# Informed Consent Form Template for Banking | Persons of full age - Capable of giving consent (AMENDED VERSION | 2023-07)

## EXPLANATORY NOTES

The wording of the clauses identified ((highlighted in black)) as being standardized is **MANDATORY AND NOT NEGOTIABLE** (see: «Note de clarification – Modèles FIC (essais cliniques) - English version» in Nagano). The «legal» clauses are so identified because of their content and their legal scope and are those of the REB.

**Only clauses highlighted in grey must be adapted to the particularities of the bank.** 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 all sections of the informed consent form, based on the context of the bank.

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| **This revised information and consent form template comes into force on April 18, 2016. It replaces all previous versions.** |

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

## TEMPLATE

## INFORMATION AND CONSENT FORM

## BANKING OF (SPECIFY: BLOOD, TISSUES, MARROW AND/OR URINE) AND ASSOCIATED CLINICAL DATA FOR RESEARCH PURPOSES - specify the type of research: genetics, pharmacogenetics, pharmacokinetics, etc. (OPTIONAL *or* MADATORY)

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| **Title of main study:** | Enter the title as found on the protocol |
| **Principal investigator:** | Enter the name of the principal investigator in charge of the main 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 anD Bank manager:** | To be completed |
| **Multicenter identifier:** | *If applicable* |
| **No of the project at the CISSS des Laurentides: xx.xxx** | To be completed |

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

## PREAMBLE (STANDARDIZED CLAUSE)

You previously agreed to participate in the main study. In the context of this study, we plan to bank samples of (*specify: blood, tissues, marrow and/or urine*) and associated clinical data. This part is an **optional** *or* **mandatory** component of the main study. [*If it is an optional component*] A decision on your part not to participate in the bank would not affect your participation in the main study. *[If it is mandatory componen]* Participation in the main study includes mandatoriy participation to the bank. **If you do not consent to the banking, you will not be able to participate in the main study.**

Before agreeing to participate in this bank, please take the time to read and understand the information below. This document may contain terms that you do not understand. Please ask the responsible researcher of the main study or members of his team any questions that you think might be helpful and to explain to you anything that is not clear*.*

## GOALS OF the RESEARCH CARRIED OUT WITH THE BANKED BLOOD and tissue SAMPLES

Suggested wording:

The research which will be conducted with the banked samples will aim to\_\_\_\_\_\_\_\_\_ Briefly explain the purpose(s) of the research to be conducted with the banked samples.

The results of the research could help us better understand \_\_\_\_\_\_\_\_\_ *specify*. Example: The results of the research could help us better understand who will benefit most from a particular type of treatment, depending on specific genetic markers.

## NATURE OF THE REQUESTED PARTICIPATIOn

Suggested wording:

If you agree to participate in the banking of your \_\_\_\_\_\_\_\_\_ *specify* *type* samples and associated clinical data for \_\_\_\_\_\_\_\_\_ *specify type* research purposes, you agree to the following terms and conditions: *Describe the participation requested, according to the information required based on the type of sample to be banked, as described below*:

Information required depending on the type(s) of sample(s) banked:

* **Banking of blood samples:**
* Specify if additional withdrawals of samples compared to those planned in the main study will have to be carried out for banking purposes and specify the number. Specify the amount of blood (in mL and the equivalent in teaspoon) that will be drawn in total for the bank.
* Indicate whether samples for the bank will be collected through one or more scheduled visits planned in the protocol of the main study or at a different time.
* **Banking of tissues samples:**
* Specify whether banked samples will be collected from a biopsy already done as part of clinical treatment in the main study or if a new biopsy will be necessary for the sole purposes of the bank.
* If applicable, specify when the biopsy will be done and the approximate dimensions of the tissue that will be removed.
* **Banking of marrow samples:**
* Specify whether banked samples will be taken from a bone marrow aspirate already done as part of clinical treatment in the main study or if a new puncture will be necessary for the sole purposes of the bank.
* If applicable, specify when the puncture will be done and the approximate amount of bone to be removed.
* **Banking of urine samples:**
* Specify if additional withdrawals compared to those planned in the main study will be carried out for banking purposes and specify the number.
* Indicate whether samples for the bank will be collected through one or more scheduled visits planned in the protocol of the main study or at a different time.

## STORAGE OF SAMPLES (STANDARDIZED CLAUSE)

The *specify* samples and related clinical data will be kept in sponsor or funding agency’s bank located at *specify the location of the bank – city and country*, by *specify* the sponsor *or* organization responsible for the bank and will be used for *specify the type* research.

*If applicable* – It is possible that once *specify* research analyzes on the samples banked have been completed, your *specify* samples will not have been fully utilized and that there remains a very small amount. If that is the case, your samples will be anonymized, that is to say that the link between your identity and your samples will be destroyed, resulting in their non-traceability and their destruction will not be possible should you ask for them to be destroyed after their anonymization.

The *specify* samples will be kept until full utilization or until x (the researcher, the funding agency or the sponsor) decides to destroy them (or specify another conservation period).

## RISKS (STANDARDIZED CLAUSE)

Information required depending on the different types of risks associated with participation in the bank:

* **Risks associated with the withdrawal of blood sample(s):**

When the blood sample(s) is/are taken, you may feel weak or faint, or experience a slight bruise, irritation or redness at the needle insertion site. In rare cases, an infection can occur.

* **Risks associated with the withdrawal of tissue:**

In case of tumor biopsy, your study doctor will explain in detail the risks associated with it, because the degree of risk depends on where the tumor(s) are located in the body.

Generally, the biopsy may cause pain, redness, swelling, excessive bleeding and bruising or infection at the biopsy site. There could be an allergic reaction to local anesthetic drug used to numb the skin overlying the biopsy site.

* **Risks associated with the withdrawal of marrow:**

During bone marrow aspiration, you may feel pain, redness, swelling, excessive bleeding and bruising or infection at the point of insertion of the needle. There could be an allergic reaction to the local anesthetic drug used to numb the skin overlying the biopsy site.

* **Risk associated with a breach of confidentiality:**

There is a risk of a possible breach of confidentiality regarding your personal information and medical records that could result in a breach of your privacy. This risk, however is minimal. Every effort will be made to protect your privacy and confidentiality as described in the "Confidentiality" section.

## BENEFITS (STANDARDIZED CLAUSE)

You will not derive any direct personal benefit from participating in this bank or in the research projects in which your samples will be used. However, the research done on the banked samples may enable the researchers to learn more about *specify*. This information could help in the future patients suffering from *specify* who may receive similar treatment.

## COMPENSATION (STANDARDIZED LEGAL CLAUSE)

Suggested wording if no compensation is offered:

You will receive no financial compensation for your participation in this bank.

Suggested wording if financial compensation is expected because of visits or additional procedures required for withdrawals of samples to be banked:

You will receive no financial compensation for your participation in this bank. However you will receive an amount of X$ *specify* in compensation for certain expenses, such as travel or parking, incurred as a result of your participation in the bank.

## SHOULD YOU SUFFER ANy harm (STANDARDIZED LEGAL CLAUSE)

General suggested wording:

Should you suffer harm of any kind an injury of any kind related to your participation in this bank for *specify the type* research you are not waiving any of your legal rights nor discharging the principal investigator, the sponsor *or* funding agency or the institution, of their civil and professional responsibilities.

Suggested wording if procedures (eg: biopsy, additional blood samples) are required solely for the purposes of banking:

Should you suffer an injury of any kind as a result of any proceedings related to participating in the bank, you will receive the appropriate care and services required by your state of health.

By agreeing to participate in the bank, you are not waiving any of your legal rights nor discharging the principal investigator, the sponsor *or* funding agency or the institution, of their civil and professional responsibilities.

## CONFIDENTIALITY (STANDARDIZED LEGAL SECTION)

The main study’s responsible researcher will protect your file so that your name, address and telephone number will remain confidential.

Your *specify* samples will be kept in the bank, and the clinical and research data entered into the computerized database will be identified only by your identification number, the study code, your initials and the blood bank code (or other types of codes). It will be possible to identify and link them only by the identification number kept by the main study’s responsible researcher.

We will provide samples only to researchers whose research proposals have been approved by the researcher, the funding agency *or* the sponsor - *specify* and who are bound by a nondisclosure agreement. In addition, a research ethics board will have first approved any research done on your samples.

The reports concerning any research done using your samples will not be sent to you or your doctor because the research done on your samples will not be of any diagnostic or therapeutic consequence to you. Nor will these reports be placed in your medical record.

In the future, people who conduct research using your *specify* samples may need additional information about your health. Even if the researchers coordinating the present study may send reports concerning your health to them, they will not send them your name, address, telephone number or any other information by which the requesting researchers could identify you.

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

The banking of *specify* samples and associated clinical data is an **optional** *or* **mandatory** part of the main study. *[If it is an optional component* ] Consequently, you can decide not to participate in this part of the study or withdraw your consent at any time and request that your banked *specify* samples not be used. A decision on your part not to participate in the bank or to subsequently withdraw your consent for this part of the study would not affect your participation in the main study. *[If it is a mandatory component]* If you decide not to participate to the bank, you will not be allowed to participate to the main study. *Specify whether or not subsequent withdrawal of consent to this component of the study will affect participation in the main study.*

If you decide to stop participating in the bank and no longer want your *specify* samples to be used for *specify* research purposes, you must inform your main study doctor. He/she will notify the sponsor *or* the funding agency, who will see to it that your banked *specify* samples are destroyed. However, if tests have already been performed on your samples, if the code originally placed on your samples has been removed *[or if it has been anonymized*], or if we have included the samples in an analysis or provided test results in a publication, it will not be possible to remove them.

## POSSIBILITY OF MARKETING (STANDARDIZED CLAUSE)

Your samples will be used solely for research purposes and will not be sold. The research using your samples may contribute to the development of new products in the future that might be sold. However, you would not be entitled to any financial benefits from this.

## FUNDING OF THE BANK (STANDARDIZED CLAUSE)

The *specify* samples bank is funded by *specify* by the sponsor *or* the funding agency.

## IDENTIFICATION OF CONTACT PEOPLE (STANDARDIZED LEGAL CLAUSE)

Should you have any question regarding this banking of your *specify* samples and associated clinical data for *specify* research purposes, you may contactthe researcher responsible for the main study, Dr. *specify*, at the following number: xxx- xxx-xxxx, extension xxx *(specify the hours and days of availability, for example:* between Xh00 and Xh00, Monday to Friday*).*

Should you have any questions about your rights as a participant in a bank or have any complaints or comments, you can contact the associate commissioner for complaints and service quality of the CISSS des Laurentides at 450-432-8708 or at 1-866-822-0549, or at this email address: info-plaintes@ssss.gouv.qc.ca .

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

*If in the context of a multicenter project* - The CISSS des Laurentides Research Ethics Board approved the study, including this *specify* optional *or* mandatory part involving participation in the banking of *specify*, and associated clinical data for *specify* research purposes and is responsible for monitoring it at all participating institutions in the health and social service network in Quebec.

*or*

The CISSS des Laurentides Research Ethics Board approved this study, including this *specify* optional *or* mandatory part involving participation in the banking of *specify* and associated clinical data for *specify* research purposes, and is responsible for monitoring it.

## SIGNATURE STANDARDIZED LEGAL CLAUSE)

I declare that I have read this consent form (or that it has been read to me), specifically as regards the nature of my participation in the bank and the extent of the associated risks. I acknowledge that the bank has been explained to me, that all of my questions have been answered and that I have been given the necessary time to make a decision.

I freely and voluntarily agree to participate in this bank. I will be given a signed and dated copy of this form. In signing this form, I am not waiving any of my legal rights or and I do not release the researchers, hospital, sponsor *or* funding agency or its business partners from their civil and professional responsibilities.

**PLEASE TICK THE APPROPRIATE BOXE BELOW BEFORE SIGNING.**

[ ]  **YES**, **I accept** the banking of *specify* samples and associated clinical data for the research purposes described in this Consent Form.

[ ]  **NO**, **I do not accept** the banking of *specify* samples and associated clinical data for the research purposes described in this Consent Form. *[If it is mandatory component]* **Consequently, I understand that I will not be able to participate in the main study even if I am eligible.**

|  |  |  |
| --- | --- | --- |
| Name (Please print)  | Participant’s signature | Date |

## SIGNATURE OF THE PERSON OBTAINING THE CONSENT, IF DIFFERENT FROM THE INVESTIGATOR IN CHARGE OF THE RESEARCH PROJECT (STANDARDIZED LEGAL CLAUSE)

I have explained to the research subject the terms of this information and consent form and I have answered all the questions he/she has asked.

|  |  |  |
| --- | --- | --- |
| Name (Please print)  | Signature of 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 information and consent form for banking was explained to the participant, and that the questions the participant had were answered.

I undertake, together with the research team, to respect what was agreed upon in the information and consent form for banking, and to give a signed and dated copy of this form to the participant in this bank.

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

## WITNESS’S SIGNATURE

YES [ ]  NO [ ]

A witness’s signature is required for the following reasons:

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| [ ]  Difficulty or inability to read: The person (impartial witness) who affixes his/her signature below certifies that the consent form was read and that the banking of *specify* and associated clinical data for *specify* research purposes was clearly explained to the participant, who seems to have understood it. |
| [ ]  Not understanding the language in which the consent form is written: The person who affixes his/her signature below served as an interpreter for the patient during the consent process. |

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

**Please note the following:**

If applicable, other information concerning assistance provided during the consent process must be recorded in the patient’s research file.