hereto agree as follows:

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### ADULT CARDIAC SURGERY DATABASE

THIS AGREEMENT is entered into effective the 1st day of January, 2021, by
and between (a) THE SOCIETY OF THORACIC SURGEONS, an Illinois not-for-profit
corporation with its principal place of business at 633 North Saint Clair Street, Chicago, Illinois,
60611 ("STS"); and (b),
an individual surgeon or a group of surgeons (all of whose members are identified in and have
signed Schedule A attached hereto), whose principal place of business is at
("Surgeon
Participant'); and, only upon Surgeon Participant's election, and only if the following identified
"Anesthesiologist Participant" has agreed to abide by the terms of this Agreement, (c)
an individual anesthesiologist or a group of anesthesiologists (all of whose members are
identified in and have signed Schedule B attached hereto), whose principal place of business is at
("Anesthesiologist Participant"); and only upon Surgeon Participant's election, and only if the following identified "Hospital Participant" has purchased or has committed to purchase "STS Certified Software" (as defined herein) for purposes of participation in the "STS National Database" (as defined herein), (d),
a, solely on behalf
of the hospital known as ("Hospital
Participant"). The Surgeon Participant, the Anesthesiologist Participant (if any) and the Hospital Participant (if any) are sometimes collectively referred to herein as the "Participant."
WHEREAS, STS 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 STS rules (said databases collectively referred to herein as the "STS National Database");
WHEREAS, STS has established an adult cardiac surgery component of the STS National Database (the "AC Database");
WHEREAS, the successful operation of the AC Database is dependent in large measure on Participants' use of computer software that meets STS specifications for content, functionality, and otherwise ("STS Certified Software"); and
WHEREAS, Participant has expressed an interest in participating in the AC Database in accordance with STS requirements;

covenants contained herein, and for other good and valuable consideration, the parties

NOW, THEREFORE, in consideration of the foregoing recitals and the

#### 1. Participation in AC Database.

1.1.	Participant agrees to participate in the AC Database by utilizing the following
STS Certified	Software for the collection and submission of data pertaining to the practice of
adult cardiac s	surgery:

- 1.2. Participant will participate in the data harvests conducted by STS and its independent data warehouse service provider (currently Outcome Sciences, Inc. d/b/a IQVIA) by submitting Participant's data to the independent data warehouse service provider and otherwise complying with the rules and harvest schedules reasonably established by STS in connection therewith.
  - 1.2.1. Participant hereby warrants that all data submitted for inclusion in the AC Database 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 STS and its designees in connection with the performance of any independent audit.
  - 1.2.2. Participant warrants that it will take all reasonable steps to avoid the submission of duplicative data for inclusion in the AC Database, including but not limited to apprising STS and the independent data warehouse service provider about any other Participation Agreements in which an individual surgeon named above or on Schedule A attached hereto (as amended from time to time) is also named.
  - 1.2.3. Participant agrees to assist and cooperate with STS and its independent data warehouse service provider in their efforts to conduct the AC Database. Without limiting the generality of the foregoing, Participant will keep STS and its independent data warehouse service provider apprised of (a) any changes in the composition of the group of surgeons 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), (b) any changes in the composition of the group of anesthesiologists identified in Schedule B attached hereto (either by addition or deletion, and if by addition, via each new anesthesiologist's execution of an addendum Schedule B), (c) any changes in the kind or nature of STS Certified Software utilized by Participant, and (d) otherwise as reasonably requested by STS and its independent data warehouse service provider.
- 1.3. Participant agrees and acknowledges that its failure to submit data to the AC Database, or its submission of data to the AC Database that does not comply with STS requirements, may result in Participant's failure to receive one or more reports generated from the AC Database (see paragraph 2) and/or an assessment of additional Participant fees to reflect additional expenses incurred by STS in order to render Participant's data appropriate for inclusion in the AC Database (see paragraph 4.2).

- 1.4. Participant agrees and acknowledges that the data captured by the AC Database 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 AC Database, and specifically agrees to indemnify, save and hold harmless STS andits independent data warehouse service provider from and against all claims and liabilities associated therewith.
- 2. <u>AC Database Reports.</u> Provided that Participant participates in the AC Database in accordance with STS requirements (including but not limited to Participant's payment of all applicable fees), Participant will be entitled to receive AC Database reports electronically, all of which will include aggregated data from the AC Database, and such other reports as STS or its independent service providers may prepare for Participants. Additional reports may be created for Participant in consideration for the fees required by STS in order to provide them. The aggregated data included in any and all reports provided hereunder constitute "STS 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.
- Participant Ad Hoc Queries. Participant may submit to STS for analysis by the 3. independent data warehouse service provider such requests for ad hoc queries (requiring access to and analysis of aggregate data from the AC Database) as Participant may desire. All such requests for ad hoc queries shall be subject to prior approval by STS, 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 thereto. In its response to each of Participant's ad hoc queries, STS shall give due consideration to scientific merit, the funds and other resources available to address ad hoc gueries and other pertinent factors; provided, however, that if adequate funding is not otherwise available, STS may condition its approval of a request for an ad hoc query upon Participant's agreement to pay the fees required by the independent data warehouse 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 STS National Database as a tool for the development of beneficial scientific information, STS 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.

- 4.1. Fees payable by Participant to STS pursuant to this Agreement are as follows:
- 4.1.1. If Surgeon Participant is an STS member or is composed of a majority of STS members, the participation fee shall be Four Thousand, Two Hundred and Fifty Dollars (\$4,250), plus a per surgeon charge of \$150 for each STS member and \$350 for each non-member. Payment of this fee shall entitle Participant to receive only one set of reports, capturing the aggregate data of all Surgeon Participants submitting data to the AC Database, as well as the aggregate data of all surgeons identified in Schedule A attached hereto (as amended from time to time) and submitting data to the AC Database, pursuant to paragraph 2.

- 4.1.2. If Surgeon Participant is not an STS member or is not composed of a majority of STS members, the participation fee shall be Six Thousand, Three Hundred and Seventy-Five Dollars (\$6,375) plus a per surgeon charge of \$150 for each STS member and \$350 for each non-member. Payment of this fee shall entitle Participant to receive only one set of reports, capturing the aggregate data of all Surgeon Participants submitting data to the AC Database, as well as the aggregate data of all surgeons identified in Schedule A attached hereto (as amended from time to time) and submitting data to the AC Database, pursuant to paragraph 2.
- 4.1.3. A special, supplemental participation fee of Twenty-Five Hundred Dollars (\$2,500) shall be payable annually if an Anesthesiologist Participant has executed this Agreement. Such supplemental participation fee shall cover an Anesthesiologist Participant whether such Anesthesiologist Participant includes one anesthesiologist or a group of anesthesiologists. Payment of this supplemental participation fee shall also entitle Participant to receive with its set of reports the aggregate data of all Anesthesiologist Participants submitting data to the AC Database, as well as the aggregate data of all anesthesiologists identified in Schedule B attached hereto (as amended from time to time) and submitting data to the AC Database, pursuant to paragraph 2.
- 4.1.4. Such participation fees as STS may establish for future calendar years, provided that said fees will be established by STS prior to December 1 in 2021 and in each succeeding year (payable by January 1, 2022, and each succeeding year).
- 4.2. Any additional fees payable by STS to the independent data warehouse service provider to address data submitted to the AC Database that fails to conform with STS requirements.
  - 4.3. Any additional report-related fees required pursuant to paragraph 2.
  - 4.4. Any additional ad hoc query fees required pursuant to paragraph 3.
- 5. <u>Confidentiality.</u> STS acknowledges that the data submitted to the AC Database by Participant are deemed confidential. Accordingly, STS 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 within its written data warehouse service contract for the STS National Database. The parties hereby agree to comply with all statutes and regulations, under federal and state laws, concerning patient privacy and data security, including but not limited to the privacy regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). To that end, it is agreed and acknowledged that they are executing the Business Associate Contract and Data Use Agreement attached hereto as Appendix I in conjunction with their execution of this Agreement.

#### 6. <u>Intellectual Property.</u>

- 6.1. It is agreed and acknowledged that all data submitted for inclusion in the AC Database by Participant are and shall remain Participant's proprietary information, and may be used by STS and its designees only in accordance with the terms of this Agreement and any subsequent instruction from Participant with respect thereto (e.g., in connection with data collection efforts of geographically based groups of surgeons).
- 6.2. Participant hereby agrees that all data submitted by or on behalf of Participant to STS or STS's designee for purposes of inclusion in the AC Database may be used by STS as a part of the STS National Database and any subset thereof that STS may choose to create and use as it sees fit for the purposes of promoting medical research, surgeon self-assessment and the other interests of the STS National Database (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 STS in writing that it has secured appropriate consent therefor.
- 6.3. Participant acknowledges that STS is and shall be deemed the owner of all rights to the STS National Database (including the AC Database, the aggregate data contained therein and subsets thereof), any and all reports based thereon, all information derived therefrom (including, without limitation, all risk algorithms and associated Beta coefficients and Y intercepts) and all trademarks (including, without limitation, THE SOCIETY OF THORACIC SURGEONS, STS, STS CERTIFIED SOFTWARE, STS NATIONAL DATABASE, AC DATABASE and all variations thereon and graphic representations thereof), trade secrets (including, without limitation, the software specifications reflected in STS Certified Software) and all other intellectual property arising from or reflected in the STS National Database (collectively, "STS Intellectual Property") with the exception of Participant's data.
- 6.4. Participant may not use STS Intellectual Property without first obtaining the express written consent of STS, provided that Participant may use aggregated data from the STS National Database that have been previously released to the public by STS (e.g., in published reports and slide sets), as well as STS risk algorithms and associated Beta coefficients and Y intercepts, without first obtaining such written consent.

Limitation of Liability. Participant acknowledges that STS is not responsible for the performance of STS Certified Software or the continued certification thereof, or for the operation of the STS National Database, and hereby waives, and covenants not to sue STS for, any and all possible claims that it might have against STS arising out of, or resulting from, the performance of STS Certified Software, the revocation of its certification for purposes of use in conjunction with the STS National Database and the operation of the STS National Database, absent the gross negligence or willful misconduct of STS. Similarly, Participant hereby waives, and covenants not to sue the independent data warehouse service provider retained by STS for, any and all possible claims that it might have arising out of, or resulting from, the performance of STS Certified Software or the revocation of its certification for purposes of use in conjunction with the STS National Database absent the gross negligence or willful misconduct of the independent data warehouse service provider, as applicable. Participant further agrees to indemnify, save and hold harmless STS and the 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 STS National Database (including, without limitation, information obtained through the application of any and all risk assessment algorithms embodied in STS Certified Software) absent the gross negligence or willful misconduct of STS or the independent data warehouse service provider, respectively. All of the foregoing rights of indemnification shall apply to any expenses incurred by STS and/or 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 December 31, 2021, and shall be automatically renewed on an annual basis thereafter unless any party provides the other(s) with a written notice of termination on or before December 1, 2021, or December 1 of any subsequent renewal year.
- 8.2. This Agreement may be terminated prior to December 31, 2021 (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 thereof; 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.
- 8.3. Upon termination of this Agreement for any reason other than the discontinuation of the AC Database, Participant's use of STS Certified Software shall simultaneously cease.

- 9. <u>Equitable Relief.</u> 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).
- 10. <u>Independent Contractors.</u> 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.
- 11. <u>Notices.</u> 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 may be served personally, by registered or certified United States mail, by facsimile transmission or by overnight courier (e.g., FedEx or DHL) to the following addressees:

If to Surgeon Participant:	
	(C 11)
	(fax #)
If to Anesthesiologist Participant (if any):	
	(fax #)
If to Hospital Participant (if any):	
-	
	(fax #)

ACSD PA: 2021

If to STS: Executive Director

The Society of Thoracic Surgeons 633 North Saint Clair Street, Suite 2100 Chicago, Illinois 60611-3658 (fax #) 312/202-5801

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 a different mailing address, a different facsimile number, or a different person to which all further notices or demands shall thereafter be addressed.

- 12. <u>Headings</u>. The headings of the various paragraphs hereof are intended solely for the convenience of reference and are not intended for any purpose whatsoever to explain, modify or place any construction upon any of the provisions of this Agreement.
- 13. <u>Assignment.</u> This Agreement may not be assigned by any party, by operation of law or otherwise, without the prior express written approval of the other party(ies).
- 14. <u>Counterparts.</u> 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.
- 15. <u>Waiver.</u> 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.
- 16. 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 State of Illinois. The parties expressly agree that the federal and state courts located in Cook County, Illinois, 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.
- 17. <u>Severability.</u> All provisions of this Agreement are severable. If any provision or portion hereof 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.
- 18. <u>Survival.</u> The provisions of paragraphs 1.4, 5-7, 8.3, 9, 11-13, 15-19 and all other terms within this Agreement that are necessary or appropriate to give meaning thereto shall survive any termination of this Agreement.

ACSD PA: 2021

- 19. Entire Agreement. This Agreement and the attached Appendix I together (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.
- 20. Electronic Signature. The parties shall be entitled to sign and transmit an electronic signature of this Amendment (whether by facsimile, PDF or other email transmission), which signature shall be binding on the party whose name is contained therein. Each party providing an electronic signature agrees to promptly execute and deliver to the other party an original signed Amendment upon request.

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

THE SOCIETY OF THORACIC SURGEONS	SURGEON PARTICIPANT
By: Elaine Weiss	See Attached Signature Page "Schedule A"
Its: CEO/ Executive Director	
ANESTHESIOLOGIST PARTICIPANT (IF ANY)	HOSPITAL PARTICIPANT (IF ANY)
By:	By:
Its:	Its:

Participant Information Data	lo. (PID #):
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### SCHEDULE A

1. Joshua Chung , M.D.	Address 400 North Pepper Avenue, Colton, CA 92324
Signature:	NPI 1528245644
Please check one: X Cardiothoracic Surgeon	☐ Vascular Surgeon
2. Rosario Floridia , M.D.	Address 400 North Pepper Avenue, Colton, CA 92324
Signature: A Horas	NPI <u>1073545125</u>
Please check one: X Cardiothoracic Surgeon	☐ Vascular Surgeon
3. David Rabkin, M.D.	Address 400 North Pepper Avenue, Colton, CA 92324
Signature:	NPI 1255595427
Please check one: X Cardiothoracic Surgeon	☐ Vascular Surgeon
4. Anees Razzouk, M.D. Signature:	Address 400 North Pepper Avenue, Colton, CA 92324
Signature:	NPI 1487682084
Please check one: Cardiothoracic Surgeon	☐ Vascular Surgeon
5. Bruce Toporoff , M.D.	Address 400 North Pepper Avenue, Colton, CA 92324
Signature: Sun //s	NPI <u>1548263205</u>
Please check one:	☐ Vascular Surgeon
6, M.D.	Address
Signature:	NPI
Please check one: Cardiothoracic Surgeon	☐ Vascular Surgeon
7, M.D.	Address
Signature:	NPI
Please check one:   Cardiothoracic Surgeon	☐ Vascular Surgeon
8, M.D.	Address
Signature:	NPI
Please check one: Cardiothoracic Surgeon	☐ Vascular Surgeon
9, M.D.	Address
Signature:	NPI
Please check one:   Cardiothoracic Surgeon	90.00
10, M.D.	Address
Signature:	NPI
Please check one:   Cardiothoracic Surgeon	☐ Vascular Surgeon

<b>Participant Information</b>	Database No. (PI	D#)
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### **SCHEDULE B**

1	, M.D.	Address
Signature:		NPI:
2Signature:	, M.D.	AddressNPI:
3Signature:	, M.D.	AddressNPI:
4 Signature:	, M.D.	AddressNPI:
5 Signature:		AddressNPI:
6 Signature:	, M.D.	AddressNPI:
7Signature:	, M.D.	AddressNPI:
8 Signature:	, M.D.	AddressNPI:
9 Signature:	, M.D.	AddressNPI:
10 Signature:	, M.D.	AddressNPI:
11Signature:		AddressNPI:

#### APPENDIX I: STANDARD FORM BUSINESS ASSOCIATE CONTRACT AND DATA USE AGREEMENT (2021 Version)

THIS AGREEMENT is entered into and made effective the 1st day of January, 2021 (the
"Effective Date"), by and between (a) THE SOCIETY OF THORACIC SURGEONS, an Illinois not-for-
profit corporation, with its principal place of business at 633 North Saint Clair Street, Chicago, Illinois
60611 ("STS"); and (b),
an individual surgeon or group of surgeons (all of whose members are identified in and have signed
Schedule A attached to the Participation Agreement defined herein), whose principal place of business is at ("Surgeon Participant"); and, only if the
following identified "Anesthesiologist Participant" has agreed to abide by the terms of the Participation Agreement, (c), an individual
anesthesiologist or group of anesthesiologists (all of whose members are identified in and have signed
Schedule B attached to the Participation Agreement defined herein), whose principal place of business is at; and, only if the
following identified "Hospital Participant" has agreed to abide by the terms of the Participation Agreement
(d), a
, whose principal place of business is at
, solely on behalf of
the hospital known as
Except as otherwise specified, the Surgeon Participant, Anesthesiologist Participant (if any), and the Hospital Participant (if any) are collectively referred to herein as "Participant." STS and Participant are each a Party to this Agreement and are referred to collectively as the "Parties."
<b>WHEREAS</b> , STS and Participant are parties to that certain Participation Agreement, dated as of $1/1/2021$ , setting forth the terms of Participant's participation in the STS National Database (such agreement to be referred to herein as the "Participation Agreement" and such STS National Database as "Database");
<b>WHEREAS</b> , the Participation Agreement permits and provides for the Participant, acting as a Covered Entity, to submit data to the Database, and for STS, acting as a Business Associate, to conduct data analyses that relate to the Participant's Health Care Operations, including but not limited to Data

**WHEREAS**, the Participation Agreement may from time to time require the Database's receipt, Use, and/or Disclosure of Protected Health Information ("PHI") from Participant;

Aggregation, quality assessment and improvement, and peer review functions;

**WHEREAS**, the Participation Agreement may from time to time require the Disclosure of PHI by Participant to Database in the form of a Limited Data Set ("Limited Data Set Information") for STS to provide services to Participant related to its Health Care Operations and for Research purposes; and

WHEREAS, the Parties desire to allocate responsibility for the Use and Disclosure of PHI, including Limited Data Set Information, and to comply with applicable requirements of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 ("HIPAA"), as amended by the Privacy and Security provisions set forth in Section 13400 of the Health Information Technology for Economic and Clinical Health Act, Public Law 111-5 ("HITECH Act") and the regulations promulgated

BADU: 2021

thereunder codified at 45 CFR Parts 160 and 164 (commonly known as the Privacy and Security Rules) (collectively referred to herein as the "HIPAA Regulations");

**NOW THEREFORE**, in consideration of the mutual promises and conditions contained herein, and for other good and valuable consideration, the Parties agree as follows:

## SECTION 1 DEFINITIONS

Capitalized terms used, but not otherwise defined, in this Agreement will have the meaning ascribed to them in the HIPAA Regulations or the Participation Agreement, as the case may be. Except as otherwise specified herein, the term "Agreement" refers to this Business Associate Contract and Data Use Agreement and not the Participation Agreement. PHI will have the meaning ascribed to it in the HIPAA Regulations, but for the purposes of this Agreement will refer solely to PHI transmitted from or on behalf of Participant to STS or Subcontractor of STS, or created by STS or its Subcontractor on behalf of Participant. PHI will include PHI in electronic form ("Electronic PHI") unless specifically stated otherwise. Limited Data Set Information will have the meaning ascribed to "Limited Data Sets" in the HIPAA Regulations, but for the purposes of this Agreement will refer solely to Limited Data Set Information transmitted from or on behalf of Participant to STS or Subcontractor of STS, or created by STS or its Subcontractor on behalf of Participant. "Subcontractor" shall have the meaning ascribed to it by the HIPAA Regulations and shall include any agent or other person who acts on behalf of an entity, provided that STS is not acting as an agent of Participant in its role as an independent contractor herein. Unless otherwise specified, the use of the term PHI will be interpreted to include Limited Data Set Information.

# SECTION 2 EFFECT AND INTERPRETATION

The provisions of this Agreement shall apply with respect to the Use or Disclosure of any PHI by the Parties under the Participation Agreement. In the event of any conflict or inconsistency between the Participation Agreement and this Agreement concerning the Use or Disclosure of PHI, the terms of this Agreement will prevail unless the Parties mutually agree that the applicable terms of the Participation Agreement would be more protective of PHI. The provisions of this Agreement are intended in their totality to implement the HIPAA Regulations as they concern Business Associate Contracts and 45 CFR 164.514(e) as it concerns Data Use Agreements. The provisions of the Participation Agreement will remain in full force and effect and are amended by this Agreement only to the extent necessary to effectuate the provisions set forth herein.

## SECTION 3 GENERAL OBLIGATIONS OF STS

Section 3.1. Business Associate Contract Obligations.

The obligations set out in this Subsection 3.1 apply with respect to STS's Use or Disclosure of PHI, other than Limited Data Set Information.

(a) STS agrees not to Use or Disclose PHI other than as permitted or required by this Agreement or as Required By Law and agrees to maintain the security and privacy of all PHI in a manner consistent with applicable laws; provided that Participant will inform STS of any specific state

laws that it believes are applicable to PHI submitted by Participant and would require STS to take compliance steps beyond those required under the HIPAA Regulations.

- (b) STS agrees to use appropriate safeguards, and comply with Subpart C of 45 CFR Part 164 with respect to Electronic PHI, to prevent Use or Disclosure of PHI other than as provided for by this Agreement. Without limiting the generality of the foregoing, STS further agrees to:
  - (i) implement Administrative, Physical, and Technical Safeguards that reasonably and appropriately protect the Confidentiality, Integrity, and Availability of the Electronic PHI that it creates, receives, maintains, or transmits on behalf of Participant as required by 45 CFR 164.308, 164.310, and 164.312;
  - (ii) ensure that any Subcontractor to whom it provides such PHI, agrees to implement reasonable and appropriate safeguards to protect the PHI and comply with Subpart C of 45 CFR Part 164 with respect to Electronic PHI; and
  - (iii) report promptly, but in no case later than thirty (30) calendar days after discovery (as defined by 45 CFR 164.410(a)), to the Participant any Security Incident or Breach of Unsecured PHI of which STS becomes aware and shall mitigate, to the extent practicable, any harmful effects of said Security Incident or Breach of Unsecured PHI that are known or should be known to it; provided, however, that the Parties acknowledge and agree that this Subsection 3.1(b)(iii) constitutes notice by STS to Participant of the ongoing existence and occurrence or attempts of Unsuccessful Security Incidents for which no additional notice to Participant shall be required. "Unsuccessful Security Incidents" means, without limitation, pings and other broadcast attacks on firewalls, port scans, unsuccessful log-on attempts, denial of service attacks, and any combination of the above, so long as no such incident results in unauthorized access, Use or Disclosure of PHI.
- (c) STS agrees to report promptly to Participant any Use or Disclosure of PHI which is not authorized by this Agreement of which STS becomes aware.
- (d) STS agrees to ensure that any Subcontractor that creates, receives, maintains, or transmits PHI, on behalf of STS, including but not limited to the Duke Clinical Research Institute ("DUKE") and Outcome Sciences, Inc. d/b/a/ IQVIA ("IQVIA"), will agree in writing to comply with the same restrictions and conditions with respect to such information that apply through this Agreement to STS, to the extent the restrictions, conditions, and requirements are required under HIPAA.
- (e) If PHI provided to STS, or to which STS otherwise has access, constitutes a Designated Record Set, STS agrees to provide Participant with timely access to such PHI, upon reasonable advance notice and during regular business hours, or, at Participant's request, to provide an Individual with access to his or her PHI in order to meet the requirements under 45 CFR 164.524 concerning access of Individuals to PHI. In the event an Individual contacts STS or its Subcontractor directly about gaining access to his or her PHI, STS will not provide such access but rather will forward such request to Participant within three (3) business days of such contact, unless otherwise required by law.
- (f) If PHI provided to STS, or to which STS otherwise has access, constitutes a Designated Record Set, STS agrees to make timely amendment(s) to such PHI as Participant may direct or agree to pursuant to 45 CFR 164.526. In the event an Individual contacts STS or its Subcontractor directly

about making amendments to his or her PHI, STS will not make such amendments, but rather will promptly forward such request to Participant.

- (g) STS agrees to make internal practices, books and records relating to the Use and Disclosure of PHI available to the Secretary of the United States Department of Health and Human Services, during regular business hours, for purposes of the Secretary's determining compliance with the HIPAA Regulations.
- (h) STS agrees to document Disclosures of PHI and information related to such Disclosures as would be required for Participant to respond to a request by an Individual for an accounting of Disclosures of PHI in accordance with 45 CFR 164.528. In addition, STS agrees to provide promptly to Participant or an Individual, upon Participant's reasonable request, information collected in accordance with this Subsection 3.1(h) in order to permit Participant to respond to a request by an Individual for an accounting of Disclosures of PHI in accordance with 45 CFR 164.528. Notwithstanding the foregoing, this Subsection 3.1(h) will not apply with respect to Disclosures made to carry out Participant's Health Care Operations or the Disclosure of Limited Data Set Information, in accordance with the exceptions to 45 CFR 164.528(a) as set forth in the HIPAA Regulations, provided that this exception shall not apply to Disclosures of PHI through an electronic health record.
- (i) STS shall mitigate, to the extent practicable, any adverse effects from any improper Use and/or Disclosure of PHI by STS that are known to STS.

#### Section 3.2. Data Use Agreement Obligations.

The obligations set out in this Subsection 3.2 apply only with respect to STS's Use or Disclosure of Limited Data Set Information.

- (a) STS agrees to not Use or further Disclose Limited Data Set Information other than as permitted by this Agreement, or as otherwise Required By Law.
  - (b) STS agrees to use appropriate safeguards to prevent Use or Disclosure of the Limited Data Set Information other than as permitted by this Agreement.
- (c) STS will report promptly to Participant any Use or Disclosure of the Limited Data Set Information not permitted by this Agreement of which STS becomes aware.
- (d) STS will not attempt to identify the Individuals to whom the Limited Data Set Information pertains, or attempt to contact such Individuals, provided that this restriction will not be interpreted to prevent STS from conducting such activities under the Business Associate Contract provisions of this Agreement. Under no circumstances will STS attempt to contact Individuals except with Participant's prior written consent.
- (e) STS agrees to require that any Subcontractor to whom it, directly or indirectly, provides Limited Data Set Information, including but not limited to DUKE and IQVIA, will agree in writing to comply with the same restrictions and conditions that apply through this Subsection 3.2 to STS.
- (f) STS agrees to enter into a written agreement with each third party to which it Discloses Limited Data Set Information, including but not limited to DUKE and IQVIA, that includes the terms and provisions required by the HIPAA Regulations for such Disclosures.

### SECTION 4 PERMITTED USES AND DISCLOSURES BY STS

#### (a) General Business Associate Contract Use and Disclosure Provisions.

Except as otherwise limited in this Agreement, STS may Use or Disclose PHI on behalf of, or in order to provide services to, Participant to the extent such Use or Disclosure is reasonably necessary to facilitate Participant's participation in the Database, consistent with the Participation Agreement, provided that such Use or Disclosure of PHI would not violate the HIPAA Regulations if done by Participant. In providing these services, STS will be acting as an independent contractor and not as an employee or agent of Participant. STS shall have no authority, express or implied, to commit or obligate Participant in any manner whatsoever.

#### (b) Specific Business Associate Contract Use and Disclosure Provisions.

The permitted Uses and Disclosures set out in this Subsection 4(b) apply only with respect to STS's Use or Disclosure of PHI other than Limited Data Set Information.

- (i) Except as otherwise limited in this Agreement or the Participation Agreement, STS may *Use* PHI for the proper management and administration of STS or to carry out the legal responsibilities of STS.
- (ii) Except as otherwise limited in this Agreement or the Participation Agreement, STS may Disclose PHI for its own proper management and administrative purposes, provided that the Disclosures are either Required By Law, or STS otherwise obtains reasonable assurances from the person to whom it Discloses the PHI that such person will a) protect the Confidentiality of the PHI; b) Use or further Disclose the PHI only as Required By Law or for the purpose for which it was Disclosed to the person; and c) promptly notify STS of any instances of which the person is aware that the Confidentiality of the PHI has been Breached.
- (iii) Except as otherwise limited in this Agreement or the Participation Agreement, STS may Use and Disclose PHI to provide Data Aggregation services to Participant as permitted by 45 CFR 164.504(e)(2)(i)(B). STS may also Use or Disclose PHI for any other purposes specified in the Participation Agreement.
- (iv) STS may de-identify any PHI, provided such de-identification conforms to the requirements of 45 CFR 164.514(b), including without limitation any documentation requirements. STS may Use or Disclose such de-identified information at its discretion, as such de-identified information does not constitute PHI and is not subject to the terms of this Agreement; provided that such Use or Disclosure is consistent with the Participation Agreement and applicable law.
- (v) STS may partially de-identify any PHI to create a Limited Data Set, provided such partial de-identification conforms to the Limited Data Set requirements of 45 CFR 164.514(e)(2).

#### (c) Minimum Necessary Requirement.

(i) The Parties agree that the permissible Uses and Disclosures of PHI set forth in the Participation Agreement and this Agreement are consistent with the Participant's minimum necessary policies and procedures.

#### (d) <u>Uses and Disclosures Under Data Use Agreement Provisions</u>.

Notwithstanding Subsection 4(b) above, STS may, consistent with this Agreement, Use or Disclose PHI that consists solely of Limited Data Set Information to a third party, including but not limited to DUKE or IQVIA, for Research, Public Health, or Health Care Operations in accordance with the provisions of the HIPAA Regulations concerning Limited Data Sets, provided that such Use or Disclosure is (i) limited to the minimum information necessary to facilitate Participant's participation in the Database or for STS's, DUKE's, or IQVIA's Research purposes; (ii) is consistent with the Participation Agreement; and (iii) would not violate the HIPAA Regulations if done by Participant. The term Health Care Operations as used herein includes Data Aggregation.

# SECTION 5 GENERAL OBLIGATIONS OF PARTICIPANT

- (a) Participant's Notice of Privacy Practices, Permissions, and Restrictions.
- (i) Participant represents and warrants that it has developed and makes available to all patients a Notice of Privacy Practices that complies with 45 CFR 164.520 and any other applicable provisions of the HIPAA Regulations. Participant will provide STS with a copy of its Notice of Privacy Practices upon request.
- (ii) Participant will provide STS with any changes in, or revocation of, the permission by an Individual to Use or Disclose PHI, if such changes affect STS's permitted or required Uses and Disclosures.
- (iii) Participant will ensure on a continuing basis that all Disclosures of PHI made to STS are permissible under the HIPAA Regulations and are not subject to restrictions that would make the Disclosure of an Individual's PHI to STS impermissible. Participant will notify STS of any specific or general restrictions on the Use or Disclosure of PHI submitted to STS that Participant has agreed to in accordance with 45 CFR 164.522, if such restrictions affect STS's permitted or required Uses or Disclosures of PHI.
- (b) <u>Permissible Requests by Participant</u>. Participant will not ask STS to Use or Disclose PHI in any manner that would not be permissible under the HIPAA Regulations if undertaken by Participant, provided that Participant may, as otherwise permitted under this Agreement, request that STS Use or Disclose PHI for the purposes of Data Aggregation or the management and administrative activities of STS, as provided for in 45 CFR 164.504(e)(4).

# SECTION 6 TERM AND TERMINATION

- (a) <u>Term</u>. This Agreement will commence as of the Effective Date and will remain in effect for a period that is coterminous with the Participation Agreement, unless (i) this Agreement is terminated sooner in accordance with either Subsection (b) or (c) of this Section 6; or (ii) the Participation Agreement is amended by written agreement of the Parties in a manner that the Parties mutually agree renders the provisions of this Agreement unnecessary.
- (b) <u>Termination for Material Breach</u>. Either Party may terminate this Agreement based upon a material breach of this Agreement by the other Party, provided that the non-breaching Party gives

the breaching Party thirty (30) days written notice and the opportunity to cure such breach, and the breach is not cured during the notice period. In the event such material breach is not cured, the non-breaching Party may terminate this Agreement immediately upon the expiration of the notice period. In the event it is not possible to cure such material breach, the non-breaching Party may terminate this Agreement immediately and without any notice.

(c) <u>Termination Permitted Due to Change in Law</u>. Either Party may terminate this Agreement as permitted in accordance with Subsection 8(b) of this Agreement upon a change in an applicable law that causes performance in compliance with this Agreement to violate the law. Except as otherwise specified herein, this Agreement shall terminate immediately upon the termination of the Participation Agreement.

#### (d) Effect of Termination.

- (i) Except as provided in paragraph (ii) of this Subsection 6(d), upon termination of this Agreement for any reason, STS will return or destroy all PHI received from Participant, or created or received by STS on behalf of Participant. STS will retain no copies of the PHI, except as provided in paragraph (ii) of this Subsection 6(d).
- (ii) In the event that STS reasonably determines that returning or destroying the PHI is infeasible due to inclusion of such PHI in a Database or for other reason, STS will not return or destroy the PHI, may retain copies of the PHI to the extent it has been entered into a Database, and will promptly notify Participant of the circumstances that make return or destruction infeasible. Based on such determination, STS will extend the protections of this Agreement to such PHI, including any Limited Data Set Information that has not been de-identified, and limit any further Use or Disclosure of such PHI to those purposes that make the return or destruction infeasible, for so long as STS maintains such PHI.
- (iii) The Parties acknowledge and agree that the provision of any PHI to STS in accordance with the Participation Agreement is conditioned upon this Agreement being in full force and effect. Therefore, upon termination of this Agreement, the Parties agree that Participant will refrain from submitting PHI to STS, and STS will refrain from accepting PHI from Participant. In the event of a termination under either Subsection (b) or (c) of this Section 6, either Party may also elect to terminate the Participation Agreement. In the event the Parties engage in negotiations undertaken in accordance with Subsection 8(b) of this Agreement, the Parties will suspend during such period of negotiation any provision of the Participation Agreement requiring or obligating either Party to Use or Disclose PHI in a manner that either Party reasonably believes would violate any applicable state or federal law or regulation, including without limitation the HIPAA Regulations.
- (iv) The obligations of this Subsection 6(d) will survive any expiration or termination of this Agreement.

### SECTION 7 INDEMNIFICATION AND BREACH NOTIFICATION

(a) <u>Indemnification</u>. STS agrees to indemnify and hold harmless Participant from direct losses and damages suffered by Participant as a result of STS's breach of its obligations under this Agreement, including but not limited to direct losses and damages relating to third party claims. Participant agrees to indemnify and hold harmless STS from direct losses and damages suffered by

STS as a result of Participant's breach of its obligations under this Agreement, including but not limited to direct losses and damages relating to third party claims, if and to the fullest extent Participant is permitted to do so under governing state law. Under no circumstances, however, will either Party be liable to the other for any indirect or consequential damages of any kind, including lost profits (whether or not the Parties have been advised of such loss or damage) arising in any way in connection with this Agreement. The Parties' obligations under this Subsection 7(a) regarding indemnification will survive any expiration or termination of this Agreement.

(b) <u>Breach Notification</u>. Participant and STS agree that if either fails to adhere to any of the provisions set forth in this Agreement or the Participation Agreement and, as a result, PHI or other confidential information is unlawfully accessed, used, or disclosed, the Party or Parties responsible for the Breach agree to pay all (or their proportionate share of) costs associated with any notification to affected individuals that is required by law, and the Party or Parties responsible will also pay any and all (or their proportionate share of) fines and/or administrative penalties imposed for such unauthorized access, use or disclosure of confidential information or for delayed reporting. Unless otherwise agreed upon by the Parties, if STS notifies Participant of a Breach of Unsecured PHI, Participant shall be responsible for providing notification to comply with the Breach Notification requirements set forth in the HIPAA Regulations. Such notification shall be provided in a form mutually agreed upon by STS and Participant.

### SECTION 8 MISCELLANEOUS

- (a) <u>Regulatory References</u>. A reference in this Agreement to a section in the HIPAA Regulations means the section as in effect or as amended from time to time and for which compliance is required.
- (b) Amendment. This Agreement may not be amended except by the mutual written agreement of the Parties. Notwithstanding the foregoing, the Parties agree to work together in good faith to take such action as is necessary to make technical amendments to this Agreement from time to time if necessary for Participant and/or STS to comply with the requirements of HIPAA, the HIPAA Regulations, or any applicable provisions of any other federal or state law, as such laws or regulations may be amended from time to time. However, should any state or federal law or regulation now existing or enacted after the Effective Date of this Agreement, including without limitation HIPAA or the HIPAA Regulations, be amended or interpreted by judicial decision or a regulatory body in such a manner that either Party reasonably determines renders any provision of this Agreement in violation of such law or regulation or adversely affects the Parties' abilities to perform their obligations under this Agreement, the Parties agree to negotiate in good faith to amend this Agreement so as to comply with such law or regulation and to preserve the viability of this Agreement. If, after negotiating in good faith, the Parties are unable to reach agreement as to any necessary amendments, either Party may terminate this Agreement without penalty.
- (c) <u>Assignment</u>. Neither this Agreement nor either Party's rights or obligations hereunder may be assigned to a third party without the prior written consent of the non-assigning Party.
- (d) <u>Interpretation</u>. Any ambiguity in this Agreement will be resolved in favor of a meaning that permits Participant and STS to comply with the HIPAA Regulations or applicable state patient privacy laws or regulations. Where provisions of this Agreement are different from those mandated in

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the HIPAA Regulations, but are nonetheless permitted by the HIPAA Regulations, the provisions of this Agreement will control.

- (e) <u>No Third Party Beneficiaries</u>. STS and Participant agree that Individuals whose PHI is Used or Disclosed to STS or its Subcontractors under this Agreement are not third-party beneficiaries of this Agreement or the Participation Agreement.
- (f) <u>Waiver</u>. No provision of this Agreement may be waived except by an agreement in writing signed by the waiving Party. A waiver of any term or provision shall not be construed as a waiver of any other term or provision.
- (g) Correspondence. The Parties will send any reports or notices required under this Agreement to the addresses set forth in the notice provision of the Participation Agreement.

**IN WITNESS WHEREOF**, the Parties hereto have entered into this Agreement on the dates set forth below, so that it may take effect as of the Effective Date.

THE SOCIETY OF THORACIC SURGEONS	SURGEON PARTICIPANT
By:	See Attached Signature Page "Schedule A"
Print Name: Elaine Weiss	
Title: CEO/ Executive Director	
Date:	
ANESTHESIOLOGIST PARTICIPANT (IF ANY)	HOSPITAL PARTICIPANT (IF ANY)
By:	By:
Print Name:	Print Name:
Title:	Title:
Date:	Date: