

Agreement ID:

NAACCR Virtual Pooled Registry Data Use Agreement ("Agreement")

Provider Registry ("Provider"):	Recipient Institution ("Recipient"): Recipient Institution FWA#:
Provider Representative Name: Email:	Recipient Scientist Name: Email:
Agreement Term: Start Date: Date of last signature below End Date (select one): <input type="checkbox"/> _____ (amount of time) after the Start Date <p style="text-align: center;">OR</p> <input type="checkbox"/> At end of Project, as defined by: _____ <p style="text-align: center;">OR</p> <input type="checkbox"/> No pre-defined end date	Project Title: Researcher Institution IRB Review Determination: <input type="checkbox"/> Human subjects research, non-exempt IRB-Approved Protocol # _____ <input type="checkbox"/> Human subjects research, exempt (per 45 CFR part 46) <input type="checkbox"/> Not human subjects research

Preamble

The parties acknowledge that, prior to the execution of this Agreement, the Recipient disclosed to the Provider certain data about individuals in a dataset the Recipient intends to use for the Project. These preliminary data may have included various identifiers, including, but not limited to, full name, Social Security Number, date of birth, and medical record number. It is understood that the Provider is charged with handling such identifiers in its regular course of business and will protect the Recipient's data according to the same standards it protects its own data. The disclosure of this preliminary data was made to link Recipient's dataset with data from Provider and provide matched case counts. The parties now agree that the Provider has significant information to assist Recipient with performance of the Project and this Agreement covers the Recipient's use of individual-level data released by the Provider.

Terms and Conditions

- 1) Provider shall provide the data set described in Attachment 1 (the "Data") to Recipient for the research purpose set forth in this agreement and Attachment 1 (the "Project"). Provider shall retain ownership of the Data, and Recipient does not obtain any rights in the Data other than as set forth herein.
- 2) Provider represents that it has full authority to share the Data with the Recipient.
- 3) By signing this Agreement, Recipient provides assurance that relevant institutional policies and applicable federal, state, or local laws and regulations (if any) have been followed, including the completion of, and compliance with, any IRB review or approval that may be required prior to Recipient's use of the Data. Upon Provider's written request to the Recipient's Contact for Formal Notices identified in the signature block, Recipient shall provide the IRB (or equivalent body) determination letter and protocol that is the basis for the IRB status determination (approval, exemption, not human subjects) herein referred to as "IRB-Approved Protocol". Recipient also provides assurance that the Data requested represents the minimum information necessary for the Recipient to complete the Project.
- 4) Recipient shall not use the Data except as authorized under this Agreement. Recipient shall use the Data only for statistical, scientific, medical research, and public health purposes that are described in the IRB-Approved Protocol (and revisions thereof), the Recipient's data sharing plan in Attachment 1, and any application(s) requesting

Agreement ID:

- Provider Data. Usage of the Data by the Recipient outside the IRB-Approved Protocol, data sharing plan, and any associated data request application(s), may require review by Provider for amendment of this Agreement as appropriate.
- 5) Recipient agrees to use the Data in compliance with all applicable laws, rules, and regulations, including but not limited to 45 CFR part 46, as well as all professional standards applicable to such research.
 - 6) Recipient will not use the Data, or permit others to use the Data, either alone or in concert with any other information, to contact individuals who are the subjects of the Data without written permission from the Provider. If Recipient contacts the subjects of the Data without having used the Data to identify these subjects, for example as part of routine activities, the Data may not be used to change what is communicated to the subjects unless written permission is obtained from the Provider.
 - 7) Recipient is encouraged to publish results of the Project. The Recipient will provide an annual list of all publications that used the Data to the Provider. All reports or analyses of the Data prepared by Recipient shall contain only aggregate data. At no time will Recipient publish any individual names or other personally identifying information or information which could lead to the identification of any Data subject. When presentations, manuscripts, or other public disclosures include registry- or state-specific data, the following requirements apply: 1.) statistical cells containing less than six (6) subjects (or as otherwise specified by the Provider in Attachment 1) must be suppressed; and 2.) the Recipient shall furnish Provider with a copy of the proposed presentation or manuscript prior to publication or use. Provider shall have thirty (30) days from receipt of a manuscript and fourteen (14) days from receipt of a presentation to disapprove such proposed presentation or submission for publication if Provider believes there is identifiable information that needs protection. In this event, Recipient may proceed with the manuscript or presentation only after addressing Provider's concerns regarding identifiable information.
 - 8) Recipient agrees to acknowledge the contribution of the Provider as the source of the Data in all written, visual, or oral public disclosures concerning Recipient's research using the Data, as appropriate in accordance with scholarly standards and any specific format that has been indicated in Attachment 1.
 - 9) The Data will be used solely by Authorized Persons that have a need to use, or provide a service in respect of, the Data in connection with the Project. Authorized Persons include:
 - a) Recipient Personnel: Recipient Scientist and Recipient's faculty, employees, fellows, students, agents, and/or contractors.
 - b) Collaborator Personnel: Faculty, employees, fellows, students, agents and/or contractors of an institution involved in the conduct of the Project, as listed in the IRB-Approved Protocol, that have executed an agreement with Recipient that is substantially similar to this Agreement.
 - 10) Except as authorized under this Agreement or otherwise required by law, Recipient agrees to retain control over the Data and shall not disclose, release, sell, rent, lease, loan, or otherwise grant access to the Data to any third party, except Authorized Persons. Recipient agrees to keep the Data in a secured environment with appropriate administrative, technical, and physical safeguards to prevent unauthorized use of or access to the Data and to maintain appropriate control over the Data at all times.
 - 11) The Data is subject to the Federal Privacy Act of 1974, as amended, at 5 U.S.C. § 552a and the Data is covered under a Certificate of Confidentiality, which must be asserted against compulsory legal demands, such as court orders and subpoenas for identifying information or characteristics of a research participant. See <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html> for further information.
 - 12) Recipient acknowledges that Data is governed by Provider's state law which likely prohibits release of Data in response to subpoena in addition to the restrictions present in Term 11. If Recipient believes it is required by law

Agreement ID:

or legal process to disclose the Data, it will promptly notify Provider, prior to such use or disclosure and will disclose the least possible amount of Data necessary to fulfill its legal obligations.

- 13) In the event Recipient becomes aware of any use or disclosure of the Data not provided for by this Agreement, Recipient shall take any appropriate steps to minimize the impact of such unauthorized use or disclosure as soon as practicable and shall notify Provider of such use or disclosure within 24 hours of discovery of the unauthorized use or disclosure. Recipient shall cooperate with Provider to investigate, correct, and/or mitigate such unauthorized use or disclosure. Recipient acknowledges that Provider may have an obligation to make further notifications under applicable laws or regulations and shall cooperate with the Provider to the extent necessary to enable Provider to meet all such obligations.
- 14) Unless stipulated otherwise herein, Recipient is permitted to share a dataset including study-acquired information augmented with elements of the Data (“Augmented Dataset”) as described in Attachment 1. The Augmented Dataset may be shared with parties other than the Authorized Persons described in Term 9 above (the “Secondary Recipient(s)”) provided conditions a-d below are all met. The ability to share an Augmented Dataset with Secondary Recipients aligns with the NIH Data Management and Sharing Policy requirements (<https://sharing.nih.gov/data-management-and-sharing-policy/about-data-management-and-sharing-policies/data-management-and-sharing-policy-overview>).
- a) The Augmented Dataset has been properly “de-identified” pursuant to 45 CFR 164.514(b)(2)(i);
- b) The identity of the subjects of the Data cannot be readily ascertained from the Augmented Dataset and the Secondary Recipient will not attempt to learn the identity of the subjects of the Augmented Dataset, nor will they attempt to link or permit others to attempt to link the Augmented Dataset with any other individually identifiable records from any other data set;
- c) The Secondary Recipient:
- (i) is a controlled access repository (e.g., dbGAP) which reviews data access requests, controls and audits dataset access, and requires a data use agreement that prohibits repository recipients from further data sharing; or
- (ii) has either 1.) executed a data use agreement with terms and conditions at least as restrictive as those set forth herein; or 2.) executed a flow-through data use agreement with Recipient that requires Secondary Recipient to abide by the terms and conditions of this Agreement in the same manner as Recipient. Such agreements shall prohibit Secondary Recipient from further data sharing, other than with a controlled access repository which reviews data access requests, controls and audits dataset access, and requires a data use agreement that prohibits repository recipients from further data sharing.

Agreement ID:

d) Recipient will submit an annual report to the Provider of any new or updated data sharing with Secondary Recipients. The report will include the name of the Recipient Personnel who authorized sharing, the Secondary Recipient name, title, address and associated organization or repository to which data were shared, the date the data use agreement was executed, the date of data sharing, the specific purpose for which the data will be used, and a list of the Data elements obtained from the Provider that were included in the Augmented Dataset. The following Provider-specific requirements, if any, must be applied to the sharing of elements of the Data:

Instructions to the drafter (completed by Provider); delete after completion of this section.

This section should include Provider-specific requirements for sharing elements of the Data with Secondary Recipients (e.g., removing data elements that Provider does not allow to be released, removing a unique patient ID that can be linked to identifiable data, cell suppression requirements, limitations on what type of organization and with whom data can be shared, and any additional requirements imposed by the Provider state/university/registry).

- 15) Recipient agrees to securely destroy or return the Data, as directed by the Provider in Attachment 1, at the earliest time at which destruction or return can be accomplished, consistent with the purpose of the Project. In all cases, Recipient shall destroy or return the Data upon expiration or termination of this Agreement. Notwithstanding the above, Recipient may securely retain one (1) copy of the Data in accordance with Term 16.
- 16) Unless terminated earlier in accordance with this section or extended via a modification in accordance with Section 21, this Agreement shall expire as of the End Date set forth above. Either party may terminate this Agreement without cause with thirty (30) days written notice to the other party's Authorized Official as set forth below. Provider may terminate this Agreement immediately upon breach by Recipient of any material provision of this Agreement. Upon expiration or early termination of this Agreement, Recipient shall follow the disposition instructions provided in Attachment 1, provided, however, that Recipient may retain one (1) archival copy of the Data in a secure manner as necessary to comply with the records retention requirements under any law, and for the purposes of research integrity and verification. Data retained in this manner shall be subject to the data security and confidentiality terms of this agreement so long as Recipient is in possession and/or control of the Data.
- 17) Except as provided below or prohibited by law, any Data delivered pursuant to this Agreement is understood to be provided "AS IS." PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE DATA WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.
- 18) Except to the extent prohibited by law, the Recipient assumes all liability for damages that may arise from its use, storage, disclosure, or disposal of the Data. The Provider will not be liable to the Recipient for any loss, claim, or demand made by the Recipient, or made against the Recipient by any other party, due to or arising from the use of the Data by the Recipient, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the Provider. No indemnification for any loss, claim, damage, or liability is intended or provided by either party under this Agreement.
- 19) Neither party shall use the other party's name, trademarks, or other logos in any publicity, advertising, or news release without the prior written approval of an authorized representative of that party. The parties agree that each party may disclose factual information regarding the existence and purpose of the relationship that is the subject of this Agreement for other purposes without written permission from the other party provided that any such statement shall accurately and appropriately describe the relationship of the parties and shall not in any manner imply endorsement by the other party whose name is being used.

Agreement ID:

- 20) This Agreement and Attachment 1 (Project Specific Information) embody the entire understanding between Provider and Recipient regarding the transfer of the Data to Recipient for the Project.
- 21) No modification or waiver of this Agreement shall be valid unless in writing and executed by duly-authorized representatives of both parties.
- 22) The undersigned Authorized Officials of Provider and Recipient expressly represent and affirm that the contents of any statements made herein are truthful and accurate and that they are duly authorized to sign this Agreement on behalf of their institution.

Agreement ID:

<p>By an Authorized Official of Provider:</p> <p>_____ Date _____</p> <p>Name: Title: Email:</p> <p><u>Contact Information for Formal Notices:</u></p> <p>Name: Address: Email: Phone:</p>	<p>By an Authorized Official of Recipient:</p> <p>_____ Date _____</p> <p>Name: Title: Email:</p> <p><u>Contact Information for Formal Notices:</u></p> <p>Name: Address: Email: Phone:</p> <p>This data use agreement has been read and understood by Recipient Scientist, who is responsible for ensuring compliance with these terms and conditions, and for communicating these obligations to Recipient Personnel who will handle the Data.</p> <p>_____ Date _____</p> <p>Name: Title: Email:</p>
--	---

Attachment 1
Data Use Agreement
Project Specific Information

1. Summary Description of Project (completed by Recipient)

Instructions to the drafter; delete after completion of this section.

This section of this attachment should provide sufficient information such that each party understands the Project that the Recipient will perform using the Data. Content of this section will be very similar to the Statement of Work used in other types of Agreements. Examples of information that should be provided include:

- * Objective or purpose of the Recipient's work*
- * A general description of the actions to be performed by the Recipient using the Data and possibly the anticipated results*

2. Summary Description of Data Sharing Plan (completed by Recipient)

Instructions to the drafter; delete after completion of this section.

This section of this attachment should provide sufficient information such that each party understands the Recipient's plan to share an Augmented Dataset with Secondary Recipients. Content of this section will briefly describe how the Augmented Dataset generated from the Project will be managed and shared. Examples of information that should be provided include:

- * Summary of the type and content of data to be shared (e.g. de-identified, cancer outcomes associated with survey data, etc.)*
- * Documentation of any known parties with whom an Augmented Dataset will be shared*
- * Plans to manage secondary data sharing requests (e.g. review process, use of controlled access repositories, requirement for DUA with Secondary Recipients, etc.)*

3. Summary Description of Data Released by Provider (completed by Recipient, reviewed by Provider)

Instructions to the drafter; delete after completion of this section.

This section of the attachment should provide sufficient information such that each party understands the information requested by Recipient and released by the Provider under this Agreement. Examples of information that should be provided include:

- * Description of the data (e.g., diagnosis years, type of cancer, etc.) released by the Provider.*
- * General overview of the type of data elements (e.g., tumor characteristics, treatment characteristics, etc.) included in the data to be released by the Provider.*

4. Expected frequency for recurring linkages, if applicable (completed by Recipient)

Instructions to the drafter; delete after completion of this section:

If the Project involves linkage of a study file with the Provider Data, describe how frequently the Recipient will provide a study file for recurring linkage. If linkages do not recur, write "None".

5. Data Transmission and Provider Support (completed by Recipient)

Provider shall electronically transmit Data to Recipient via a secure mechanism. Upon execution of this Agreement, Provider will contact Recipient individual below to coordinate Data transfer.

Name:	
Address:	
Email:	
Phone:	

6. Technical Requirements for Data Transmitted to Recipient (completed by Provider)

Instructions to the drafter; delete after completion of this section.

This section of this attachment should provide sufficient information such that each party understands the technical requirements of the data to be supplied to the Recipient. Examples of information that may be appropriate to include in this section are:

- * *Format of Data*
- * *Provision of Data dictionary*
- * *Availability of Provider to assist Recipient in understanding the Data structure (e.g. variables, code lists, etc.)*
- * *If/how Provider will address Recipient concerns and questions about the Data*

7. Publication Requirements (completed by Provider)

In order to simplify cell size suppression requirements across registries, Term 7 of this Agreement requires Recipient to suppress state-specific or registry-specific cell sizes containing less than six (6) subjects. Please indicate whether the Provider accepts the standard suppression rule as written:

- Yes, Provider accepts the standard cell size suppression rule of less than six (6) subjects as stated in Term 7 of this Agreement.
- No, Provider requires the following alternative cell size suppression rule:

Enter cell size suppression rule here:

8. Acknowledgement Statement for Publications (completed by Provider)

In order to simplify the list of acknowledgements in publications including data from numerous central cancer registries, the following standard acknowledgement is proposed (and has been approved by the referenced Federal funding organizations):

“The authors would like to acknowledge the contribution to this study from central cancer registries supported through the *Centers for Disease Control and Prevention’s National Program of Cancer Registries (NPCR)* and/or the *National Cancer Institute’s Surveillance, Epidemiology, and End Results (SEER) Program*. Central registries may also be supported by state agencies, universities, and cancer centers. Participating central cancer registries include the following: <list of participating registries>.

Please indicate what acknowledgement the Provider requires the Recipient to use in publications:

- Provider requires the standard acknowledgement (stated above).
- Provider requires that the standard acknowledgement (stated above) be used for publications that **DO NOT INCLUDE** state-specific or registry-specific results. For any publications that **DO INCLUDE** state-specific or registry-specific results, the following acknowledgement is required:

Enter acknowledgement here:

- Provider requires that the following acknowledgement statement be used for all publications, regardless of whether state-specific or registry-specific results are included:

Enter acknowledgement here:

9. Data Destruction and/or Retention Requirements (completed by Recipient, reviewed by Provider)

Instructions to the drafter; delete after completion of this section.

This section of this attachment should include sufficient information such that each party understands the Recipient’s obligations with regards to the destruction or return of the Provider Data at the earliest time possible consistent with the purpose of the Project or upon the expiration or early termination of this Agreement. Please be sure to specify the methods and timeline for data destruction.