

## TVT REGISTRY PUBLIC REPORTING PROGRAM CONSENT FORM

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

\_\_\_\_\_ [Participant]

#### CONSENT FORM AUTHORIZING AND DIRECTING THE SOCIETY OF THORACIC SURGEONS AND THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION TO PUBLICLY REPORT CERTAIN PARTICIPANT DATA.

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.

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

1. Participant has entered into a TVT Registry Participation Agreement, including any previous amendments (collectively, "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.
2. The data provided by Participant to ACCF/STS under the Participation Agreement includes facility, physician, and patient-level data. Such data shall be referred to herein as the "TVT Registry Data". Participant acknowledges that in submitting TVT Registry Data, it shall comply with the TVT Registry Core Data Element Documentation. Participant agrees to submit patient-level data in accordance with published data specifications.
3. The Participant hereby gives permission to ACCF/STS and their data analytics services provider (currently the Duke Clinical Research Institute) (the "Services Provider") to publish the specific outcomes and demographic information derived from the TVT Registry Data submitted by Participant to the TVT Registry (the "Information") via a website operated by STS or ACCF (the "Public Reporting Website"). Participant acknowledges that the Information to be made public will include: Hospital name, Hospital city/state, Hospital aggregated measure data, and Hospital categorical measure performance (i.e. better than registry, same as registry, worse than registry) for the specific measures specified by the Public Reporting Program, which may change from time to time and are identified in the STS/ACC TVT Registry Public Reporting Companion Guide. The Information may also include time interval represented by the TVT Registry Data, and confidence limits for composite score and domain measures.
4. Participant acknowledges that the specific URL of the Public Reporting Website may change from time to time and will be identified in the STS/ACC TVT Registry Public Reporting Companion Guide.
5. Participant hereby agrees to hold ACCF/STS, Services Provider, and their respective representatives, harmless in connection with their actions taken in good faith reliance on this TVT Registry Public Reporting Program Consent Form. Participant also agrees that ACCF/STS may publicly identify the Hospital Participant as the source(s) of the information disseminated to the public as contemplated herein. Participant understands that NO patient identifying data OR individual provider level data will be published and/or shared.
6. The signatories below represent and warrant that they have full right and authority to act on behalf of the Surgeon Participant, Cardiologist Participant and Hospital Participant identified below in this matter as set forth above. Participant authorizes ACCF/STS to accept this signed form via hard copy, fax, or e-mail as and for counterparts of hard copy originals, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.
7. This Addendum shall be effective for the duration of Participant's participation in the TVT Registry. 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 provided by Participant or ACCF/STS.

8. The Participation Agreement and this Addendum shall be read, taken, and construed as one and the same instrument. To the extent any inconsistency exists between the BAC/DUA and this Addendum, the terms of such BAC/DUA shall control. In all respects not inconsistent with the terms of this Addendum, the Participation Agreement is hereby ratified, approved, and confirmed.

**IN WITNESS WHEREOF**, each of the Parties hereto has caused this Addendum to be executed as of \_\_\_\_\_, 202\_\_.

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

Please scan and email this completed form to:

[ncdr@acc.org](mailto:ncdr@acc.org)

ACCF reserves the right to return any incomplete form to Participant for completion prior to execution.