American College of Surgeons' Commission on Cancer
National Cancer Database Participant User Files Purpose and Terms of Agreement

The Participant User Files (PUF) program supports investigators at Commission on Cancer (CoC) accredited institutions to conduct research derived from the National Cancer Database (NCDB). Specific research proposals are submitted designed around data that can be derived from the NCDB, a joint program of the American College of Surgeons Commission on Cancer (CoC) and the American Cancer Society (ACS), and is offered as an added value to clinical investigators at CoC-accredited cancer programs who desire to conduct their own studies. Since the PUF is a perquisite of CoC accreditation, the clinical investigator of a facility that loses or withdraws from accreditation for any reason, will agree to destroy the data file(s) and contact ncdb_puf@facs.org and confirm the file(s) destruction.

The aim of the CoC and NCDB is to position investigators at CoC-accredited facilities to successfully use the PUFs to conduct relevant cancer research and should not be used to promote marketing such as using the file to compare your facility's practice to the hospitals contributing data to this PUF. The user also shall not sell, rent, loan, or otherwise grant access to the PUF files to anyone outside of their hospital without permission of the CoC NCDB.

Prior to planning to submit a PUF, you are advised to read the information provided on the Participant User Files website. It is important that you also read the Getting Started document in order to understand the variables and their limitations that could impact your proposed research.

PUF applications must be focused on a specific research question that should be stated clearly in the application. Please note that targeted PUFs for the November 2023 RFA are available for diagnosis years 2004-2021.

Available PUF Types:

- Pediatric: Ages 0-17
- Pediatrics / Young Adult: Ages 0-39
- Adult: Ages 18-90+
- All Ages: Ages 0-90+

I am the Principal Investigator, and I will share these Terms of Agreement with all of the Co-Investigators, Statisticians, Data Analysts, and any other researchers on this proposal. If you are NOT the Principal Investigator, do NOT complete this Terms of Agreement.

I am the Principal Investigator
o Yes

I will share the Terms of Agreement
o Yes

PUF applications will be screened by NCDB staff for technical feasibility, if requested. If the data requested are sufficient to power the aims of the research question, and the research question is well defined and fits the criteria of the PUF program, the application will be approved. If there are any questions by the NCDB staff on the feasibility of an application, the Principal Investigator will be sent an e-mail asking for clarifications or revisions.

NCDB PUFs are delivered electronically as compressed, encrypted text files that are accompanied by the SAS import script. Prior to the download of the file, a Data Use Agreement (DUA) must be signed electronically before the data can be received.

The (DUA) will specify rules for data use and must be signed prior to your download of the data. Any data breach will be subject to investigation by the CoC. If confirmation of data breaches exists, the investigator will be subject to future barring from receiving NCDB data as part of the PUF process or related processes. The institutional cancer program administrator, cancer committee chair, and cancer liaison physician will be notified. If multiple data breaches are found from an institution, investigators from that institution will be barred from receiving NCDB data as part of the PUF or related processes until a corrective action plan has been received and approved by CoC.

Do you agree to and understand this provision?

o Yes

PUF users are not allowed to share data outside of their facility.

I agree not to share data outside of my CoC-accredited facility.

o Yes

You may share data within your facility for the same application if the investigators are included as Co-Investigators in your application. If an investigator at your institution wants to analyze PUF data for a different analysis than what you are proposing, they will need to submit a separate PUF application.

Do you agree to and understand this provision?

o Yes

If you are granted a PUF, you are prohibited from attempting to identify hospitals and/or patients in the PUF.

Do you agree to and understand this provision?

o Yes

If you receive a PUF, you must include the following disclosure in any presentation or published material using the PUF:

The National Cancer Database (NCDB) is a joint project of the Commission on Cancer (CoC) of the American College of Surgeons and the American Cancer Society. The CoC's NCDB and the hospitals participating in the CoC's NCDB are the source of the de-identified data used herein; they have not verified and are not responsible for the statistical validity of the data analysis or the conclusions derived by the authors.

Do you agree to and understand this provision?

o Yes

The NCDB PUF data are NOT population based; they are hospital based. I will not refer to the NCDB data as population based in any presentations or publications.

Do you agree to and understand this provision?

o Yes

Upon publication or presentation of any manuscripts utilizing PUF data, researchers are requested to submit a copy of the manuscript to the NCDB.

Do you agree to and understand this provision?

o Yes

If at a future date, I want to add additional investigators, statisticians or data analysts to this proposal, I will send a request to do so to ncdb_puf@facs.org.

Do you agree to and understand this provision?

If at a future date, I want to revise the proposal I have submitted I will send an email to ncdb_puf@facs.org with a summary of the proposed changes.

Do you agree to and understand this provision?

This study includes data from the year 2020 which was the first year of the COVID-19 pandemic. The year 2020 was associated with significant variance in cancer care due to the pandemic and this variance must be considered when interpreting these results, especially when conducting comparisons with prior years.

Do you agree to and understand this provision?

o Yes

This study includes newly introduced variables specific to the COVID-19 disease, which were captured under the limitations and duress imposed by the pandemic. This effort was historic and unique on the part of accredited programs and data infrastructure. Accordingly, the consistency with which these variables were able to be documented across U.S. hospitals is unclear and should be considered when interpreting results.

Do you agree to and understand this provision?

o Yes

Electronic Signature By Jason Brant DN: cn=Jason Brant

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Application ID : 2021.688

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