

**DATA RELEASE CONSENT FORM AND  
ADDENDUM TO THE TVT REGISTRY PARTICIPATION AGREEMENT  
BETWEEN THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION, THE SOCIETY  
OF THORACIC SURGEONS AND PARTICIPANT**

This Data Release Consent Form and Addendum (“Addendum”) to the TVT Registry Participation Agreement (“Participation Agreement”) between the undersigned Hospital Participant (“Hospital Participant”), the undersigned Surgeon (“Surgeon Participant”), the undersigned Cardiologist (“Cardiologist Participant”), the American College of Cardiology Foundation (“ACCF”) and The Society of Thoracic Surgeons (“STS”) is entered into and made effective on the latest date signed below (“Effective Date”). 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 each be referred to herein as a “Party” and collectively as the “Parties.” All existing terms and conditions of the Participation Agreement shall remain in full force and effect.

For good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties further acknowledge and agree as follows:

**SAMPLE – DO NOT USE**

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

2. Pursuant to Sections 97140-97160 of Title 22 of the California Code of Regulations, as amended, Participant is required to participate in the TVT Registry and confer the right to transfer the TAVR data submitted by the Participant to the California Department of Health Care Access and Information (“HCAI”). To fulfill such requirement, Participant agrees to permit the transmission by ACCF/STS to HCAI of Participant’s data submitted to the TVT Registry, and to further permit the disclosure of Participant’s PHI to HCAI.

3. Participant acknowledges that it has been informed that ACCF/STS and HCAI have entered or will enter into an agreement, the purposes of such agreement being to provide to HCAI in a secure manner reports, including Participant’s row-level data and aggregate data, to HCAI.

4. Participant authorizes and directs ACCF/STS to transmit Participant’s TVT Registry data to HCAI for the purposes described in Paragraph 3 above.

**SAMPLE – DO NOT USE**

5. This Addendum shall be effective for the duration of Participant’s participation in the TVT Registry unless earlier terminated as permitted herein. This Addendum may be terminated by Participant or ACCF/STS upon written notice to the other Party at any time. Termination of this Addendum shall not constitute a termination of the Participation Agreement, unless otherwise agreed to by Participant or ACCF/STS.

6. As amended by this Addendum, the Participation Agreement is in all respects ratified and confirmed, and the Participation Agreement and this Addendum shall be read, taken, and construed as one and the same instrument. 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.

7. 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.

**IN WITNESS WHEREOF**, each of the Parties hereto has caused this Addendum to be executed as of the \_\_\_\_ day of \_\_\_\_\_, 20\_\_ :

**SAMPLE – DO NOT USE**

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