Health Services
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To ensure access to high-quality, patient-centered, cost-effective health care to Los Angeles County residents through direct services at DHS facilities and through collaboration with community and university partners.

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December 11, 2012

The Honorable Board of Supervisors
County of Los Angeles
383 Kenneth Hahn Hall of Administration
500 West Temple Street
Los Angeles, California 90012

Dear Supervisors:

APPROVAL OF TRANSCATHETER VALVE THERAPY REGISTRY PARTICIPATION AGREEMENT AND BUSINESS ASSOCIATE CONTRACT AND DATA USE AGREEMENT
(ALL SUPERVISORIAL DISTRICTS)
(3 VOTES)

SUBJECT

Request approval to execute Agreements with the Society of Thoracic Surgeons and the American College of Cardiology for Transcatheter Valve Therapy Registry Participation and Business Associate Contract and Data Use Agreement at Harbor UCLA Medical Center.

IT IS RECOMMENDED THAT THE BOARD:

Authorize the Director of Health Services (Director), or his designee, to execute an Agreement with the Society of Thoracic Surgeons and the American College of Cardiology (STS/ACC) for Transcatheter Valve Therapy (TVT) Registry Participation and a Business Associate Contract Data Use (BACDU) Agreement (Exhibit I) at Harbor-UCLA Medical Center (H-UCLA MC) effective January 1, 2013 to December 31, 2013 with automatic one year renewals at an initial cost of $25,000 and $10,000 annually thereafter.

PURPOSE/JUSTIFICATION OF RECOMMENDED ACTION

Approval of the recommendation will allow the Director to execute Agreements with STS/ACC for TVT Registry Participation and BACDU at H-UCLA MC effective January 1, 2013.

In November 2011, the Food and Drug Administration (FDA) approved a new heart procedure called Transcatheter Aortic Valve Replacement (TAVR) that provides a minimally invasive means of replacing a heart valve damaged by senile aortic valve stenosis without open heart surgery.

Centers for Medicare and Medicaid Services (CMS) approved coverage of this new procedure in May 2012 under certain conditions and requirements. One of those requirements is that all hospitals performing TAVR procedures on Medicare patients must participate in a CMS approved prospective, national, audited registry. Since this is a new procedure, clinical data is needed to measure long-term outcomes.

The STS/ACC TVT Registry was developed in collaboration with CMS and the FDA, and currently is the only approved registry. The Participation Agreement (see Exhibit I) between H-UCLA MC and the STS/ACC TVT Registry will require that all patients meeting the inclusion criteria must be entered into the Registry. The STS/ACC TVT Registry is designed to monitor the safety and efficacy of this new procedure as well as subsequent devices and procedures for the treatment of aortic stenosis in patients who undergo the procedure.

Implementation of Strategic Plan Goals

The recommended action supports Goal 1, Operational Effectiveness, of the County's Strategic Plan.

FISCAL IMPACT/FINANCING

The initial fee to participate in the STS/ACC TVT Registry is $25,000 and the annual renewal fee is $10,000 per year. The total estimated cost for Fiscal Year (FY) 2012-13 is $25,000, which covers the initial $25,000 participation fee for 2012. Funding is included in the FY 2012-13 Final Budget and the $10,000 will be requested in future fiscal years as necessary.

FACTS AND PROVISIONS/LEGAL REQUIREMENTS

H-UCLA MC staff has been trained by the manufacturer of TAVR equipment and performed the procedure beginning in October 2012. CMS has confirmed that H-UCLA MC may perform the life-saving procedure prior to signing the Participation Agreement as long as data is entered retroactively within the required timeframe to ensure compliance. The first procedures performed in October 2012 would fall under the 4th quarter reporting period and the data completion deadline for 4th quarter data is February 28, 2013. All other requirements were met and CMS point of contact confirmed that as long as H-UCLA MC met the deadline to enter data retroactively then H-UCLA MC would be in compliance.

County Counsel and Chief Executive Office (CEO) Risk Management have reviewed Exhibit I as to form. Since participation in the TVT Registry is a mandated requirement by CMS to perform this life-saving procedure, STS/ACC standard agreement is being used here and not the County's standard agreement. STS/ACC refused to negotiate any of its standard terms and conditions.

The Participation Agreement and the BACDU Agreement has placeholders for Indemnification. This means equitable principals will most likely govern if there is a cause of action for indemnity.

CONTRACTING PROCESS

Not Applicable.

IMPACT ON CURRENT SERVICES (OR PROJECTS)

Approval of the recommendations will ensure that objective clinical data is available to assess the safety and efficacy of the TAVR procedure and ensure compliance with CMS requirements.

Respectfully submitted,

Mitchell H. Katz, M.D.

Director

MHK:mm

Enclosures

c: Chief Executive Office
County Counsel
Executive Office, Board of Supervisors

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

REGISTRY ENROLLMENT FORM

THE FOLLOWING INFORMATION IS REQUIRED FOR REGISTRY ENROLLMENT

1. Attach documentation of completed or scheduled Edwards Lifesciences verification of formal clinical training.
2. Attached the completed TVT Registry Participation Agreement.
3. Attached the invoice and payment.
4. Indicate which registries you currently participate (check all that apply):
   - ☐ ACTION Registry®–GWTG™ ☐ CathPCI Registry® ☐ CARE Registry® ☐ IMPACT Registry™
   - ☐ ICD Registry™ ☐ PINNACLE Registry™
   - ☐ STS Adult Cardiac Surgery Database ☐ STS General Thoracic Surgery Database
   - ☐ STS Congenital Heart Surgery Database
5. Indicate the following Participant IDs if applicable
   NCDR Participant ID Number _____
   STS Participant ID Number _____
6. Complete the following contact information.

HOSPITAL (please print clearly and legibly)

Health System (if applicable)	
Hospital Name	
Address 1	
Address 2	
City/State/ZIP Code	

REGISTRY SITE MANAGER (please print clearly and legibly)

Contact (First Name, Last Name)	
Title	
Address 1	
Address 2	
City/State/ZIP Code	
Telephone	( )
Fax	( )
Email	@

CONTRACT MANAGER (please print clearly and legibly)

Contact (First Name, Last Name)	
Title	
Address 1	
Address 2	
City/State/ZIP Code	
Telephone	( )
Fax	( )
Email	@

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

INVOICE

Please complete this form and mail it with your check payment to:

American College of Cardiology Foundation
Attn: 2011 TVT Registry Participation
P.O. Box 79231
Baltimore, MD 21279-0231

Date of Enrollment	1st Year Participation Dues	Total Due
Initial fee includes participation through December 31, 2012	$25,000.00	$25,000.00
** The standard implementation fee of $1,000.00 will be waived for all TVT Registry enrollments* **After the first year of participation the annual participation fee is $10,000 per hospital*		

Please make your check payable to the *American College of Cardiology Foundation*

Amount Enclosed $_____

Your Name (please print clearly)_____

Title_____

Facility Name_____

Address _____

Phone Number _____

Email Address _____

City_____ State_____ ZIP_____

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 _____ [insert type of entity], solely with respect to the hospital known as _____ [name of specific hospital], located at _____ (city/state); _____, 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.

   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.

   i. 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.

   ii. 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.

g. 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.

h. 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.g. shall be enforced.

i. Identifiers. Participant agrees that unique patient identifiers and unique physician identifiers will be collected for each record submitted to the TVT Registry.

j. 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.g.

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.g. 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 Business Associate/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.

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 Business Associate/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 Business Associate/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 Dollars ($25,000) to participate in the TVT Registry for the first year of participation then an annual fee of Ten Thousand Dollars ($10,000) 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 in 2012 and by December 1 in each succeeding year (payable by January 1, 2013, and by January 1 in each succeeding 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, 2012, 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 non-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.g. 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. RESERVED.

11. Limitation of Liability. RESERVED

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. RESERVED

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 Business Associate/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: _____	
CARDIOLOGIST PARTICIPANT	
Signature:_____	
Name:_____	
Title: _____	
Date: _____	

APPENDIX A
STANDARD FORM
BUSINESS ASSOCIATE CONTRACT
AND DATA USE 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 ("ACCF/STS"), a not-for-profit, tax-exempt Illinois corporation located at 633 N. Saint Clair Street, Floor 23, Chicago, IL 60611; _____ ("Hospital Participant"), a _____ [insert type of entity], solely with respect to the hospital known as _____ [name of specific hospital], located at _____ (city/state); _____, 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 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 STS National TVT Registry 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, 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 ACCF/STS to provide services to Participant related to its Health Care Operations and for Research purposes; and

WHEREAS, the Parties desire to allocate responsibility for the Use and Disclosure of PHI, including Limited Data Set Information, and to comply with applicable requirements of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 ("HIPAA") and the regulations promulgated thereunder by the United States Department of Health and Human Services ("HHS") codified at 45 CFR Parts 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;" 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 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 ACCF/STS or an agent or subcontractor of ACCF/STS, or created by ACCF/STS 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 ACCF/STS or an agent or subcontractor of ACCF/STS, or created by ACCF/STS 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 Parties mutually agree that the applicable terms of the Participation Agreement would be more protective of PHI. The provisions of this Agreement are intended in their totality to implement 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. 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 ACCF/STS

Section 3.1. Business Associate Contract Obligations.

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

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

(b) ACCF/STS 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, ACCF/STS 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 it creates, receives, maintains, or transmits on behalf of Participant as required by 45 CFR 164.314(a);

(ii) ensure that any agent, including any subcontractor, to whom it provides such PHI agrees to implement reasonable and appropriate safeguards to protect the PHI; and

(iii) report promptly, but in no case later than two (2) calendar days after discovery, to the Participant any Security Incident or Breach of Unsecured PHI of which ACCF/STS become aware and shall mitigate, to the extent practicable any harmful effects of said Security Incident or Breach that are known or should be known to it;

(c) ACCF/STS agree to report promptly to Participant , but in no case later than five (5) calendar days after discovery, any Use or Disclosure of PHI which is not authorized by this Agreement of which ACCF/STS becomes aware.

(d) ACCF/STS agree to ensure that any agent or subcontractor to whom, directly or indirectly, 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 ACCF/STS. For the purposes of this Agreement, all PHI provided at ACCF/STS's direction to an agent or subcontractor of ACCF/STS will be deemed to have been provided to ACCF/STS.

(e) If PHI provided to ACCF/STS, or to which ACCF/STS otherwise have access, constitutes a Designated Record Set, ACCF/STS 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 ACCF/STS or its agent or subcontractor directly about gaining access to his or her PHI, ACCF/STS will not provide such access but rather will forward such request to Participant within three (3) business days of such contact.

(f) If PHI provided to ACCF/STS, or to which ACCF/STS otherwise have access, constitutes a Designated Record Set, ACCF/STS 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 ACCF/STS or its agent or subcontractor directly about making amendments to his or her PHI, ACCF/STS will not make such amendments, but rather will promptly forward such request to Participant.

(g) ACCF/STS agree to make internal practices, books and records relating to the Use and Disclosure of PHI available to the Secretary of the United States Department of Health and Human Services, during regular business hours, for purposes of the Secretary's determining Participant's compliance with HIPAA or the HIPAA Regulations.

(h) ACCF/STS 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, ACCF/STS 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 made to carry out Participant's Health Care Operations or the Disclosure of Limited Data Set Information, in accordance with the exceptions to 45 CFR 164.528 as set forth in the HIPAA Regulations, provided that this exception shall not apply to Disclosures of PHI through an electronic health record.

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

Section 3.2. Data Use Agreement Obligations.

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

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

(b) ACCF/STS agree to use appropriate safeguards to prevent Use or Disclosure of the Limited Data Set Information other than as permitted by Section 4(c) of this Agreement. Without limiting the generality of the foregoing, ACCF/STS 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 agent, including any subcontractor, to whom it provides such Limited Data Set Information agrees to implement reasonable and appropriate safeguards to protect such information;

(iii) report promptly, but in no case later than five (5) calendar days after discovery, to the Participant any Security Incident or Breach of Unsecured PHI of which ACCF/STS becomes aware.

(c) ACCF/STS will report promptly but in no case later than five (5) calendar days to Participant any Use or Disclosure of the Limited Data Set Information not permitted by Section 4(c) of this Agreement of which ACCF/STS becomes aware.

(d) ACCF/STS will not attempt to identify the Individuals to whom the Limited Data Set Information pertains, or attempt to contact such Individuals, provided that

this restriction will not be interpreted to prevent ACCF/STS from conducting such activities under the Business Associate Contract provisions of this Agreement. Under no circumstances will ACCF/STS attempt to contact Individuals except with Participant's prior written consent.

(e) ACCF/STS agree to require that any agent or subcontractor to whom it, directly or indirectly, provides Limited Data Set Information, including but not limited to DUKE, will agree in writing to comply with the same restrictions and conditions that apply through this Section 3.2 to ACCF/STS.

(f) ACCF/STS agree to enter into a written agreement with each third party to which it Discloses Limited Data Set Information, including but not limited to DUKE, that includes the terms and provisions required by the HIPAA Regulations for such Disclosures.

SECTION 4
PERMITTED USES AND DISCLOSURES BY ACCF/STS

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

Except as otherwise limited in this Agreement, ACCF/STS may Use or Disclose PHI on behalf of, or in order to provide services to, Participant to the extent such Use or Disclosure is reasonably necessary to facilitate Participant's participation in the ACCF/STS National 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 ACCF/STS's Use or Disclosure of PHI other than Limited Data Set Information.

(i) Except as otherwise limited in this Agreement or the Participation Agreement, ACCF/STS may ***Use*** PHI for the proper management and administration of ACCF/STS or to carry out the legal responsibilities of ACCF/STS.

(ii) Except as otherwise limited in this Agreement or the Participation Agreement, ACCF/STS may ***Disclose*** PHI for its own proper management and administrative purposes, provided that the Disclosures are either Required By Law, or ACCF/STS otherwise obtains reasonable assurances from the person to whom it Discloses the PHI that such person will a) protect the Confidentiality of the PHI; b) Use or further Disclose the PHI only as Required By Law or for the purpose for which it was Disclosed to the person; and c) promptly notify ACCF/STS of any instances of which the person is aware that the Confidentiality of the PHI has been breached.

(iii) Except as otherwise limited in this Agreement or the Participation Agreement, ACCF/STS may Use and Disclose PHI to provide Data Aggregation services to Participant as permitted by 45 CFR 164.504(e)(2)(i)(B).

(iv) ACCF/STS may de-identify any PHI, provided such de-identification conforms to the requirements of 45 CFR 164.514(b), including without limitation any

documentation requirements. ACCF/STS may Use or Disclose such de-identified information at its discretion, as such de-identified information does not constitute PHI and is not subject to the terms of this Agreement; provided that such Use or Disclosure is consistent with the Participation Agreement.

(v) ACCF/STS may partially de-identify any PHI to create a Limited Data Set, provided such partial de-identification conforms to the Limited Data Set requirements of 45 CFR 164.514(e)(2).

(c) Uses and Disclosures Under Data Use Agreement Provisions.

Notwithstanding Subsection 4(b) above, ACCF/STS 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 ACCF/STS's Research purposes; (ii) is consistent with the Participation Agreement; and (iii) would not violate the HIPAA Regulations if done by Participant. The term "Health Care Operations" as used herein includes Data Aggregation.

SECTION 5
GENERAL OBLIGATIONS OF PARTICIPANT

(a) Participant's Notice of Privacy Practices, Permissions, and Restrictions.

(i) Participant represents and warrants that it has developed and makes available to all patients a Notice of Privacy Practices that complies with 45 CFR 164.520 and any other applicable provisions of the HIPAA Regulations. Participant will provide ACCF/STS with a copy of its Notice of Privacy Practices upon request.

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

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

(b) Permissible Requests by Participant. Participant will not ask ACCF/STS to Use or Disclose PHI in any manner that would not be permissible under the HIPAA Regulations if undertaken by Participant, provided that Participant may, as otherwise permitted under this Agreement, request that ACCF/STS Use or Disclose PHI for the purposes of Data Aggregation or the management and administrative activities of ACCF/STS, as provided for in 45 CFR 164.504(e)(4).

(c) Breach Notification. Participant and ACCF/STS agree that if either fails to adhere to any of the provisions set forth in this Agreement or the Participation Agreement and, as a result, PHI or other confidential information is unlawfully accessed, used, or disclosed, the party 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 will pay any and all fines and/or administrative penalties imposed for such unauthorized access, use or disclosure of confidential information or for delayed reporting. Unless otherwise agreed upon by the Parties, if ACCF/STS notify Participant of a Breach of Unsecured PHI, Participant shall be responsible for providing notification to comply with the Breach Notification requirements set forth in the HIPAA Regulations. Such notification shall be provided in a form mutually agreed upon by ACCF/STS and Participant.

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, the non-breaching Party may terminate this Agreement immediately and without any notice.

(c) Termination Permitted Due to Change in Law. Either Party may terminate this Agreement as permitted in accordance with Section 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, ACCF/STS will return or destroy all PHI received from Participant, or created or received by ACCF/STS on behalf of Participant. ACCF/STS 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 ACCF/STS reasonably determine that returning or destroying the PHI is infeasible due to inclusion of such PHI in a TVT Registry or for other reason, ACCF/STS will not return or destroy the PHI, may retain copies of the PHI to the extent it has been entered into a TVT Registry, and will promptly notify Participant of the circumstances that make return or destruction infeasible. Based on such determination, ACCF/STS will extend the protections of this Agreement to such PHI, including any Limited Data Set Information that has not been de-identified, and limit any further Use or

Disclosure of such PHI to those purposes that make the return or destruction infeasible, for so long as ACCF/STS maintain such PHI.

(iii) The Parties acknowledge and agree that the provision of any PHI to ACCF/STS in accordance with the Participation Agreement is conditioned upon this Agreement being in full force and effect. Therefore, upon termination of this Agreement, the Parties agree that Participant will refrain from submitting PHI to ACCF/STS, and ACCF/STS will refrain from accepting PHI from Participant. In the event of a termination under either Subsection (b) or (c) of this Section 6, either Party may also elect to terminate the Participation Agreement. In the event the Parties engage in negotiations undertaken in accordance with Subsection 8(b) of this Agreement, the Parties will suspend during such period of negotiation any provision of the Participation Agreement requiring or obligating either Party to Use or Disclose PHI in a manner that either Party reasonably believes would violate any applicable state or federal law or regulation, including without limitation the HIPAA Regulations.

(iv) The obligations of this Subsection 6(d) will survive any expiration or termination of this Agreement.

SECTION 7
INDEMNIFICATION

ACCF/STS agree to indemnify and hold harmless Participant from direct losses and damages suffered by Participant as a result of ACCF/STS's breach of its obligations under this Agreement, including but not limited to direct losses and damages relating to third party claims. Participant agrees to indemnify and hold harmless ACCF/STS from direct losses and damages suffered by ACCF/STS as a result of Participant's breach of its obligations under this Agreement, including but not limited to direct losses and damages relating to third party claims, if and to the fullest extent Participant is permitted to do so under governing state law. Under no circumstances, however, will either Party be liable to the other for any indirect or consequential damages of any kind, including lost profits (whether or not the Parties have been advised of such loss or damage) arising in any way in connection with this Agreement. The Parties' obligations under this 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 ACCF/STS to comply with the requirements of HIPAA, the HIPAA Regulations, or any applicable provisions of any other federal or state law, as such laws or regulations may be amended from time to time. However, should any state or federal law or regulation now existing or enacted after the Effective Date of this Agreement,

including without limitation HIPAA or the HIPAA Regulations, be amended or interpreted by judicial decision or a regulatory body in such a manner that either Party reasonably determines renders any provision of this Agreement in violation of such law or regulation or adversely affects the Parties' abilities to perform their obligations under this Agreement, the Parties agree to negotiate in good faith to amend this Agreement so as to comply with such law or regulation and to preserve the viability of this Agreement. If, after negotiating in good faith, the Parties are unable to reach agreement as to any necessary amendments, either Party may terminate this Agreement without penalty.

(c) Interpretation. Any ambiguity in this Agreement will be resolved in favor of a meaning that permits Participant and ACCF/STS 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. ACCF/STS and Participant agree that Individuals whose PHI is Used or Disclosed to ACCF/STS 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.

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

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

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