DATA REQUEST FORM *BIOBANQUE QUÉBÉCOISE DE LA COVID-19*

The mission of The *Biobanque québécoise de la COVID-19* (BQC19) is to ensure that the scientific community has access to the biological material and data necessary for their research efforts on COVID-19 and its associated diseases. The scientific community can, therefore, effectively respond to public health challenges represented by the pandemic, in a context of solid scientific bases within an appropriate ethical and legal framework. The notion of sharing research results is also at the heart of the BQC19’s mission.

**Eligibility criteria for requesting access**

The requesting party must be one of the following:

* Canadian academic researcher;
* International academic researcher; and
* Researcher from a private entity.

**Evaluation criteria**

* Scientific contribution of the project to research on COVID-19 and its associated diseases in accordance with the mission of the BQC19;
* Robustness of the project;
* Feasibility of the project (validation of techniques in the applicant’ laboratory, adequate financial support to achieve the objectives).
* Expertise of the team in the specific field;
* Potential impact of access to sample on the risk of depletion of the collection;
* The requesting party must have practices in place ensuring:
* Accurate data protection: all data must be kept confidential and secure with minimal risk of re-identification;
* The respect of the terms of the consents given by the Study Subjects (available on BQC19 website): access must respect the rights, interests and expectations of participants of the BQC19; and
* Proper training of investigators and personnel, that would be required under the rules and policies regarding the research use of human biological data. Particular attention will be paid to the expertise of the teams in handling data, minimizing the risk of re-identification.

It is important that sufficient details are provided to ensure a proper evaluation of the study.

Once a request is approved, the requesting party will be asked to sign a Data Transfer Agreement with the BQC19 and McGill University.

For any question, please email the BQC19 Access Officer at doris.ransy@affiliate.mcgill.ca

*All sections must be filled out.*

Date:

|  |  |
| --- | --- |
| **SECTION 1** | **APPLICANT INFORMATION** |
| **Principal investigator (PI)**\*\*Please provide your **CV (CIHR or NIH format)**  | Name |       |
|  | Institution |       |
|  | Address |       |
|  | Email |       |
|  | Phone |       |
| **Co-investigator** | Name |       |
|  | Institution |       |
|  | Address |       |
|  | Email |       |
|  | Phone |       |
| **Co-investigator** | Name |       |
|  | Institution |       |
|  | Address |       |
|  | Email |       |
|  | Phone |       |
| **Co-investigator** | Name |       |
|  | Institution |       |
|  | Address |       |
|  | Email |       |
|  | Phone |       |
| **Co-investigator** | Name |       |
|  | Institution |       |
|  | Address |       |
|  | Email |       |
|  | Phone |       |

\*If you need to add more co-investigators to the request, please contact doris.ransy@affiliate.mcgill.ca

|  |  |
| --- | --- |
| **SECTION 2** | **RESEARCH PROJECT DESCRIPTION** |
| **Title** |       |
| **Lay Title *(for the BQC19 public website)*** |       |
| **Lay summary (maximum 650 characters)*****(for the BQC19 public website)*** |       |
| **Summary of the proposal** (limited to one page, Calibri font 11, single spacing).References can be added using additional pages.  |
|       |
| Please clearly explain how the BQC19 samples will be used in your project. |       |
| **PROJECT DERIVED DATA (must be provided by the User-Researcher to the BQC19)** |
| **Specify the exact nature of the project derived data to be provided to the BQC19** (newly acquired data, such as data acquired from recontacting participants) (maximum 2000 characters): |  |
| **Timeframe** within which the Project Derived Data will be provided to the BQC19: |  |

|  |  |
| --- | --- |
| **SECTION 3** | **DATA CONFIDENTIALITY AND SECURITY** |
| The use of data (clinical and/or experimental data derived from human biological samples) for research purposes in accordance with the BQC19 commitment to study participants requires that the applicant: (1) protect coded data; and and (2) make no attempt to re-identify participants and minimize this risk during analyses.The following safety and confidentiality rules must be observed when using the data:The researcher's institution and the researcher agree:* To sign, or have people accessing the research data sign a confidentiality agreement and to provide a copy of these documents to the BQC19.

The researcher or any member of his research team accessing the data agree:* To comply with the obligations provided for, in the material and data transfer agreement, throughout its duration and, thereafter, with all those having implications beyond this duration, in particular with regard to confidentiality;
* To comply with all instructions given by the BQC19 for the use of its data, in particular with regard to physical security, IT security and confidentiality;
* To use the data only for the project which has received approval from a Research Ethics Board and from the BQC19 Access Committee;
* Not to use the data for administrative or commercial purposes;
* Not to make any attempt to re-identify individuals;
* Not to give access to the data to any other person working on the same premises; and
* Not to disseminate any results which could make it possible to link information, even indirectly, to an individual or to any other identifiable unit, such as a company, a health establishment, a school, etc.

[ ]  I agree to comply with the BQC19 recommendations above for best practices in data privacy. |
| Data sharing between institutions\* | If data obtained through this application need to be accessed by a co-investigator outside of your institution, they will have to sign a separate DTA with the BQC19. |
|  | Do data need to be accessed by outside co-investigators? | [ ]  Yes[ ]  No |
|  | Specify who:       |
| If you have publications that support the fact that you have previous experience or knowledge in the use of data derived from human participants, provide a list below: (maximum 2000 characters) |
|       |

*\* Data sharing between co-ivestigators must respect the safety and confidentiality rules stated above, that were signed by the PI. i.e. The PI is responsible for sharing the data securely (not by email).*

|  |  |
| --- | --- |
| **SECTION 4** | **SCIENTIFIC REVIEW AND ETHICS APPROVAL** |
| [ ]  This project is funded by an organization that uses peer review and was approved by its peer review committee – Please provide the confirmation letter.  |
|  Organization: |       |
|  Grant number: |       |
|  Funding period: |       |
| [ ]  This project is funded by a non-peer reviewed source - Please provide the confirmation letter. |
|  Organization/Company: |       |
|  Funding period: |       |
| **Approval by a Research Ethics Board:** |
| [ ]  Approval received | Organization:       |
|  | Document number:       |
| [ ]  Not approved yet (will be mandatory for final approval of your request) |

|  |  |
| --- | --- |
| **SECTION 5** | **DATA REQUESTED1** |
| **PARTICIPANTS** |
| **COVID status\*** | COVID (+) n=      | COVID (-) n=      |
| **Age range\*** | [ ]  Unspecified | [ ]  <18 (n=     ) | [ ]  >18 (n=     ) | [ ]  Specify:       (n=     ) |
| **Sex at birth\*** | Male n=      | Female n=      |
| **Pregnant participants\*** | [ ]  Yes (n=     ) | [ ]  No (n=     ) |
| **Hospitalized participants\*** | [ ]  Yes (n=     ) | [ ]  No |
|  Hospitalization visit | [ ]  D0 | [ ]  D2 | [ ]  D7 | [ ]  D14 | [ ]  D30 |
|  Follow-up post discharge  | [ ]  D30 post discharge | [ ]  D90 | [ ]  D180 |
| [ ]  D365 | [ ]  D540 | [ ]  D730 |
| **Outpatients \*** | [ ]  Yes (n=     ) | [ ]  No |
|  Follow-up post diagnostic  | [ ]  D30 post diagnostic | [ ]  D90 | [ ]  D180 |
| [ ]  D365 | [ ]  D540 | [ ]  D730 |
| **Specify any other clinical parameter that you would like to base your studied population on** (*e.g., diabetes, coronary artery disease etc.*)Specify the minimum number of participants required for each population.*check the availability of patients with these clinical parameters on* [***Bento***](https://www.quebeccovidbiobank.ca/bento)***.*** |       |
| **CLINICAL DATA** |
| Clinical data are always offered with the samples requested. To see what kind of clinical data we offer, visit our [**Bento**](https://www.quebeccovidbiobank.ca/bento) platform. |
| **ANALYTICAL DATA (**[**please click here for additional details**](https://www.bqc19.ca/docs/support/coreanalysesdescriptionfeb162021webfinal.pdf)**)** |
| [ ]  Proteomics-1 SomaScan® | Simultaneous measurement of 5,000 proteins (<https://somalogic.com>) |
| [ ]  Proteomics-2 Circulating markers | Measurement of established markers of inflammation/disease activity using the Olink technology  |
| [ ]  Roche Laboratory analysis  | Analyses performed on clinical-grade Roche platform carried out on samples collected from patients. They include evaluations of liver, heart, and kidney damage, as well as measurements of standard inflammatory markers. |
| [ ]  Metabolomics | Plasma metabolomic profile (<https://www.metabolon.com>) |
| [ ]  Immuno-serology | Detailed quantitative measurements of specific antibodies against the SARS-CoV-2 virus including the ability of these antibodies to neutralize the virus.  |
| [ ]  Transcriptomics | Transcriptomic analyses performed on RNA extracted from whole blood will generate important data in this area of COVID-19 research. |
| [ ]  Genome-wide genotyping (GWAS) and Whole genome sequencing (WGS) | Identification of all genetic variants in the host genome and genetic variations such as changes in the copy number of certain genes (genome-wide sequencing) as well as common genetic variations across the genome (genome-wide genotyping) associated with COVID-19 enables studies on the susceptibility and risk of developing a severe form of the disease and complications. |
| [ ]  Viral Sequencing: | Sequencing of viral samples from individuals who have tested positive (PCR) for the SARS-CoV-2 virus. Enables genomic-based tracking and analysis of the evolving traits of the SARS-CoV-2 virus throughout the pandemic waves. |
| **RECONTACTING PARTICIPANTS** |
| [ ]  Contact information of participants | Contact information of participants who have consented to be recontacted to provide additional information about them, or to be invited to participate in new research projects.  |

\*Section must be filled in

*1Please refer to the list of available participants in* [***Bento***](https://www.quebeccovidbiobank.ca/bento) ***,*** *Please refer to the complete list of parameters available* [*here*](https://en.quebeccovidbiobank.ca/donnees-partagees)*.*

If this request is approved, The Data will be provided on the following **terms and conditions**:

1. The Data are provided to the investigators requesting them, hereafter referred to as "the Receiving Party". The Receiving Party will ensure that The Data will only come into the possession and control of those who are engaged in the above-mentioned Research under the supervision of the Receiving Party and who have accepted the same obligations and restrictions in respect of The Data. The Data shall not be transferred, sold, or otherwise used or made available to any person, and the Receiving Party must not offer to do so.
2. The Data are provided to the Receiving Party exclusively and solely for use in the Research described in section 2 above ("Research project description"). The Receiving Party shall not use, and shall require any person having access to the Data not to use said Data for any purpose other than the one described in section 2. In case the Receiving Party would like to use The Data for other research purposes, a new Material and Data Request Form should be submitted.
3. All publications shall acknowledge the use of Material and Data from the *Biobanque québécoise de la COVID-19*, as well as the support of *the Fonds de Recherche du Québec* (FRQ), the *Fonds de Recherche du Québec - Santé* (FRQ-S), *Génome Québec (GQ), the Ministère de la Santé et des Services sociaux (MSSS),* and the Public Health Agency of Canada (PHAC). No authorship is required.
4. On completion of the Research, and at the time of submitting the results obtained through the use of the Data for peer-review, the Receiving Party shall report the derived data to the BQC19 for broad sharing.
5. The Receiving Party shall not make any attempt to re-identify individuals in the data set.
6. The Receiving Party will treat the Data as strictly confidential and will ensure that the Data will be retained using the adequate safeguards.
7. Access to the Data will be subject to an access fee of $ 1,500 per dataset, for both academic researchers and researchers from a private entity. Researchers from a private entity will be charged an additional $ 10,000 per project, plus additional cost-recovery fees for analytical data depending on the number of datasets requested.
8. The initial acceptance of the present request will be conditional. Final approval will be given upon receipt of approval of the project by a recognized research ethics board.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |
| --- |
| **ATTESTATION BY THE APPLICANT (PI)** |
| [ ]  I confirm that all the information provided in this request, as well as any other information that I may subsequently provide, is true to the best of my knowledge. |
| [ ]  I am committed to acknowledging the *Biobanque québécoise de la COVID-19*, as well as the support of *the Fonds de Recherche du Québec* (FRQ), the *Fonds de Recherche du Québec - Santé* (FRQ-S), *Génome Québec (GQ), the Ministère de la Santé et des Services sociaux (MSSS),* and the Public Health Agency of Canada (PHAC). |
| [ ]  Regarding the access fees, once the request is approved, I agree to send back my purchase order number within 45 days of receiving the quote sent by the BQC19. I also agree to pay the access fees to the BQC19 within 60 days of receiving the BQC19 Invoice. Otherwise the BQC19 reserves the right to cancel my application  |
| [ ]  I agree to sign the Data transfer agreements once the request is approved. I understand that the agreement should be signed and returned to the BQC19 within 6 months, otherwise the BQC19 reserves the right to cancel my application. |
| [ ]  I agree to have the title and the lay summary describing my project appear in the public registry of approved projects on the BQC19 website. |
| [ ]  I acknowledge that I have read and understood this document in its entirety and will abide by the terms and conditions. |

|  |  |
| --- | --- |
| **Name:**  | **Date:**  |

**Signature:**

**CHECKLIST:**

[ ]  The current form completed and signed

[ ]  Proof of approval of the project by a recognized Research Ethics Board\*

[ ]  CV of the Principal Investigator in PDF format

[ ]  Proof of funding (confirmation letter)\*

[ ]  References for the summary of proposal, if applicable.

\* If document not available yet, will have to be provided at time of MTA signature.

Please combine all your documents in a single **PDF file** titled as follows: “**Last name\_First name of PI”** and submit it via the [BQC19 web portal](https://www.bqc19.ca/en/access-data-samples).