

Investigator:	
Date	
Project title:	

**NCI PATTERNS OF CARE (POC) DATA USE AGREEMENT
(DUA) PRINCIPAL INVESTIGATOR**

Information pertaining to an individual’s health status and medical treatment is sensitive. Therefore, specific laws, including the Privacy Act of 1974 and the Health Insurance Portability and Accountability Act of 1996, have been enacted to ensure the confidentiality of health information. In utilizing health data for research purposes, it is absolutely necessary to ensure, to the extent possible, that uses of such data will be limited to research. Uses for any other reason, particularly those resulting in personal disclosures, will be prosecuted to the full extent of the law. In addition, release of information about providers, i.e., the physicians and hospitals that provide care for cancer patients, may compromise the willingness of these providers to cooperate with the activities of the cancer registries. Therefore, considerations regarding the privacy of providers are also of great importance.

In order for the National Cancer Institute to provide the Patterns of Care (POC) data to you, it is necessary that you agree to the following provisions:

1. You agree that the statements and methods made in your attached research proposal are complete and accurate. Further, you represent and warrant that said study proposal represents the total use(s) to which the data will be put.
2. You will not use the data for purposes other than described in your research proposal. You represent and warrant that, except as specified in an Attachment to this Agreement or except as NCI shall authorize in writing, that you shall not disclose, release, reveal, show, sell, rent, lease, loan, or otherwise grant access to the data covered by this Agreement to any person. Access to these data will not be made available to any researcher outside of the research team identified in the proposal without the written approval from the NCI POC point of contact.
3. The parties mutually agree that NCI retains all ownership rights to the POC data referred to in this Agreement, and that the User does not obtain any right, title, or interest in any of the data furnished by NCI.
4. You will not permit others to use the data except for collaborators at your institution involved with the research as described in your proposal. Access to the NCI POC data shall be limited to the minimum number of individuals necessary to achieve the purpose stated in your proposal. The specific location details of where the data will be stored must be provided in your proposal’s data storage and management plan. If you plan to move the data to a new location at your institution you must contact NCI in writing prior to moving the data for instructions on how to handle the POC data.

5. You will establish and maintain the appropriate administrative, technical, and physical safeguards to protect the confidentiality of the data and to prevent unauthorized use or access to it, as described in your proposal. The safeguards shall provide a level and scope of security that is not less than the level and scope of security established by the Office of Management and Budget (OMB) in OMB Circular No. A-130, Appendix III—Security of Federal Automated Information Systems, which sets forth guidelines for security plans for automated information systems in Federal agencies. You acknowledge that the use of unsecured telecommunications, including the Internet, to transmit individual-level information derived from the POC data is prohibited. Further, you agree that the data must not be physically moved or transmitted in any way from the institution approved for POC data storage and analysis without written approval from NCI.
6. You agree not to place the POC data on personal computers, portable devices, and removable media without permission. Portable devices include any non-fixed equipment that contains an operating system which may be used to create, access or store POC data. This includes but is not limited to laptops, personal digital assistants (PDAs), and smart phones. Removable media include, but are not limited to CDs, DVDs, MP3 players, removable memory, and USB drives (thumb drives). If approved, all data stored on any of these devices must be password protected AND encrypted. Approved encryption standards must be FIPS-140 compliant and include Advanced Encryption Algorithm (AES) that uses a 128, 192, or 256-bit key size. In the event that the data are lost or stolen, you agree to report the loss to the NCI POC contact within 24-hours/ first business day of discovering the loss.
7. You may use an institutionally provided VPN to link to a time-sharing system for data access. In this case, the remote PC may support the VPN, but the POC data must remain on the server.
8. You will store all media on which the POC data are delivered in a secure location, such as a locked file cabinet in a locked office, only accessible by you or appropriate designated staff.
9. All POC data must reside at your institution under your purview. If you plan to leave this institution, you must contact NCI in writing prior to the transition for instructions on how to handle the POC data. You may not duplicate any POC files prior to the transition nor can you take POC data with you without written permission from NCI. All files under your purview must be destroyed prior to your departure or someone must agree to assume the responsibilities of the PI as described in this document.
10. You will not attempt to link nor permit others to link the POC data with another database or source of data without the written consent from the NCI POC point of contact.
11. No one having access to the data will attempt to learn the identity of any persons with cancer in these data and/or their physicians or treating hospitals. If you discover or are able to deduce the identity of a specific patient or provider (individual or institution), you agree that you will not attempt to contact these individuals or institutions.
12. I acknowledge that NCI has substantive concerns about using the radiation and chemotherapy data to address certain research questions as described on the above website. I understand that any findings from such analyses may be inaccurate or misleading.

13. No findings or information derived from the POC data may be released if such findings contain any combination of data elements that might allow the deduction of a patient's or providers' (individual or institution) identity. Numbers less than 5 (five) must be suppressed. Also, no use of percentages or other mathematical formulas may be used if they allow the derivation of patient, facility, or provider counts less than 5. Mapping of data related to reflect incidence, treatment, or survival at the registry-specific level or at other small areas is not permitted without prior approval from NCI. You agree that NCI shall be the sole judge as to whether the anonymization sufficiently precludes one from identifying or deducing the identity of a specific patient, provider (individual or institution) or registry with a reasonable degree of certainty.
14. You agree to provide a copy of all manuscripts, abstracts, and book chapters to NCI for review and comment prior to publication or conference submission. You further agree not to submit such findings to any third party prior to completion of NCI review. NCI agrees to complete the manuscript review process within 4 weeks of receiving any manuscript. NCI's review of these materials is for the purpose of assuring that data confidentiality is maintained (e.g., individual patients and/or providers cannot be identified) and that the focus of the manuscript was outlined in the approved POC proposal. Revisions will be necessary if NCI determines that the format in which data are presented may result in identification of individual patients and/or providers or if the scope of the manuscript is not consistent with the approved proposal.
15. You agree that in the event NCI determines or has a reasonable belief that you have violated any terms of this agreement, NCI may request that you destroy the data and all derivative files and send a certificate/ notification of destruction to NCI. You understand that as a result of NCI's determination or reasonable belief that a violation of this agreement has taken place, NCI may refuse to release further data to you for a period of time to be determined by NCI.
16. All files received may be retained for a maximum of one year. At the completion of the project or one year from receipt all files including all back-up files and original media must be destroyed and notification of destruction must be sent to NCI unless at data use extension has been granted by NCI. Investigators who need to retain files beyond that period must contact NCI to request permission. You understand and agree that you may not reuse original or derivative data without prior written approval from the NCI POC contact beyond this approved study period.
17. Any manuscript or book chapter using these data should follow the publication policy and acknowledge funding from NCI if present). Manuscripts and chapters should also include the following acknowledgment:

"This study used data provided by the National Cancer Institute's Patterns of Care studies. The interpretation and reporting of these data are the sole responsibility of the authors. The authors acknowledge the efforts of the NCI Healthcare Delivery Research Program and the Surveillance, Epidemiology, and End Results (SEER) Program tumor registries in the creation these data."