#### WSPCHS

#### World Society for Pediatric and Congenital Heart Surgery Database

**Data Use Agreement**

**MEMORANDUM OF AGREEMENT**

**between**

**WORLD SOCIETY FOR PEDIATRIC AND CONGENITAL HEART SURGERY**

**and**

**[Hospital]**

This memorandum of agreement (this “Agreement”) is made this \_\_\_\_ day of \_\_\_\_\_\_, 201\_ (the “Effective Date”) between the World Society for Pediatric and Congenital Heart Surgery (“Data Recipient”) and \_\_\_\_\_\_\_\_\_\_\_. (“Hospital”).

**Introduction**

The World Society for Pediatric and Congenital Heart Surgery Database is owned and operated by the World Society for Pediatric and Congenital Heart Surgery (WSPCHS). This International Database intends to enroll and follow patients who undergo surgical correction or palliation of a congenital cardiac defect.

**Purpose**

The purpose of this “Agreement” is to define roles and delineate responsibilities of the WSPCHS and the “Hospital” in the exchange of data relating to the conduct and outcomes in patients undergoing operative therapy for a congenital cardiac defect. The purpose of the Database is to provide a quality improvement tool, generate scientific outcomes analyses, and improve overall surgical outcomes for patients with congenital cardiac defects.

**Ownership of Data**

Each “Hospital” retains ownership of the data submitted to the WSPCHS Database. The “Hospital” may withdraw from the Database and may request that their data be removed from the Database.

**Limitations of WSPCHS’s use of Exchanged Data**

WSPCHS agrees to utilize exchanged data only in aggregate analyses. A “Hospital” will receive individual confidential reports regarding its own data. No center-specific data reporting beyond this scope will be performed without the express consent of the centers. No country-specific data reporting will be performed without the express consent of all participating centers within the country. Data reporting by the WSPCHS which would reveal the individual identity of any “Hospital” will not be published or presented without prior approval from that “Hospital”. WSPCHS agrees that any agents, including technical administration of the database, agree to the same restrictions and conditions that apply to the WSPCHS with respect to such information. WSPCHS will report to the “Hospital” any use or disclosure of data which WSPCHS becomes aware that is not permitted by this “Agreement”.

**“Hospital” Responsibilities**

“Hospital” agrees to the following:

1. Identify eligible patient participants according to guidelines outlined in the accompanying WSPCHS Database Instruction Manual, to include operative cases outlined.
2. Collect and submit required data to the WSPCHS Database via the WSPCHS Database WEB-based data entry system or via data entered into another national or international database (“Collective”) which is shared with the WSPCHS Database.
3. Collect and submit complete required data based on the requirement listed in the WSPCHS Database Instruction Manual.
4. Designate a Physicians representative for the hospital. This individual must be an active member of the WSPCHS in good standing
5. Designate an “Administrator” as the official contact for WSPCHS Database communications, provide current mail, phone, fax, and e-mail contact information to the WSPCHS, and notify the WSPCHS promptly if the “Administrator” is changed.
6. Assume responsibility for maintaining security of its assigned login names and passwords.
7. Provide the WSPCHS with documentation verifying that the “Hospital” has approved the participation in this database and that the “Hospital” meets all local regulatory requirements for participation.
8. Understands that incomplete data submissions or submissions on partial patient populations are considered non-compliant with the WSPCHS policies and procedures and entitle WSPCHS, at its discretion, to discontinue the “Hospital’s” participation in the database.

**WSPCHS Responsibilities**

1. WSPCHS will provide the “Hospital” with data dictionary quality assurance standards (such as general field descriptions) and technical details for each data element collected in the Database.
2. WSPCHS will provide training on data entry and support as needed to individual “Hospitals” regarding database function and data entry questions.
3. WSPCHS will provide periodic reports at least annually to the “Hospital” that will summarize the data submitted to the Database by the “Hospital”.
4. WSPCHS will provide advance notification to the “Hospital” of any system and/or application modifications to the WSPCHS database.
5. Periodic Review: Representatives of the “Hospital” and the WSPCHS database will confer annually to evaluate operational aspects of this Agreement. Any dispute among parties relating to any matter concerning this agreement shall be arbitrated to the exclusion of the courts, in “English” at Montreal, Quebec before one arbitrator in virtue of the rules for arbitration set out in the “Quebec Code of Civil Procedure”. The arbitration decision may be ratified as necessary before a competent court.

**Agreement**

By signing this Memorandum of Agreement, the “Hospital” agrees to the terms and conditions outlined in the Agreement and the WSPCHS protocols as outlined in the WSPCHS Database Instruction Manual. This Agreement will be renewed automatically annually and may be cancelled with 30 days’ advance written notice by the “Hospital” or WSPCHS without liability owed to the other party relating to such particular termination.

**Responsible Parties**

We agree to the roles and responsibilities outlined in the preceding Memorandum of Agreement and WSPCHS Database Instruction Manual.

**Choice of Law**

This Agreement is governed by the laws of both the Province of Quebec and [Country or State].

**“Hospital”**

\*Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Title:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**WSPCHS**

\*Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\*Signature should be made by the appropriate authority to bind the Hospital to the provisions in the Agreement.