



**Ministère de la Santé  
et des Services sociaux**

**Standard legal clauses for information  
and consent forms for clinical trials**

## **Members of the working group who participated in the review:**

M<sup>e</sup> Marie-Josée Bernardi, CHUM  
M<sup>e</sup> Geneviève Cardinal, CHU Sainte-Justine  
M<sup>e</sup> Édith Deleury, CHU de Québec – Université Laval  
M<sup>e</sup> Mylène Deschênes, FRQS  
Ms. Nadine Gagnon, MSSS  
M<sup>e</sup> Marie Hirtle, CUSM  
Ms. Jenny Kaeding, MSSS  
M<sup>e</sup> Valéry Lussier, CIUSSS de l'Estrie-CHUS  
Ms. Brigitte Paquet, CUSM

## **Coordination of the working group:**

Ms. Danika Laberge, CATALIS Québec  
Mr. Patrick Gogognon, CHU Sainte-Justine

**Pharmaceutical companies that are members of CATALIS Quebec have been consulted.**

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This document is intended for researchers and research ethics committees of the Quebec health and social services network for the drafting of information and consent forms for clinical trials.

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## **ACKNOWLEDGEMENTS**

This document is the result of work begun several years ago on achieving informed consent forms that are consistent and that meet the ethical and legal requirements of research in Quebec. Over the years, many experts in research ethics have generously helped write and improve its contents, while the document's end-users—the participants—have remained the focus of all discussions.

We would like to thank Fonds de recherche du Québec – Santé (FRQS), which, in collaboration with its research centres, put together a working group in 2005 on consent form and information harmonization that has supported the initiative over the years.

In 2015 at the request of Ministère de la Santé et des Services sociaux (MSSS), FRQS presided over the work of another working group made up of experts on research law and ethics. This working group was tasked with determining the wording of legal clauses in informed consent forms for clinical research involving legally competent adults in Quebec. Its work led to FRQS's first versions of standard legal clauses for informed consent forms in clinical trials, which were published in 2016.

We would also like to thank CATALIS Québec, which has coordinated the creation of a revised set of legal clauses since 2018 with the help of a new working group made up of experts from FRQS and MSSS. Representatives of pharmaceutical companies were also involved. The legal clauses were revised in order to accelerate the work of the research ethics committees (CER) reviewing informed consent forms, while ensuring legal compliance. All in all, few changes were made, and the new document builds on the version published in 2016. The details are laid out in the summary of changes.

In closing, we would like to thank the research ethics committees of Réseau québécois de la santé et des services sociaux (RSSS) for making sure since 2016 that the clauses are used as-is for the vast majority of clinical trials conducted through Quebec's health and social services network. Thanks to their conviction and watchful oversight, the clauses already enjoyed widespread consensus in Quebec, which we hope will be strengthened further with this revised version.

## TABLE OF CONTENTS

INTRODUCTION .....	1
STANDARD LEGAL CLAUSES.....	2
A.    COMPENSATION.....	2
B.    SHOULD YOU SUFFER ANY HARM .....	2
C.    CONFIDENTIALITY .....	3
D.    VOLUNTARY PARTICIPATION AND THE RIGHT TO WITHDRAW .....	4
E.    COMMERCIALIZATION .....	6
F.    CONTACT INFORMATION .....	6
G.    SIGNATURE .....	7
H.    CONSENT OF THIRD PARTY LEGALLY AUTHORIZED TO CONSENT IN LIEU OF PARTICIPANT WHO IS INCAPACITATED.....	8
ADDENDUM FOR USE IF THE <i>GENERAL DATA PROTECTION REGULATION</i> (GDPR) APPLIES .....	13
EXPLANATORY TABLES.....	14
A.    COMPENSATION .....	14
B.    SHOULD YOU SUFFER ANY HARM .....	16
C.    CONFIDENTIALITY .....	17
D.    VOLUNTARY PARTICIPATION AND THE RIGHT TO WITHDRAW .....	23
E.    COMMERCIALIZATION .....	25
F.    CONTACT INFORMATION .....	26
G.    SIGNATURE .....	27
H.    CONSENT OF THIRD PARTY LEGALLY AUTHORIZED TO CONSENT IN LIEU OF A PARTICIPANT WHO IS INCAPACITATED .....	31
REFERENCES .....	35

## INTRODUCTION

The purpose of this document is to harmonize the legal clauses used in the informed consent forms required for clinical trials, such as to obtain consensus among the various players and reduce the number of discussions about them. Over the past 10 years, the FRQS and the MSSS have strived to develop and periodically update the standard legal clauses presented in this document. The aim is to make the process of drafting and approving the legal clauses for informed consent forms more efficient.

This document is intended primarily for researchers drafting informed consent forms and for the Research Ethics Boards (REBs) that review them. It presents the standard clauses used in informed consent forms for clinical trials conducted in Quebec. These clauses are compliant with Quebec laws, rules and regulations as listed in the Appendix and are also consistent with Canadian and international laws, rules and regulations generally applicable to clinical trials. They are written in plain language to facilitate readability and participant understanding. A number of tables, including explanatory notes and legal references, are presented in the Appendix to assist in drafting the clauses and support further reflection when developing informed consent forms. It is strongly recommended they be **used as is, without changes**, to ensure consistency with the decisions of the REBs in the health and social services network.

This document is the fruit of many hours of committee work on the part of legal experts and lawyers working in research ethics. Representatives from pharmaceutical companies were also involved in the review.

**The committee wishes to stress that informed consent is a process, dependent not only on the actual wording of the ICF but on the continued exchange between the research team and participants. The use of tools adapted to participants, as well as the quality and continuous nature of the exchange of information, are essential if we are to truly speak of “informed” consent.**

## LEGAL CLAUSES

### NOTE

The areas italicized and highlighted in grey are to guide the research team in the drafting of an appropriate informed consent form. Please remove them from the final informed consent form sent in to the Research Ethics Board.

### A. COMPENSATION

#### *Compensation in the form of an amount proportional to research participation*

You will receive *[indicate compensation offered]*: an amount of \$X per visit scheduled as per protocol, for a total of X visits, for a total amount of \$X], as compensation for costs incurred during your participation in this research study. If you withdraw from the study, (or are withdrawn) before it is completed, compensation will be proportional to the length of your participation.

and/or

#### *Compensation in the form of reimbursement or coupons covering expenses*

Your expenses for *[choose: travel, meals, parking...]* related to your participation in this research study will be *[choose: reimbursed upon presentation of receipts OR paid by a coupon which will be given to you at specify a time]*.

**OR**

#### *No compensation*

You will not receive financial compensation for participating in this research study.

**AND**

#### *Medications offered*

*[Optional: The research drug X will be offered to you free of charge for the duration of this research study.]*

### B. SHOULD YOU SUFFER ANY HARM

#### *Damages/medical care*

Should you suffer harm of any kind following administration of the study drug or any other procedure related to this research 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 research study, you are not waiving any of your rights nor discharging the doctor in charge of the study, the sponsor, or the institution of their civil and professional responsibilities.

## **C. CONFIDENTIALITY**

### *Collection – Who? Reason for which personal information is requested*

During your participation in this study, the doctor in charge of the study and the research team will collect, in a study file, the information about you needed to meet the scientific objectives of the study.

**AND**

### *Collection – What?*

The study file may include information from your medical charts [*choose*: including your identity, such as your name, gender, date of birth, ethnicity], past and present health status, lifestyle, and the results of all tests, exams, and procedures that will be performed.

**AND**

### *Storage of data/samples – Protection*

All study data collected during this research study (including personal information and samples) will remain confidential to the extent provided by law. You will be identified by a code number only. The key to the code linking your name to your study file will be kept by the doctor in charge of this research study.

and

To ensure your safety, a document indicating your participation in this study [*specify the type of information (see Section “Collection – What”), e.g., a copy of the Informed Consent Form or a data information sheet*] is included in your medical chart. The results of certain tests conducted as part of the research may be included as well, 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 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.

**AND**

*Storage of data– Duration*

Study data will be stored for at least 25 years following the end of the study by the doctor in charge of this research study [*where applicable, choose:* and the study sponsor and/or funding agency.] [*Optional: (specify a different duration for study samples)*]

**AND**

*Dissemination of overall results*

The study data may be published or shared at scientific meetings; however, it will not be possible to identify you.

**AND**

*Right of access for monitoring and safety, including “Measure 9”*

For monitoring, control, safety, security, and approval of the study drug by regulatory agencies, your study file as well as your medical charts may be examined by a person mandated by Canadian or international regulatory authorities, such as Health Canada, as well as by authorized representatives of the study sponsor, the institution, or the Research Ethics Board. All these individuals and organizations will have access to your personal data, but they adhere to a confidentiality policy.

**AND**

*Right of access by the participant (Access to Information Act)*

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

[*Where applicable:* However, to protect the scientific integrity of this study, you may have to withdraw from the study if you access certain information before the study ends.]

## **D. VOLUNTARY PARTICIPATION AND THE RIGHT TO WITHDRAW**

*Voluntary participation and the right to withdraw*

Your participation in this research study is voluntary. Therefore, you may refuse to participate. You may also withdraw at any time, without giving any reasons, by informing the doctor in charge of this research study or a member of 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 investigator, the Research Ethics Board, the funding agency or the sponsor*

The doctor in charge of this research study, the Research Ethics Board, 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 in this research study is no longer in your best interests, if you do not follow study instructions, or if there are administrative reasons to terminate the study.

**AND**

*Withdrawal from the study*

However, before you withdraw from the study, we suggest *[to be adapted based on the study protocol:]* that you take part in a final evaluation, for safety reasons.

**AND**

*Modulating your withdrawal from the study*

*[if scientifically warranted]* You have the right to modulate your withdrawal from the study at any time, by *[to be adapted based on the study protocol:]*

- Stopping the study drug,
- Stopping the follow-up visits on site,
- Stopping telephone follow-up,
- Allowing only medical chart information to be transmitted to the sponsor, or
- Withdrawing from the study completely.

**AND**

*Consequences of withdrawal – data storage*

If you withdraw or are withdrawn from the study, no further data or samples will be collected. However, the information and *[if relevant]* biological material, blood and tissue samples, audio and video recordings, images and MRI already collected for the study will be stored, analyzed and

used to ensure the integrity of the study, as described in this document.

**AND**

*New information*

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

**E. POSSIBILITY OF COMMERCIALIZATION**

The results of the research 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.

**F. CONTACT INFORMATION**

*Contact information*

If you have any questions or if you have a problem you think might be related to your participation in this research study, or if you would like to withdraw, you may communicate with the doctor in charge of this research study or with someone on the research team at the following number: *[insert phone number]*.

and

*Questions regarding participant rights or complaints*

For any questions regarding your rights as a research participant in this study, or if you have comments or wish to file a complaint, you may communicate with:

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

**AND**

*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 research study and is responsible for monitoring the study at all participating institutions in the health and social services network in Quebec.

or

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

## G. SIGNATURE

### *Signature of participant*

I have reviewed the Informed Consent Form. Both the research study and the Informed Consent Form were explained to me. My questions were answered, and I was given sufficient time to decide. After reflection, I consent to participate in this research study in accordance with the conditions stated above, including the use of all personal data and samples collected.

I authorize the study team to access my medical chart.

**[Optional:** In addition, I authorize the researcher or research team to inform my family doctor or treating physician, in writing, that I am taking part in this research study, and to send them all relevant information.

Yes     Initials

No     Initials

and

### *Communication with the participant regarding future research*

**[Optional:** I authorize the researcher in charge of this study to communicate with me to see if I am interested in participating in other research studies.]

Yes     Initials

No     Initials

and

### *Specific authorization*

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

**For instance:**

- 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

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Name of participant

Signature

Date

**AND**

*Signature of the person obtaining consent*

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

---

Name of the person obtaining consent	Signature	Date
--------------------------------------	-----------	------

**AND**

*Commitment of the Principal Investigator*

**[Optional]:** I certify that this Informed Consent Form was explained to the research participant, and that the participant's questions were answered.

I undertake, together with the research team, to respect what was agreed upon in the Informed Consent Form, and to give a signed and dated copy of this form to the research participant.]

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Name of the Principal Investigator	Signature	Date
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**H. CONSENT OF THIRD PARTY LEGALLY AUTHORIZED TO CONSENT  
IN LIEU OF A PARTICIPANT WHO IS INCAPACITATED**

As the legal representative of the participant (guardian, trustee, mandatary; or in cases of sudden incapacity, spouse, close relative, or person close to the participant), I have reviewed the Informed Consent Form. 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 research study is underway, that person will be invited to sign the Informed Consent Form.

After reflection, I consent that the person I represent may participate in this research study in accordance with the conditions stated above, including the use of personal data 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 I represent.

**[Optional]:** I also authorize the researcher or their team to inform the person's family doctor or treating physician that that the person I represent is taking part in this research study and to send them all relevant information.]

---

**Name of research participant represented**

**Name of legal representative:**

\_\_\_\_\_ (guardian, trustee, mandatary, spouse, close relative or person close to the participant) \_\_\_\_\_ *specify below:*

- Trustee
- Guardian
- Mandatary
- Spouse
- Close relative
- Person close to the participant

\_\_\_\_\_  
Signature of legal representative

\_\_\_\_\_  
Date

**SIGNATURE OF PERSON OBTAINING CONSENT**

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

\_\_\_\_\_  
Name and signature of the person obtaining consent

\_\_\_\_\_  
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 he can withdraw the participant he represent from the study at any time.

I undertake, together with the research team, to respect what was agreed upon in the Informed Consent Form, and to give a signed and dated copy of this form to the legal representative.

\_\_\_\_\_  
Name and signature of the Principal Investigator

\_\_\_\_\_  
Date

**SIGNATURE OF WITNESS**

YES       NO

A witness' signature is required in the following cases:

- Reading disability or inability to read – The witness (impartial) signing below attests to the fact that they read the Informed Consent Form, that the study was precisely explained to the participant, and that the participant seems to have understood it.
- Foreign language (participant does not understand the language in which the Informed Consent Form was written) – The signatory attests to acting as interpreter for the participant throughout the consent process.

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Name of witness	Signature	Date
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**Note:**

Please add to the participant's study file the details of any other assistance given during the consent process.

**SIGNATURE OF PARTICIPANT HAVING REGAINED DECISION-MAKING CAPACITY**

I have examined the Informed Consent Form and I understand that my legally authorized representative has accepted, on my behalf, that I participate in this research study. I attest that the research study and this Informed Consent Form were explained to me, that my questions were answered to my satisfaction, and that I was given enough time to decide.

After reflection, I consent to continue participating in this research study in accordance with the conditions stated above, including the use of my personal data 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 research study. **[Optional:** I also authorize the researcher or their team to inform my family doctor or treating physician, in writing, that I am taking part in this research study, and to send them all relevant information.]

Please check the appropriate box to indicate your decision:

- I wish to remain in this research study.
- I wish to withdraw from this research study.

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Name of participant	Signature	Date
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* Name of witness/relationship with participant	Signature	Date
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*\*The signature of a witness is required: 1) in addition to the participant's, if the Informed Consent Form is read to the participant; or 2) instead of the participant's, if the participant is legally capable of consent but is unable to read or write (e.g., the witness signs beside the participant's thumbprint).*

**SIGNATURE OF THE PERSON OBTAINING CONSENT**

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

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Name of the person obtaining consent	Signature	Date
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**[Optional] COMMITMENT OF THE PRINCIPAL INVESTIGATOR**

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

I undertake, together with the research team, to respect what was agreed upon in the Informed Consent Form, and to give a signed and dated copy of this form to the research participant.

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Name of the Principal Investigator	Signature	Date
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## **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)***

**Research 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 research 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 and Quebec legislation and that therefore do not appear in the Informed Consent Form that you signed for the research 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. These will be deleted if no longer needed or if there is no other legal requirement for their use.

If you have any questions, please contact the doctor in charge of this study.

## EXPLANATORY TABLES

The legal clauses are the result of a legal consensus. The purpose of the following explanatory tables is to make it easier to draft informed consent forms.

**It is up to the research personnel to clearly explain the Informed Consent Form and ensure that the participants understand it. The committee wishes to stress that tools adapted to participants' needs and the quality and continuity of information sharing between participants and the research team are essential to truly "informed" consent.**

Description	Explanatory Notes
<i>Informed Consent Form</i>	May also be called "Information and Consent Form" or "Research Study Information and Consent Form"

### A. COMPENSATION

Description	Text	Explanatory Notes	References
<i>Compensation in the form of an amount proportional to participation</i>	You will receive [ <i>indicate compensation offered</i> ]: an amount of \$X per visit scheduled as per protocol, for a total of X visits, for a total amount of \$X] as compensation for costs incurred during your participation in this research study. If you withdraw from the study, (or are withdrawn) before it is completed, compensation will be proportional to the length of your participation.	Compensation must not be construed as financial payment, except as indemnity for losses and inconveniences; should not unduly influence the decision to participate in the study; and should be proportional to expenses incurred.  The protocol may stipulate that some visits not be compensated.	A person's participation in research may not give rise to financial reward – CCQ 25(2).
<i>Compensation in the form of reimbursement or coupons covering expenses</i>	and/or Your expenses for [ <i>choose</i> : travel, meals, parking, ...] related to your participation in this research study will be [ <i>choose</i> : reimbursed upon presentation of receipts OR paid by a coupon which will be given to you at <i>specify a time</i> ].		Informed consent form should include explanations of the "anticipated prorated payment" and anticipated expenses to the participant – ICH GCP 4.8.10 (k, l).
<b>OR</b>			"(...) information regarding payment (...), including the methods, amounts, and schedule of payment (...), is set forth in the written informed consent form" – ICH GCP 3.1.9. Inform participant about reimbursement for participation-related expenses – TCPS 2, art. 3.2(j); No reprisal for participant withdrawal

<i>No compensation</i>	You will not receive financial compensation for participating in this research study.	Although compensation in the form of a lump sum may be a suitable option for some types of research, it is highly recommended that the amount offered be proportional to the individual's participation. You will not receive financial compensation for participating in this research study.	<p>nor withholding of payments due prior to the point of withdrawal. If the research project used a lump-sum incentive for participation, the participant is entitled to the entire amount. If a payment schedule is used, participants shall be paid in proportion to their participation – TCPS 2, art. 3.1 (b), Application.</p> <p>Absence of undue (or excessive) reward AND compensation proportional to actual participation – <i>Standards du FRSQ sur l'éthique de la recherche en santé humaine et l'intégrité scientifique</i>, s. 14.</p>
<b>AND</b>			
<i>Medications offered</i>	<i>[Optional:</i> The research drug X will be offered to you for free for the duration of this research study].	Only if applicable.	

## B. SHOULD YOU SUFFER ANY HARM

Description	Text	Explanatory Notes	References
<i>Damages/medical care</i>	Should you suffer harm of any kind following administration of the study drug and/or any procedure related to this research study, you will receive all the care and services required by your state of health.	<p>As per article 1474 of the <i>Civil Code of Québec</i>, a participant has the right to expect compensation for injury of any kind. The research contract or informed consent form should not in any way limit the research team’s responsibilities in case of bodily or moral harm.</p> <p>To avoid participant confusion, the clause on commercialization should not follow directly after the one on the non-waiver of rights.</p>	<p>A person may not exclude or limit his liability for bodily or moral injury caused to another – CCQ 1474.</p> <p>Informed consent includes information about compensation for injury – TCPS 2, art. 3.2 (j).</p> <p>If required by applicable regulatory requirement(s), the sponsor should provide insurance or should indemnify (legal and financial coverage) the investigator/institution against claims arising from the trial, except for claims that arise from malpractice and/or negligence – ICH GCP 5.8.1.</p>
<i>Non-waiver of rights</i>	By agreeing to participate in this research study, you are not waiving any of your rights nor discharging the doctor in charge of the study, the sponsor, or the institution of their civil and professional responsibilities.	<p>The term “sponsor” refers to any person, business, institution, or organization responsible for implementing, managing, or funding a clinical trial.</p>	<p>Appropriate compensation and treatment for subjects who are harmed as a result of participating in research must be ensured – Helsinki, 15.</p> <p>The protocol should include information regarding provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study – Helsinki, 22.</p> <p>By consenting, participants have not waived any rights to legal recourse in the event of research-related harm – TCPS 2, art. 3.2 (k).</p> <p>ICH GCP, 1.5.3</p>

### C. CONFIDENTIALITY

Description	Text	Explanatory Notes	References
<p><i>Collection – Who? Reason for which personal information is requested</i></p>	<p>During your participation in this study, the doctor in charge of the study and the research team will collect, in a study file, the information about you needed to meet the scientific objectives of the study.</p>	<p>It is legally required to state who will collect data of any kind and for which purposes it will be collected.</p> <p>Only data necessary to stated research goals may legally be collected.</p>	<p>Serious and legitimate reason to gather information, and only information which is relevant to the stated objective – CCQ 37; <i>Act Respecting the Protection of Personal Information in the Private Sector</i>, 2, 5, 8, 14, 83; <i>Act Respecting Access to Documents Held by Public Bodies and the Protection of Personal Information</i>, 54, 56, 64, 65, 65.1; <i>Regulation respecting records, places of practice and the cessation of practice by a physician</i>, 4, 5, 6, 7; TCPS 2, art. 3.2 (i).</p> <p>Definition of “qualified investigator” – <i>Food and Drug Regulations</i>, C.05.001.</p>
<b>AND</b>			
<p><i>Collection – What?</i></p>	<p>The study file may include information from your medical chart [<i>choose</i>: including your identity, such as your name, gender, date of birth, ethnicity], past and present health status, lifestyle, and the results of all tests, exams, and procedures that will be performed.</p>	<p>According to the TCPS 2, all data collected must be listed.</p> <p>The information listed must correspond to the specifics of the particular research study.</p> <p>Adapt according to the specifics of the particular research study.</p>	<p>May gather only information which is relevant to the stated objective – CCQ 37; TCPS 2, art. 3.2 (i); <i>Regulation respecting records, places of practice and the cessation of practice by a physician</i>, 5, 6, 7.</p> <p>Personal information – <i>Act Respecting the Protection of Personal Information in the Private Sector</i>, 2; <i>Act Respecting Access to Documents Held by Public Bodies and the Protection of Personal Information</i>, 54, 56.</p> <p><i>Guide d’élaboration des cadres de gestion des banques de données et de matériel biologique constituées à des fins de recherche</i></p>

		<p>This section is only for samples used in baseline analyses, e.g., urine analysis, blood work, diagnostic genetic testing.</p> <p>Results of medical tests to validate study inclusion criteria (such as blood tests and diagnostic genetic testing) generally have to be added to the participant’s medical chart. Therefore, any individual or company with access to medical chart will be able to access the participant’s test results.</p> <p>Note: A more detailed form for databanks and biobanks is required for samples stored in biobanks for future use in other research projects (i.e., stored for purposes other than the study for which the participant was recruited).</p> <p>A separate document is generally required, as the responsibilities of the investigator, institution, and Research Ethics Board will likely be different from those of the current research study.</p>	<p>Governance Framework for Data Banks and Biobanks used for Health Research</p> <p>The use of samples taken as part of a person’s health care – CCQ 22.</p> <p>TCPS 2, art. 12.1.</p>
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<b>AND</b>			
<p><i>Storage of data/samples – Protection</i></p>	<p>All study data collected during this research study (including personal information and samples) will remain confidential to the extent provided by law. You will be identified by a code number only. The key to the code linking your name to your study file will be kept by the doctor in charge of this research study.</p>	<p>As a rule, information collected as part of a research study must be protected and confidentiality ensured, but the means to do so may vary from one study to another.</p> <p>to the extent provided by law”: examples could be specified if within the context of the research study, e.g., reportable diseases, compulsory treatment orders, youth protection, College of Physicians, <i>Highway Safety Code</i>, elder abuse.</p>	<p>– ICH GCP 2.11, 4.8.10 (o); <i>Act Respecting the Protection of Personal Information in the Private Sector</i>, 8 (3) and 10; <i>Act Respecting Access to Documents Held by Public Bodies and the Protection of Personal Information</i>, 63.1, 63.2; Helsinki, 9 and 24; TCPS 2, art. 3.2 (i), 5.1, 5.2, 5.4; <i>Code of Ethics of Physicians</i>, 20 (1), 20 (3).</p> <p>– Parent c. R., 2014, QCCS 132 (CanLII) (Judgement of the Honourable Sophie Bourque, Magnotta case).</p> <p>Examples of legal requirements for disclosure of personal information:</p> <p>Reportable diseases – <i>Public Health Act</i>, 79 to 82.</p> <p>Child safety and development – <i>Youth Protection Act</i>, 39; <i>Code of Ethics of Physicians</i>, r. 17.</p> <p>Breaching patient confidentiality in order to prevent an act of violence, including a suicide – <i>Code of Ethics of Physicians</i>, s. 20 (5) and 21.</p> <p><i>Highway Safety Code</i>, s. 603.</p>

	<p>To ensure your safety, a document indicating your participation in this study, [<i>specify the type of information (see Section “Collection – What”), e.g., a copy of the informed consent form or a data information sheet</i>] is included in your medical chart. The results of tests</p>	<p>Clinical trials, by their very nature as research, may entail certain health risks. It is therefore necessary to add this information to the participant’s</p>	
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	conducted as part of the research may be included as well, 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.	medical chart. Further, in a changing healthcare system, it is justified that in some cases, tests conducted as part of a research study appear in the participant's medical chart.	
<b>AND</b>			
	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.	Consent is required before communicating a participant's personal information to others.	Consent to communicate such information to third parties – CCQ 37; <i>Act Respecting the Protection of Personal Information in the Private Sector</i> , 8, 12, 14; <i>Act Respecting Access to Documents Held by Public Bodies and the Protection of Personal Information</i> , 65 (2) and (3) and 65.1; <i>Regulation respecting records, places of practice and the cessation of practice by a physician</i> , 4; TCPS2, art. 3.2 (i).
	and		

<i>Storage of data – Duration</i>	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.	Legally, data cannot be released outside Canada, unless similar protection is provided.	Consent to communicate such information to third parties – CCQ 37.  Who will be granted direct access to the subject’s data – ICH GCP 4.8.10 (n); <i>Act Respecting the Protection of Personal Information in the Private Sector</i> , 8, 10, 17; <i>Act Respecting Access to Documents Held by Public Bodies and the Protection of Personal Information</i> , 65 (3) and 70.
	and Study data will be stored for at least 25 years following the end of the study by the doctor in charge of this research study [ <i>where applicable, (choose: and the study sponsor and/or funding agency). [Optional: (specify a different duration for study samples)]</i> ]	Time specified by Canada’s Food and Drug Regulations.  Some studies require longer storage durations, e.g., 30 years for cell therapy (FDA regulation). The REB will adapt the duration on a case-by-case basis.  Although this is not the case in Canada, some international sponsors do keep the data.	– <i>Act Respecting the Protection of Personal Information in the Private Sector</i> , 8 and 12.  Maintain all records for a period of 25 years – <i>Food and Drug Regulations</i> , C.05.012 (4).
<b>AND</b>			
<i>Dissemination of overall results</i>	The study data may be published or shared at scientific meetings; however, it will not be possible to identify you.		– CCQ 37; ICH GCP 4.8.10 (o); <i>Act Respecting Access to Documents Held by Public Bodies and the Protection of Personal Information</i> , 65(2); <i>Act Respecting the Protection of Personal Information in the Private Sector</i> , 8; TCPS 2, art. 3.2 (f), (i).

<b>AND</b>			
<i>Right of access for monitoring and safety, including “Measure 9”</i>	For monitoring, control, safety, security, and approval of the study drug by regulatory agencies, your study file as well as your medical charts may be examined by a person mandated by Canadian or international regulatory authorities, such as Health Canada, as well as by authorized representatives of the study sponsor, the institution, or the Research Ethics Board. All these individuals and organizations will have access to your personal data, but they adhere to a confidentiality policy.	In Quebec, the Minister of Health and Social Services (MSSS), the College of Physicians ( <i>Collège des médecins</i> ) and other professional orders may have access to study files by virtue of their administrative and legislative powers.  This section includes the norm 7 of the <i>Cadre de référence en recherche</i> .	– ICH GCP 1.21, 4.8.10 (n), 5.15.1 and 5.15.2; <i>Act Respecting Access to Documents Held by Public Bodies and the Protection of Personal Information</i> , 65 (2); <i>Act Respecting the Protection of Personal Information in the Private Sector</i> , 8; <i>Cadre de référence en recherche</i> , norm 7  <i>Cadre de référence en recherche</i> , norm 7: The MSSS requires institutions to adopt a mechanism for identifying participants who have agreed to take part in a research study that the institution has authorized to carry out. There are exceptions to this rule, namely, if participant anonymity is necessary.
<b>AND</b>			
<i>Right of access by the participant (Access to Information Act)</i>	You have the right to consult your study file in order to verify the information gathered, and to have it corrected if necessary.		Right of access to personal information and correction of errors or omissions – CCQ 38, 39, 40; <i>Act Respecting Access to Documents Held by Public Bodies and the Protection of Personal Information</i> , s. 65 (6), 83, 84, 89; <i>Act Respecting the Protection of Personal Information in the Private Sector</i> , 8, 27, 28, 37.
	and [Where applicable: However, to protect the scientific integrity of this study, you may have to withdraw from the study if you access certain information before the study ends.]	This could happen, for example, in a double- blinded study.	

## D. VOLUNTARY PARTICIPATION AND THE RIGHT TO WITHDRAW

Description	Text	Explanatory Notes	References
<i>Voluntary participation and the right to withdraw</i>	<p>Your participation in this research study is voluntary. Therefore, you may refuse to participate. You may also withdraw at any time, without giving any reasons, by informing the doctor in charge of this research study or a member of the research team.</p> <p><b>[Where applicable:]</b> 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.</p>	Contact information for the research team, or for a contact person on the research team, is provided at the end of the consent form (Section F below).	<p>Withdrawal of consent and withdrawal from study – CCQ 24, para 3; No need to give reasons for withdrawal – TCPS 2, art. 3.1, Application; at any time – ICH GCP 4.8.10 (m).</p> <p>Consent should be free and informed – CCQ 10; Consent should be given voluntarily – TCPS 2, art. 3.1 and 3.2; ICH GCP 4.8.10 (m).</p>
<b>AND</b>			
<i>Consequences for care</i>	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.	See explanatory note regarding compensation in the form of lump sum incentives.	<p>Withdrawal from the trial, at any time, without penalty or loss of benefits – TCPS 2, art. 3.1, Application; ICH GCP 4.8.10 (m); without prejudice to pre-existing entitlements – TCPS 2, art. 3.2; and ICH GCP 4.8.10 (m).</p> <p>Payment due to the participant shall not be withheld. If the research project used a lump-sum incentive, the participant is entitled to the entire amount. If a payment schedule is used, participants shall be paid in proportion to their participation – TCPS 2, art. 3.1, Application.</p>
<b>AND</b>			
<i>Withdrawal of the participant from the study</i>	The doctor in charge of this research study, the Research Ethics Board, the funding agency, or the sponsor may put an end to your participation without your consent. This may		The information generally required for informed consent includes: - stopping rules for the clinical trial; when researchers may remove participants from the trial.

<i>by the investigator, the Research Ethics Board, the funding agency, or the sponsor</i>	happen if new findings or information indicate that participation in this research study is no longer in your best interests, if you do not follow study instructions, or if there are administrative reasons to terminate the study.		– TCPS 2, art. 3.2 (l), Application.  The information provided should include explanations of foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated – ICH GCP 4.8.10 (r).
<b>AND</b>			
<i>Withdrawal from the study</i>	However, before you withdraw from the study, we suggest <i>[to be adapted based on the study protocol:]</i> that you take part in a final evaluation, for safety reasons.		The information generally required for informed consent includes: - stopping rules for the clinical trial; - circumstances under which researchers may remove participants from the trial. – TCPS 2, art. 3.2 (l), Application.
<b>AND</b>			
<i>Means of withdrawal from the study</i>	<i>[If scientifically warranted]</i> You have the right to modulate your withdrawal from the study by <i>[to be adapted based on the study protocol:]</i> <ul style="list-style-type: none"><li>• Stopping the study drug;</li><li>• Stopping the follow-up visits on site;</li><li>• Stopping telephone follow-up;</li><li>• Allowing only medical chart information to be transmitted to the sponsor; or</li><li>• Withdrawing from the study completely.]</li></ul>	If scientifically warranted, participants in certain studies have the right to alter their participation at any time, namely, to choose to remain as active participants only for the collection of data related to overall survival.	
<b>AND</b>			
<i>Consequences of withdrawal – data storage</i>	If you withdraw or are withdrawn from the study, no further data or samples will be collected. However, the information and <i>[if relevant]</i> biological material, blood and tissue samples, audio and video recordings, images and MRI already collected for the study will be stored, analyzed and used to ensure the integrity of the study, as described in this document.	This section should be consistent with the “Collection” sections of the confidentiality clause.	In a clinical trial setting, storage and safekeeping are subject to regulatory requirements.  Where the terms of the research do not allow for withdrawal of data or human biological materials, the identity of the participants shall be protected at all times during the project and after its completion – TCPS 2, art. 3.1 (c), Application.
<b>AND</b>			

<i>New information</i>	Any new findings acquired during the course of the study that could influence your decision to continue your participation will be shared with you quickly.	The research team should be prompt and inform the participant in a timely manner. It is strongly recommended to keep written documentation of all such communications.	<p>Participants will be given, in a timely manner throughout the course of the research project, information that is relevant to their decision to continue or withdraw – TCPS 2, art. 3.2 (d).</p> <p>Consent is an ongoing process. Researchers have an ongoing duty to provide participants with all information relevant to their ongoing consent and to disclose any material incidental findings discovered in the course of research – TCPS 2, art. 3.3 and 3.4.</p> <p>The participant should be informed in a timely manner if new information becomes available that may be relevant to willingness to continue participation in the trial. The communication of this information should be documented – ICH GCP 4.8.2.</p>
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### E. POSSIBILITY OF COMMERCIALIZATION

Description	Text	Explanatory Notes	References
<i>Commercialization</i>	The results of the research 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.		

## F. CONTACT INFORMATION

Description	Text	Explanatory Notes	References
<i>Contact information</i>	If you have any questions or if you have a problem you think might be related to your participation in this research study, or if you would like to withdraw, you may contact the doctor in charge of this research study or someone on the research team at the following number: <i>[insert phone number]</i> .	To be adapted depending on the study site responsible for recruiting participants.	
	and		
<i>Questions regarding participant rights or complaints</i>	For any questions regarding your rights as a research participant in this study, or if you have comments or wish to file a complaint, you may contact:  The local service quality and complaints commissioner at <i>[insert the commissioner's contact information]</i> .	To be adapted depending on the study site responsible for recruiting participants. If the grievance involves a physician, dentist or pharmacist, or even a resident, the complaints commissioner must transfer it without delay to the designated medical examiner.	The information required for informed consent includes: name(s) and contact information of the appropriate individual(s) outside the research team whom participants may contact regarding possible ethical issues in the research – TCPS 2, art. 3.2 (h), Application.  Complaints to the ombudsman (service quality and complaints commissioner) – <i>Act Respecting Health Services and Social Services</i> , 30 to the end of the Complaints chapter.
<i>Approval of the Research Ethics Board</i>	The Research Ethics Board of <i>[insert name of institution with which the REB is affiliated]</i> has given ethics approval to this research study and is responsible for monitoring the study at all participating institutions in the health and social services network in Quebec.  or  The Research Ethics Board of <i>[insert name of institution with which the REB is affiliated]</i> has given ethics approval to this research study and is responsible for monitoring the study.		Referral of complaint to designated medical examiner – <i>Act Respecting Health Services and Social Services</i> , 34 (5) and 42.

## G. SIGNATURE

Description	Text	Explanatory Notes	References
<p><i>Signature of participant</i></p>	<p>I have reviewed the Informed Consent Form. Both the research study and the Informed Consent Form were explained to me. My questions were answered, and I was given sufficient time to decide. After reflection, I consent to participate in this research study in accordance with the conditions stated above, including the use of all personal data and samples collected.</p> <p>I authorize the study team to access my medical chart.</p> <p><b>[Optional:</b> In addition, I authorize the researcher or research team to inform my family doctor or treating physician, in writing, that I am taking part in this research study, and to send them all relevant information.]</p>	<p>For clinical trials, Canada's <i>Food and Drug Regulations</i> require written consent.</p>	<p>As a rule, consent to research must be given in writing. However, consent to such research may be given otherwise than in writing if justified in the circumstances in the opinion of a research ethics committee. In such a case, the committee determines the proper manner, for evidential purposes, of obtaining consent.</p> <p>It may be withdrawn at any time, even verbally.– CCQ 24.</p> <p>Evidence of consent shall be contained either in a signed consent form or in documentation by the researcher of another appropriate means of consent – TCPS 2, art. 3.12.</p> <p>Written informed consent is obtained from every participant in a clinical trial – <i>Food and Drug Regulations</i>, Part C, Division 5.</p> <p>Prospective participants shall be given adequate time and opportunity to assimilate the information and pose any questions they may have – TCPS 2, art. 3.2, Application.</p> <p>Prior to a subject's participation in the trial, the written informed consent form should be signed and personally dated by the subject or by the subject's legally acceptable representative, and by the person who conducted the informed consent discussion – ICH GCP4.8.8.</p>

<p><i>Communication with the participant regarding future research</i></p>	<p>and</p>		
<p><i>Specific authorization</i></p>	<p>[Optional: I authorize the researcher in charge of this research study to communicate with me to see if I am interested in participating in other research studies.]</p>		
	<p>and</p>		
	<p>[Include all other authorization clauses relevant to the research study]:</p>	<p>Add authorization clauses specific to the research study. Previous sections of the consent form should have provided the necessary information for such authorization to be given.</p>	
	<p><i>For instance:</i></p> <ul style="list-style-type: none"> <li>• <i>Diagnostic tests required for validating inclusion criteria (and sending such test results to an institution in the healthcare network);</i></li> </ul>	<ul style="list-style-type: none"> <li>- <i>Blood tests;</i></li> <li>- <i>Photos or recordings (audio or video) to be done/stored;</i></li> <li>- <i>The participant's doctor to be informed of participation in the research study and to receive any useful information;</i></li> <li>- <i>Individual results to be communicated to the participant.</i></li> </ul>	

	<p><b>For instance:</b></p> <ul style="list-style-type: none"> <li>• Potential participants unable to read the Informed Consent Form;</li> </ul>	- Signature of witness.	
	<p><b>For instance:</b></p> <p>Ⓜ Any death or incapacity anticipated during the study, in light of the condition being studied</p>	<ul style="list-style-type: none"> <li>- In case of death, information regarding the death will be communicated to the Principal Investigator;</li> <li>- Instructions as to continuing the study following the death or incapacity of the participant.</li> </ul>	
<b>AND</b>			
<i>Signature of the person obtaining consent</i>	I have explained the research study and the terms of this Informed Consent Form to the research participant, and I answered all questions asked.		<p>Prospective participants shall be given adequate time and opportunity to assimilate the information and pose any questions they may have – TCPS 2, art. 3.2, Application.</p> <p>Before informed consent may be obtained, the investigator, or a person designated by the investigator, should provide the subject ample time to inquire about details of the trial and to decide whether or not to participate in the trial. All questions about the trial should be answered to the satisfaction of the subject or the subject’s legally acceptable representative – ICH GCP 4.8.7.</p>
<b>AND</b>			
<i>Commitment of the Principal Investigator</i>	<p><b>[Optional]:</b> I certify that this Informed Consent Form were explained to the research participant, and that the participant’s questions were answered.</p> <p>I undertake, together with the research team, to</p>	The commitment of the researcher, in and of itself, is not optional. What varies from one institution to another is where this commitment	<p>Prospective participants shall be given adequate time and opportunity to assimilate the information and pose any questions they may have – TCPS 2, art. 3.2, Application.</p>

	<p>respect what was agreed upon in the Informed Consent Form, and to give a signed and dated copy of this form to the research participant].</p>	<p>appears in written form (sometimes in the consent form, at other times in other documents).</p>	<p>Before informed consent may be obtained, the investigator, or a person designated by the investigator, should provide the subject ample time to inquire about details of the trial and to decide whether or not to participate in the trial. All questions about the trial should be answered to the satisfaction of the subject or the subject's legally acceptable representative – ICH GCP 4.8.7.</p>
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## H. CONSENT OF THIRD PARTY LEGALLY AUTHORIZED TO CONSENT IN LIEU OF A PARTICIPANT WHO IS INCAPACITATED

Description	Text	Explanatory Notes	References
<p><i>Signature of the third party legally authorized to consent in lieu of a participant who is incapacitated</i></p>	<p>As the legal representative of the participant (guardian, trustee, mandatary; or in cases of sudden incapacity, spouse, close relative, or person close to the participant), I have reviewed the Informed Consent Form. The study and the Informed Consent Form were explained to me. My questions were answered, and I was given sufficient time to decide</p> <p>I was also informed that in the event that the person I represent becomes able to give consent for themselves while this research study is underway, that person will be invited to sign the Informed Consent Form.</p> <p>After reflection, I consent that the person I represent may participate in this research study in accordance with the conditions stated above, including the use of personal data and samples. I will receive a copy of this consent form, signed and dated.</p> <p>I authorize the research team to access the medical chart of the person I represent. <b>[Optional:</b> I also authorize the researcher or their team to inform the person’s family doctor or treating physician that that the person I represent is taking part in this research study and to send them all relevant information.</p>	<p>For clinical trials, the <i>Food and Drug Regulations</i> require written consent for clinical trials.</p>	<p>As a rule, consent to research must be given in writing. However, consent to such research may be given otherwise than in writing if justified in the circumstances in the opinion of a research ethics committee. In such a case, the committee determines the proper manner, for evidential purposes, of obtaining consent. It may be withdrawn at any time, even verbally. – CCQ 24.</p> <p>Evidence of consent shall be contained either in a signed consent form or in documentation by the researcher or another appropriate means of consent. – TCPS 2, art. 3.12.</p> <p>Written informed consent is obtained from every participant in a clinical trial – Food and Drug Regulations, Part C, Division 5.</p> <p>Prospective participants shall be given adequate time and opportunity to assimilate the information and pose any questions they may have – TCPS 2, art. 3.2, Application.</p> <p>Prior to a subject’s participation in the trial, the written informed consent form should be signed and personally dated by the subject or by the subject’s legally acceptable representative, and by the person who conducted the informed consent discussion – ICH GCP 4.8.8</p>

<p><i>Signature of the person obtaining consent</i></p>	<p>I have explained the terms of this Informed Consent Form to the legal representative, and I answered all questions asked.</p>		<p>Prospective participants shall be given adequate time and opportunity to assimilate the information and pose any questions they may have – TCPS 2, art. 3.2, Application.</p> <p>Before informed consent may be obtained, the investigator, or a person designated by the investigator, should provide the subject ample time to inquire about details of the trial and to decide whether or not to participate in the trial. All questions about the trial should be answered to the satisfaction of the subject or the subject’s legally acceptable representative – ICH GCP 4.8.7.</p>
<p><i>Commitment of the Principal Investigator</i></p>	<p><b>[Optional:</b> I certify that the terms of this Informed Consent Form were explained to the legal representative, and that their questions were answered, and that it was clearly indicated that he can withdraw the participant he represent from the study at any time.</p> <p>I undertake, together with the research team, to respect what was agreed upon in the Informed Consent Form, and to give a signed and dated copy of this form to the legal representative].</p>	<p>The commitment of the researcher, in and of itself, is not optional. What varies from one institution to another is where this commitment appears in written form (sometimes in the consent form, at other times in other documents).</p>	<p>Prospective participants shall be given adequate time and opportunity to assimilate the information and pose any questions they may have – TCPS 2, art. 3.2, Application.</p> <p>Before informed consent may be obtained, the investigator, or a person designated by the investigator, should provide the subject ample time to inquire about details of the trial and to decide whether or not to participate in the trial. All questions about the trial should be answered to the satisfaction of the subject or the subject’s legally acceptable representative – ICH GCP 4.8.7.</p>
<p><i>Signature of participant having regained decision-making capacity</i></p>	<p>I have examined the Informed Consent Form and I understand that my legally authorized representative has accepted, on my behalf, that I participate in this research study. I attest that the research study and this Informed Consent Form were explained to me, that my questions were answered to my satisfaction, and that I was given enough time to decide.</p>	<p>The Food and Drug Regulations require written consent for clinical trials.</p>	<p>As a rule, consent to research must be given in writing. However, consent to such research may be given otherwise than in writing if justified in the circumstances in the opinion of a research ethics committee. In such a case, the committee determines the proper manner, for evidential purposes, of</p>

	<p>After reflection, I consent to continue participating in this research study in accordance with the conditions stated above, including the use of my personal data and my samples. I will receive a copy of this Informed Consent Form, signed and dated.</p> <p>I authorize the research team to access my medical chart for the purposes of this research study.</p> <p>[Optional: I also authorize the researcher or their team to inform my family doctor or treating physician, in writing, that I am taking part in this research study, and to send them all relevant information.]</p>		<p>obtaining consent. It may be withdrawn at any time, even verbally. – CCQ 24.</p> <p>Evidence of consent shall be contained either in a signed consent form or in documentation by the researcher or another appropriate means of consent. – TCPS 2, art. 3.12.</p> <p>Written informed consent is obtained from every participant in a clinical trial – Food and Drug Regulations, Part C, Division 5.</p> <p>Prospective participants shall be given adequate time and opportunity to assimilate the information and pose any questions they may have – TCPS 2, art. 3.2, Application.</p> <p>Prior to a subject’s participation in the trial, the written informed consent form should be signed and personally dated by the subject or by the subject’s legally acceptable representative, and by the person who conducted the informed consent discussion – ICH GCP 4.8.8</p>
<p><i>Signature of the person obtaining consent</i></p>	<p>I have explained the research study and the terms of this Informed Consent Form to the research participant, and I answered all questions asked.</p>		<p>Prospective participants shall be given adequate time and opportunity to assimilate the information and pose any questions they may have – TCPS 2, art. 3.2, Application.</p> <p>Before informed consent may be obtained, the investigator, or a person designated by the investigator, should provide the subject ample time to inquire about details of the trial and to decide whether or not to participate in the trial. All questions about the trial should be answered to the satisfaction of the</p>

			subject or the subject's legally acceptable representative – ICH GCP 4.8.7.
<i>Commitment of the Principal Investigator</i>	<p>[Optional: I certify that this Informed Consent Form was explained to the research participant, and that the participant's questions were answered.</p> <p>I undertake, together with the research team, to respect what was agreed upon in the Informed Consent Form, and to give a signed and dated copy of this form to the research participant].</p>	The commitment of the researcher, in and of itself, is not optional. What varies from one institution to another is where this commitment appears in written form (sometimes in the consent form, at other times in other documents).	<p>Prospective participants shall be given adequate time and opportunity to assimilate the information and pose any questions they may have – TCPS 2, art. 3.2, Application.</p> <p>Before informed consent may be obtained, the investigator, or a person designated by the investigator, should provide the subject ample time to inquire about details of the trial and to decide whether or not to participate in the trial. All questions about the trial should be answered to the satisfaction of the subject or the subject's legally acceptable representative – ICH GCP 4.8.7.</p>

## 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 2013.
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