

## **The Trauma Quality Programs Participant Use File (PUF) Data Use Agreement**

This Data Use Agreement (“Agreement”) by and between the American College of Surgeons (“ACS”) and the Data Recipient listed below implements the data protections of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Any individual seeking to obtain or use the data in Trauma Quality Programs (“TQP”) Participant Use File (“PUF”) must agree to the terms in this Data Use Agreement prior to the release of the designated PUF.

The ACS established the TQP as a public service to be a repository of trauma related data voluntarily reported by participating trauma centers. The aim of the ACS TQP in providing the PUF is to position Data Recipients to conduct relevant trauma research.

PUF applications must be focused on a specific research question that should be stated clearly in the application. Prior to planning to submit a PUF application, you are advised to read the information on the [PUF Website](#). Specifically, applicants should review the appropriate PUF User Manuals and [NTDS Data Dictionary](#) in order to understand available data elements and their limitations that could impact the proposed research.

The data contained in the PUF reflect those which are submitted by participating trauma centers in accordance with the NTDS Data Dictionary. The ACS aggregates these data and performs necessary data cleaning techniques and creates calculated data elements. The ACS reserves the right to make corrections as needed and will notify researchers if such a correction occurred.

### **No Identification of Person(s) or Trauma Center(s):**

The data in the PUF have been de-identified. Any effort to determine the identity of any individual, (including but not limited to patient, surgeon, and any other healthcare provider or hospital), or to use the information for any purpose other than for research activities, advocacy, medical education, patient education, quality improvement analysis, and aggregate statistical reporting for research purposes would violate the conditions of this Agreement and HIPAA, unless otherwise specifically permitted by representatives of the ACS. Data Recipients of the PUF are prohibited under this Agreement and HIPAA from releasing, disclosing, publishing, or presenting any individually identifying information. Every effort has been made to exclude patient and institutional identifying information from the PUF. It may be possible, in limited situations, through deliberate technical analysis, and with outside information, to ascertain from the de-identified data set the identity of particular persons. Considerable harm could result if this were to occur. Therefore, any attempts to identify individuals are prohibited and information that could identify individuals directly or by inference must not be released or published. In addition, the users of the PUF must not attempt to contact any individuals or hospitals for any purpose, including verifying information or data supplied in the PUF. Any questions about the PUF must be referred exclusively to the ACS staff.

### **Permission to use and disclose the data:**

Permission to use and disclose the PUF is granted from the ACS to each Data Recipient for the research purpose defined in their application. The Data Recipient should also not sell, rent, loan, or otherwise grant access to the PUF to anyone not mentioned in their application without permission of the ACS. The ACS also reserves the right to deny access to the PUF at its discretion.

**By signing this Agreement, the Data Recipient warrants that he/she will:**

1. Communicate with ACS staff if the analyses proposed in their application are changed or modified. Any additional projects require a new application and approval.
2. Will not use or further disclose the PUF in a manner that would violate the HIPAA regulations.
3. Use appropriate safeguards to prevent use or disclosure of the information other than as provided by this Agreement, including administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the electronic PUF that it receives, maintains, or transmits on behalf of the Hospital as required by 45 CFR 164.314. This responsibility extends to sharing the data with other researchers involved with the proposal.
4. Not use the data in any way other than for research activities, advocacy, medical education, patient education, quality improvement analysis, and aggregate statistical reporting for research purposes. ACS staff must be notified if it is discovered that there has been any other use of the data.
5. Not use this data as a basis for legal, administrative or other actions that can directly affect an individual whose medical or personal information is included in a case in the data.
6. Not attempt to link nor permit others to link the data with another database.
7. Not refer to the TQP PUF as population-based in any presentations or publications. The TQP PUF is NOT population based, and solely represents the data submitted by participating trauma centers.
8. Not attempt to learn the identity of any person or any trauma program whose data is contained in the provided file(s). If the identity of any person or any trauma program is discovered inadvertently, then the Data Recipient must do the following:
  - a. Will not use this knowledge.
  - b. Will notify the ACS staff of the incident.
  - c. Will not disclose to anyone else the discovered identity.
9. Not use the PUF to contact the individuals or trauma programs who are the subject of the information.
10. Include in all presentations/published materials the following statement:  
*Committee on Trauma, American College of Surgeons. TQP PUF Version Admission Year.X.X (e.g. 2019.1.1) Chicago, IL, 20XX The content reproduced from the PUF remains the full and exclusive copyrighted property of the American College of Surgeons. The American College of Surgeons is not responsible for any claims arising from works based on the original data, text, tables, or figures.*
11. Provide, at a minimum, an abstract and reference for any published materials resulting from their analyses to the ACS staff as soon as possible once materials are published.

12. Not copy or distribute the data to any parties not identified in the application. If at a future date the Data Recipient finds it necessary for others to access the record-level data for analysis purposes, they must notify ACS staff.
13. Report to ACS staff any use or disclosure of information from the PUF not provided for in this Agreement within three (3) business days of becoming aware of such use or disclosure.
14. Ensure that any agents, including a subcontractor, to whom he/she provides any information from the PUF, agrees to the same restrictions and conditions that, apply to the data recipient under this Agreement.
15. Not use or disclose the PUF other than as permitted by this Agreement or as otherwise required by law. Data Recipient agrees that this precludes them from using the data for any commercial purposes unless given written authorization from ACS staff.
16. The Data Recipient agrees to indemnify the ACS and its employees and agents from any liability, claims, or expenses arising from use of the PUF.
17. Any noncompliance by the Data Recipient with the terms of this Agreement or failure on their part to correct any breach or violation of this Agreement to the satisfaction of the ACS will be grounds for immediate termination of the Agreement by the ACS.
18. This Agreement will remain in effect as of the date of execution and shall terminate when all copies of the PUF are destroyed and the PUF is no longer in use. The PUF should be destroyed prior to the one-year anniversary of the date the PUF application was submitted. If an extension is needed, Data Recipient should email ACS staff with that request. Data Recipient shall notify ACS in writing when it has destroyed the PUF.
19. Make available to the ACS staff, upon request, Data Recipient's internal records related to the use, distribution, and destruction of the PUF as requested.

As the undersigned, my electronic signature confirms my agreement to comply with the above stated requirements. Violators of this Agreement may also be subject to penalties under statutes that may apply to these data.

Any inquiries about this Agreement can be sent to the ACS staff at [TraumaQuality@facs.org](mailto:TraumaQuality@facs.org).