MANAGEMENT FRAMEWORK

SIGNATURE MEDICAL/PSYCHOSOCIAL DATA AND HUMAN BIOLOGICAL MATERIALS BANK

WRITING AND EDITING COMMITTEE:

Marie-Hélène PARIZEAU, Ph.D., Professor, Faculty of Philosophy, Université Laval
Sonia LUPIEN, Ph.D., Scientific Director, Research Centre
Nathe FRANÇOIS, Ph.D., Management and Knowledge Transfer Associate, Research Centre
Guylaine LAROCQUE, M.B.A., Centre Signature Implementation Coordinator, Institut universitaire en santé mentale (editing)

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LIST OF ACRONYMS

CAI: Commission de l'Accès à l'Information du Québec
REC: Research Ethics Committee
SEC: Scientific Evaluation Committee
CN: Council of Nurses
CPDP: Council of Physicians, Dentists and Pharmacists
MC: Multidisciplinary Council
FRQ: Fonds de Recherche du Québec
MEL: Evaluation-Liaison Module
RAMQ: Régie de l'Assurance Maladie du Québec
SIS: Système Informatisé Signature
SSL: Secure Sockets Layer

SOME PRELIMINARY DEFINITIONS

- **BIOMARKER:** Biomarkers are biological molecules found in blood, bodily fluids and organic tissue. Biomarkers may indicate normal or abnormal processes and the presence of a disorder or disease.

- **BIOSPECIMEN:** A sample of blood, bodily fluid or organic tissue.

- **CLINICIAN:** In the following document, the term “clinician” includes all professional staff on treatment teams with access to users’ medical files.

- **RAW DATA:** *Raw data* represents the individual responses to each of the psychosocial signature questionnaires filled out by participants.

- **AGGREGATE DATA:** *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 graphic form.¹

- **PARTICIPANT:** In the following document, this term refers to patients using Institut universitaire en santé mentale de Montréal’s health care services who have agreed to participate in the Signature Bank as a research subject.

¹ Some examples of aggregate data represented in graphic form are provided in Appendix H.
The present management framework is intended to explain the rules and procedures governing the operation of the signature medical/psychosocial data and human biological materials bank. It also states the principles guiding the signature bank’s use and describes the general mandate of the bank, which focuses on Institut universitaire en santé mentale de Montréal patients.²

1. GENERAL DEFINITION OF A DATA AND HUMAN BIOLOGICAL MATERIALS BANK

A data and biological materials bank is a technical and administrative infrastructure in which the following are stored and preserved:

1. human biological material (tissue, blood, etc.)
2. donors’ personal information.

2. PRINCIPLES AND OBJECTIVES OF THE SIGNATURE PSYCHOSOCIAL/MEDICAL DATA AND HUMAN BIOLOGICAL MATERIALS BANK

2.1. ETHICAL PRINCIPLES OF THE SIGNATURE BANK

The first principle of the Signature Bank is the principle of benefiting people—i.e., it aims to promote the health of Institut universitaire en santé mentale de Montréal patients. This principle impacts patients through advances in research and prevention and the continuous improvement of care quality.

The second principle of the Signature Bank is to encourage mental health research in the areas of care, prevention and basic research for the benefit of Institut universitaire en santé mentale de Montréal patients suffering from mental illness.

The third principle of the Signature Bank is to serve as a tool that will enable clinicians³ to improve medical management, intervention and care for Institut universitaire en santé mentale de Montréal patients. The improved intervention and care may then serve as best practices for other fields of psychiatric care.

2.2. OBJECTIVES OF THE SIGNATURE BANK

On the one hand, the Bank aims to collect medical and psychosocial data on participants⁴ from Institut universitaire en santé mentale de Montréal. (The list of requested information is detailed in Appendix A).

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² This is what distinguishes it from a biobank.
³ See definition on p. 4.
⁴ See definition on p. 4.
On the other hand, the Bank aims to collect *human biological materials* from the same hospital participants. (The list of requested human biological materials is detailed in Appendix B.)

The Bank will enable greater use of medical and psychosocial data in combination with human biological materials for the following purposes:

- Developing mental health research in terms of its psychosocial and biological aspects as well as its medical aspects;
- Helping clinicians to improve the care provided to Institut universitaire en santé mentale de Montréal patients as well as the care provided in the general mental health field;
- Facilitating Institut universitaire en santé mentale de Montréal participants’ involvement in their treatment and care—e.g., by making aggregate data available to the treatment team.
- Promoting knowledge transfer between clinicians and patients. Encouraging collaboration with patients based on the results of research derived from the Signature Bank—e.g., through the use of innovative research tools such as the iPad.

### 3. GOVERNANCE MECHANISMS

#### 3.1. HISTORY AND DESCRIPTION OF THE SIGNATURE BANK

When it comes to mental health research in Canada, the Signature Bank project builds on the “decade of the brain.” During this period, the development of basic research laid the groundwork for improved prevention and treatment of mental illness, which the governments of Quebec and Canada wish to make a priority. Mental illness is a significant social issue: it affects one Canadian in five over the course of his life, and mental health-related spending (over C$8 billion) is increasing. Now, the “decade of the patient” has begun with a focus on applied mental health research. The Signature Bank is aligned with this vision. The project aims to build bridges between basic research and applied research on the one hand and between applied research and clinical practice on the other. It provides an innovative approach—e.g., collecting data using iPads—in order to facilitate the systematic quantifying of patients’ mental and physical conditions at key moments during crisis periods, treatment or prevention. The reason for this pooling of information is to better customize medication and intervention as well as to better document clinical decisions based on scientific data.

The Signature Bank is therefore designed to systematically amass a vast collection of “signatures”—biological, psychosocial and clinical indicators—from volunteer participants who are patients of Institut universitaire en santé mentale de Montréal. The project involves collecting data each time a patient is observed, at critical moments before, during and after hospitalizations (including management by outpatient clinics). All of this data can be used for research projects on the population as a whole or specific subgroups. Psychiatrists will be able to access data in real time, while other clinicians on the treatment team will be able to rapidly retrieve it from medical files. The goal is optimal use of research data to promote better clinical practices.
Over the course of a lengthy process, a team of more than 80 people, comprising clinicians, researchers and international specialists, was consulted for the purpose of:

- Determining the best biomarkers to study in order to understand the mechanisms at the root of human mental disorders.

The biological element consists of biomarkers obtained from blood, hair and saliva specimens. However, only a minority of these biomarkers will be analyzed immediately; most specimens will be stored at -80°C in freezers located in the Centre Signature at the Institut universitaire en santé mentale de Montréal’s Pavillon Fernand-Seguin for the purpose of future analysis.

- Identifying the best psychological and social measures to obtain in order to better understand the psychological and social aspects of mental illness.

These measures can provide a comprehensive snapshot of the participant's emotional well-being and mental state, as well as capturing other characteristics related to mental health, such as lifestyle habits, sleep patterns and socio-demographic background.

- Identifying the best methods for the tests to be conducted within Institut universitaire en santé mentale de Montréal's clinical populations (e.g., optimal moments for testing and taking samples, number of measures, etc.).

This kind of project is not possible without the active participation of clinicians and, most importantly, patients. In order to promote research subjects' active participation in the project, a customized iPad application was developed. It was tested by means of a pilot project in 2010 with 120 patients in order to ensure its technical viability and suitable conditions for obtaining consent from patients asked to participate in the research (e.g., informing them via video).

As part of the Signature Bank’s implementation, participants will use an iPad to watch a video explaining the project as a whole and the terms of their involvement. They will then be able to sign a consent form, following which they will complete a series of self-assessments. The collected psychosocial signature data will then be transferred in anonymized form to a centralized database. Researchers and clinicians interested in accessing the database for research purposes will submit a data access request, which will be reviewed by the Scientific Evaluation Committee and Research Ethics Committee.

The data obtained also has the potential to provide direct clinical benefits: psychiatrists (and other clinicians) will have access to a summary of participants’ scores on the various psychosocial questionnaires. Based on their clinical judgment, psychiatrists will therefore be able to use participants’ aggregate data to complete their clinical evaluation or discuss it with them. For example, once several signatures have been collected, they will be able to visually portray participants’ clinical evolution. Aggregate data reports kept in a participant's medical file will also include the following official disclaimers:

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5 See definition on p. 4.

6 On May 6, 2011, it was decided during a departmental retreat that Institut universitaire en santé mentale de Montréal’s Psychiatry Department would support the Signature Bank project and, by extension, that psychiatrists would take part in it.

7 See Section 4.3.2, Use of Data.

8 See definition on p. 4.
1) In accordance with existing professional codes of ethics, under no circumstances whatsoever may data from the Signature Bank be used or interpreted for diagnostic or therapeutic purposes except by those with the necessary professional qualifications. These assessment tools are not a valid substitute for a clinician’s judgment. They represent one source of information among many that may offer avenues for reflection and observation or enable the validation of hypotheses over time.11

2) Research data has no legal bearing on clinical practice.

The Signature Bank therefore offers patients the possibility of actively participating in research that could potentially have an impact on their own care.

Figure 1 below presents a diagram showing the transfer of data to the Signature Bank database and the transfer of average scores on psychosocial scales to the attending physician.

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9 Research data has no legal bearing on the clinical practice of psychiatrists and other clinicians. The American Psychiatric Association has adopted the following position: “This practice guideline is based on available evidence and clinical consensus and offers recommendations to help psychiatrists in assessing and treating adult patients with suicidal behaviors. This report is not intended to be construed or to serve as a standard of medical care. Standards of medical care are determined on the basis of all clinical data available for an individual patient and are subject to change as scientific knowledge and technology advance and practice patterns evolve. These parameters of practice should be considered guidelines only. Adherence to them will not ensure a successful outcome for every individual, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care aimed at the same results. The ultimate judgment regarding a particular clinical procedure or treatment plan must be made by the psychiatrist in light of the clinical data presented by the patient and the diagnostic and treatment options available.” (Practice Guideline for the Assessment and Treatment of Patients with Suicidal Behaviors).

10 During the first three years of the Signature Bank’s existence, the Bank’s team is committed to conducting surveys in order to identify and document the actual benefits of including aggregate data in participants’ medical files, for the purpose of demonstrating the clinical contribution provided by this innovative aspect of the project.

11 While researchers are not responsible for the accurate interpretation of research data by clinicians, the Research Ethics Committee emphasizes that professional discipline leaders and administrative managers of clinical departments should make sure that the relevant professional staff are reminded of this fact.
While self-reported questionnaires have indisputable benefits with respect to the various psychological dimensions experienced by participants, patients are clearly not in a position to self-report their psychiatric diagnosis and may not always be able to adequately report the various medications prescribed to them. What’s more, a large number of people suffering from psychiatric disorders have other chronic disorders as well, and it may be difficult for some patients to recall all of the medical conditions with which they have been diagnosed during previous years.

For the purpose of obtaining this key information, it is therefore appropriate to use additional methods that make it possible to validate information via multiple sources. On the one hand, the Signature Bank will obtain information relating to participants’ diagnosis and psychiatric medication from their attending psychiatrist. Meanwhile, a request will be made to the Commission d’Accès à l’Information du Québec (CAI) and the Régie de l’Assurance Maladie du Québec (RAMQ) each year for all participants who took part in the Signature project during the previous 12 months. The following information will be requested for the preceding two-year period with the aim of fully understanding all the chronic diseases from which participants are suffering: past and present mental and physical illnesses; medications prescribed for past and present mental and physical illnesses; medical complications; and causes of death. This information request will serve to confirm the diagnoses obtained from participating psychiatrists while also contributing to making better diagnostic assessments based on all available medical information and to identifying physical disorders whose presence may be linked to mental disorders.
3.2. SUPERVISING ORGANIZATION AND ADMINISTRATIVE STRUCTURE

The Signature Data and Biological Materials Bank has been an integral part of Institut universitaire en santé mentale de Montréal’s strategic planning since 2009 and is the institution’s responsibility.

The project was approved and ratified by Institut universitaire en santé mentale de Montréal’s Board of Directors on October 23, 2012.

While the Signature Bank is the institution’s responsibility, the IUSMM Research Centre’s senior management (or designated representatives) and the Research Ethics Committee must be formally consulted regarding any changes to the organizational structure, the cessation or resumption of activities, the preservation or destruction of data and any other ethics-related matters.

Any changes to the project’s organizational structure must then be presented to the institution for final approval.

Due to this administrative structure, all data and biological materials contained in the Signature Bank belong to the institution, which ensures that the project is managed properly. In the event of a cessation in the Signature Data and Biological Materials Bank’s activities, all its contents become the responsibility of the institution, which may then decide on the Bank’s future by choosing to resume its activities or to either preserve or destroy the data.

Responsibility for managing the Signature Bank lies with the senior management of Institut universitaire en santé mentale de Montréal’s Research Centre.

3.3. FUNDING

Initial funding for the Signature Data and Biological Materials Bank is provided by the Institut, the Institut Fondation and the IUSMM Research Centre, while additional funding will be generated over time by the fees for accessing data and biological materials requested by researchers using the Bank. The ultimate goal is for the Signature Bank to be self-financing. The Coordinating Committee\(^\text{12}\) must make sure that any profits generated will be first used to create a reserve fund of $500,000 which will ensure the Bank’s long-term survival. This reserve fund must be used to support the inherent costs of maintaining the Bank and acquiring new equipment.

The Signature Bank therefore has no commercial or profit-making goals. It is for use by researchers, with priority given to those at Institut universitaire en santé mentale de Montréal.

The Research Centre’s senior management is committed to pursuing any possible grants that would increase the Signature Bank’s funding in order to support its ongoing management and the development of its infrastructure.

3.4. STRUCTURE OF THE BANK

The Signature Data and Biological Materials Bank is guided by a Coordinating Committee. This Committee is integrated into the institution’s organizational structure. It reports to the IUSMM Research Centre’s Executive Committee, which in turn reports to the Executive

\(^{12}\) See Section 3.4, Structure of the Bank.
Management of Institut universitaire en santé mentale de Montréal. The Executive Management itself falls under the authority of Institut universitaire en santé mentale de Montréal’s Board of Directors.

The Coordinating Committee works with the Management Committee, which is responsible for supervising the proper functioning of the Signature Bank in the various hospital units targeted by the project with respect to taking biological, psychosocial and medical measurements.

The Coordinating Committee makes sure that research projects are reviewed by the Scientific Evaluation Committee, which reports to the IUSMM Research Centre’s senior management, and by Institut universitaire en santé mentale de Montréal’s Research Ethics Committee, which reports to the hospital’s Board of Directors.
FIGURE 2
Signature bank organizational chart / governance structure
3.4.1. The Management Committee

The Signature Bank Management Committee is responsible for seeing to the proper day-to-day functioning of the Signature Bank with respect to the taking of biological, psychosocial and medical measurements and the management of data and biological materials. It ensures the proper functioning of the Signature Bank in the various hospital units where measurements are taken and resolves internal Signature Bank management issues at the operational level. All problems raised within the Management Committee are conveyed to the Coordinating Committee via the Bank coordinator, who sits on both the Signature Bank’s Management Committee and Coordinating Committee. The Management Committee meets on a monthly basis to discuss the Signature Bank’s management. As part of its functions, the Committee must regularly consult with groups/individuals who are impacted by changes it makes to the Bank’s direction or the technical and administrative processes involved in its operation. Examples of groups/individuals who could be consulted when needed include the users committee, professional associations and orders, the person in charge of protecting the privacy of personal information, the Public Trustee, the Research Ethics Committee and managers (especially the clinical and administrative heads) of programs related to the hospital units involved in the project.

THE MANAGEMENT COMMITTEE COMPRIZES:

- the Bank coordinator
- the data management technician
- the biospecimen management technician
- research nurses
- research technicians

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Bank Coordinator

The coordinator is appointed by the Scientific Director of the research centre with an initial mandate of four (4) years and reports to the direction committee of the IUSM Research Centre. His role is to ensure the proper management of the Signature Bank’s data and biological materials as well as access requests for said data and biological materials. He serves as an intermediary between the various parties involved (researchers, clinicians/users, scientific director, Scientific Evaluation Committee members, data management and biological material management technicians).

One of his primary responsibilities is the preliminary evaluation of access requests for data and biological materials. In this capacity, he receives access requests from researchers and clinicians and informs them of the data or materials’ availability, the amount of data available and the potential existence of similar requests.

With respect to access requests for non-analyzed biological materials, the Bank coordinator ensures that the access request involves the selected biomarkers described in Appendix B of this document. If the coordinator discovers that an access request overlaps with another request, he will inform the researchers involved with the goal of enabling them to collaborate on accessing data or biological materials.
The Bank coordinator is also responsible for keeping an inventory, which includes a complete
list of the raw data and biospecimens, as well as their availability (the amount of available data
and the dates they were received by the Bank). This inventory is updated on a monthly basis,
and a quarterly update is submitted to the Coordinating Committee and then posted on the
website as an inventory of the available data.

The Bank coordinator is also responsible for maintaining a log that keeps track of access
requests. This log will help make it possible to follow and manage each access request,
ensure compliance with the terms of use described in the management framework (data
exclusivity period, provision of results by end of grant period, etc.) and cross-reference
requests to avoid overlap between different research projects. A quarterly document listing
the approved access requests from the previous three months is submitted to the
Coordinating Committee.

Finally, the Bank coordinator is responsible for ensuring the appropriate operation of the
Signature Bank in accordance with the management framework and specified ethical
regulations. In this regard, he is the only person other than the database management
technician with access to the source code linking study participants’ demographic information
to their anonymized code.

Daniel Management Technician

The database management technician is appointed by the Scientific Director of the research
centre with an initial mandate of four (4) years and reports to the Bank coordinator and the
direction committee of the research centre. His role is to ensure the confidentiality of data stored
in the Signature database. He works in tandem with the Bank coordinator and informs him of the
available data when data access requests are received. He is the only person (other than the
Bank coordinator) with access to the source code linking study participants’ demographic
information to their anonymized code. He serves as a technical resource person for
researchers/users and liaises between the various parties (nurses, biospecimen technicians,
research technicians) involved in the medical and psychosocial data collection process. He
supplies data to researchers whose research projects have been approved by the Scientific
Evaluation Committee and Research Ethics Committee.

 Biospecimen Management Technician

The biospecimen management technician is appointed by the Scientific Director of the research
centre with an initial mandate of four (4) years and reports to the Bank coordinator and the
Direction committee of the research centre. His role is to ensure the confidentiality of biospecimens stored in the Signature Bank. He works in tandem with the Bank coordinator to inform him of the available biospecimens when biospecimen access requests are received. He is in charge of the technical team that collects and stores the biospecimens. He oversees the appropriate management and preservation of biospecimens and liaises between the various parties (research nurses, clinical nurses, research technicians) involved in the biospecimen collection process.

In the event of the Bank coordinator and database management technician becoming simultaneously unavailable for a period of time (for whatever reason), a copy of the source code (kept in a sealed envelope inside a safe) may be retrieved by Institut universitaire en santé mentale de Montréal’s director general, who must first sign a register (for which the head of medical archives is responsible) and indicate the date and reason for accessing it.

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13 In the event of the Bank coordinator and database management technician becoming simultaneously unavailable for a period of time (for whatever reason), a copy of the source code (kept in a sealed envelope inside a safe) may be retrieved by Institut universitaire en santé mentale de Montréal’s director general, who must first sign a register (for which the head of medical archives is responsible) and indicate the date and reason for accessing it.
Research Nurses

Research nurses are appointed by the Scientific Director of the research centre and report to the Bank coordinator and direction committee of the research centre. Research nurses obtain the psychiatrist or treatment team’s opinion on patients’ capacity to consent to participate in the project. They inform patients of the project, explain it to them and have them sign the consent form. They make notes in participants’ files regarding their participation in the Signature Bank. They arrange and conduct follow-up of participants with the relevant personnel for the various tests and samples taken at different points. They help participants with tests completed using the iPad, schedule sample appointments and take biospecimen samples (blood, hair and saliva) according to the various predetermined measurement points. Research nurses are responsible for informing the Management Committee of any problems encountered during testing and sample-taking. The Bank coordinator informs the Coordinating Committee of any problems that may require changes to the measurement protocol.

Research Technicians

Research technicians are appointed by the Scientific Director of the research centre and report to the Bank coordinator and direction committee of the research centre, and work under the supervision of the biospecimen management technician. Research technicians prepare biospecimen sample materials in collaboration with research nurses. They also handle the labelling of secondary tubes when stabilizing biological specimens prior to storing them. They order the required materials and, in collaboration with research nurses, handle the shipping of sample materials and biospecimens to the Signature Centre. Research technicians inform the Management Committee of any problems encountered when obtaining biospecimens. The Bank coordinator then informs the Coordinating Committee of any problems that may require changes to the measurement protocol.

3.4.2. Coordinating Committee

The Signature Bank Coordinating Committee is responsible for coordinating the Signature Bank’s various resources—i.e., data collection personnel (research nurses and technicians) and Signature Bank management technicians—as well as coordinating with the various bodies involved in approving data and biospecimen access requests (i.e., the Scientific Evaluation Committee and Research Ethics Committee).

The Coordinating Committee sees to it that the Signature Bank is run properly by ensuring the integration of the various parties involved. It is also the body tasked with receiving, handling and making an initial attempt to resolve any dispute or complaint concerning access requests for data or biological materials.

The Coordinating Committee ensures that individuals specializing in the three types of signature (biological, psychological and social) are equally represented on the Scientific Evaluation Committee in order to provide objective, balanced evaluations of access requests for data or biological materials.

The Coordinating Committee validates the annual report produced by the Bank coordinator before handing it over to the Executive Management, which submits it to Institut universitaire en santé mentale de Montréal's Board of Directors. The annual report provides a progress report on data collection activities, the number of access requests and publications arising from Signature Bank-related research.
The Coordinating Committee evaluates any requests for changes to the Signature Bank (modifying the Bank’s structure, expanding its operations to include other programs or institutions, adopting new directions arising, for example, from recent scientific discoveries, etc.) proposed by the IUSMM Research Centre’s senior management. When the requested change is deemed beneficial by the Coordinating Committee, it must then, if necessary, be presented to the Scientific Evaluation Committee and Research Ethics Committee before being presented to the institution for final evaluation and approval.

The Coordinating Committee meets every two (2) months to discuss the Signature Bank’s management.

THE COORDINATING COMMITTEE COMPRISES:

- the IUSMM Research Centre’s scientific director
- the director of clinical research
- the Bank coordinator
- a clinical psychiatrist
- a representative of other clinical professions
- a representative of nurses
- a researcher
- a secretary

The various representatives sitting on the Coordinating Committee are appointed for an initial mandate of four (4) years. The Coordinating Committee may also request the attendance of other resource persons—such as hospital administrators, a patient representative, etc.—on an ad hoc basis, when required, in order to examine a specific problem related to the successful running of the project in the designated Institut units.

Institut’s Research Centre Director

The scientific director of the IUSMM Research Centre chairs the Signature Bank’s Coordinating Committee. He serves as the Coordinating Committee’s representative with respect to the IUSMM Research Centre’s Executive Committee, Institut universitaire en santé mentale de Montréal’s Executive Committee and IUSMM’s Board of Directors. He receives the Management Committee’s reports via the Bank coordinator and sets the agenda for meetings aimed at addressing problems raised by the Management Committee. The Research Centre’s scientific director may exercise veto power during Coordinating Committee votes if he believes that the Committee’s decisions are not aligned with the Bank’s mission or management framework. He is also responsible for asking the Research Ethics Committee and Scientific Evaluation Committee to form an Ad Hoc Committee to handle any dispute or complaint unable to be handled or resolved to the satisfaction of all concerned parties by the Coordinating Committee.
Clinical Research Director

The IUSMM Research Centre’s clinical research director informs the committee members about clinical problems related to the Signature Bank which are reported during Institut universitaire en santé mentale de Montréal psychiatry department meetings or Council of Physicians, Dentists and Pharmacists (CPDP) meetings attended by the clinical research director.

The Coordinating Committee suggests ways of resolving these problems by communicating directly with either hospital clinicians or, if the problem relates to the current management of the Signature Bank, the Management Committee. The clinical research director reports the Committee’s conclusions to Institut universitaire en santé mentale de Montréal’s psychiatrists and clinicians.

The Bank Coordinator

The Signature Bank coordinator informs members of problems related to the Signature Bank’s management that are reported during Signature Bank Management Committee meetings. The Bank coordinator serves as the Management Committee’s representative on the Coordinating Committee. The Bank coordinator reports the Coordinating Committee’s conclusions to the Signature Bank’s Management Committee.

The coordinator receives any complaints from researchers or clinicians relating to problems with access to data or biological materials and informs the Coordinating Committee about them.

The Bank coordinator produces an annual report that is validated by the Coordinating Committee before being handed over to the Executive Management, which submits it to Institut universitaire en santé mentale de Montréal’s Board of Directors. The annual report provides a progress report on data collection activities, the number of access requests and publications arising from Signature Bank-related research.

Once per quarter, the Bank coordinator provides a written update on the Signature Bank’s state of progress (new data obtained during the past quarter, problems with specific tests, etc.) to the members of the Scientific Evaluation Committee in order to help them evaluate access requests. At the request of the Research Ethics Committee, the Bank coordinator also supplies relevant information about research projects for the purposes of the report that the Committee must submit to the Ministère de la Santé et des Services Sociaux.

Clinical Psychiatrist

The clinical psychiatrist is appointed by IUSMM's Executive Committee, based on the recommendation of the psychiatry department head, in order to represent clinical psychiatrists on the Coordinating Committee. The clinical psychiatrist ensures that the clinical aspects of the Signature Bank are presented to and discussed by the Coordinating Committee and that clinical issues related to the project receive their due recognition within the Committee. The clinical psychiatrist also supports the Coordinating Committee with respect to the provision of clinical information in order to help members understand the clinical realities of the hospital when related questions are raised.
Representative of Other Clinical Professionals and Nurses’ Representative

These representatives are appointed by Institut universitaire en santé mentale de Montréal’s Multidisciplinary Council (MC) and Council of Nurses (CN) to represent other professionals involved in the interdisciplinary clinical management of Institute patients. Like the clinical psychiatrist, they ensure that clinical aspects of the Signature Bank are presented to and discussed by the Coordinating Committee and that clinical issues related to the project receive their due recognition within the Committee. These representatives also support the Coordinating Committee with respect to the provision of clinical information in order to help members understand the clinical realities of the hospital when related questions are raised.

Researcher

The researcher is appointed by the IUSMM Research Centre’s Executive Committee to represent researchers on the Coordinating Committee. The researcher ensures that the Signature Bank’s scientific aspects and research problems are presented to and discussed by the Coordinating Committee and that research issues related to the project receive their due recognition within the Committee. The researcher also supports the Coordinating Committee with respect to the provision of scientific information in order to help members understand aspects of the project involving scientific protocols when related questions are raised.

Secretary

The secretary reports to the Bank coordinator and the scientific director of the research centre. She organizes Coordinating Committee meetings, takes the minutes of these meetings and prepares documents arising as a result of the meetings and Coordinating Committee decisions.

The secretary organizes all Ad Hoc Committee meetings called by the Coordinating Committee and takes the minutes.

3.4.3. The Scientific Evaluation Committee

The mission of the Scientific Evaluation Committee is to conduct scientific reviews of all research projects involving an access request for Signature Bank data or biological materials. The Committee reports to the IUSMM Research Centre’s Executive Committee. The three (3) types of signature in the Bank (biological, psychological and social) must be equally represented by specialized researchers on the Scientific Evaluation Committee.
THE SCIENTIFIC EVALUATION COMMITTEE COMPRISSES:

- the chair
- three experienced researchers with up-to-date expertise in one of the Signature Bank’s three major focal areas (biological, psychological and social signatures) who serve as regular members of the Scientific Evaluation Committee
- a secretary

⇒ Chair

The chair is appointed by the IUSMM Research Centre’s Executive Committee with a renewable mandate of two (2) years. The chair of the Scientific Evaluation Committee is a senior researcher who has an exceptional background in scientific research and has demonstrated significant leadership in the Quebec research field. This researcher may be from the IUSMM Research Centre or from any other research centre affiliated with the Fonds de Recherche Santé Québec (FRQ-S).

The chair ensures that the committee members have the expertise required to review research projects involving an access request for Signature Bank data or biological materials. He ensures that projects have received initial approval from the Bank coordinator with respect to the availability of the requested data or biological materials and the absence of overlapping requests. As such, he ensures that committee members receive the quarterly updates from the Bank coordinator.

In cases where a research project review involves a conflict of interest (e.g., one of the Scientific Evaluation Committee members makes a data access request), the chair replaces the relevant member with another researcher from the IUSMM Research Centre with similar expertise. If none of the regular researchers on the Scientific Evaluation Committee have the expertise required to evaluate a specific research project, the chair requests outside input from a non-member. Finally, the chair provides researchers with a written report evaluating their research project.

⇒ Researchers

The researchers on the Scientific Evaluation Committee are recommended by the Scientific Evaluation Committee chair and presented to the IUSMM Research Centre’s Executive Committee for final approval. The mandate of the Scientific Evaluation Committee researchers is to evaluate research projects involving a request to access Signature Bank data or biological materials. In this regard, they are highly familiar with the Signature Bank database and biological materials and keep up to date with its development based on the quarterly reports provided by the Bank coordinator. The researchers provide their evaluation reports as a plenary committee. The researcher members of the Scientific Evaluation Committee have a renewable mandate of two (2) years.

⇒ Secretary

The secretary is shared by the Scientific Evaluation Committee and Research Ethics Committee. With respect to her duties on the Scientific Evaluation Committee, she reports to the chair of the Scientific Evaluation Committee. She organizes Committee meetings, takes the minutes of these meetings and prepares documents arising as a result of the meetings and Committee decisions.
3.4.4. The Research Ethics Committee

As with any other institutional database, the Research Ethics Committee plays a double role in the context of the Signature Bank—namely, to ensure that the Bank’s management framework complies with ethical regulations and that these regulations are properly respected when it comes to the framework’s practical application. As a result, the Research Ethics Committee must carry out whatever ethical supervision it deems necessary, as with any other project, in accordance with the responsibilities entrusted to it by government authorities. It is recommended that two (2) meetings per year be held with the Signature team to monitor the work’s progress. Therefore, the first meeting could take place six (6) months after the project’s launch and the second meeting at the end of the project’s first year.

What’s more, the Research Ethics Committee will evaluate submitted research projects involving an access request for Signature Bank data or biological materials after they have been approved by the Scientific Evaluation Committee, in the same manner as any other project that falls under its jurisdiction.

In cases where the submitted research requires comprehensive expertise in a specific field for which none of the regular members possesses relevant, in-depth knowledge, the Research Ethics Committee may—and should—add an individual with the required expertise in order to enable it to make an informed decision. It is therefore incumbent upon the Research Ethics Committee to seek additional expertise on an ad hoc basis when needed for the analysis of a particular research project.

3.4.5. The Ad Hoc Dispute Resolution Committee

The Ad Hoc Dispute Resolution Committee is a body that is formed each time it becomes necessary to do so. Any complaints from researchers or clinicians concerning problems with accessing data or biological materials from the Signature Bank must first be addressed in writing to the Bank coordinator, who informs the Coordinating Committee. If a complaint is maintained or a dispute is not resolved, despite being reviewed and handled by the Coordinating Committee, the complaint must then be addressed in writing to the senior management of the IUSMM Research Centre, which will then ask the Research Ethics Committee and Scientific Evaluation Committee to jointly appoint the members of the Ad Hoc Committee tasked with reviewing and handling the dispute or complaint.

The Ad Hoc Committee must be comprised of three (3) or more members, depending on the specific nature of the complaint or dispute, including a representative of the Signature Bank Coordinating Committee, a representative of the Research Ethics Committee and a representative of the Scientific Evaluation Committee, as well as any other internal and/or external individual whose expertise is deemed relevant by the REC or SEC in order to ensure impartial, objective analysis and handling of the complaint or dispute.

Chairing of the Ad Hoc Committee will be handled by the representative of the Research Ethics Committee. The Ad Hoc Committee must be formed, analyze the complaint or dispute and render its decision (in the case of a dispute) or make its recommendation (in the case of a complaint) in writing within a period of at most three (3) months.

The data or biological materials that are under dispute or related to the complaint shall be placed in quarantine during this period—i.e., they cannot be subject to other access requests as long as the complaint or dispute is under review.
4. MEANS OF IMPLEMENTATION

4.1. USER CONSENT TO BECOME RESEARCH SUBJECTS

✓ Recruitment and Eligibility Criteria

It is possible for any user of Institut universitaire en santé mentale de Montréal’s clinical services (including the hospital’s outpatient clinics) to participate in the Signature Data and Biological Materials Bank. Study participants will be recruited when they are admitted to Institut universitaire en santé mentale de Montréal’s emergency department or inpatient unit, when they are transferred to a hospital outpatient clinic or when they present directly at an outpatient clinic from the evaluation-liaison module (MEL).

✓ Participant Consent in the Unique Context of a Psychiatric Hospital

In the psychiatric field, obtaining patient consent for a research project is a process that must be handled in a balanced way. Some patients are incapable of providing consent due to the stage of their illness while some are perfectly capable of providing consent despite their mental illness; in others, the capacity to consent varies depending on their current state. The capacity to consent is a continuum rather than a black-or-white scenario. The patients treated in a psychiatric hospital have differing degrees of risk based on their mental illness; any research project must therefore take this into account both in its eligibility criteria and its implementation.

As a general rule, it is necessary to ensure that one has the practical means to verify the capacity to consent of patients who are potential participants. The attending psychiatrist and research nurse are the key people in this process. The psychiatrist (who may also delegate this responsibility to other professionals on the clinical treatment team) first verifies that the patient is in a suitable condition to meet with the research nurse. The latter then definitively determines the patient’s capacity to consent to the Signature project in a free and informed manner, after describing the project to him and answering any questions. At each new measurement stage, in order to ensure the patient’s continued consent, the research nurse verbally confirms that he still agrees to participate in the project and reiterates that he has the option of withdrawing at any time.

The Signature Data and Biological Materials Bank received approval from Institut universitaire en santé mentale de Montréal’s Research Ethics Committee on September 26, 2012. This is another mechanism for ensuring that the conditions under which hospital patients consent to participate in the Signature Bank are appropriate from an ethical perspective. There are two key ethical arguments weighing in favour of the Signature Bank: on the one hand, there are the potential individual benefits for the patient’s treatment as well as the potential collective benefits for all hospital patients; on the other hand, there are the minimal risks involved and the implementation of appropriate measures to ensure the confidentiality of collected data.

In Appendix C you will find the information and consent form approved by the Research Ethics Committee on September 26, 2012. This form explains the objectives and functioning of the Signature Bank as well as the practical terms of participation, thereby helping patients to make an informed decision. This information is also available in video form for viewing on an iPad to facilitate patients’ comprehension.
There are three more complex situations which may arise:

1) The first involves the consent of a user whose mental state dictates that he cannot provide consent while in an acute stage of his illness but who will recover his capacity after the current stage has passed. In this situation, it is not possible to take measurements and biological materials during the period of temporary incapacity, except where already scheduled as part of clinical care (e.g., blood samples).\(^\text{14}\) Biospecimens collected at this time will be preserved but not processed\(^\text{15}\) until the user has recovered the capacity to consent. In the event that the user does not give his consent once capable of doing so, the collected biospecimens will be destroyed after a period of quarantine.\(^\text{1}\)

2) A “Ulysses contract” procedure has been put in place for patients who have already consented to participate in the Signature Bank in the event of a future relapse and temporary period of incapacity.\(^\text{17}\) This procedure makes it possible for the patient to continue participating in the Signature Bank project, at least with regard to the taking of biological material samples, if circumstances permit and the attending psychiatrist agrees (see consent form in Appendix C). The patient’s participation must be suspended, as stipulated by law (art. 16, CCQ) if he categorically refuses to have samples of biological materials (other than blood) or measurements taken; in such a case, it is legally impossible for the research team to continue even if the patient’s future consent is anticipated. In all other cases, only biological measurements will be obtained from the patient, given that it is impossible for him to respond to questionnaires due to his mental condition. As soon as he has regained his capacity, the patient will have the opportunity to reiterate his consent in order to continue taking part or to instead withdraw and even request the destruction of the relevant data.

3) The third situation involves incapable patients under protective supervision and incapable patients not under protective supervision. In view of the principles of equality, it would be unfair if these patients did not also benefit from data that could help with their treatment. Article 21 of the Civil Code of Quebec opens the way for their participation by making it possible to support these higher-risk populations while also protecting them from discrimination.

\(^{14}\) In this regard, the Research Ethics Committee agrees that slightly more blood than is normally required may be taken for strictly clinical purposes, since this does not represent an added procedure. It simply involves taking a little more blood—i.e., 2.5 tbsp—without performing any added procedures for the future needs of the Signature Bank, conditional upon the patient’s future consent.

\(^{15}\) The exception is metabolic biomarkers, which must be analyzed within the following hours or risk being lost and which are also of considerable clinical interest.

\(^{16}\) In the case of users who, after regaining their capacity, refuse to participate in the study and ask that their data be withdrawn from the database, the “quarantine” clause involves retaining their data for 30 days in the event that they change their opinion during this time. The justification for this clause is based on the practical experiences of research nurses, who have observed many instances where users wish to change their minds about a decision and are disappointed to discover that it is unfortunately too late to do so, since their data has already been destroyed. At the end of the 30-day period, the Signature team will not exert any pressure on users based on whether they wish to maintain their initial refusal or agree to have their data placed in the database. The decision they take must be noted in their file, and no justification for it may be requested from the user.

\(^{17}\) The attending physician of a user undergoing a crisis may not, under any circumstances, consent on the user’s behalf.
ARTICLE 21

✓ Paragraph 1

“A minor or a person of full age who is incapable of giving consent may not be submitted to an experiment if the experiment involves serious risk to his health or, where he understands the nature and consequences of the experiment, if he objects.”

✓ Paragraph 2

“Moreover, a minor or person of full age who is incapable of giving consent may be submitted to an experiment only if, where the person is the only subject of the experiment, it has the potential to produce benefit to the person’s health or only if, in the case of an experiment on a group, it has the potential to produce results capable of conferring benefit to other persons in the same age category or having the same disease or handicap. Such an experiment must be part of a research project approved and monitored by an ethics committee. The competent ethics committees are formed by the Minister of Health and Social Services or designated by that Minister among existing research ethics committees; the composition and operating conditions of the committees are determined by the Minister and published in the Gazette officielle du Québec.”

In the case of an incapable person of full age under protective supervision, the proxy, guardian or trustee named for him by the court may represent the patient (legal representation) and provide substitute consent. In the case of incapable individuals without legal protective supervision (i.e., assigned by the court), they may be represented by a civil union or de facto spouse or, if there is no spouse and/or there are impediments to obtaining the latter’s consent, by a close relative or other individual with a special interest in the patient, in accordance with the conditions for substitute consent to care stipulated in the Civil Code of Quebec.

4.2. CONFIDENTIALITY MEASURES

Participants’ biological material samples and medical/psychosocial data will be stored in a strictly confidential manner. To this end, data will be denominalized.

The denominalization process involves replacing identified, personal information—e.g., surname, given name, alphanumerical coordinates or ID such as medicare number comprised of the patient’s initials and date of birth—using a simple algorithm. The sensitive nature of Signature Bank data must be weighed against the importance of being able to contact participants again in future. As a result, the database management technician maintains and has secure access to a confidential list (along with the coding key and computer passwords) that links personal information with the associated code. This list will never be shared with researchers using the Bank. The only other person who may access it is the Bank coordinator. All data and biological materials from the Bank will be given to researchers in denominalized form.

4.2.1. Data Storage (Withdrawal, Destruction)

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. Participants may withdraw from the Signature Bank at any time simply by giving verbal
notice. They may also request in writing that data and biological materials pertaining to them be destroyed. When such a request is made, the database management technician must place the participant’s data and biological materials in quarantine\textsuperscript{18} 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 denominalized data has been aggregated with other data and provided to one or more researchers for an analysis or publication, it is impossible to withdraw the data from that particular analysis or publication, since it has already been anonymized.

\section*{4.2.2 Physical and Computer Security Measures}

\subsection*{Psychosocial and Medical Data Self-Reported by Participants}

In order to ensure the confidentiality of data, all psychosocial and medical data will be obtained by means of an IT tool, the Système Informatisé Signature (SIS). Participants will access a secure SIS website containing the questionnaires via which they will input data.

To reach the questionnaire website, they must identify themselves to the system by using an access code and personal password. Other security measures, such as regular updating of passwords and locking of the system when not in use, have also been put in place.

Questionnaire responses are denominalized, meaning that a code is used to identify the participant. This ensures that data transferred to the server does not contain any identifying information.

Once questionnaires have been filled out on the secure website, the data is encrypted (as a series of random symbols), making it completely non-identifiable if intercepted while being transferred to the server.

To ensure the security of data during transfer from a computer to the server, the standard method of Secure Sockets Layer (SSL) technology is used. SSL technology is used by banks to ensure complete confidentiality for data transferred during online banking transactions.

\textsuperscript{18} As mentioned previously, this waiting period, during which data and material is placed in quarantine but not destroyed, enables users to change their mind if they wish to do so, since it will be impossible to recover the data once it has been destroyed.
Data collection is carried out in two (2) stages: demographic information, then questionnaire responses.

Demographic data (name, age, gender, etc.) is the first information provided by participants. This data will be immediately encrypted and sent to the server. Personal demographic data and the code that will identify the participant henceforth are stored in an encrypted table separate from the data table containing the questionnaire responses. This process prevents any connection being made between the demographic data and questionnaire responses.

The system then generates a unique, temporary access code that allows the participant to begin filling out questionnaires on an iPad. The entered data is denominalized, encrypted and sent to the server to be stored in the database.

Once the participant has finished filling out the questionnaires, his attending psychiatrist may immediately consult his aggregate data by securely accessing it using a personal access code and password. After connecting to the site, the attending psychiatrist will have access to a customized list of participants and must click on the participant’s name to consult the aggregate data report. This report will not include any information relating to the participant’s identity or the participant’s code. A hard copy of this report will be placed in the participant’s medical file, so that the rest of the authorized clinical team may access it.

**Medical Data Obtained from Attending Psychiatrists**

With the same access code and password used to consult the participant’s aggregate data, the attending psychiatrist may input the medical data required by the Signature Bank (diagnosis and prescribed medication). The denominalized data will then be encrypted and sent to the database.

In order to not excessively burden attending psychiatrists with the Signature Bank’s requirements, there are two other secure methods they may also use to provide the medical data needed for the Signature Bank.

For psychiatrists who prefer to input the required data using the Prescripteur application (in-house software developed with Access to collect medical data about participants required from psychiatrists for the Signature Bank while facilitating their work with respect to preparing and following up on medical prescriptions), the research nurse will obtain an access code (username and password) enabling her to access the Prescripteur program in order to consult the data (diagnosis and medication) that needs to be input into the SIS medical questionnaire. By opening the two programs at once (SIS and Prescripteur), she can copy and paste the data, thereby avoiding the inherent risk of error in manual data entry.

Finally, in order to offer an alternative option for those who are not comfortable with technology, attending psychiatrists may ask the research nurse to directly access the participant’s medical file in order to input the two required items of medical data herself.

**Medical Data Obtained from the Régie de l’Assurance Maladie du Québec**

Quebec’s public health and social services system is an asset for health research in Canada due to its databases covering the entire population. In all Canadian provinces, health care systems collect information on all medical services, hospitalizations and prescribed medications in their administrative databases.
This data is considered reliable for identifying diagnoses of illnesses, medical procedures, medications, medical complications and deaths, and it has been used for over five years by the Public Health Agency of Canada to establish a chronic illness monitoring system.

Within the Signature project, this information source will be used to document the following elements:

- participants’ past and present mental disorders;
- participants’ past and present chronic illnesses (e.g., diabetes, hypertension);
- medication prescribed for past and present chronic illnesses and mental disorders;
- medical complications and causes of death.

The law allows personal information to be shared, but the person making the request must obtain approval in advance from the Commission d’Accès à l’Information du Québec (CAI) and the person in charge of document access and private information protection at the Régie de l’Assurance Maladie du Québec (RAMQ). A formal request will be made to the CAI each year using forms provided for this purpose for each participant who has taken part in the Signature Bank during the previous year. The costs of accessing the RAMQ’s data will be covered by the IUSMResearch Centre.

**Biospecimens**

Collected biospecimens will be placed in cryogenic tubes specific to each type of biospecimen. These will be coded with the predetermined code for each participant. Biospecimen-related data will therefore be denormalized as soon as the sample is taken. Once biospecimens have been analyzed, the biological data will be incorporated into the central database by the same method used for transferring medical and psychosocial data.

For the purpose of collecting biospecimens, the nurse’s office will receive an access code generated after demographic data has been inputted. This access code will make it possible to print barcodes for biospecimen containers. Reading the barcode will make it possible to obtain the participant’s code and store data derived from biospecimen analysis in the database of biological, psychological and social data.

### 4.3. MANAGING ACCESS REQUESTS AND DATA USE

#### 4.3.1. Definitions: Types of Data and Biospecimens

There are two types of data in the Signature Bank database: raw data and aggregate data. **Raw data** refers to the individual responses to each of the questions on the psychosocial signature-related questionnaires filled out by participants. It also covers data on individual concentrations of specific biomarkers based on the results of biospecimen analysis.

**Aggregate data** refers to the average scores obtained by each participant on the various psychosocial signature scales and subscales. This aggregate data may be represented in table or graphic form. (Some examples of graphic representations of aggregate data are provided in Appendix H.)

There will be two types of biospecimen available in the Signature Bank’s biospecimen bank: primary biospecimens and secondary biospecimens.

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19 These are tubes designed for storing biological samples which can be frozen at extremely low temperatures.
**Primary biospecimens** refer to biospecimens that may only be used for analyzing the biomarkers described in Appendix B of this document. After consulting with national and international researchers, it was agreed that these biomarkers are the most likely to lead to major new discoveries in human mental health research. No primary biospecimens may be used to analyze biomarkers other than those described in Appendix B. Of the biospecimens in the Signature Bank, 70% will be reserved for analyzing primary biomarkers.

**Secondary biospecimens** refer to biospecimens that will be frozen for future analysis of emerging biomarkers. Emerging biomarkers are biomarkers that may become of interest in mental health research based on new research data that appears in the coming years. Of the biospecimens in the Signature Bank, 30% will be reserved for analysis of emerging biomarkers. In order to access and analyze these emerging biomarkers, researchers will have to submit a request to the Management Committee which provides a scientific basis for measuring them.

### 4.3.2. Use of Data

**Raw data** is stored in the Signature Bank’s secure, encrypted database. Only researchers (including clinical researchers) who submit a data access request may access the Bank’s raw data. Immediate access to the Signature Bank’s raw data will not be possible, however, due to the delay while data access requests are evaluated by Institut universitaire en santé mentale de Montréal’s Scientific Evaluation Committee and Research Ethics Committee. Researchers or clinical researchers who submit a data access request will receive only denormalized data. If psychiatrists or clinicians wish to have access to raw questionnaire data, they must submit a request to access Bank data. Specifically, they must present a research project involving a request to access the Bank’s data, which will be evaluated by the Scientific Evaluation Committee and Research Ethics Committee.

**Aggregate data** will only be available to Institut universitaire en santé mentale de Montréal clinicians with access to participants’ medical files and will be forwarded to them for the purpose of supporting the care provided to the patient, based on the treatment team’s clinical judgment. (Some examples of aggregate data represented in graphic form are provided in Appendix H.) Participants’ average scores and population norms for the various psychosocial signature questionnaire scales and subscales will be transferred after assessment.20

Data derived from biochemical analysis of metabolic markers will also be transferred to participants’ clinical files once the biochemical analysis has been conducted. Only metabolic data is transferred to clinicians, with the aim of supporting their clinical decisions, since clinicians have access to current clinical norms and can refer to these in order to better understand the participant’s medical condition. No other biological data (genetic, hormonal, immune, infectious or toxicological data) is sent to clinicians in the form of aggregate data, since no clinical norms currently exist for this data, and in the absence of clinical norms, the data is of no use in making clinical decisions. Using a secure website, the attending psychiatrist accesses an aggregate data report which enables him to then input the required medical data for the participant. The aggregate data will then be printed and appended to the patient’s clinical file, thereby making it available to all health care professionals with access to the medical file, who can use it to help with their clinical decisions.

20 Aggregate data reports will also include the following official disclaimer: “In accordance with existing professional codes of ethics, under no circumstances whatsoever may data from the Signature Bank be used or interpreted for diagnostic or therapeutic purposes except by those with the necessary professional qualifications. These assessment tools are not a valid substitute for a clinician’s judgment. They represent one source of information among many that may offer avenues for reflection and observation or enable the validation of hypotheses over time. Research data has no legal bearing on clinical practice.”
4.3.3. Access to Data and Biospecimens

The procedures for accessing raw data, aggregate data and biospecimens are explained in detail in Appendix G. Some aspects of these procedures will be validated once put into practice and may eventually be modified over time. The various procedures and required forms will also be available on the Signature Bank website.

4.3.4. Handling Access-Related Complaints or Disputes

All complaints from researchers or clinicians concerning a problem with accessing data or biological materials must first be submitted in writing to the Bank coordinator, who will inform the Coordinating Committee. If a complaint is maintained or a dispute is not resolved, despite being reviewed and handled by the Coordinating Committee, it must then be addressed in writing to the senior management of the IUSMM Research Centre, which will then ask the Research Ethics Committee and Scientific Evaluation Committee to jointly appoint the members of the Ad Hoc Committee that will be tasked with reviewing and handling the dispute or complaint (see Section 3.4.5, The Ad Hoc Dispute Resolution Committee).

5. SIGNATURE BANK USERS

5.1. RULES RELATING TO INTELLECTUAL PROPERTY AND RESEARCHERS’ AND CLINICIANS’ AUTHORSHIP RIGHTS

The Signature Bank is the product of efforts undertaken by a large group of people, especially the researchers and clinicians involved in its creation. In this regard, the Signature Bank is similar to major international projects that use collective names to identify the group of contributors involved in their development. For the Signature Bank, this group is collectively referred to as the “Signature Consortium.” Appendix F provides a complete list of everyone included in the Signature Consortium.

Members of the Signature Consortium who have contributed to the implementation of the project, the development of psychosocial or biological signatures or the Signature Bank research protocols do not have individual authorship rights for research publications resulting from psychosocial data or biological materials accessed through the Signature Bank.

All researchers and clinicians who access data from the Bank agree to credit the Signature Consortium as an author in scientific papers, book chapters, scientific reports, popular science publications and knowledge transfer documents resulting from analysis based on Signature Bank data.
**With regard to psychosocial data**, there is no authorship condition attached to publications resulting from access to Signature Bank data.

With regard to **publications dealing with Signature Bank biological data**, it is mandatory that researchers who have obtained research grants to analyze biospecimens and who include the biological data derived from their analyses in the Signature Bank be credited as co-author(s) of any publications resulting from the use of said data.

What's more, researchers who have obtained research grants to analyze biospecimens shall have right of review pertaining to analysis and interpretation of their results. This procedure has been implemented to ensure, firstly, that researchers who access biological data have the expertise required to understand the significance of analysis conducted on that data and, secondly, that scientific papers describing the various biomarkers of mental illness are of extremely high quality, thereby enabling significant scientific contributions to this field of research. Researchers who publish material based on biological data must also credit the **Signature Consortium** as an author.

In the case of applying for a university promotion, individual members of the **Consortium** may add their name in italics to the list of authors of scientific papers resulting from the Signature Bank when submitting their CV. However, the CV must include a note indicating that the member's individual contribution was made as part of the **Signature Consortium**.

### 5.2. PRIVATE PARTNERS

Private partners such as pharmaceutical companies are not excluded from accessing the Signature Bank, but requests must be made by means of research projects with at least one lead researcher or clinician who is affiliated with Institut universitaire en santé mentale de Montréal. These research projects must be evaluated and approved by the Scientific Evaluation Committee and Research Ethics Committee. The private partner shall agree in writing to comply with the management framework’s rules and must sign a contract, whose terms will be discussed and ratified by the Coordinating Committee.

### 5.3. USER REQUESTS TO MODIFY THE BANK

Given its longitudinal nature, it is to be expected that the Signature Data and Biological Materials Bank will make changes over time, based on new psychological, medical or biological discoveries. It is possible that new psychiatric facilities will wish to join the Signature Bank, creating mental health research partnerships.

All requests to modify the Signature Bank or its operation must be made by the Scientific Director of the research centre, who will ensure that the various concerned parties (if necessary, the Scientific Evaluation Committee and Research Ethics Committee) are consulted and provide their opinion on the proposed change. If these parties’ opinions are favourable, the Coordinating Committee will submit the proposed change to the hospital’s Executive Management for ratification by the institution.
5.4. USING THE WEBSITE TO INTERACT WITH SIGNATURE BANK USERS

A website will be created to make forms, procedures, scientific papers published by researchers and other relevant information accessible to anyone interested in becoming involved in the Signature Bank as a participant (Institut universitaire en santé mentale de Montréal patient), attending clinician or researcher.

This website will also be used to inform researchers and clinicians about the number of participants who have been tested on each medical, psychosocial and biological measure, with the aim of better managing access requests for data and biological materials.
APPENDIX A

LIST OF INFORMATION REQUESTED AS PART OF THE MEDICAL AND PSYCHOSOCIAL SIGNATURE
TABLE I

LIST OF INFORMATION REQUESTED AS PART OF THE MEDICAL AND PSYCHOSOCIAL SIGNATURE

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Scale Used or Data Collected</th>
<th>No. of Items</th>
<th>Time (min.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Childhood experiences</td>
<td>Statistics Canada (Childhood Experiences of Violence Questionnaire)</td>
<td>7</td>
<td>4</td>
</tr>
<tr>
<td>Impulsivity</td>
<td>UPPS-P Impulsive Behavior Scale – Short Version</td>
<td>20</td>
<td>5</td>
</tr>
<tr>
<td>Aggression</td>
<td>Brown-Goodwin History of Aggression</td>
<td>11</td>
<td>5</td>
</tr>
<tr>
<td>Dependence I</td>
<td>Alcohol Use Disorders Identification Test (AUDIT-10)</td>
<td>10</td>
<td>3</td>
</tr>
<tr>
<td>Dependence II</td>
<td>Smoking – from CCHS-2008</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Dependence III</td>
<td>Drug Abuse Screening Test (DAST-10)</td>
<td>10</td>
<td>3</td>
</tr>
<tr>
<td>Anxiety</td>
<td>State-Trait Anxiety Inventory Form Y6 (STAI-Y6)</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>Depression</td>
<td>Patient Health Questionnaire (PHQ-9)</td>
<td>9</td>
<td>3</td>
</tr>
<tr>
<td>Risk of suicide</td>
<td>Suicidal Behavior Questionnaire – Revised (SBQ-R)</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Psychosis</td>
<td>Psychosis Screening Questionnaire (PSQ)</td>
<td>12</td>
<td>5</td>
</tr>
<tr>
<td>Sleep</td>
<td>Sleep Habits Questionnaire</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Socio-demographic variables</td>
<td>Part of PSR Toolkit, CCHS and Canadian Census</td>
<td>21</td>
<td>5</td>
</tr>
<tr>
<td>Social functioning</td>
<td>World Health Organization Disability Assessment Schedule (WHODAS 2.0)</td>
<td>12</td>
<td>3</td>
</tr>
<tr>
<td>Spirituality</td>
<td>Statistics Canada CCHS (Spirituality)</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Family lineage</td>
<td>Part of Diagnostic Interview for Genetic Studies (DIGS) and Family Interview for Genetic Studies (FIGS)</td>
<td>14</td>
<td>5</td>
</tr>
<tr>
<td>Chronic health problems</td>
<td>Part of CCHS-2008</td>
<td>21</td>
<td>3</td>
</tr>
<tr>
<td>Biological variables</td>
<td>Results of metabolic biomarker analyses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnosis(es)</td>
<td>Psychiatric diagnosis(es) issued by the psychiatrist at each measurement point</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medication</td>
<td>Medication prescribed by the attending psychiatrist at each measurement point</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RAMQ data</td>
<td>- Past and present mental disorders;</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Past and present physical illnesses;</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Medication prescribed for past and present chronic illnesses and mental disorders;</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Medical complications and causes of death</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Total                            | 168                                          | 57           |

REFERENCES:
WHODAS 2.0: http://www.who.int/classifications/icf/whodas2/en/index.html
APPENDIX B

LIST OF HUMAN MATERIALS REQUESTED AS PART OF THE BIOLOGICAL SIGNATURE
### Table I
LIST OF HUMAN MATERIALS REQUESTED AS PART OF THE BIOLOGICAL SIGNATURE

<table>
<thead>
<tr>
<th>BIOMARKER</th>
<th>TYPE OF SAMPLED BIOSPECIMEN</th>
<th>MEASUREMENT POINT</th>
<th>SAMPLE</th>
<th>STORED BIOSPECIMEN</th>
<th>VOLUME STORED (1 ml = 1000 µl)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>METABOLIC</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glycated hemoglobin</td>
<td>Blood</td>
<td>T1, T4</td>
<td>Lavender tube (3 ml)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cholesterol</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HDL cholesterol</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LDL cholesterol (calculated)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Triglycerides</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glucose</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insulin</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emerging biomarkers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>HORMONES</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17 β Estradiol</td>
<td>Saliva</td>
<td>T1, T2, T3, T4</td>
<td>Saliva tube (2 ml)</td>
<td>Saliva</td>
<td>3 x 500 µl</td>
</tr>
<tr>
<td>Testosterone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Progesterone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emerging biomarkers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cortisol</td>
<td>Hair</td>
<td>T1, T4</td>
<td>Aluminum packaging</td>
<td>Hair</td>
<td>0.5 cm x 3 cm</td>
</tr>
<tr>
<td>Melatonin</td>
<td>Blood</td>
<td>T1, T2, T3, T4</td>
<td>Lavender tube (same tube as for insulin)</td>
<td>Plasma</td>
<td>1 x 800 µl</td>
</tr>
<tr>
<td><strong>INFLAMMATORY AND IMMUNE</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C-reactive protein</td>
<td>Blood</td>
<td>T1, T2, T3, T4</td>
<td>Lavender tube (10 ml)</td>
<td>Plasma</td>
<td>3 x 800 µl</td>
</tr>
<tr>
<td>Insulin-like growth factor</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TNF-alpha</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IL-1-beta</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interleukin-6 (IL-6)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emerging biomarkers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Endocannabinoids</td>
<td>T1, T4</td>
<td></td>
<td></td>
<td></td>
<td>2 x 500 µl</td>
</tr>
<tr>
<td><strong>INFECTIOUS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxoplasmosis (IgM and IgG)</td>
<td>Blood</td>
<td>T1, T2, T3, T4</td>
<td>Yellow tube (6 ml) (same tube as for insulin)</td>
<td>Serum</td>
<td>1 x 800 µl</td>
</tr>
<tr>
<td>Emerging biomarkers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>TOXIC</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PCBs, organochlorine pesticides, PBFRs (flame retardants)</td>
<td>Blood</td>
<td>T2, T4</td>
<td>Lavender tube (10 ml)</td>
<td>Plasma</td>
<td>1 x 2000 µl</td>
</tr>
<tr>
<td>Emerging biomarkers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1 x 800 µl</td>
</tr>
<tr>
<td>Heavy metals – lead, manganese</td>
<td></td>
<td></td>
<td></td>
<td>Whole blood</td>
<td>1 x 800 µl</td>
</tr>
<tr>
<td>Emerging biomarkers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1 x 800 µl</td>
</tr>
<tr>
<td>Heavy metals – mercury</td>
<td>Hair</td>
<td>T3</td>
<td>Box + Ziploc</td>
<td>Hair</td>
<td>0.5 cm x 1 cm</td>
</tr>
<tr>
<td><strong>GENETIC</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DNA</td>
<td>Blood</td>
<td>T1</td>
<td>Lavender tube (10 ml)</td>
<td>DNA</td>
<td>1 x 800 µl</td>
</tr>
<tr>
<td>RNA</td>
<td>Blood</td>
<td>T1, T2, T3, T4</td>
<td>PAXgene tube (2.5 ml)</td>
<td>Whole blood + additive</td>
<td>1 x 5 ml</td>
</tr>
<tr>
<td>White blood cells or PBMCs (leukocyte fraction)</td>
<td>Blood</td>
<td>T1, T2, T3, T4</td>
<td>Lavender tube (same tube as for inflammatory/immune and toxins)</td>
<td>Intact cells in DMSO and fetal bovine serum</td>
<td>2 x 500 µl</td>
</tr>
<tr>
<td><strong>CELLS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Red blood cells</td>
<td>Blood</td>
<td>T1, T2, T3, T4</td>
<td>Lavender tube (same tube as for inflammatory and immune)</td>
<td>Intact cells in DMSO</td>
<td>2 x 800 µl</td>
</tr>
</tbody>
</table>

**BLOOD – TOTAL VOLUME REQUIRED:**

- 37.5 ML = 6 SAMPLE TUBES (T1, T4)
- 34.5 ML = 5 SAMPLE TUBES (T2)
- 24.5 ML = 4 SAMPLE TUBES (T3)

It should be noted that the composition of blood is 55% liquid and 45% solid (cells). For most biomarkers, only the liquid portion of the blood will be preserved. With regard to white cells, sample tubes with a diameter of 16 mm (10 ml) will be used in order to obtain a sufficient quantity of cells.
APPENDIX C

INFORMATION AND CONSENT FORM FOR PARTICIPATION OF INSTITUT UNIVERSITAIRE EN SANTÉ MENTALE DE MONTRÉAL PATIENTS IN THE SIGNATURE MEDICAL/PSYCHOSOCIAL DATA AND BIOLOGICAL MATERIAL BANK
PARTICIPATION IN THE SIGNATURE MEDICAL/PSYCHOSOCIAL DATA AND BIOLOGICAL MATERIALS BANK

INFORMATION AND CONSENT FORM

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.

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. The Bank’s management framework is available for you to consult on the www.centresignature.ca website.

You have been invited to take part in the Bank as a research subject. We would now like to receive your consent to preserve some of your psychosocial information (which will be obtained through questionnaires that you fill out) and medical data in the Signature Bank, 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 as part of mental health-related research projects. What’s more, an overall summary of your psychosocial data (technically referred to as aggregate data) will be available to your doctor and members of the treatment team who have access to your medical file.

This form may contain words that you do not understand. If you have any questions, we encourage you to ask the members of the Signature Bank Management Committee and in particular 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.

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 Hocheлага 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 Fondation 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 medium 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 IUSMM patients 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) and biospecimens from saliva, blood and hair samples.

- **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.

- **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 tests relate to various aspects of mental health and feature questions concerning, for example, sleep, anxiety and depression. They are tests which 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.

To correlate your questionnaire responses with your medical condition, you authorize your attending psychiatrist to input two types of medical data into the Signature Bank: your diagnosis and the medication he has prescribed for you. You also authorize the research nurse to consult your medical file if your attending physician’s workload prevents him from having time to input the two data items into the Signature Bank himself.

Also for the purpose of correlating your questionnaire responses to your medical condition, your participation means that the Signature Bank coordinator may request data from the Régie de l’Assurance Maladie du Québec about your use of public medical services during the two years before taking part in the Signature Bank. This information will be requested only one time, after you stop participating in the Signature Bank. The requested information will concern your various diagnoses of physical and mental illness in the previous two years, as well as the medications prescribed to you for the various illnesses and any medical complications that you may have experienced in the previous two years. It is agreed that information related to your Régie de l’Assurance Maladie du Québec 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) and saliva. These will be preserved in the Signature Bank. The nurse will also record your blood pressure, weight and waist size and, if you are female, ask you the date of your last menstruation as well as the age at which you had your first menstruation.

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 Institut universitaire en santé mentale de Montréal 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 coordinator, who will then advise your attending psychiatrist.
The overall results of your psychosocial questionnaire responses, as well as certain blood sample analysis results 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. All the information contained in your medical file could potentially impact your ability to obtain certain types of insurance (including life insurance) if an insurance company consults your medical file with your express permission, or it could impact your employability if you authorize a potential employer to consult your file.

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. 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 remunerate you for the time spent and travel involved.

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 (Institut universitaire en santé mentale de Montréal, Attention: Ms. Nathalie François, Pavillon Riel, Room 2824, 7401 Hochelaga St., Montreal, QC, H1N 3M5) asking that your samples and all files containing your data be destroyed.

Footnotes:
22 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.
23 Analysis of metabolic biomarkers.
These will be destroyed after a short period of **quarantine**\(^{24}\), 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

The Management Committee and Coordinating Committee are the two bodies responsible for the Signature Bank’s operation, and any questions or feedback may be addressed to them via the Bank coordinator, who sits on both committees. For more information about the Bank or to notify us of your withdrawal, you may contact the Bank coordinator, Ms. Nathe François, by phone at 514-251-4000 (ext. 3796) or by email at nfrancois.hlhl@ssss.gouv.qc.ca.

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**FOR ALL QUESTIONS REGARDING PARTICIPANT RIGHTS OR TO FILE A COMPLAINT OR PROVIDE FEEDBACK, YOU MAY CONTACT EITHER:**

Institut universitaire en santé mentale de Montréal’s Local Service Quality Commissioner by telephone at ☏ 514-251-4000 (ext. 2920) or in writing at the following address:

7401 Hochelaga St.
Pavillon Bédard – Room 2148
Montreal, QC
H1N 3M5

the Research Ethics Committee Representative by phone at ☏ 514-251-4015 (ext. 2442) or by email at comite.ethique@crfs.rtss.qc.ca.

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### MONITORING OF PROJECT’S ETHICAL ASPECTS

Institut universitaire en santé mentale 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 ☏ 514-251-4015 (ext. 2442).

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\(^{24}\)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.

☐ Yes  ☐ No

I consent to authorized personnel from the Signature Bank contacting me in future with the intention of inviting me to participate in a new research project or to obtain supplementary information needed for a research project involving a request for data from the Signature Bank. At that time, I will be entirely free to agree or refuse to participate further.

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’S TELEPHONE NO. ___________________________

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
PARTICIPATION IN THE SIGNATURE MEDICAL/PSYCHOSOCIAL DATA AND BIOLOGICAL MATERIALS BANK APPENDIX

ADVANCE CONSENT FORM IN THE EVENT OF TEMPORARY INCAPACITY

The advance consent form in the event of temporary incapacity is a supplement to the general consent form which applies solely in certain cases of mental illness. It pertains to acute episodes of illness during which the user is temporarily unable to provide consent, whether for care or research. The purpose of this form is to ensure the uninterrupted collection of samples for the Signature Bank during the acute stage, so that this phase may also be documented in order to advance our general understanding of the illness.

I, the undersigned, ________________________________________, having previously consented to participate in the Signature Medical/Psychosocial Data and Biological Materials Bank on the date of _____________, hereby declare that I also authorize Signature Bank personnel to proceed with taking samples of biological materials (blood, hair, saliva) if I suffer a relapse and return to the hospital’s emergency department while temporarily incapable of reaffirming my consent.

Once my condition has stabilized, the Signature Bank’s personnel agree to inform me of the samples that were taken. At that point, and at any subsequent time, I have the option of withdrawing from the Signature Bank and requesting the destruction of collected data and biological material samples. A duly signed and dated copy of the present form will be given to me, if I choose to sign it.

PARTICIPANT’S SURNAME ___________________________ GIVEN NAME ___________________________

_________________________ DATE ___________________________ PARTICIPANT’S TELEPHONE NO. ___________________________

SIGNATURE BANK MANAGEMENT COMMITTEE MEMBER’S SIGNATURE AND AGREEMENT

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

_________________________ DATE ___________________________

BANK REPRESENTATIVE’S NAME ___________________________ SIGNATURE ___________________________
APPENDIX D

ATTENDING PSYCHIATRIST AGREEMENT FORM
PARTICIPATION IN THE SIGNATURE
MEDICAL/PSYCHOSOCIAL DATA AND BIOLOGICAL MATERIALS BANK

ATTENDING PSYCHIATRIST AGREEMENT FORM

I, the undersigned, ____________________________, consent to participate in the Signature Medical/Psychosocial Data and Biological Materials Bank at Institut universitaire en santé mentale de Montréal Research Centre.

As such, I shall become a member of the “Signature Consortium.”

AS AN ATTENDING PSYCHIATRIST

✓ … I shall automatically receive aggregate questionnaire data in real time for each user for whom I am the attending clinician and who has consented to participate in the Signature Bank. This customized report shall be provided by means of an IT resource. The report must be printed and added to the participant’s medical file.

USE OF THE REPORT

Aggregate data is provided to support attending psychiatrists in delivering care to participants, based on their clinical judgment. The aggregate data report is not intended to serve as a standard for medical care. The interpretation of data evolves in accordance with scientific knowledge and technology. The final judgment regarding a specific clinical procedure or treatment plan is made by the psychiatrist in light of the user’s clinical data and the available diagnostic and treatment options.

Aggregate data may not be used for research purposes under any circumstances. Whenever psychiatrist-researchers wish to use any data for research purposes, they must submit an access request for raw data (see the Signature Bank data access request procedures).

✓ I will automatically receive data on participants for whom I am the attending clinician, which is derived from biochemical analysis of metabolic markers conducted as part of biological signature collection for the Signature Bank, as soon as they have been analyzed.

✓ I agree to provide the diagnosis (primary, secondary, etc.) and medication (treatment) for each user under my clinical care who has consented to participate in the Signature Bank. This data will be collected, after the appointment with the participant, via IT resources or with the help of the research nurse.
AS A CLINICIAN/PROFESSOR/RESEARCHER

… I will have access to the complete list of publications arising from Signature Bank data for which the “Signature Consortium” is credited as one of the authors. I may cite these articles in my CV only if applying for a university promotion while complying with the terms stipulated in the management framework.

If my contribution to the text or data analysis in a publication is considered substantial, my name will also be included in the list of authors (see the rules relating to intellectual property and authorship rights in the Signature Bank management framework).

☐ I have read the management framework.

On __________________________ at __________________ Signature __________________________
APPENDIX E

RESEARCHER AGREEMENT FORM
 PARTICIPATION IN THE SIGNATURE MEDICAL/PSYCHOSOCIAL DATA AND BIOLOGICAL MATERIALS BANK

RESEARCHER AGREEMENT FORM

I, the undersigned, ____________________________________________, hereby declare that I have read the management framework for the Signature Bank at Institut universitaire en santé mentale de Montréal Research Centre (available from the Signature Bank coordinator).

SPECIFICALLY, IN MY CAPACITY AS A RESEARCHER, I AGREE,

… to credit the "Signature Consortium" in the list of authors for any publication (scientific paper, book chapter, scientific report, statement, popular science text, knowledge transfer document, etc.) based on analysis derived from Signature Bank data.

… to credit the author(s) responsible for the grant that led to the analysis of biospecimens and to submit any planned publication or statement to said author(s) prior to its submission.

… to submit an access request for data in the Signature Bank in accordance with the following procedure:

✓ Availability analysis and cost estimate
✓ Approval from the Scientific Evaluation Committee (SEC)
✓ Approval from the Research Ethics Committee (REC)

… to submit proof of my capacity to cover the data access costs.

… to only use the provided data for the projects cited in my request (any new projects require submitting another Signature Bank data access request and an evaluation request to the Scientific Evaluation Committee and Research Ethics Committee).

… to submit biospecimen analysis data to the Signature Bank no later than the end of the grant period.

… to notify the Signature Bank coordinator of any abnormal results (according to the standards of current medical practice) arising from biospecimen analysis which should be relayed by the Bank coordinator25 to the participant’s attending clinician.

On ____________________ at ______________ Signature ____________________

On page 48

25 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.
APPENDIX F

LIST OF DIRECTORS, MANAGERS AND PROFESSIONALS, INCLUDING RESEARCHERS, THAT WERE CONSULTED DURING THE DESIGN AND PLANNING STAGES OF THE BANK PROJECT, REFERED TO AS THE 'SIGNATURE CONSORTIUM'
### Table III

**List of people who contributed to the signature bank’s implementation and are collectively referred to as the “signature consortium”**

List updated in August 2012

<table>
<thead>
<tr>
<th>AARDEMA, Frederic</th>
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APPENDIX G

PROCEDURES FOR ACCESSING DATA AND BIOSPECIMENS
1. PROCEDURE FOR ACCESSING RAW DATA

1.1 DEFINITIONS

Researchers or clinical researchers submit requests to access “data series.”

One datum represents the raw scores on the questions for a specific questionnaire—for example, the responses of a group of participants to twenty-five (25) questions on a specific questionnaire.

One “data series” represents a specific subset of the data available in the database, which the researcher or clinical researcher wishes to access for a research project with a clearly specified scientific rationale supporting the use of that particular data.

A data series may consist of the “raw scores” for all questions on one or more specific questionnaires or the concentrations of one or more specific biomarkers. A data series represents all of the data requested by a researcher.

1.2 GENERAL PROCEDURE FOR ACCESSING RAW DATA

All researchers and clinical researchers who wish to conduct a research project may access medical/psychosocial data and analyzed biomarkers from the Signature Bank’s database and biological materials bank. The list of available data/materials may be obtained from the Bank coordinator.

However, in order to access the Bank’s data, researchers or clinical researchers must follow the three (3) steps of the process below.

STEP 1: Submit an access request (form) to the Bank coordinator.

STEP 2: The Bank coordinator assesses the request and responds to the researcher who made the request with an access fee estimate. This assessment involves verifying the availability of data and possible replication of another request. Specifically, if a researcher wishes to obtain a data series for which 70% or more of the data is identical to a previous request, the Bank coordinator will inform the researcher making the request of his project’s overlap with an existing project. If the latter still wishes to make the request, the coordinator will consult the Scientific Evaluation Committee, which will make a ruling regarding the project’s replication of another project. The researcher making the request must then comply with the Scientific Evaluation Committee’s recommendation in order to access the data.

STEP 3: Submit the scientific project to the Scientific Evaluation Committee and the Research Ethics Committee. Once it has been accepted by these two (2) committees, the researcher may access raw data from the Signature Medical/Psychosocial Data and Human Biological Materials Bank.
Researchers and clinical researchers from Institut universitaire en santé mentale de Montréal’s Research Centre take precedence when it comes to accessing raw data from the Signature Bank’s database for a period of two (2) years. If, after this period of two (2) years, no access request has been made for given data by this group, the data will be made available to other Quebec researchers for a period of two (2) years in order to promote the optimization of research. If, after this period, no access request has been made for the given data by Quebec researchers, the data will be made available to researchers across Canada for a period of one (1) year. After this period, data for which no request has been made will be made available to international researchers.

Researchers and clinical researchers who have obtained access to a data series from the Signature Bank have two (2) years to publish the results of their analysis. If, after this period, there has been no scientific publication (a scientific paper that has been submitted for publication or is in press, with supporting evidence), the same data series may be provided to another researcher or clinical researcher.

It is not necessary for researchers and clinical researchers to have a research grant in order to access raw data from the database. However, an access fee will be charged for the purpose of covering the Signature Bank’s operating expenses. Detailed cost information will be available on the Centre Signature’s website and at its office. When submitting a data access request to the Bank coordinator, researchers must provide proof of their ability to cover the cost of accessing the Signature Bank.
FIGURE A
PROCEDURE FOR ACCESSING RAW DATA

1- ACCESS REQUEST (FORM)
   • List of desired data
   • Description of research project

REQUEST ASSESSMENT
   (Bank coordinator)

2- RESPONSE TO RESEARCHER MAKING REQUEST
   • Notice of data availability
     (number, quantity, access priority and exclusivity*)
   • List of authors associated with any publication
   • Analysis of similarities to previous requests**
   • Access fee estimate

PROVISION OF APPROVAL BY SEC (or other recognized organization) AND CERTIFICATE OF ETHICAL APPROVAL

3- DATA DELIVERY
   • Payment of access fees
   • Endorsement of management framework rules
   • Delivery of data to researcher making request

Follow-up

4- LIST OF PUBLICATIONS RESULTING FROM PROVIDED DATA

* The management framework prioritizes access for various groups, ranging from Institut’s Research Centre members to international researchers, in a hierarchical manner, and stipulates a two-year exclusivity period with regard to data analysis for each request.
** If a request overlaps another request by 70% or more, the SEC must be consulted.
2. PROCEDURE FOR ACCESSING AGGREGATE DATA

Aggregate data will only be available to Institut universitaire en santé mentale de Montréal clinicians with access to a participant’s medical file. Researchers do not have access to aggregate data (since they are specific to a particular patient and not denormalized).

Medical and psychosocial data obtained from participants via an IT resource are sent to the server, analyzed electronically and made directly accessible to psychiatrists (and other clinicians with access to a participant’s medical file), with the goal of ensuring ongoing medical follow-up of the participant. Therefore, psychiatrists automatically have access to aggregate data from the psychosocial/medical database. However, psychiatrists participating in the Signature Bank must sign an agreement in order to access data for clinical purposes (see Appendix D).

3. PROCEDURES FOR ACCESSING BIOSPECIMENS

3.1 GENERAL OPERATING PROCEDURE

Only biospecimens related to metabolic biomarkers will be analyzed upon receipt by the laboratory, since these biospecimens are difficult to freeze. The metabolic analysis results will be sent to the attending psychiatrist and placed in the participant’s medical file. All other biospecimens (primary and secondary/emerging) will be frozen for future analysis by researchers who have received research funding to conduct such analysis. All submitted projects involving analysis of Bank biospecimens must correspond to the primary biomarkers described in Appendix B. Biospecimens may only be used to analyze these biomarkers. Any request to analyze biospecimens for secondary biomarkers (i.e., biomarkers other than those described in Appendix B) must be presented to the Coordinating Committee for evaluation of the request’s validity. If necessary, the Coordinating Committee may request the opinion of the Scientific Evaluation Committee in order to better understand the scientific validity of the biospecimen analysis request. While the Coordinating Committee determines the validity of using biological samples for measuring biomarkers other than those described in Appendix B, its decision must nevertheless be presented to the IUSMM Research Centre’s Executive Committee for final approval.

3.2 BIOSPECIMEN ACCESS PROCEDURES FOR RESEARCHERS

Researchers who wish to access biospecimens in order to analyze biomarkers of interest must have obtained a research grant covering all the biomarker analysis fees or be able to prove their ability to cover these costs by other means. Furthermore, they must include a biospecimen access fee estimate budget in their grant request. Researchers who have obtained a grant and approval from the Scientific Evaluation Committee and Research Ethics Committee to analyze a series of biospecimens have complete exclusivity over data from analyzed biomarkers for the duration of the obtained grant. Researchers are also asked to analyze immune and hormonal biomarkers at the IUSMM Research Centre’s analysis laboratory in order to ensure that the analysis methods are consistent. Researchers provide written agreement to the Bank coordinator indicating that they will share data derived from analysis of biomarkers obtained from Signature Bank data and biological materials at the end of the grant period. The data will therefore become available to all researchers.
FIGURE B
BIOSPECIMEN ACCESS PROCEDURE

1. ACCESS REQUEST (FORM)
   - List of biomarkers being researched (primary or secondary)
   - List of desired biospecimens
   - Description of research project
   - Proof of funding for analysis

   ASSESSMENT OF REQUEST
   (Bank coordinator)

2. RESPONSE TO RESEARCHER MAKING REQUEST
   - Notice of biospecimen availability
     (number, quantity, access priority and exclusivity)
   - Coordinating Committee’s recommendation and Executive Committee’s
decision in the case of secondary biomarkers
   - Access and analysis fee estimate, if applicable

   PROVISION OF ETHICAL APPROVAL CERTIFICATE

3. DATA DELIVERY
   - Payment of access fees
   - Endorsement of management framework rules
   - Delivery of data to researcher making request

   Follow-up

4-5. RETURN OF BIOSPECIMEN ANALYSIS DATA
   (RESULTS) NO LATER THAN THE END OF THE GRANT PERIOD
   LIST OF PUBLICATIONS RESULTING FROM RECEIVED DATA
Researchers from the IUSMM Research Centre take precedence over all other Quebec researchers when it comes to accessing biospecimens from the Signature Bank’s database. However, this precedence is only for a period of two (2) years. If, two (2) years after at least two hundred (200) biospecimens suitable for analysis have been collected and stored by the Signature Bank, no researcher from the Centre has submitted a request to analyze primary biomarkers, the biospecimens will be made available to other Quebec researchers, who will be subject to the same rules for accessing biospecimens. If, after this period, no access request has been made for given biospecimens by Quebec researchers, the biospecimens will be made available to researchers across Canada for a period of one (1) year. After this period, biospecimens for which no request has been received will be made available to international researchers. A notice to this effect will be posted on the Signature Data and Biological Materials Bank website.

3.3 BIOSPECIMEN ACCESS PROCEDURE FOR CLINICIANS

Only data related to metabolic biomarkers will be made available to clinicians, in the form of identified aggregate data placed in the participant’s medical file. However, the Management Committee may consider requests to access biological data for clinical purposes only.
AGGREGATE DATA AND EXAMPLES OF GRAPHIC REPRESENTATION
APPENDIX H: AGGREGATE DATA AND EXAMPLES OF GRAPHIC REPRESENTATION

 Aggregate data reports synthesize the responses of patients who filled out questionnaires into either graphs of their scores or tables. Only questionnaires for which it is possible to calculate a score and/or provide an interpretation are represented.

For each questionnaire, the following will be provided: the questionnaire title, the scores or responses illustrated graphically over time and the interpretation of the scores. The data will be presented as a graph in the case of numerical scores (example 1), tables in the case of documenting whether or not certain factors are present (example 2) and basic text in the case of reporting the answer to a specific question (example 3). It is anticipated that the graphic format and number of graphics will be modified and enhanced based on survey feedback from clinicians who use aggregate data reports.

EXAMPLE 1: GRAPHIC REPRESENTATION OF PHQ-9 DEPRESSION QUESTIONNAIRE (9 ITEMS)

[Graph legend]
5-9 = Mild depression
10-14 = Moderate depression
15-19 = Moderately severe depression
≥ 20 = Severe depression

[Table title and left column]
Psychosis – PSQ
Hypomania
Thought interference
Paranoia
Strange experiences
Hallucinations

EXAMPLE 2: GRAPHIC REPRESENTATION OF PSQ PSYCHOSIS QUESTIONNAIRE (12 ITEMS)

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EXAMPLE 3: REPRESENTATION OF BASIC RESPONSES (QUESTIONNAIRE ON SMOKING AND SPIRITUALITY)

**Spirituality**
- In general, to what extent are religious or spiritual beliefs important in your daily life?
  *Response: Very important*
- To what extent do your religious or spiritual beliefs give you the strength to face everyday difficulties?
  *Response: Very much*

**Official Disclaimers on Each Report**

In order to make optimal use of the research data collected about users as part of the Signature project and placed in each user’s medical file, the following disclaimers will be appended to each aggregate data report:

1) “In accordance with existing professional codes of ethics, under no circumstances whatsoever may data from the Signature Bank be used or interpreted for diagnostic or therapeutic purposes except by those with the necessary professional qualifications. These assessment tools are not a valid substitute for a clinician’s judgment. They represent one source of information among many that may offer avenues for reflection and observation or enable the validation of hypotheses over time.”

2) “Research data has no legal bearing on clinical practice.”

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26 During the first three years of the Signature Bank’s existence, the Bank’s team is committed to conducting surveys in order to identify and document the actual benefits of including aggregate data in participants’ medical files, for the purpose of demonstrating the clinical contribution provided by this innovative aspect of the project.

27 While researchers are not responsible for the accurate interpretation of research data by clinicians, the Research Ethics Committee emphasizes that professional discipline leaders and administrative managers of clinical departments should make sure that the relevant professional staff are reminded of this fact.