

**STS RESEARCH CENTER – PARTICIPANT USER FILE RESEARCH PROGRAM
DATA USE AGREEMENT**

THIS DATA USE AGREEMENT (the “Agreement”) is entered into and made effective the ___ day of _____, 20__ (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, 21st Floor, Chicago, Illinois 60611 (“STS”); (b) [_____], the Principal Investigator for the research project described herein, with a principal place of business at [_____] (the “Principal Investigator”); and (c) all investigators whose signatures appear on **Exhibit A** attached hereto and incorporated herein (collectively, the “Investigative Team”). STS, the Principal Investigator and the Investigative Team are each a Party to this Agreement, and are collectively referred to herein as the “Parties.”

WHEREAS, STS has developed and owns certain computerized databases containing information relating to patient treatment and the practice of medicine, and certain surgeons and hospitals (collectively referred to herein as the “Participants”) submit data to these databases pursuant to STS rules (said databases collectively referred to herein as the “STS National Database” or the “Database”);

WHEREAS, in compliance with the requirements established under the STS Research Center’s Participant User File Research Program, the Principal Investigator has submitted an application and an accompanying application review fee to STS, requesting the creation of a customized electronic data file containing certain de-identified data extracted from the STS National Database to be used by the Investigative Team in a specific research project as set forth in the application (said data file referred to herein as the “PUF”);

WHEREAS, the application was reviewed by STS’s PUF Task Force, which approved the application, either as submitted or as conditioned on changes specified by the PUF Task Force (said application and specified modifications, if any, attached hereto and incorporated herein as **Exhibit B** and collectively referred to herein as the “Application,” with the research project described in the Application referred to herein as the “Project”);

WHEREAS, the PUF Task Force assigned the following unique study number and title to the Project:

PUF Study Number: _____
Project Title: _____

WHEREAS, the Investigative Team wishes to obtain a license from STS to receive and use the PUF and the data contained therein in connection with the Project, subject to the terms and conditions set forth in this Agreement; and

WHEREAS, STS wishes to grant the Investigative Team a license to receive and use said PUF and the data therein, so as to increase the usefulness and impact of the Database on quality of care and improved patient outcomes;

NOW THEREFORE, in consideration of the foregoing recitals and the mutual promises and conditions contained herein, and for other good and valuable consideration, the Parties agree as follows:

1. PUF. Provided that the Investigative Team complies with the terms and conditions of this Agreement, including but not limited to payment of all applicable royalties and fees, STS will cause its independent data warehouse service provider (the “Data Warehouse”) to prepare and send to the Principal Investigator the PUF in the form of an electronic file containing data formatted as a comma-separated-value file, Microsoft Excel file, or other format on which the Parties mutually agree, on password-protected media, reflecting certain de-identified data in the STS National Database that are described in the Application.

(a) The PUF provided will contain de-identified data only and will not identify specific Participants, individual surgeon or hospital components thereof, or patients.

(b) The Investigative Team will use the PUF provided pursuant to this Agreement solely in connection with the Project, and in the manner set forth in the Application and the terms of this Agreement.

(c) STS makes no representations or warranties as to the accuracy or completeness of the PUF or the data contained therein, and disclaims responsibility for any errors in such PUF that are caused by inaccuracies or incompleteness of the underlying data.

2. Dissemination of Research Results. The Investigative Team shall seek to disseminate the results of the Project in the form of a scientific research abstract and/or a manuscript, and shall do so in a manner that is not false or misleading, as follows:

(a) The Investigative Team shall ensure that all proposed abstracts and manuscripts arising from its use of the PUF and the data contained therein are submitted to STS for review and comment at least fifteen (15) days prior to meeting abstract submission deadlines, and at least thirty (30) days prior to journal article submission deadlines. The PUF Task Force will provide timely feedback to Principal Investigator, and a representative of the PUF Task Force will discuss with the Principal Investigator in good faith all comments and suggested edits for the benefit of the Project. If STS disagrees with the presentation or interpretation of the data in a proposed abstract or manuscript, then the Investigative Team shall delay submission for an additional period not to exceed thirty (30) days for the purpose of meeting with STS representatives to attempt in good faith to resolve the disagreement. It is understood and agreed that if STS still disagrees with the presentation or interpretation of data in the proposed abstract or manuscript after such meeting, then STS may require the Investigative Team to ensure that the author(s) both add the disclaimer below as a part of any abstract submission process and/or as a prominent footnote, preferably on the title page of any manuscript, and include in the presentation of any abstract a slide consisting of the following text that will be read aloud:

“The views or opinions presented in this document (or abstract or presentation as applicable) are solely those of the author(s), and do not represent those of The Society of Thoracic Surgeons.”

Without limiting the generality of the foregoing, STS reserves the right to publicly critique the output of the Project as it deems appropriate.

(b) The Investigative Team hereby acknowledges the strong suggestion of STS that the Investigative Team target the STS Annual Meeting and *The Annals of Thoracic Surgery* as the meeting and publication forums, respectively, for dissemination of the Investigative Team's PUF-based research. The Investigative Team further agrees and acknowledges that pursuant to STS policy, if PUF research output is presented at the STS Annual Meeting, then the Investigative Team is required to submit a manuscript derived from that presentation to *The Annals of Thoracic Surgery* for publication, provided that the Investigative Team may seek a waiver of said requirement from the STS Board of Directors or Executive Committee, and that in exceptional circumstances such a waiver may be granted.

(c) The Investigative Team shall ensure that any published article utilizing PUF data recognize the STS Participant User File Research Program contribution by including the following statement in its Acknowledgement (or equivalent) section:

“The data for this research were provided by The Society of Thoracic Surgeons' National Database Participant User File Research Program. Data analysis was performed at the investigators' institution(s)”.

3. Intellectual Property. It is agreed and acknowledged that STS owns all right, title, and interest in, including all intellectual property rights to, the PUF to be provided hereunder, the aggregated data included therein, and any information (including but not limited to risk-adjusted or other calculated output, risk models or other models, or formulae) derived through any use of the PUF or the data contained therein.

4. License

(a) STS grants the Investigative Team a non-exclusive, time-limited, world-wide license to use the PUF generated pursuant to this Agreement solely for the purposes authorized herein, and the Investigative Team may not further reproduce, distribute, use, or disclose said PUF or any data contained therein except as otherwise approved by STS in writing. Without limiting the generality of the foregoing, the Investigative Team will create and maintain appropriate safeguards to prevent any further unauthorized reproduction, distribution, use, or disclosure by its own personnel or by any third parties.

(b) The Investigative Team will report promptly to STS any reproduction, distribution, use, or disclosure of the PUF or any data contained therein that is not permitted by this Agreement of which the Investigative Team becomes aware.

(c) The Investigative Team acknowledges and agrees that the PUF generated pursuant to this Agreement may contain proprietary information, including trade secrets, know-how and confidential information that is the exclusive property of STS and/or Participants. The Investigative Team and its members' respective employees and agents shall maintain the confidentiality of this information, and shall not sell, license, publish, display, distribute, disclose

or otherwise make available this information to any third party nor use such information except as authorized by this Agreement. The restrictions in this Subsection 4(c) will not apply to information that is: (i) already known to or otherwise in the possession of the Investigative Team at the time of receipt from STS and that was not known or received as the result of violation of any obligation of confidentiality; (ii) publicly available or otherwise in the public domain prior to disclosure by STS; (iii) rightfully obtained by the Investigative Team from a third party having a right to disclose such information without restriction and without breach of any confidentiality obligation by such third party; (iv) developed by the Investigative Team independent of any disclosure hereunder, as evidenced by written records; or (v) disclosed pursuant to the order of a court or administrative body of competent jurisdiction or a government agency, provided that the Investigative Team shall promptly notify STS prior to such disclosure and shall cooperate with STS in the event STS elects to legally contest, request confidential treatment of, or otherwise avoid such disclosure.

5. Royalties and Fees. As consideration for the intellectual property licensed by STS under this Agreement, the Principal Investigator (on behalf of himself or herself and the Investigative Team) shall pay to STS as a royalty an amount based on the volume of data to be provided by STS in accordance with the Application, computed in accordance with the formula set forth in Exhibit C attached hereto and incorporated herein, within thirty (30) days after receipt of an invoice therefor from STS. In addition, if the Principal Investigator requests support from STS in connection with the intellectual property licensed by STS under this Agreement (see Subsection 7(f)), any such support that STS agrees to provide shall be provided for a fee to be agreed upon in advance. STS shall have no obligation to provide the PUF or otherwise perform any of its obligations under this Agreement until it has received full payment of all monies owed hereunder.

6. Representations and Warranties. The Investigative Team and each of its members individually jointly and severally make the following representations and warranties, and acknowledges that STS has relied upon them in making this Agreement:

(a) Exhibit A hereto and the Application attached hereto as Exhibit B accurately and truthfully set forth the experience, institutional resources and capacity of the Investigative Team to carry out the Project, and identifies all individuals, including a PhD biostatistician (or equivalent individual approved in advance by the PUF Task Force), who will actively participate in the Project.

(b) Exhibit B accurately reflects any revisions to the Project mandated by the PUF Task Force as a condition of its approval.

(c) The Principal Investigator is currently a Surgeon Participant in the STS National Database in good standing, one of the surgeons in a group that comprises a Surgeon Participant in the STS National Database in good standing, or a research scientist who is affiliated with a Hospital Participant in the STS National Database in good standing.

(d) The statistical analysis for the Project will be conducted by the members of the Investigative Team that have a checkmark in the box next to their name on Exhibit A hereto, as modified from time to time upon the review and approval of the PUF Task Force as provided in Subsection 7(d), and only by the foregoing persons.

(e) The Project is currently the only active study based on an STS participant user file where the Principal Investigator is serving as a principal investigator. "Active," as used in the foregoing sentence, means before formal submission of a manuscript for publication.

(f) The Application only describes a PUF containing data fields from the STS National Database that are pertinent to the research aim of the Project, and does not seek a broad download of data from the STS National Database without justification.

7. Additional Terms and Conditions. The Investigative Team and each of its members individually jointly and severally agree to comply with the following additional terms and conditions governing the Project and use of the PUF, the failure to comply with any one of which constitutes a material breach for purposes of Subsection 8(b):

(a) Any material changes to the Application must be presented by the Principal Investigator to the PUF Task Force, whose approval must be obtained prior to implementation of such changes. The Investigative Team acknowledges that, depending on the nature of the proposed changes, the PUF Task Force may need to conduct an additional internal review, and that STS provides no assurance that the PUF Task Force will approve the proposed changes.

(b) The PUF is licensed only for use in association with the Project. In rare instances, deriving from the PUF an additional related abstract or manuscript may be justifiable, but any such additional use of the PUF may necessitate payment of additional fees (to be determined by STS) and shall be permissible only with the advance written approval of the PUF Task Force, which approval may be withheld or denied at the sole discretion of the PUF Task Force. The PUF and any copies of the data therein must be destroyed within one year after the Application is approved. Upon request of STS, the Principal Investigator will provide a Declaration of Document Destruction substantially in the form of **Exhibit D** attached hereto and incorporated herein.

(c) The Principal Investigator shall submit progress reports to the PUF Task Force at least once every two months from the date of receipt of the PUF until completion of the Project.

(d) The Principal Investigator will promptly inform the PUF Task Force of any change in the identity and/or institutional affiliation of each member of the Investigative Team performing statistical analysis for the Project, and in particular any change affecting the biostatistics resources available to the Investigative Team. The Investigative Team shall suspend any statistical analysis for the Project until the PUF Task Force has reviewed and approved any such change.

(e) Any individuals added to the Investigative Team must add their names and signatures to Exhibit A hereto.

(f) If research support from STS Research Center personnel is desired, any request for such support must be made by the Principal Investigator. Such requests will be evaluated by STS on a case by case basis; the ability to grant them will depend on the available resources within the STS Research Center, and may require the payment of additional fees to

STS. The Principal Investigator and STS shall agree on the amount of such additional fees, if any, to be paid to STS before any additional research support is provided.

(g) The Investigative Team is expected to complete the Project within 6 months, depending on the scope and complexity of the Project. The Investigative Team acknowledges that if the Project is not completed within 6 months, the PUF Task Force may approve a similar or closely related proposal submitted by other investigators unless the PUF Task Force has granted an extension.

(h) The Principal Investigator will hold the primary scientific roles on the Project, including materially participating in the actual research effort, eventual authorship and other related responsibilities.

(i) The Principal Investigator will not submit any other application for proposed research based on an STS participant user file in which he or she is to be the principal investigator as long as the Project output has not yet formally been submitted as a manuscript for publication.

(j) The Principal Investigator shall not submit any application for proposed research based on an STS participant user file in which he or she is to be the principal investigator within one year of approval of the Application.

(k) The PUF contains only de-identified data and does not contain any “protected health information” or any information that could identify Participants, individual surgeon or hospital components thereof, or patients, and therefore is outside the scope of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, as amended.

(l) The PUF and the data contained therein shall not be used by the Investigative Team to link to other sources of medical data (e.g., CMS Medicare Data).

8. Term and Termination

(a) Term. This Agreement will commence as of the Effective Date and will remain in effect until the Parties have satisfactorily fulfilled all of their obligations hereunder unless the Agreement is terminated sooner in accordance with Subsection (b) of this Section 8, provided that Sections 3, 4, 9, 15, and 16 herein shall survive any termination or expiration of this Agreement.

(b) Termination for Material Breach. Any Party may terminate this Agreement based upon a material breach of this Agreement by any other Party, provided that the non-breaching Party seeking to terminate this Agreement gives the breaching Party at least thirty (30) days written notice and the opportunity to cure such breach (copy to the other Party), and the breach is not cured during the notice period. In the event such material breach is not cured, the non-breaching Party seeking to terminate this Agreement 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 seeking to terminate this Agreement may terminate this Agreement immediately and without any notice.

9. Indemnification. The Investigative Team and each of its members individually jointly and severally agree to defend, indemnify, save and hold harmless STS and the Data Warehouse from and against any and all claims, costs and expenses (including attorneys' fees and expenses), demands, actions and liabilities of every kind and character whatsoever arising or resulting in any way from the Investigative Team's breach of its obligations under this Agreement and/or use or disclosure of any data obtained from STS or the Data Warehouse hereunder, absent the gross negligence or willful misconduct of the entity seeking indemnification. All of the foregoing rights of indemnification shall apply to any expenses incurred by STS and the Data Warehouse in defending themselves, respectively, against claims covered by this indemnification, including but not limited to claims of gross negligence or willful misconduct, unless a court of competent jurisdiction concludes in a final judgment that such party seeking indemnification has committed gross negligence or willful misconduct.

10. Entire Agreement; Amendment. This Agreement (a) constitutes the entire agreement between the Parties hereto with respect to the subject matter hereof; (b) supersedes and replaces all prior agreements, oral or written, between the Parties relating to the subject matter hereof; and (c) except as otherwise indicated herein, may not be modified, amended or otherwise changed in any manner except by a written instrument executed by the Party against whom enforcement is sought.

11. Independent Contractors. The relationship between STS on the one hand and the remaining Parties on the other hand is that of independent contractors, and not that of master and servant, principal and agent, employer and employee, or partners or joint venturers.

12. 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.

13. Severability. All provisions of this Agreement are severable. If any provision or portion hereof is determined to be unenforceable by a court of competent jurisdiction, then the rest of this Agreement shall remain in full effect, provided that its general purposes remain reasonably capable of being effected.

14. Assignment. This Agreement may not be assigned by any Party without the written consent of the other Parties.

15. Governing Law and Forum. All disputes regarding the meaning, effect, force or validity of this Agreement shall be determined according to federal law and the law of the State of Illinois. The Parties expressly agree that the federal and state courts located in Cook County, Illinois, are the most reasonable and convenient forums for resolutions of any such disputes, and designate said courts as the exclusive forums in which all such disputes shall be litigated. Accordingly, the Parties consent to the jurisdiction and venue of, and service of process by, said courts. Each Party agrees that the provisions of this paragraph are specifically enforceable, and that it shall pay all expenses, damages, and costs (including attorneys' fees and expenses) of the other Parties if it commences, prosecutes, or permits to continue any actions in any other forum.

16. Equitable Relief. The Parties understand and agree that money damages may not be a sufficient remedy for the breach of the provisions of this Agreement, and that each Party shall be entitled to emergency injunctive relief as a remedy for any such breach by any other

Party. Such remedy shall not be deemed to be the exclusive remedy for the breach of this Agreement, but shall be in addition to all other remedies available at law or in equity to the non-breaching Party. Each Party agrees that the provisions of this paragraph are specifically enforceable, and that it shall pay all expenses and costs (including attorneys' fees and expenses) of any other Party if said other Party is successful in securing equitable relief as a remedy.

17. Notices. All notices and demands of any kind or nature which any Party to this Agreement may be required or may desire to serve upon the other in connection with this Agreement shall be in writing, and may be served personally, by registered or certified United States mail, by facsimile transmission, or by overnight courier (e.g., Federal Express or DHL) to the following addressees:

If to the Principal Investigator: _____

(fax #) _____

If to the Investigative Team: _____, Principal Investigator

(fax #) _____

If to STS: Executive Director
The Society of Thoracic Surgeons
633 North Saint Clair Street, 21st Floor
Chicago, Illinois 60611-3658
(fax #) 312/202-5801

Service of such notice or demand so made shall be deemed complete on the day of actual delivery. Without limiting the generality of the foregoing, if notice is given by facsimile transmission, such notice shall be deemed to be provided upon confirmation of the receipt of the transmission. Any Party hereto may, from time to time, by notice in writing served upon the other Parties as aforesaid, designate a different mailing address or a different person to which all further notices or demands shall thereafter be addressed.

[Remainder of page intentionally blank]

18. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be considered an original, and all of which taken together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the Parties hereto have entered into this Agreement as of the Effective Date.

THE SOCIETY OF THORACIC SURGEONS

By: _____
Its: _____

PRINCIPAL INVESTIGATOR

INVESTIGATIVE TEAM

By: [Type name of Principal Investigator]

EXHIBIT A

INVESTIGATIVE TEAM:

Principal Investigator:

Name	Signature	Academic institution or hospital	<input type="checkbox"/> Providing statistical analysis services
------	-----------	----------------------------------	---

Additional Investigators:

Name	Signature	Academic institution or hospital	<input type="checkbox"/> Providing statistical analysis services
------	-----------	----------------------------------	---

Name	Signature	Academic institution or hospital	<input type="checkbox"/> Providing statistical analysis services
------	-----------	----------------------------------	---

Name	Signature	Academic institution or hospital	<input type="checkbox"/> Providing statistical analysis services
------	-----------	----------------------------------	---

Name	Signature	Academic institution or hospital	<input type="checkbox"/> Providing statistical analysis services
------	-----------	----------------------------------	---

Name	Signature	Academic institution or hospital	<input type="checkbox"/> Providing statistical analysis services
------	-----------	----------------------------------	---

Name	Signature	Academic institution or hospital	<input type="checkbox"/> Providing statistical analysis services
------	-----------	----------------------------------	---

Name	Signature	Academic institution or hospital	<input type="checkbox"/> Providing statistical analysis services
------	-----------	----------------------------------	---

Name	Signature	Academic institution or hospital	<input type="checkbox"/> Providing statistical analysis services
------	-----------	----------------------------------	---

PUF Study Number: _____

EXHIBIT B

Application

With Any Modifications Required by PUF Task Force

EXHIBIT C

Royalty Rate

The royalty payable pursuant to this Agreement shall be \$2,000.00 plus the applicable amount shown in the chart below, based on the volume of data points (defined as the number of data elements requested per patient record multiplied by the number of patient records) in the requested PUF:

Volume of Data Points Resulting from Request	Amount
Standard Volume (< 1 Million Data Points)	\$2,500.00
Large Volume (1 to < 5 Million Data Points)	\$5,000.00
Very Large Volume (5 to 50 Million Data Points)*	\$7,500.00

*PUF requests exceeding the very large volume of 50 million data points must be justified, and will be considered for approval by the PUF Task Force on a case by case basis. If approved, such PUF requests may incur additional royalty charges.

EXHIBIT D

Declaration of Document Destruction

_____, subject to penalties of perjury, hereby deposes and states as follows:

1. My name is _____, and I am over the age of twenty-one and I have personal knowledge of the facts stated herein.

2. I am the Principal Investigator in Participant User File (“PUF”) Study No. _____ titled _____. I am a party to that certain Data Use Agreement into which an investigative team and I entered with The Society of Thoracic Surgeons dated _____, 20__ (the “DUA”). This Declaration is provided at the request of STS in accordance with Subsection 7(b) of the DUA.

3. The PUF that was provided to me in connection with the DUA, and all copies of the data therein in my possession or in the possession of the Investigative Team (as defined in the DUA), have been destroyed.

4. I declare under penalty of perjury that the foregoing is true and correct. This Declaration is prepared in accordance with 28 U.S.C. § 1746.

Executed on (date): _____

Printed Name: _____