



PTOS Data Application and Data Use Agreement

2025

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Pennsylvania Trauma Outcome Study (PTOS)
Research Data Application and Agreement

Overview

Thank you for your interest in obtaining data from the Pennsylvania Trauma Systems Foundation (PTSF) Statewide Trauma Registry Database (PTOS). The PTOS contains data submitted by Pennsylvania trauma centers that are accredited by PTSF (“Accredited Trauma Centers”) since 1986 and is regarded as one of the premier trauma databases in the United States. PTSF and its staff manage and ensure the integrity of the database through a variety of automatic and manual data processing steps in addition to assuring ongoing training requirements for Accredited Trauma Center registrars to assure quality data abstraction and submission.

PTOS data is made available to researchers to facilitate trauma systems research and trauma outcomes studies and ultimately improve trauma care in the Commonwealth of Pennsylvania and beyond.

Research data is provided for certain specific data elements in the PTOS database only as specifically requested by the applicant as necessary for the purposes of the particular research study.

General Requirements:

1. PTSF provides certain PTOS data to requestors for purposes of conducting trauma -related research studies. Please provide the following related to the specific research study:
 - A. Complete the attached data application. Proposals are subject to review by the PTSF Research Committee with available mentoring by the committee.
 - B. Provide a signature of support from the Trauma Medical Director if the research is being conducted by staff at an Accredited Trauma Center. This is not required for out of state researchers not affiliated with an Accredited Trauma Center.
 - C. Provide a letter from the Internal Review Board (IRB) showing evidence of review and support specific to the study.
 - D. Within two years of receiving data submit a research abstract to PTSF. Additionally, you may be asked to present your abstract at the PTSF annual fall conference at the PTSF Research Committee’s discretion.
 - E. Within thirty (30) days of completing the PTSF-approved research project described in this PTOS Data Application, which must occur no later than two years from the receipt of data, submit the data destruction attestation form attached at Appendix B to PTSF certifying the destruction and discontinued use of the data, including any and all original files, copies made of the files, any derivatives or subsets of the files and any manipulated files.
2. Note in the application the type of data being requested and applicable fees.

3. Read and then sign the PTOS Data Use Agreement acknowledging terms and conditions.

I. PTOS Data Fees

Fees

PTSF charges Requestors the cost-based fee to cover the cost of making PTOS data available. Fees are charged at the rate of \$100/hr for labor necessary to query the database and submit the data. PTSF will provide a cost estimate based on the specific data upon request. The fee for Requestors at a PA accredited trauma center is waived because it is included in the cost of accreditation.

Data Sets

Data sets are given for certain available data elements in the PTOS database only as specifically requested by the applicant for the particular research study and, unless an exception is granted by PTSF, for a one to ten-year time period, as necessary for the purposes of the study. Researchers will need indicate in their application the data elements and timeframe necessary for their research study. The data elements and timeframe requested must be the minimum necessary to achieve the purposes of the study.

Questions? Please contact Stephanie Radzevick at the Pennsylvania Trauma Systems Foundation at (717) 697-5512 ext. 109 or sradzevick@ptsf.org

II. PTOS Data Application: Contact Information

Name of Primary Contact:

Organization:

Phone Number:

Email Address:

Preferred Mailing Address:

FEE CATEGORY ACKNOWLEDGEMENT(check appropriate category)

☐ Requestor is PTSF Accredited Trauma Center - No separate fee (included in cost of accreditation)

☐ Requestor is not at a PTSF Accredited Trauma Center

DATA SET

Please list data elements and timeframe requested below. These elements and timeframe requested must be the minimum necessary to achieve the purposes of the study. For a list of data elements, please contact Stephanie Radzevick, PTSF Trauma Data Analyst, for a copy of the current PTOS Manual.

PTOS Data Application: Research Proposal
For Completion by Organizations using PTOS for research

Title of Proposal:

Calendar years the data should be queried for:

Full Name of Principle Investigator:

Title:

Country of Residence:

Country of Citizenship:

Employer Name:

Employer Address:

Contact Information:

Regulatory Questions:

- a. Is your primary residence in a "Country of Concern," as defined in 28 CFR 202.209 and as may be designated pursuant to 202.601 (currently designated as China (including Hong Kong and Macau), Cuba, Iran, North Korea, Russia, and Venezuela)?

☐ Yes

☐ No

- b. Have you been designated a "Covered Person" by the U.S. Attorney General pursuant to 28 CFR 202.211(a)(5) and/or 202.701?

☐ Yes

☐ No

- c. Are you employed by the government of a Country of Concern?

☐ Yes

☐ No

- d. Are you employed by an entity that has a primary place of business in or was formed under the laws of a Country of Concern?

☐ Yes

☐ No

- e. Are you employed by an entity that is otherwise deemed a “Covered Person” under the regulations at 28 CFR 202.211 as a result of its ownership (50% or greater, direct or indirect, individual or aggregate, ownership by a Country of Concern or Covered Person (including any entity that is a Covered Person))?

☐ Yes

☐ No

Purpose/Specific Aims (limit to one page): Concisely state the intended purpose and scope of the proposed project. Present the rationale for your project. Clearly specify the research questions, hypothesis, or system components this research is designed to answer. References are suggested.

Methodology and Timetable: Clearly specify the patient population being requested. Be sure to include age ranges and/or applicable diagnosis or procedure codes. Include the proposed timetable for the study/project and anticipated date of completion. Discuss the plans for analysis/interpretation of the data.

Dissemination: Specify where and when the research is expected to be presented or published.

Third Party Disclosure: Answer the following questions to identify any third party to whom you will, or for whom there is a possibility that you may, disclose the research and/or the data, e.g., a sponsor, a co-researcher, etc. Please use additional sheets if necessary. All third parties that will need access to data for the research study must be approved by PTSF and also execute a data use agreement.

Full Name of Individual:

Title:

Country of Residence:

Country of Citizenship:

Employer Name:

Employer Address:

Additional Contact Information:

Regulatory Questions:

- a. Is your primary residence in a “Country of Concern,” as defined in 28 CFR 202.209 and as may be designated pursuant to 202.601 (currently designated as China (including Hong Kong and Macau), Cuba, Iran, North Korea, Russia, and Venezuela)?

☐ Yes

☐ No

- b. Have you been designated a “Covered Person” by the U.S. Attorney General pursuant to 28 CFR 202.211(a)(5) and/or 202.701?

☐ Yes

☐ No

- c. Are you employed by the government of a Country of Concern?

☐ Yes

☐ No

- d. Are you employed by an entity that has a primary place of business in or was formed under the laws of a Country of Concern?

☐ Yes

☐ No

- e. Are you employed by an entity that is otherwise deemed a “Covered Person” under the regulations at 28 CFR 202.211 as a result of its ownership (50% or greater, direct or indirect, individual or aggregate, ownership by a Country of Concern or Covered Person (including any entity that is a Covered Person))?

☐ Yes

☐ No

III. APPENDIX A:
PTOS Data Use Agreement
Terms and Conditions for the Use of PTOS

This Data Use Agreement ("Agreement") is effective as of the date executed below ("Effective Date") and is made between Pennsylvania Trauma Systems Foundation ("PTSF") and
[Organization requesting data from the PTOS database]
("Requestor"). This Agreement governs the disclosure and use of data from the PTSF Statewide Trauma Registry Database ("PTOS") to Requestor. Requestor must sign and submit this Agreement with the PTOS Data Application shall comply with the following terms and conditions at all times:

- A. This Agreement incorporates the terms and conditions set forth in the PTOS Data Application and any policy, guidance or instruction provided by PTSF related to the PTOS database.
- B. The Principal Investigator identified in the Application will be the primary responsible party on behalf of Requestor.
- C. All correspondence will be directed to the Primary Contact as listed on the Application.
- D. Requestor is responsible for its compliance, including by its employees, directors, managers, subcontractors, agents and volunteers, with the terms and conditions of this Agreement at all times to the exclusion of any other party, regardless of such party's role in sponsoring or funding the research.
- E. Requestor recognizes that data obtained from the PTOS database is highly confidential and the data set requested may comprise a Limited Data Set, as defined under the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations ("HIPAA"). PTOS data may only be used to conduct the research project as described in the PTOS Data Application as approved by PTSF and not for any other purpose,
- F. Regulatory Compliance: For the purposes of this Section, "Data User" shall mean any person who has access to the PTOS data under this Agreement. Requestor attests that:
 - a. Each Data User is not a Covered Person, as defined in 28 CFR 202.211.
 - b. Each Data User is not employed by a Country of Concern as defined in 28 CFR 202.209.
 - c. Each Data User is not employed by a Covered Person, as defined in 28 CFR 202.211.
 - d. If at any time any of these attestations become untrue, Requestor will immediately terminate access to any PTOS data for such Data User and Requestor shall immediately contact PTSF to provide notice of any change, including any change in a Data User's status as a Covered Person, employment by a Country of Concern or Covered Person.
- G. PTOS data shall not be shared with any third party, including, but not limited to, a Covered Person as defined in 28 CFR 202.211, to a Country of Concern as define in 28 CFR 202.209, to an affiliated entity in the same health system. another hospital

participating in the research study, a contractor, etc. except upon express written permission by PTSF and only following the submission of a completed PTOS Data Application to PTSF, approval by the PTSF Research Committee, and execution of the PTSF Data Use Agreement by such third party, except to the extent PTSF determines Section U applies.

- H. PTOS data shall not be used or disclosed for another research study, except with written consent from PTSF.
- I. Requestor shall not use or further disclose the information other than as permitted by this Agreement or as otherwise required by law and shall not use or disclose PTOS data in any manner that would violate the requirements of HIPAA, if done by a Covered Entity, as that term is defined by HIPAA.
- J. The trauma-related research project identified on the PTOS Data Application shall at all times have direct relevance and applicability to a trauma patient or evaluation of the trauma system.
- K. The Requestor affirms that the requested data is the minimum necessary to achieve the purposes of the research study described in the Application.
- L. Requestor shall not use, disclose, store, transmit, or access any data outside of the continental United States without PTSF's prior written consent.
- M. PTOS contains data provided by Accredited Trauma Centers whose staff is trained by PTSF staff to assure quality data abstraction and submission based on training modules developed by PTSF. However, PTSF makes no representation, guarantee or warranty, express or implied, that the data are error-free or that other parties will agree with the results of any research using the data. PTSF is not responsible or liable for the results or consequences of its use.
- N. The following disclaimer must be used for any research published utilizing PTOS data:

THESE DATA WERE PROVIDED BY THE PENNSYLVANIA TRAUMA SYSTEMS FOUNDATION, MECHANICSBURG, PA. THE FOUNDATION SPECIFICALLY DISCLAIMS RESPONSIBILITY FOR ANY ANALYSES, INTERPRETATIONS, OR CONCLUSIONS.

- O. Published studies utilizing PTOS must be shared with PTSF.
- P. Requestor shall use appropriate safeguards to protect the confidentiality of the data and to prevent use or disclosure of the information other than as provided for by the data use agreement. Requestor shall store, maintain, and use PTOS data only in a secure

environment, e.g., at all times on encrypted information systems based on industry-standard encryption standards.

- Q. PTSF reserves the right to approve or deny a request for data at its discretion and to modify fees at any time.
- R. Requestor will destroy the data following the conclusion of the PTSF-approved research project described in the PTOS Data Application, within thirty (30) days of completing the PTSF-approved research project described in the PTOS Data Application which must occur no less than two years following receipt, unless the requestor has obtained permission in writing from PTSF to maintain the data for continued research use and explained how it will ensure that the data will remain confidential. PTSF shall review such request and approve or deny it in its sole discretion. At any time PTSF may request from Requestor information on the status of the research study. A data destruction attestation form must be submitted to PTSF to verify destruction within thirty (30) days of completing the PTSF-approved research project described in the PTOS Data Application.
- S. Requestor will be fully responsible for the costs related to a breach of the data in violation of federal or state law or this Agreement, or any other violation of this Agreement.
- T. Requestor acknowledges that data elements in the data and the software that supports the PTOS database or such data elements may be proprietary to PTSF, a vendor or another third party, and Requestor agrees to not use, and to the extent that PTSF has approved disclosures to any third parties to prohibit any such third parties from using, any such data elements or software for any other purpose other than as permitted under this Agreement. Requestor further agrees not to disassemble, decompile, or otherwise reverse-engineer any such data elements or software and also will prohibit others from doing so.
- U. To the extent that PTSF has approved disclosures to any third party contractor, as determined by PTSF in its sole discretion, Requestor shall ensure that any such third party contractor agrees in writing to the same restrictions, conditions, obligations, and attestations that apply through this Agreement to Requestor with respect to such information and shall provide a copy of such agreement to PTSF upon request.
- V. Requestor shall not re-identify or attempt to re-identify any information or contact or attempt to contact the individuals who are the subject of the information.
- W. Requestor will indemnify, defend, and hold harmless PTSF, including any employees, contractors, directors, officers, agents, or volunteers, including individuals who serve on the PTSF Research Committee and other committees, and the Accredited Trauma Centers that provide data to PTOS from any or all liability, damages, expenses, fees (including reasonable attorney's fees), fines, claims and losses accruing to any person, organization, or other legal entity as a result of violation of this Agreement. This section shall survive termination of this Agreement.

- X. Requestor will report any actual or suspected violation or apparent violation of any term of this Agreement, including, but not limited to, any use or disclosure of the PTOS data not provided for by this Agreement of which it becomes aware, to PTSF without unreasonable delay and in no case later than five (5) calendar days of becoming aware of the actual, suspected or apparent violation.
- Y. Upon request by PTSF, Requestor shall provide PTSF with information concerning Requestor's use or disclosure of PTOS data, and any safeguards, policies and procedures and written agreements related to the use and disclosure of PTOS data or other information reasonably requested by PTSF for the purpose of enabling PTSF to investigate or audit the Requestor's compliance with the terms of this Agreement. Requestor acknowledges that PTSF has the right, but not the obligation, to conduct an audit of Requestor's use and disclosure of PTOS data in order to verify Requestor's compliance with this Agreement.
- Z. The term of this Agreement shall be effective as of the Effective Date and shall continue for as long as Requestor maintains any data provided by PTSF or until terminated as set forth below.
- AA. This Agreement may be terminated by PTSF upon 30 days prior written notice to Requestor. PTSF may terminate this Agreement immediately upon written notice to Requestor if PTSF determines in its discretion that Requestor has violated or breached any term of this Agreement. In the event that PTSF determines that Requestor has violated the terms of this Agreement, PTSF shall determine in its sole discretion what corrective actions if any shall be undertaken including but not limited to providing notice of the termination or violation to affected parties and prohibiting Requestor from receiving PTOS data in the future.
- BB. In the event that PTSF terminates this Agreement, Requestor shall immediately return or destroy all copies of the data or reports provided by PTSF without refund of fees.
- CC. PTSF reserves the right to pursue any claim against Requestor for violation of this Agreement as permitted under law, including in equity or for damages.
- DD. No person may release PTOS data in response to a subpoena or court order (or on the basis that a disclosure is required by law) without immediate, written notification to PTSF of such potential release. PTSF reserves the right to respond and/or intervene in order to ensure the protection of the data.
- EE. This Agreement shall be governed by and construed and enforced in accordance with the laws of the Commonwealth of Pennsylvania, without reference to conflicts of laws principles.

FF. Any ambiguity in this Agreement will be resolved in favor of a meaning that permits the PTSF to comply with HIPAA and any other applicable federal or state law.

GG. Failure of PTSF to enforce any of the provisions of this Agreement, or of any rights with respect thereto, or failure to exercise any election provided for herein, shall in no way be considered a waiver of such provisions, rights or elections, or in any way affect the validity of this Agreement. The failure by PTSF to enforce any of such provisions, rights, or elections shall not prejudice PTSF from later enforcing or exercising the same or any other provisions, rights or elections which it may have under this Agreement.

HH. This Agreement constitutes the entire understanding and agreement between the parties concerning the subject matter of this Agreement, and supersedes all prior negotiations, agreements and understandings between the parties, whether oral or in writing, concerning its subject matter. It may not be amended or modified except through a later written agreement, signed by both parties,

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be signed by their duly authorized representatives below.

REQUESTOR: [Organization requesting data]

Name:

Signature:

Title:

Date:

REQUESTOR'S TRAUMA PROGRAM MEDICAL DIRECTOR
(if Requestor is Accredited Trauma Center)

Name:

Signature:

Title:

Date:

PRINCIPAL INVESTIGATOR

Name:

Signature:

Title:

Date:

PENNSYLVANIA TRAUMA SYSTEMS FOUNDATION

Name:

Signature:

Title:

Date:

Assurance of Compliance with Data Use Agreement

The following research team members at Requestor need access to the data for purposes of conducting the research study listed in the Data Application. By signing below, the following individuals certify that the statements in this proposal are true and complete and acknowledge and agree to the obligation to comply with the terms and conditions of the access and use of data from the PTSF PTOS Database as set forth in this PTOS Data Use Agreement.

PRINCIPAL INVESTIGATOR

Name:

Signature:

Title:

Date:

RESEARCH TEAM MEMBERS AT REQUESTOR WHO NEED ACCESS TO DATA FOR STUDY (Add additional signature lines as necessary)

Name:

Signature:

Title:

Date:

Name:

Signature:

Title: .

Date:

Name:

Signature:

Title:

Date:

IV. APPENDIX B: Data Destruction Attestation Statement

Note: To be completed and returned after completion of the approved research



PTOS Data Destruction Attestation Statement

This document certifies the destruction of the dataset received from the Pennsylvania Trauma Systems Foundation ("PTSF") Statewide Trauma Registry Database ("PTOS Data") covered by the Data Application and Data Use Agreement listed below. This document is to be completed and submitted to PTSF to certify the destruction/discontinued use of all PTOS data covered by the listed Data Application and Data Use Agreement (DUA) at all locations and/or under the control of all individuals with access to the data. This includes any and all original files, copies made of the files, any derivatives or subsets of the files and any manipulated files.

Requestor/PI Hospital Affiliation: _____

Name of Primary Investigator (PI) that received PTOS Data: _____

Address: _____
Street City State Zip Code

PTOS Data Application/Data Use Agreement Dated: _____

By signing below, I hereby attest that all PTOS Data previously supplied to me pursuant to the PTOS Data Application and Data Use Agreement referenced above, including all original files, copies made of the files, any derivatives or subsets of the files and any manipulated files in any format held by all individuals who had access to, and from all the computers/storage devices where the files were processed/stored have been destroyed in accordance with the PTOS Data Application and Data Use Agreement previously signed by me

Signature (Requestor) Date

Print Name (Requestor)

Signature (Principal Investigator)

Date

Print Name (Principal Investigator)

Signature (Trauma Medical Director)

Date

Print Name (Trauma Medical Director)

Please return the above attestation by 30 days after completion of the approved research project to:

Stephanie Radzevick, CPC

Trauma Registry Data Analyst, Pennsylvania Trauma Systems Foundation

275 Cumberland Parkway, #234

Mechanicsburg, PA 17055

sradzevick@ptsf.org