Québec City, June 1, 2023

Clinical research conducted by private entities acting as sponsors: Statement on optimizing the contract negotiation process

This statement presents Ministère de la Santé et des Services sociaux (MSSS) recommendations and guidelines for negotiating and entering into clinical research contracts with private entities acting as sponsors, specifically, clinical trial agreements (CTAs) and confidential disclosure agreements (CDAs).

The purpose of these recommendations is to improve and harmonize processes, including the contract negotiation process, and to reduce start-up time for clinical trials in Québec.

1. **Objective**: To accelerate the process for negotiating and entering into CDAs and CTAs, and to foster their effectiveness, efficiency, and consistency.

   In this regard, several public- and private-sector partners, including MSSS, various public health and social services network (RSSS) institutions, and pharmaceutical companies have joined forces, under the coordination of CATALIS Québec,[1] to make the following recommendations regarding CDAs and CTAs to be concluded between RSSS institutions and private companies.

2. **Recommendations**: Given the importance of reducing start-up times, the public- and private-sector partners involved in the initiative have established several recommendations and two options (at the sponsor's choice) to accelerate the process for evaluating research contracts in Québec.

Options	Processes and templates	CDA approval: provincial target[2] (legal portion)	CTA approval: provincial target[3] (legal and financial portions)
Option 1 **Use a model contract**	The sponsor submits the following models to RSSS institutions directly, **in their original form and without any modifications**: • **Provincial model confidential disclosure agreement** (French, bilingual, or English **mCDA**) • **Pan-Canadian model clinical trial agreement** (French, bilingual, or English **mCTA**), developed by the Canadian Clinical Trials Coordinating Centre (CCTCC) and updated by public and private CATALIS Québec members Having actively participated in the work sessions, the RSSS institutions have confirmed that they **(i)** adhere to mCTA and mCDA principles; **(ii)** agree to promote the use of these models and recommend from the outset that industry partners use these models from the beginning of the contract negotiation process. In the event that it is not possible for the sponsor to adhere to the above recommendation, the sponsor and any relevant institution **may jointly agree to use any of these agreements**: • Master agreement previously accepted by such institution • Specific agreement previously accepted by such institution	Maximum of five business days	Maximum of eight weeks (56 calendar days)

[1] Funded mainly by the Government of Québec, CATALIS Québec is an NPO whose mission is to optimize the clinical research environment in Québec in order to maximize private investment and accelerate the development of innovative patient care.
[2] Time between the date on which the institution receives the CDA to review the legal portion, and the date on which the CDA (including any appendices, if applicable) is finalized, approved and signed by all parties.
[3] Time between the date on which the institution receives the CTA to review the legal and financial portions, and the date on which the CTA (including the budget and appendices) is finalized, approved and signed by all parties.

	• New agreement (master or specific) in line with applicable provincial standards		
Option 2 **FAST TRACK evaluation service**	The sponsor uses the FAST TRACK evaluation service coordinated by CATALIS (central bureau). The sponsor uses the FAST TRACK evaluation service master agreements and other documents **in their original form and without any modifications**. The sponsor should refer to the most recent instructions provided by CATALIS. For more information regarding the service, please contact info@catalisquebec.com.	Maximum of five business days	Maximum of six weeks (42 calendar days) (This period of time is not in addition to the deadline for the budget approval process, which will take place in parallel.)

3. **Obligations**: In Québec, public institutions and their investigators are required to comply with applicable federal and provincial laws (including directives, guidelines, and ministerial circulars, as well as any rules of professional conduct if and as may be applicable to them), which set out various rules which may not be departed from, including those listed in the table on the following page.

4. **Requirements imposed by Direction des assurances du réseau de la santé et des services sociaux (DARSSS) and the Canadian Medical Protective Association (CMPA)**: DARSSS' insurance branch secures and manages RSSS insurance coverage, which: (i) provides coverage to all insureds, i.e., all public institutions and their employees (with the exception of third parties, including all physicians and all subcontractors, including those of the institution or sponsor); (ii) has limitation coverages that are shared among all institutions; and (iii) includes various standard and non-negotiable terms and conditions (including exclusions and limitations). Institutions may oppose any limitations and/or exclusions, as they do not want the indemnification to which they would otherwise be entitled to be denied or restricted (given their limited financial and other resources). By way of example, with this kind of insurance coverage, CTAs and/or CDAs may not contain any statement that (a) an institution will "defend, indemnify, and hold harmless" any third party (with the understanding that the institution may nevertheless assume its own liability for any wrongful act or omission); (b) choice of law and choice of forum clauses refer to foreign laws and/or courts; (c) an institution assumes any form of liability for acts or omissions of investigators or subcontractors (e.g., any nurse who is not employed by the institution but is dispatched for its benefit to perform certain research activities). Investigators rely on the assistance provided by the CMPA to its members. The assistance offered by the CMPA has similar limitations and exclusions.

Considering the importance of achieving the aforementioned objective, and in order to promote excellence in clinical research in Québec and increase the number of research projects undertaken in the province, MSSS reiterates the importance of adhering to the recommendations and performance targets set out in this statement.

Lastly, MSSS would like to thank all RSSS institutions, industry partners, CATALIS Québec, and other collaborators for their cooperation and contribution to improving clinical research processes in Québec.

Rules in force in Québec which may not be departed from

	Background	CTA and CDA
Parties to CTAs and CDAs	Investigators have research privileges, but they are not public institutions employees. Institutions and investigators are therefore "independent contractors."[4]	Institutions and investigators must: • be parties to all CDAs and CTAs; • enter into contracts in their own name. They cannot contractually agree to be jointly and severally liable for fulfilling any obligation.
Personal information and samples	Under the laws in force in Québec: • all personal information must be processed and, if applicable, transferred outside Québec in accordance with local laws; • no right of ownership can be granted over human samples.[5]	Institutions and investigators will require that: • the laws in force in Québec govern the processing of personal information, including any transfer outside the province, which must take place **(i)** in accordance with the consent of any participant; **(ii)** only to the extent that (1) such personal information is afforded proper protection, including with regard to generally accepted privacy principles; (2) such protection is the subject of a written agreement respecting the applicable legal requirements;[6] • the samples collected as part of any clinical trial are used only as required to conduct such trial, without any rights of ownership being granted over them.
Prohibition on certain limitations	In accordance with local laws: • no public institution can limit or renounce to their right to participate in other clinical trials;[7] • no person can limit their liability for bodily or moral injury, or for injury caused by their intentional or gross fault.[8]	Institutions and investigators: • will require that any limitation that may be sought by the sponsor on their right to concurrently take part in other clinical trials apply only to investigators. • cannot accept that a sponsor limits its liability **(i)** for any injury suffered by a participant as a result of the study product or a protocol procedure; or **(ii)** with respect to any obligation to assume the cost of diagnosing and treating such a participant (including cases where: (1) their medical condition is exacerbated by their participation in the clinical trial; (2) they have not fully complied with the instructions received), unless such amounts have already been reimbursed by a public or private insurance plan.
French language	Under local law, all CTAs and CDAs must be written in French. However, in some cases, they may be drawn up in another language to the extent provided by the *Charter of the French Language* and other applicable standards.[9]	As applicable, institutions will require the addition of a provision explaining the application of this exception, immediately before the signature page.
Financial issues	The budget must be consistent with applicable normative and legislative frameworks.[10]	Institutions will request that indirect costs (equivalent to at least 30% of the direct costs of research) be budgeted, as required by circular 2023-15 (formerly 2003-012), and that the budget otherwise reflect the amounts prescribed by circular 2023-16 (formerly 2016-029).

[4] *Act respecting health services and social services* (CQLR, c. S-4.2) and *Act to modify the organization and governance of the health and social services network, in particular by abolishing the regional agencies* (CQLR, c. O-7.2).
[5] *Civil Code of Québec* (CQLR, c. CCQ-1991), sections 3, 19, 22, 23, 25 and ss.
[6] *Act respecting Access to documents held by public bodies and the Protection of personal information* (CQLR, c. A-2.1), section 70.1; *Act respecting the protection of personal information in the private sector* (CQLR, c. P-39.1), section 17; and *Personal Information Protection and Electronic Documents Act* (S.C. 2000, c. 5), principle 4.3.1.
[7] *Act respecting health services and social services*, section 265.
[8] *Civil Code of Québec*, section 1474; see also the *Charter of human rights and freedoms* (CQLR, c. C-12).
[9] *Charter of the French language* (CQLR, c. C-11).
[10] See circular 2023-015 (formerly 2003-012), circular 2023-016 (formerly 2016-029) and the *Manuel de gestion financière* (specifically annexe 1H).