STS/ACC TVT Registry™

Thank you for your interest in the STS/ACC TVT Registry – a benchmarking tool created by The Society of Thoracic Surgeons (STS) and the American College of Cardiology (ACC) to track patient safety and real-world outcomes for patients undergoing aortic and mitral transcatheter valve replacement and repair procedures.

Through the capture and reporting of patient demographics, procedural details, and facility and physician information, the TVT Registry serves as a data repository capable of delivering insight into your clinical practice patterns and patient outcomes for these novel therapies.

For participating hospitals, the TVT Registry offers:

- Quarterly reports containing practice patterns, demographics and outcomes of procedures that compare an institution's performance with that of the national experience
- Standardized, evidence-based data elements and definitions
- A secure web-based data collection tool
- Security and confidentiality of information about your hospital site and patient information
- A wide range of other quality improvement tools to advance quality improvement initiatives
- Fulfillment of the Centers for Medicare and Medicaid Services (CMS) registry participation requirement for transcatheter aortic valve replacement and transcatheter mitral valve repair.

Get started today
Enclosed materials include a registry enrollment form, invoice, participant agreement, business associate contract and data use agreement and CMS data release consent form. Once we receive your completed paperwork and 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.

STS/ACC TVT Registry™
An initiative of the STS National Database and the ACC's NCDR

The Society of Thoracic Surgeons

AMERICAN COLLEGE of CARDIOLOGY FOUNDATION

2019 ENROLLMENT DOCUMENTS

Note: All forms below are required before activation of an account/registry.

- Hospital Master Agreement
- Order Form & Invoice
- Payment
- Contact Information Sheet

MAIL ALL COMPLETED FORMS TO:

Note: You may choose to scan & email all forms to ncdr@acc.org

American College of Cardiology Foundation
Attn: 2019 NCDR Renewal
P.O. Box 37095
Baltimore, MD 21297-3095

ORDER FORM & INVOICE

If you are an existing NCDR Participant, please enter your **NCDR Participant ID** here →

Please indicate which registries your hospital wishes to enroll in for calendar year 2019

NCDR REGISTRY *- Participation through December 31, 2019 -*	**2019 ENROLLMENT** *-Check all that apply-*	**AMOUNT**
STS/ACC TVT Registry	☐ **Enroll today**	$25,000.00
TOTAL INVOICE AMOUNT		**$25,000.00**

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PAYMENT OPTIONS

Method of payment: ☐ **Check** ☐ **Electronic Fund Transfer**

If you are paying by **CHECK,** please indicate the amount enclosed below.
Checks should be made payable to the **"American College of Cardiology Foundation,"** sent along with the invoice above.

Amount Enclosed $_____

If you are paying by **Electronic Fund Transfer (EFT),** please see below:

Bank: BB&T (Branch Banking and Trust Co.)
1909 K St. NW, Washington, DC 20006

Account Name: American College of Cardiology Foundation
Routing #: 054001547
Account#: 0005163211329

Swift Code: BRBTUS33

For questions relating to the electronic fund transfer, please contact us at ncdr@acc.org.

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TVT CONTACT INFORMATION SHEET

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

☐ Chest Pain- MI Registry ® ☐ AFib Ablation Registry ™ ☐ CathPCI Registry ® ☐ Diabetes Registry ® ☐ ICD Registry ™
☐ IMPACT Registry ® ☐ LAAO Registry ™ ☐ PINNACLE Registry® ☐ PVI Registry ™ ☐ STS National Database

NCDR Participant ID Number (if applicable): _____

STS Participant ID Number (if applicable): _____

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 contact details for a designated **Program Manager for Quality Improvement for Institutions** here:
Note: Only one Program Manager per hospital.

Program Manager's Name:	Program Manager's Title:
Physical Address (no PO boxes):	
Program Manager's Email Address:	Program Manager's Telephone:

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STEP 3: 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 4: 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 5: 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

THIS AGREEMENT is entered into and made effective this ____ day of _____, 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, Floor 23, 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 initial annual fee of Twenty-Five Thousand US Dollars (USD$25,000.00) to participate in the TVT Registry for the first year of participation then an annual fee of Ten Thousand Five Hundred US Dollars (USD $10,500.00) to participate in the TVT Registry for each subsequent year thereafter. 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 December 31, 2019, 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.

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, or by overnight courier (*e.g.*, FedEx, DHL, or UPS) to the following addresses:

If to Participant: _____
_____
_____
_____
_____

With a copy to: _____
_____
_____
_____
_____

If to ACCF/STS: American College of Cardiology Foundation
2400 N Street NW
Washington, DC 20037
Attn: General Counsel

With a copy to: The Society of Thoracic Surgeons
633 N. Saint Clair Street, Floor 23
Chicago, IL 60611
Attn: Executive Director & General Counsel

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 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.

[Remainder of page intentionally left blank. Signature page to follow.]

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

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

APPENDIX A - STANDARD FORM
BUSINESS ASSOCIATE CONTRACT AND DATA USE AGREEMENT

THIS BUSINESS ASSOCIATE CONTRACT AND DATA USE AGREEMENT ("Agreement") is entered into and made effective this ____ day of _____, 20___ ("Effective Date"), by and between the American College of Cardiology Foundation ("ACCF"), a nonprofit, 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, Floor 23, 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"). ACCF and STS have entered into this single agreement for convenience of the parties. ACCF and STS collaborate to provide the TVT Registry, as defined below. However, nothing in this Agreement shall make either ACCF or STS vicariously responsible for a breach of this Agreement by the other. Hospital Participant, Surgeon Participant, and Cardiologist Participant have entered into this single Agreement for convenience of the parties. Each collaborates under the Participation Agreement (as defined below). Each is a separate Covered Entity under HIPAA, and the obligations of ACCF and STS under this Agreement and HIPAA run severally to each, depending on which Covered Entity is responsible under HIPAA for specific Protected Health Information ("PHI") received, Used, Maintained, and/or Disclosed pursuant to the Participation Agreement. 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 "Business Associates." Business Associates and Participant shall be referred to herein collectively as the "Parties" and individually as a "Party." STS authorizes ACCF to execute this Agreement on its behalf.

WHEREAS, Business Associates and Participant are parties to that certain Participation Agreement, dated as of _____, setting forth the terms of Participant's participation in the STS/ACC TVT Registry, an initiative of the Society of Thoracic Surgeon's National Database and the American College of Cardiology Foundation's NCDR and referred to herein as the "TVT Registry" (such agreement to be referred to herein as the "Participation Agreement");

WHEREAS, the Participation Agreement permits and provides for the conduct of data analyses that relate to the Participant's Health Care Operations, including but not limited to Data Aggregation, quality assessment, and peer review functions;

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

WHEREAS, the Participation Agreement may from time to time require the Disclosure of PHI in the form of a Limited Data Set ("Limited Data Set Information") for Business Associates 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") and the regulations promulgated thereunder by the United States Department of Health and Human Services ("HHS") codified at 45 CFR §160 and 164 (commonly known as the Privacy and Security Rules), 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 its implementing regulations (the Privacy and Security Rules and HITECH Act regulations are collectively referred to herein as the "HIPAA Regulations"), as they pertain to Business Associates and Limited Data Sets;

NOW THEREFORE, in consideration of the mutual promises and conditions contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged by the Parties, the Parties agree to amend the Participation Agreement 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 Business Associates or an agent or Subcontractor of Business Associates, or created or maintained by Business Associates or its agent or Subcontractor on behalf of Participant. 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 Business Associates or an agent or Subcontractor of Business Associates, or created or maintained by Business Associates or its agent or Subcontractor on behalf of Participant. 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 applicable terms of the Participation Agreement would be more protective of PHI. The provisions of this Agreement are intended in their totality to implement 45 CFR §164.504(e) and 45 CFR §164.314(a) as they concern Business Associate contracts and 45 CFR §164.514(e) as it concerns data use agreements ("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 BUSINESS ASSOCIATES

Section 3.1. Business Associate Contract Obligations. The obligations set out in this Section 3.1 apply with respect to Business Associates' Use, Maintenance, or Disclosure of PHI, other than Limited Data Set Information.

a. Business Associates agree not to Use or Disclose PHI other than as permitted or required by this Agreement or as Required By Law and agree to maintain the security and privacy of all PHI in a manner consistent with applicable laws.

b. Business Associates agree to use appropriate safeguards to prevent Use or Disclosure of PHI other than as provided for by this Agreement. Without limiting the generality of the foregoing, Business Associates further agree to:

   i. Implement Administrative, Physical, and Technical Safeguards that reasonably and appropriately protect the Confidentiality, Integrity, and Availability of the electronic PHI that is created, received, maintained, or transmitted on behalf of Participant as required by 45 CFR §164.314(a);
   ii. Ensure that any agent or Subcontractor to whom it provides such PHI agrees to implement reasonable and appropriate safeguards to protect the PHI;
   iii. Report promptly, but in no case later than thirty (30) calendar days after discovery, to the Participant any Security Incident or Breach of Unsecured PHI of which Business Associates become aware and mitigate, to the extent practicable any harmful effects of said Security Incident or Breach that are known or should be known to it; and
   iv. The Parties agree that Subsection 3.1(b)(iii) satisfies any notices necessary by Business Associates to Participants of the ongoing existence and occurrence of Unsuccessful Security Incidents, and no additional notice to Participants shall be required for such Unsuccessful Security Incidents. For purposes of this Agreement, Unsuccessful Security Incidents include without limitation activity such as pings and other broadcast attacks on Business Associates' firewall, port scans, unsuccessful log-on attempts, denial of service, and any combination of the above, so long as no such Unsuccessful Security Incident results in unauthorized access, Use, Disclosure, modification or destruction of electronic PHI or interference with information system operations related to the ePHI. Upon written request from Participants, Business Associates will provide a log or similar documentation of Unsuccessful Security Incidents for the period of time reasonably specified in Participants' request. Successful Security Incidents will be reported to Participants within thirty (30) business days after the date the Successful Security Incident is, or in the exercise of reasonable efforts should have been known, to Business Associates. If the Successful Security Incident constitutes a Breach, the parties will proceed as required under Section 5.c. of this Agreement as to a Breach.

c. Business Associates agree to report promptly to Participant any Use or Disclosure of PHI which is not authorized by this Agreement of which Business Associates become aware. Without limiting the foregoing, Business Associates agree to report to Participants any Breach of Protected Health Information accessed, maintained, retained, modified, stored,

destroyed or otherwise held or used in Unsecured form by Business Associates or an agent or Subcontractor of Business Associates within thirty (30) days after the first day the Breach is known, or reasonably should have been known, to the Business Associates ("Breach Notice"). The Breach Notice will include the identification of each Individual whose Unsecured PHI was subject to the Breach, the nature of the PHI that was subject to the Breach and the circumstances of the Breach, to the extent known to Business Associates as of the date of the Breach Notice. Business Associates will promptly provide other information relating to the Breach as reasonably requested by Participants. If Business Associates believe that the facts related to a Breach justify the application of a statutory exceptions specified at Section 13400 of the HITECH Act and regulatory exclusions specified at 45 CFR §164.402, Business Associates shall describe those facts in the Breach Notice and the parties shall thereafter discuss the possible application of an exception or an exclusion. Unless otherwise agreed upon by the Parties, Participants 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 Business Associates and Participants.

d. Business Associates agree to ensure that any agent or Subcontractor to whom, it provides PHI, will agree in writing to comply with the same restrictions and conditions with respect to such information that apply through this Agreement to Business Associates ("Subcontractor Business Associate Agreement"). For the purposes of this Agreement, all PHI provided at Business Associates' direction directly to an agent or Subcontractor of Business Associates will be deemed to have been provided to Business Associates. A Subcontractor is a person or entity to which Business Associates delegate a function, activity, or service involving PHI or ePHI of Participants, other than as a member of either Business Associate's Workforce.

e. If PHI provided to or maintained by Business Associates, constitutes a Designated Record Set, Business Associates agree 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 Protected Health Information. In the event an Individual contacts Business Associates directly about gaining access to his or her PHI, Business Associates will not provide such access but rather will forward such request to Participant within three (3) business days of such contact. Business Associates will require in any Subcontractor Business Associate Agreement that any Subcontractor report any such requests to Business Associates, who will promptly forward it to Participants. In addition, if PHI is in an Electronic Designated Record Set, Business Associates will provide Participants with access in an electronic form and format subject to and in accordance with 45 CFR §164.524(c)(2)(ii) and if requested by Participants will transmit the PHI directly to a person designated by the Individual, subject to and in accordance with 45 CFR §164.524 (c)(3)(ii). The foregoing obligations of access and transmission are conditioned on timely receipt by Business Associates of documentation contemplated under the HIPAA Regulations. In the event an Individual contacts Business Associates, Business Associates will not make such amendments, but rather will promptly forward such request to Participant. Business Associates will require in any Subcontractor Business Associate Agreement that any Subcontractor report any such requests to Business Associates, who will promptly forward it to Participants.

f. If PHI provided to or maintained by Business Associates, constitutes a Designated Record Set, Business Associates agree 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 Business Associates Business Associates will not make such amendments, but rather will promptly forward such request to Participant. Business Associates will require in any Subcontractor Business Associate Agreement that any Subcontractor report any such requests to Business Associates, who will promptly forward it to Participants.

g. Business Associates agree to make internal practices, books and records relating to the Use and Disclosure of PHI available to the HHS Secretary ("the Secretary"), during regular business hours, for purposes of the Secretary's determining compliance with HIPAA or the HIPAA Regulations.

h. Business Associates agree 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, Business Associates agree 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 subject to the exceptions to 45 CFR §164.528 as set forth in the HIPAA Regulations.

i. Business Associates shall mitigate, to the extent practicable, any adverse effects from any improper Use and/or Disclosure of Protected Health Information by Business Associates that are known to Business Associates.

Section 3.2. Data Use Agreement Obligations. The obligations set out in this Subsection 3.2 apply only with respect to Business Associates' Use or Disclosure of Limited Data Set Information.

a. Business Associates agree to not Use or further Disclose Limited Data Set Information other than as permitted by Subsection 4(c) of this Agreement, or as otherwise Required By Law.

b. Business Associates agree to use appropriate safeguards to prevent Use or Disclosure of the Limited Data Set Information other than as permitted by Subsection 4(c) of this Agreement. Without limiting the generality of the foregoing, Business Associates further agree to:

    i. implement Administrative, Physical, and Technical Safeguards that reasonably and appropriately protect the Confidentiality, Integrity, and Availability of the electronic Limited Data Set Information that it creates, receives, maintains, or transmits on behalf of Participant as required by 45 CFR §164.314(a);

ii. ensure that any Subcontractor, including any agent, to whom it provides such Limited Data Set Information agrees to implement reasonable and appropriate safeguards to protect such information; and

iii. report promptly, but in no case later than thirty (30) calendar days after discovery, to the Participant any Security Incident or Breach of Unsecured PHI of which Business Associates become aware in accordance with Sections 3.1(b)(iii) and 3.1(c), respectively.

c. Business Associates will report promptly to Participant any Use or Disclosure of the Limited Data Set Information not permitted by Subsection 4(c) of this Agreement of which Business Associates become aware in accordance with Subsections 3.1(b)(iii) and 3.1(c) respectively.

d. Business Associates will not attempt to identify the information to which the Limited Data Set Information pertains, or attempt to contact the Individuals, provided that this restriction will not be interpreted to prevent Business Associates from doing so if necessary to fulfill its obligations under the Business Associate Contract provisions of Section 3.1 of this Agreement, subject to reasonable advance notice to Participants.

e. Business Associates agree to require that any agent or Subcontractor to whom they provide Limited Data Set Information will agree in writing to comply with the same restrictions and conditions that apply through this Section 3.2 to Business Associates in the Subcontractor Business Associate Agreement.

f. Business Associates agree to enter into a written agreement with each third party to which they Disclose Limited Data Set Information, that includes the terms and provisions required by the HIPAA Regulations for such Disclosures.

SECTION 4
PERMITTED USES AND DISCLOSURES BY BUSINESS ASSOCIATES

a. General Business Associate Contract Use and Disclosure Provisions. Except as otherwise limited in this Agreement, Business Associates may Use or Disclose PHI on behalf of, or in order to provide services to, Participant as to the Business Associates' TVT Registry, consistent with the Participation Agreement, provided that such Use or Disclosure of PHI would not violate the HIPAA Regulations if done by Participant.

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 Business Associates' Use or Disclosure of PHI other than Limited Data Set Information.

i. Business Associates may Use PHI for the proper management and administration of Business Associates or to carry out the legal responsibilities of Business Associates.

ii. Business Associates may Disclose PHI for its own proper management and administrative purposes, provided that the Disclosures are either Required By Law, or Business Associates otherwise obtain reasonable assurances from the person to whom the PHI is Disclosed 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 Business Associates of any instances of which the person is aware that the Confidentiality of the PHI has been breached.

iii. In accordance with the Participation Agreement, Business Associates may Use and Disclose PHI to provide Data Aggregation services to Participant as permitted by 45 CFR §164.504(e)(2)(i)(B).

iv. Business Associates may de-identify any PHI, provided such de-identification conforms to the requirements of 45 CFR §164.514(b). Business Associates 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. Such de-identified PHI will be the property of the Business Associates.

v. Business Associates 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. Uses and Disclosures Under Data Use Agreement Provisions. Notwithstanding Subsection 4(b) above, Business Associates may, consistent with this Agreement, Use or Disclose PHI that consists solely of Limited Data Set Information to a third party 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 TVT Registry or for Business Associates' 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 Business Associates with a copy of its Notice of Privacy Practices upon request.

ii. Participant will provide Business Associates with any changes in, or revocation of, the permission by an Individual to Use or Disclose PHI, if such changes affect Business Associate's permitted or required Uses and Disclosures.

iii. Participant will ensure on a continuing basis that all Disclosures of PHI made to Business Associates are permissible under the HIPAA Regulations and are not subject to restrictions that would make the Disclosure of an Individual's PHI to Business Associates impermissible. Participant will notify Business Associates of any specific or general restrictions on the Use or Disclosure of PHI submitted to Business Associates that Participant has agreed to in accordance with 45 CFR §164.522.

b. Permissible Requests by Participant. Participant will not request that Business Associates 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 Business Associates Use or Disclose PHI for the purposes of Data Aggregation or the management, administrative activities, or the legal responsibilities of Business Associates, as provided for in 45 CFR §164.504(e)(4).

c. Breach Costs. Participant and Business Associates 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 responsible for the Breach agrees to pay all costs associated with any notification to affected individuals that is required by law, and the party responsible will also pay any and all fines and/or administrative penalties imposed for such unauthorized access, Use or Disclosure of confidential information or for delayed reporting.

d. Notice of Restrictions. Participants shall notify Business Associates of any Restriction on the Use or Disclosure of Protected Health Information that Participants have agreed to in accordance to the extent that such restriction will affect Business Associates' Use or Disclosure of Protected Health Information. In order to allow Business Associates to comply with such agreed restriction, such notice will be provided a period of time in advance of the date upon which compliance by the Business Associates is required that is reasonable under the Participation Agreement. Conditioned upon receipt of timely notice, Business Associates will comply with the agreed Restriction.

e. Minimum Necessary Standard. Participants will provide, and Business Associates will request, no more than, the minimum necessary amount of PHI required for the performance of Business Associates' services under the Participation Agreement ("Minimum Necessary Standard"). Business Associate and Participant will comply with any guidance issued by HHS regarding the Minimum Necessary Standard as of the date upon which such compliance is required. To the extent that an amendment to this Agreement is required for such compliance, Participants will provide such an amendment in accordance with Subsection 8(b).

SECTION 6
TERM AND TERMINATION

a. Term. 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; 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. Termination for Material Breach. 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 as reasonably determined by the non-breaching party, the non-breaching Party may terminate this Agreement immediately upon notice to the other Party.

c. Termination Permitted Due to Change in Law. 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.

d. Effect of Termination.

i. Except as provided in paragraph (ii) of this Subsection and except with respect to Limited Data Set Information, upon termination of this Agreement for any reason, Business Associates will return or destroy all PHI received from Participant, or created or maintained or received by Business Associates on behalf of Participant. Business Associates will retain no copies of the PHI, except as provided in paragraph (ii) of this Subsection or to the extent that the PHI constitutes Limited Data Set Information.

ii. In the event that Business Associates reasonably determine that returning or destroying the PHI is infeasible due to inclusion of such PHI in a TVT Registry or for other reason, Business Associates will not return or destroy the PHI, may retain copies of the PHI and will promptly notify Participant of the circumstances that make return or destruction infeasible. Business Associates 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 Business Associates maintain such PHI.

iii. The Parties acknowledge and agree that the provision of any PHI to Business Associates 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 Business Associates, and Business Associates 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 contemporaneously with the termination of this Agreement, upon notice to the other Party. 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

To the extent that it is responsible under HIPAA for specific PHI received, Used, Maintained, and/or Disclosed pursuant to the Participation Agreement, each Business Associate agrees to indemnify and hold harmless Participant from direct losses and damages suffered by Participant as a result of that Business Associate'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 Business Associates from direct losses and damages suffered by Business Associates 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 or operating revenue (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 Section 7 regarding indemnification will survive any expiration or termination of this Agreement.

SECTION 8
MISCELLANEOUS

a. Regulatory References. 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 Business Associates 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. Interpretations. Any ambiguity in this Agreement will be resolved in favor of a meaning that permits Participants and Business Associates to comply with the HIPAA Regulations. Where provisions of this Agreement are different from those mandated in the HIPAA Regulations, but are nonetheless permitted by the HIPAA Regulations, the provisions of this Agreement will control.

d. Third Party Beneficiaries. Business Associates and Participant agree that Individuals whose PHI is Used or Disclosed to Business Associates or its agents or subcontractors under this Agreement are not third-party beneficiaries of this Agreement or the Participation Agreement.

e. Waiver. 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.

f. 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.

g. 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.

[Remainder of page intentionally left blank. Signature page to follow.]

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

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

CMS DATA RELEASE CONSENT FORM

ADDENDUM TO THE TVT REGISTRY PARTICIPATION AGREEMENT BETWEEN THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION, THE SOCIETY OF THORACIC SURGEONS AND PARTICIPANT

This Addendum's terms and conditions are hereby added to the TVT Registry Participation Agreement between _____ ("Hospital Participant"), _____ ("Surgeon Participant"), _____ ("Cardiologist Participant"), the American College of Cardiology Foundation ("ACCF"), and The Society of Thoracic Surgeons ("STS"). 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" and as a "Party" hereunder. ACCF/STS and Participant shall each be referred to herein as a "Party" and collectively as the "Parties". All existing terms and conditions of the TVT Registry Participation Agreement shall remain in full force and effect.

The Parties hereby acknowledge and agree as follows:

1. Participant has entered into a TVT Registry Participation Agreement ("Participation Agreement") and a Business Associate Contract and Data Use Agreement ("BAC/DUA") with ACCF/STS to provide certain transcatheter valve therapies data encompassing patient level data to ACCF/STS and to receive certain comparative and benchmark reports from ACCF/STS ("TVT Data"). TVT Data include certain required patient identifiers and such data include Protected Heath Information as defined under the regulations issued pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA").

2. Participant acknowledges and agrees that the TVT Registry is an approved registry under a Centers for Medicare and Medicaid Services ("CMS") National Coverage Determination. In order for Participant to qualify for reimbursement under the CMS coverage determination, Participant must submit data to an approved registry, such as the TVT Registry, and must grant such registry permission to disclose its TVT Data to CMS on Participant's behalf.

3. The Participant hereby authorizes ACCF/STS to transmit its TVT Data directly to CMS. The TVT Data will be submitted only during the term of the Participation Agreement.

4. This Addendum shall be effective for the duration of the term, and any subsequent renewals, of the Participation Agreement but may be terminated by either Party upon written notice by one Party to the other Party, at any time. Termination of this Addendum shall not constitute a termination of the Participation Agreement.

5. If there is any inconsistency between (a) the Participation Agreement and/or the BAC/DUA and (b) this Addendum, then the terms of the Participation Agreement and/or the BAC/DUA shall control and prevail.

6. This Addendum 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.

[SIGNATURE PAGE TO FOLLOW]

CMS DATA RELEASE CONSENT FORM

IN WITNESS WHEREOF, each of the Parties hereto has caused this Addendum to be executed as of the _____ day of _____, 20___.

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