**Pediatric Infectious Diseases Transplant Network (PIDTRAN)**

**Coded Data Transfer Agreement**

This Data Transfer Agreement (the “Agreement”) made as of \_\_\_\_\_\_\_\_\_\_\_\_\_, 20\_\_ is between \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (“Provider”) and St. Jude Children's Research Hospital, Inc., ("Recipient"). Before receiving the data, Recipient agrees to the following terms and conditions:

1. The data to be provided to Recipient are deidentified routine care patient clinical data for the study **“A multi-center study to describe the epidemiology, clinical presentation, and outcomes of pediatric patients with Covid-19 across the United States (PIDTRAN-6\_COVID-19) – St. Jude IRB number 20-0465”** ("Data"). The Recipient acknowledges that the Data are or may become the subject of a patent application. Except as provided in this Agreement, no express or implied licenses or other rights are provided to the Recipient under any patents, patent applications, trade secrets or other proprietary rights of Provider, including any altered forms of the Data made by Provider.

2. The Data will be used exclusively for nonclinical, non-commercial research by Recipient, and will not be used in the diagnosis or treatment of humans. Use will be in compliance with all Federal, State and local laws and regulations. This Agreement may be terminated upon thirty (30) days written notice by either party to the other. Upon termination of the Agreement, Recipient shall destroy all Data in its possession.

3. The Data will not be transferred, distributed or released to any third party unless prior written permission is obtained from Provider. The Data may not be taken or sent to another institution without written permission from Provider. The Data may not be provided to a commercial entity, and may not be used in research that is subject to consulting, a first option right to negotiate a license or other licensing obligations to another party (other than those obligations imposed upon grantee institutions of the U.S. government) without express written consent of Provider. Recipient, its affiliates, agents and subcontractors agree to comply with all U.S. export control laws, rules and regulations with respect to its use and any permitted distribution of the Data.

4. The Recipient agrees to use the Data in compliance with all applicable statutes and regulations, and specifically agrees to adhere to all requirements necessary for maintaining patient confidentiality associated with the Data.

5. Recipient agrees to provide Provider with a copy of any publication that contains experimental results obtained from the use of the Data, and will acknowledge Provider as the source of the Data.

6. Recipient acknowledges that Provider is a “Covered Entity” as that term is defined by the Health Insurance Portability and Accountability Act of 1996 (codified at 42 U.S.C. 1320d-1329d-8; 42 U.S.C. 1320-d)(“HIPAA) and regulations promulgated thereunder codified at 45 CFR Parts 160, 162 and 164 *et seq* (“HIPAA Regulations”).

7. To the extent that any Data is accompanied by or associated with individually identifiable health information or protected health information as defined by HIPAA and HIPAA Regulations (including 45 C.F.R. §160.103), the Recipient agrees to: (a) execute whatever agreements are necessary for the permitted use and/or disclosure of such individually identifiable Data or protected health information, including a Data Use Agreement, in a form consistent with 45 C.F.R. §164.514(e)(4) that shall be attached hereto and incorporated herein; or (b) to use and/or disclose such individually identifiable Data or protected health information consistent with individual Authorization(s) or Waiver of Authorization(s) obtained in accordance with HIPAA Regulations including an IRB-approved informed consent document when the Authorization form is combined with an informed consent consistent with HHS regulations 45 CFR part 46 and/or FDA regulations at 21 CFR parts 50 and 56; or (c) if Provider assigns and retains a code or other means of record identification which links the individually identifiable health information or protected health information and the code will be disclosed to the Recipient, then the code will not be derived from or related to information about the individual human subject nor can it be translated to identify the individual human subject. Provider will not use, disclose or release the code for other purposes or disclose the mechanism for re-identification to the Recipient nor will the Recipient have access to link the code to the individually identifiable health information or protected health information.

8. Recipient shall not commercialize any product that contains Data without the prior written approval of Provider. The Recipient is free to file patent application(s) claiming inventions made by Recipient through use of the Data but agrees to notify Provider within sixty (60) days of any such filing.

9. The Data provided are experimental in nature, and are provided WITHOUT ANY WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR USE. PROVIDER MAKES NO REPRESENTATION AND PROVIDES NO WARRANTY THAT THE USE OF THE DATA WILL NOT INFRINGE ANY PATENT OR OTHER PROPRIETARY RIGHT. IN NO EVENT SHALL PROVIDER BE LIABLE FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

10. Except to the extent prohibited by law, the Recipient assumes all liability for damages that may arise from its use of the Data. The Provider will not be liable to the Recipient for any loss, claim or demand made by the Recipient, or made against the Recipient by any other party, due to or arising from the use of the Data by the Recipient, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the Provider.

**IN WITNESS WHEREOF**, each of the parties has caused this Agreement to be executed by its authorized representative in its name and on its behalf.

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| Provider: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Recipient: St. Jude Children’s Research Hospital |
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| Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Name: Robyn Diaz |
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| Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Title: SVP/Chief Legal Officer, Office of Legal Services |