Note: SickKids will not entertain proposals for changes to this Agreement unless they are demonstrably required by applicable law.

CGEn HostSeq Data and Biological Samples Contribution Agreement

This CGEn HostSeq Data and Biological Samples Contribution Agreement ("Agreement") is entered into as of the last date of signature (the "Effective Date") by and between:

The Hospital for Sick Children ("HSC") 555 University Avenue Toronto, Ontario, M5G 1X8	**X** ("Institution")
Dr. Stephen Scherer ("HSC Investigator", and collectively with HSC, "SickKids") 555 University Avenue Toronto, Ontario, M5G 1X8	**X** ("Investigator, and collectively with Institution, "Contributor")

HSC, HSC Investigator, Institution and Investigator are hereinafter referred to individually as "Party" and collectively as "Parties".

WHEREAS, SickKids has developed the CGEn HostSeq – Canadian Covid-19 Human Host Genome Sequencing Databank ("Program") together with its collaborators at McGill University and the University of British Columbia (collectively, "CGen"), funded by the Government of Canada through Innovation, Science, and Economic Development Canada (ISED) and administered by Genome Canada (collectively, "Funders"), pursuant to which CGen proposes to conduct the whole genome sequencing ("WGS") of 10,000 human genomes using genetic samples by persons confirmed to have been infected with the novel coronavirus SARS-CoV2 ("Participants"); and

WHEREAS, Contributor has collected Biological Samples (defined below) and Research Data (defined below) from Participants (defined below), and wishes to contribute to the Program by making Biological Samples available for WGS by SickKids and to make Research Data available to SickKids for the purpose of enabling Researchers to have access to Program Data through the data access modalities contemplated by the Program;

NOW, THEREFORE, in consideration of the mutual covenants and promises herein contained, the Parties hereby agree as follows:

1. Definitions

Terms defined in the preamble hereof shall have the meaning ascribed to them therein for purposes of this Agreement. In addition, the following terms shall have the indicated meanings.

"*Biological Samples"* means the genetic samples from persons affected by SARS-CoV2 collected by Contributor and made available to SickKids for WGS pursuant to this Agreement.

"*Contributor-Specific Contribution Conditions*" means such conditions and agreements (if any) with respect to the contribution of Biological Samples and/or Research Data by Contributor to SickKids as are specific to Contributor and as are set forth in Exhibit D.

"*Databank Access Agreement*" means the agreement entered into by SickKids and Researcher that sets forth the terms and conditions regarding access by a Researcher to Program Data.

"*IRB/REB*" means any institutional review board, research ethics board or other similar body or committee that has reviewed the collection and/or conditions of use of Biological Samples and Research Data by Contributor or that is required to review the contribution of Biological Samples and Research Data to SickKids for use in connection with the Program.

"*Participant*" means an individual research participant from whom Contributor has collected Biological Samples and/or Research Data as part of the Program.

"*Participant Consent*" means the informed consent form approved by Contributor's IRB/REB to be executed by each Participant, and/or their legal guardian, to Contributor, or terms of the IRB/REB waiver of consent, as applicable.

"*Program Data*" means WGS Data and associated Research Data assembled by SickKids and made available for access to Researchers in accordance with the Program Data Policy and this Agreement.

"*Program Data Policy*" means the Program Data Sharing Policy and Procedures for access by Researchers to Program Data, a copy of which is attached hereto as Exhibit A.

"*Program Materials Standards*" means the standards of the Program establishing the characteristics that contributed Biological Samples and Research Data are required to have in order to enable the objectives of the Program to be achieved, a copy of which is attached hereto as Exhibit B.

"*Program Materials Transfer Requirements*" means the requirements and specifications established by SickKids that Biological Samples and Research Data are required to meet in order to be properly configured for transfer to the Program, a copy of which is attached hereto as Exhibit C.

"*Researcher(s)"* means a person and/or institution seeking access to Program Data in accordance with the Program Data Policy.

"*Research Data*" means de-identified phenotypic and other data and information of Participants collected by Contributor, and any other data and information which Contributor makes available to SickKids, as part of the Program pursuant to this Agreement.

"*WGS Data*" means raw data generated from WGS using Contributor's Biological Samples.

2. <u>Contribution of Biological Samples and Research Data</u>

(a) On and subject to the terms and conditions hereof, Contributor hereby contributes to SickKids for use in connection with the Program such Biological Samples and Research Data as Contributor shall elect to contribute to SickKids.

(b) Contributor represents and warrants that the (i) transfer of Biological Samples and Research Data to SickKids, and (ii) the availability of the resulting Program Data in accordance with the Program Data Policy, will be in accordance with all applicable laws (including, as applicable, Canada's

Personal Information and Electronic Documents Act or provincial privacy legislation governing Contributor), this Agreement, IRB/REB approved Participant Consents and/or any IRB/REB approved conditions with respect to such Biological Samples and Research Data.

(c) Contributor represents and warrants that it has obtained IRB/REB approvals for the contribution of Biological Samples and Research Data as Contributor is required to obtain (pursuant to applicable laws, the terms of the Participant Consents or the ethical or institutional standards that Contributor is required to observe or regularly observes) for use in connection with the Program, including but not limited to (i) WGS of Biological Samples; and (ii) availability and storage of the resulting Program Data in accordance with the Program Data Policy. Contributor shall not transfer any Biological Samples or Research Data to SickKids prior to obtaining such IRB/REB approvals, and shall only transfer Biological Samples and Research Data of Participants in respect of for whom a Participant Consent has been signed.

(d) Contributor represents and warrants that it has provided to SickKids true, correct and complete copy of Contributor's IRB/REB approved Participant Consent. SickKids will not use Biological Samples or Research Data until Contributor has provided a copy of the form of Participant Consent approved by Contributor's IRB/REB. Notwithstanding the foregoing, the Parties acknowledge that SickKids is not responsible for analyzing Participant Consent for the purposes of confirming the representations and warranties of Contributor in this Section 2.

(e) Contributor represents and warrants that Biological Samples and Research Data will, when transferred to SickKids, be in accordance with the Program Material Standards and will be prepared in a manner that complies with the Program Materials Transfer Requirements.

(f) Contributor acknowledges that Biological Samples will be consumed in the course of the WGS of Biological Samples, and therefore Biological Samples will only be returned to Contributor, i) if available, and ii) if requested by Contributor within ninety (90) days of notification by SickKids of the completion of the experiment. DNA is the only Biological Sample that may be returned.

(g) Any Contributor-Specific Contribution Conditions are set forth in Exhibit D. Contributor agrees to immediately report to SickKids any errors discovered by Contributor relating to Biological Samples and Research Data that it has submitted to SickKids under this Agreement. Contributor further agrees to promptly take all steps necessary on its part to correct such errors.

(h) SickKids shall use appropriate safeguards to prevent any unauthorized use or disclosure of Biological Samples and Research Data, and shall report to Contributor any unauthorized use or disclosure of which SickKids becomes aware.

(i) The following constitute permitted uses of Biological Samples and Research Data: (i) SickKids will house Program Data in an access-controlled databank which may be hosted on a cloud platform and/or local server; (ii) SickKids will be permitted to distribute Program Data to Researchers in accordance with the Program Data Policy; and (iii) Researchers may publish any findings arising from their research use of Program Data in accordance with, and subject to, the Databank Access Agreement.

3. <u>WGS and Program Data Availability</u>

(a) SickKids agrees, upon receipt of Biological Samples in accordance with the requirements of this Agreement, and subject to the availability of sequencing and other resources, to conduct DNA

extraction, if required, and WGS of Biological Samples. Contributor acknowledges that WGS of Biological Samples is for research purposes only and carried out in a research laboratory which is not an accredited or licensed clinical laboratory, and that as a result, SickKids will not perform WGS for the purposes of obtaining information for diagnosis, prophylaxis or treatment.

(b) SickKids shall comply with applicable laws and regulations with respect to Biological Samples. SickKids represents and warrants to Contributor that SickKids will perform WGS to the same reasonable standards and professional skill and competence applicable to generally recognized providers of similar services using the disclosed methodology(ies).

(c) SickKids agrees to provide Contributor WGS Data in accordance with Contributor-Specific Contribution Conditions, if any. Contributor acknowledges WGS Data is suitable for research purposes only and shall not be used for any other purposes such as forensic, diagnostic, prophylaxis or treatment purposes, or for any purposes prohibited by applicable laws and regulations.

(d) SickKids shall make Program Data available to Researchers in accordance with the Program Data Policy. SickKids shall further require each Researcher having access to Program Data to enter into a Databank Access Agreement, requiring Researcher to utilize Program Data in accordance with the Program Data Policy and not to make any effort to re-identify such Program Data. For clarity, should Contributor wish to access any Program Data other than WGS Data, Contributor shall do so in accordance with the Program Data Policy.

4. Acknowledgments

(a) SickKids agrees to acknowledge in publications and presentations regarding the Program the contribution of Contributor to the Program in a manner that is no less favorable than that accorded to other similarly situated contributors in the Program. SickKids agrees to include in the Databank Access Agreement a provision requiring any Researcher who publishes any manuscript with respect to any Program Data to acknowledge the contribution of Contributor.

(b) Contributor acknowledges and agrees that the continuation of the Program is subject to the availability of resources as determined by the Funders in its sole discretion. If the Funders or SickKids elect to terminate funding for the Program, SickKids shall give notice of such termination to Contributor and the Parties shall cooperate to effect the disposition of any unused Biological Samples and any Research Data as is directed by Contributor by written notice given to SickKids within thirty (30) days after such notification of termination is given, and as Contributor warrants is consistent with the terms of the Participant Consents and any applicable IRB/REB approvals. If no such notice of disposition is given by Contributor to SickKids within such thirty (30) day period, SickKids shall destroy any unused Biological Samples and Research Data.

5. Intellectual Property

Contributor waives and releases any rights that it might otherwise have to claim any interest in any inventions or discoveries arising out of the use of Program Data by Researchers.

6. Disclaimer and Limitation of Liability

(a) Except as expressly set out in this Agreement, no Party makes any representations or warranties, express or implied, statutory or otherwise in law or form a course of dealing or usage in the industry, with respect to any matter hereunder, including without limitation, any and all implied or statutory warranties or conditions of merchantability, merchantable quality, durability or fitness for a particular purpose.

(b) No Party will be liable to any other Party for any consequential, exemplary, incidental, special, indirect or other similar damages of any kind, including but not limited to lost data, lost profits, lost business revenue, failure to realize expected savings, unexpected outcome, lost time, lost opportunity or other commercial, economic or research and development losses of any kind arising out of or in connection with this Agreement, even if such other Party has been advised of the possibility of such damage, claim or injury.

7. Miscellaneous

(a) The Parties hereto are independent contractors. Nothing contained herein shall be deemed or construed to create between or among the Parties hereto a partnership, joint venture, employment or principal-agent relationship.

(b) This Agreement shall be governed by and construed according to the laws of the Province of Ontario and the laws of Canada applicable therein. Each of the Parties hereto agrees irrevocably to attorn to the exclusive jurisdiction of the courts of Ontario.

(c) Contributor shall not assign this Agreement or delegate any of its duties hereunder without the express prior written consent of SickKids which may be granted or withheld in SickKids's sole reasonable discretion.

(d) This Agreement sets forth the entire understanding between the Parties and supersedes all other understandings, whether written or oral, between any of the Parties with respect to the same subject matter. In the event of a conflict between the terms of this Agreement and the Program Data Policy or any appendices to this Agreement, the terms of this Agreement shall govern. This Agreement shall not be amended, modified, varied or supplemented except in writing signed by each of the Parties.

(e) All notices, requests, directions, reports, or other documents that any of the Parties are required or may desire to deliver to any other Party must be in writing and may be delivered only by personal delivery or by registered or certified mail, or courier or facsimile, all postage and other charges prepaid, at the address for such Party set forth below or at such other address as any Party may hereinafter designate in writing to the others:

If to HSC:	If Institution:
The Hospital for Sick Children 555 University Avenue Toronto, Ontario M5G 1X8 Canada Attn: Legal Services Fax: 416-813-5968	X

If to HSC Investigator:	If to Investigator:
The Hospital for Sick Children 555 University Avenue Toronto, Ontario M5G 1X8 Canada Attn: Dr. Stephen Scherer stephen.scherer@sickkids.ca	X

(f) This Agreement may be signed in counterparts, and each counterpart may be delivered by facsimile or signed PDF by email. Each counterpart shall constitute an original, and when taken together, shall constitute one and the same instrument.

[Signature Page to follow]

In witness whereof, the authorized representatives of the parties have executed this Agreement.

The Hospital for Sick Children	X
Signature	Signature
Ramune Pleinys Executive Director, Research Operations	Name Title
Date	Date
Dr. Stephen Scherer	X
Signature HSC Investigator	Signature Investigator
Date	Date

Exhibit A
Program Data Sharing Policy and Procedures
CGEn HostSeq

1. Introduction

CGEn HostSeq is a research program ("Program") of The Hospital for Sick Children ("SickKids"), together with its collaborators at McGill University and the University of British Columbia, funded by the Government of Canada through Innovation, Science, and Economic Development Canada (ISED) and administered by Genome Canada, pursuant to which SickKids and its collaborators propose to conduct the whole genome sequencing ("WGS") of 10,000 human genomes using genetic samples donated by persons confirmed to have been infected with the novel coronavirus SARS-CoV2; SickKids and any other organizations that SickKids elects to collaborate with as co-leaders of the Program are referred to herein as the "Collaborators".

The goal of the Program is to sequence the DNA of 10,000 individuals confirmed to have been infected with the novel coronavirus SARS-CoV2, and provide the whole genome sequencing results and associated meta-data to the researcher community, in a cloud-based and/or local server data environment for research and analysis. Through the Program authorized researchers will have access to a large databank of whole genome sequenced data on thousands of SARS CoV2 positive cases, which should speed discovery of COVID-19 disease severity biomarkers, treatments, and ultimately vaccines. It is the policy and objective of the Program to make the Program Databank available to the broadest possible research community, as quickly as possible.

The Program Databank contains Research Data, WGS Data, Contributor Provided Data and other data or information that SickKids elects to make available through the Program. Program Data will be obtained from (or derived from biomaterials provided by) retrospectively and prospectively recruited cohorts of Participants, where appropriate Review Board waivers are obtained.

This Program Data Sharing Policy and Procedures (this "Policy") states the policy of CGEn HostSeq with respect to (1) access by Researchers to the Program Databank and the downloading by Researchers of copies of Program Data from Program Databank; and (2) addresses the procedures for approval of individual researchers to access the Program Databank. This controlled access is to be offered to Researchers from around the world who are conducting research on COVID-19 and other conditions.

2. Definitions

"*Access Authorization Letter*" means the formal letter sent by the Coordinating Center to Researcher to advise him/her of the decision of the DACO in connection with Researcher's Researcher Application.

"*Access Renewal Letter*" means the formal letter sent by the Coordinating Center to Researcher to advise him/her of the decision of the DACO in connection with Researcher's Renewal Form.

"*CanCoGen Steering Committee***"** means an expert committee appointed by the Funder that oversees the Program Databank.

"*CGEn HostSeq Website*" means the CGEn HostSeq website at http://cgen.ca/hostseq.

"*Consultant*" means Policy Partnerships Project for Genomic Governance (P3G2) at McGill University or such other independent consultant as SickKids may appoint from time to time.

"*Contributor*" means the contributing organization/institution and/or individual that made the Participant's biological materials available for WGS for the Program and the associated Research Data available for deposit into the Program Databank.

"*Contributor Provided Data*" means any and all data provided by any other researcher other than Researcher to SickKids for inclusion into the Program Databank.

"*Coordinating Center*" means the Program Coordinating Center at SickKids.

"*DACO*" means the Program's independent Data Access Compliance Office.

"*Databank Access Agreement*" or "*DAA*" means the databank access agreement between Researcher, the Institution (if any) and SickKids that sets forth the terms and conditions regarding access by a Researcher to the Program Databank.

"*Funder*" means Genome Canada with the financial responsibility and oversight of the funding.

"*Institution*" means the organization at which Researcher is employed, affiliated or enrolled.

"*Participant*" means a provider of Biological Samples and/or Research Data that is used as part of the Program.

"*Program Data*" means Research Data, WGS Data and Contributor Provided Data and other data or information that SickKids elects to make available through the Program Databank in accordance with the Policy.

"*Program Databank*" means the cloud based and/or local-server data environment maintained by SickKids as part of the Program that stores Program Data.

"*Research Data*" means de-identified information concerning Participants, which may include family configuration, age at time of testing, sex, diagnosis, family and medical history, and any other clinically relevant information collected by Contributor and deposited into the Program Databank. For clarity, Research Data shall not include any personally identifying information about the Participant, his/her family or its members.

"*Renewal Form*" means the form submitted by Researcher to renew access to the Program Databank, which will be reviewed and approved DACO in accordance with this Policy.

"*Research Project***"** means the research project that a Researcher intends to conduct using Program Data accessed through the Program Databank as described in the Researcher Application.

"*Research Team*" means the research staff employed by Institution and assisting Investigator in the conduct of the Research Project.

"*Researcher*" means a person and/or institution seeking access to the Program Databank in accordance with this Policy.

"*Researcher Application*" means the application submitted by Researcher to obtain access to the Program Databank, which will be reviewed and approved DACO in accordance with this Policy.

"*Review Board*" means the Institutional Review Board, Research Ethics Committee, Research Ethics Board or another equivalent body under the laws or regulations governing a Researcher and a Research Project.

"*WGS Data*" means whole genome sequencing data derived from Biological Samples of Participants.

3. Governance

The Program Databank is subject to oversight by the CanCoGen Steering Committee.

The Coordinating Centre and DACO will have the responsibility for implementing this Policy as set forth herein. The Coordinating Center and the DACO will provide reports to the CanCoGen Steering Committee regarding implementation of this Policy.

The independent DACO will be composed of a minimum of eight (8) members, including:

- At least one (1) bioinformatics researcher;
- At least one (1) technical expert;
- At least one (1) expert on the legal/ethical aspect of genomic research and data sharing;
- At least one (1) expert in privacy and data protection;
- At least three (3) investigators representing cohorts included in HostSeq;
- At least one (1) patient/participant representative or member of the public.

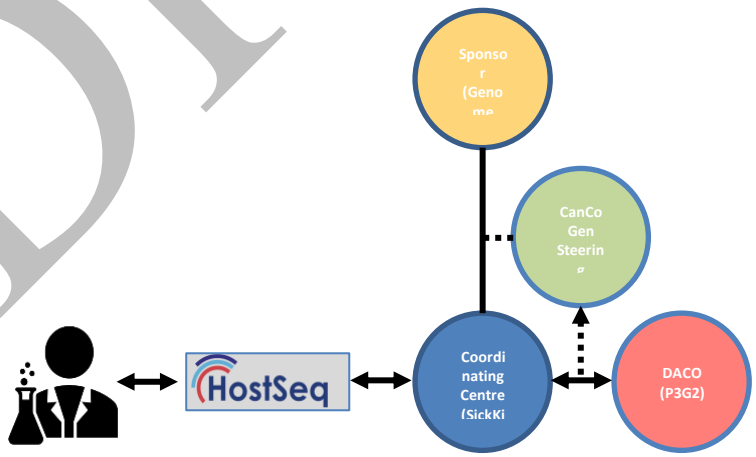

Figure 1: Program Databank Governance

4. Application Procedure

In order to access the Program Databank, Researcher must apply for and receive approval for access to the Program Databank in accordance with the following procedures.

Step 1: Completion of Researcher Application and Signed DAA

Researcher must prepare a (i) completed Researcher Application and (ii) a signed DAA by Researcher and/or authorized representative of the Institution, as applicable.

The Researcher Application will require Researcher to provide:

1. Name and credentials of Researcher
2. Institutional affiliation (if applicable)
3. List of all individuals in Research Team with their respective job titles, institutional affiliations and institutional e-mail addresses;
4. Title of Research Project(s);
5. Research question proposed to be answered by Research Project (as it relates to COVID-19 or related conditions) in no more than 500 words;
6. Summary of Research Project suitable for a lay audience in no more than 200 words;
7. Country(ies) where Research Project will be conducted and downloaded copies of Program Data will be held;
8. Description of Program Data proposed to be downloaded from the Program Databank;
9. Confirmation that Researcher, if any, has implemented the minimum data security safeguards described in Section 7 of this Policy;
10. Confirmation that a Review Board has approved Researcher's use and receipt of Program Data (including the name of the approved protocol, the date of approval and the name, address and email address of the Review Board)*;
11. List of up to 5 peer reviewed publications by Researcher; and
12. If Researcher is not affiliated with an Institution, an up-to-date curriculum vitae and names and addresses of two references who have agreed to be contacted.

*Should Researcher seek an exemption from a Research Board review, Researcher shall request a Review Board to consider such exemption

Step 2: Submission of the Researcher Application and Signed DAA

The completed Researcher Application and signed DAA must be sent to the Coordinating Center by e-mail or mail as follows:

Email: coordinatingcenter@cgen.ca

Mail: CGEn HostSeq Program
The Centre for Applied Genomics
The Hospital for Sick Children
Peter Gilgan Centre for Research and Learning
686 Bay St., Room 13.9800
Toronto, ON M5G 0A4

Step 3: Review by the Coordinating Center

Once the Researcher Application and DAA are received, the Coordinating Center will review the Researcher Application to confirm the following:

- The Researcher Application is complete and the DAA has been properly completed and signed;
- Researcher is not on a debarment list (USA);
- The Research Project is feasible given the resources in the Program Databank; and
- The Research Project has scientific validity, including whether the research question proposed to be answered is relevant to the objectives of Program and the scope of the Research Project is relevant to COVID-19 or related conditions.

Step 4: Review by the Data Access Compliance Office

Once the Coordinating Center has confirmed the matters described in Step 3 above, the Researcher Application and the DAA will be submitted by the Coordinating Center to the independent DACO for review. The DACO will have the discretion to approve or decline a Researcher Application based on ethical, scientific, programmatic or other relevant considerations. Among other things, the DACO may consider the following criteria:

- Researcher is qualified to conduct the Research Project and undertake the proposed analysis;
- Researcher has confirmed that the minimum data security safeguards described in Section 7 of this Policy have been implemented;
- Researcher has confirmed that Review Board approval has been obtained, or, if no confirmation of Review Board approval is provided, whether the explanation as to why Review Board approval is not required is adequate; and
- The lay summary of the Research Project is comprehensible to the general public.

For Researcher Applications from Researcher who are affiliated with known institutions, the DACO will endeavor to render its decision within ten (10) business days after receipt by the DACO of the Researcher Application. For the avoidance of doubt, all Researcher Applications will be considered from Researchers who do not have an institutional affiliation, but review of such Researcher Applications is likely to take more time.

Step 5: Notification of Decision

The DACO will submit to the Coordinating Center its decision as to whether a Researcher Application is approved, declined or conditionally approved. The Coordinating Center will then send an Access Authorization Letter to Researcher to advise him/her of the decision. A copy of the Access Authorization Letter will also be provided to the DACO.

If the DACO has approved a Researcher Application, the Access Authorization Letter will assign access to the email address provided by Researcher(s) in the Researcher Application. This account will be owned by Researcher and all costs associated with work undertaken in that account will be the responsibility of Researcher.

The Access Authorization Letter will also be accompanied with a copy of the fully executed DAA. The DAA will govern the Researcher's access to the Program Databank. The terms of the DAA will prevail over any inconsistent terms of this Policy, the CGEn HostSeq Website or elsewhere, and over any oral or written statement made by the staff of the Coordinating Center or of the DACO or any other representative of SickKids.

If the DACO has conditionally approved a Researcher Application, the Access Authorization Letter will set forth the additional information required to be submitted to the Coordinating Centre. Upon receipt of such additional information, the Coordinating Centre and the DACO will review the Researcher Application, together with the additional information in accordance with Steps 3 and 4 above, and a notification of the decision of the DACO will be provided in accordance with this Step 5.

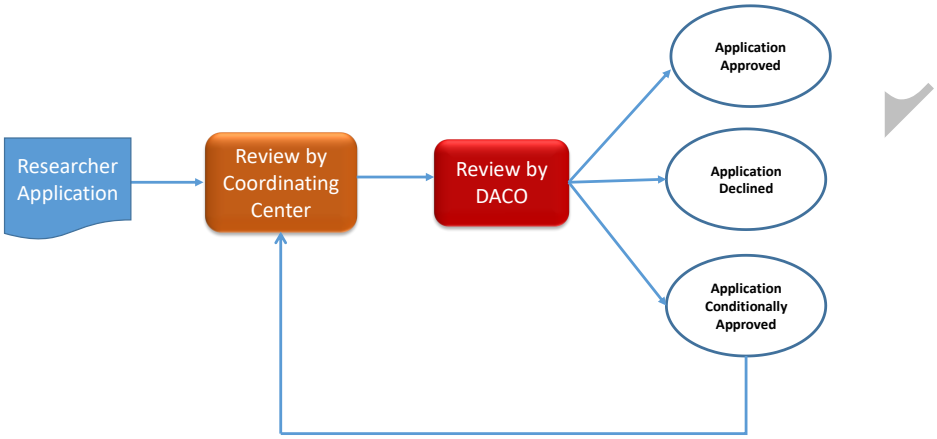

Figure 2: Overview of Application Procedure

5. Duration of Access and Renewal Procedure

Each DAA will have a term of one (1) year from the date of execution of the DAA by SickKids. Notification will be given by the Coordinating Center to Researcher prior to the annual expiration of the DAA.

To renew a DAA and continue access to the Program Databank after termination of the then-existing DAA, Researcher will be required to submit a Renewal Form. The Renewal Form will require Researcher to provide:

- An updated Researcher Application, or confirmation that the content of the Researcher Application originally submitted remains correct and complete;
- An updated list of and contact information for the members of the Research Team, or confirmation that the list of and contact information for the members of the Research Team remains correct and complete; and
- Report on all publications prepared using the results of the Research Project.

Researcher must send the completed Renewal Form to the Coordinating Center by e-mail or mail using the information set forth in Step 2 of the Application Procedure. It is recommended that Researcher sends the Renewal Form within thirty (30) days prior to expiration of a DAA.

The Coordinating Center will submit the Renewal Form to the DACO for review, together with any additional information related to Researcher, including a summary of reports of unauthorized use or security breaches received by the Coordinating Center related to Researcher.

Upon approval of the Renewal Form by the DACO, the Coordinating Center will send an Access Renewal Letter to Researcher to advise him/her of the renewal. A copy of the Access Renewal Letter will also be provided to the DACO. The Access Renewal Letter will renew the DAA and Researcher and the Research Team can continue access of the Program Databank using the existing log-on credentials. The renewal term will be for one (1) year.

If a DAA expires without being renewed, the log-on credentials of Researcher and the Research Team will expire simultaneously, but the obligations of Researcher that survive termination of the DAA will remain in effect, including, without limitation, the obligation to provide the Final Report (as defined in the DAA).

6. CGEn HostSeq Researcher Application Registry

The DACO will create a registry of the names, affiliated institutions and Research Project summaries for all Researchers who have been approved for access to the Program Databank. This registry will be available for public access. Other aspects of the Researcher Application will not be disclosed to the public.

7. Data Security Assessment

In order to avoid, among other things, inadvertent disclosure of the data of Participants to unauthorized individuals, the DAA requires that Researcher implement data security safeguards, including appropriate technical and organisational measures to protect Program Data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access, and which provide a level of security appropriate to the risk represented by the processing and the nature of the data to be protected.

Minimum data security safeguards are as follows:

- *Physical Security* – Downloaded copies of Program Data must be maintained on physically secure computer systems, such as a locked office. If downloaded copies of Program Data are stored on a portable device (*e.g.*, laptop, tablet, USB thumb drive, external drives), the portable device must be encrypted to avoid its disclosure in case of loss or theft.

- *Access Security* – Only Researcher and Research Team should have access to Program Data. If downloaded copies of Program Data are stored locally on a shared computer system or a file server, then the downloaded data must be password or encryption protected so that only Researcher and the Research Team have access to the downloaded copies. Any backup media must either be encrypted or stored in a physically secure location. Any remote access to Program Data must be done using multi factor authentication.

- *Network Security* – If downloaded copies of Program Data are stored on a network-accessible computer, some combination of network firewalls, network intrusion monitoring and virus scanning software must be implemented. If Program Data is used on multiple systems, Researcher must ensure that the data access security policies are retained throughout the processing of Program Data on all other systems.

- *Destruction of Data* – Upon completion of the Research Project (or the earlier expiration or termination of the DAA), Researcher must delete and destroy all copies of Program Data in accordance with the DAA.

- *Data Security Policies* –Researcher must have an information technology (IT) policy in place that addresses at a minimum the following items:

    - Logging and auditing of access to data and the computer network;
    - Password protection of the computer network;
    - Virus and malware protection of the computer network;
    - Auditable data destruction procedure;
    - Secure data backup procedure; and
    - Strong encryption on any portable device which may store or provide access to Program Data.

Upon reasonable request of SickKids, Researcher will submit its data processing facilities, data files and documentation needed for processing to reviewing, auditing and/or certifying by Researcher (or any independent or impartial inspection agents or auditors, selected by SickKids and not reasonably objected to by the Researcher) to ascertain compliance with the warranties and undertakings in these clauses, with reasonable notice.

8. <u>Amendement of this Policy</u>

SickKids may at any time and without notice amend this Policy in any manner in which SickKids determines to be in the best interest of the Program.

Exhibit B
Program Materials Standards

Contributor agrees to submit either blood or DNA, as well as clinical and phenotypic information, as follows:

1. **Blood**. If submitting blood, Contributor shall send a minimum of 4 milliliters of whole blood for each Participant, which blood shall be collected in an EDTA tube with a lavender top.

2. **DNA**. If submitting DNA, Contributor shall submit a minimum of 2 ug DNA for each Participant at a minimum concentration of 20ng/uL and a minimum volume of 20 uL. The 260/280 ratio for the DNA using a spectrophotometer (eg. Nanodrop) shall be 1.8-2.0.

3. **Clinical and Phenotypic Information**. The minimum clinical and phenotypic information is defined on the CGEn HostSeq website (www.cgen.ca/hostseq).

Contributor represents and warrants that all data submitted to SickKids pursuant to this Agreement meets the following minimum data quality standards:

1. All phenotypic data has been double entered and the entries compared for accuracy;

2. All clinical assessments were performed by trained and reliable raters under the supervision of a certified clinician to ensure quality;

3. Phenotypic data does not contain identifying information;

4. All phenotypic data and biological samples are coded with unique identifiers to be easily linked; and

5. All biological samples submitted to SickKids have not been compromised due to inadequate storage or shipping procedures.

Exhibit C
Program Materials Transfer Requirements

Contributor will distribute Biological Samples and Research Data to SickKids in the following ways:

1. All Biological Samples will be shipped to:

   The Hospital for Sick Children
   Genome Diagnostics/ The Centre for Applied Genomics
   555 University Avenue, Black Wing, Room 3-416
   Toronto, Ontario, M5G 1X8, Canada
   Attention: Dr. Steve Scherer

2. All Research Data will be submitted through a RedCap database hosted at SickKids or by sending password protected spreadsheets in XLS format.

Exhibit D
Contributor-Specific Contribution Conditions

Contributor is requesting WGS Data from Biological Samples: Yes☐ No☐

Other Conditions: