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RECHERCHE CLINIQUE QUÉBEC
CLINICAL TRIALS QUEBEC

UPDATE TO STANDARD LEGAL CLAUSES AND OTHER STANDARDIZED CLAUSES

The **Standard legal clauses for information and consent forms for clinical trials** were adopted by the Ministère de la Santé et des Services sociaux (MSSS) in 2021. In 2024, these clauses were revised to adapt to legislative and normative changes, including the Act respecting health information and social services (AHSSS or Act 5), the Act to modernise legislative provisions regarding the protection of personal information (Act 25), and the Tri-Council Policy Statement (TCPS2). The aim was to simplify the wording, as well as produce clauses adapted to pediatric studies. Following consultations with the CATALIS network's Research Ethics Board (REB) Advisory Committee, proposals to update the clauses were submitted to the MSSS for final approval, with a view to have them endorsed in a ministerial document.

While the ministerial review is underway, the Research Ethics Boards of the healthcare network may exercise their autonomy to make certain interim modifications to the standard legal clauses, in order to ensure compliance with the current legal framework.

If you have any questions about the contents of this document, please email us at info@catalisquebec.com

MSSS STANDARD LEGAL CLAUSES

- **CONFIDENTIALITY CLAUSE**

Storage of data/samples – Protection

Previous wording (2021)

> *The doctor in charge of this research study or a member of the research team will forward your coded data to the sponsor or its representatives.*
>
> ***AND***
>
> *However, the sponsor and any partners outside of Quebec are required to respect confidentiality rules equivalent to those in effect in Quebec and Canada, regardless of the country to which your data may be transferred.*

New wording (2025 - in the interim period prior to the official launch by the MSSS)

> *The study team will send your coded study data to the sponsor of this research project or their representatives. The sponsor may also forward this data to their partners.*
>
> *If the sponsor and their partners are based outside Quebec, they are required to provide adequate protection.*

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OTHER STANDARDIZED CLAUSES

- The standard clauses below are not standard MSSS legal clauses, but rather clauses developed by the CATALIS network's REB Advisory Committee, with the aim of harmonizing and accelerating the ethics review process in Québec.

SECONDARY USE OF STUDY DATA

Context

- *This clause applies regardless of the type of sponsor (industry sponsor or institution in the case of investigator-initiated studies).*
- ***Biological materials are not covered by this clause**; it applies only to data.*
- *Research ethics boards recommend inserting this clause in the information and consent form for any study where secondary use of data is planned.*
- *If the sponsor allows secondary use of data to be optional for the participant, a Yes/No choice should be added to the signature pages.*

Your coded study data may be used by the sponsor of this project to answer questions of medical or scientific interest other than those of the current study. This is known as secondary use of the data.

[If applicable, specify the types of secondary uses by adding the list below:

Your data may be used to:

- Conduct research on [specify disease types or research areas] and related health issues;
- Develop more effective ways to analyze and use scientific data;
- Develop and provide access to new drugs, medical devices, and healthcare solutions.]

The sponsor may also share your coded study data with other companies, partners, government agencies or academic researchers, for the same purposes. Your coded study data will remain protected as described in the Confidentiality section.

The research ethics board of [insert institution name] and the study team will not know when or for what purpose your coded study data will be used for secondary purposes.

However, if the sponsor plans to use your coded study data for a purpose other than those specified in this consent form, the sponsor must first obtain approval from an ethics committee.

- [*If the participant can choose Yes/No regarding the secondary use of their data, include the following sentence and add a Yes/No option on the signature page:* You may choose whether to allow the secondary use of your data at the end of this consent form.]

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CLAUSES RELATING TO THE USE OF THIRD-PARTY SERVICE PROVIDERS, CONNECTED DEVICES AND/OR APPLICATIONS

CONFIDENTIALITY AND USE OF A CONNECTED DEVICE OR APPLICATION

To take part in this study, you will need to use a device or application provided by a company called [*insert company name*]. When you use it, your study data will be coded and shared. Coded data may be stored in a cloud solution outside Canada, for example, in the United States. The company may also use this coded study data for other purposes, such as commercial or marketing purposes. The [*Name of Institution*] Research Ethics Board and the research team cannot guarantee that your coded study data will be completely secure (i.e. kept private, accurate and available). The [*Name of Institution*] Research Ethics Board does not assess the level of risk to your privacy when using the services of this company. You should ensure that you understand how the use of this device or application may affect your privacy. If you would like more information, please discuss this with the research team.

CONFIDENTIALITY AND SERVICES OFFERED BY THIRD PARTIES

The sponsor has asked an independent company, [*Company Name*], to manage [*adapt:* your travel and/or reimburse any expenses you incur as a result of participating in this study (e.g. parking fees)]. Using the services of [*Company Name*] is not mandatory in order to participate in the study and receive your compensation. However, if you choose to use these services, you will be required to share some of your information with the company. Using these services is not part of the study procedures, and the research ethics committee of [*Name of institution*] has not assessed the risks involved. However, the study sponsor confirms that [*Company Name*] will not share any information with them that could identify you. If you would like more information about using the company's services, please discuss this with the study team.