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.
* Researcher from a private entity.

**Evaluation criteria:**

* Scientific contribution of the research project on COVID-19 and its associated diseases in accordance with the mission of the BQC19.
* Scientific validity of the research project (to be evaluated only if the project has not been previously peer-reviewed).
* The requesting party has previously demonstrated (supporting documents attached) or outlined their capacity to handle sensible data containing clinical information, in order to ensure:
* 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 to the BQC19.
* 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 and protecting data and 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.

For any question, please email the BQC19 Access Officer at acces@rqcp.ca

*All sections must be filled out.*

Date:

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| **SECTION 1** | **APPLICANT INFORMATION** |
| Principal investigator (PI)\*\*Please provide your **CV** in the format of a CIHR project biosketch or NIH biographical sketch. | Name |       |
|  | Institution |       |
|  | Address |       |
|  | Email |       |
|  | Phone |       |
| Co-investigator | Name |       |
|  | Institution |       |
|  | Address |       |
|  | Email |       |
|  | Phone |       |
| Co-investigator | Name |       |
|  | Institution |       |
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|  | Phone |       |
| Co-investigator | Name |       |
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| Co-investigator | Name |       |
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|  | Phone |       |

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| **SECTION 2** | **RESEARCH PROJECT DESCRIPTION** |
| Title |       |
| Lay Title *(for the BQC19 website)* |       |
| Lay summary (maximum 650 characters)*(for the BQC19 website)* |       |
| Scientific summary (maximum 1850 characters) |       |
|  **Summary of the proposal** (limited to one page, Calibri font 10, single spacing).References can be added using additional pages.  |
|       |
| **PROJECT DERIVED DATA (which 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 (maximum 2000 characters): |  |
| Timeframe within which the Project Derived Data must be provided to the BQC19: |  |

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| **SECTION 3** | **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 (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 Contract 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 and
* 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 in the same premises;
* 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 for best practices in data privacy. |
| 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) |
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| **SECTION 4** | **SCIENTIFIC REVIEW AND ETHICS APPROVAL** |
| [ ]  This project is approved by a peer reviewed 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 (please provide a copy) |
| Organization: |       |
| Document number: |       |

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| **SECTION 5** | **COHORT\*** |
| [ ]  **Access to the entire dataset** |
| COVID status | COVID (+) n=      | COVID (-) n=      |
| Age range | [ ]  Unspecified | [ ]  <18 (n=     ) | [ ]  >18 (n=     ) | [ ]  Specify:       (n=     ) |
| Sex at birth | Male n=      | Female n=      |
| Pregnant | Yes (n=     ) | No (n=     ) |
| Type of participant | [ ]  Hospitalized | [ ]  Outpatient |
| Hospitalization visit | [ ]  D0 | [ ]  D2 | [ ]  D7 | [ ]  D14 | [ ]  D30 |
| Follow-up post discharge (H) or post diagnostic (O) | [ ]  D30 | [ ]  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 *n* required for each population. |       |

\*n represents the minimum number of participants required for your study; D = days

\*\*Please refer to the list of parameters available [here](https://www.bqc19.ca/en/study-design)

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| **SECTION 6** | **DATA REQUESTED** |
| **CLINICAL DATA‡** |
| [ ]  **Access to the entire dataset** |
| **General information on participant** | [ ]  Participant profile | Age, sex, weight, BMI, country of birth, smoking status and drugs |
|  |  |
| [ ]  Pediatric participant | Weight at birth, gestational outcome |
| [ ]  Obstetrics (if applicable) |  |
| [ ]  Type of participant | Healthcare worker, employed in a microbiology laboratory, etc. |
| **COVID diagnostic test and pathogen tests** | [ ]  SARS-CoV-2 diagnostic test results (PCR) |
| [ ]  Other pathogen tests | Viral, bacterial |
| **Others clinical parameters** | [ ]  Medical history | Past medical conditions and home medications |
| [ ]  Symptoms documented |  |
| [ ]  Frailty score |  |
| **Vital sign at arrival** | [ ]  Temperature[ ]  Systolic / Diastolic blood pressure[ ]  Respiratory rate[ ]  Heart rate [ ]  O2 saturation at room air[ ]  Oxygen administered [ ]  O2 saturation with oxygen therapy (with FiO2) |  |
| **Laboratory analyses** | [ ]  White blood cells count[ ]  Neutrophils count[ ]  Lymphocytes count[ ]  Monocytes count[ ]  Eosinophils count[ ]  Basophils count[ ]  Platelet count[ ]  Hemoglobin measurement[ ]  Urea[ ]  Creatinin[ ]  NT-proBNP[ ]  BNP[ ]  Sodium Na+[ ]  Potassium K+[ ]  C-reactive protein (CRP)[ ]  Lactate dehydrogenase (LDH or LD)[ ]  Creatin phosphokinase (CPK)[ ]  Albumin[ ]  AST[ ]  ALT[ ]  Procalcitonin (PCT)[ ]  Troponin T hs (high sensitivity)[ ]  Troponin I hs (high sensitivity)[ ]  Troponin T[ ]  Troponin I[ ]  APTT[ ]  International Normalized Ratio (INR)[ ]  Triglycerides[ ]  Total bilirubin[ ]  Direct bilirubin (conjugated)[ ]  Glucose[ ]  Venous lactate[ ]  D-Dimer[ ]  Fibrinogen[ ]  Ferritin[ ]  IL-6[ ]  CD4[ ]  CD8 |
| **Vital signs during hospitalization** | [ ]  Temperature[ ]  Systolic / Diastolic blood pressure[ ]  Respiratory rate[ ]  Heart rate [ ]  O2 saturation at room air[ ]  Oxygen administered [ ]  O2 saturation with oxygen therapy (with FiO2)[ ]  AVPU scale[ ]  Glasgow Coma scale[ ]  Urine output over 24h |  |
| **Support and therapy - hospitalization** | [ ]  Ventilatory support (and its parameters) |  |
| [ ]  Adjuvant therapy |  |
| **Hospitalization summary** | [ ]  Emergency visit only[ ]  Hospital arrival/admission (duration of hospitalization - date available but possibility of re-identification of the participant to be validated if this data is submitted)[ ]  Is it a transfer from another facility?[ ]  If transferred from another facility (total duration of hospitalization - date available but possibility of re-identification of the participant to be validated if this data is provided)[ ]  ICU admission (duration of stay at the ICU - date available but possibility of re-identification of the participant to be validated if this data is given)[ ]  Disposition[ ]  Discharge status[ ]  Ability to self-care at discharge vs. pre-COVID[ ]  Level of care (last status)[ ]  Other tests performed during hospitalization (no test results available)[ ]  Complications during hospitalization[ ]  Treatment (at any time during hospitalization)[ ]  Medications during hospitalization[ ]  If a screening test for SARS-CoV-2 by PCR was performed, what is the highest severity level (according to WHO) achieved? |
| **Summary of laboratory tests during hospitalization (highest or lowest)** | [ ]  White blood cells count[ ]  Neutrophils count[ ]  Lymphocytes count[ ]  Monocytes count[ ]  Eosinophils count[ ]  Basophils count[ ]  Platelet count[ ]  Hemoglobin measurement[ ]  Urea[ ]  Creatinin[ ]  NT-proBNP[ ]  BNP[ ]  Sodium Na+[ ]  Potassium K+[ ]  C-reactive protein (CRP)[ ]  Lactate dehydrogenase (LDH or LD)[ ]  Creatine phosphokinase (CPK)[ ]  Albumin[ ]  AST[ ]  ALT[ ]  Procalcitonin (PCT)[ ]  Troponin T hs (high sensitivity)[ ]  Troponin I hs (high sensitivity)[ ]  Troponin T[ ]  Troponin I[ ]  APTT[ ]  International Normalized Ratio (INR)[ ]  Triglycerides[ ]  Total bilirubin[ ]  Direct bilirubin (conjugated)[ ]  Glucose[ ]  Venous lactate[ ]  D-Dimer[ ]  Fibrinogen[ ]  Ferritin[ ]  IL-6[ ]  CD4[ ]  CD8 |
| **Follow up (post discharge or post diagnostic)** | [ ]  Vital status[ ]  New or recurrent case of COVID since last follow-up (based on PCR testing)[ ]  Re-hospitalization[ ]  Current symptoms[ ]  Functional status[ ]  Complications post-COVID[ ]  Frailty scale[ ]  Vaccination |
| **ANALYTICAL DATA (**[**please click here for additional details**](https://www.bqc19.ca/docs/support/coreanalysesdescriptionfeb162021webfinal.pdf)**)** |
| [ ]  Proteomics-1 SomaScan® | Simultaneous measurement of 5000 proteins (<https://somalogic.com>) |
| [ ]  Proteomics-2 Circulating markers | Measurement of established markers of inflammation/disease activity using a very specific and sensitive technique developed by nplex (List of markers [here](https://www.bqc19.ca/docs/support/coreanalysesdescriptionfeb162021webfinal.pdf)) (<https://www.nplexbio.com>) |
| [ ]  Roche Laboratory analysis for outpatients  | Analyses performed on clinical-grade Roche platform carried out on samples collected from non-hospitalized 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 (GWS) and Whole genome sequencing (GWAS) | 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. |

**‡** Please refer to the complete list of parameters available [here](https://www.bqc19.ca/en/study-design)

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 ("the Purpose of Use"). The Receiving Party shall not use, and shall require any person having access to the Materials and the Data not to use said Materials and Data for any purpose other than the Purpose of Use. In case the Receiving Party would like to use the Data for other research purposes, a new Data Request Form should be submitted.
3. All publications shall acknowledge the use of 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* and the Public Health Agency of Canada (PHAC). No authorship is required.
4. The Receiving Party shall not in any case attempt to re-identify individuals in the data set.
5. The Receiving Party will treat the Data as strictly confidential and will ensure that the Data will be retained using the adequate safeguards.
6. Access to the Data will be subject to an access fee of $ 1,500 for academic researchers. Researchers from a private entity will be charged an additional $ 10,000 plus additional cost-recovery fees for analytical data depending on the number of datasets requested.

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| **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* and the Public Health Agency of Canada (PHAC). |
| [ ]  I agree to pay the access fee to the BQC19 once the request is approved. |
| [ ]  I acknowledge that I have read and understood this document in its entirety and will abide by the terms and conditions. |
| [ ]  I agree to sign the Material and Data transfer agreements once the request is approved. |

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| --- | --- |
| 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.

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).