives of such a person, to address a complaint to the local service quality and complaints commissioner concerning the research.

LEGISLATION AMENDED BY THIS ACT:

- Civil Code of Québec;
- Act respecting health services and social services (chapter S-4.2).

Bill 30

AN ACT TO AMEND THE CIVIL CODE AND OTHER LEGISLATIVE PROVISIONS WITH RESPECT TO RESEARCH

THE PARLIAMENT OF QUÉBEC ENACTS AS FOLLOWS:

CIVIL CODE OF QUÉBEC

1. Article 20 of the Civil Code of Québec is amended

(1) by replacing “submit to an experiment” by “participate in research that could interfere with the integrity of his person”;

(2) by adding the following sentence at the end: “The research project must be approved and monitored by a research ethics committee.”

2. Article 21 of the Code is replaced by the following article:

“21. A minor or a person of full age who is incapable of giving consent may participate in research that could interfere with the integrity of his person only if the risk incurred, taking into account his state of health and personal condition, is not disproportionate to the benefit that may reasonably be anticipated.

Moreover, a minor or a person of full age incapable of giving consent may participate in such research only if, where he is the only subject of the research, it has the potential to produce benefit to his health or only if, in the case of research on a group, it has the potential to produce results capable of conferring benefit to other persons in the same age category or having the same disease or handicap.

In all cases, a minor or a person of full age incapable of giving consent may not participate in such research where he understands the nature and consequences of the research and objects to participating in it.

The research project must be approved and monitored by a competent research ethics committee. Such a committee is formed by the Minister of Health and Social Services or designated by that Minister from among existing research ethics committees; the composition and operating conditions of such a committee are determined by the Minister and published in the *Gazette officielle du Québec*.

Consent to research that could interfere with the integrity of a minor may be given by the person having parental authority or the tutor. A minor 14 years of age or over, however, may give consent alone if, in the opinion of the competent research ethics committee, the research involves only minimal risk and the circumstances justify it.

Consent to research that could interfere with the integrity of a person of full age incapable of giving consent may be given by the mandatory, tutor or curator. However, where such a person of full age is not so represented and the research involves only minimal risk, consent may be given by the person qualified to consent to any care required by the state of health of the person of full age. Consent may also be given by such a qualified person where a person of full age suddenly becomes incapable of giving consent and the research, insofar as it must be undertaken promptly after the appearance of the condition giving rise to it, does not permit, for lack of time, the designation of a legal representative for the person of full age. In both cases, it is incumbent upon the competent research ethics committee to determine, when evaluating the research project, whether it meets the prescribed requirements.”

3. Article 22 of the Code is amended by adding “or, if he has died, be so used with the consent of the person who could give or could have given consent to any care required by his state of health” at the end.

4. Article 24 of the Code is amended

(1) by replacing “an experiment” in the first paragraph by “research that could interfere with the integrity of his person”;

(2) by inserting the following paragraph after the first paragraph:

“However, consent to such research may be given otherwise than in writing if justified in the circumstances in the opinion of a research ethics committee. In such a case, the committee determines the proper manner, for evidential purposes, of obtaining consent.”

5. Article 25 of the Code is amended by replacing “An experiment” in the second paragraph by “A person’s participation in research that could interfere with the integrity of his person”.

ACT RESPECTING HEALTH SERVICES AND SOCIAL SERVICES

6. Section 34 of the Act respecting health services and social services (chapter S-4.2) is amended by replacing the second paragraph by the following paragraphs:

“If an institution carries on research activities, the procedure must also enable any person, whether or not a user, who participates in research to make a complaint concerning the research. This division applies to such a complaint,

and “user”, with the necessary modifications, includes any person who participates in research.

The procedure must also allow the heirs or the legal representatives of a deceased user to make a complaint regarding the services the user received or ought to have received or regarding any research referred to in the second paragraph in which the user participated.”

FINAL PROVISION

- 7.** This Act comes into force on 14 June 2013.