



NATIONAL ASSEMBLY

FIRST SESSION

FORTIETH LEGISLATURE

Bill 30

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

Introduction

**Introduced by
Mr. Réjean Hébert
Minister of Health and Social Services**

**Québec Official Publisher
2013**

EXPLANATORY NOTES

This bill amends certain provisions of the Civil Code of Québec that pertain to research. The term “experiment” is replaced by “research” and various changes are 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 part of the body 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 BILL:

- 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 by replacing “submit to an experiment” by “participate in research”.

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 not participate in research if, in the circumstances, the research involves serious risk to his health or, where he understands the nature and consequences of the research, if he objects.

Moreover, a minor or a person of full age who is incapable of giving consent may participate in research only if, where the person is the only subject of the research, it has the potential to produce benefit to the person’s 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. The research project must be approved and monitored by a research ethics committee. The competent ethics committees are 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 the committees are determined by the Minister and published in the *Gazette officielle du Québec*.

Consent to research may be given, in the case of a minor, 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 research ethics committee, the research involves only minimal risk and the circumstances justify it.

Consent to research may be given, in the case of a person of full age incapable of giving consent, by the mandatary, 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 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 research ethics committee to determine, when evaluating the research project, whether it meets the prescribed requirements.

Care considered by the research ethics committee to be innovative care required by the state of health of the person concerned does not constitute research.”

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”;

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

“However, consent to 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”.

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 (*insert the date of assent to this Act*).

