THE WORLD DATABASE FOR PEDIATRIC AND CONGENITAL HEART SURGERY

# PARTICIPATION AGREEMENT

**CONGENITAL HEART SURGERY DATABASE**

THIS AGREEMENT is entered into effective the (Date), by and between (a) the World Society for Pediatric and Congenital Heart Surgery, a Canadian not-for-profit corporation with its principal place of business at The Montreal Children's Hospital of the McGill University Health Centre 1001 Décarie Boulevard Room B 04.2915 Montreal, QC H4A 3J1 Canada, Montreal, Canada (“WSPCHS”); and (b)

(“Participant”), an individual cardiothoracic surgeon or a group of cardiothoracic surgeons (all of whose members are identified in and have signed Schedule A attached hereto), whose principal place of business is at

(“Hospital”)

WHEREAS, WSPCHS has developed and owns certain computerized databases containing information relating to patient treatment, the practice of medicine, and third parties submitting data to these databases (the “Participants”) pursuant to WSPCHS rules (said databases collectively referred to herein as the “World Database for Pediatric and Congenital Heart Surgery” [WDPCHD]);

WHEREAS, the successful operation of the WDPCHS is dependent in large measure on “Participants“ use of computer on-line access that meets WDPCHS specifications for content, functionality, and otherwise; and

WHEREAS, “Participant” has expressed an interest in participating in the WDPCHS in accordance with WSPCHS requirements;

NOW, THEREFORE, in consideration of the foregoing recitals and the covenants contained herein, and for other good and valuable consideration, the parties here to agree as follows:

1. Participation in WDPCHS.
   1. “Participant” agrees to participate in the WDPCHS by utilizing WDPCHS data collection website based entry program for the collection and submission of data pertaining to the practice of congenital heart surgery.
   2. “Participant” will participate in the data harvests conducted by WSPCHS and its “Independent Data Warehouse Service Provider” (currently University of Alabama at Birmingham) by submitting “Participant’s” data to the “Independent Data Warehouse Service Provider” and otherwise complying with the rules and harvest schedules reasonably established by WSPCHS in connection there with.
      1. Participant here by warrants that all data submitted for inclusion in the WDPCHS will be accurate and complete, and acknowledges that such data may be subject to independent audit. “Participant” will use its best efforts to address any data or related deficiencies identified by the “Independent Data Warehouse Service Provider”, and agrees to cooperate with and assist WSPCHS and its designees in connection with the performance of any independent audit.
      2. “Participant” warrants that it will take all reasonable steps to avoid the submission of duplicative data for inclusion in the WDPCHS.
      3. “Participant” agrees to assist and cooperate with WSPCHS and its “Independent Data Warehouse Service Provider” in their efforts to conduct the WDPCHS. Without limiting the generality of the foregoing, “Participant” will keep WDPCHS and its “Independent Data Warehouse Service Provider” apprised of (a) any changes in the composition of the group of cardiothoracic surgeons (“Participant”) identified in Schedule A attached hereto (either by addition or deletion, and if by addition, via each new surgeon’s execution of an addendum Schedule A)
   3. “Participant” agrees and acknowledges that its failure to submit data to the WDPCHS, or its submission of data to the WDPCHS that does not comply with WSPCHS requirements, may result in Participant’s failure to receive reports generated from the WDPCHS (see paragraph 2).
   4. “Participant” agrees and acknowledges that the data captured by the WDPCHS will include certain hospital, physician, and patient identifying information. “Participant” agrees that it is “Participant’s” responsibility to obtain any permissions required in order to submit such data for inclusion in the WDPCHS, and specifically agrees to indemnify, save and hold harmless WSPCHD and its “Independent Data Warehouse Service Provider” from and against all claims and liabilities associated there with.
2. WDPCHS Reports. Provided that “Participant” participates in the WDPCHS (in accordance with WSPCHD requirements), “Participant” will be entitled to receive WDPCHS reports electronically, all of which will include both aggregated data from the WDPCHS and Participant-specific information, and such other reports as WSPCHD or its “Independent Data Warehouse Service Providers” may prepare for “Participants”. Additional reports may be created for “Participant” in consideration for the fees required by WSPCHD in order to provide them. The aggregated data included in any and all reports provided here under constitute “WSPCHD Intellectual Property” (as defined herein) and, as such, may not be reproduced, further disseminated or otherwise used except as provided in paragraph 6.4 of this Agreement.
3. Participant Ad Hoc Queries. “Participant” may submit to WSPCHS for analysis by the “Independent Data Warehouse Service Provider” such requests for ad hoc queries (requiring access to and analysis of aggregate data from the WDPCHS) as “Participant” may desire. All such requests for ad hoc queries shall be subject to prior approval by WSPCHS, in accordance with such procedures and other requirements as it may reasonably establish, before efforts are undertaken by the “Independent Data Warehouse Service Provider” to respond there to. In its response to each of Participant’s ad hoc queries, WDPCHS shall give due consideration to scientific merit, the funds and other resources available to address ad hoc queries and other pertinent factors; provided, however, that if adequate funding is not otherwise available, WSPCHS may condition its approval of are request for an ad hoc query upon “Participant’s” agreement to pay the fees required by the “Independent Data Warehouse Service Provider” and any other service providers required in order to appropriately address “Participant’s” ad hoc query. As a part of its efforts to promote the use of the WDPCHS as a tool for the development of beneficial scientific information, WSPCHS will provide reasonable assistance to “Participant” in refining “Participant’s” requests for ad hoc queries so as to enhance their potential for approval in light of the pertinent factors noted above.
4. Participant Fees.
   1. Members that are in “good standing” with the WSPCHS will have full access to the database free of charge:
      1. This condition will remain in place for no longer than three years from the inception of the database (January 2017). Following this period, the WSPCHS retains the right to reassess the payment schedule and with due process, request payment for some or all services provided within the WDPCHS and the “Independent Data Warehouse Service Provider”.
5. Confidentiality. WSPCHS acknowledges that the data submitted to the WDPCHS by “Participant” are deemed confidential. Accordingly, WSPCHS agrees and acknowledges that it has required its current “Independent Data Warehouse Service Provider” (and will require any future data warehouse service providers) to treat such information as confidential pursuant to an appropriate and material term with in its written data warehouse service contract for the WDPCHS. The parties hereby agree to comply with all statutes and regulations, under the appropriate national laws, concerning patient privacy and data security. To that end, it is agreed and acknowledged that they are executing Data Use Agreement.
6. Intellectual Property.
   1. It is agreed and acknowledged that all data submitted for inclusion in the WDPCHS by “Participant” are and shall remain “Participant’s” proprietary information, and may be used by WSPCHS and its designees only in accordance with the terms of this “Agreement” and any subsequent instruction from “Participant” with respect there to (e.g., in connection with data collection efforts of geographically based groups of cardiothoracic surgeons).
   2. “Participant” hereby agrees that all data submitted by or on behalf of “Participant” to WSPCHS or WSPCHS’s designee for purposes of inclusion in the WDPCHS may be used by WSPCHS as a part of the WDPCHS and any subset thereof that WSPCHS may choose to create and use as it sees fit for the purposes of promoting quality assessment and improvement, medical research, surgeon self-assessment and the other interests of the WDPCHS (including, without limitation, publication of such data); provided, however, that no such data shall be used in such a way as to identify “Participant” or any patient or institution of “Participant” unless and until “Participant” advises WSPCHS in writing that it has secured appropriate consent therefore.
   3. “Participant” acknowledges that WSPCHS is and shall be deemed the owner of all rights to the WDPCHS (including the WDPCHS, the aggregate data contained therein and subsets thereof ) , any and all reports based thereon, all information derived there from (including, without limitation, all risk algorithms and associated Beta coefficients and Y intercepts) and all trademarks (including, without limitation), World Society for Pediatric and Congenital Heart Surgery and all variations there on and graphic representations thereof ), trade secrets and all other intellectual property arising from or reflected in the WDPCHS(collectively, “WSPCHS Intellectual Property”) with the exception of “Participant’s” data.
   4. It is recognized and understood the existing inventions, data, and technologies of the Parties are their separate property, respectively, and are not affected by this Agreement. WSPCHS shall not have a claim to or rights in such existing inventions, data and technologies of the University of Alabama, and WSPCHS shall not have any claim to or rights in such existing inventions, data, and technologies of the University of Alabama. Specifically, it is understood that the University of Alabama owns the platform and programming for the database, and WSPCHS has no ownership interest therein. The data contained in the WDPCHS shall be owned by the WSPCHS to the extent permitted under governing law and the informed consent. Determination of ownership for all other inventions shall be determined in accordance with the U.S. patent laws.
   5. “Participant” may not use “WSPCHS Intellectual Property” without first obtaining the express written consent of WSPCHS, provided that “Participant” may use aggregated data from the WDPCHS that have been previously released to the public by WSPCHS (e.g., in published reports and slide sets), as well as WSPCHS risk algorithms without first obtaining such written consent.

7) Limitation of Liability.

“Participant” agrees to indemnify, hold harmless WSPCHS and its “Independent Data Warehouse Service Provider” from and against any and all claims, costs and expenses(including attorneys’ fees and expenses), demands, actions and liabilities of every kind and character whatsoever arising or resulting in any way from “Participant’s” use of data obtained through the WDPCHS(including, without limitation, information obtained through the application of any and all risk assessment algorithms) absent the gross negligence or willful misconduct of WSPCHS or the “Independent Data Warehouse Service Provider”, respectively. All of the foregoing rights of indemnification shall apply to any expenses incurred by WSPCHS and the “Independent Data Warehouse Service Provider” in defending themselves, respectively, against claims of gross negligence or willful misconduct unless a court of competent jurisdiction concludes in a final judgment that such party seeking indemnification has committed gross negligence or willful misconduct.

8) Term and Termination.

8.1. Subject to the terms of paragraph 8.2, this “Agreement” shall be effective through (DATE), and shall be automatically renewed on an annual basis there after unless any party provides the other(s) with a written notice of termination on or before (DATE), or December 1 of any subsequent renewal year.

8.2. This “Agreement” maybe terminated prior to (DATE) (or December 31 of any subsequent renewal year) upon any party’s material breach of this “Agreement” and any other party’s provision of written notice there of; provided, however, that if said breach is cured to the non-breaching party’s(ies’) satisfaction (as reflected in written notice thereof) within thirty (30) days after the provision of such notice, said termination notice shall be of no further force or effect and this Agreement shall be fully reinstated.

1. Equitable Relief. The parties understand and agree that money damages may not be a sufficient remedy for the breach of the provisions of this “Agreement”, and that each party shall be entitled to emergency injunctive relief as a remedy for any such breach by any other party. Such remedy shall not be deemed to be the exclusive remedy for the breach of this “Agreement”, but shall be in addition to all other remedies at law or in equity to the non-breaching party(ies).
2. Independent Contractors. The relationship of the parties to this Agreement is that of independent contractors, and not that of master and servant, principal and agent, employer and employee, or partners or joint venturers.
3. Notices. All notices and demands of any kind or nature which any party to this Agreement may be required or may desire to serve upon the other in connection with this Agreement shall be in writing, and maybe served personally, by registered or certified United States mail, by facsimile transmission or by overnight courier (e.g., Federal Express or DHL) to the following addressees:

If to Surgeon Participant:

(fax #)

If to Hospital Participant (if any):

(fax #)

If to WSPCHS: James D St. Louis M.D.

Secretary. World Society of Pediatric and Congenital Heart Surgery

Database Committee

The Montreal Children's Hospital of the McGill University Health Centre

1001 Décarie Boulevard

Room B 04.2915

Montreal, QC  H4A 3J1

Canada

Service of such notice or demand so made shall be deemed complete on the day of actual delivery. Without limiting the generality of the foregoing, if notice is given by facsimile transmission, such notice shall be deemed to be provided upon confirmation of the receipt of the transmission. Any party hereto may, from time to time, by notice in writing served upon the other party (ies) as aforesaid, designate different mailing address, a different facsimile number, or a different person to which all further notices or demands shall thereafter be addressed.

1. Headings. The headings of the various paragraphs here of are intended solely for the convenience of reference and are not intended for any purpose what so ever to explain, modify or place any construction upon any of the provisions of this Agreement.
2. Assignment. This Agreement may not be assigned by any party without the prior express written approval of the other party(ies).
3. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original and all of which taken together shall constitute one and the same instrument.
4. Waiver. A waiver by any party to this Agreement of any of its terms or conditions in any one instance shall not be deemed or construed to be a general waiver of such term or condition or a waiver of any subsequent breach.
5. Choice of Law and Forum. All disputes regarding the meaning, effect, force or validity of this Agreement shall be determined according to federal law and the law of the Montreal Quebec. The parties expressly agree that the federal and state courts located in Montreal Quebec, are the most reasonable and convenient forums for resolutions of any such disputes, and designate said courts as the exclusive forums in which all such disputes shall be litigated. Accordingly, the parties consent to the jurisdiction and venue of, and service of process by, said courts. Each party agrees that the provisions of this paragraph are specifically enforceable, and that it shall pay all expenses, damages, and costs (including attorneys’ fees and expense) of any other party if said other party commences, prosecutes, or permits to continue any actions in any other forum.
6. Severability. All provisions of this Agreement are severable. If any provision or portion here of is determined to be unenforceable by a court of competent jurisdiction, then the rest of this Agreement shall remain in full effect, provided that its general purposes remain reasonably capable of being effected.
7. Survival. The provisions of paragraphs 1.4, 5-7, 8.2, 9, 11-13, 15-19 and all other terms within this Agreement that are necessary or appropriate to give meaning there to shall survive any termination of this Agreement.
8. Entire Agreement. This Agreement (a) constitutes the entire agreement between the parties hereto with respect to the subject matter hereof; (b) supersedes and replaces all prior agreements, oral or written, between the parties relating to the subject matter hereof; and (c) except as otherwise indicated herein, may not be modified, amended or otherwise changed in any manner except by a written instrument executed by the party against whom enforcement is sought.

IN WITNESS WHEREOF, the parties here to have duly executed this Agreement, as of the date and year first written above.

World Society for Pediatric and Congenital

Heart Surgery “PARTICIPANT”

By: James D St. Louis M.D. By:

Its: Secretary, World Database Its:

HOSPITAL (IF ANY)

By:

Its:

2016 Congenital Heart Surgery Participation Agreement.docx

# SCHEDULE A

(Name of Participant Group)

1. , M.D. Address

Signature: NPI:

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