**Information and consent form**

**LOGO**

**TEMPLATE**

Genetic Substudy

OPTIONAL

|  |  |
| --- | --- |
| **Title of the research study:**  | Information to be completed |
| **Principal Investigator:** | Information to be completed (title and specialty) |
| **Co-investigators:** | The list of co-investigators is available upon request |
| **Protocol number:** | Information to be completed, if applicable |
| **Sponsor:** | Information to be completed, if applicable |

**PREAMBLE**

You are being invited to participate in a genetic substudy because you are participating in the study (complete). However, before giving your consent to participate in this substudy and signing the information and consent form, please take the time to read, understand and carefully consider the information contained within this document.

This document may contain words that you do not understand. We encourage you to ask any questions you may find useful to the researcher in charge of this study or to a member of their research staff and ask them to explain any word or information that is not clear.

Your decision to participate in this genetic substudy will not affect your participation in the main study.

**NATURE AND OBJECTIVES OF THE GENETIC SUBSTUDY**

* Describe the **nature** and **purpose** of the substudy, as well as its scope, in simple, lay terms. The language used must be clear, accessible, and understandable. **Whenever possible, avoid using scientific or technical language.**

**COURSE OF THE SUBSTUDY**

* This section should be very clear and provide enough information to allow the research participant to understand and visualize what their participation consists of and what they will have to do during the substudy. **Make sure to group ideas to avoid duplication**.
* Describe the **nature of participation**: number and/or duration of interventions performed on the participant during the conduct of this substudy.
* Indicate the **total duration of the substudy.**
* Indicate, **if *applicable***, the **documents** that will be **consulted** **and that contain personal** and identifiable information about the participant **to** the **substudy** (e.g., medical charts).
* Specify, ***if applicable***, whether secondary uses of the **data** are envisaged or whether it will be **linked** with other information.
* Indicate, ***if applicable***, the **possibility** for the researcher in charge of the substudy **to inform the** participant’s treating doctor if the information collected during the substudy could be of clinical utility.

**BENEFITS SPECIFIC TO THIS SUBSTUDY**

* *If there is a* ***possible******advantage for the participant*** *in taking part in this substudy, insert the following text:*

You may or may not personally benefit from your participation in this study. However, your participation in this study will contribute to the advancement of scientific knowledge in this field.

* *If there is no* ***benefit to the participant***, mention that, at the very least, their participation will contribute to the advancement of knowledge in this field.

**RISKS SPECIFIC TO THIS SUBSTUDY**

Pay particular attention to the necessary balance between the risk(s) incurred by the research participant and the benefits that the participant or others may derive from the substudy. To this end, the **following information must be mentioned, in a comprehensible manner:**

* Indicate the **nature of the** physical, psychological, socio-economic and family risks and, where appropriate, for specific populations.

***Proposed text for socio-economic risks:***

A possible harm associated with the genetic aspect of this study is the disclosure of your genetic information by accident, by mistake or when it should not be released. Despite the protection offered by the Genetic Non-Discrimination Act, as a result of your participation in a research project involving genetic data, you and your biological family members may have difficulty getting or keeping a job or insurance (life, disability, medical, etc.).

***Applicable only when the return of results is expected:***

There can also be risks in learning about your own genetic information. During a study, discoveries about hereditary traits that could affect you and your blood relatives may be made. Sometimes this is upsetting to families or they wish they did not know the information. We encourage you to discuss this study with your family before you decide whether to participate in the genetic aspect of this study.

***Proposed text for specific populations studies:***

Since the substudy is about (specify: social group, ethnic group, sub-population, visible minority), the dissemination of general results may associate you with this gene even if you are not a carrier, and you may be identified as a person at risk by being a member of this group.

**INCONVENIENCES**

* Indicate the known or foreseeable disadvantages for the research participant taking part in the substudy. For example: discomfort, embarrassment, anxiety, travel, or time spent on research.

**VOLUNTARY PARTICIPATION AND THE RIGHT TO WITHDRAW**

***Proposed text, specific for coded data and samples:***

Participation in this genetic substudy is voluntary and optional to the main study. Therefore, you may refuse to participate; your decision will have no impact on your participation in the main study.

***[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.

Your decision not to participate in this substudy, 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.

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.

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 in this substudy 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.

If you withdraw from this substudy, your sample will be traced and destroyed. The information already collected for the substudy will be stored, analyzed, or used to ensure the integrity of the study, as described in this document.

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

***Proposed text, specific for anonymized data and samples:***

Participation in this genetic substudy is voluntary and optional to the main study. Therefore, you may refuse to participate; your decision will have no impact on your participation in the main study.

***[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.

Your decision not to participate in the substudy, 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 doctor in charge of this research study, the Research Ethics Board, the funding agency, or the sponsor may put an end to your participation in this substudy 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.

Since your sample will be anonymized (specify a time), it will be impossible to trace and destroy it. Therefore, you will not be able to remove your sample from the substudy after (specify).

**CONFIDENTIALITY**

***Proposed text, specific for coded data and samples:***

During your participation in this genetic substudy, 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 substudy.

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. We will protect the confidentiality of samples and data by assigning them a specific code. Your sample will therefore not be identified by your name, but the code will link you to the sample. The key to the code linking your name to your sample will be kept by the doctor in charge of the substudy.

The doctor in charge of this substudy or a member of the research team will forward your coded data and samples to the sponsor or its representatives.

Samples, as well as research data on their own or in combination with data from other projects, may be shared with regulatory agencies in Canada or other countries, or with the sponsor’s commercial partners. This means that your samples and research data may be transferred to countries other than Canada.

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.

***Where applicable*** Your sample will only be used for the purposes of this substudy.

The results of this substudy may be published or shared at scientific meetings; however, it will not be possible to identify you.

Your participation in this substudy and the results of the research will not be included in your medical chart.

For monitoring, control, safety, and approval 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, but they adhere to a confidentiality policy.

***Proposed text, specific for anonymized data and samples:***

During your participation in this substudy, 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 this substudy.

All study data collected during this research study (including personal information and samples) will remain confidential to the extent provided by law. Your samples will be made anonymous, i.e., all traceable identification will be removed following collection. The researcher may decide that it is necessary to attach information to the sample, such as (specify: your age, gender or certain essential clinical, pathological, or demographic data, etc.), but this will not be identifiable or traceable to you.

Samples, as well as research data on their own or in combination with data from other projects, may be shared with regulatory agencies in Canada or other countries, or with the sponsor’s commercial (*or academic*) partners. This means that your samples and research data may be transferred to countries other than Canada.

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.

***Where applicable*** Your sample will only be used for the purposes of this substudy.

The results of this substudy may be published or shared at scientific meetings; however, it will not be possible to identify you.

Your participation in this substudy and the results of the research will not be included in your medical chart.

For monitoring, control, safety, and approval 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, but they adhere to a confidentiality policy.

**INCIDENTAL FINDINGS *[If applicable]***

***Proposed text, specific for coded data and samples:***

In the event that a scientifically validated result is found that is significant to your health and that preventive measures or treatment are available, you may be informed of this through your researcher, with your consent. A specific clause on this subject is available at the end of this document.

The communication of such information involves certain risks for you and your family, such as anxiety, stress, discrimination (employers, insurers, …), and consequences on your decision whether to have children. Indicate the possibility of meeting with a genetic counsellor, if necessary.

***Proposed text, specific for anonymized data and samples:***

As your samples and data will be anonymized, it will not be possible to communicate personal results to you.

**POSSIBILITY OF COMMERCIALIZATION (Normative, non-negotiable, *if applicable*)**

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

**COMPENSATION (Normative, non-negotiable *to adapt accordingly to the* *chosen modalities*)**

You will receive 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 substudy. 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***

Your expenses for [*choose*: travel, meals, parking, etc.] 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 substudy.

**SHOULD YOU SUFFER ANY HARM (Normative, non-negotiable)**

Should you suffer harm of any kind as a result of taking part in this substudy, you will receive all the care and services required by your state of health.

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

**CONTACT INFORMATION (Normative, non-negotiable)**

If you have any questions or if you have a problem you think might be related to your participation in this substudy, 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].

For any questions regarding your rights as a research participant in this substudy, or if you have comments or wish to file a complaint, you may communicate with the CHU de Québec-Université Laval’s local service quality and complaints commissioner at 418-525-5312, by email at plaintes@chudequebec.ca or online at “chudequebec.ca : formulaire de plainte ou d’insatisfaction.”

***Multicentric study*:**

The Research Ethics Board of the CHU de Québec-Université Laval 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.

***Add*** *the following text* ***in case of transfer of data and samples outside of Canada:***

However, the sponsor becomes the owner of any tissue or samples and the information related to them once you consent to this research study. Accordingly, the CHU de Quebec-Université Laval’s Research Ethics Board and the principal investigator will have no authority over the use made of your samples in the future.

***Monocentric study:***

The Research Ethics Board of the CHU de Québec-Université Laval has given ethics approval to this research study and is responsible for monitoring the study.

**SIGNATUREGenetic substudy**

OPTIONAL

|  |  |
| --- | --- |
| **Title of the research study:** | Information to be completed |

I have reviewed the Information and Consent Form. Both the genetic substudy and the Information and 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 substudy in accordance with the conditions stated above, including the use of all personal data and samples collected.

I also authorize the study team to access my medical chart.

I understand that a signed and dated copy of this Information and Consent Form will be given to me.

***[If applicable]*** I agree to be informed if an incidental finding relevant to my health is made during my participation in this genetic substudy.

☐ Yes Initials\_\_\_\_\_\_\_\_\_\_\_\_\_\_

☐ No Initials\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[***Optional***] In addition, I authorize the researcher or research team to communicate genetic research results relevant to my health to my family doctor or treating physician, in writing, and to send them all relevant information.

☐ Yes Initials\_\_\_\_\_\_\_\_\_\_\_\_\_\_

☐ No Initials\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

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Name of participant Signature Date

**SIGNATURE OF THE PERSON OBTAINING CONSENT**

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

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Name of the person obtaining consent Signature Date

**[*OPTIONAL*] COMMITMENT OF THE PRINCIPAL INVESTIGATOR**

I certify that this Information and 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 Information and 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

**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 Information and Consent Form, that the research 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 Information and Consent Form was written) — The signatory attests to acting as interpreter for the participant throughout the consent process.

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Name (Print) Signature of witness Date

**Note:**

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