HostSeq COVID-19 DATABANK
Participant Informed Consent Form

Study Title: HostSeq – Canadian COVID-19 Human Host Genome Sequencing Databank

Principal Investigator: Insert name, department and contact information

Co-Investigator(s):

Manager/Coordinator:

Study Funder:

Introduction
We would like to invite you to take part in the HostSeq COVID-19 Databank. This consent form describes the Databank and what it means to participate. This consent form may have words that you do not understand. Please ask the study staff to explain anything that you do not understand. Please take as much time as you need to think about your decision to participate or not, and ask any questions you have. All participation is voluntary and you are not under any obligation to participate.

Why is this Databank being created?
A Databank receives, stores, processes and distributes data. Databanks provide scientists with access to the study data to conduct different kinds of research. You are being invited to take part in this Databank because you received a diagnosis of Coronavirus (COVID-19). We hope to study the genomes of thousands of Canadians in order to better understand the body's response to COVID-19 and other health outcomes. We also want to learn why some people get COVID-19 and others don't and why the severity of the illness is so different among people.

The **HostSeq Databank** was created to collect and store health information related to COVID-19. It involves the collection your genetic and clinical information to store for present and future research on COVID-19 and other health outcomes, by researchers in Canada and abroad.

The Databank will involve genetic research. Genetic research involves isolating your genes (DNA) from biological sample(s) collected. Every person has their own unique set of genes, or "genome". Genetic research enables better understanding of what causes disease or health, and improve the diagnosis, treatment and prevention of diseases, like COVID-19. This Databank will provide a centralized resource in Canada for COVID-19 research and other health outcomes.

What happens if I agree to participate?
You are being asked to consent for the whole genome sequencing of the DNA from your sample and to the storage of your **genetic data** in the HostSeq COVID-19 Databank, to be used for research purposes.

The study doctor will also be asked to provide **clinical data** which includes some personal information about yourself and your health, as well information such as your age, ethnicity, and family's health history. We will also request health information about you from your family doctor and from other institutions or registries that may have your health information, for example, [*where applicable, include any relevant governmental/administrative health data repository in your province*]. We may get research data from other studies that you were involved in or future studies, if you agree. Your clinical data will be stored in the HostSeq Databank, along with your genetic data.

Your stored genetic and clinical data will be shared by the HostSeq Databank for future research on COVID-19 and other health outcomes, as explained below.

How will my data be stored in the HostSeq Databank?

Data in the HostSeq Databank is under the responsibility of CGen. CGen is a Canadian, federally funded national platform for genome sequencing and analysis.

Data in the HostSeq Databank is stored on cloud servers (i.e. online), based in Canada. The data stored in the HostSeq Databank will be kept indefinitely, or until it is no longer useful for research.

How will my genetic and clinical data be shared?

The HostSeq Databank will share your genetic and clinical data with approved researchers in Canada and around the world (which may include national and international researchers from academia, charitable organisations, hospitals, and 'for-profit' private companies, such as drug companies). Before it is shared, your research data will be labelled with a code, as explained in the section "How will my privacy be protected?", below.

Data sharing is mandatory and fundamental to this Databank. This means it is required for the research study. If you do not want your data to be shared, you should not consent to be part of the Databank. By participating, you agree that your genetic and clinical data may be used for future research on COVID-19 and other health outcomes.

Your data will only be shared with researchers approved by CGen (the sponsor) after review by a Data Access Committee (DAC). This DAC will verify, among other criteria, that the proposed research use is in conformity with the objectives of the HostSeq Databank, and that the research team applying for access has obtained the proper research ethics approval. Approved researchers will sign agreements. These agreements will control how the data will be used. Sharing may also include collaborations with industry/for-profit partners. An industry partner is an organization that may be a pharmaceutical company that wants to make a new drug or test a currently approved drug for another disease or population. It may also be a biotechnology company that develops new ways to treat or diagnose disease. If you do not want your data to be shared with collaborators, including industry partners, you should not consent to be part of the Databank

How will my privacy be protected?

No information about your identity will be given to anyone or be published without your permission, unless the law requires us to do this. The sponsor, CGen, and the Databank are committed to respecting your privacy.

If you decide to participate in this study, the research team at [insert local institution] (study investigators, coordinators, nurses, and delegates) will collect personal information about you, including personal health information from your medical records and other sources of clinical data, as well as your contact information (name, address, phone number, email) for the purposes of re-contacting you, if you agree to it. This personal information will not be shared outside of the [insert local institution] research team.

All your genetic and clinical data will be "de-identified" by replacing your identifying information with a code, before being sent to the HostSeq Databank for storage, only the 'study code key' can connect the information collected about you to your identity. This means that researchers accessing the Databank will not see your identifiable information (i.e., name, address, phone number, email, etc.). The study code key, which links your identifiable information to the code, will be safeguarded by the [insert local institution] research team and will not be sent to the HostSeq Databank.

The Databank is open to international researchers, and so your information may be sent outside of Canada. Any study data sent outside of Canadian borders may increase the risk of disclosure of information because the laws in those countries dealing with protection of information may not be as strict as in Canada. All information sent outside of Canada will be transferred in compliance with all relevant Canadian privacy laws.

The following individuals may request access to your identifiable information and personal health information to check that the information collected is correct and to make sure the study followed the required laws and guidelines:

- Representatives of the [insert local institution] Research Ethics Board and/or Research Quality and Risk Management team
- Representatives of Health Canada, a group of people who oversee the use of drugs and medical devices in research in Canada, and (if applicable) other regulatory bodies such as the United States Food and Drug Administration (FDA).

What if the researchers discover something about me?

Individual results of any research conducted using your samples or any individual incidental findings will not be shared with you, as the research conducted on your data will have no individual diagnostic or therapeutic significance to you. General research results will be shared through journal publications, academic conferences, and any other means of disseminating information. When such general results of this study are shared and disseminated, your identity will not be disclosed.

What are the risks, harms or discomforts?

There is always a small risk that your data may lead to you being re-identified one day. Genetic information is unique to every person, just like a fingerprint. This means that theoretically you can

be identified by your genetic code. However, this is not easy to do. As technology advances, there may be new ways of linking data back to you that we cannot foresee today, in spite of the strict security measures. The potential re-identification or unintentional release of your genetic and clinical research data could lead to loss of privacy and to possible future discrimination against you or your biological relatives.

Are there benefits to me for participating?

Because this research is on-going and will take many years, it is unlikely that you will get any direct benefit from taking part. The Databank may lead to better diagnosis and treatment in the future for COVID-19 and other health outcomes.

Can I choose to withdraw my data?

Your participation in HostSeq Databank is voluntary. You are therefore free to refuse to participate or to withdraw at any time, for any reasons by contacting the Principal Investigator or a member of the study team. This will will not have any effect on the care you or your family will receive.

If you decide to withdraw from the HostSeq Databank, your data will no longer be shared, and no new data will be collected. If you decide to withdraw from the study, data stored in the HostSeq Databank will be destroyed as of the time of your notification. However, it may be impossible to withdraw the results once they have been compiled with the results of others participating in the study or if they have been published.

Furthermore, if some of the data have been shared with other researchers, it may not be possible to remove this part of the data. In these cases of total withdrawal being impossible, your identity will still be protected.

Will I be paid and/or reimbursed?

You will not be paid or reimbursed for any expenses.

It is possible that future research conducted using your data combined with data from others will eventually lead to the development of new diagnostic tests, new drugs or other commercial products. If this happens, you will not receive any part of the profits from such products. The rights to the commercial products will belong to the sponsor, collaborators or future unknown researchers.

What are my rights when participating?

By signing this form, you do not give up any of your legal rights against the principal investigator, sponsor or involved institutions for compensation, nor does this form relieve the principal investigator, sponsor or their agents of their legal and professional responsibilities.

Who can I call if I have questions?

If you have any questions during your participation in this Databank you can contact the Principal Investigator, [PI NAME] at [insert phone #] or the research team members listed at the beginning of this consent form.

Research Ethics Board Contact Information

The study protocol and consent form have been reviewed by the [insert local institution] Research Ethics Board (REB). If you have any questions regarding your rights as a research participant, you may contact the Office of the Research Ethics Board at [insert phone #] during business hours.

Consent to Participate in the HostSeq COVID-19 Databank

Study Title: HostSeq – Canadian COVID-19 Human Host Genome Sequencing **Databank**

By signing this research consent form, I understand and confirm that:

1. All of my questions have been answered,
2. I understand the information included in this informed consent form,
3. I understand my blood/tissue sample will be analyzed using whole genome sequencing,
4. I allow the collecting of data from my medical record, chart and other clinical records,
5. My health information will be updated by linking it to other institutions or registries [*include any relevant governmental/administrative repository in your province*],
6. My genetic and clinical data will be stored in the HostSeq Databank indefinitely or until no longer useful for research purposes,
7. My coded genetic and clinical data will be shared within and outside of Canada,
8. I do not give up any of my legal rights by signing this consent form,
9. I have been given a signed and dated copy of this consent form,
10. I agree to take part in this study.

PLEASE INITIAL YOUR CHOICE BELOW BEFORE SIGNING:

I agree to be re-contacted to update my personal information, to obtain additional health information, or, to be invited to participate in new research projects:

_____Yes _____ initials

_____No _____initials

Printed Name of Participant	Participant signature & date (DD/MMM/YYYY)

Printed Name of person who obtained consent	Role of person obtaining consent	Signature & date (DD/MMM/YYYY)

Person Obtaining Informed Consent:
My signature below signifies that I have explained the nature and purpose of the study and the risks involved to the study participant, and I have answered all questions to the best of my ability.

Name of Person Obtaining Informed Consent (print)	Signature of Person Obtaining Informed Consent	Date (DD/MMM/YYYY)

Was the participant assisted during the consent process? ___ ***YES*** ___ ***NO***

*If **YES**, please check the relevant box and complete the signature space below:*

☐ The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to, and appeared to be understood by the participant.
☐ The person signing below acted as a translator for the participant during the consent process. Language: _____

Name (print)	Signature	Date (DD/MMM/YYYY)

CONSENT OF THE LEGAL REPRESENTATIVE OF THE PARTICIPANT INCAPABLE OF CONSENTING (IF APPLICABLE)

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 HostGen Databank 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)
_____

Name (print)	Signature	Date (DD/MMM/YYYY)

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 of Person Obtaining Informed Consent (print)	Signature of Person Obtaining Informed Consent	Date (DD/MMM/YYYY)

SIGNATURE OF THE PARTICIPANT WHO HAS GAINED/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 HostSeq Databank.

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 HostSeq Databank 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 HostSeq Databank under the conditions stated in this form.

_____ I wish to end my participation in the HostSeq Databank under the conditions stated in this form.

Name (print)	Signature	Date (DD/MMM/YYYY)

HostSeq COVID-19 DATABANK

Additional template language for local sites

- **Blood/tissue sampling**

If collecting blood/tissue sample specifically in the context of data submission to HostSeq, local site should detail sampling procedure.

What will happen if I agree to participate?
If applicable, provide information regarding the local site collection of blood/tissue sample, for example:

We ask for your permission to collect [e.g. XXXX ml of blood, a saliva sample, etc.]

- **Blood/tissue storage at local site**

If applicable, local sites can include information about sample storage

How will my blood/tissue samples be stored?
Blood/tissue samples collected for this study will be stored at [insert local institution] for [insert duration of conservation].

Part of your sample will be sent to HostSeq for whole genome sequencing.

- **Local requirements regarding the conservation of records**

If applicable Insert any locally applicable data conservation requirements regarding research records in section on "How will my privacy be protected?"

- **Risks related to blood collection at local site**

If applicable to local site, include information on risks of having an additional blood draw in addition to routine clinical blood draw, for example:

What are the risks, harms or discomforts?
As with all blood collection you may experience weakness, fainting, local pain, bruising, discomfort, irritation, redness, or bleeding at the needle entry point. In rare cases, infection may occur. But if at all possible, these samples will be taken as part of your medical care.

No	Version	Date	Description
1	v.1.0	07 May 2020	-First draft circulated to the HostSeq Scientific Committee
2	v.2.0	15 May 2020	-Changed CGenSeq to Host Seq -Broadened future research use -Added suggestions made by SickKids REB.
3	v.3.0	TBD	-Changes made following SickKids REB review -Clarification on commercial/for-profit data sharing