

## OTHER HARMONIZED CLAUSES

The clauses below are clauses developed by the CATALIS network's REB Advisory Committee, with the aim of harmonizing and accelerating the ethics review process in Québec.

If you have any questions about the contents of this document, please email us at [info@catalisquebec.com](mailto:info@catalisquebec.com)

### SUMMARY OF CHANGES FROM VERSION DATED 2025-11-24

The English-language updates were made solely to align terminology and phrasing with the French version, to ensure consistency between both official language versions. No substantive changes to meaning, intent, or requirements were introduced; the revisions are editorial in nature and are intended to support clear interpretation across both texts.

### 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.]

## **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 study 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 Research Ethics Board of the [Name of Institution] and the research team cannot guarantee that your coded study data will be completely secure (i.e. kept private, accurate and available). The Research Ethics Board of the [Name of Institution] 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. If you choose to use these services, you will need to share some of your information with the company. Using these services is not part of the study procedures, and the Research Ethics Board of [Name of institution] did not evaluate the risks of using the services offered by [Company Name]. However, the study sponsor confirms that [Company Name] will not share information with them that could identify you. If you would like more information about the use of [Company Name]'s services, please discuss this with the research team.