Centre intégré universitaire de santé et de services sociaux du Centre-Ouest-de-l'Île-de-Montréal
Québec

Title:	Policy and procedure on biobanking and management of biological materials, and related data, for research purposes	
Code:	**1100_01_03_00F**	
Responsible for application:	**Academic Affairs and Research Ethics Directorate**	
Approved by:	**Board of Directors, on recommendation of the Academic Affairs Committee**	
Policy:	**New** ☒	**Revised** ☐
Related procedure:	**Yes** ☒	**No** ☐
Recipient:	☐ Intra-directorate: Specify the directorate ☐ Inter-directorate: ☐ Multidisciplinary: Specify disciplines (e.g., social workers, physicians, etc.) ☐ Governance and senior management ☒ Entire CIUSSS du Centre-Ouest-de-l'Île-de-Montréal	

1. Scope

This policy and procedure applies to all research studies undertaken at the CIUSSS du Centre-Ouest-de-l'Île-de-Montréal or within the institutions it administers ("CCOMTL"), which require the formation of collections of biological materials and related data for future research studies. These biological materials or related data may be kept in research biobanks or research databanks formed by CCOMTL researchers, but also by third parties, in which case the CCOMTL researchers are considered contributors. In particular, these banks include research databanks or biobanks formed by external academic researchers or by industry.

This policy and procedure must also be followed by the research staff responsible for managing the biological materials and data, and for banking them for secondary use, where applicable. The related data covered by this policy and procedure include, but are not limited to:

- All genetic and molecular data obtained from the analysis of the biological materials;
- All data in the database related to the analysis of the biological materials; and
- All digital files created from the biological materials, including virtual slides.

It is important to distinguish between biobanks formed for research purposes and biological materials collected for clinical purposes. **Residual biological materials may not be used for research purposes.** However, patients from whom these materials were collected may be contacted to sign an informed consent form (ICF) to consent to their use for research purposes. This policy and procedure governs the use of residual tissues, organs, and biological fluids that CCOMTL patients consented to be used anonymously for research purposes.

2. Reference framework

This policy is consistent with the vision and strategic orientations of the CCOMTL, which in turn are based on the legal framework of the Ministère de la Santé et des Services sociaux. Since the implementation, in 1998, of measure 1 of the *Plan d'action ministériel en éthique de la recherche et en intégrité scientifique*, institutions in the health and social services network (HSSN) are required to have a policy on the management of databanks and biological materials. As such, this policy and procedure is one of the obligations arising from the following normative or regulatory documents:

- *Civil Code of Québec*, CCQ-1991
- *Act respecting health services and social services*, CQLR, c. S-4.2
- *Personal Information Protection and Electronic Documents Act*, S.C. 2000, c. 5
- *Act to modernize legislative provisions as regards the protection of personal information*, SQ 2021, c. 25
- *Regulatory framework for research involving humans at the Centre intégré universitaire en santé et services sociaux du Centre-Ouest-de-l'Île-de-Montréal,* adopted on January 27, 2022
- *Policy and procedure for managing allegations of breach of responsible conduct of research at CIUSSS du Centre-Ouest-de-l'Île-de-Montréal,* adopted on January 27, 2022
- *Standard operating procedures of the Research Ethics Board of the CIUSSS du Centre-Ouest-de-l'Île-de-Montréal*, adopted on September 30, 2021
- Ministère de la Santé et des Services sociaux (MSSS), *Guide d'élaboration des cadres de gestion des banques de données et de matériel biologique constituées à des fins de recherche*, 2012
- Interagency Advisory Panel on Research Ethics (the Panel), *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS2), 2018
- McGill University - Faculty of Medicine, *General Guidelines for Biobanks and Associated Databases,* 2015
- Ministère de la Santé et des Services sociaux (MSSS), *Cadre de référence ministériel pour la recherche avec des participants humains*, 2020
- Fonds de recherche du Québec - Santé (FRQS), *Rapport final du groupe-conseil sur l'encadrement des banques de données et des banques de matériel biologique à des fins de recherche en santé*, 2006
- Government of Canada, *Tri-Agency Research Data Management Policy,* 2021

3. Purpose

3.1. This policy and procedure describes the obligations surrounding the management of biological materials, such as blood and its components, cells, tissues, and organs collected from participants in a research study or kept **for future research purposes, and their related data**. The processes described include the collection, processing, storage, and handling of the biological materials and data, up until their destruction.

The basic elements involved in the formation of databanks and biobanks include collection, storage, and access to and usefulness of the contents, from a perspective of sustainability. Accordingly, this policy and procedure governs the:

- collection of the biological materials and data;
- storage of the biological materials and data;

- access to biological materials and data from databanks and biobanks formed by third parties; and
- sustainable governance of these databanks and biobanks.

4. Definitions

Bank: Systematic collection of data or biological materials that can be used for health research purposes (FRQS 2006). For the purposes of this policy and procedure, this term includes biobanks and databanks.

Bank manager: Researcher who is responsible for the management and administration of a bank. The bank manager must be a clinician assigned to the CCOMTL and/or a recipient of a research grant or account administered by the CCOMTL.

Biobank: A collection of human biological materials. It may also include associated information about individuals from whom biological materials were collected (TCPS2, 2018).

Biological materials: Any substance of human origin (e.g., organs, tissue, cells, serum, and tissue obtained postmortem). The analysis of a biological sample may generate data (FRQS, 2006).

Board of Directors: The CCOMTL's Board of Directors, as defined by sections 9 and 10 of the *Act to modify the organization and governance of the health and social services network, in particular by abolishing the regional agencies* (CQLR, c. O-7.2) (CCOMTL, 2022).

Data: Data from research activities, as well as health and social services data, regardless of the medium (CCOMTL, 2022).

Data management plan: A living document, typically associated with an individual research project or program that consists of the practices, processes and strategies that pertain to a set of specified topics related to data management and curation (Tri-Agency Research Data Management Policy, 2021).

Management framework: A framework document for a database or a biobank that lists the elements to be considered given the sensitive nature of the personal information and biological materials, and the need to protect the rights of research participants (FRQS, 2006).

Nagano: An online computer system used by most public institutions in Quebec's health and social services network (HSSN) as a multifunctional planning and management platform for research studies (CCOMTL, 2022).

Researcher: A person to whom the CCOMTL has granted research privileges, excluding research personnel and students (CCOMTL, 2022).

Research activities or research: All steps included in the life cycle of knowledge creation through rigorous methodologies that are—or are in the process of becoming—recognized by peers, spanning from the initial project proposal to the dissemination of results, including applications for research funding and peer review. These steps also include activities related to research management. (CCOMTL, 2022).

Research Ethics Board (REB): A group of individuals with specific expertise (e.g., in ethics or relevant research disciplines) established by an organization to review the ethical acceptability of all research involving humans conducted within the organization's jurisdiction or under its auspices, in accordance with applicable standards and laws (CCOMTL, 2022).

Research Review Office (RRO): Office comprised of staff that coordinate and support the institutional feasibility and ethics review of research conducted at the CCOMTL or that involves users of its care and services, under the authority of the person formally designated to authorize the research (CCOMTL, 2022).

Secondary use: The use in research of information or human biological materials originally collected for a purpose other than the current research purpose (TCPS2, 2018).

5. Governing principles

The purpose of this policy and procedure is to promote the implementation and use of databanks and biobanks for research purposes, within a framework for the responsible, transparent, secure, ethical and compliant collection, storage and use of the data and biological materials for future research studies.

6. Terms and conditions

Formation of the bank

The formation of any bank requires the following elements:

- Management framework;
- Approval from the REB; and
- Institutional authorization.

Management framework

Best practices in biobanking recommend that a management framework be drafted for the formation of any bank. The RRO therefore requires such a document for the formation of any bank. This framework must be drafted according to the guidelines suggested by the RRO in Appendix A.

The management framework must specifically include all the information needed for potential participants and researchers to understand who may have rights to any commercial applications or intellectual property generated. Bank managers must ensure that this plan covers the entire life cycle of the banks. The plan must set out the length of time the biological materials and data will be kept, as well as the appropriate transfer or destruction procedures for the biological materials and data upon closure of the biobank. The plan must be referenced in the ICF, specifically the possibility of transferring the biological materials and data to a third party, and the need for REB approval. These elements must also be clearly set out in the ICF and in third-party access agreements.

Note that this management framework may need to be supplemented with a research data management plan.

Approval from the REB

The ethics review must be conducted by the CIUSSS du Centre-Ouest-de-l'Île-de-Montréal's REB and give final approval to all documents submitted.

Institutional authorization

This is obtained following the revision of the complete file submitted on the Nagano platform and positive results on the triple review of the research activities (scientific review, ethics review, research suitability review).

Participant's consent

The banking of biological materials or data requires the voluntary and informed consent of the potential participant. The potential participant must be fully informed of the purpose of the procedure and must have understood and signed the ICF, in accordance with the principles outlined in the *Regulatory framework for research involving humans at the CCOMTL*. As part of the informational discussion with the potential participant, their right to withdraw—and the limitations of that right—must be clearly explained to them. Any limitations on the participant's right to withdraw, including for reasons of anonymization or aggregation of the data and biological materials, must be set out in the management framework and clearly explained to any potential participant.

Collection of biological materials

The equipment required to collect, process, and store the biological materials and related data must be available and meet the requirements of each biobank's management framework, which must outline the collection conditions and procedure. An equipment maintenance and calibration procedure must also be outlined and a cost review carried out. All equipment maintenance documents must be kept with the essential biobank documents, in accordance with the CCOMTL's retention schedule, where applicable. Depending on the type of biological materials to be collected, it is important to follow the specific instructions for collection and preparation of the biological materials, as defined in the management framework.

The participant's safety and well-being during collection of the biological materials remains the highest priority. To avoid any risk of error, it is recommended that each sample be labelled as accurately as possible according to the specifications in the management framework.

The collection of biological materials from healthy participants must be specifically addressed in the management framework.

Storage of biological materials

Biological materials must be stored in a secure, appropriate environment, in accordance with the requirements of the biobank management framework. The conditions must be monitored on a regular basis and documented. The log must be kept with the essential biobank documents. Procedures must be in place to monitor and restrict physical and electronic access to the biological materials and data storage area to authorized individuals only, so as to ensure the participants' confidentiality and the integrity of the biological materials. The length of time for which the biological materials will be stored must be defined and set out in the biobank management framework. Procedures must be in place in the event of equipment failure or breakdown, so as to preserve the integrity of the biological materials. Staff must be informed of these procedures and trained to implement them.

Use of biological materials or data for research purposes

Any research study requiring access to a bank must have received all the authorizations set out in its management framework, as well as the approval of the bank manager and an appropriate REB. This obligation applies to all research studies, including those led by the bank manager.

Any request for access to biological materials or data for analysis purposes must be submitted in accordance with the participant's consent. Procedures for approving access requests must be fair and transparent and set out in detail in the management framework. These procedures must include sub-procedures to ensure that external researchers have obtained the appropriate ethics approvals from the relevant REBs for the planned analyses, that they will take steps to limit the use of the biological materials to approved purposes, that they will protect the biological materials and data from unauthorized access, and that they will not make any attempt at re-identification. These obligations must be set out in a legally binding access agreement in accordance with Appendix B.

Use and dissemination of analysis results

Participants must not be identified in any articles stemming from bank-related research activities. This must be explained during the consent process and must be stipulated as a condition of any publication by the external researchers or scientists using the data and/or biological materials from these banks.

Transfer of biological materials outside the biobank

Any transfer of biological materials, even within the CCOMTL, requires a contractual agreement in accordance with Appendix B and approval from the relevant REB. This agreement must include, but is not limited to, the terms of use of the materials to be sent, the timeframes for transportation, the measures to be respected, and the conditions for the use of the biological materials and data.

Receipt of biological materials from third parties

Biological materials from third parties must be received in accordance with the biobank's management framework and the applicable instructions and procedures.

Destruction of biological materials

The ICF and the management framework must indicate how long the biological materials and data will be kept and whether they will be destroyed, transferred, or anonymized, unless the REB decides otherwise. Such destruction, transfer, or anonymization must be done in accordance with the biobank's management framework and the applicable instructions and procedures. Anonymized biological materials and data may be kept indefinitely with the permission of the REB.

Biological materials may need to be destroyed, in accordance with the information contained in the REB-approved ICF provided to the participants. Where applicable, any destruction of biological materials must be documented, and this documentation must be kept with the essential biobank documents.

Reporting of results and feedback to participants

The management framework provides for the reporting of results. It specifies the general or individual results that will be sent to the participants, where applicable. It also specifies whether or not researchers must report their research or analysis results to the bank. The management framework outlines procedures for dealing with incidental findings.

7. Roles and responsibilities

Person formally mandated to authorize the research

The CCOMTL must formally authorize the conduct of all research activities taking place under its auspices or responsibility. As such, the Board of Directors appoints a person formally mandated to authorize a researcher to form a databank and/or a biobank for research purposes (bank manager) or to contribute to an existing bank, under the auspices of the CCOMTL.

RRO

The RRO is responsible for the review and ongoing monitoring of biobanks. The RRO is also responsible for:

- ensuring, prior to the REB review, that the application submitted is complete and compliant, by contacting the researcher as needed;
- developing and maintaining a comprehensive directory of all banks (including the title and purpose of the bank, and the name and contact information of the bank manager);
- making this directory available to CCOMTL researchers;
- notifying the Commission d'accès à l'information of the formation of biobanks and data transfers, where applicable; and
- ensuring that these banks are managed by a researcher who is responsible for controlling access and ensuring all ethical and privacy guidelines are followed.

REB

The REB is responsible for the ethics review of biobanks under the responsibility of the CCOMTL. Prior to the REB review, the RRO, in support of the REB, ensures that the researcher has collected all the essential information for the review, which must be written according to the established guidelines suggested by the RRO in Appendix A, in keeping with MSSS and TCPS2 (2018) guidelines. In its review, the REB ensures that the management framework complies with applicable laws and ethics standards. It also determines the terms and conditions of the bank's ethical monitoring.

Bank manager

Researchers who are **responsible for a bank** (bank manager) must submit an application to the REB, via the Nagano platform, that includes the following:

- identification of the bank: name of the bank, name of bank manager and other researchers involved, source of funding, host institution of the bank, purpose of the collection;
- identification of a substitute researcher, with appropriate research privileges at the CCOMTL (https://www.ciussswestcentral.ca/about-us/academic-affairs/research-review-office/research-privileges/) who is, at all times, willing and able to replace the bank manager;
- recruitment, consent, and data collection procedures; and
- terms and conditions related to privacy and the protection of personal information, including the access mechanism.

No biobank may commence operations until the REB has given final approval and until institutional approval has been granted. The REB must approve any changes or updates to a biobank's management framework or appendices. The REB is responsible for conducting annual reviews of biobank research activities.

Databanks and biobanks formed for research purposes at the CCOMTL must remain there for the duration stipulated in their management framework. The bank infrastructure belongs to the CCOMTL. Formal approval from the CCOMTL and its REB is required to transfer responsibility to another researcher as the new bank manager, or to another institution. Biobanks located at more than one institution must be subject, upon their formation, to contractual agreements aimed at providing a framework for the transfer of data or biological materials, the roles and responsibilities of each institution, and their compliance with Quebec and Canadian legislation. These contractual agreements must be drafted in accordance with Appendix B.

The bank manager must register the biobank in an authorized directory (e.g., the Canadian Tissue Repository Network/CTRNet directory) and with the RRO. Moreover, each bank manager must, at all times, keep an up-to-date list of all biobanks for which they are responsible, whether or not hosted within the CCOMTL, and share it with the RRO upon request.

The bank manager is responsible for ensuring that the bank's management framework is up to date and that all obligations related to the maintenance of the related ethical and institutional authorizations are met.

The bank manager may delegate some of their responsibilities for the application of this policy and procedure, although they remain ultimately responsible for it. However, this delegation must be documented and kept with the essential study documents.

Researcher who participates in a bank

In the case of a bank formed outside the CCOMTL, whether public or private, in which the researcher participates, they must:

- obtain detailed instructions for the management of biological materials and data;
- implement procedures to ensure the security of biological materials and the confidentiality of information related to the biological materials;
- ensure the biological materials are collected in accordance with the protocol and the informed consent form;
- obtain, where applicable, the required approvals for the use of the biobank for secondary uses.

8. Policy application review process

Control and monitoring process

An annual update of bank authorizations must be performed in accordance with the management framework. Any closure of a biobank or database must also be done in accordance with the instructions of the Research Ethics Board and the Research Review Office. Researchers must also comply with all requests from the RRO or the REB related to this policy and procedure.

Update and effective date

This policy and procedure will take effect following its approval by the CCOMTL's Board of Directors.

This policy and procedure will be reviewed and revised, at a minimum, every three years.

9. References

- *Civil Code of Québec*, CCQ-1991
- *Act respecting health services and social services*, CQLR, c. S-4.2
- *Personal Information Protection and Electronic Documents Act*, S.C. 2000, c. 5
- *Act to modernize legislative provisions as regards the protection of personal information*, SQ 2021, c. 25
- *Regulatory framework for research involving humans at the Centre intégré universitaire en santé et services sociaux du Centre-Ouest-de-l'Île-de-Montréal,* adopted on January 27, 2022
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- Ministère de la Santé et des Services sociaux (MSSS), *Guide d'élaboration des cadres de gestion des banques de données et de matériel biologique constituées à des fins de recherche*, 2012
- Interagency Advisory Panel on Research Ethics (the Panel), *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS2), 2018
- McGill University - Faculty of Medicine, *General Guidelines for Biobanks and Associated Databanks,* 2015
- Ministère de la Santé et des Services sociaux (MSSS), *Cadre de référence ministériel pour la recherche avec des participants humains*, 2020
- Ministère de la Santé et des Services sociaux (MSSS), *Recherche clinique réalisée par l'entreprise privée à titre de promoteur : énoncé sur l'optimisation du processus de négociation des contrats*, 2022
- Fonds de recherche du Québec - Santé (FRQS), *Rapport final du groupe-conseil sur l'encadrement des banques de données et des banques de matériel biologique à des fins de recherche en santé*, 2006
- Government of Canada, Tri-Agency Research Data Management Policy, 2021

10. Appendices

Appendix A

Instructions for drafting a database and/or biobank management framework

Identification

Bank name:
Name of bank infrastructure owner (must be the institution):
Bank manager's name:
Co-investigators' names and contact information, including site information:
Source of funding:

1. **General description**
   - ⇒ Provide an introduction that briefly explains the nature and objectives of the bank.
   - ⇒ Provide context, i.e., why the bank is needed, whether there are other banks, and if so, why a bank is needed in Quebec.

2. **Governance and administration**
   - ⇒ Provide the name and describe the role of the bank holder.
   - ⇒ Provide the name and describe the role of the researcher in charge of the bank.
   - ⇒ Describe the bank's oversight mechanisms and bodies, such as advisory boards, steering committee, scientific review committee, data access committee, etc.
   - ⇒ Describe the different roles within the bank (staff) and how the bank staff will be trained, initially and on an ongoing basis.
   - ⇒ Describe the succession plan for the bank and appoint a co-investigator with appropriate research privileges at the institution to replace the researcher in charge of the bank in the event the latter can no longer continue in the role.

3. **Objectives**
   - ⇒ Indicate the specific purpose of the bank. Why are the materials/data being collected and what will they be used for?
   - ⇒ Identify the materials and data that will be collected and stored in the bank.
   - ⇒ State the purpose of the materials/data collection and type of research that will be conducted (scientific objectives of the biobank).
   - ⇒ Provide a timeline for the materials/data collection.

4. **REB monitoring**
   - ⇒ Indicate that REB approval will be required prior to the start of biobank operations and for all future secondary use studies involving data or materials from the bank.
   - ⇒ Indicate the bank's REB of record. The REB of record must be consulted on any issues or situations not covered by this framework during the lifetime of the biobank.
   - ⇒ Indicate that no materials or data will be analyzed, used, transported, or shared without appropriate REB approval.

5. **Recruitment and consent**

Important note: Research involving human materials requires specific voluntary and informed consent from the participant, unless a specific waiver is granted by the appropriate REB.

- ⇒ Indicate the study population (inclusion/exclusion criteria).
- ⇒ Indicate the types of materials and data that will be collected.
- ⇒ Indicate whether identifiers will be collected (what personal information will be collected).
- ⇒ Indicate, where applicable, whether the participants' data will be linked to medical records, healthcare databases, or other information (e.g., results of other studies).
- ⇒ Indicate what information will be collected from which sources (e.g., medical records, healthcare databases, etc.).
- ⇒ Explain the recruitment strategy (who will contact potential participants, when, where and how).
- ⇒ Describe the voluntary and informed consent process and the type of consent (verbal, written, etc.) the bank will use. Indicate if and how participants can withdraw from the bank.
- ⇒ Indicate how a bank participant can file a complaint (contact information for the CIUSSS du Centre-Ouest-de-l'Île-de-Montréal's local service quality and complaints commissioner must be included in the consent form).
- ⇒ Indicate whether there is a plan for contacting the participants.
- ⇒ Indicate whether there are any plans for ongoing communication with the participants (e.g., monthly newsletter).

6. **Privacy and confidentiality**
   - ⇒ Describe how the materials and data will be kept confidential.
   - ⇒ Describe the coding process of the materials and data collected, indicate who will oversee the process and who has access to the key.
   - ⇒ Describe the information that will appear on the sample labels.
   - ⇒ Identify who has access to information about the study participants.

7. **Storage, security and infrastructure**
   - ⇒ Indicate how long the data and materials will be kept.
   - ⇒ Indicate where the data and materials will be stored, including all participant information.
   - ⇒ Describe the physical and IT infrastructure in place to protect the data and materials.

8. **Collection and processing of biological materials (this section is specific to biobanks)**
   - ⇒ Specify the types of biological materials that will be collected (blood, tissue, bone marrow, saliva, etc.).
   - ⇒ Indicate whether the biological materials will be collected prospectively, or whether the samples were collected during clinical procedures and only unused biological materials will be added to the biobank (or both).
   - ⇒ Describe the collection process and the origin of the sample, e.g., cell lines (where applicable).
   - ⇒ Indicate if and what type of genetic material will be isolated, processed and analyzed.
   - ⇒ Indicate what will be done with the derived data (e.g., it will be added to the biobank).

9. **Access to and use of data and materials**

Access to and use of the data and materials are the responsibility of the steering committee appointed in accordance with the framework of each bank.

- ⇒ Indicate how access to the data and materials will be granted and controlled. Describe the process/procedures for obtaining access to the bank.
- ⇒ Indicate what is accessible and for what purpose.

⇒ Indicate the ethics approval process for gaining access to the materials and data held by the bank.

⇒ Indicate whether the bank will be accessible to external researchers/third parties and if so:

- Who these researchers might be;
- Describe where the bank will be publicly listed;
- Describe the access criteria (scientific objectives, availability of materials, etc.);
- Indicate when a data or materials transfer agreement would be required;
- Describe how the data and materials will be distributed;
- Describe how the confidentiality and security of the data and materials will be ensured;
- Describe the restrictions on sharing de-identified information;
- Describe any intellectual property and marketing policies (including publications);
- Indicate whether there will be a fee to access the bank.

⇒ See that measures are in place to ensure the samples, as limited resources, are used appropriately and that scientific integrity is maintained.

10. Reporting of research results

⇒ Indicate the bank's policy on the reporting of individual research results: Will individual research results be given to the participants?

⇒ Indicate the bank's policy on reporting incidental findings: Will incidental findings be passed on to the participants?

⇒ In both cases:

- If not, justification is required;
- If so, how will the results be reported?

⇒ Indicate how the general research results will be communicated to the participants.

11. Dissemination of research results

⇒ Indicate the plans for disseminating any scientific research based on the bank (e.g., publications).

12. Intellectual property and marketing

⇒ Describe the intellectual property and marketing policy (see also *Access to and use of data and materials*).

13. Closure and decommissioning

⇒ If known, indicate how long materials are expected to be stored in the bank.

⇒ Describe the bank's closure strategy

- Will the materials and data be destroyed?
- Will the materials and data be transferred to another bank?

14. References

⇒ List all references used to draft your bank's management framework.

Appendix B

Mandatory contractual elements

An agreement must be signed:

- prior to the transfer of biological materials or data outside of the CCOMTL (contract governing contribution of CCOMTL biological materials to third party banks); and
- prior to any use of biological materials or data stored in a biobank or database (CCOMTL bank access contract).

This agreement must include at least the following elements and is subject to the policies, procedures, and standard operating procedures of the CCOMTL's Access to information and protection of personal information committee and to review by the Commission d'accès à l'information du Québec.

The following elements must be included in the agreements governing the use of any bank:

Ownership of the data or biological materials and freedom of use	No property rights may be granted on human biological materials. Public institutions may not limit or waive their right to participate in other research studies.
Liability	The CCOMTL cannot compensate parties that contribute to biobanks or databanks formed by its researchers. However, each party to the agreement is liable for their own actions. No one may limit their liability for any physical or moral damage, nor for any injury caused by their gross negligence or wilful misconduct.
Compliance and applicable laws	The CCOMTL and its researchers are required to comply with applicable federal and provincial laws, ministerial directives, guidelines and circulars, as well as any ethical guidelines that may be applicable to them, which set out various obligations that cannot be waived.
Insurance	Each party to the agreement must confirm that it has sufficient insurance to cover any loss arising from its fault in connection with this policy and procedure.

Moreover, the following elements must be included in agreements governing uses external to the CCOMTL:

Compliance and applicable laws	As a public institution, the CCOMTL cannot make representations under foreign laws. As such, when a researcher with research privileges at the CCOMTL participates in a biobank or database, they must ensure that the same protections apply as those granted under Quebec or federal laws.
Use of data and biological materials	The bank management framework must stipulate that the researcher contributing to the bank and the CCOMTL may submit access requests for secondary use.
Budget	Indirect fees must be charged and budgeted for, in accordance with the regulatory framework. Moreover, all amounts prescribed by Circular 2016-029 (https://www.ciussswestcentral.ca/about-us/academic-affairs/research-review-office/rec-fees/) will also need to be collected, in accordance with the regulatory framework.

Governing law and choice of forum	Unless expressly and exceptionally authorized by the CCOMTL's authorized signatory, any dispute related to the agreement and involving the CCOMTL or its researchers must be heard by the competent courts located in the province of Quebec. These hearings must be governed by the applicable laws of Quebec and Canada.
Contract language	All agreements must be written in French. However, if the parties so indicate and if such an exclusion is provided for by law, they may, in certain cases, be drafted in another language.