



NATIONAL ASSEMBLY

SECOND SESSION

THIRTY-FIFTH LEGISLATURE

Draft Bill

**An Act to amend the Civil Code
as regards medical research**

Tabled by
Mr Serge Ménard
Minister of Justice

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EXPLANATORY NOTES

This draft bill amending the Civil Code provides that an experiment on a minor or a person of full age who is incapable of giving consent may only be carried out within the framework of a research project approved by an ethics committee designated or formed by the Minister of Health and Social Services and under conditions determined by the Minister.

Moreover, the draft bill provides for the possibility for other persons than the tutor, curator or mandatary of a person of full age to give the necessary consent in the case of certain biomedical research projects. Finally, ethics committees are empowered, in lieu of the court, to approve experiments conducted on a single subject who is either minor or of full age but incapable of giving consent.

LEGISLATION AMENDED BY THIS DRAFT BILL :

- Civil Code of Québec ;
- Code of Civil Procedure (R.S.Q., chapter C-25).

Draft Bill

AN ACT TO AMEND THE CIVIL CODE AS REGARDS MEDICAL RESEARCH

THE PARLIAMENT OF QUÉBEC ENACTS AS FOLLOWS :

1. Article 20 of the Civil Code (1991, chapter 64) is amended by adding, at the end, the following paragraph :

“A minor or a person of full age who is incapable of giving consent may not be submitted to an experiment except in the absence of serious risk to his health and of objection on his part if he understands the nature and consequences of the act; the consent of the person having parental authority or of the mandatary, tutor or curator is necessary.”

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

“21. Any experiment on a minor or a person of full age who is incapable of giving consent, or on a group of minors or of such persons, may only be carried out within the framework of a research project approved by an ethics committee designated or formed by the Minister of Health and Social Services and under conditions determined by the Minister. Moreover, the experiment must have the potential to produce a benefit to the health of the person concerned or, if it is conducted on a group, to the health of persons of the same age group or having the same illness or handicap as the persons submitted to the experiment.

In the case of a biomedical research project which presupposes that it will be implemented in emergency situations, the committee may, when approving the project, provide that if a person of full age who is to be submitted to the experiment is incapable of giving consent owing to a sudden and temporary condition, consent may be given by the person qualified to give consent to care required by the person’s state of health.

Care considered by the ethics committee to be innovative care required by the state of health of the person who submits to it is not an experiment.”

3. Article 23 of the said Code is amended by replacing the words “with respect to care, the alienation of a part of the body, or an experiment” in the first paragraph by the words “with respect to care or the alienation of a body part”.

4. Article 776 of the Code of Civil Procedure (R.S.Q., chapter C- 25) is amended by replacing the words “with respect to care, the alienation of a part of the body or an experiment” in the first paragraph by the words “with respect to care or the alienation of a body part”.
5. Article 777 of the said Code is amended by replacing the words “treatment, specimen taking, removal of tissue or experiment” in the first paragraph by the words “treatment, specimen taking or removal of tissue”.
6. This Act comes into force on (*insert here the date of assent to this Act*).