Data Transfer Agreement

This Data Transfer Agreement ("Agreement"), effective as of the date of final signature, is made by and between The Children's Hospital Corporation doing business as Boston Children's Hospital, located at 300 Longwood Avenue, Boston, MA 02115 ("Repository Provider"), and _____ ("Contributor" or "Contributing Institution"), located at _____. Repository Provider and Contributor are referred to in this Agreement individually as a "Party" and collectively, as the "Parties".

Whereas, the Parties wish to enter into this Agreement so that Repository and Contributor may share certain de-identified data (the "Data") related to the multi-center study titled, *Repository of Aggregated Pediatric International Data on COVID-19 (RAPID-19)* (the "Repository"), for the purpose of research and in a manner that complies with federal, state and local laws, including 45 C.F.R. 164 ("HIPAA") for the Repository Provider and with applicable legislation at the Contributor sites.

Now therefore, the Parties hereby agree as follows:

1. Definitions

   a) "Aggregate Results" refer to results that have been generated from patient-level Data provided by one or more Contributor Sites.

   b) "Committee" refers to the Data Access Committee that reviews study-specific data requests submitted by Contributor Scientists.

   c) "Contributor" shall refer to an investigator, research organization, or other entity that wishes to participate in the Repository.

   d) "Contributing Institution" shall refer to a healthcare institution that wishes to participate in the Repository.

   e) "Contributor Scientist" shall refer to the principal investigator, primary collaborator, or representative from a Contributor or Contributing Institution.

   f) "Contributor Study" shall refer to a specific study proposed by a Contributor or Contributing Institution using patient-level Data from the Repository.

   g) "Data" shall refer to de-identified[1] patient-level demographic, clinical, and other data on pediatric patients with COVID-19. The standard for de-identification will combine the requirements for the Repository Provider and the Contributor.

[1] Data shall not include any of the following US "Prohibited Identifiers" under HIPAA, or equivalents in other jurisdictions: names, postal address information other than towns, cities, states and zip codes, telephone and fax

h) "Repository" shall refer to the multi-center study titled, *Repository of Aggregated Pediatric International Data on COVID-19 (RAPID-19).*

i) "Repository Provider" shall refer to Boston Children's Hospital.

j) "Repository Director" shall refer to Florence Bourgeois, MD, MPH.

k) "Work Product" shall refer to a publication, abstract, or other research product.

2. Repository Provider shall manage the Repository under the direction of Florence Bourgeois, MD, MPH ("Repository Director"). Contributor shall contribute to the Repository under the direction of _____ ("Contributor Scientist").

3. Contribution of Data to the Repository: Contributor will have the ability to transfer Data to the Repository, which the Repository Director will use to build a central repository.

a) Contributor retains ownership of the Data, which includes any related know-how provided to Repository along with the Data.

b) Repository Provider agrees to use, store, and disclose the Data solely for the performance of the Repository and any subsequently agreed upon purposes. Repository Provider shall manage the Repository in compliance with all applicable federal, state and local laws, rules and regulations including, but not limited to, laws regarding the privacy or protection of personal or medical information, and HIPAA.

c) Repository Provider agrees to use appropriate safeguards to prevent any use or disclosure of the Data other than as specified in this Agreement. Repository Provider will not use the Data, alone or in combination with other information, to identify the individuals or contact the individuals from whom the Data were derived.

d) Repository Provider agrees that the Data obtained for the Repository: (a) are to be used only by the Repository, by Repository Director or under the direction of Repository Director, or by investigators under the governance of the RAPID-19 Data Access Committee ("Committee"); (b) will not be transferred to anyone else by Repository Provider or to any other third party.

e) Repository Provider agrees to indemnify Contributor for Repository Provider's gross negligence arising from its use, storage or disclosure of the Data. Repository Provider's indemnity resulting from such actions of gross negligence shall be limited to $10,000 USD.

f) Repository Provider is responsible for the safe handling and destruction or return (including the cost of the return) of the Data in accordance with all federal and state laws, and in the manner agreed to by the Parties.

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numbers, e-mail addresses, URLs and IP addresses, social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate and license numbers; vehicle identification numbers; device identifiers and serial numbers; biometric identifies (such as voice prints and finger prints); and full face photographs or comparable images. If any Prohibited Identifiers within US or other jurisdictions are included in the Data, a Business Associate Agreement must be executed and attached as an exhibit to this Agreement.

g) Repository Provider agrees that the Data provided are experimental in nature, and Contributor makes, and will make, no warranties, expressed or implied, regarding the quality of any product produced under this Agreement.

h) Contributor agrees to make no representation about the Registry or its work without the permission of the Repository Director.

4. Access to Data in the Repository: Contributor will have access to Data from all Contributors in the Repository, both as aggregate results ("Aggregate Results") and patient-level Data.

a) Contributor will have access to Aggregate Results from queries using Data in the Repository once this Agreement is fully executed. This does not include access to patient-level Data or option to export Data from any Contributor.

b) To access patient-level Data in the Repository and export Data from the Repository, Contributor will provide a study-specific request outlining the study proposed by Contributor ("Contributor Study") to the Committee. The Committee will review each individual request and grant Contributor access to data for the specific requested Contributor Study. Individual requests for Data can be sent to the Committee by emailing contact@RAPID-19.org. The Committee may set conditions for the design, conduct, analysis and dissemination of each Contributor Study.

c) Contributor acknowledges that there may be other institutions who have not contributed data to the central repository who may want access to patient-level Data ("Non-Contributing Institutions"). Contributor agrees to grant access to its patient-level Data to these Non-Contributing Institutions to the extent that (a) the Non-Contributing Institution has a separate agreement in place with the Repository Provider that is at least as protective as this Agreement, and (b) the Non-Contributing Institution submits its request for patient-level Data to the Committee in the same manner as the Contributor, as outlined in the sub-paragraph immediately above and follows the procedures described in paragaphs 5 – 13 below.

d) Contributor agrees to use, store, and disclose the Data provided by Repository Provider solely for the performance of the Contributor Study (according to any conditions set by the Committee) and any subsequently agreed upon purposes. Contributor shall conduct the Contributor Study in compliance with all applicable federal, state and local laws, rules and regulations including, but not limited to laws regarding the privacy or protection of personal or medical information, and HIPAA.

e) Contributor agrees to use appropriate safeguards to prevent any use or disclosure of the Data provided by the Repoistory other than as specified in this Agreement. Contributor will not use the Data, alone or in combination with other information, to identify the individuals or contact the individuals from whom the Data were derived.

f) Contributor agrees that the Data obtained for the Contributor Study: (a) are to be used solely for teaching and academic research purposes; (b) are to be used only by Contributor, by Contributor Scientist or under the direction of Contributor Scientist; (c) will not be transferred to anyone else by Contributor or to any other third party.

g) Contributor is responsible for the safe handling and destruction or return (including the cost of the return) of the Data provided by the Repository in accordance with all federal and state laws, and in the manner agreed to by the Parties.

h) Contributor agrees that the Data provided by the Repository is experimental in nature, and Repository Provider makes, and will make, no warranties, expressed or implied, regarding the quality of any product produced under this Agreement.

5. The Parties acknowledge that the Repository is a collaborative effort. The Parties agree to coordinate their respective activities regarding publication prior to submission of a paper or abstract for publication or any other dissemination of data or studies arising from the Repository. The purpose of this coordination is to ensure the proper use and presentation of Data and to reflect the collaborative nature of the Repository. The points below describe the requirements for the publishing Party if it uses data from Contributors in a proposed publication, abstract, or other research product ("Work Product"):

a) All Work Products shall contain an acknowledgment stating, "Data for this study were obtained from the RAPID-19 Repository," and provide a link to a list of Contributors that supplied data used in the Work Product.

b) The publishing Party agrees that Contributors will have the opportunity to contribute at the level of an author in said Work Product at the time of application to use Data in the Repository (see Paragraph 4) and subsequently. Authorship credit shall not be given if a Contributor's Data are merely being used in the publishing Party's proposed publication. Rather, authorship credit shall reflect a collaboration between the publishing Party and Contributor(s), and shall be made in accordance with the most recently released version of the "Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals"[2] produced by the International Committee of Medical Journal Editors. The publishing Party will allow authors from Contributor site(s) a minimum of thirty (30) days to contribute to the Work Product as an author. Broadly, any resulting publications and authorship credit shall be made in good faith, and in accordance with scientific and academic standards.

c) Contributor will inform the Repository Director of all Work Products that have been made publically available within seven (7) calendar days of the Work Product being made publically available.

6. Transparency regarding Data access and Work Products: The Repository will be responsible for making the following information available to all Contributors with updates at least biannually:

a) A list of all Contributors participating in the Repository;

b) A list of all studies approved by the Access Committee along with a brief description of each study and a list of the Contributors who have provided Data for the study; and

c) A list of Work Products that have been made publicly-available.

[2] Available at: http://www.icmje.org/icmje-recommendations.pdf

7. Data Integrity
   a) The Parties agree to use best efforts and work in good faith to maintain the integrity of the Data.
   b) If a Party becomes aware of any breaches in Data integrity, it will notify the Access Committee within seven (7) days.
   c) If a Party needs to amend or withdraw Data, the Party will notify the Access Committee with full details of the circumstances, any accompanying investigations and the specification of the amendments or withdrawal.
   d) Access Committee will notify all Contributor Scientist(s) who have been provided Data from the Repository affected by breaches in Data integrity.
   e) Contributor Scientist(s) will review the results of all analyses regarding need for errata or retraction of Work Products and notify Access Committee if these occur.

8. Term and Termination
   a) Term. The term of this Agreement will commence as of the effective date and will continue for five (5) years, unless sooner terminated as set forth in this Agreement.
   b) Termination by Repository. Repository may terminate this Agreement at any time by notifying Contributor and returning or destroying the Data.
   c) Termination by Contributor. Contributor may terminate this Agreement at any time by providing thirty (30) days' prior written notice to Repository.
   d) For Breach. In cases of termination for breach of this Agreement, the terminating Party shall provide written notice to the other Party within ten (10) days of any determination that the other Party has breached a material term of this Agreement. The terminating Party will afford the other Party an opportunity to cure said alleged material breach upon mutually agreeable terms. Failure to agree on mutually agreeable terms for cure within thirty (30) days will be grounds for the immediate termination of this Agreement by the terminating Party.
   e) Effect of Termination.
      i. Except as provided in paragraph (e)(ii) of this Section 9, upon termination of this Agreement, for any reason, Contributor shall return or destroy all Data received from the Study. This provision shall apply to Data that are in the possession of subcontractors or agents of Contributor. Contributor shall retain no copies of the Data provided by the Repository.
      ii. In the event that Contributor determines that returning or destroying the Data is infeasible, Contributor shall extend the protections of this Agreement to such Data and limit further uses and disclosures of such Data to only those purposes that make the return or destruction infeasible, for so long as Contributor maintains such Data.
      iii. Provider Repository shall maintain Data in the Repository that is affected by termination of an agreement associated with the Repository, but only for use in the aggregate results queries, as described in Section 4(a) of this

Agreement. Provider Repository shall not make this Data available for further use in Contributor Studies.

f) Survival. Sections 3(a), 3(b), 3(d), 5, 4(g), 4(h), 4(i), 9(e), 9(f), 11 and 12 of this Agreement will survive any termination of this Agreement under subsections 9(b), 9(c) and 9(d).

9. Force Majeure

In the event a Party is unable to comply with obligations under this Agreement due to circumstances beyond its control, such as an earthquake, hurricane, blizzard, flood, tornado, fire, act of God, other similar natural disaster including but not limited to catastrophe, war, riots, terrorism or other debilitating action of a third party, such Party shall be excused from such obligation for such period of inability, provided that the excused party shall take reasonable steps to remedy such noncompliance once it is able. For purposes of this Section, a lack of funds shall not be considered a cause beyond the reasonable control of the Parties.

10. Contributor will report any violation to this Agreement to Boston Children's Hospital's Clinical Trials Business Office at ctbo@childrens.harvard.edu within seven (7) days.

11. This Agreement shall be governed by and interpreted under the laws of the Commonwealth of Massachusetts.

12. Repository Provider and Contributor will use best endeavours to maintain the provisions of this Agreement.

The Children's Hospital Corporation	August Cervini	Date:
	Name (Please Print)	Date:

Read and acknowledged:

Repository Director	Florence Bourgeois, MD, MPH	Date:
Contributor Scientist		Date: