APPROUVÉ – CÉR CHUM

DATE: 14 septembre 2020
INITIALES: MJB

INFORMED CONSENT FORM

Biobanque québécoise de la COVID-19 (BQC19)

Directors of the Biobank:	Dr. Michaël Chassé, Clinician Scientist, Centre de Recherche du Centre Hospitalier de l'Université de Montréal Dr. Vincent Mooser, Canada Excellence Research Chair in Genomic Medicine, McGill University
Co-director of the Biobank:	Simon Rousseau, Ph. D., Principal Investigator, Research Institute of McGill University Health Centre
Funding:	FRQS, Génome Québec
No of the biobank at the CHUM:	19.389

PREAMBLE

This informed consent form is intended for the participant or, in the event of legal or sudden incapacity, his/her legal representative.

We invite you to participate in the **Biobanque québécoise de la COVID-19 (BQC19) because you were tested for COVID-19 whose result is positive or negative.** Before agreeing to participate in this biobank, please take the time to read and understand the following information. This document may contain words that you do not understand. We invite you to ask any questions you may have to the director of the biobank or members of his team and ask them to explain anything that is not clear.

PURPOSE OF THE BIOBANK OF SAMPLES AND CLINICAL DATA

The BQC19 is a provincial infrastructure that aims to support institutions of the Réseau de la Santé et des Services Sociaux du Québec (RSSS) by facilitating the framing and common management of the biological samples and clinical data stored in the biobank. These banked samples and clinical data are obtained from individuals who have undergone a diagnostic test for COVID-19 (regardless of the test result) in institutions participating in the BQC19, or who are involved in a research project.

The purpose of the BQC19 is to collect blood samples from both COVID-19 negative and positive participants and make the banked samples and data available to Canadian and international researchers to conduct biomedical, including genetic, research on COVID-19 and other related diseases. These studies may include whole-genome analyses. The research results from the analysis of BQC19 data and samples will be shared with the scientific community to promote rapid advances in the study of COVID-19. For confidentiality measures, see the "Access to samples and data, confidentiality and publications" section.

NATURE OF THE PARTICIPATION

-**Questions about your health**

If you agree to participate in the BQC19, we may ask you questions about your health, which should take between five (5) and fifteen (15) minutes. **Your data and answers** will be kept in the BQC19.

-**Blood samples**

- **If you are hospitalized**

If you are hospitalized and consent to this study, we will draw your blood for the BQC19 during the routine blood tests requested by your doctor as part of your regular clinical care on Days 0, Day 2 and Day 7 of your hospitalization.

On Days 14 and 30 of your hospitalization (when applicable) and if you consent, we may also collect your blood sample only for the BQC19 even if you do not have a routine blood sample requested by your doctor.

A maximum of 240mL (or approximately 15 tablespoons) of your blood will be drawn during your hospitalization only for biobanking in the BQC19, for research purposes described in this form. This volume of blood will be drawn in 1 to 5 different times, containing 48mL (less than 3 tablespoons) each, depending on the length of your hospital stay and your initial diagnostic test for COVID-19.

Once you have been discharged from the hospital, you could be invited to participate to follow-up assessments in an outpatient clinic or at home, approximately 1, 3, 6, 12, 18 and 24 months after your hospitalization. If you consent, you will be contacted by phone to plan these meetings. During these appointments, which is expected to last approximately 1 hour each, you will be asked questions about your health and a blood sample of 60 mL (or 4 tablespoons) will be drawn during each of these visits.

- **If you are not hospitalized:**

If you are not hospitalized and you have had an initial diagnostic test for COVID-19 whose result is positive or negative, and if you consent, we may collect your blood samples at months 1, 3, 6, 12, 18 and 24 (about 60 mL or 4 tablespoons per sample) only for biobanking in the BQC19, for research purposes described in this form, even if you do not have a routine blood sample collection planned (maximum 200 mL/month, or about 12 tablespoons). During these

appointments, you will be asked questions about your health and a blood sample will be drawn. You have the right to refuse this extension as well.

In addition, we could bank **any remaining portion** (which would normally be destroyed) **of your biological samples** (such as blood, stool, urine, respiratory secretions, alveolar lavage, etc.) that have already been taken or which will be taken within the framework of your care or during your participation in a research project, with the clinical data associated with it (such as your name, age, gender, ethnicity, diagnosis, treatment, evolution and medication), always for the same purposes described in this form.

If you consent, the BQC19 personnel could make **one or more telephone follow-ups** of approximately 10-15 minutes. This will essentially include questions concerning your overall health status and your functional level. Your telephone number and/or those of one of your representatives will be recorded so that the study team can contact you.

If you are a pregnant woman and if you consent, the following additional samples will be taken:

- Vaginal swabs (2), on admission and childbirth (if more than 7 days between admission and childbirth). Note that there will be the possibility of self-sampling
- Amniotic fluid sample (10 mL or 2/3 tablespoon or 2 teaspoons) in case of cesarean section
- Cord blood sample (25 mL or about 2 tablespoons or 5 teaspoons)
- Breast milk sample (maximum 5 mL or 1/3 tablespoon or 1 teaspoon): within 24 hours and between 24-48 hours after childbirth, then once a week if you or your child are hospitalized or seen again in outpatient clinic

In addition, the remaining portions of your pregnancy-specific biological samples (especially the placenta samples) will be banked. There will be one placenta sample to be taken per quadrant.

By signing this form, you also authorize the consultation of your data contained in your medical records, including those held by other hospitals in the province of Quebec and files concerning you held by the Institut de la Statistique du Québec (ISQ) and the Laboratoire de Santé Publique du Québec (LSPQ), so that they may be used in the context of duly approved research projects. In addition, the BQC19 may link your data with data from population studies in which you have previously participated and consented. All necessary measures will be put in place to minimize the risk of re-identification that such linkage could cause.

ACCESS TO SAMPLES AND DATA, CONFIDENTIALITY AND PUBLICATIONS

BQC19 samples and data will be stored locally, at the RSSS facility where they were collected, or at a BQC19 participating facility when necessary. Data containing information that identifies you will be deposited on a local database stored on a secure server. In order to preserve your confidentiality, your data and samples will only be identified by a code. Only this code will be associated with the biological samples and the clinical data in the BQC19's central database, in order to prevent any association between this information and the information that identifies you. Only staff members of the local biobank will have access to the code key and will be able to identify you.

If you agree to participate in the BQC19, the samples and associated clinical data will be used exclusively by researchers from academia, the RSSS or private industry to conduct research on COVID-19 and other related diseases. Researchers may apply from outside of Canada. If so, they will be required to adhere to privacy rules equivalent to those in Canada. The BQC19 is one of the tools used to make "open science" possible. In this regard, it is essential that samples stored and data collected in the BQC19 be classified according to how they will be made available to researchers. The projects for which your samples and data will be shared will have been approved by an Access Committee and a duly constituted Research Ethics Board. As part of their evaluation, the Access Committee will take into account the measures necessary to ensure your confidentiality, your consent, the degree of sensitivity of the sample or data, and the potential risk of re-identification. No data that directly identifies you will be given to a researcher.

Research data may be published, shared or discussed for scientific purposes, but it will not be possible to identify you through them. For purposes of monitoring and control, protection, and security, your file at the participating biobank and the BQC19, as well as your medical records, may be consulted by a person mandated by regulatory bodies in Canada or abroad, such as Health Canada, as well as by representatives of the institution or the Research Ethics Board. These individuals and organizations adhere to a confidentiality policy. You have the right to access your research file to verify the information collected and to have it rectified if necessary.

DURATION OF CONSERVATION, VOLUNTARY PARTICIPATION AND RIGHT OF WITHDRAWAL

Your samples and data will be kept for as long as their scientific interest justifies it, and for an undetermined period. At the end of this period, the participating biobank may apply to the Research Ethics Board of the participating healthcare institution for permission to retain your samples and data for a further period to be determined. If they refuse, the samples and associated data may be destroyed in accordance with applicable standards.

Your participation in the BQC19 through your institution's biobank is voluntary. You are therefore free to refuse to participate or to withdraw at any time, for any reasons, by notifying the coordinator of the participating biobank or one of the staff members of the participating biobank of your decision. Your decision will not affect the quality of care and services to which you are entitled, or your relationship with your physician and other providers. If you decide to withdraw from the BQC19, your data will no longer be shared, and no new data will be collected. If you decide to withdraw from the BQC19, your samples and data will be destroyed as of the time of your notification, unless they are the subject of completed or ongoing studies. In these cases, they will not be destroyed in order to ensure the scientific integrity of those studies.

RETURN OF INFORMATION ON THE SAMPLES AND DATA

You will not receive information on the specific use of your samples and data, but a public registry of research projects using them will be available on the BQC19 website. In addition, results of any research conducted using your samples or any incidental findings (in principle, based on the participating institution) will not be shared with you or your physician, as the research conducted on your samples will have no diagnostic or therapeutic significance to you. Nor will these reports be placed in your medical file.

BENEFITS THAT MAY ARISE FROM YOUR PARTICIPATION, COMPENSATION AND POSSIBILITY OF COMMERCIALIZATION

You will derive no personal benefit from your participation in the participating biobank and no financial compensation will be provided to you. However, if you accept to present yourself at the hospital/outpatient clinic for a blood test for the only purpose of biobanking in the BQC19, a compensation for your transportation of $ 50.00 will be given to you at each follow-up visit, as a reimbursement of your transportation costs. Please note that you will not receive any compensation if the blood test is carried out by a nurse at your home. The research results obtained may contribute to the advancement of scientific knowledge on COVID-19 and other medical conditions. Your samples will be used for research purposes only and will not be sold. Research using your samples may contribute to the development of new products in the future that could be sold. However, you will not receive any financial benefit from that research.

RISK S ASSOCIATED WITH YOUR PARTICIPATION

- **Risks associated with additional quantities of blood samples for biobanking (if applicable):**

When drawing your blood for the BQC19, you may experience weakness, fainting, local pain, bruising, discomfort, irritation, redness, or bleeding at the needle entry point. In rare cases, infection may occur. All precautions will be taken to avoid these complications.

The additional amount of blood that will be drawn to contribute to the BQC19 (40 to 60 mL per draw) is not enough to cause you a health problem or symptoms other than those described above. For the purpose of comparison, a volume of 450 mL of blood is usually drawn when donating blood to Héma-Québec.

- **Risks related to samples for pregnant women (if applicable):**

Vaginal samples: risk of slight discomfort which will be minimized if self-sampling.

There are no risks associated with collecting amniotic fluid, cord blood, placenta and breast milk.

- **Risks of breach of confidentiality:**

In determining the different levels of access to your data and samples, our goal is to reduce the risk of re-identification and possible misuse of the data, but we cannot guarantee that this will never happen. There is therefore a risk that a

possible breach of confidentiality regarding your personal information and medical records to third parties, such as employers or insurance companies, could result in a breach of your privacy, and affect your chances of obtaining insurance or certain types of employment. Every effort will be made to protect your privacy and confidentiality to minimize this risk, as described in "Access to Samples and Data, Confidentiality and Publications" section.

COMPENSATION FOR PREJUDICE AND THE RIGHTS OF THE RESEARCH PARTICIPANT

Should you suffer any harm as a result of any BQC19-related procedure, you will receive all the care and services required by your state of health.

By agreeing to participate in the BQC19, you do not waive any of your rights and you do not release the bank, the participating biobank and the health institution from their civil and professional liability.

MONITORING ETHICAL ISSUES AND IDENTIFICATION OF CONTACT INFORMATION

The Research Ethics Board of the Université de Montréal (CHUM) has approved the BQC19 and will monitor the project for the participating RSSS institutions.

If you have any questions or problems related to the BQC19 or the participating biobank, or if you wish to withdraw, you may contact Dr. Michael Chassé director of the biobank at the CHUM at 514-890-8000, extension 30816 or the research team at 20064, 20065, 20094 or 20093 or the biobank coordinator at the CHUM, Nathalie Brassard at (514) 890-8000, extension 31244 or (514) 585-0613. You can also contact the coordinator of the BQC activities, Mrs Mylène Bertrand, at (418) 656-8711, extension 2746, or at mylene.bertrand@bqc19.ca.

If you have any questions about your rights as a participant in this research project or if you have any complaints or comments, you may contact the Local Service Quality and Complaints Commissioner at your institution at (514) 890-8484.

PARTICIPANT CONSENT

I have read this informed consent form. I consent to participate in the BQC19 through the participating biobank of my healthcare institution under the conditions set out above. A signed and dated copy of this informed consent form will be forwarded to me.

☐ Yes ☐ No I agree to be recontacted to provide additional information about me or to be invited to participate in new research projects.

☐ Yes ☐ No I consent to the collection of blood samples for biobanking in the BQC19 and to be used for research purposes described in this form, even if I do not have scheduled routine blood tests, or at the same time as my scheduled routine blood tests when this is the case.

☐ Yes ☐ No I consent to being contacted for one or more telephone follow-ups.

In the event that it would not be possible to communicate with me if I consented to telephone follow-ups, the person from BQC19 can contact the person identified below to obtain information on my general health.

☐ Yes ☐ No I consent to be invited to participate in follow-up visits in an outpatient clinic or at home.

☐ Yes ☐ No I consent, if I am a pregnant woman, to the associated samples described in this form (vaginal samples, collection of amniotic fluid, cord blood, breast milk, placenta samples).

Name and contact details of the authorized contact person:

Name of Participant	Signature	Date	Time

Undertaking and signature of the person obtaining consent

I have explained to the participant the terms of this informed consent form and have answered the questions that he/she has asked me.

Name (in print)	Signature of the person obtaining consent	Date	Time

UNDERTAKING OF THE DIRECTOR OF THE BQC19

I confirm that the nature and purpose of this biobank and any risks and benefits have been explained to the participant whose name and signature appear above. I certify that the questions asked by the participant in this regard have been satisfactorily answered. I certify that it has been made clear to him/her that he/she remains free to end his/her participation in this biobank at any time. A signed and dated copy of this form will be forwarded to him/her.

CONSENT OF THE LEGAL REPRESENTATIVE OF THE PARTICIPANT INCAPABLE OF CONSENTING

In my capacity as legal representative (curator, tutor, mandatary, or, if sudden incapacitation occurs, as spouse, close relative, or interested person), I have read the informed consent form. I acknowledge that this research and this informed consent form have been explained to me, that my questions have been answered and that I have been given sufficient time to make a decision.

I further acknowledge that I have been informed that in the event that the person I represent is again able to consent on his or her own and that his participation in the research is still ongoing, he or she will be asked to sign the informed consent form.

After consideration, I agree that the person I represent can participate in the BQC19 under the conditions set out above. A signed and dated copy of this form will be forwarded to me.

Name of the represented participant

Name of the legal representative:

_____ (Curator, tutor, mandatary, spouse, close parent, interested person) _____specify by checking one of the boxes below:

☐ Curator ☐ Mandataire

☐ Tutor ☐ Spouse

☐ Close relative ☐ Interested person

Signature of the legal representative Date Time

Undertaking and signature of the person obtaining consent

I have explained to the ~~participant~~ legal representative of the participant the terms of this informed consent form and have answered the questions that he/she has asked me.

Name (in print) Signature of the person obtaining consent Date Time

UNDERTAKING OF THE DIRECTOR OF THE BQC19

I confirm that the nature and purpose of this biobank and any risks and benefits have been explained to the participant whose name and signature appear above. I certify that the questions asked by the participant in this regard have been satisfactorily answered. I certify that it has been made clear to him/her that he/she remains free to end his/her participation in this biobank at any time. A signed and dated copy of this form will be forwarded to him/her.

SIGNATURE OF THE PARTICIPANT WHO HAS REGAINED CAPACITY (TO BE SENT TO THE PARTICIPANT, IF APPLICABLE)

I have reviewed the entire informed consent form and understand that my legal representative has agreed on my behalf to participate in the BQC19. I acknowledge that this research project has been explained to me, that my questions have been answered to my satisfaction, and that I have had sufficient time to make a decision.

I agree to continue participating in the BQC19 in accordance with the conditions set out above. A signed and dated copy of this form will be forwarded to me. I authorize the research team to access my medical records for the purposes of this research.

Please check the appropriate box to indicate your decision:

☐ I wish to continue my participation in the BQC19 under the conditions stated in this form.

☐ I wish to end my participation in the BQC19 under the conditions stated in this form.

☐ Yes ☐ No I agree to be recontacted to provide additional information about me or to be invited to participate in new research projects.

☐ Yes ☐ No I consent to the collection of blood samples for biobanking in the BQC19 and to be used for research purposes described in this form, even if I do not have scheduled routine blood tests, or at the same time as my scheduled routine blood tests when this is the case.

☐ Yes ☐ No I consent to being contacted for one or more telephone follow-ups.

In the event that it would not be possible to communicate with me if I consented to telephone follow-ups, the person from BQC19 can contact the person identified below to obtain information on my general health.

☐ Yes ☐ No I consent to be invited to participate in follow-up visits in an outpatient clinic or at home.

☐ Yes ☐ No I consent, if I am a pregnant woman, to the associated samples described in this form (vaginal samples, collection of amniotic fluid, cord blood, breast milk, placenta samples).

Name of the participant	Signature	Date	Time

Undertaking and signature of the person obtaining consent

I have explained to the participant the terms of this informed consent form and have answered the questions that he/she has asked me.

Name (in print)	Signature of the person obtaining consent	Date	Heure

UNDERTAKING OF THE DIRECTOR OF THE BQC19

I confirm that the nature and purpose of this biobank and any risks and benefits have been explained to the participant whose name and signature appear above. I certify that the questions asked by the participant in this regard have been satisfactorily answered. I certify that it has been made clear to him/her that he/she remains free to end his/her participation in this biobank at any time. A signed and dated copy of this form will be forwarded to him/her.