

SickKids Master CHSS Biobank Genomic Registry Agreement (“Agreement”)

BETWEEN:

AND

<p>The Hospital for Sick Children (“SickKids”) 555 University Avenue Toronto, ON, M5G 1X8, Canada</p>	<p>XXXXX (“Provider Institution”) [Insert name of organization and address for legal purposes]</p>
<p>SickKids Investigator: Dr. William G. Williams (SickKids and SickKids Investigator are together, “CHSS Data Center”)</p>	<p>Provider Investigator(s): Dr. [Insert name] (Provider Institution and Provider Investigator are together “PROVIDER”)</p>
<p>CHSS Data Center’s Managing Director: Dr. William M. DeCampli</p>	

Name of Registry Project: Congenital Heart Surgeons’ Society (“CHSS”) Biobank Genomic Registry

PROVIDER Institutional Review Board (“IRB”)/Research Ethics Board (“REB”) File Number: [Insert number]

SickKids REB File Number: 1000051497

Data to be provided (“Data”): Coded personal health information data as per the IRB/ REB approved Registry Project (“Project”), incorporated herein by reference.

WHEREAS SickKids Investigators are members of the Congenital Heart Surgeons’ Society (“CHSS”); and the CHSS Data Center is the coordinating site for CHSS studies and projects involving the collection and analysis of data from CHSS members and/or non-members;

AND WHEREAS this Agreement, effective as of the last date of signature below, is entered into between the parties to govern the transfer of the Data from PROVIDER to the CHSS Data Center for inclusion in the Registry Project;

NOW THEREFORE, the parties hereto agree as follows:

1. PROVIDER will securely provide to the CHSS Data Center only Data for inclusion in the Registry Project in accordance with applicable laws and if applicable in compliance with IRB/REB approved subject informed consent forms (“ICFs”) provided by the individuals from whom the Data were collected, or terms of an IRB/REB Waiver of Consent, as applicable.
2. After receiving the Data from the PROVIDER, the CHSS Data Center will double-code the Data and securely enter that data via Research Electronic Data Capture (REDCap) Internet-based database into the server maintained by the CHSS Data Center at SickKids, using the Project data entry form, incorporated herein by reference.

3. If an investigator not listed above is acting as the principal investigator at SickKids or PROVIDER with respect to the CHSS Project, such investigator must first sign the Rider attached hereto as Appendix A before participating in the Project.
4. PROVIDER retains ownership of its Data provided under this Agreement.
5. CHSS Data Center shall use the Data in compliance with all applicable laws and regulations; and shall specifically only use or disclose the Data for the conduct of the Project for which the Data was transferred, in accordance with (if applicable) the permitted uses of the Data specified in the applicable ICFs or Waiver as set out above, or otherwise as required by law or regulatory authorities, as applicable. CHSS Data Center shall ensure that all Data is maintained in a secure form and location.
6. The parties shall have the right to use aggregate, non-identifying data and results derived from use and analysis of the Data as part of a publication or presentation of the results of the Project. Each party's contribution to the Project shall be acknowledged appropriately by the parties hereto, and/or any third party accessing the aggregate, non-identifying data, in any publication or presentation related to the Project in accordance with academic standards.
7. Data is "non-identifying" if it does not identify an individual and if there is no reasonable basis to believe it could be used alone, or with other available information, to identify an individual. Only aggregate, non-identifying data may be included in any publication or presentation. CHSS Data Center may disclose or provide access to aggregate, non-identifying data derived from the Data to (a) regulatory authorities, as applicable; and (b) third party researchers, as provided for in the Project.
8. CHSS Data Center shall use appropriate safeguards to prevent any unauthorized use or disclosure of the Data and shall promptly report to the PROVIDER any unauthorized use or disclosure of which CHSS Data Center becomes aware, or of any breach of this Agreement.
9. Upon completion or termination of the Project, or upon written request from PROVIDER, CHSS Data Center shall return to PROVIDER, or securely destroy, as requested, the Data as received by the CHSS Data Center from PROVIDER in its raw form for the Project, subject to applicable law, including regulations regarding retention of project data. Secure destruction shall mean: (i) shredding or destroying paper, film, or other hard copy media to ensure that the Data cannot be read or otherwise reconstructed or (ii) clearing, purging or destroying electronic media such that the Data cannot be read or otherwise reconstructed, and providing written confirmation of such destruction to PROVIDER.
10. PROVIDER may, upon reasonable notice, arrange with CHSS Data Center to attend CHSS Data Center's site within normal business hours to conduct audits of the CHSS Data Center (no more frequently than once per calendar year) concerning the maintenance of appropriate security safeguards to ensure compliance with this Agreement.
11. Unless otherwise required by law, CHSS Data Center may give access to the Data only to its staff and project governance committee, and access to its own Data and to aggregate, non-identifying data to each CHSS institution PROVIDER investigator, and access to aggregate, non-identifying data to the CHSS members with a need to know

for the purpose of conducting the Project.

SICKKIDS	Insert Name of Organization
Signature:	Signature:
I have authority to bind the organization.	I have authority to bind the organization.
Date:	Date:
Name & Title:	Name & Title:
Dr. William G. Williams	Provider Investigator:
Signature:	Name: Dr. _____
Date:	Signature:
Dr. William M. DeCampli	Date:
Signature:	Provider Investigator: Name: Dr. _____
Date:	Signature:
	Date:

APPENDIX A – RIDER

I, _____, am the principal investigator at _____ with respect to the CHSS Project. I acknowledge that I have read and understood, and hereby agree to abide by, the terms of the SickKids Master Biobank Genomic Registry Agreement to which this Rider constitutes Appendix A.

Signed By:

Name:

Date: