Prepared by CATALIS and its network of public-private partners

Standardized Clauses for Information and Consent Forms for Clinical Trials

Version, November 2025

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INTRODUCTION

This document is intended for those involved in preparing clinical trial information and consent forms, such as sponsors, principal investigators and research teams, as well as the Research Ethics Boards (REBs) that review these forms. It outlines the standardised clauses that must appear in information and consent forms to ensure compliance with regulatory and normative requirements when conducting a clinical trial in Quebec. This standardisation is the result of a consensus among REBs of Santé Québec institutions and members of the CATALIS Québec network. Their aim is to ensure consistency in decision-making across the network.

Although the focus is on the content of the consent form itself, consent is a process that cannot be reduced to simply drafting an appropriate text. For consent to be truly "informed", it is essential that tools are adapted to participants and that the quality and continuity of the exchange of information between them and the research team is maintained.

This document is a work tool to facilitate the action of copying and pasting text into informed consent forms. It is not an official document

STANDARDIZED CLAUSES

NOTES

In this section, the parts *italicized and highlighted in grey* are there to guide the research team in the drafting of an appropriate information and consent form. Please therefore remove these from the final information and consent form submitted to the Research Ethics Board.

To simplify the text, the phrase “the study doctor and the research team” used in the previous version (2021) of the standardized clauses has been replaced by “the research team” where the task described may be delegated to a team member. Where this was not possible, the term “study doctor” was retained. Please ensure consistent use of this in the information and consent form.

Furthermore, the term “study doctor” used in this document is equivalent to the term “qualified investigator.” The term “qualified investigator” is a regulatory term used by Health Canada to designate the person responsible to the sponsor for conducting clinical research at a given location (site). However, this term may not mean anything to a participant, particularly as the following standardized clauses and research consent forms may also be used for studies not governed by Health Canada.

A. VOLUNTARY PARTICIPATION AND THE RIGHT TO WITHDRAW

Voluntary participation and the right to withdraw

Your participation in this study is voluntary. Therefore, you may refuse to participate. You may also withdraw at any time, without giving any reasons, by informing the research team.

[*Where applicable*] Your doctor is one of the investigators in this study. As such, your doctor's interest lies primarily in your well-being and also in the successful pursuit of this study. Therefore, before you sign up for the study or at any time thereafter, you may wish to consult with another doctor who is not part of this study. You are by no means obligated to participate in whatever study is offered to you

AND

Consequences for care

Your decision not to participate in the study, or to withdraw from it, will have no impact on the quality of care and services to which you are otherwise entitled, or on your relationship with the teams providing them.

AND

Withdrawal of the participant from the study by the study doctor, the Research Ethics Board, the funding agency or the sponsor

The study doctor, the Research Ethics Board, [***where applicable*:** the funding agency] or the sponsor may put an end to your participation without your consent. This may happen if new findings or information indicate that participation is no longer in your best interests, if you do not follow study instructions or if the study is terminated for administrative reasons.

AND

Modulating withdrawal from the study (where applicable). Choose one of the following two options, if the right to withdraw can be modulated. For studies where it is not possible to modulate the right to withdraw, remove this section.

[***When warranted***] You have the right to stop your participation in certain parts of this study. The research team can provide more information about your options.

OR

[***When warranted***] You have the right to modulate your withdrawal from the study at any time by choosing to [***List to be adapted according to the research protocol****]*:

- Stop receiving the study drug,
- Stop on-site follow-up visits,
- Stop telephone follow-ups,
- Allow only medical chart information to be transmitted to the sponsor, or
- Withdraw from the study completely.

AND

Withdrawal from the study

However, before you withdraw from the study, we suggest, for safety reasons, that you [***choose***

take part in a final evaluation, take part in follow-up visits, ***describe other suggested follow-ups***].

AND

Consequences of withdrawal on retention of study data

If you withdraw completely from the study or are withdrawn from the study, no additional data will be collected [***where applicable:*** and no further samples will be taken]. Study data [***select if applicable:*** and samples, audio and video recordings, images, MRIs] already collected as part of this study will nevertheless continue to be retained, analyzed, or used to ensure the integrity of the study.

OR

[***When justified and possible depending on the study, without impacting the quality of the research and analysis***] If you withdraw completely from the study or are withdrawn from the study, no additional data will be collected [***where applicable:*** and no further samples will be taken]. You may request the removal of your study data [***select if relevant*:** and samples, audio recordings, video recordings, images, MRIs] collected as part of this study.

AND

New information

Any new findings acquired during the course of the study that may influence your decision whether to continue your participation will be shared with you promptly.

B. CONFIDENTIALITY

Collection – Who? Reasons for which personal information is requested

During your participation in this study, the research team will collect certain information about you [***where applicable:*** as well as some samples]. The team needs this information [***where applicable:*** and these samples] to meet the objectives of the study.

AND

Collection – What?

This information, also known as "study data," will be kept in a study file. It may include:

- Information from your medical charts. This may include [***choose:*** your name, gender, date of birth and ethnicity], past and present health status, and lifestyle information.
- The results of all tests, exams and procedures that will be performed.
- [***Where applicable:*** *Add any other data that may be collected about the participant as part of the study (for example, answers to questionnaires or interviews, audio or video recordings made as part of the study)*]
- [***Where applicable:*** Sample analysis results]

AND

Storage of data/samples – Protection

All study data [***where applicable:*** and samples] will remain confidential to the extent provided by law and the agreement with the sponsor. You will be identified by a code number only, which will prevent you from being identified directly. The key linking your code number to your identity will be kept by the study doctor.

AND

To ensure your safety, a document indicating your participation, namely [*specify the type of information (see "Collection – What?" section) – e.g., a copy of the informed consent form, a data information sheet or a summary of the study*], will be placed in your medical chart. The results of certain tests conducted as part of the study may also be included, depending on the situation. As a result, any person or company to whom you give access to your medical chart will have access to this information.

AND

The research team will send your coded study data to the sponsor of this study or its representatives. The sponsor may then forward the coded study data to its partners.

This sponsor and its partners may be located outside Quebec, in which case they will be required to provide adequate protection.

AND

Storage of data – Duration

This coded study data [***where applicable****:* and samples] will be retained for at least 15 years following the end of the study by the study doctor [***where applicable:*** the funding agency] and the sponsor.

OR

This coded study data will be retained for at least 15 years following the end of the study by the study doctor [***where applicable:*** the funding agency] and the sponsor. [***Where applicable:*** *If the retention period for samples, questionnaires, recordings, videos and/or photos is different, please specify the duration and the job title of the person responsible:* The [***choose:*** samples, recordings, videos, photos] will be retained for [*specify duration*] years following the end of the study by [***(choose):*** the study doctor, the sponsor, the funding agency.]

AND

Dissemination of overall results

The results of this study may be published or be the subject of scientific discussions. However, these publications or discussions will not enable you to be identified.

AND

Right of access for monitoring and safety

For monitoring, safety or approval of the drug [***OR where applicable*****:** a drug (*when more than one drug is being studied),* ***OR when applicable, choose:*** the medical device [*name of device*], the natural health product [*name of natural health product*]] being studied*,* your study file and medical charts may be examined by authorized representatives or persons mandated by certain organizations. These organizations include:

- Regulatory agencies, in Canada or abroad, such as Health Canada,
- The sponsor,
- The institution or its Research Ethics Board.

These individuals and organizations are required to maintain the confidentiality of your file.

AND

Right of access by the participant

You have the right to view your study file in order to verify the information and to have it corrected if necessary.

[***Where applicable**:* However, accessing certain information before the end of the study may mean that you have to be withdrawn from the study. The research team will explain the reasons for this.]

C. POSSIBILITY OF COMMERCIALIZATION

The results derived in part from your participation in the study may lead to the development of new commercial products. However, you will not be entitled to any financial gain thereof.

D. COMPENSATION

Compensation in the form of an amount proportional to participation

As compensation for costs incurred as a result of your participation in the study, you will receive [*insert compensation offered. If the amount does not vary by visit, please use the following wording*: the amount of $x per visit for a total of x visits. *If the amount varies depending on the visit, you can include a simple summary table to explain the amounts*]. If you withdraw from the study before it is completed, compensation will be proportional to the length of your participation. The same is true if your participation is terminated before the end of the study.

AND/OR

Compensation in the form of reimbursement or coupons covering expenses

Your expenses for [***choose***: travel, meals, parking, etc.] related to your participation in the study will be [***choose***: reimbursed upon presentation of receipts, paid by a coupon to be given to you] [***specify when***].

OR

No compensation

You will not receive financial compensation for participating.

AND

Medications provided (or where applicable: Medical device or natural health product)

Optional**:* Also, throughout your participation in this study, the study drug [*name of drug*] [OR where applicable, choose:*** the medical device [*name of device*], the natural health product [*name of natural health product*], the placebo] will be provided to you free of charge.

E. SHOULD YOU SUFFER ANY HARM

Harm / medical care

Should you suffer harm of any kind following administration of the study drug [***OR where applicable, choose:*** the medical device [*name of device*], the natural health product [*name of natural health product*], the placebo] being studied or any procedure related to this study, you will receive all the care and services required by your state of health.

AND

Non-waiver of rights

By agreeing to participate in this study, you are not waiving any of your rights nor discharging the study doctor, the sponsor, or the institution of their civil and professional responsibilities.

F. OVERSIGHT OF THE ETHICAL ASPECTS OF THE STUDY

Approval of the Research Ethics Board

The Research Ethics Board of [*insert name of institution with which the REB is affiliated*] has given ethics approval to this study and is responsible for its ongoing ethics oversight at all participating institutions within the health and social services network of Quebec.

OR

The Research Ethics Board of [*insert name of institution with which the REB is affiliated*] has given ethics approval to this study and is responsible for its ongoing ethics oversight.

G. CONTACT INFORMATION

Contact information

If you have any questions or are experiencing any problems in relation to the study, or would like to withdraw from it, you can contact the research team at: [*insert phone number*].

AND

Questions regarding participant rights or complaints

If you have any questions regarding your rights as a participant in this study, or have any complaints, you may contact:

The local service quality and complaints commissioner at [*insert name of institution and commissioner's contact information].*

H. SIGNATURE

Important: Please select the signature block(s) based on the competency of the study participants.

The choices are as follows:

- Assent and consent for a **participant who is a minor and their parent/guardian**
- Addendum to consent form for a participant who has **reached 18 years of age**
- Consent for a **participant who is an adult and legally competent**
- Consent for a **participant who is an adult and incapacitated** with a person who is legally authorized to consent in lieu (excluding studies with minimal risk or focusing on situations of sudden incapacity)
- Consent for a **participant who is an adult and incapacitated** with a person who is legally authorized to consent in lieu, when the study poses minimal risk or focuses on situations of **sudden incapacity**
- Consent **– Signature of adult participant who has regained capacity** following sudden incapacity
- **Signature of a witness** when the conditions requiring a witness are met.

ASSENT AND CONSENT– Participant who is a minor and their parent/tutor

Title of study: [Indicate title of study.]

I have reviewed the Informed Consent Form. Both the study and the Informed Consent Form were explained to me. My questions were answered, and I was given sufficient time to decide. Upon reflection, I consent to allow my child to participate in this study under the conditions set out therein. This participation includes the use of their study data [***where applicable:*** and samples].

I authorize the research team to access my child's medical chart to obtain information relevant to this study.

I also authorize the research team to inform the family doctor or treating physician, in writing, that my child is taking part in this study and to send them all relevant information.

Child's name (please print)	Assent of child capable of understanding the nature of the study (signature) or Verbal assent obtained by	Date

Name of parent or guardian (please print)	Consent (signature)	Date

Is the child capable of assent?

☐ Yes

☐ No, the child is not capable of understanding the nature of the study.

I have explained the study and the terms of this Informed Consent Form to the participant and/or their parent/tutor, and I have answered all questions asked. I undertake to provide a signed and dated copy to the participant and/or their parent/tutor.

Name of the person obtaining consent (please print)	(signature)	Date

AND

(OPTIONAL) **COMMITMENT OF THE PRINCIPAL INVESTIGATOR**

I certify that this Informed Consent Form was explained to the study participant, and that the participant's questions were answered.

I undertake, together with the research team, to respect what was agreed to in the Informed Consent Form.

_____

Name of Principal Investigator Signature Date

AND

***(OPTIONAL)* COMMUNICATION WITH THE PARTICIPANT REGARDING FUTURE RESEARCH**

I authorize the Principal Investigator of this study to communicate with me to see if I am interested in participating in other research studies.

☐ Yes Initials _____

☐ No Initials _____

AND

***(WHERE APPLICABLE)* SPECIFIC AUTHORIZATION**

[*Include all other authorization clauses relevant to the study*]

For example:

- *Diagnostic tests required for validating inclusion criteria and sending of such test results to an institution in the healthcare network*
- *Potential participants unable to read the Informed Consent Form*
- *Any death or incapacity anticipated during the study, in light of the condition being studied*
- *Secondary use of data*

CONSENT FORM ADDENDUM – Participant who has reached 18 years of age

Title of study: [Indicate title of study.]

Today, I reviewed the consent that my parents or my guardian signed at the time of my entry into this study, and a copy of this signed Informed Consent Form was also provided to me. Both the study and the Informed Consent Form were explained to me. My questions were answered, and I was given sufficient time to decide.

I agree to continue my participation in this study. This includes the use of my study data [***where applicable:*** and my samples].

I understand that my participation is voluntary and free, and that I may withdraw from this study at any time.

I authorize the research team to access my medical chart to obtain information relevant to this study.

In case of withdrawal from the study, no additional data will be collected [***where applicable:*** and no further samples will be taken]. Study data [***select if relevant:*** and samples, audio recordings, video recordings, images, MRIs] already collected as part of this research project will nevertheless continue to be stored, analyzed, or used to ensure the integrity of the research project.

OR

[***When justified and possible depending on the study, without impacting the quality of the research and analysis:]*** In case of withdrawal from the study, no additional data will be collected [***where applicable:*** and no further samples will be taken]. You may request the removal of your study data [***select if relevant*:** and samples, audio recordings, video recordings, images, MRIs] collected as part of this study.

Name of participant (please print)	Consent (signature)	Date

I have explained the study and the terms of this Informed Consent Form to the participant, and I have answered all questions asked.

Name of the person obtaining consent (please print)	(signature)	Date

(OPTIONAL) **COMMUNICATION WITH THE PARTICIPANT REGARDING FUTURE RESEARCH**

I authorize the Principal Investigator of this study to communicate with me to see if I am interested in participating in other research studies.

☐ Yes Initials _____

☐ No Initials _____

AND

(WHERE APPLICABLE) **SPECIFIC AUTHORIZATION**

[*Include all other authorization clauses relevant to the study*]

For example:

- *Diagnostic tests required for validating inclusion criteria and sending of such test results to an institution in the healthcare network*
- *Potential participants unable to read the Informed Consent Form*
- *Any death or incapacity anticipated during the study, in light of the condition being studied*
- *Secondary use of data*

CONSENT – Participant who is an adult and legally competent

Title of study: [Indicate title of study.]

I have reviewed the Informed Consent Form. Both the study and the Informed Consent Form were explained to me. My questions were answered, and I was given sufficient time to decide. Upon reflection, I consent to participate in this study under the conditions set out therein. This includes the use of my study data [***where applicable:*** and my samples].

I authorize the research team to access my medical chart to obtain information relevant to this study.

I also authorize the research team to inform my family doctor or treating physician, in writing, that I am taking part in this study and to send them all relevant information.

[***Optional****: These checkboxes may be removed if, in the opinion of the research team, the treating physician must be informed for the participant's safety, due to the level of risk of the research project.]*

☐ Yes Initials _____

☐ No Initials _____

Name of participant (please print)	Consent (signature)	Date (dd/mm/yyyy)

I have explained the study and the terms of this Informed Consent Form to the participant, and I have answered all questions asked. I undertake to provide a signed and dated copy to the participant.

Name of the person obtaining consent (please print)	(signature)	Date (dd/mm/yyyy)

AND

(OPTIONAL) **COMMITMENT OF THE PRINCIPAL INVESTIGATOR**

I certify that this Informed Consent Form was explained to the study participant, and that the participant's questions were answered.

I undertake, together with the research team, to respect what was agreed to in the Informed Consent Form.

_____

Name of Principal Investigator Signature Date (dd/mm/yyyy)

AND

(OPTIONAL) **COMMUNICATION WITH THE PARTICIPANT REGARDING FUTURE RESEARCH**

I authorize the Principal Investigator of this study to communicate with me to see if I am interested in participating in other research studies.

☐ Yes Initials _____

☐ No Initials _____

AND

(WHERE APPLICABLE) **SPECIFIC AUTHORIZATION**

[*Include all other authorization clauses relevant to the study*]

For example:

- *Diagnostic tests required for validating inclusion criteria and sending of such test results to an institution in the healthcare network*
- *Potential participants unable to read the Informed Consent Form*
- *Any death or incapacity anticipated during the study, in light of the condition being studied*
- *Secondary use of data*

CONSENT – Participant who is an adult and incapacitated with a person who is legally authorized to consent in lieu
(Excluding studies with minimal risk or focusing on situations of sudden incapacity)

Title of study: [Indicate title of study.]

As the legal representative (tutor or mandatary), I have reviewed the Informed Consent Form. Both the study and the Informed Consent Form were explained to me. My questions were answered, and I was given sufficient time to decide.

Upon reflection, I consent to allow the person who I represent to participate in this study under the conditions set out therein. This participation includes the use of their study data [***where applicable:*** and samples].

I will receive a copy of this consent form, signed and dated.

I authorize the research team to access the medical chart of the person who I represent to obtain information relevant to this study.

I also authorize the research team to inform the family doctor or treating physician, in writing, that this person is taking part in this study and to send them all relevant information.

Name of represented participant (please print)

Name of legal representative (please print)	Consent (signature)	Date

- ☐ Tutor
- ☐ Mandatary

I have explained the study and the terms of this Informed Consent Form to the legal representative and, as applicable, the participant, and I have answered all questions asked. I undertake to provide a signed and dated copy to the legal representative and, as applicable, the participant.

Name of the person obtaining consent (please print)	(signature)	Date

(OPTIONAL) **COMMITMENT OF THE PRINCIPAL INVESTIGATOR**

I certify that the terms of this Informed Consent Form were explained to the legal representative, that their questions were answered, and that it was clearly indicated that they are free to withdraw the person they represent from the study at any time.

I undertake, together with the research team, to respect what was agreed to in the Informed Consent Form.

_____

Name of Principal Investigator Signature Date

(OPTIONAL) **COMMUNICATION WITH THE PARTICIPANT REGARDING FUTURE RESEARCH**

I authorize the Principal Investigator of this study to communicate with me to see if I am interested in participating in other research studies.

☐ Yes Initials _____

☐ No Initials _____

AND

(WHERE APPLICABLE) **SPECIFIC AUTHORIZATION**

[*Include all other authorization clauses relevant to the study*]

For example:

- *Diagnostic tests required for validating inclusion criteria and sending of such test results to an institution in the healthcare network*
- *Potential participants unable to read the Informed Consent Form*
- *Any death or incapacity anticipated during the study, in light of the condition being studied*
- *Secondary use of data*

CONSENT – Participant who is an adult and incapacitated with a person who is legally authorized to consent in lieu, when the study poses minimal risk or focuses on situations of sudden incapacity

Title of study: [Indicate title of study]

As the person who is legally authorized to consent (tutor or mandatary, or if the person of full age is not so represented, spouse, close relative or person with a close relationship to the participant), I have reviewed the information and consent form. Both the study and the Informed Consent Form were explained to me. My questions were answered, and I was given sufficient time to decide.

I was also informed that, in the event that the person I represent becomes able to give consent for themselves while this study is under way, that person will be invited to sign the Informed Consent Form.

Upon reflection, I consent to allow the person who I represent to participate in this study under the conditions set out therein. This participation includes the use of his/her study data [***where applicable:*** and samples].

I will receive a copy of this consent form, signed and dated.

I authorize the research team to access the medical chart of the person who I represent to obtain information relevant to this study.

I also authorize the research team to inform the family doctor or treating physician, in writing, that this person is taking part in this study and to send them all relevant information.

Name of represented participant (please print)		
Name of person legally authorized to consent (please print)	Consent (signature)	Date

- ☐ Guardian
- ☐ Mandatary

OR, if the participant does not have a tutor or mandatary:

- ☐ Spouse

OR, if the participant does not have a tutor, mandatary or spouse:

☐ Close relative

☐ Person close to the participant

I have explained the study and the terms of this Informed Consent Form to the legal representative and, as applicable, the participant, and I have answered all questions asked. I undertake to provide a signed and dated copy to the person legally authorized to consent.

Name of the person obtaining consent (please print)	(signature)	Date

(OPTIONAL) **COMMITMENT OF THE PRINCIPAL INVESTIGATOR**

I certify that the terms of this Informed Consent Form were explained to the person who is legally authorized to consent, that their questions were answered, and that it was clearly indicated that they are free to withdraw the person they represent from the study at any time.

I undertake, together with the research team, to respect what was agreed to in the Informed Consent Form.

Name of Principal Investigator	Signature	Date

(OPTIONAL) **COMMUNICATION WITH THE PARTICIPANT REGARDING FUTURE RESEARCH**

I authorize the Principal Investigator of this study to communicate with me to see if I am interested in participating in other research studies.

☐ Yes Initials _____

☐ No Initials _____

AND

(WHERE APPLICABLE) **SPECIFIC AUTHORIZATION**

[*Include all other authorization clauses relevant to the study*]

For example:

- *Diagnostic tests required for validating inclusion criteria and sending of such test results to an institution in the healthcare network*
- *Potential participants unable to read the Informed Consent Form*
- *Any death or incapacity anticipated during the study, in light of the condition being studied*
- *Secondary use of data*

CONSENT – Signature of adult participant having regained decision-making capacity
[*Applicable when the study focuses on situations of sudden incapacity*]

Title of study:

I have reviewed the Informed Consent Form, and I understand that my legally authorized representative has agreed, on my behalf, to my participation in this study. Both the study and the Informed Consent Form were explained to me. My questions were answered, and I was given sufficient time to decide.

Upon reflection, I consent to continue participating in this study in accordance with the conditions stated above. This includes the use of my study data [***where applicable:*** and my samples].

I will receive a copy of this Informed Consent Form, signed and dated.

I authorize the research team to access my medical chart for the purposes of this study.

I authorize the researcher or their team to inform my family doctor or treating physician, in writing, that I am taking part in this study and to send them all relevant information.

[***Optional****: These checkboxes may be removed if, in the opinion of the research team, the treating physician must be informed for the participant's safety, due to the level of risk of the research project.*

☐ Yes Initials _____

☐ No Initials _____

In case of withdrawal from the study, no additional data will be collected [***where applicable:*** and no further samples will be taken]. Study data [***select if relevant:*** and samples, audio recordings, video recordings, images, MRIs] already collected as part of this research project will nevertheless continue to be stored, analyzed, or used to ensure the integrity of the research project.

OR

[***When justified and possible depending on the study, without impacting the quality of the research and analysis***] If you withdraw completely from the study or are withdrawn from the study, no additional data will be collected [***where applicable:*** and no further samples will be taken]. You may request the removal of your study data [***select if relevant*:** and samples, audio recordings, video recordings, images, MRIs] collected as part of this study.

Name of participant	Signature	Date

SIGNATURE OF THE PERSON OBTAINING CONSENT

I have explained the study and the terms of this Informed Consent Form to the participant, and I have answered all questions asked. I undertake to provide a signed and dated copy to the participant.

Name of the person obtaining consent	Signature	Date

(OPTIONAL) **COMMITMENT OF THE PRINCIPAL INVESTIGATOR**

I certify that this Informed Consent Form was explained to the study participant, and that the participant's questions were answered.

I undertake, together with the research team, to respect what was agreed to in the Informed Consent Form.

Name of the Principal Investigator	Signature	Date

(OPTIONAL) **COMMUNICATION WITH THE PARTICIPANT REGARDING FUTURE RESEARCH**

I authorize the Principal Investigator of this study to communicate with me to see if I am interested in participating in other research studies.

☐ Yes Initials _____

☐ No Initials _____

AND

(WHERE APPLICABLE) **SPECIFIC AUTHORIZATION**

[*Include all other authorization clauses relevant to the study*]

For example:

- *Diagnostic tests required for validating inclusion criteria and sending of such test results to an institution in the healthcare network*
- *Potential participants unable to read the Informed Consent Form*
- *Any death or incapacity anticipated during the study, in light of the condition being studied*
- *Secondary use of data*

SIGNATURE OF WITNESS

[Applicable if any of the conditions listed below are met]

YES ☐ NO ☐

A witness's signature is required in the following cases:

- ☐ *Reading disability or inability to read* – The witness (impartial) signing below attests to the fact that they have read the Informed Consent Form, that the study was explained accurately to the participant and/or the person legally authorized to consent.
- ☐ *Inability to understand the language of the consent form* – The person signing below attests to acting as interpreter for the participant and/or the person legally authorized to consent throughout the consent process.
- ☐ *Inability to write* – The participant and/or the person legally authorized to consent is able to consent but is unable to sign.

Name of witness (please print)	(signature)	Date

I. ADDENDUM FOR USE IF THE GENERAL DATA PROTECTION REGULATION (GDPR) APPLIES

Additional Information on Data Privacy Following the Application of the General Data Protection Regulation (GDPR)

Study: Insert name of study
Sponsor: Insert name of sponsor and address of sponsor's head office in Europe

Dear Sir/Madam,

The international sponsor of this study, Insert name of sponsor, has a head office in Europe. As such, the sponsor must comply with the European Union *General Data Protection Regulation* (GDPR). The GDPR gives you additional rights that are not specified in Canadian or Quebec legislation and therefore do not appear in the Informed Consent Form that you signed for the study stated above. For more information, see below.

As per the GDPR, you have the following rights to data privacy, in addition to those specified in the Informed Consent Form you signed:

- Should you request corrections to the data collected about you during the project, please note that you have the ***right to restrain*** the processing and use of that data while your request is being evaluated. For example, you may ask that your data not be processed until your request has been reviewed.

- You have the ***right to request a transfer*** of your study data to yourself or to anyone else in any commonly used and accessible format, such as a computer-readable format.

- You have the ***right to file a complaint*** with a European data protection authority, such as Insert the name and contact information of a competent European authority designated by the study sponsor.

- You have the ***right to request the deletion*** of your study data. This data will be deleted if no longer needed or if there is no other legal requirement for its use.

Your study data will be retained for 25 years following the completion of the study, or longer if required by law.

Should you have any further questions, please contact the research team.

REFERENCES

The following references were consulted in the drafting of the present document:

- WORLD MEDICAL ASSOCIATION (2013) Declaration of Helsinki, *Ethical Principles for Medical Research Involving Human Subjects*, last updated October 2024.

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