



# The Society of Thoracic Surgeons National Database Managers' HIPAA UPDATE

Please share this correspondence with legal counsel at your site.  
October 17, 2003

At the beginning of the year the Society of Thoracic Surgeons (STS) sent a DRAFT version of the Standard Form Business Associate Contract and Data Use Agreement (Standard Form Agreement) to all Participating Sites that contribute to one of the three STS databases: Adult Cardiac, Congenital and General Thoracic. The DRAFT version was sent with the request that sites read the document and send suggestions for changing the content of the document. This "open comment period" resulted in many changes to the Standard Form Agreement based on suggestions from sites.

The FINAL version of the Standard Form Agreement was sent to all Participating Sites in late April/early May. To date, out of 579 sites, the STS has received 347 signed Standard Form Agreements. Therefore, there are 232 sites that have not signed the Standard Form Agreement.

You are receiving this HIPAA Update because our records indicate that the STS **does not** have a signed Standard Form Agreement for your site on file. The STS greatly encourages you to contact the appropriate people/departments at your institution to find out the status of the Standard Form Agreement. Unfortunately, we are not in the position to negotiate changes to the Standard Form Agreement because we have not heard from all sites. Because of the enormous administrative burden, the STS will not be able to individualize the Standard Form Agreements with sites. Therefore, we will need the agreement signed as is, without changes. For sites that have submitted suggested changes to the Standard Form Agreement after the "open comment period", we ask that you review the suggested changes to evaluate if the suggested changes are important or necessary enough to not allow your data to be included in future harvests and upcoming database research projects.

The first General Thoracic harvest will begin Monday, October 20, 2003. The STS has not received a signed Standard Form Agreement from 11 General Thoracic Sites, eight of which will not be able to participate in this month's harvest without signing a Standard Form Agreement. The STS and Duke Clinical Research Institute (DCRI) will not accept data from sites that have not signed the Standard Form Agreement. All General Thoracic Sites will need to have a signed Standard Form Agreement on file with the STS before they can participate in the October 2004 harvest.

The next Adult Cardiac harvest is scheduled for March 2004. The STS has not received a signed Standard Form Agreement from 220 Adult Cardiac Sites, two of which will not be able to participate in the March 2004 harvest without signing a Standard Form Agreement. The STS and DCRI will not accept data from sites that have not signed the Standard Form

Agreement. All Adult Cardiac sites will need to have a signed Standard Form Agreement on file with the STS before they can submit data in the August 2004 harvest.

The next Congenital harvest is scheduled for May 2004. The STS has not received a signed Standard Form Agreement from one Congenital site. All Congenital sites will need to have a signed Standard Form Agreement on file with the STS before they can participate in the May 2004 harvest. The STS and DCRI will not accept data from sites that have not signed the Standard Form Agreement.

If you have received the appropriate signatures for the Standard Form Agreement, please mail two copies to:

The Society of Thoracic Surgeons  
633 N. St. Clair  
Suite 2320  
Chicago, Illinois 60611  
Attn: Lauracyn Montgomery

Once the STS has received your signed copies, the Executive Director and General Counsel countersigns them. One copy will be mailed back to the Primary Data and File Contact at your institution, while the second copy remains at the STS. The turn around time for the STS to send back your signed version of the Standard Form Agreement is about seven business days from the day that it arrives at the STS. However, it is important to note that as soon as the signed copies of the Standard Form Agreement arrive at the STS you will be eligible to harvest.

If you have not received the standard form agreement or have questions pertaining to completing and signing the Standard Form Agreement, please contact Lauracyn Montgomery at 312-202-5833 or [lmontgomery@sts.org](mailto:lmontgomery@sts.org).

We look forward to receiving your signed Standard Form Agreement as soon as possible and to your continued participation in the STS National Database.