



Lawrence N. Shulman, MD, FACP | *Chair*

David P. Winchester, MD, FACS | *Medical Director*

## The Commission on Cancer's National Cancer Data Base Participant User File (PUF) Data Use Agreement

It is of utmost importance to ensure the confidentiality of patients who have been diagnosed with cancer, and the institutions that have reported these cases to the NCDB. This Data Use Agreement ("Agreement") by and between the American College of Surgeons ("ACS") and the Principal Investigator listed below implements the data protections of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the American College of Surgeons, Commission on Cancer Business Associate Agreement. Any individual ("Principal Investigator (PI)") seeking to obtain or use the data in the Commission on Cancer's (CoC), National Cancer Data Base (NCDB) Participant User File ("PUF") must be representing a CoC-accredited cancer program ("Program"), must agree to the terms in this Data Use Agreement (DUA), and must submit this DUA electronically prior to the release of the designated PUF.

Consistent with the CoC Business Associate Agreement (BAA) and in accordance with HIPAA, any Protected Health Information ("PHI"), as defined by 45 CFR 164.501, submitted to the CoC NCDB by the Program for inclusion in the NCDB may be used and disclosed to create a de-identified data set as defined by 45 CFR 164.514(b), containing aggregate, patient-level data, as it is with the PUF. The NCDB PUF also retains the right to release the PUF at its discretion to CoC-accredited programs for the purpose of engaging in research activities, quality improvement analysis, and aggregate statistical reporting.

**No Identification of Person(s) and Providers:** The data in the PUF have been de-identified to the extent that they are no longer a limited data set as defined by Health Insurance Portability and Accountability Act (HIPAA). Any effort to determine the identity of any individual, (including but not limited to patient and other health care provider or Program), or to use the information for any purpose other than for research, quality improvement, and aggregate statistical reporting, would violate the BAA, the conditions of this Agreement, and HIPAA. PIs of the PUF are prohibited under HIPAA, the BAA, and this Agreement (DUA) from releasing, disclosing, publishing or presenting any individually identifying information. Every effort has been made to exclude patient and institutional identifying information from the NCDB PUFs. The NCDB PUF omits from the PUF all identifiers required to be excluded from de-identified data sets as defined by the HIPAA Privacy Rule. 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. Any questions about the PUF must be referred exclusively to the NCDB staff.

**Permission to use and disclose the data:** Permission to use and disclose the PUF is granted from ACS to each PUF Recipient. The PI must be associated with a CoC-accredited Program. Intentional misrepresentation of association with the Program by the PI will void this Agreement, prohibit future access to the PUF by the PI, and result in legal action taken by ACS. ACS also reserves the right to deny access to the PUF at its discretion.

**Expectations:** In order for the ACS to provide a PUF, it is necessary that the Principal Investigator (PI) agree to the following expectations:

1. Each PUF PI must communicate with the NCDB staff if the analyses proposed in their awarded application are changed or modified.
2. Each PUF PI is expected to participate in assisting in the development and refinement of the NCDB PUF Data Dictionary for future PUFs.
3. Each PUF PI is expected to act as a resource or mentor to future PUF recipients.
4. Each PUF PI is encouraged to submit abstracts developed for review at least 5 business days prior to the abstract submission deadline. If a PUF PI chooses not to submit an abstract for review by NCDB staff, then the PI and researchers assume all responsibility for any judgment regarding the appropriateness of the statistical review and the discussion/conclusions discerned.

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

1. Use appropriate safeguards to prevent use or disclosure of the information other than as provided by this Agreement. This responsibility extends to sharing the data with other researchers involved with the proposal.
2. Assure that anyone participating with the PUF will be affiliated with a CoC-accredited program as the privilege of using a PUF is extended only to researchers in CoC-accredited programs
3. Not use the data in any way other than for research activities, quality improvement analysis, and aggregate statistical reporting for research purposes. The CoC must be notified if it is discovered that there has been any other use of the data.
4. Suppress reporting of small cell sizes ( $n < 10$ ).
5. Not attempt to link nor permit others to link the data with another database.
6. Not attempt to learn the identity of any person or any cancer program whose cancer data is contained in the provided file(s). If the identity of any person or any cancer program is discovered inadvertently, then the PIs must do the following:
  - 6.1. Will not use this knowledge.
  - 6.2. Will notify the Medical Director of the CoC of the incident.
  - 6.3. Will not disclose to anyone else the discovered identity.
7. Secure IRB permission, if a hospital or cancer program requires IRB review, in advance of using the PUF. Note: Some major clinical journals require a statement regarding this.
8. Include in all presentations/published materials the following statement: "The NCDB is a joint project of the Commission on Cancer of the American College of Surgeons and the American Cancer Society."
9. Also, include the following acknowledgement in all presentations/publications: "The data used in the study are derived from a de-identified NCDB file. The American College of Surgeons and the Commission on Cancer have not verified and are not responsible for the analytic or statistical methodology employed, or the conclusions drawn from these data by the investigator."
10. Provide, at a minimum, an abstract and reference for any published materials resulting from their analyses to the Senior Manager, CoC NCDB.
11. Not copy or distribute the data to any parties not identified in the research proposal, nor share the PUF with people outside of your hospital.

12. Not profit from the sale or use of the data as the PUF is the property of the American College of Surgeons.
13. Report to the American College of Surgeons 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 you under this Agreement.
15. Not use or disclose the PUF other than as permitted by this Agreement or as otherwise required by law. PI agrees that this precludes him/her from using the data for any commercial purposes.

**Additional Terms:**

1. 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 by the PI;
2. Except as provided below, 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. PI shall notify ACS in writing when it has destroyed the PUF.
3. Any noncompliance by the PI with the terms of this Agreement or failure on the part of the PI to correct any breach or violation of this Agreement to the satisfaction of the CoC will be grounds for immediate termination of the Agreement by the American College of Surgeons, CoC.
4. The NCDB does not allow researchers to compare any data from their institution to the NCDB data, whether that be survival data, treatment or other data. In addition, you are prohibited from identifying any facility in the PUF data.
5. Since the PUF is a benefit of CoC accreditation, should the facility under which you applied for the PUF lose or withdraw from CoC accreditation for any reason, you agree to destroy the PUF data file(s) immediately.

As the undersigned, my signature confirms my affiliation at the participating CoC-accredited Program and 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 American College of Surgeons:

ncdb\_puf@facs.org  
American College of Surgeons  
Commission on Cancer  
633 N. Saint Clair Street  
Chicago, IL 60611

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*PUF Data Use Agreement  
Commission on Cancer  
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