**Description of BQC19 JGH Site Data and Access Procedures**

2020/7/15

**In total, the JGH Site of the BQC19 has collected samples and/or data from 862 individuals. The characteristics of this data and sample collection are below. Here we describe the data that will be released in the next ~10 days for use by approved investigators.**

**Note that this preliminary release of data represents a small proportion of the data that will be released. Nevertheless, this data is being released rapidly to enable COVID-19 research. Note also, that this data release is governed by the data release mechanism approved by the JGH Research Ethics Board and is not a data release organized by the BQC19 itself. Nevertheless, the BQC19 Executive Committee is supportive of this data release to approved investigators.**

**Applications for access to data are encouraged from investigators at academic institutions, within industry and from all countries.**

**BQC19 at the JGH.**

*Inclusion criteria:*

1. Underwent a nasal swab for clinical reasons at a hospital for SARS-CoV-2 testing
2. Cases are those who were PCR positive for SARS-CoV-2. Most patients were admitted.
3. Controls are those who were negative and most were admitted to hospital for other reasons.

Subjects who were SARS-CoV-2 positive represent more severe infection than those discharged, since they were admitted to hospital. Controls, who are those who were negative on all SARS-CoV-2 swabs, but had symptoms, or history, consistent with infection, but no evidence of infection on PCR testing. Approximately half of the sample are cases and half controls. Subjects have been consented for use of ***all data*** captured during their clinical care (including all laboratory, medications, treatment, radiology, viral data etc…), genomics and re-contact for future studies, and sample collection. Samples were collected at day 0, day 2 and day 7 for participants remaining in the hospital. Follow-up visits on day 30 have started and additional follow-ups on days, 60, 180 and 365 are funded.

**The data that will be released for the Preliminary Data Release:**

1. Age
2. Sex
3. Results of SARS-CoV-2 testing
4. Date of blood tests
5. Vital Signs in the Emergency Room
6. Whether the patient died during hospitalization
7. Admission to the ICU
8. Whether the patient was hospitalized
9. Date of hospitalization
10. FiO2
11. PaO2
12. Whether the patient was receiving respiratory support, as reported in blood gas test results.
13. Genome-wide genotyping data on available individuals: ~562 to date.

The non-genomic data will be shared in a .csv format.

The genome-wide genotyping data will be shared in a PLINK or similar format.

**Process for Data Access:**

All applicants must fill out the BQC19-JGH data access application form, with an accompanying one-page project description. This must be submitted to BCQ19imi4.med@mcgill.ca by July 22nd 2020 at 1700 EST.

1. Applications will be judged to ensure that they ask a scientific or medical question relevant to COVID-19 and that the applicant agrees to respect the data confidentiality and other conditions below.
2. The proposed project must be subject to approval and oversight by the applicant’s research ethics board. The applicant must provide written approval of the project by their research ethics board, for secondary use of data. This proof does not need to accompany the data access application form, but no data will be released without research ethics board approval.
3. An access fee of $500 CAD will be charged to academic investigators for this preliminary data release and $5000 CAD to investigators from industry.
4. The applicant must enter into a data access agreement (DTA) with the JGH. In this DTA, the following stipulations will be made:
	1. The applicant must not share any data with any investigators not listed in the application.
	2. The applicant must agree to acknowledge the use of data from the BQC19-JGH in any publication. No authorship is requested by the BQC19.
	3. The applicant must agree to return any data derived from analysis of BQC19-JGH data to BQC19-JGH for broad sharing, at the time that the investigators submits data for peer-review.
	4. The applicant must agree not to attempt to re-identify any individual within the BQC19 study.
	5. The applicant must agree to safeguard the data using the below safeguards as a minimum:
		1. All computers with access to the Information must employ logical access controls (passwords) at the device and network level.
		2. Where the Information is held on laptops, CD-ROMs, flash memory sticks or other transportable media of any type, passwords and full encryption must be used. This applies equally to backups of the Information stored on transportable media.
		3. The Information cannot be electronically transmitted, except as described below. This includes the transmittal of the Information by facsimile or by e-mail.
		4. Servers storing and transmitting unencrypted data, where used, must be located in a secure, controlled-access area, preferably in the same area where the Information is accessed. If located in a separate area, controls must be in place to ensure that only approved researchers can access the server. Unless the Information is encrypted continuously while outside the secure area, conduit must be used for all cabling and all cross-connect areas must be physically secured.
		5. Network firewalls and access rules must be in place to prevent access to the Information, other than to approved researchers. Information may be stored on and transmitted over networks not meeting these requirements, provided that it is encrypted, except when in use by an Identified Person. Alternatively, the Information may be stored on a stand-alone computer with no external connections, or on a closed network. When a network transmits information that leaves a secure area (for example, when a series of buildings house employees within a single organization), the data must be encrypted whenever it is outside the secure area.