

SIGNATURE BIOBANK APPLICATION GUIDE

Biobanque Signature

Biobanque de spécimens et de données biologiques, psychosociales et cliniques en
santé mentale

CRIUSMM

2023-10-01



Centre intégré
universitaire de santé
et de services sociaux
de l'Est-de-
l'Île-de-Montréal

Québec



APPLICATION GUIDE SIGNATURE BIOBANK

Prepared by Cécile Le Page
Biobank Signature Coordinator

TABLE DES MATIERES

1- DOCUMENT LISTS	1
1.1- DOCUMENTS REQUIRED FOR ANY APPLICATION	1
1.2- DOCUMENTS OBLIGATOIRES, SI APPLICABLES :	1
2- LIST OF APPENDICES TO THE GUIDE	2
3- STEPS TO ACCESS THE BIOBANK MATERIAL	3
3.1- APPLICATION :	3
3.2- ANALYSIS:.....	3
3.3-	3
3.4- SUBMISSION OF THE STUDY BY THE RESEARCHER TO THE ETHICS REVIEW BOARD (ERB):	4
3.5- SIGNATURE OF BIOBANK AGREEMENT SIGNATURE AND COLLECTION OF MATERIAL TRANSFER FEES:	4
3.6-	4
3.7- THE RESEARCHER IS RESPONSIBLE FOR RETURNING THE RESULTS DERIVED FROM THESE ANALYSES, THE DERIVED VARIABLES, THE GROUPINGS.....	4
4- SCHEMATIC REPRESENTATION OF THE SUBMISSION STAGES FOR OBTAINING MATERIAL FROM THE SIGNATURE BIOBANK:.....	5

1- DOCUMENT LISTS

1.1- DOCUMENTS REQUIRED FOR ANY APPLICATION

1- Financial estimate for the biobank, approved by the researcher	
4- Research protocol for the use of biobank material	
5- Research Ethics Board (REB) approval	
6- Signed Researcher Agreement	

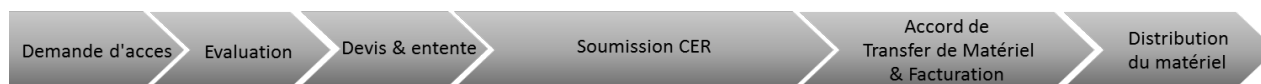
1.2- DOCUMENTS MANDATORY FOR SPECIFIC SITUATIONS:

The new questionnaire to recontact participants	
Material transfer Agreement signed by your institution (multicentric studies)	
Proof of concept for new assays on biological samples	
Award letter from funding agency (for REB approval)	

2- LIST OF APPENDICES TO THE GUIDE

1. Study protocol template for your REB
Study protocol outline for Signature data analysis, including description of biobank variables. An outline is available [here](#).
2. Guide to completing the Nagano F11d form
3. Management framework: available [here](#).
4. The informed consent form (ICF): available [here](#) for the control group and [here](#) for patients.
5. The researcher's signed undertaking.
6. The financial declaration signed by the researcher and approved by the research department.
This is a Word document, which you can also download from the Nagano platform of your institution.

3-STEPS TO ACCESS THE BIOBANK MATERIAL



3.1- APPLICATION :

The researcher submits an informal request to the Biobank Signature Access Committee or to the coordinator using the online form available on the Biobank website (www.banquesignature.ca) by email : signature.iusmm@ssss.gouv.qc.ca OR cecile.le.page.cemtl@ssss.gouv.qc.ca

La application includes :

- The researcher's contact details
- List of desired biomarkers and biospecimens
- Participant/biospecimen selection criteria
- A brief description of the research project
- Proof of funding for the study (financial statement)

3.2- ANALYSIS:

The access committee reviews the request and issues a response to the requesting researcher with an estimate of access costs (Quotation). The analysis consists of verifying :

- The eligibility of the principal investigator,
- Study feasibility (number of subjects, objectives, selection criteria),
- Availability of material (psychosocial medical data and biospecimens),
- The originality of the request in comparison with projects already approved or in progress,
- Estimate the cost of access to the requested material.

3.3- SUBMISSION AND APPROVAL OF SPECIFICATIONS BY THE RESEARCHER:

The Biobank coordinator sends the researcher a cost estimate and a statistical report from the analyst. The costs represent the actual costs of data collection and analysis for the biobank. The project can be adjusted according to the researcher's needs and the analyst's recommendations. Consultation with the analyst may be necessary to better define the choice of variables. Certain analyses may be requested in order to improve a research protocol for a funding application or approval by the scientific/ethics committee.

- The researcher then signs and approves the quotation for the biospecimen and/or data transfer fees, and sends it back to the coordinator by e-mail.
- The biobank then issues a letter of support to the researcher confirming the availability of the biospecimens and/or data for his/her study. This letter can be used to apply for approval from the REB of the researcher's institution.

- The researcher must also sign and approve the commitment form, or MTA, which binds him/her to the conditions of use of the Biobank's material (compliance with the rules of confidentiality and the Biobank's management framework, undertaking to provide the necessary approvals for the transfer of material, undertaking to return the results derived from his/her analyses).

3.4- SUBMISSION OF THE STUDY BY THE RESEARCHER TO THE ETHICS REVIEW BOARD (ERB):

Researchers must obtain approval for their study from their REB.

Following evaluation of your application, the REB may issue a letter of approval without further question, or ask you to provide additional justification before approving your application. Certain analyses may be requested from the biobank in order to improve a research protocol for REB approval.

3.5- SIGNATURE OF BIOBANK AGREEMENT SIGNATURE AND COLLECTION OF MATERIAL TRANSFER FEES:

Following receipt of the REB's project approval letter, the Signature Biobank sends you the final invoice MTA for signature.

3.6- DELIVERY OF DATA, BIOSPECIMENS AND/OR BIOLOGICAL ANALYSES:

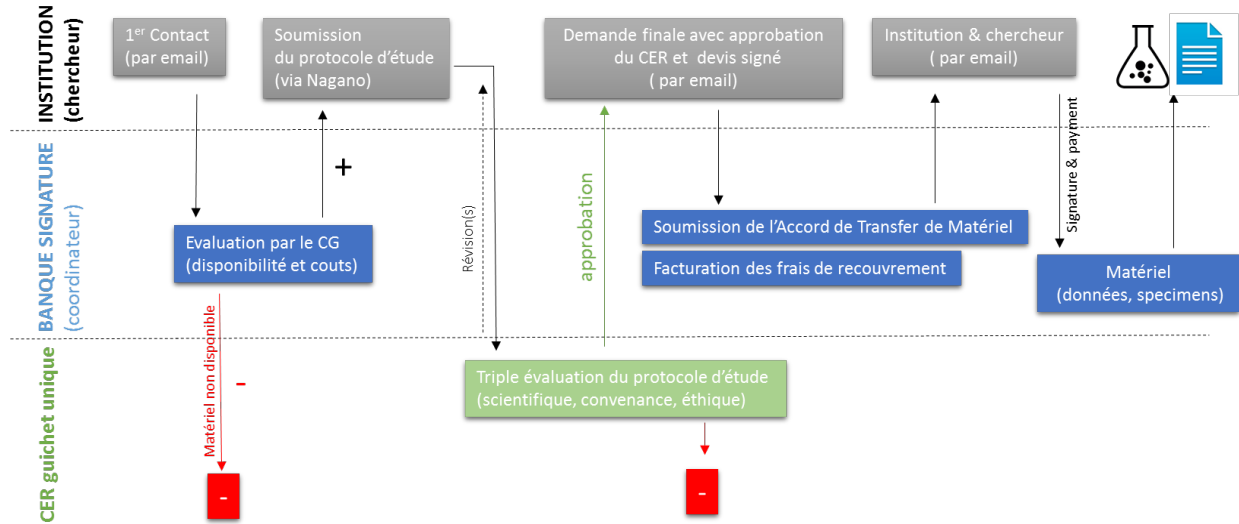
Following receipt of the material transfer fee recovery, researchers will be able to obtain raw medical and psychosocial data from the Biobank, and additional biological analysis data, as well as the requested human biological material.

- Raw medical and psychosocial data are sent within two weeks of the lifting of these access conditions. As the majority of IUSMM researchers use SPSS software, data is sent in this format. The researcher can contact the analyst to analyze the data in another software or statistical environment.
- Biospecimens are also delivered as quickly as possible. The researcher will receive the biospecimens in a cooler or other specialized container, depending on the type of biospecimen. **Transportation costs are billed to the research.**
- Additional biological analyses can be carried out either by the Signature laboratory or by an external laboratory. Communication with external laboratories is handled by the Signature biospecimen coordinator during sample preparation. Only the final results are sent to the researcher. If the researcher requires more detailed results, he/she should contact the analyst, who will liaise with the laboratory technician if necessary.

3.7- THE RESEARCHER IS RESPONSIBLE FOR RETURNING THE RESULTS DERIVED FROM THESE ANALYSES, THE DERIVED VARIABLES, THE GROUPINGS.

Derived variables (new scales) and new groupings (clusters and trajectories) are part of the results that must be returned to the Biobank, once the publication has been accepted.

4- SCHEMATIC REPRESENTATION OF THE SUBMISSION STAGES FOR OBTAINING MATERIAL FROM THE SIGNATURE BIOBANK:



*Centre intégré
universitaire de santé
et de services sociaux
de l'Est-de-
l'Île-de-Montréal*

Québec

