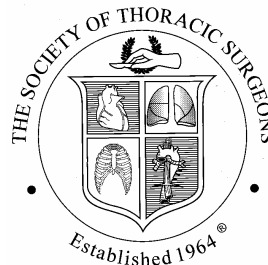


THE SOCIETY OF THORACIC SURGEONS

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April 21, 2003

Dear STS National Database Participant:

The Society of Thoracic Surgeons (STS) is pleased to enclose for your review and signature a copy of the final version of our Standard Form Business Associate Contract and Data Use Agreement (Standard Form Agreement) for execution by the appropriate individual(s) at your site. An instructions sheet has been included to help participants properly fill in the Standard Form Agreement. For those Participant Sites that signed the DRAFT version of our Standard Form Agreement, please note that the two enclosed copies of the final version are the copies that must be signed and sent back to the STS.

To Participant Sites that responded to our request for feedback, thank you. We received numerous comments and have made every attempt to evaluate them objectively. Based on participant input, changes have been made to the Standard Form Agreement that we feel are in the best interest of all Participant Sites. A redlined version of the Standard Form Agreement showing the changes that were made is also enclosed.

Some Participant Sites asked us to sign their own Business Associate (BA) Agreement instead of the Standard Form Agreement. The STS has concluded, however, that the unique needs of the National Database preclude STS from accepting Participant Sites' BA Agreements. The enclosed STS Standard Form Agreement is a special "hybrid" format, one that complies with the HIPAA Privacy Rule's provisions for both BA Contracts and Data Use Agreements. This "hybrid" structure, which is expressly permitted under the Privacy Rule, is designed to meet the current operational needs and requirements of the STS National Database and provide flexibility for expanded operations in the future.

The data that Participant Sites currently contribute to the National Database are partially de-identified and, hence, constitute Limited Data Set information. As such, these data can be used and disclosed to the STS and its agents or subcontractors under the HIPAA Privacy Rule in accordance with the rules for Limited Data Sets and Data Use Agreements. However, by expanding its provisions to satisfy the Privacy Rule's requirements for BA Contracts, the Standard Form Agreement provides the flexibility to permit you to disclose Protected Health Information beyond Limited Data Set information to the Database in the future without amending the Agreement should such a need arise.

The Privacy Rule also requires BA Contracts and Data Use Agreements to ensure that subcontractors agree to the same restrictions and conditions that apply to the Business Associate. To satisfy this requirement, the STS has negotiated a HIPAA Amendment Agreement with its subcontractor, Duke University's Clinical Research Institute (DCRI). This Amendment Agreement revises the STS existing contract with Duke under which Duke performs data aggregation and research functions in connection with the operation and maintenance of the STS National Database. At the same time, the Amendment Agreement also prohibits Duke from collecting or handling PHI beyond Limited Data Set information, unless it specifically agrees to comply with the relevant Business Associate provisions of the Standard Form Agreement.

As you can see, the STS Standard Form Agreement satisfies the unique needs of the STS National Database. The various BA Agreements that we received from Participant Sites cannot meet these needs and still allow the STS to carry out the responsibilities necessary for continued operation of the STS National Database. We

do acknowledge the concerns, expressed in several participants' e-mails and phone conversations, regarding use of our Standard Form Agreement instead of a given institution's BA Agreement. We trust that those participants can appreciate the special needs of the STS National Database. And we hope that any lingering concerns are not so critical that they preclude their execution of the Standard Form Agreement and continued participation in the STS National Database. Our timeline is intended to permit each Participant Site to enter into the STS Standard Form Agreement prior to its Database's next harvest so as not to put the Participant Site or its harvest information in jeopardy. For the Adult Cardiac Database, the next harvest is tentatively set for September 2003; for the Congenital Database, the next harvest is tentatively set for May 2003; and for the General Thoracic Database, the next harvest is tentatively set for October 2003. To ensure there is no lapse in your participation, we ask that you return the executed Standard Form Agreement to us as soon as possible.

We appreciate your continued support and interest in the STS National Database. We sincerely hope that together we will continue to have a positive impact on cardiothoracic surgery, today and in the future.

Sincerely,

A handwritten signature in black ink that reads "Mary C. Eiken". The signature is written in a cursive, slightly slanted style.

Mary C. Eiken RN, MS
Director, Quality, Research and Outcomes

cc: Frederick L. Grover, MD
T. Bruce Ferguson, MD
Mr. Robert A. Wynbrandt
Ms. Barbara A. Garren RN, MJ