# TEMPLATE: INFORMATION AND CONSENT FORM



# Person of full age - capable of giving consent

#### EXPLANATORY NOTES

The wording of the clauses identified (highlighted in black) as being standardized is MANDATORY AND NOT NEGOTIABLE.

Please note that the wording of the standardized clauses said «legal» listed thereafter, is the one of the[*Clauses légales types des formulaires d’information et de consentement dans le cadre d’essais cliniques*](https://publications.msss.gouv.qc.ca/msss/document-002922/)(MSSS, 2021):

* Confidentiality
* Compensation
* Should you suffer any harm
* Voluntary participation and the right to withdraw
* Identification of contact people
* Signature

Please note that this English version of this template is not official and is provided only for informational purposes. The official French version always takes precedence.

**Only clauses highlighted in grey must be adapted to the particularities of the project**. If applicable, please refer to the most recent of your consent forms approved by the REB as a personalized guide.

Also, please note that the REB reserves the right to adjust the wording of any section of the informed consent form, based on the context of the study.

Warning: this English version is provided strictly for informational purposes. The French version being the only official version, **the present document should not be reverse translated into French.**

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| **This revised information and consent form template comes into force on February 2, 2023. It replaces all previous versions.**  For more information: [Standard legal clauses for information and consent forms for clinical trials (gouv.qc.ca)](https://publications.msss.gouv.qc.ca/msss/fichiers/2020/20-727-01WA.pdf) |

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|  | DT6145 |

(Le code à barres n’est requis, en principe, que pour les essais cliniques.)

TEMPLATE

**INFORMATION AND CONSENT FORM**

|  |  |
| --- | --- |
| **Project title:** | Enter the title as found on the protocol. |
| **Principal investigator:** | Enter the name of the principal investigator in charge of the study and its title and affiliation |
| **Co-investigator(s):** | Enter the name of the co-investigators as well as their titles and affiliations |
| **Sponsor *or* Funding Agency or Funding (if researcher’s personal funds *or* Department funds):** | To be completed |
| **Multicenter identifier:** | To be completed |
| **No of the project at the CISSS des Laurentides:** | xxx |

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

## PREAMBLE (STANDARDIZED CLAUSE)

You are being invited to take part in a research project because *specify –* example: you are suffering from *specify.* Before agreeing to take part in this project and to sign this informed consent form, please take your time to read and consider carefully the following information.

This form may contain terms which you do not understand. Please ask the principal investigator or other members of the research team any questions you feel might be helpful and to explain any word or information which is not clear to you.

## NATURE AND OBJECTIVES OF THE STUDY

Describe briefly and in plain language the nature and objectives of the study, in the following order **(MANDATORY)**:

* **Nature and context of the study (briefly contextualize the study explaining why it is conducted** (rationale)).
* **Nature of the experimental study drug (or medical device) and whether the approval of the interested regulatory agencies have been obtained or not.** Mention whether or not the study treatment has already been approved by Health Canada for the treatment of the disease being studied or has been approved by Health Canada for use in the context of this study.
* **Research hypothese(s).**
* **Purpose(s) of the study.**

## NUMBER OF STUDY PARTICIPANTS AND LENGTH OF THE PARTICIPATION

Specify the total number of study participants at all sites and the number of participants that are expected to be recruited at the CISSS des Laurentides.

Also specify the duration of the study and the duration of individual participation.

## NATURE OF PARTICIPATION REQUESTED

Describe briefly and in plain language the participation requested from the participants, beginning as follows: "If you agree to participate in the study, and after signing this form, you ...".

If necessary, describe the groups and the study cycles, the meaning of a randomized project, double-blinded or open. If applicable, quantify the possibility to be randomized in either of the study groups.

## CONDUCT OF THE STUDY/PROCEDURES

*Description of the conduct of the study*

Start as follows: «You will find a schedule of the study visits and procedures at the end of this form».

Describe the number of phases of the study; *for example:*

The study will include 3 phases:

1) the determination of eligibility phase,

2) the treatment phase and,

3) the follow-up phase.

*Description of study procedures*

Describe the procedures based on the visits scheduled in the protocol, avoiding repetitions. Specify the approximate completion time for each visit.

We ask that you describe the procedures in **point form («bullets») or tables** rather than as a linear text for easier reading and understanding.

You must make sure that the style used for the description of the procedures of the study is coherent from one sentence to another.

Please avoid using descriptions starting with «We…» «You…» and favor the use of briefs descriptions. Examples:

* Review of your medical history
* Complete physical examination, including …
* Electrocardiogram (ECG)
* X questionnaire to be completed *[always group the questionnaires together]*:
* Questionnaire on ECOG [Eastern Cooperative Oncology Group] Performance Status on your daily activities and your level of autonomy to accomplish them.
* Etc.
* Withdrawal of blood samples (X mL or X teaspoons) for the following purposes [*always group all blood samples together] Examples:*
* Routine lab safety tests.
* [If applicable] Tests to screen for HIV, hepatitis B and hepatitis C.
* You must know that hepatitis B and C are reportable diseases. So, if you test positive for these conditions, your study doctor will be required by law to disclose your identity to the appropriate authority.
* Pregnancy test if you are able to have children. If the test is positive, you will not be able to continue participating in the study.
* Etc.
* *[If applicable]* **Banking (mandatory or optional):** *[If participation is optional] -* If you consent, X mL additional will be banked and used for research *purposes x specify and briefly define the type of research*. (see section «Banking» for more details). **If you do not consent to the banking, you will not be able to participate in the main study, even if you are eligible.**

*Or, in case of withdrawal of more than one type of sample, always group together all samples to be withdrawn - Examples:*

* Withdrawal of:
* Blood samples (X mL or X teaspoons) for the following purposes:
  + Routine lab safety tests;
  + Biochemical analysis (assays of enzyme and minerals);
  + Etc.
* Urine sample for the following purposes:
  + Routine lab safety tests;
  + Pregnancy test, if you are able to have children. If the test is positive, you will not be able to continue participating in the study.

*[If applicable -]* In the event that it is not possible to contact you to carry out this follow-up, and if you consent to it at the end of this form, the principal investigator responsible for this research project or a member of his staff may contact your attending physician or the identified person(s) that you will have designated to obtain information on your general health. The research team may also attempt to obtain information from public records, if available.

## *If applicable* - BANKING OF *specify* AND ASSOCIATED CLINICAL DATA FOR RESEARCH *specify the type of research which will be conducted* (optional *or* mandatory) (STANDARDIZED CLAUSE)

[*If it is an optional component* - If you agree,] any remaining portion of *specify* samples after analysis in this main study *or* extra sample(s) of your *specify* will be banked with the associated clinical data and will be used for purposes of research *specify*. This is an optional *or* mandatory component of this main study. *[If it is an optional component]* You can thus refuse that your sample(s) be banked and still participate in the main study*. [If it is a mandatory component]* Participation in the main study includes mandatory participation to the bank. If you do not consent to the banking, you will not be able to participate in the main study.

Please read the separate consent form for concerning this optional *or* mandatory bank of *specify* and the associated clinical data regarding the modalities of participation.

## YOUR RESPONSIBILITIES AND IMPORTANT PRECAUTIONS TO BE TAKEN

* By signing this present consent form, you agree to follow the instructions given by your study doctor, to go to the visits as scheduled in connection with the study and to submit to all assessments required as part of the study.
* You should inform as soon as possible your study doctor, or a member of his team, if you have any unusual symptoms or side effects, as it could affect your health. You can contact them at the phone number(s) *[eliminate the «()» if more than one phone number]* listed in the «Identification of contact people» clause.

In case of emergency (evening, night, weekend and holiday week day), to report any side effects or injury related to the research, you must go at the xxx *specify* emergency room  as needed and you will be seen by the doctor *state the speciality* on call. You must mention that you are participating in this research project**.**

* Describe any other instructions that participants will have to respect and/or any special precautions they will need to take.

## RISKS AND INCONVENIENCES

**Describe the risks and inconvenience related to the study treatment(s), preferably in point form («bullets») or tables.**

*Example* *to start the section:*Participation in this study will expose you to the side effects listed below. Your study doctor will discuss this with you. As with any experimental drug, other unexpected and sometimes serious side effects may emerge. Your study doctor will monitor you closely to see if you have any side effects. If possible, you will be given other medications to reduce them and make them more tolerable. Many adverse effects disappear shortly after the end of the study treatment, but they can sometimes be serious, last a long period of time, be permanent or even cause death. ***You must provide an order of frequency associated with percentages and, if relevant, an order of severity, to enable risk assessment.***

Describe only those risks associated with the study treatment(s), according notably to the study phase (i, ii or iii, etc.), and avoid as much as possible describing  the risks associated with treatments that will be received in the course of the usual clinical treatment outside the protocol.

Present the risks and inconveniences according to the following subsections:

* **Risks associated with the study medication (*or* the study medical device)**
* Very common (between x% et y%)
* Side effect 1
* Side effect  2
* Etc.
* Common (between x% et y%)
* Side effect 1
* Side effect  2
* Etc.
* Less common (between x% et y%)
* Side effect 1
* Side effect 2
* Etc.
* Rares (between x% et y%)
* Side effect 1
* Side effect 2
* Etc.
* **Risks associated with the procedures:**

*Exemples:*

* **Risks associated with blood sampling**

*Describe*

* **Risques associates with ECG**

*Describe*

* **Etc.**
* *If applicable -* **Risk related to genetic analysis**

In Canada, a federal law protects your genetic information. Third parties (such as insurance companies) cannot require you to disclose the results of a genetic test. All efforts will be made to protect your privacy and the confidentiality of your genetic test results (see "Confidentiality" section). Nevertheless, there is a risk that a third party may access your genetic information and identify you. Researchers believe that this risk is minimal.

* *If applicable -* **Risk of breach of confidentiality related to the use of emails**

There may be an increased risk in loss of confidentiality if you use your personal email address to communicate with a member of the study team. Unsecured emails are not a secure method of communication. The content of an unsecured email may be viewed by any person who has access to your email account and/or to the device you are using to send it.

## *If applicable* – RISKS RELATED TO PROCREATION (STANDARDIZED CLAUSE)

**Women**

Your participation in this research project may involve risks, known and unknown, to pregnant women, unborn children or infants breastfed. This is why pregnant and nursing women cannot participate in this project.

Women who could become pregnant will have to undergo a pregnancy test before the start of their participation in the project. Also, if they are having sexual intercourse they absolutely must use an acceptable method of contraception from a medical perspective throughout their participation in the research project *[and x weeks or months after the end of their participation to the study].*

Your study doctor or the research project staff will verify your contraceptive method to ensure that it is medically acceptable.

Acceptable methods of contraception, from a medical point of view, are the following: xxx. [Please note that the partner wearing a condom is not a contraceptive method for women.]

*If applicable -* If you practice total sexual abstinence and if this is your standard lifestyle choice, or if your partner is sterile and you don’t have sexual intercourse with anybody else, it will be considered to be medically acceptable.

If you think you have become pregnant during your participation in this project, you will need to report immediately to your study doctor in order to discuss with him the different options. *Specify if the participant will be removed from the study or not*. If you agree, we will ask you to allow your treating doctor to forward to the study doctor and the sponsor *or* funding agency the information about the follow-up of your pregnancy and your baby’s health at birth. You will need to sign a separate consent form.

*If applicable -* You must not donate eggs for the duration of your participation in the research project and for a period of X months after taking the last dose of the study drug.

*If applicable -* If you have parenting plans and are able to procreate, you may wish to discuss with the study doctor possible options for fertility management, such as the possibility of freezing eggs (cryopreservation) before starting the study treatment.

**Men**

If you are a man, you must use effective contraception such as xxx, during your participation in the study and in x *weeks or months* after the end of the study treatment. Your partner should use effective contraception during the same period as a precautionary measure. If your partner becomes pregnant during your participation in the study or during x *weeks or months* after the end of the study, you will have to inform your study doctor. Since the risk to your partner and baby are unknown, it is advisable that your partner accepts medical follow-up for her during pregnancy and for the baby after birth. If you agree, you should ask your partner to sign a consent form authorizing the doctor to forward to the study doctor and sponsor *or* funding agency the data on her health during pregnancy and the baby's health at birth.

*If applicable -* You must not donate sperm for the duration of your participation in the research project and for a period of X months after taking the last dose of the study drug.

*If applicable -* If you have parenting plans, your study doctor will discuss with you the possibility of freezing your sperm (cryopreservation for sperm) before starting the X treatment given the possibility of treatment-related irreversible infertility.

## BENEFITS (STANDARDIZED CLAUSE)

You may obtain a personal benefit from your participation in this study but we cannot guarantee it. [*Or* You will not obtain any personal benefit from your participation in this research project.] At the very least, the results obtained will contribute to the progress of the knowledge in this field.

## CONFIDENTIALITY (STANDARDIZED LEGAL CLAUSE)

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

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.

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 principal investigator of this research study.

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.

The principal investigator of this research study or a member of the research team will forward your coded data to the sponsor *or* its representatives. 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.

Study data will be stored for at least 15 years following the end of the study by the principal investigator of this research study [*where applicable, choose*: and the study sponsor and/or funding agency.] *[Optional: (specify a different duration for study samples)]*

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

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.

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.

## COMMUNICATION OF OVERALL RESULTS (STANDARDIZED CLAUSE)

You can find out the overall results of this study if you ask the principal investigator at the end of the study. (Mention any other means by which the overall results of the research may be communicated to the participants, for example via letter, website, etc.)

## POSSIBILITY OF COMMERCIALIZATION (STANDARDIZED CLAUSE)

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.

## FUNDING OF THE PROJECT (STANDARDIZED CLAUSE)

The principal investigator and the institution received funding of the sponsor *or* funding agency to carry out this research project.

## COMPENSATION (STANDARDIZED LEGAL CLAUSE)

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*

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

*and*

*If applicable –* The research drug X will be offered to you free of charge for the duration of this research study.

## SHOULD YOU SUFFER ANY HARM (STANDARDIZED LEGAL CLAUSE)

## 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.

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

## VOLUNTARY PARTICIPATION AND THE RIGHT TO WITHDRAW (STANDARDIZED LEGAL CLAUSE)

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 principal investigator of this research study or a member of the research team.

*[Where necessary]* 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.

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.

The principal investigator 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.

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

*[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

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.

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.

## SECONDARY USE OF DATA (STANDARDIZED CLAUSE)

*Context*

* *The following clause is applicable to all sponsors (industry and academic).*
* *The following clause applies only if the researcher has answered the questions intended to describe the mechanisms for regulating secondary use of data.*
* *Biological material is not covered in this clause, applies only to data.*
* *REBs propose that this clause should always be part of the ICF, unless otherwise justified. (There will be no opt-in or opt-out).*

*Cut and paste this clause:* [*https://www.catalisquebec.com/wp-content/uploads/Clause-Fr-En-a-integrer-au-FIC-en-cas-dutilisation-secondaire-de-donnees.docx*](https://www.catalisquebec.com/wp-content/uploads/Clause-Fr-En-a-integrer-au-FIC-en-cas-dutilisation-secondaire-de-donnees.docx)

## ALTERNATIVE TREATMENTS (STANDARDIZED CLAUSE)

If you do not wish to take part in the study, your doctor will discuss your treatment options with you.

## IDENTIFICATION OF CONTACT PEOPLE (STANDARDIZED LEGAL CLAUSE)

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 principal investigator of this research study or with someone on the research team at the following number: *[insert phone number].*

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 of CISSS des Laurentides at 450-432-8708 or at 1-866-822-0549, or at this email address: [info-plaintes@ssss.gouv.qc.ca](mailto:info-plaintes@ssss.gouv.qc.ca) .

## INFORMATION CONCERNING THE STUDY AVAILABLE ON THE INTERNET (STANDARDIZED CLAUSE)

A description of this study is available in English only on the web site [http://www.ClinicalTrials.gov](http://www.clinicaltrials.gov). This site does not contain any information that could identify you. The site will mainly include a summary of the results when they become available. You can check this web site any time. The registration number for this project is (*add the number*).

## APPROVAL OF THE RESEARCH ETHICS BOARD (STANDARDIZED CLAUSE)

*If the project is multicentric -* The Research Ethics Board of CISSS des Laurentides 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 CISSS des Laurentides has given ethics approval to this research study and is responsible for monitoring the study.

## SIGNATURE (STANDARDIZED LEGAL CLAUSE) For possible options please see the French version

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.

*If applicable -* The type of study in which I am being asked to participate generally requires, further to the active treatment component, follow-up for the rest of my life. Sometimes, however, over time, we lose contact with some participants. To ensure the validity of the research, it is important that we find out the date and cause of any deaths. By signing this consent form, you authorize the Department of Health and Social Services to convey this personal information to the investigator when necessary.

I authorize the study team to access my medical chart.

*Specific authorization*: I also agree that the research team can continue to have access to my medical file and use my information or samples if I lose my decision-making ability, or after my death, for the sole purpose of the research project objective.

*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  No

Name and contact information of the treating doctor:

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*Specific authorization:* I agree that the person whose contact information are indicated below can be contacted by my study doctor or a member of his research team, to follow up on my health if I cannot be reached:

Yes  No

Name and contact information of the contact person:

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*If applicable -* Include all other authorization clauses relevant to the research protocol.

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|  |  |  |
| --- | --- | --- |
| Name (Please print) | Signature of the participant to the research project | Date |

## SIGNATURE OF THE PERSON OBTAINING CONSENT*, if other than the investigator responsible for the research project* (STANDARDIZED LEGAL CLAUSE)

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 (Please print) | Signature of the person obtaining consent | Date |

## COMMITMENT OF THE PRINCIPAL INVESTIGATOR *if in the context of a multicenter project* AT THE CISSS DES LAURENTIDES (STANDARDIZED LEGAL CLAUSE)

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.

|  |  |  |
| --- | --- | --- |
| Name (Please print) | Signature of the principal investigator | Date |

## WITNESS SIGNATURE

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.

|  |  |  |
| --- | --- | --- |
| Name (Please print) | Signature of witness | Date |

**Please Note :**

Any additional information about assistance given to the participant during the consent process must be noted in his/her research file.

**Insert study visits and procedures chart(s) here.**