

Please sign and return this Agreement to The Society of Thoracic Surgeons

**APPENDIX I: STANDARD FORM
BUSINESS ASSOCIATE CONTRACT
AND DATA USE AGREEMENT**

THIS AGREEMENT is entered into and made effective the 1st day of April, 2003 (the "Effective Date"), by and between (a) **THE SOCIETY OF THORACIC SURGEONS**, an Illinois not-for-profit corporation, with its principal place of business at 633 North Saint Clair Street, Chicago, Illinois, 60611 ("Business Associate" or "STS"); and (b)

_____, an individual cardiothoracic surgeon or group of cardiothoracic surgeons (all of whose members are identified in and have signed Schedule A attached to the Participation Agreement defined herein), whose principal place of business is at _____ ("Surgeon Participant"); and, if, and only if, a Party to the Participation Agreement, (c) _____, a _____, with its principal place of business at _____, solely on behalf of the hospital known as _____, ("Hospital Participant").

Except as otherwise specified, the Surgeon Participant and the Hospital Participant (if any) are collectively referred to herein as "Covered Entity" or "Participant." STS and the Participant are each a Party to this Agreement and are referred to collectively as the "Parties."

WHEREAS, STS and Participant are parties to that certain Participation Agreement, dated as of _____, setting forth the terms of Participant's participation in the STS National Database (such agreement to be referred to herein as the "Participation Agreement" and such STS National Database as "Database");

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 Business Associate to provide services to Participant related to its health care operations and for research purposes; and

WHEREAS, the Parties desire to amend the Participation Agreement so as 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 rules promulgated thereunder by the United States Department of Health and Human Services ("HHS") titled "Standards for Privacy of Individually Identifiable Health Information," 45 CFR part 160 and part 164, subparts A and E (the "Privacy Rule"), as it pertains 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 Privacy Rule or the Participation Agreement, as the case may be. Except as otherwise specified herein, the term “Agreement” refers to this Agreement and not the Participation Agreement. PHI will have the meaning ascribed to it in the Privacy Rule, but for the purposes of this Agreement will refer solely to PHI transmitted from or on behalf of Participant to STS or an agent or subcontractor of STS, or created by 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 Privacy Rule, but for the purposes of this Agreement will refer solely to Limited Data Set Information transmitted from or on behalf of Participant to STS or an agent or subcontractor of STS, or created by 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) as it concerns 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 extent necessary to effectuate the provisions set forth herein.

SECTION 3
GENERAL OBLIGATIONS OF STS

Section 3.1. Business Associate Contract Obligations.

The obligations set out in this Subsection 3.1 apply with respect to STS’s use or disclosure of PHI, other than Limited Data Set Information.

- (a) STS agrees not to use or disclose PHI other than as permitted or required by this Agreement or as required by law.
- (b) STS agrees 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, STS further agrees 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 C.F.R. §164.314;

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

(iii) report promptly to the Participant any security incident of which it becomes aware.

(c) STS agrees to report promptly to Participant any use or disclosure of PHI which is not authorized by this Agreement of which it becomes aware.

(d) STS agrees to ensure that any agent or subcontractor, including but not limited to the Duke Clinical Research Institute ("DUKE"), to whom, directly or indirectly, it provides PHI, will agree to comply with the same restrictions and conditions with respect to such information that apply through this Agreement to STS. For the purposes of this Agreement, all PHI provided at STS's direction to an agent or subcontractor of STS will be deemed to have been provided to STS. Notwithstanding the foregoing, STS agrees to disclose, or arrange for Participant to disclose, only Limited Data Set Information to DUKE and therefore, unless and until such time as DUKE has access to PHI other than Limited Data Set Information, STS will ensure only that DUKE agrees to comply with the Limited Data Set Information provisions of this Agreement as they apply to STS.

(e) If PHI provided to STS, or to which STS otherwise has access, constitutes a Designated Record Set, STS agrees 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 STS or its agent or subcontractor directly about gaining access to his or her PHI, 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 STS, or to which STS otherwise has access, constitutes a Designated Record Set, STS agrees to make timely amendment(s) to such PHI as Participant may reasonably direct or agree to pursuant to 45 CFR 164.526. In the event an individual contacts STS or its agent or subcontractor directly about making amendments to his or her PHI, STS will not make such amendments, but rather will promptly forward such request to Participant.

(g) STS agrees 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 the Privacy Rule.

(h) STS agrees 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, STS agrees to provide promptly to Participant or an Individual, upon Participant's reasonable request, information collected in accordance with this Subsection (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 (h) will not apply with respect to disclosures made to carry out Participant's Health Care Operations or the disclosure of a Limited Data Set Information, in accordance with the exceptions to 45 CFR 164.528 as set forth in the Privacy Rule.

Section 3.2. Data Use Agreement Obligations.

The obligations set out in this Subsection 3.2 apply only with respect to STS's use or disclosure of Limited Data Set Information.

(a) STS agrees 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) STS agrees 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, STS further agrees 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 C.F.R. §164.314;

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

(iii) report promptly to the Participant any security incident of which it becomes aware.

(c) STS will report to Participant any use or disclosure of the Limited Data Set Information not permitted by Section 4(c) of this Agreement of which STS becomes aware.

(d) 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 STS from conducting such activities under the Business Associate Contract provisions of this Agreement. Under no circumstances will STS attempt to contact individuals except with Participant's prior written consent.

(e) STS agrees 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 to comply with the same restrictions and conditions that apply through this Section 3.2 to STS.

(f) STS agrees to enter into an 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 Privacy Rule for such disclosures.

SECTION 4
PERMITTED USES AND DISCLOSURES BY STS

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

Except as otherwise limited in this Agreement, 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 STS National Database, consistent with the Participation

Agreement, provided that such use or disclosure of PHI would not violate the Privacy Rule 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 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, STS may *use* PHI for the proper management and administration of STS or to carry out the legal responsibilities of STS.

(ii) Except as otherwise limited in this Agreement or the Participation Agreement, STS may *disclose* PHI for its own proper management and administrative purposes, provided that the disclosures are either required by law, or STS otherwise obtains reasonable assurances from the person to whom it discloses the information 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 STS of any instances of which the person is aware that the confidentiality of the information has been breached.

(iii) Except as otherwise limited in this Agreement or the Participation Agreement, 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) 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. 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) 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, STS may, consistent with this Agreement, use or disclose PHI that consists solely of Limited Data Set Information to a third party, including but not limited to DUKE, for Research, Public Health, or Health Care Operations in accordance with the provisions of the Privacy Rule 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 STS National Database or for STS's or DUKE's research purposes; (ii) is consistent with the Participation Agreement; and (iii) would not violate the Privacy Rule if done by Participant. Consistent with the Privacy Rule and HHS' December 3, 2002 Guidance Document, the term Health Care Operations includes Data Aggregation.

SECTION 5
GENERAL OBLIGATIONS OF PARTICIPANT

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

(i) Participant will specifically include a reference to use and disclosure of PHI for Health Care Operations and research purposes, including without limitation quality assessment and Data Aggregation, in the Notice of Privacy Practices that Participant produces in accordance with 45 CFR 164.520. Participant will provide STS with a copy of its Notice of Privacy Practices and advise STS of any material changes or modifications to such Notice. To the extent that Participant has already created its Notice of Privacy Practices without specific reference to use and disclosure for quality assessment or Data Aggregation purposes, and that it would be infeasible for Participant to amend its Notice prior to the Effective Date of this Agreement, Participant agrees that it will make such amendments to its Notice to include this specific reference as soon as, in its reasonable judgment, it is feasible to do so.

(ii) Participant will provide STS with any changes in, or revocation of, the permission by an Individual to use or disclose PHI, if such changes affect STS's permitted or required uses and disclosures.

(iii) Participant will ensure on a continuing basis that all disclosures of PHI made to STS are permissible under the Privacy Rule and are not subject to restrictions that would make the disclosure of an Individual's PHI to STS impermissible. Participant will notify STS of any specific or general restrictions on the use or disclosure of PHI submitted to STS that Participant has agreed to in accordance with 45 CFR 164.522.

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

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.

(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, STS will return or destroy all PHI received from Participant, or created or received by STS on behalf of Participant. 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 STS reasonably determines that returning or destroying the PHI is infeasible due to inclusion of such PHI in a Database or for other reason, STS will not return or destroy the PHI, may retain copies of the PHI to the extent it has been entered into a Database, and will promptly notify Participant of the circumstances that make return or destruction infeasible. Based on such determination, STS will extend the protections of this Agreement to such PHI and limit any further use or disclosure of such PHI to those purposes that make the return or destruction infeasible, for so long as STS maintains such PHI.

(iii) The Parties acknowledge and agree that the provision of any PHI to 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 STS, and STS will refrain from accepting PHI from Participant. In the event of a termination under either Subsection (b) or (c) of this Section 6, the Party terminating this Agreement, may also elect to terminate the Participation Agreement. In the event of negotiations or Alternative Dispute Resolution (“ADR”) undertaken in accordance with Subsection 8(b) of this Agreement, the Parties will suspend during such period of negotiation or ADR any provision of the Participation Agreement requiring or obligating either Party to use or disclose PHI in a manner that would violate any applicable state or federal law or regulation, including without limitation the Privacy Rule.

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

SECTION 7

INDEMNIFICATION

STS agrees to indemnify and hold harmless Participant from direct losses and damages suffered by Participant as a result of 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 STS from direct losses and damages suffered by 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. 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 Privacy Rule 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 to take such action as is necessary to make technical amendments to this Agreement from time to time if necessary for Participant and/or STS to comply with the requirements of HIPAA, the Privacy Rule, 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 and the Privacy Rule, be amended or interpreted by judicial decision or a regulatory body in such a manner that 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 remain compliant 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, the Parties will engage in third party mediation, or other form of ADR as is mutually agreed to by the Parties. If the Parties are unable to reach agreement through the good faith use of ADR within 120 days, then 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 STS to comply with the Privacy Rule. Where provisions of this Agreement are different from those mandated in the Privacy Rule, but are nonetheless permitted by the Privacy Rule, the provisions of this Agreement will control.

(d) Third Party Beneficiaries. STS and Participant agree that Individuals whose PHI is used or disclosed to 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.

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.

THE SOCIETY OF THORACIC SURGEONS

By: _____
Title: _____

Date:

SURGEON PARTICIPANT

By: _____
Title: _____

Date:

HOSPITAL PARTICIPANT (if any)

By: _____
Title: _____

Date: