

**PATTERNS OF CARE DATA USE AGREEMENT
(AGREEMENT FOR USE OF NATIONAL CANCER INSTITUTE INFORMATION)**

In order to secure data that resides in an National Cancer Institute (NCI) Privacy Act System of Records, and in order to ensure the integrity, security, and confidentiality of information maintained by the NCI, and to permit appropriate disclosure and use of such data as permitted by law, NCI and _____ enter into this agreement to comply with the following specific paragraphs.

1. This Agreement is by and between the NCI, a component of the U.S. Department of Health and Human Services, and _____, hereinafter termed "User."
2. This Agreement addresses the conditions under which NCI will disclose and the User will obtain and use the NCI tabular data specified in section 7. This Agreement supersedes any and all agreements between the parties with respect to the use of data from the tables specified in section 7 and preempts and overrides any instructions, directions, agreements, or other understanding in or pertaining to any grant award or other prior communication from the Department of Health and Human Services or any of its components with respect to the data specified herein. Further, the terms of this Agreement can be changed only by a written modification to this Agreement or by the parties adopting a new agreement. The parties agree further that instructions or interpretations issued to the User concerning this Agreement or the data specified herein, shall not be valid unless issued in writing by the NCI point-of-contact specified in section 5 or the NCI signatory to this Agreement shown in section 22.
3. The parties mutually agree that NCI retains all ownership rights to the data table(s) 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. The parties mutually agree that the following named individual is designated as "Custodian" of the table(s) on behalf of the User and will be personally responsible for the observance of all conditions of use and for establishment and maintenance of security arrangements as specified in this Agreement to prevent unauthorized use. The Custodian may be the SEER registry PI or another investigator approved by the SEER registry PI to be responsible for the security of the POC data. The User agrees to notify NCI within fifteen (15) days of any change of custodianship. The parties mutually agree that NCI may disapprove the appointment of a custodian or may require the appointment of a new custodian at any time.

(Name of Custodian)

(Company/Organization)

(Street Address)

(City/State/ZIP Code)

(Phone No. - Including Area Code and E-Mail Address, If Applicable)

5. The parties mutually agree that the following named individual will be designated as “point-of-contact” for the Agreement on behalf of NCI.

(Name of Contact)

(Title/Component)

(Street Address)

(Mail Stop)

(City/State/ZIP Code)

(Phone No. - Including Area Code and E-Mail Address, If Applicable)

6. The User represents and warrants, and in furnishing the data tables specified in section 7. NCI relies upon such representation and warranty, that such data tables will be used solely for the following purpose (brief description of study):

7. The User represents and warrants further that the facts and statements made in any study or research protocol or project plan submitted to NCI for each purpose are complete and accurate. Further, the User represents and warrants that said study protocol(s) or project plans, as have been approved by NCI or other appropriate entity as NCI may determine, represent the total use(s) to which the data tables specified in section 7 will be put.

The User represents and warrants further that, except as specified in an Attachment to this Agreement or except as NCI shall authorize in writing, the User shall not disclose, release, reveal, show, sell, rent, lease, loan, or otherwise grant access to the data covered by this Agreement to any person. The User agrees that, within the User organization, access to the data covered by this Agreement shall be limited to the minimum number of individuals necessary to achieve the purpose stated in this section and to those individuals on a need-to-know basis only.

The following NCI data tables is/are covered under this Agreement.

8. The parties mutually agree that the aforesaid tables (and/or any derivative tables may be retained by the User until _____, hereinafter known as the “retention date.” The User agrees to notify NCI within 30 days of the completion of the purpose specified in section 6 if the purpose is completed before the aforementioned retention date. Upon such notice or retention date, whichever occurs sooner, NCI will notify the User either to return all data tables to NCI at the User’s expense or to destroy such data. If NCI elects to have the User destroy the data, the User agrees to certify the destruction of the tables in writing within 30 days of receiving NCI’s instruction. A statement certifying this action must be sent to NCI. If NCI elects to have the data returned, the User agrees to return all tables to NCI within 30 days of receiving notice to that effect. The User agrees that no data from NCI records, or any parts thereof, shall be retained when the aforementioned tables are returned or destroyed unless authorization in writing for the retention of such tables has been received from the appropriate Systems Manager or the person designated in item No. 22 of this Agreement. The User acknowledges that stringent adherence to the aforementioned retention date is required, and that the User shall ask NCI for instructions under this paragraph if instructions have not been received after 30 days after the retention date.

9. The User agrees to establish appropriate administrative, technical, and physical safeguards to protect the confidentiality of the data and to prevent unauthorized use or access to it. 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. The User acknowledges that the use of unsecured telecommunications, including the Internet, to transmit individually identifiable or deducible information derived from the tables specified in section 7 is prohibited. Further, the User agrees that the data must not be physically moved or transmitted in any way from the site indicated in item number 4 without written approval from NCI.

10. The User agrees that the authorized representatives of NCI or DHHS Office of the Inspector General will be granted access to premises where the aforesaid tables are kept for the purpose of inspecting security arrangements confirming whether the User is in compliance with the security requirements specified in paragraph 9.

11. The User agrees that no findings, listing, or information derived from the tables specified in section 7, with or without identifiers, may be released if such findings, listing, or information contain any combination of data elements that might allow the deduction of a beneficiary's identification without first obtaining written authorization from the appropriate System Manager or the person designated in item number 22 of this Agreement. Examples of such data elements include but are not limited to geographic indicator, age, sex, diagnosis, procedure, admission/discharge date(s), or date of death. The User agrees further that NCI shall be the sole judge as to whether any finding, listing, information, or any combination of data extracted or derived from NCI's tables identifies or would, with reasonable effort, permit one to identify an individual or to deduce the identity of an individual to a reasonable degree of certainty.

12. The User agrees that, absent express written authorization from the appropriate System Manager or the person designated in item number 22 of this Agreement to do so, the User shall make no attempt to link records included in the tables specified in section 7 to any other identifiable source of information. This includes attempts to link to other NCI data tables. The inclusion of linkage of specific tables in a study protocol approved in accordance with section 6 is considered express written authorization from NCI.

13. The User agrees to submit a copy of all findings within 30 days of making such findings to NCI. The parties mutually agree that the User has "made findings" with respect to the data covered by this Agreement when the User conveys any report or other writing to any third party (including but not limited to any manuscript submitted for publication) concerning any purpose specified in section 6 (regardless of whether the report or other writing expressly refers to such purpose, to NCI, or to the tables specified in section 7 or any data derived from such tables). The User agrees further to submit its findings to the National Technical Information Service (NTIS, 5301 Shawnee Road, Alexandria, Virginia 22312) within 30 days of receiving notice from NCI to do so.

14. The User understands and agrees that they may not reuse original or derivative data tables without prior written approval from the appropriate System Manager or the person designated in section 22 of this Agreement.

15. The parties mutually agree that the following specified Attachments are part of this Agreement:

Attachment 1 SEER-Patterns of Care Data Use / Confidentiality Agreement
Attachment 2: Project proposal

16. The User agrees that in the event NCI determines or has a reasonable belief that the User has made or may have made disclosure of the aforesaid tables that is not authorized by this Agreement or other written authorization from the appropriate System manager or the person designated in item number 22 of this Agreement, NCI in its sole discretion may require the User to: (a) promptly investigate and report to NCI the User's determinations regarding any alleged or actual unauthorized disclosure, (b) promptly resolve any problems identified by the investigation; (c) if requested by NCI, submit a formal response to an allegation of unauthorized disclosure; (d) if requested by NCI, submit a corrective action plan with steps designed to prevent any future unauthorized disclosures; and (e) if requested by NCI, return data tables to NCI. The User understands that as a result of NCI's determination or reasonable belief that unauthorized disclosures have taken place, NCI may refuse to release further NCI data to the User for a period of time to be determined by NCI.

17. The User hereby acknowledges that criminal penalties under § 1106(a) of the Social Security Act (42 U.S.C. § 1306(a)), including a fine not exceeding \$1,000 or by imprisonment not exceeding 1 year, or both, may apply with respect to any disclosure of information in the tables specified in section 7 that is inconsistent with the terms of this Agreement. The User further acknowledges that criminal penalties under the Privacy Act (5 U.S.C. § 552a(1) and (3)) may apply if it is determined that the Requestor or Custodian, or any individual employed or affiliated therewith, knowingly and willfully obtained the tables under false pretenses. Any person found guilty under the Privacy Act shall be guilty of a misdemeanor and fined not more than \$5,000. Further, the User acknowledges that criminal penalties may be imposed under 18 U.S.C. § 641, which provides that if it is determined that the User, or any individual employed or affiliated therewith, has taken or converted to his own use data tables, or received the tables knowing that they were stolen or converted, they shall be fined not more than \$10,000 or imprisoned not more than 10 years, or both. In addition, the User and any individual employed or affiliated therewith, may be subject to civil suit under the Privacy Act for damages which occur as a result of willful or intentional actions which violate an individual's rights under the Privacy Act.

18. By signing this Agreement, the User agrees to abide by all provisions set out in this Agreement for protection of the data tables specified in section 7, and acknowledges having received notice of potential criminal, administrative, or civil penalties for violation of the terms of the Agreement.

19. On behalf of the User the undersigned individual hereby attests that he or she is authorized to enter into this Agreement and agrees to all the terms specified herein.

(Name and Title of Individual - Typed or Printed)

(Company/Organization)

(Street Address)

(City/State/ZIP Code)

(Phone No. - Including Area Code and E-Mail Address, If Applicable)

(Signature) (Date)

20. The Custodian, as named in paragraph 4, hereby acknowledges his/her appointment as Custodian of the aforesaid tables on behalf of the User, and agrees personally and in a representative capacity to comply with all of the provisions of this Agreement on behalf of the User.

(Typed or Printed Name and Title of Custodian of Tables)

(Signature) (Date)

21. On behalf of the NCI the undersigned individual hereby acknowledges that the aforesaid Federal agency sponsors or otherwise supports the User's request for and use of NCI data, agrees to support NCI in ensuring that the User maintains and uses NCI's data in accordance with the terms of this agreement, and agrees further to make no statement to the User concerning the interpretation of the terms of this Agreement and to refer all question of such interpretation or compliance with the terms of this Agreement to the NCI official names in section 22 (or to his or her successor).

(Typed or Printed Name and Title of Federal Representative)

(Signature) (Date)

(Phone No. - Including Area Code and E-Mail Address, If Applicable)

22. On behalf of NCI the undersigned individual hereby attests that he or she is authorized to enter into this Agreement and agrees to all the terms specified herein.

(Typed or Printed Name and Title of NCI Representative)

(Signature) (Date)

Attachment 1

National Cancer Institute (NCI) Patterns of Care Data Use / Confidentiality Agreement

The provisions of the agreement are as follows:

1. _____, will be provided with _____ .
2. These data are to be used only in the analysis outlined in the proposal. They may not be used in any other application without the express written consent of the NCI, Division of Cancer Control and Population Sciences, Healthcare Delivery Research Program.
3. These data are not to be reproduced in any form.
4. Access to these data will not be made available to any researcher outside of research team identified in the proposal without the written consent of the NCI, Division of Cancer Control and Population Sciences, Healthcare Delivery Research Program.
5. NCI must review and approve any manuscripts using these data prior to submission for publication. NCI must be informed once any manuscript using these data is published. Abstract submitted for presentation at meetings will be submitted to the NCI representative.
6. Upon completing the analysis, _____, will return the data to the NCI.
7. Any manuscript using these data should follow the SEER publication policy and acknowledge funds from NCI. Acknowledgment sentence:

"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 Healthcare Delivery Research Program and the Surveillance, Epidemiology, and End Results (SEER) Program tumor registries in the creation these data."

Name

Please print

Signature

Date

Attachment 2: Project Proposal