

Signature

Participation In The Signature Medical/Psychosocial Data And Biological Materials Bank

INFORMATION AND CONSENT FORM

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⇒ Introduction

The Signature Medical/Psychosocial Data and Biological Materials Bank aims to advance mental health research and help clinicians improve the care provided to Institut universitaire en santé mentale de Montréal patients, a CEMTL facility.

The Bank was launched in 2012 following careful deliberation and consultations with the hospital and research centre during its development. The decision to implement the Bank was ratified by Institut universitaire en santé mentale de Montréal's Board of Directors on October 23, 2012, after being approved by the Research Ethics Committee on September 26, 2012.

The Bank is managed in accordance with various ethical and administrative regulations.

You have been invited to take part in the Bank as a research subject. We would now like to receive your consent to preserve in the Signature Bank some of your psychosocial information (answers to questionnaires) and medical data (results of blood and urine analysis, medical file at the Institut, RAMQ), as well as samples of your saliva, blood and hair.

The preservation of this data and biological materials in the Signature Bank will enable them to be used for health-related research projects. Those projects will be previously approved by a scientific committee and an ethics committee to ensure that the use of your data will not identify you in any publication or scientific communication. What's more, an overall summary of your psychosocial data will be available to your doctor and members of the treatment team who have access to your medical file, under technical term « **aggregate data**¹ ».

This form may contain words that you do not understand. If you have any questions, we encourage you to ask the research nurse who has presented the project to you and invited you to participate. To facilitate your understanding of the project, the research nurse has suggested that you view a video presentation on an iPad.

¹ *Aggregate data* represents the average scores obtained by participants on the psychosocial signature's various scales and subscales. This aggregate data may be presented in table or graph form.

⇒ General overview of the signature bank

- **Researchers who developed the Bank:** This is a group of over 80 international clinicians, researchers and specialists. They worked together under the “Signature Consortium” name.
- **Location of the Signature Bank:** It is located at the Institut universitaire en santé mentale de Montréal Research Centre, 7331 Hochelaga St., Montreal, QC, H1N 3V2.
- **Funding and management:** Initial funding for the Signature Data and Biological Materials Bank is provided by the hospital, the IUSMM Foundation and the Research Centre, while additional funding will be generated over time by fees charged to researchers who use the Bank to access data and biological materials. The Signature Bank has no commercial or profit-making purposes; rather, its goal is to become self-financing (i.e., to cover its operating costs) in the long term. It is for use by researchers, with priority given to those at Institut universitaire en santé mentale de Montréal. Only the hospital’s clinicians may access it. The Bank’s administration is handled by a Management Committee and Coordinating Committee.
- **Overview of Bank participants:** The people who contribute to the Bank are all patients of the Institut universitaire en santé mentale de Montréal who agree to participate in the Bank as research subjects.
- **Contents of the Bank:** The Bank contains psychosocial data (on sleep, anxiety, depression, etc.), medical data (such as diagnosis and medication, use of services, treatments) and biospecimens from saliva, blood and hair samples, as well as information regarding geographical location (for example, in order to identify areas exposed to pollution).
- **Expected lifespan of the Bank:** The Bank was instituted for an unlimited period, but if it were to terminate its activities, all its contents would become the responsibility of the institution (Institut universitaire en santé mentale de Montréal), which may then decide on the Bank’s future by choosing to resume its activities or to either preserve or destroy the data.
- **Intended methods of preserving data and biological materials:** Collected information will be stored in a secure, computerized database in accordance with the document storage regulations governing health and social services institutions in Quebec. Biological material samples will be frozen and preserved in secure freezers at IUSMM Research Centre. The data and samples will be preserved for as long as the Bank is active. They belong to Institut universitaire en santé mentale de Montréal.
- **Researchers with access to the Bank and purposes for which data and biological materials will be used:** Bank data will be available for research purposes to IUSMM researchers and clinicians as well as researchers in Quebec, Canada and abroad. Only the psychiatrist and other professionals on the clinical treatment team will be able to directly access the psychosocial data summaries for patients who have agreed to participate in the Signature Bank. A portion of the biological samples will be used immediately for metabolic analyses including cholesterol and glucose in the blood sample and drugs screening in the urine. The remaining sample portions (blood, hair and saliva) will be stored at the Bank and may be used to conduct biological analyses on hormones (testosterone, progesterone, etc.), inflammatory and immune agents, infectious agents, toxins, or genetic analyses.
- **Ethical approval of projects:** Research projects for which data and biological materials will be used must receive approval in advance from the Research Ethics Committee.

⇒ The nature of your participation in the bank

Your participation in the Bank involves answering psychosocial questionnaires for about one hour. These questionnaires relate to various aspects of mental health and feature questions concerning, for example, sleep, anxiety and depression. They are tests that are currently used in the field of psychiatry. You answer the questions directly on an IT tool (an iPad), with the help of the research nurse if needed.

In order to establish a link between your questionnaire responses, your biological analyses results, and your medical condition, you authorize a research nurse or any other research assistant who has signed a confidentiality agreement with the CEMTL to consult your medical file. The data collected may concern any information available in your medical file that would help to establish a link with your health condition, such as different diagnoses received, treatments and their results on your health, services used, behaviors, habits of life and geographical location.

Also for the purpose of correlating your questionnaire responses to your medical condition, your participation means that the Signature Bank coordinator may request access to recognized administrative database information such as the Régie de l'Assurance Maladie du Québec (RAMQ). It is agreed that information related to your file may only be used by those responsible for the purposes stated in the present document.

You will also provide a sample of blood (equivalent to around 2.5 tablespoons), hair (equivalent to the diameter of a drinking straw, or 0.5 cm), saliva and urine (only at time 1 and 4). Part of the blood sample will be analyzed immediately to get a lipid profile as well as urine for a drug screening (amphetamines, cannabinoids, cocaine and opiates). The rest of the blood sample as well as the saliva and the hair will be preserved in the Signature Bank. The nurse will also take your blood pressure, your weight, your height and measure your waist size and hips. If you are a woman, she will ask you some questions about your period.

The process of filling out psychosocial questionnaires and giving samples will take place from one (1) to four (4) times while you are receiving care at the hospital and being monitored as an outpatient, based on when you begin participating in the Signature Bank. If you begin while in emergency, the process will be repeated four (4) times. If you begin while being monitored as an outpatient, the process will be repeated two (2) times. Each time, the research nurse will ask if you are still willing to take part in the Signature Bank.

⇒ Benefits of the bank

The benefits derived from your participation in the Signature Bank are mainly communal in nature, in the sense that the Bank will make it possible to advance mental health research and improve the care and services provided to CEMTL's patients.

The Signature Bank promotes participants' involvement in their own treatment and care by providing their psychiatrist and clinical treatment team with access to a summary of the scores obtained on various psychosocial tests.

You will also be contacted if we observe abnormal results: your attending psychiatrist will automatically receive the data obtained from biochemical analysis of metabolic markers, as soon as they have been analyzed in a laboratory. Meanwhile, researchers who analyze frozen biological samples agree to report

any abnormal results (according to current medical practice) to the Bank coordinator², who will then advise your attending psychiatrist.

⇒ Risks and drawbacks of the bank

The overall results of your psychosocial questionnaire responses, as well as certain blood sample analysis results³ that may be valuable in terms of care and treatment, will be sent to your attending psychiatrist and placed in your medical file. They are subject to Institut universitaire en santé mentale de Montréal's regulations governing confidentiality and privacy protection.

There are no major risks associated with the Bank as long as confidentiality is maintained. That's why extremely rigorous measures have been put in place with regard to this issue (see section below). However information contained in your research file like the results from genetic results might compromise or diminish your chances of insurability (life, invalidity, or health insurance) or to obtain some jobs. In the case of genetic diseases this risk might span to the members of your biological family.

Your research file is subject to the rules of the Institut universitaire en santé mentale de Montréal which governs confidentiality and the protection of privacy and personal data. Research data will never be transmitted to a third party unless you make a written request to do so.

Another very minor drawback is the discomfort involved when your blood sample is taken and the fact that a small lock of your hair is cut off.

⇒ Respect for privacy and confidentiality protection

Samples of your biological material as well as your medical and psychosocial data will be stored in a strictly confidential manner. For this reason, your data will be denormalized.

Denormalization involves replacing identifiable personal information with a code. The management technician in charge of the database and the Bank coordinator—and no one else—maintain and have secure access to the confidential list matching the codes with personal information. This list will never be disclosed to researchers. All data and biological materials from the Bank will be provided to researchers in denormalized form.

⇒ Compensation

You will receive compensation of \$20 each time you fill out questionnaires and have samples taken (one to four times in total) as part of your participation in the Signature Bank. This is to compensate you for the time spent and travel involved.

² The Bank coordinator is the only person other than the database management technician with access to the source code linking participants' demographic information with their anonymized code.

³ Analysis of metabolic biomarkers

⇒ Freedom of participation and withdrawal

Participation in the Signature Bank is entirely voluntary. You are therefore free to refuse to participate. You may also withdraw at any time simply by providing verbal or written notice. In the case of withdrawal, you may also submit a written request to the Bank coordinator, asking that your samples and all files containing your data be destroyed at the following address:

CIUSSS de l'Est-de-l'Île de Montréal
Centre de recherche de l'Institut universitaire en santé mentale de Montréal,
Pavillon Riel – porte RI-226-90, 7401, rue Hochelaga, Montréal, H1N 3M5

These will be destroyed after a short period of **quarantine**⁴, which is provided in case you wish to change your mind, since it will be impossible to recover data once it has been destroyed.

Your refusal to participate in the Bank or your decision to withdraw along the way will have no impact on the quality of care and services to which you are entitled.

⇒ Participant rights

By agreeing to participate in this bank, you do not waive any of your rights nor do you release researchers and institutions from their civil and professional responsibilities.

⇒ Resource persons

If you have any questions or problems related to the research project, or if you wish to withdraw from it, you can contact the researcher responsible for this research project or with someone from the research team at the following number 514 251 4000 extension 3796

If you have any questions regarding your rights as a participant in this research project or if you have any complaints or provide feedback, you may contact the CIUSSS de l'Est-de-l'Île-de-Montréal's Service Quality Commissioner by phone at 514 252-3400, extension 3510.

⇒ Monitoring of project's ethical aspects

The CIUSSS de l'Est-de-l'Île-de-Montréal's Research Ethics Committee approved the Signature Bank and ensures that it is monitored from an ethical perspective. To obtain information, you can reach the Committee's secretary at 514-252-3400, extension 5708.

⁴ When such a request is made, the Bank's management technician must place the participant's data and biological materials in "quarantine" and, after one month has passed, proceed with their destruction and notify the participant in writing that the process has been carried out. However, participants' right of withdrawal includes the following limitation: once their anonymized data has been aggregated with other data and provided to one or more researchers for analysis or publication, it is impossible to withdraw the data from that particular analysis or publication, since it has already been anonymized

⇒ Participant consent

I hereby declare that I have read the present information and consent form. I acknowledge that the nature of the Signature Medical/Psychosocial Data and Biological Materials Bank has been explained to me. I was able to ask all the questions I had, and they were answered to my satisfaction. I acknowledge that I was given the time I needed to make a decision. I understand that I am free to agree to participate in the Bank, just as I am free to withdraw at any time, without prejudice, by advising the Management Committee.

I authorize the authorized personnel of the Signature Bank to access my medical file.

I authorize the researchers to utilize the data with a possibility of matching it with other sources of data, such as the information contained in my medical file and my RAMQ file, and for the purposes set out in the Signature Bank's management framework.

Yes No

I consent to being contacted by authorized personnel from the Signature Bank in order to obtain supplementary information needed for a research project that requested access to the Signature Bank. At that time, I will be entirely free to accept or to refuse to provide the requested information.

Yes No

I consent to being contacted by authorized personnel inviting me to participate in future research projects on similar topics taking place at the Institut universitaire en santé mentale de Montréal. At that time, I will be entirely free to accept or to refuse participation in these new projects.

I, the undersigned, hereby consent to participate in the Signature Medical/Psychosocial Data and Biological Materials Bank under the stipulated terms. I understand that I will be given a duly signed and dated copy of the present form.

Participant

Surname of participant

Given Name

Signature

Date

Participant telephone number

I agree to be contacted by SMS

Participant mail

Parent / Legal representative (if applicable):

Surname of parent / Legal representative

Given name

Signature

date

Telephone number

Signature bank management committee member's signature and agreement

I certify that I have explained the terms of the present consent form to the participant and/or his/her parent/guardian, that I have answered his/her questions and that I have clearly indicated that the participant remains free to terminate his/her participation at any time, without prejudice. I agree to give the signatory a duly signed and dated copy of the present form.

Bank representative's name

Signature

Date