

Investigator: _____ Date: _____
 Last name, first

Project title: _____

SEER-MEDICARE HEALTH OUTCOMES SURVEY 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 the health plans, hospitals, and other providers that provide health care, may compromise the willingness of these organizations 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 linked Surveillance, Epidemiology and End Results (SEER)-Medicare Health Outcomes Survey (MHOS) 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.
2. You will not use the data for purposes other than described in your research proposal.
3. You will not permit others to use the data except for collaborators within your institution involved with the research as described in your proposal. Within your institution or organization, access to the SEER-MHOS data shall be limited to the minimum number of individuals necessary to achieve the purpose stated in your proposal. The number of locations where the data are located shall also be minimized and specific location details 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 institute you must contact NCI in writing prior to moving the data for instruction on how to handle the SEER-MHOS data.
4. 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. You agree to allow NCI to conduct on-site inspections to ensure compliance with the data storage/confidentiality/security policies. 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
http://csrc.nist.gov/drivers/documents/appendix_iii.pdf which sets forth guidelines for security plans for automated information systems in Federal agencies.
5. You agree not to place the SEER-MHOS 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 SEER-MHOS 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). 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 SEER-MHOS contact within 24 hours/first business day of discovering the loss. Cloud storage does not meet privacy rules and is not acceptable for storing SEER-MHOS data.

6. 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 SEER-MHOS data must remain on the institution's server. Additionally access to the VPN shall be restricted to persons residing in the United States.
7. You will store all media on which the SEER-MHOS 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.
8. You must maintain all datasets containing restricted variables physically separate from any other SEER-MHOS files. Separate access controls with strong user authentication (username/password, digital certifications, etc.) must be established to allow limited access to these files. You should be able to track all access to these files.
9. All SEER-MHOS data must reside at your institution under your purview. If you plan to move to a different institution, you must contact NCI in writing prior to moving for instructions on how to handle the SEER-MHOS data. You may not duplicate any SEER-MHOS files prior to moving nor can you take SEER-MHOS data with you without written permission from NCI. If you chose not to take the data with you, you must destroy the files or designate a new PI prior to moving and notify NCI. SEER-MHOS data are not permitted to be housed outside of the United States.
10. You will not attempt to link nor permit others to link the SEER-MHOS data with individually identified records in another database without the written consent from the applicable SEER registries.
11. No one having access to the data will attempt to learn the identity of any persons with or without cancer in these data. In the event that you discover or are able to deduce the identity of a specific patient, you agree that you will not attempt to contact these individuals.
12. No findings or information derived from the SEER-MHOS data may be released if such findings contain any combination of data elements that might allow the deduction of a patient's identity. In tables, cell sizes less than 11 (eleven) must be suppressed. You agree that NCI shall be the sole judge as to whether any finding derived from the SEER-MHOS data would, with reasonable effort, permit one to identify an individual, or to deduce the identity of an individual to a reasonable degree of certainty. Although it is permissible to report registry names with registry-specific cancer rates (e.g., incidence, complications, mortality), registry names must be anonymized when reporting the quality or completeness of registry-specific data (e.g., case or treatment ascertainment).
13. You agree to provide a copy of all manuscripts to NCI for review and comment prior to publication 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 the manuscript is for the sole 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 SEER-MHOS 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

14. You agree that in the event NCI determines or has a reasonable belief that you have violated any term(s) of this agreement, NCI may request that you return the data and all derivative files 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 SEER-MHOS data to you for a period of time to be determined by NCI.
15. All files received may be retained for a maximum of five years. At the completion of the project or five years from receipt, all files must be destroyed, and notification of destruction must be sent to NCI. Investigators who need to retain files beyond that period must contact NCI.

Please indicate the SEER-MHOS files you are requesting. Note, data for the non-linked/non- cancer MHOS respondents are not permitted to be shared alone; they can only be requested with the cancer cases.

1. **SEER-linked cancer cases diagnosed through 2017 and their MHOS Baseline Survey data from 1998 to 2017 and Follow-up Survey data from 2000 to 2019. Include Part D Event (PDE) on SEER-linked cancer cases:** Yes No
(years = 2007 to 2019).
2. **Non-linked (non-cancer) MHOS respondents with Baseline Survey data from 1998 to 2017 and Follow-up Survey data from 2000 to 2019. Include Part D Event (PDE) on non-linked/non-cancer cases:** Yes No
(years = 2007 to 2019).
3. **Ancillary Files:**
- Part D Plan Characteristics File:** Yes No
- Formulary File:** Yes No
- Prescriber Characteristics and Bridge Files:** Yes No
- Pharmacy Characteristics and Bridge Files:** Yes No

Please consider the following carefully: Multiple requests to use SEER-MHOS data may be received, and the approval process should not be understood as a guarantee preventing overlapping research aims. Reviewers intend to be good stewards of the data and will make efforts to notify investigators when this may be the case. Thus, to promote transparency and collaboration where possible, the leadership team of SEER-MHOS is interested in making selected information about new and existing DUAs public.

Check this box if you are willing to allow the National Cancer Institute to make the title, name/affiliation of PI(s), and specific aims of your DUA public and included on our SEER-MHOS public website (<http://healthcaredelivery.cancer.gov/seer-mhos/>). Questions should be directed to SEER-MHOS@hsag.com.

Signature of Principal Investigator: In the case of students and fellows, the department chair or advisor from the student's academic institution must sign the data request.

Signature of Data Analysts/Additional Study Personnel: **Anyone who will be working with the data needs to provide their name, contact information, and signature. Use the next additional boxes and duplicate for any additional study personnel.** In the case of students and fellows, the department chair or advisor from the student's academic institution must also sign the data request.

Your signature indicates that you agree to comply with the above stated provisions. Deliberately making a false statement regarding any matter within the jurisdiction of any department or agency of the Federal Government violates 18 USC 1001 and is punishable by a fine up to \$10,000 or up to five years in prison.

Signature of Principal Investigator

Date

Name of Principal Investigator

Title

Institution/Organization

Street Address

City/State/ZIP code

Phone number – including Area Code

Fax number

Email address

Optional: Additional Study Personnel with Access to SEER-MHOS Data (if more than one person, duplicate boxes below)

Signature of Additional Study Personnel Date

Name of Additional Study Personnel

Title (in association with this DUA)

Institution/Organization

Street Address

City/State/ZIP code

Phone number – including Area Code Fax number

Email address

Role (if applicable):

Student

Fellow