

Bill 30

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

Section 1

AMENDMENT:

Replace by:

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.”

*Adopté
vr*

Bill 30

**An Act to amend the Civil Code and
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to research**

Section 2

AMENDMENT:

Replace by:

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 is not disproportionate to the benefit that may reasonably be anticipated, taking into account his state of health and personal condition.

Sam 1

Moreover, a minor or a person of full age who is 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. Participation in such research is possible 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*.

Sam 2

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.

Sam 3

Consent to research may be given, in the case of a person of full age incapable of giving consent, by the mandatory, tutor or curator. However, where

Sam 4

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 research ethics committee to determine, when evaluating the research project, whether it meets the prescribed requirements."

*Adopté tel
qu'amendé
VR*

SAM 1
AM 2
s. 2 (21)

Bill 30

**An Act to amend the Civil Code and
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Section 2

SUBAMENDMENT:

Replace the first paragraph, proposed by amendment, by:

“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.

Adopté
VR

SAM 2
AM 2
s. 2 (21)

Bill 30

**An Act to amend the Civil Code and
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Section 2

SUBAMENDMENT:

Replace the third paragraph, proposed by amendment, by:

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*.

Adopté
VR

SAM 3
AM 2
s. 2 (21)

Bill 30

**An Act to amend the Civil Code and
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Section 2

SUBAMENDMENT:

Replace the fourth paragraph, proposed by amendment, by:

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.

Adopté
VR

Bill 30

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Section 2

SUBAMENDMENT:

Replace the fifth paragraph, proposed by amendment, by:

Consent to research that could interfere with the integrity of a person of full age incapable of giving consent may be given 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 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.

Adopte
VR

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Section 4

AMENDMENT:

(1) Add "that could interfere with the integrity of his person" after "research" in paragraph 1.

(2) Replace the paragraph proposed by paragraph 2 by:

"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."

*Adopté
vr*

Bill 30

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Section 5

AMENDMENT:

Add "that could interfere with the integrity of his person" after "research".

*Adopté
VR*