

Companion Document for NAACCR Virtual Pooled Registry Data Use Agreement (VPR DUA)

(September 9, 2022)

1. Background and need for the NAACCR VPR DUA

The majority of central cancer registries in the United States require that a data use agreement (DUA) be in place prior to releasing data to external parties. Until now, each registry had a different DUA with varying terms and conditions that require legal review. This review and negotiation process is time intensive and leads to significant delays in release of data for approved research studies. In addition, the recipient of the cancer registry data must then remain in compliance with the varying requirements across the individual DUAs.

The NAACCR VPR DUA is a common agreement designed to be used in lieu of the individual registry DUAs, thereby minimizing the number of separate DUAs and ensuring consistency in the terms and conditions. The VPR DUA was specifically developed for use with linkage studies facilitated by NAACCR's Virtual Pooled Registry Cancer Linkage System (VPR-CLS). This online system, hosted by IMS, Inc., streamlines the linkage, application, and data release process between cohort studies and U.S. cancer registries. Use of the VPR DUA is voluntary, but strongly encouraged, as a way to ensure a standardized agreement and reduce the administrative burden associated with sharing data.

2. Process for creating the NAACCR VPR DUA

The VPR DUA was created by the NAACCR DUA Task Force. This task force included registry staff, legal and contract staff, researchers, and NAACCR representatives. The Federal Demonstration Partnership Data Transfer and Use Agreement (FDP-DTUA) served as the basis for creating the VPR DUA and was modified to address the needs of this project. The VPR DUA was vetted with registries and their legal teams, as well as researchers and NCI's Technology Transfer Center. This collaboration has resulted in a common DUA that reflects a widely accepted set of standard terms and conditions.

3. Implementation and expectations for use of the NAACCR VPR DUA

- a. **Intended Use:** The VPR DUA is intended for use with linkage studies facilitated by the Virtual Pooled Registry Cancer Linkage System (VPR-CLS). The VPR DUA covers release of registry data to researchers when individual-level data on linked cases are requested. The VPR DUA is used in lieu of individual registry agreements (DUAs, researcher agreements, confidentiality agreements, etc.). Registry use of the VPR DUA is voluntary, but strongly encouraged as a way to minimize the number of different agreements across registries.

Expectations for VPR DUA use by participating registries and researchers are as follows:

- For VPR Registries: Registries wishing to adopt the VPR DUA will afford their legal counsel, as necessary, the opportunity to review the terms and conditions and approve use of the VPR DUA for all linkage studies facilitated by the VPR-CLS. In order to be adopted, registries and their legal counsel must agree to use the VPR DUA "as is" without the need for state-specific changes.

- For VPR Researchers: Research institutions are discouraged from proposing changes to the terms and conditions for their individual project. Any such changes will necessitate additional review by and/or negotiation with legal counsel from every registry that has adopted the VPR DUA, thereby slowing down finalization of the DUA. In the event that a research institution proposes changes to the terms and conditions, modifications will be entered into the online VPR-CLS for review by participating registries.
 - b. **Other Use**: Registries wishing to use the VPR DUA language for studies other than linkage studies facilitated by the VPR-CLS may do so only after removing the Preamble and all reference to “NAACCR VPR DUA” so it is clear that the VPR DUA standard template language was altered. If modifying the VPR DUA, it is important to note that the current version was designed for studies where unique IDs and complete dates are the only identifiable data released by the cancer registry. Other types of studies may require modification of the VPR DUA to enforce stricter requirements, based upon the nature of the data released.
 - c. **Future Revisions to VPR DUA**: NAACCR recognizes the dynamic regulatory and scientific environment concerning the content addressed in the VPR DUA. As such, revisions to the VPR DUA will be considered as needed. Registries are encouraged to submit requested changes for future version of the VPR DUA to the VPR-CLS Manager. If needed, NAACCR will reassemble a committee to address substantive and material changes to maximize the utility of the VPR DUA.
4. Background and Instructions for completing the VPR DUA

Page 1, Header: Complete this information as indicated below. The information provided here should match the information provided in the VPR-CLS application to use data.

- The Agreement ID is optional but highly recommended for project management purposes. The Parties are free to use tracking numbers as determined by their internal contract management systems. If the VPR DUA is processed through the online VPR-CLS, however, Agreement ID may be automatically assigned.
- The End Date represents the expiration of the Agreement, and the date when the Data must be destroyed and/or returned to the Provider according to the disposition instructions at the end of Attachment 1.
 - Select the “X (amount of time) after Start Date” option if the Parties are reasonably confident that the Project can be completed within the specified time or if there are institutional limits on the allowable timeframe.
 - Select the “At End of Project” option if the Project is subject to multiple extensions. Be sure to define what constitutes the end of the project so it is clear to both parties.
 - Select “No Pre-Defined End Date” if it is appropriate and necessary for the Recipient to hold the Data indefinitely.

- Researcher Institution IRB Review Determination: The Recipient should provide this information to document appropriate oversight of the project at the Recipient Institution. Flexibility is provided to accommodate a variety of projects. If Recipient has IRB approval for the Project, the reference number for their IRB approved protocol must be provided.

Page 1, Preamble: The NAACCR DUA Task Force carefully examined many issues surrounding the creation of the VPR DUA, including the fact that prior to initiation of the data release addressed by this DUA, encrypted, confidential data from the Recipient Institution was transmitted to Provider Registry in order to perform a linkage and generate match counts only. The VPR DUA is intentionally focused on the ensuing release of individual-level cancer information for matched cases from the Provider Registry to the Recipient. This is not intended to minimize the Registry's responsibility in data protection, but rather to avoid the many complexities involved in a two-way DUA, which often requires more customization than this template can accommodate. Because the Provider handles sensitive, identifiable data as part of its regular business, the Provider has in place robust systems to protect such data and is well-equipped to protect any identifiers received from the Recipient.

Page 2, #6: This provision is intended to clarify that the Recipient receives no additional permissions through this agreement to contact individuals who may be the subject of the Data. If a Recipient already has permission to contact individuals (e.g., via their institution's IRB approval), they may continue to do so. However, the Recipient may not use any elements of the Data received solely from the Provider to make contact or re-identify these individuals.

Page 3, #14: This provision is intended to clarify the circumstances under which the Recipient may further share the Data (that is, data elements received from Provider) with parties other than the Authorized Persons described in the DUA. Compliance with these terms is critical to ensure protection of individuals who may be the subject of the Data. To be clear, any data elements that Recipient holds that are related to the Project but were not received from the Provider or derived from data received from Provider, are not subject to the terms and conditions of this agreement. The open text box should be used by the Provider to convey any data-specific restrictions that apply. This box should not be used to insert additional terms and conditions. If the Recipient is not permitted to share data with any other entities, this may be documented in the text box.

Attachment 1, General Instructions: Each item in the attachment should be completed by the party specified (e.g. Recipient or Provider). The response text boxes contain instructions for the Provider and Recipient, including examples of the information required. The instructions should be deleted and replaced with the information requested.

- #1, Summary Description of Project: This should be a short, abstract-like summary of the Project described in the application to receive data. Write in a manner that a non-scientific, legal reviewer of the contract will understand what is being done with the Data.
- #2, Summary Description of Data Released by the Provider: Please provide a brief summary of the Data, including salient variables or sets of variables (e.g. treatment, stage, etc.). Do not provide a full variable list, but rather sufficient information for a non-

scientific, legal reviewer of the contract to determine if the terms in the agreement are appropriate for the type of data released.

- **#3, Expected Frequency for Recurring Linkages, if applicable:** If future recurring linkages are anticipated, the frequency is to be noted.
- **#4, Data Transmission and Provider Support:** The Recipient should insert the day-to-day technical contact person who will receive the Data. This may not be the Researcher, but should be someone taking direction from the Researcher.
- **#5, Technical Requirements for Data Transmitted to Recipient:** The Provider should document how they will assist the Recipient with accessing and utilizing the Data.
- **#6, Acknowledgement Statement for Publications:** This section was designed to ensure consistent acknowledgements in manuscripts that result from these Projects, while simultaneously providing flexibility for those Providers who have special requirements for acknowledgements. The acknowledgement statement has been approved by NCI-SEER and CDC-NPCR. The Provider is expected to select one of the three check boxes. If the second or third boxes are selected, the Provider is expected to insert their required acknowledgement language, which the Recipient will utilize when submitting manuscripts. The disclaimer language should be used as-is.
- **# 7, Data Destruction and/or Retention Requirements:** The Parties shall insert instructions for how the Data shall be disposed of upon expiration/termination of the agreement, taking into account the nature of the Project and all legal and regulatory factors applicable to the Data. Include data destruction methods and timeline.

Glossary of VPR DUA Terms

TERM	DEFINITION
Authorized Officials	Individuals who are authorized by their respective institutions to sign agreements that legally bind their institutions; typically these people are located in central administration and are not the PIs.
Data	A defined term in the DUA, this only refers to the Data provided by the Registry to the Recipient, and does not include any data that the Recipient holds separately, even if related to the Data provided.
Data Breach	Unauthorized acquisition and/or loss of custody and control of data that compromises the security, confidentiality, or integrity of personal or other information maintained by the institution; an impermissible use or disclosure under the DUA or any applicable law or regulation.
Data Linkage (linked data)	A method of exposing, sharing, and connecting data from different sources, or (sometimes) the data itself that is connected or aggregated so as to access or provide more information.
Honest broker	An entity that keeps sets of private information but distributes parts of those sets, as authorized, to other entities who should not have access to the entire set.

TERM	DEFINITION
IRB Review Determination	Various levels of oversight provided by an IRB: Human Subjects Research; IRB exempt status; Not human subjects research
Personally Identifiable Information (PII)	Any information maintained by an agency, including: (1) any information that can be used to distinguish or trace an individual's identity, such as name, social security number, date and place of birth, mother's maiden name, or biometric records; and (2) any other information that is linked or linkable to an individual, such as medical, educational, financial, employment information, or specific dates, such as diagnosis or treatment. PII is necessary for a successful data linkage. When allowing access to PII care should be taken that the data or combination of data elements when linked (i.e. taken in combination) do not allow the individual to be distinguished or traced. A list of direct identifiers is defined by HIPAA.
Protocol, IRB-Approved Protocol	A document that describes the objective(s), design, methodology, statistical considerations, and organization of a study. In the VPR DUA, the Protocol is referred to as the IRB-Approved Protocol regardless of the Protocol's IRB status.
Provider Registry (Provider)	This is the organization that acts as the public health registry collecting cancer data, and providing the Data to the Recipient Institution
Provider Scientist	Usually a Registry Director or their delegate.
Recipient Institution (Recipient)	The organization employing the Recipient Scientist.
Recipient Institution FWA#	Federalwide Assurance (FWA) number, this references the specific authorization held by the IRB of an institution which permits them to oversee human subjects research. A FWA is searchable at: https://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc
Recipient Scientist	The researcher receiving the Data, who acts as the Principal Investigator at Recipient Institution.
Record Retention	The period of time a document(s) or data should be kept or retained, whether in electronic format or physical format. Record Retention period usually depends on the record type and the business, legal and compliance requirements associated with the record. Record Retention periods may be determined by both federal and state law.
Re-identification	Re-identification is the process of attempting to discern the identities that have been removed from de-identified data.
Research	A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research (e.g., a published article, book, or book chapter) and product development (e.g., a diagnostic test or drug).