

DATA USE AGREEMENT BETWEEN

The Corporation for the Advancement of Pediatric Cardiac Services – aka “The Pediatric Cardia Care Consortium”

And

Recipient Name and Institution

This Data Use Agreement (“Agreement”) by and between **The Pediatric Cardiac Care Consortium** (“Holder”), and **Insert Recipient name** (“Recipient”), is effective as of the last signature date below and shall remain in effect pursuant to the terms set forth in Section 5 herein.

1. This Agreement sets forth the terms and conditions pursuant to which Holder will disclose certain protected health information (“PHI”) in the form of a Limited Data Set (the “Data Set”) to the Recipient.
2. Terms used, but not otherwise defined, in this Agreement shall have the meaning given the terms in the HIPAA Regulations at 45 CFR Part 160-164.
3. Permitted Uses and Disclosures
 - 3.1 Except as otherwise specified herein, Recipient may use and disclose the Data Set as necessary to conduct the research described herein: **The PCCC will grant access to the Data Set for each research project that the Recipient proposes provided that:**
 - 3.1.1 **The Recipient submits a proposal for research that in the determination of the PCCC Proposal Review Committee is scientifically valid and consistent with the mission of the PCCC;**
 - 3.1.2 **The Recipient has obtained all required internal review board (IRB) approvals;**
 - 3.1.3 **The Recipient, upon IRB approval, has access to data pertaining to children with CHD until completion of the IRB approved project (results summarized in a paper);**
 - 3.1.4 **The Recipient will be provided with a query of the registry to identify the cohort that meets the needs of the proposed project based on inclusion/exclusion criteria and will be granted access to pdfs to perform data abstraction related to the approved project;**
 - 3.1.5 **The Recipient may create or submit unlimited publications based on this query with review of the content by Dr. Lazaros Kochilas and/or other appointed PCCC collaborator to verify the integrity of the data and analysis;**
 - 3.1.6 **The Recipient agrees to acknowledge the PCCC as the source of the data and to include Dr. Lazaros Kochilas and/or collaborators in any such research to knowledge the PCCC contribution to the research. The PCCC can revoke this agreement at any time its board considers the collaboration outside of its scope and mission or for deviations from this agreement. (“Research Project”).**
 - 3.2 In addition to the Recipient, the individuals, or classes of individuals, who are permitted to use or receive the Data Set for purposes of the Research Project include:

The researchers staff and any collaborators. To the extent that any such individuals or classes of individuals are not part of the Recipient's workforce, the Recipient shall ensure that any such individuals agree to the same terms and conditions that apply to Recipient hereunder with respect to the Data Set.

4. Recipient Responsibilities

- 4.1 Recipient will not use or disclose the Data Set for any purpose other than as permitted by this Agreement or as required by law;
- 4.2 Recipient will use appropriate administrative, physical and technical safeguards to prevent use or disclosure of the Data Set other than as provided for by this Agreement;
- 4.3 Recipient will report to the Holder any use or disclosure of the Data Set not provided for by this Agreement of which the Recipient becomes aware within 15 days of becoming aware of such use or disclosure;
- 4.4 Recipient will ensure that any agent, including a subcontractor, to whom it provides the Data Set, agrees to the same terms and conditions that apply to Recipient hereunder with respect to the Data Set;
- 4.5 Recipient will not identify the information contained in the Data Set for any purpose other than to complete the Research Project as described herein; and
- 4.6 Recipient will not contact the individuals who are the subject of the PHI contained in the Data Set.

5. Term and Termination

- 5.1 This Agreement shall be effective as of the last signature date set forth below, and shall remain in effect until all PHI in the Data Set provided to the Recipient is destroyed or returned to the Holder.
- 5.2 Upon the Holder's knowledge of a material breach of this Agreement by the Recipient, the Holder shall provide an opportunity for Recipient to cure the breach or end the violation. If efforts to cure the breach or end the violation are not successful within the reasonable time period specified by the Holder, the Holder shall discontinue disclosure of PHI to the Recipient and report the problem to the Secretary of the Department of Health and Human Services or its designee. The Holder shall immediately discontinue disclosure of the Data Set to the Recipient if the Holder determines cure of the breach is not possible.

6. General Provisions

- 6.1 Recipient and Holder understand and agree that individuals who are the subject of PHI are not intended to be third party beneficiaries of this Agreement.
- 6.2 This Agreement shall not be assigned by Recipient without the prior written consent of the Holder.

6.3 Each party agrees that it will be responsible for its own acts and the results thereof to the extent authorized by law and shall not be responsible for the acts of the other party or the results thereof.

IN WITNESS WHEREOF, the parties hereto execute this agreement as follows:

HOLDER

Date: _____

By: _____
Lazaros K. Kochilas, MD, President,
Pediatric Care Consortium

RECIPIENT

Date: _____

By: _____
(Title and signature of person with authority to sign for
the Recipient)