

Thank you for your interest in the NCDR – the American College of Cardiology’s suite of data registries helping hospitals and private practices measure and improve the quality of cardiovascular care they provide.

When you take part in the ACC’s cardiovascular data registries, you join a global community of cardiovascular professionals committed to improving patient outcomes by using data to inform research, change practice and, ultimately, save lives.

Get started today
Enrollment materials:

- TVT Participation Agreement
- Contact Information Sheet
- Invoice to be sent separately

Please email your complete paperwork to ncdr@acc.org. We will return a customized invoice. Once we receive and process the participation dues, it will take approximately two weeks to process the paperwork and enroll your facility. Your Registry Site Manager will receive a welcome email with further instructions.

If you have any questions or need assistance with the enrollment process, please contact us at 800-257-4737 or ncdr@acc.org Monday through Friday, 9 a.m. – 5 p.m. ET.

Sincerely,

Barbara J. Christensen, MSHA, RN, CPHQ, AACC
Senior Director, NCDR Registry Services
American College of Cardiology

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The mission of the American College of Cardiology and the American College of Cardiology Foundation is to transform cardiovascular care and improve heart health for all.



GENERAL INFORMATION SHEET

Indicate which other registries you currently participate (check all that apply):

- AFib Ablation Registry™ CathPCI Registry® Chest Pain - MI Registry™ EP Device Implant Registry™
 IMPACT Registry® LAAO Registry™ STS National Database

STS Participant ID Number (if applicable): _____

NCDR Participant ID Number: _____

CONTACT INFORMATION SHEET

STEP 1: Please provide the **hospital information** requested below.

Note: Health systems must complete one form (Steps 1-5) for each hospital enrolling.

Health System (if applicable):
Hospital's legal entity name:
Hospital Physical Address (no PO boxes):

STEP 2: Please provide details for the STS/ACC TVT Registry™ **Registry Site Manager (RSM)**

RSM's Name:	RSM's Title:
RSM's Physical Address:	
RSM's Email Address:	RSM's Telephone:



STEP 3: Please provide details for the **Surgeon Participant**

Surgeon Participant's Name:	Surgeon Participant's Title:
Surgeon Participant's Physical Address:	
Surgeon Participant's Email Address:	Surgeon Participant's Telephone:

STEP 4: Please provide details for the **Cardiologist Participant**

Cardiologist Participant's Name:	Cardiologist Participant's Title:
Cardiologist Participant's Physical Address:	
Cardiologist Participant's Email Address:	Cardiologist Participant's Telephone:

TVT REGISTRY PARTICIPATION AGREEMENT v2.4

THIS AGREEMENT (“Agreement”) is entered into and made effective this _____, 20____ (“Effective Date”), by and between the American College of Cardiology Foundation (“ACCF”), a non-profit, tax-exempt District of Columbia corporation located at 2400 N Street NW, Washington, DC 20037; The Society of Thoracic Surgeons (“STS”), a not-for-profit, tax-exempt Illinois corporation located at 633 N. Saint Clair Street, Suite 2100, Chicago, IL 60611; _____ (“Hospital Participant”), a _____, solely with respect to the hospital known as _____, located at _____; _____, the cardiothoracic surgery staff at Hospital Participant (“Surgeon Participant”); and with _____, the cardiology staff at Hospital Participant (“Cardiologist Participant”). The Hospital Participant, Surgeon Participant, and Cardiologist Participant shall be referred to herein collectively as “Participant.” ACCF and STS shall be referred to herein collectively as “ACCF/STS.” ACCF/STS and Participant shall be referred to herein collectively as the “Parties” and individually as a “Party.”

WHEREAS, ACCF/STS have developed and own a computerized database containing standardized, national, clinical cardiovascular data in connection with transcatheter valve therapies (“TVT”), and third parties submit data to this database pursuant to ACCF/STS rules (formally known as the STS/ACC TVT Registry, an initiative of the STS National Database and the American College of Cardiology Foundation’s NCDR and referred to herein as the “TVT Registry”);

WHEREAS, ACCF/STS permit comparisons of TVT Registry participant data with national or regional aggregated data to aid TVT Registry participants in their efforts to improve patient care;

WHEREAS, Participant desires to participate in the TVT Registry in accordance with ACCF/STS requirements; and

WHEREAS, the Parties understand that the provision by ACCF/STS of benchmarking and data aggregation services to Participant qualifies ACCF/STS as a “Business Associate” with respect to Participant pursuant to the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (45 C.F.R. Parts 160 and 164, as amended) (“HIPAA”);

NOW, THEREFORE, in consideration of the mutual promises and Agreements set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged by the Parties:

IT IS AGREED:

1. Participation in TVT Registry. Participant hereby agrees to participate in the TVT Registry, and ACCF/STS hereby agree to permit Participant to participate in the TVT Registry as provided herein.
2. Participant Responsibilities.
 - a. Submission of Clinical Data. Participant agrees to furnish clinical data to the TVT Registry as provided under this Agreement.
 - i. Participant agrees that its data may be rejected by ACCF/STS if Participant data are determined by ACCF/STS to fail the TVT Registry data evaluation and acceptance process.
 - ii. Participant agrees to submit data within the “call-for-data period” as established and updated from time to time by the ACCF/STS. The initial “call-for-data” period will be based on calendar quarters.

- iii. The Parties agree that specific elements collected in the TVT Registry are also collected in STS's Adult Cardiac Surgery Database. If Participant also participates in the STS Adult Cardiac Surgery Database, then Participant authorizes ACCF/STS to transmit to the STS Adult Cardiac Surgery Database those data that Participant submits to the TVT Registry so as to eliminate data collection redundancy, provided that the mode and manner of such transmission complies with the applicable requirements of HIPAA.
- b. Use of ACCF/STS Data Set and Data Submission. Participant will submit a data record on each patient who receives medical care and who is eligible for inclusion in the TVT Registry. Participant agrees to use the TVT Registry-specific data elements, definitions, and transmission format approved by ACCF/STS and published in the TVT Registry Core Data Element Documentation ("TVT Data Set") provided to Participant, and as amended by ACCF/STS from time to time. Data must be submitted through the secure web-based portal described in Section 2.c.
- c. Manner of Communication. Participant shall provide data to ACCF/STS for purposes of the TVT Registry by secure website at www.tvtregistry.org. In addition, Participant shall designate a primary, valid e-mail address that ACCF/STS shall utilize to communicate with Participant; such e-mail address shall only be accessible by Participant's Registry Site Manager. Participant hereby acknowledges that ACCF/STS will use such e-mail address to communicate pertinent information regarding TVT Registry-specific issues. Participant shall submit data to ACCF/STS for the TVT Registry electronically, utilizing methods determined by the ACCF/STS. Furthermore, Participant shall maintain an updated profile with ACCF/STS including ensuring that ACCF/STS have a valid e-mail address for Participant's Registry Site Manager at all times in the form specified by ACCF/STS.
- d. Corroboration of Patient Data. Participant shall, upon ACCF/STS's request, furnish to ACCF/STS independent corroboration, in a form satisfactory to ACCF/STS in their sole, reasonable discretion, that all eligible procedure records have been submitted, based upon case volume counts or similar data from Participant's admitting/registration, cath lab log, OR log, billing, and/or medical records information or other hospital- or physician-based information system.
- e. Data Collection Staff. Participant's data collection shall be performed by staff trained through the ACCF/STS's training program, including TVT Registry-specific offerings from ACCF/STS, promptly after any such training program is made available by ACCF/STS to Participant. Participant agrees that its data collection staff shall adhere to the standards published in the current TVT Data Set provided to Participant, and as updated from time to time. The current ACCF/STS training program, included in the annual fee, consists of webinars, self-directed study using resources on the ACCF/STS website as well as individualized clinical support. ACCF/STS also offer additional and optional training, available for an additional charge at ACCF/STS workshops which Participant shall encourage its staff to attend.
- f. Registry Site Manager. Participant will designate a Registry Site Manager who will serve as the primary point of contact for the TVT Registry and will supervise the data collection, confirm the accuracy of the data, receive the confidential reports, and act as direct liaison with ACCF/STS. Participant shall submit to ACCF/STS the Registry Site Manager's information which includes, but is not limited to, his or her name, title, email, phone, and physical address via the site profile housed on www.tvtregistry.org. ACCF/STS recommend that the Registry Site Manager be an experienced clinical professional such as the Clinical Service Line Director, a senior-level Registered Nurse, or a similarly trained and qualified

representative of the quality improvement department; and if ACCF/STS determine that any Registry Site Manager is not sufficiently trained or credentialed in this manner, Participant will identify an alternate individual to serve in that capacity. Participant also agrees to notify ACCF/STS within ten (10) working days of any change in the Registry Site Manager.

- g. Medical Directors. Surgeon Participant and Cardiologist Participant shall each designate an individual to serve as the Participant's Medical Directors for purposes of this Agreement. The Medical Directors' duties will include acting as the medical staff liaison for the TVT Registry. The Medical Directors shall work in concert with the Registry Site Manager to champion TVT Registry activities, including but not limited to introducing TVT Registry activities to medical staff, assisting in the interpretation and analysis of outcome reports ("Outcome Reports") and disseminating the findings of the Outcome Reports. The Medical Directors shall approve all data submissions. ACCF/STS recommend that the Medical Directors be experienced, appropriately credentialed physicians with an understanding of quality improvement methods, data analysis, and the authority or empowerment to lead quality improvement activities in the clinical setting.
- h. Executive Sponsor. Participant will designate an Executive Sponsor who will ensure adequate resources are in place to support TVT Registry activities. The Executive Sponsor shall work in concert with the Registry Site Manager on activities including but not limited to championing TVT Registry activities to senior leadership and ensuring that adequate resources are in place to meet stated TVT Registry deadlines and to support full adoption and use of TVT Registry data in quality improvement initiatives.
- i. Data Evaluation and Acceptance Process. Participant hereby warrants that all data submitted for inclusion in the TVT Registry will be accurate and complete, and acknowledges that its submitted patient data may be audited for accuracy and completeness by or on behalf of ACCF/STS. In addition, all submissions are required to meet the TVT Registry inclusion thresholds as defined in the current TVT Registry release provided to Participant, and as updated by ACCF/STS from time to time, in order for Participant's data to be included in the aggregated TVT Registry data. Participant understands and agrees that auditing may include review of patient medical records and additional supporting documentation. The audit process will include, but not be limited to, an audit of selected charts and an evaluation of the process for data collection. In the event that Participant is selected for an audit, the initial audit will be at the expense of ACCF/STS, and Participant agrees to cooperate in such audit through making available documentation and access to Participant's staff. Participant agrees that if an audit process or the application of threshold criteria find that the data do not conform to ACCF/STS standards, as a condition of continued participation in the TVT Registry, Participant shall use its best efforts to address any related deficiencies identified and will submit within forty-five (45) days of notice of the results of the initial audit an action plan, in a form acceptable to ACCF/STS, to correct such data issues, as well as, in the sole discretion of ACCF/STS, submit to an audit conducted by a third-party auditor chosen by ACCF/STS at Participant's sole expense. Furthermore, the non-conforming data submitted by Participant will be withheld from the TVT Registry for national reporting purposes until such data are brought up to standard and re-submitted to the TVT Registry by Participant. Moreover, during any such correction period, while Participant may receive information comparing its data to general data from the TVT Registry, ACCF/STS make no representation or warranty concerning the reliability of any such comparison or the conclusions Participant may draw from it.
- j. Voluntary Audit Process. If Participant voluntarily chooses to have its data audited, Participant will fund the full cost of the audit, the results of which shall be made available to the Parties. Only ACCF/STS-approved auditors may perform the audit process. If such

voluntary audit reveals data that do not conform to ACCF/STS standards or this Agreement, the process described in Section 2.i. shall be enforced.

- k. Identifiers. Participant agrees that unique patient identifiers and unique physician identifiers will be collected for each record submitted to the TVT Registry.
 - l. Data Confidentiality. Participant shall maintain appropriate procedures to safeguard data confidentiality in compliance with applicable law. Participant will be solely responsible for any and all of its acts or omissions regarding the privacy and security of the data it furnishes hereunder. Participant shall maintain appropriate liability insurance for its acts and omissions under this section.
3. ACCF/STS Responsibility.
- a. Acceptance of Data. ACCF/STS agree to accept Participant's clinical data, subject to review by ACCF/STS, except where the submitted data do not conform to this Agreement, including, without limitation, the data evaluation and acceptance process and standards established by ACCF/STS, and as updated from time to time by ACCF/STS. In such cases, ACCF/STS reserve the right to either reject the data submission in its entirety, or to limit the use of such data, if they do not meet the required ACCF/STS standards, both with respect to new data and as set forth in Section 2.i.
 - b. Reports. Provided that Participant participates in the TVT Registry in accordance with TVT Registry requirements (including but not limited to Participant's payment of all applicable fees), ACCF/STS agree to generate reports based on Participant's submitted data and to distribute such reports to Participant. Participant agrees and acknowledges that its failure to submit data to the TVT Registry, or its submission of data to the TVT Registry that do not comply with ACCF/STS requirements, may result in Participant's failure to receive one or more reports generated by the TVT Registry and/or an assessment of additional Participant fees to reflect additional expenses incurred by ACCF/STS in order to render Participant's data appropriate for inclusion in the TVT Registry. Reports will include aggregated demographic, general procedural information, and patient outcomes in a form made available by ACCF/STS to Participant, and as updated by ACCF/STS from time to time. Data quality reports will be distributed quarterly. Participant-specific and national outcomes reports will be distributed both quarterly and annually. ACCF/STS may choose to produce physician-level reports for individuals who are part of Surgeon Participant or Cardiologist Participant in consideration for the fees required by ACCF/STS. To that end, Participant authorizes ACCF/STS to generate such physician-level reports for such individuals, each such report directly utilizing the relevant physician's National Provider Identifier ("NPI"). ACCF/STS similarly may choose to generate such physician-level reports for individuals who are affiliated with more than one Hospital Participant, provided that such reports shall include only data that are subject to a TVT Registry Participation Agreement to which the individual is bound as a part of a Surgeon Participant or a Cardiologist Participant.
 - c. Training. ACCF/STS will provide documents and programs that serve as resources that guide Participant's data collection activities.
 - d. Data Accuracy. ACCF/STS will analyze Participant's submitted data records by means of electronic data checks, consistency checks, and range checks to review data accuracy and completeness and determine aggregate completion rates, and will return data quality reports to Participant promptly after submission. All reasonable efforts will be made by ACCF/STS to communicate with Participant's Registry Site Manager to assist Participant in providing the submitted data.

- e. Data Assessment Audit. ACCF/STS may, at their option, audit submitted patient data to review their accuracy and completeness. ACCF/STS will notify Participant within forty-five (45) days of the completion of the audit process (completion and return of data from the auditor) of the results of the audit and any action that Participant may need to take as a result of the audit, and may take any actions in response as provided in Section 2.i. of this Agreement.
 - f. Identifiers. ACCF/STS will accept unique patient identifiers and unique physician identifiers for each record submitted to the TVT Registry by Participant.
 - g. Value-Added Programs and Tools. ACCF/STS reserve the right to develop and provide quality improvement and patient safety programs and tools using certain TVT Registry data. ACCF/STS shall make such programs and tools available to Participant on a voluntary basis. ACCF/STS reserve the right to charge Participant additional fees for use of value-added products and services.
4. Privacy Laws; Security.
- a. Compliance with Privacy Laws. The Parties agree to abide by all federal, state, and local laws pertaining to confidentiality and disclosure with regard to all information or records obtained and reviewed hereunder. ACCF/STS acknowledge that they collectively are a “Business Associate” as defined and referred to under HIPAA. Accordingly, ACCF/STS shall take reasonable steps to comply with the requirements under HIPAA for Business Associates as set forth in Appendix A to this Agreement (“Standard Form Business Associate Contract and Data Use Agreement”). ACCF/STS will have all rights, as well as all responsibilities, set forth in Appendix A as if fully set forth herein. Participant agrees and acknowledges that the data captured by the TVT Registry will include certain health care facility identifying information, as well as certain physician identifying information (the latter in an encrypted form). Participant agrees that it is Participant’s responsibility to obtain any permissions required in order to submit such data for inclusion in the TVT Registry, and specifically agrees to indemnify, save and hold harmless ACCF/STS from and against all claims and liabilities associated therewith.
 - b. Security. ACCF/STS will take reasonable steps to maintain their security policies and procedures to protect Participant data as provided in Appendix A. If ACCF/STS determine that a breach of security has occurred, ACCF/STS will promptly notify Participant’s Privacy Officer as identified on the site profile housed on www.tvtregistry.org. ACCF/STS will be responsible for their acts and omissions regarding the privacy and security of the data they maintain under this Agreement.
5. Use of Names and Logos.
- a. Use of ACCF/STS Names. Without the express prior written consent of ACCF/STS, Participant shall not make any announcements concerning the matters set forth in this Agreement, use the word or symbol ACCF or STS, or any other trademarks or service marks of ACCF and/or STS, or make any reference to ACCF, STS, or the TVT Registry in any advertising or promotional material, letterhead, symbol or logo, or in any other promotional manner, including, without limitation, press releases.
 - b. Use of Participant’s Logo/Trademarks. Without the express prior written consent of Participant, ACCF/STS shall not use the logos, trademarks or service marks of Participant.

6. Data and Copyright Ownership.

- a. Individual Patient Data. The data for individual patients submitted by Participant shall be the exclusive property of Participant, subject to the rights, if any, of Participant's patients in their Individually Identifiable Health Information (as defined under HIPAA), and subject to the rights granted to ACCF/STS in this Agreement and the Standard Form Business Associate Contract and Data Use Agreement. Participant hereby agrees that the return of this information is infeasible as it has been integrated into the TVT Registry. Participant hereby agrees that all data submitted by or on behalf of Participant to ACCF/STS or ACCF/STS's designee for purposes of inclusion in the TVT Registry may be used by ACCF/STS as a part of the TVT Registry and any subset thereof that ACCF/STS may choose to create and use as they see fit for the purposes of ACCF/STS and the other interests of the TVT Registry (including, without limitation, publication of such data); provided, however, that no such data shall be used in such a way as to identify Participant unless and until Participant advises ACCF/STS in writing that it has secured appropriate consent for such use. Participant grants to ACCF/STS a perpetual, enterprise-wide, royalty-free license, that is worldwide and in all forms and all media (including derivative works), to use the data of individual patients submitted by Participant in such manner that is consistent with this Agreement.
 - b. Intellectual Property; Aggregated Data. All right, title, and interest, including but not limited to all Intellectual Property Rights (as defined below), to the TVT Registry and any proprietary information and intellectual property relating to the TVT Registry, including without limitation any database, aggregated data developed from Data submitted by Participant and the compilation of the same with any other data received in connection with the TVT Registry, and any derivative works, including, without limitation, any reports, analyses, calculations and models based thereon, shall be jointly owned by ACCF/STS. For purposes of this Agreement, "Intellectual Property Rights" means all (i) trademarks, trade name, service marks, slogans, domain names, uniform resource locators or logos; (ii) copyrights, moral rights, and other rights in works of authorship, including, but not limited to, compilations of data; (iii) patents and patent applications, patentable ideas, inventions and innovations; (iv) know-how and trade-secrets; and (v) registrations, applications, renewals, extensions, continuations, divisions or reissues of the foregoing. ACCF/STS reserves the right to use aggregated data and Protected Health Information (as defined by HIPAA) in electronic or other format whether or not contained in a Limited Data Set as discussed more fully in the Standard Form Business Associate Contract and Data Use Agreement set forth in Appendix A, including, without limitation, to support ongoing improvements and enhancements to the TVT Registry. Once Participant data are accepted by ACCF/STS into the TVT Registry, these data become part of the TVT Registry aggregated data and cannot be retracted from the TVT Registry by Participant. Information to which ACCF/STS have access or ownership under this Section 6 shall not be considered Confidential Information to be returned to Participant under Section 9.
 - c. Publication. If Participant desires to publish or otherwise distribute or use, in whole or in part, any aggregated data or reports provided by ACCF/STS, or produced in connection with or derived from the TVT Registry, with the exception of strictly internal use within Participant, Participant must first obtain the prior express written consent of ACCF/STS. To the extent Participant is permitted to publish aggregated data, such aggregated data and any related information published in connection with them must be reviewed and approved by ACCF/STS prior to publication.
7. Participant Fees. Participant will pay ACCF/STS an annual fee of Twelve Thousand Seven Hundred Forty-Five US Dollars (USD\$12,745.00) to participate in the TVT Registry. Payment of the annual fee covers ACCF/STS-supplied self-training documentation, and distribution of data quality reports

and Participant-specific reports. ACCF/STS may, at the request of the Participant, develop other reports and products for an additional charge. Participant will pay such participation fees as ACCF/STS may establish for future calendar years, provided that said fees will be established by ACCF/STS prior to December 1 of the then current year and payable by January 1 of the following year. Participant will also be responsible for any additional fees payable to address data submitted by Participant that fail to conform with ACCF/STS requirements as well as any additional report-related fees required pursuant to Section 3.b. All annual fees owed under this Agreement shall be paid in advance of the services performed and shall be invoiced by ACCF/STS. Participant shall have thirty (30) days from the receipt of an invoice in which to pay the fees due. If Participant fails to pay the fees when due Participant shall not receive any reports. If ACCF/STS do not receive payments of past-due amounts, within three (3) months following the date of the initial request for payment, Participant shall be in breach of this Agreement and subject to immediate termination of this Agreement. Termination for breach of a failure to pay fees owed shall not be subject to the written notification requirements of Section 8.a.

8. Term, Enforcement and Termination. This Agreement shall be effective until the end of the current calendar year and will renew automatically for additional one (1) year terms unless Participant provides ACCF/STS with at least ninety (90) days advance written notice of Participant's desire to terminate the Agreement at the end of the then-current term.
 - a. Termination for Breach. Either Party may terminate this Agreement upon the other Party's material breach of this Agreement by providing the breaching Party with thirty (30) days written notice of its intention to terminate for a material breach. The breaching Party shall have thirty (30) days from the date of such notice to cure the breach. If thirty (30) days after the date of such notification, the breach is not cured to the reasonable satisfaction of the non-breaching Party, this Agreement will immediately terminate automatically. Notwithstanding the foregoing, the non-breaching Party may determine in its sole discretion that the breach cannot be reasonably cured within the foregoing thirty (30)-day period and may extend the cure period by written notice to the breaching Party.
 - b. Termination without Cause. Either Party may terminate this Agreement without cause by providing the other with at least ninety (90) days written notice.
 - c. Termination for Failure to Meet Data Completeness and Consistency Requirements. ACCF/STS reserve the right to immediately terminate this Agreement and Participant's participation in TVT Registry if they determine that any two (2) calendar quarters of Participant's data within a rolling twelve (12) calendar-month period are noncompliant with TVT Registry standards or otherwise unacceptable for inclusion in the TVT Registry. ACCF/STS may, in their sole discretion, provide Participant with the opportunity to cure the inadequate data as stated in Section 2.i. without affecting the rights of ACCF/STS to terminate this Agreement under this Section or otherwise.
 - d. Termination for Insolvency. ACCF/STS may terminate this Agreement effective immediately upon written notice to Participant in the event the Participant files for protection under bankruptcy laws, makes an assignment for the benefit of creditors, appoints or suffers appointment of a receiver or trustee over its property, files a petition under any bankruptcy or insolvency act, or has any such petition filed against it which is not discharged within sixty (60) days of the filing thereof.
 - e. Termination for Non-Payment. ACCF/STS may, in ACCF/STS's sole discretion: (a) terminate this Agreement effective immediately and upon written notice to Participant or (b) limit Participant's access to the TVT Registry, in the event the Participant fails to pay the applicable participation fees when due, and such failure continues for a period of sixty (60)

days after payment is due.

- f. Termination Due to Acquisition. In the event that Participant is acquired by, merged into, or otherwise becomes subject to the control and oversight of an entity that is a party to a TVT Corporate Participation Agreement with ACCF/STS (a “Controlling Entity”), and the Controlling Entity has contracting authority on behalf of the Participant, the Participant or ACCF/STS may terminate this Agreement upon written notice to the other Party. Such termination shall not be effective until: (i) all actions required to terminate this Agreement and to carry out wind down procedures consistent with applicable program offerings have been fulfilled; and (ii) Participant is included as an affiliate Participant pursuant to the agreement between the Controlling Entity and ACCF/STS, such that there is no lapse in the provision of applicable program offerings provided to the Participant hereunder.

9. Confidentiality.

- a. Confidentiality. For the purposes of this Agreement, “Confidential Information” means any software, material, data, or business, financial, operational, customer, vendor and other information disclosed by one Party to the other and not generally known by or disclosed to the public or known to the receiving Party solely by reason of the negotiation or performance of this Agreement. Each Party shall maintain all of the other Party’s Confidential Information in strict confidence and will protect such information with the same degree of care that such Party exercises with its own Confidential Information, but in no event with less than a reasonable degree of care. Except as provided in this Agreement, a Party shall not use or disclose any Confidential Information of the other Party in any manner without the express prior written consent of such Party. Access to and use of any Confidential Information shall be restricted to those employees and persons within a Party’s organization with known discretion and with a need to use the information to perform such Party’s obligations under this Agreement. A Party’s consultants, subcontractors, and business partners shall be included within the meaning of “persons within a Party’s organization,” provided that such consultants (other than attorneys who have independent confidentiality obligations), subcontractors, and business partners have executed a non-disclosure or confidentiality agreement with provisions no less stringent than those applicable to such Party under this Agreement, and such Party shall make such signed agreements available to the other Party upon request. Notwithstanding anything herein to the contrary, Confidential Information shall not include information that is: (i) already known to or otherwise in the possession of a Party at the time of receipt from the other Party, and that was not known or received as the result of a violation of any obligation of confidentiality; (ii) publicly available or otherwise in the public domain prior to disclosure by a Party; (iii) rightfully obtained by a Party from any third party having a right to disclose such information without restriction and without breach of any confidentiality obligation by such third party; (iv) developed by a Party independent of any disclosure hereunder, as evidenced by detailed written records made in the normal course of Participant’s business during the development process; or (v) disclosed pursuant to the order of a court or administrative body of competent jurisdiction or a government agency, provided that the Party receiving such order shall notify the other prior to such disclosure, and shall cooperate with the other Party in the event such Party elects to legally contest, request confidential treatment, or otherwise avoid such disclosure.
- b. Return of Confidential Information. Except as otherwise provided herein, all of a Party’s Confidential Information disclosed to the other Party, and all copies thereof, shall be and remain the property of the disclosing Party. All such Confidential Information, and any and all copies and reproductions thereof, shall, upon the expiration or termination of this

Agreement for any reason, or within fifteen (15) days of written request by the disclosing Party, be promptly returned to it, or destroyed, at the disclosing Party's direction. In the event of such requested destruction, the Party receiving such request shall provide to the other Party written certification of compliance therewith within fifteen (15) days of such written request. Notwithstanding the provisions of this Section 9, any information governed by Section 6.a. or 6.b. or the provisions of the Business Associate Agreement shall be governed, respectively, by those Sections of this Agreement, as applicable.

10. Indemnification.

a. ACCF/STS Indemnification.

- i. ACCF/STS will indemnify, defend, and hold Participant harmless from any third party claim, demand, cause of action, lawsuit, or proceeding brought against Participant based upon any gross negligence or willful misconduct on the part of ACCF/STS relating to the development and operation of the TVT Registry, provided, however, that any such liability for any such indemnification shall be limited to and not exceed the amount of any fees paid by Participant in the year the liability arose. Such indemnification may include: (1) reasonable attorneys' fees and costs associated with defense of such claim; (2) damages and costs finally awarded; and (3) the cost of any settlement entered into by ACCF/STS.
- ii. ACCF/STS's indemnification obligation described in this section is contingent on Participant: (1) notifying ACCF/STS of any such claim within thirty (30) days after Participant's notice of such claim; (2) providing ACCF/STS with reasonable information, assistance, and cooperation in defending the lawsuit or proceeding (to the extent requested by ACCF/STS); and (3) giving ACCF/STS full control and sole authority over the defense and settlement of such claim; provided that ACCF/STS will not enter into any settlement or compromise of any such claim without Participant's prior consent, which shall not be unreasonably withheld.

b. Participant's Indemnification.

- i. Participant will indemnify, defend, and hold ACCF/STS and ACCF/STS's employees, officers, directors, agents, contractors, and business partners (collectively as the "ACCF/STS Indemnitees") harmless from any third party claim, demand, cause of action, lawsuit, or proceeding brought against one or more ACCF/STS Indemnitees based upon: (1) any errors or inaccuracies contained in the data as submitted by Participant to the TVT Registry; (2) any medical treatment, diagnosis or prescription rendered by Participant or its agents (including physicians and healthcare professionals); (3) Participant failing to have all rights in the data necessary to use the TVT Registry and to disclose such information to ACCF/STS; (4) the use of TVT Registry reports in connection with any quality assurance, peer review, or similar administrative or judicial proceeding; and (5) any claim that is based, in whole or in part, on a breach of any warranty, representation or covenant made by Participant under this Agreement, including, but not limited to, any third party lawsuit or proceeding brought against ACCF/STS or any of the ACCF/STS Indemnitees based upon a claim that any data submitted by Participant infringe any third party rights. Participant's indemnification will include: (1) all attorneys' fees and costs associated with defense of such claim; (2) all damages and costs finally awarded; and (3) the full cost of any settlement entered into by Participant.
- ii. Participant's indemnification obligation described in this section is contingent on ACCF/STS: (1) notifying Participant of any such claim within thirty (30) days after ACCF/STS's notice of such claim; (2) providing Participant with reasonable information, assistance, and cooperation in defending the lawsuit or proceeding

(to the extent requested by Participant); and (3) giving Participant full control and sole authority over the defense and settlement of such claim; provided that Participant will not enter into any settlement or compromise of any such claim without ACCF/STS's prior consent, which shall not be unreasonably withheld.

11. Limitation of Liability. The aggregate liability of the ACCF/STS Indemnitees under this Agreement for any and all claims and causes of action, including, without limitation, any action predicated on indemnification as set forth in Section 10.a. above, shall be limited to and not exceed the amount of any fees paid by Participant in the year the liability arose, regardless of whether ACCF/STS has been advised of the possibility of such damages, or any remedy set forth herein fails of its essential purpose or otherwise. ACCF/STS Indemnitees shall not be liable for any other damages or costs, including costs of procurement of substitutes, loss of profits, loss of activity data or other information, inability to access the services, interruption of business, or for any other special, consequential, or incidental damages, however caused, whether, without limitation, for breach of warranty, contract, tort, infringement, negligence, strict liability or otherwise. Participant acknowledges that the TVT Registry fees and business model reflect this allocation of risk. Participant agrees it will take no legal action against ACCF/STS, ACCF/STS subcontractors, ACCF/STS business partners or other Participants.
12. Notices. All notices and demands of any kind or nature which either 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 overnight courier (e.g., FedEx, DHL, or UPS) or electronic mail to the following addresses:

If to Participant: _____

Email: _____

With a copy to: _____

Email: _____

If to ACCF/STS: American College of Cardiology Foundation
2400 N Street NW
Washington, DC 20037
Attn: General Counsel
Email: ACCLegal@acc.org

With a copy to: The Society of Thoracic Surgeons
633 N. Saint Clair Street, Suite 2100
Chicago, IL 60611
Attn: Executive Director
Email:

Service of such notice or demand so made shall be deemed complete on the day of actual delivery. Any Party hereto may, from time to time, by notice in writing served upon the other Party as aforesaid, designate a different mailing address or a different person to which all further notices or demands shall thereafter be addressed.

- 13 Headings. The headings of the various sections 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.

- 14 Assignment. Neither this Agreement nor either Parties' rights and obligations hereunder may be assigned to a third party, by operation of law or otherwise, without the prior written consent of the non-assigning Party; provided, however, that ACCF/STS may assign this Agreement and its rights and obligations to a parent or an entity controlled by or under common control with ACCF/STS, or a venture or entity in which ACCF/STS has a majority ownership interest, or upon a change of control of ACCF/STS, without the consent of Participant.
- 15 Relationship of Parties. 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.
- 16 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.
- 17 Waiver. A waiver by either Party to this Agreement of any of its items 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.
- 18 Governing Law. This Agreement will be governed by and construed exclusively in accordance with the laws of the District of Columbia, without regard to any conflicts of law principles applied. The Parties agree that the United Nations Convention on Contracts for the International Sale of Goods does not apply to this Agreement. Any suit or proceeding relating to this Agreement shall be brought only in the District of Columbia. Each Party consents to the exclusive personal jurisdiction and venue of the courts located in the District of Columbia.
- 19 Severability. 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 the Agreement shall remain in full effect, provided that its general purposes remain reasonably capable of being effected.
- 20 Entire Agreement. This Agreement and the attached Appendices: (a) constitute the entire Agreement between the Parties with respect to the subject matter; (b) supersede and replace all prior agreements, oral or written, between the Parties relating to the subject matter hereof; and (c) except as otherwise indicated, may not be modified or otherwise changed in any manner except by a written instrument executed by both Parties.
- 21 Survival. The following sections of this Agreement shall survive any termination or expiration of this Agreement: Sections 4, 6, 9, 10, 11, 18, and 23, as well as the provisions of the Standard Form Business Associate Contract and Data Use Agreement set forth in Appendix A.
- 22 No Third-Party Beneficiaries. The Parties agree there are no third party beneficiaries, intended or otherwise, to this Agreement, including, without limitation, patients of any Participant.
- 23 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.
- 24 Participant Representations and Warranties. The signatories to this Agreement each represent and

warrant that they have the authority to enter into this Agreement and bind the entities or individuals that they purport to represent. Without limiting the generality of the foregoing, the signatories for the Surgeon and Cardiologist Participants each represent and warrant that s/he has the authority to enter into this Agreement on behalf of Surgeon Participant and Cardiologist Participant, respectively, and to bind the physicians who are members of or otherwise affiliated with Surgeon Participant and Cardiologist Participant to the terms and conditions of this Agreement.

IN WITNESS WHEREOF, each of the Parties hereto has caused this Agreement to be executed as of the Effective Date:

<p>HOSPITAL PARTICIPANT</p> <p>Signature: _____</p> <p>Name: _____</p> <p>Title: _____</p> <p>Date: _____</p> <p>E-Mail Address: _____</p> <p>Phone: _____</p> <p>SURGEON PARTICIPANT</p> <p>Signature: _____</p> <p>Name: _____</p> <p>Title: _____</p> <p>Date: _____</p> <p>E-Mail: _____</p> <p>CARDIOLOGIST PARTICIPANT</p> <p>Signature: _____</p> <p>Name: _____</p> <p>Title: _____</p> <p>Date: _____</p> <p>E-mail: _____</p>	<p>ACCF/STS</p> <p>Signature: _____</p> <p>Name: _____</p> <p>Title: _____</p> <p>Date: _____</p>
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