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HARMONIZATION OF CLINICAL RESEARCH CONTRACTS IN QUEBEC

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Over the past few decades, a high-quality system of research and innovation has been built in the Province of Quebec. The contractual research conducted by university-affiliated health-care institutions in Quebec has become a fundamental scientific, economic and social activity. In order to benefit from the high calibre and know-how of the researchers working in the research centres, pharmaceutical companies retain the services of Quebec health-care institutions to conduct work pursuant to research protocols aimed at validating the drug or medical device being tested.

When negotiating a clinical research contract, each health-care institution, pharmaceutical company or contract research organization ("CRO") has very specific, and often conflicting, expectations and needs. However, the Council of Academic Hospitals of Ontario ("CAHO") reviewed the situation more closely in Ontario and succeeded in consolidating the principles common to clinical research contracts in order to facilitate and accelerate the negotiation process for its members. These common principles are set out in the form of a list of minimum standards.

Building on the experience of CAHO, and to ensure that Quebec remains a dynamic and effective player in research and innovation in the life sciences industry, Quebec's Ministry of Health and Social Services is studying the possibility of developing a version of this statement of principles intended for Quebec's health-care institutions. As such, our firm, which is a pioneer in contractual research management, has been retained to advise the Ministry on formulating this document.

As in Ontario, these principles are meant to serve as a statement or guide which provides the recommended minimum standards to the institutions for the negotiation of clinical research contracts submitted to them.

In this context, through a series of publications on the subject, we will be examining the clauses which, in our view, are crucial when a clinical research contract is being reviewed. In this article, we propose to consider the indemnification clause in detail, and the provisions for compensating study subjects in the event of adverse effects.

INDEMNIFICATION

The issue of indemnification is always delicate, since each party involved will seek to limit its liability. Indeed, the parties to a research contract use the indemnification clause to allocate the risk of claims from third parties relating to the study. Essentially, the undertaking to indemnify allows the "indemnitee", who is potentially liable for damage caused to a third party, to be relieved of its liability by transferring the risk to the party that has undertaken to indemnify it. It is generally acknowledged that the sponsor must specifically undertake to indemnify the institution and its investigator for any damages arising from the conduct of the study. However, the scope of the indemnification is the nub of the matter.

One must first ensure that the obligation to indemnify extends to the trustees, officers, directors, affiliated companies, employees, representatives, medical and professional personnel, students and subcontractors of the institution/investigator, and that each of these persons is a distinct "indemnitee".

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The sponsor must also clearly undertake to hold the "indemnitees" harmless of all claims arising from or caused by i) the conduct of the study as set out in the research protocol, ii) the negligence, errors, omissions or intentional fault of the sponsor and iii) the sponsor's use of the research results. This indemnification by the sponsor must not be subject to any time limits and must survive the termination of the contract.

The "indemnitees" generally have to agree to some exclusions. The following exclusions are considered acceptable to the extent that the breach by the indemnitee is related to or affects the claim:

- the negligence, error, omission or intentional fault of the indemnitee;
- its failure to comply with legal or regulatory requirements;
- substantial breach of contract;
- failure to substantially adhere to the terms of the protocol (except for deviations required to protect the safety or welfare of participants).

In addition to the exclusions, one should pay particular attention to the terms and conditions of indemnification, which can vary. One frequently sees provisions dealing with cross-indemnification, the disclosure of claims to the sponsor and the control of the conduct of the defence, including the right to conclude an out-of-court settlement and make admissions of liability.

If a CRO is involved, the sponsor must at the very least confirm in writing to the institution that the CRO has the authority to bind the sponsor to all of its obligations set out in the contract, and an explicit letter of indemnification by the sponsor should be attached as a schedule to the contract. The letter of indemnification must refer to the insurance coverage, to the warranty for the drug or device used in the study and to the sponsor's obligation to comply with the applicable laws.

The obligation to hold sufficient insurance coverage must not be overlooked. Quebec institutions hold the general liability coverage of the Association québécoise d'établissements de santé et de services sociaux (AQESSS), which does not, however, cover the clinical work of physicians, who should maintain their membership with the Canadian Medical Protective Association (CMPA) or equivalent. As for the sponsor, it must hold insurance coverage for its general liability, product liability or liability for clinical trials. Although the minimum coverage must be assessed according to the specific risk involved in the study, for interventional trials, the suggested minimum is $5 million per event.

COMPENSATION FOR STUDY SUBJECTS

When the sponsor refers in the contract to compensation for study subjects in the event of adverse effects arising from the study, one must first ensure that this undertaking is consistent with the compensation offered in the consent form signed by the subject.

Special attention must also be paid to disclaimers of liability which may deprive study subjects of compensation for medical expenses incurred to treat injuries and illness caused by the study. The exclusion of civil liability for bodily or moral injury caused to study subjects is prohibited under the *Civil Code of Québec*.

This overview of the indemnification clauses and clauses for the compensation of study subjects in clinical research contracts is primarily intended to illustrate the high degree of care which institutions and their investigators should exercise when reviewing the contents of agreements which are submitted to them, as well as the resulting obligations.

In a subsequent publication, we will discuss the confidentiality clause. In the meantime, our team of professionals in the life sciences sector would be pleased to review your research contracts to ensure that they conform to the applicable standards.

RECENT CASES IN THE QUEBEC COURT OF APPEAL ON AUTHORIZATION OF CARE

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In the past 18 months, the Quebec Court of Appeal has rendered several decisions in matters of judicial authorization of care where an adult incapable of consenting to the care required by his health condition categorically refused such care. Four of these decisions are of particular interest. In these cases the Court of Appeal considered such issues as the necessity of confinement in a mental-health facility, the length of the authorization, the situation of the adult under protective supervision and, finally, the notion of categorical refusal.

Firstly, we should bear in mind that the autonomy, inviolability and integrity of persons are fundamental values in Quebec law recognized by the *Charter of Human Rights and Freedoms* and by the *Civil Code of Québec*.[1] Except as provided by law, no one may interfere therewith without the free and informed consent of the person in question or of his representative if the person is incapable of giving such consent and has not categorically refused such care. If the incapable adult has categorically refused such care, authorization of the court is required prior to an intervention, except in cases of hygienic care or an emergency.[2]

CAN CONFINEMENT IN A MENTAL-HEALTH FACILITY BE AUTHORIZED IF THE PHYSICIAN DOES NOT INTEND TO GIVE EFFECT TO IT IMMEDIATELY?

In the case of *J... R...* v. *Centre hospitalier de l'Université de Montréal*,[3] a decision rendered on March 17, 2009, the appellant, a woman suffering from paranoid schizophrenia with the presence of depressive symptomatology since 1986, argued that the judge of first instance had erred, particularly by authorizing her confinement in a supervised residence for psychiatric patients.

On the question of confinement, the psychiatrist had noted in her report that she did not intend to confine the appellant immediately, as her goal was to keep her in her apartment. However, if the appellant's psychiatric condition did not improve with medication, she asked the court to authorize the hospital to place the appellant in a supervised residence for psychiatric patients, which the judge of first instance agreed to. On appeal, the appellant argued that if the confinement was not necessary when the judge rendered his decision, he could not delegate his powers to the medical authorities or give them carte blanche that they could subsequently use at will.

[1] *Charter of Human Rights and Freedoms*, R.S.Q. c. C-12, s.1; *Civil Code of Québec*, sec. 10, 11; *An Act respecting health services and social services*, R.S.Q. c. S-4.2, sec. 9.

[2] *Civil Code of Québec*, sec. 10, 11, 15 and 16; *An Act respecting health services and social services*, R.S.Q. c. S-4.2, sec. 9.

[3] 2009 QCCA 480.

The Court of Appeal noted that the evidence in this case showed that, in reality, it was preferable for the appellant to be confined in a mental-health facility because it was probable that, if she stayed at home alone, she would sooner or later stop taking her medication. We must add that the appellant had been hospitalized nearly 23 times since 1986. The Court of Appeal stated that the hospital authorities, aware of the appellant's desire to stay at home, wished to give her the benefit of the doubt and that she would follow the physician's prescription to the letter. In the Court of Appeal's opinion, this was not therefore a case where the judge finds that there is no reason to order the confinement of a person nor does it give the hospital authorities carte blanche. Rather, this was a case in which, instead of ordering the confinement of a person, the judge permitted the person not to be confined until she gave hospital authorities reason to believe that she could no longer function without being hospitalized.

Conclusion: confinement need not be immediate for authorization to be granted. However, it must be shown that the confinement is a component of the required care. In other words, there must be proof of the reasons justifying the confinement, even if the physician, wishing to give his patient the benefit of the doubt, intends to postpone the confinement until the patient gives him reasons to believe that he will not comply with the treatment and cannot function without being confined to a health-care facility.

UNDER WHAT CIRCUMSTANCES WILL AUTHORIZATION OF CARE BE ORDERED FOR MORE THAN 3 YEARS?

The courts have always been reluctant to authorize extended periods of treatment, the maximum term generally being 3 years. In a decision rendered in 2008,[4] the Quebec Court of Appeal held that once there was a finding of incapacity, the power of the judge hearing a motion for the authorization of care was a matter of judicial discretion. The judge must, however, exercised this discretion judicially by assessing and weighing the relevant factors.

Extended periods of treatment should not be permitted only to give more latitude to the treating physician.[5] In this case, the hospital sought authorization for a period of 5 years, which the judge of first instance had granted. The Court of Appeal, considering the case law on the subject, the fact that this was the first order for treatment and the underlying reasons of the physician (the desire to avoid having to return to court too quickly if the patient maintained his refusal), reduced the term of the authorization to 3 years.

That being said, in January 2010, the Court of Appeal, in the case of *Québec (Curateur public du Québec)* v. *Centre de santé et de services sociaux de Drummond*,[6] recognized that an extended period of authorization may be justified in some exceptional situations. That case dealt with a woman aged 85 who suffered from both obsessive delusional disorder and Alzheimer's disease. Two treatment authorizations, each for a term of 24 months, had already been granted since November 2003. This time around, the CSSS Drummond, where the patient was lodged, applied for a 5-year term of authorization, which the judge of first instance granted.

On appeal, the Public Curator of Quebec, as curator for the patient, criticized the judge of first instance for giving precedence to the administrative concerns of the CSSS, which was obliged to seek new treatment orders on a regular basis, over the patient's fundamental rights.

Referring to its decision in 2008, the Court of Appeal, while stressing both the exceptional nature of any treatment order, which is clearly coercive in nature, and the serious analysis which the judge must engage in, concluded that there may nevertheless be some exceptional circumstances in which a judge may grant an authorization for a term of more than 3 years.

In the instant case, given that three treatment orders had already been issued , and that the illness was constant and permanent, the Court of Appeal concluded that this was an exceptional situation which permitted the judge, in his discretion, to render a longer treatment order. It was not true, wrote the court, that the judge of first instance gave precedence to the administrative convenience of the CSSS Drummond over the patient's fundamental rights. Rather, the judge held that, given the special circumstances of the case, it was appropriate to issue a treatment order for a 5-year term. In doing so, the judge's exercise of discretion was not so inappropriate as to warrant intervention by the Court of Appeal.

Conclusion: a judge may, in exceptional circumstances, and in the exercise of his discretion, after assessing and weighing the relevant factors, grant an authorization of care for a term of 4 or 5 years. However, the onus is on the institution seeking authorization for such a term to prove that there are indeed exceptional circumstances.

ADULTS UNDER SUPERVISORY PROTECTION ARE NOT PRESUMED TO BE INCAPABLE OF CONSENTING TO CARE

Already in 1994,[7] the Court of Appeal established the principle that an order instituting supervisory protection does not necessarily entail a finding that the person under supervisory protection is incapable of consenting to care. As the Court of Appeal noted, the specific assessment of whether a person under protective supervision is incapable of consenting to the medical care required by his health condition may be different from the assessment that led to the institution of protective supervision in the first place.

[4] *Québec (Curateur public) agissant pour et au nom de Y...V...* v. *Institut Philippe-Pinel de Montréal*, February 14, 2008, 2008 QCCA 286.

[5] *Ibid.*, paragraph 34.

[6] 2010 QCCA 144.

[7] *Institut Philippe-Pinel de Montréal* v. *Gharavy*, [1994] R.J.Q. 2523 (C.A.).

Sixteen years later, in June 2010, the Court of Appeal reiterated this principle in the case of *M... C...* v. *Service professionnel du Centre de santé et de services sociaux d'Arthabaska-et-de-l'Érable et al.*[8] Indeed, the Court reaffirmed that the existence of supervisory protection does not give rise to a presumption that the patient is incapable of consenting to care. The Court stated that there must be a "finding", through a specific assessment, of the patient's inability to consent to care. This assessment should answer the following questions: whether the patient understands the nature of the illness for which treatment is proposed, the nature and goal of the treatment, the risks and advantages, the risks of no treatment, and, finally, whether the patient's ability to understand is impaired by the illness. These criteria are not cumulative and must be assessed broadly. Ultimately, the key issue is to determine whether the person truly understands the parameters of the decision to be made, even if he refuses care that is in his own interest.

In this case, the Court of Appeal concluded that the judge of first instance erred in law by inferring from the judgment ordering the curatorship that the patient was incapable of consenting to care. He ought instead to have conducted a specific assessment of the situation of the person in question based on the aforementioned criteria. Furthermore, the Court of Appeal found that the evidence showed on the balance of probabilities that the person was incapable of consenting to the care required by her condition, as she demonstrated a total lack of any self-critical ability and an apparent lack of judgment. As a result of her denial, she did not understand the nature of the multi-faceted illness for which treatments were proposed, the goal and benefits of the proposed care, including confinement, or the risk of remaining at home.

Conclusion: a person is not presumed to be incapable of consenting to care merely because he is under supervisory protection. There must be a specific assessment of the person's ability to consent to care to determine whether the person truly understands the parameters of the decision to be made, i.e. the nature of the illness for which treatment is proposed, the nature and goal of the treatment, the risks and benefits, and the risks of not receiving treatment.

EXISTENCE OF A CATEGORICAL REFUSAL

In the case of *W... S...* v. *Hôpital Charles-Lemoyne et al.*,[9] the issue the Court of Appeal had to consider was essentially whether or not the appellant, a man, aged 49, who was hospitalized in the psychiatric unit for an unspecified psychotic disorder, had categorically refused treatment.

In this case, the appellant argued that the judge of first instance who had granted the motion for authorization of care had erred in "presuming" that the appellant's refusal was categorical because, after refusing the medication at the start of his hospitalization, he had changed his mind and finally agreed to take the medication, even stating that he intended to continue doing so after his medical release. Thus, he submitted that he had not categorically refused treatment, and there was therefore no reason to grant the motion. On the other hand, the patient's history indicated that he had undergone psychiatric hospitalization several times in the past, that his cooperation in receiving treatment was generally limited while he was followed as an outpatient, and that there were frequent interruptions in the taking of his medication.

Based on the evidence, the Court of Appeal found that the appellant lacked self-critical ability in relation to his illness, that his true intentions concerning the taking of medication were ambiguous, that he had frequently stopped treatment in the past, and that his current consent was strategically motivated. It concluded that the finding of the judge of first instance that the appellant had categorically refused treatment within the meaning of section 16 of the *Civil Code of Québec* was understandable in the circumstances. The Court of Appeal held that the judge of first instance had committed no error which warranted the intervention of the Court.

Conclusion: the following are factors one must consider in determining whether a person has "categorically refused treatment": the reasons motivating a person to willingly take the medication required by his condition during the debate on his consent or refusal, and the person's history of taking medication, particularly where he is being followed as an outpatient. Thus, a strategic consent that is given in order to leave the hospital more quickly or to avoid a coercive judgment will not be indicative of a true and continuous consent to care and may constitute a "categorical refusal". As a judge in another case wrote:

> [translation] Announcing that one intends to comply and take the medication does not necessarily mean that the medication will be taken or, beyond announcing one's intention, that one truly intends to act on it.[10]

In this sense, the patient's past record of taking medication is a strong indicator of true intention in this regard.

Conclusion: an apparent consent given for strategic reasons is not necessarily valid consent and may even be found to be a refusal.

[8] 2010 QCCA 1114.

[9] 2010 QCCA 1209.

[10] *Centre de santé et de services sociaux de Laval* v. *L.L.*, judge Marie St-Pierre, 2006 QCCS 1330.

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