VA PITTSBURGH HEALTHCARE SYSTEM

**RESEARCH DATA USE AGREEMENT (RDUA)**

1. **PURPOSE OF THE AGREEMENT**

This Research Data Use Agreement (RDUA) establishes the terms and conditions under which VAPHS will provide VA Research Data to a collaborator for research purposes.

1. **SCOPE OF THE AGREEMENT**
2. **VAPHS Principal Investigator (PI) and Study Information**

*All subsequent references to “Sender” reflect the details that are described in this Section, II.A.*

* 1. **PI Name and Degree\*:** Click here to enter text.

**\*This individual will serve as the VAPHS Point of Contact.**

* 1. **PI Address:** Click here to enter text.
	2. **PI Email:** Click here to enter text.
	3. **PI Phone Number:** Click here to enter text.
	4. **Study Identification Number (ProSPECT ID# or MIRB#):** Click here to enter text.
	5. **Study Name/Title:** Click here to enter text.
	6. **Sponsor, if applicable:** Click here to enter text.
1. **VA Research Data Recipient Information**

*All subsequent references to “Recipient” reflect the details that are described in this Section, II.B.*

* 1. **Please select Recipient type:**

[ ] **VAPHS Collaborator (i.e. recipient of data or specimens from a research repository)**

[ ] **VA Collaborator (Non-VAPHS)\***

[ ] **Non-VA Collaborator\***

[ ] **Review Preparatory to Research**

**\****All Non-VAPHS collaborations must have documentation of whether or not the collaboration engages the Non-VAPHS affiliated institution in human research. Examples of documentation may include, approval from the collaborating institution’s IRB, a letter from the collaborating institution’s confirming that the research is “exempt”, or confirmation that said institution is not engaged in research.*

* 1. **Recipient Name** (Institution, Repository, Individual Collaborator, etc. If recipient is a collaborator, please also list the affiliated institution): Click here to enter text.
	2. **Recipient Address:** Click here to enter text.
	3. **Recipient Phone Number:** Click here to enter text.
	4. **Recipient Email:** Click here to enter text.
	5. **Regulatory and Approval Information, if engaged in research. If “N/A” please leave blank.**
		1. **Name of Collaborating Institution:** Click here to enter text.
		2. **IRB of Record, if applicable:** Click here to enter text.
		3. **Chair, IRB of Record (Name):** Click here to enter text.
		4. **Address:** Click here to enter text.
		5. **Approval/Decision/Status:** Click here to enter text.
1. **Purpose of Transfer**
	1. **What is the purpose of the study for which the shared data will be used?** Click here to enter text.
	2. **How will the shared VA research data be used to achieve the aims of the study?** Click here to enter text.
2. **Data Type**
	1. **Please select all that apply to the data being transferred:**

**Individual Level Data**

[ ] **De-Identified Data –** Data that cannot be linked to a specific individual either because the existing link (such as code key) to the identity of the individual was destroyed or because the data was completely de-identified at the time of collection. De-identified data lack all 18 personal identifiers specified by the Health Insurance Portability and Accountability (HIPAA) Act of 1996. Information that cannot be used to identify the individual [such as diagnosis, age (below 90), and gender] may be recorded with or linked to the data. This option should only be selected if there is no-PHI included with the data. *NOTE: Coded data is data identifiable by the individual(s) who has access to the code. Therefore, coded data are not considered to be de-identified or anonymous.*

[ ] **Coded Data –** The term “**coded data**” means “coded private information” in that identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens. If any PHI are included with the data (in the form of dates/limited data set), please check the “PHI” option below, and indicate the identifiers. *NOTE: Coded data is data identifiable by the individual(s) who has access to the code. Therefore, coded data are not considered to be de-identified or anonymous.*

[ ] **Limited Data Set –** A limited data set is protected health information from which certain specified direct identifiers of the individuals and their relatives, household members, and employers have been removed. These identifiers include name, address (other than town or city, state, or zip code), phone number, fax number, e-mail address, Social Security Number (SSN), medical record number, health plan number, account number, certificate and/or license numbers, vehicle identification, device identifiers, web universal resource locators (URL), internet protocol (IP) address numbers, biometric identifiers, and full-face photographic images. A limited data set is not de-identified information or data. (45 CFR § 164.514(e)). Please also check the “PHI” option below, and specify the HIPAA identifiers that will be included.

[ ] **Identifiable Data/Protected Health Information (PHI) –** Per VHA Handbook 1200.05, PHI is individually identifiable health information transmitted or maintained in any form or medium. VHA further defines PHI as information that is covered by HIPAA which may or may not be covered by the Privacy Act or Title 38 confidentiality statutes.

* + - 1. **If PHI is selected, please check all HIPAA Identifiers that will be included** *(45 CFR Part 160 and Part 164, Subparts A and E):*

[ ] Names

[ ] E-mail addresses

[ ] All elements of dates (except year) associated with an individual & any age over 89. Specify: Click here to enter text.

[ ] Telephone numbers

[ ] Fax numbers

[ ] All geographic subdivisions smaller than state

Specify: Click here to enter text.

[ ] Social Security numbers (SSN) or scrambled SSNs

[ ] Medical record numbers

[ ] Health plan beneficiary numbers

[ ] Account numbers

[ ] Certificate or license numbers

[ ] Vehicle IDs and serial numbers including license plate numbers

[ ] Device identifiers and serial numbers

[ ] URLs (Universal Resource Locator)

[ ] IP addresses (Internet Protocol)

[ ] Biometric identifiers including finger and voice print

[ ] Full face photographic images and any comparable images

[ ] Other unique identifying number, characteristic, or code.

 Specify (e.g., scrambled SSN): Click here to enter text.

* 1. **List VA variables and descriptors, or if a known VA dataset with pre-defined variables, list the VA dataset(s) to be used under this RDUA:** Click here to enter text.
	2. **At what point in the study protocol will data be transferred from VAPHS to the Collaborator?** Click here to enter text.
	3. **How will the data be managed after it is received?** Click here to enter text.
1. **Method of Transfer**
	1. **Describe how data will be transmitted or transported. If transfer method is not applicable, please type “N/A”:** (VHA Handbook 1200.05, 10.j.)
		1. **Hardcopy data:** Click here to enter text.
		2. **Portable electronic media containing data:** Click here to enter text.
		3. **Electronic data:** Click here to enter text.
2. **Data Security and Storage**
	1. **Identify the physical site where the data will be used. If storage type is not applicable, please type “N/A”:** (VHA Handbook 1200.05, 10.j. and VA Handbook 6500, Appendix D, AC-19)
		1. **Hardcopy data:** Click here to enter text.
		2. **Portable electronic media containing data:** Click here to enter text.
		3. **Electronic data:** Click here to enter text.

1. **Data Access and Accountability**
	1. **Describe how data will be accounted for (e.g., a tracking log for audit purposes):** Click here to enter text.
2. **Disposition and/or Return of VA Research Data**
	1. **Describe how and when (include dates) the VA Research Data will be returned to the VAPHS Investigator or destroyed by the Recipient:** Click here to enter text.
3. **TERMS OF THE AGREEMENT**
4. **Data Use and Security Safeguards**
5. This RDUA is between the *Recipient* and VAPHS with the *Sender,* designated as custodian of the data described above. The *Sender* will be responsible for the observance of all conditions for the use of these data in accordance with the terms described below. These items include: (a) scientific use and publication of data; (b) establishing and maintaining appropriate administrative, technical, and physical security safeguards to prevent unauthorized access or use of the data; and (c) protecting the confidentiality of the data.
6. This RDUA covers the transfer and the use of VA data detailed in Section I, which also describes plans for security safeguards to prevent unauthorized use and to protect the confidentiality of the data. These plans shall provide a level and scope of security that is not less than the level and scope established by applicable Federal and VA regulations and policies for data use, transfer, and security for research. Copies of these documents can be provided upon request.
7. Data provided to the *Recipient* shall be used only for those purposes outlined in Section I, and shall not be used in any other way without the prior written agreement of VAPHS (see item 30).
8. The *Recipient* acknowledges that failure to comply with VA policies and regulations pertaining to data use and safeguarding confidential and privacy protected data may violate federal law, some of which may carry civil and/or criminal penalties.
9. **Authorization**
10. VA is authorized to share the data for the purposes indicated under theHealth Insurance Portability and Accountability Act (HIPAA) Privacy Rule, 45 CFR 164.512(i) and authorities stated in the Veterans Health Administration (VHA) Handbook 1200.12.
11. **Institutional Approvals of Project/Protocol**
12. If applicable, the *Recipient* will obtain the necessary documentation from the responsible Institutional Review Board (IRB) that the research activities using these data are approved. If the activity is exempt or non-human subjects’ research, the *Recipient* will obtain the necessary documentation from the responsible institutional authority. The VAPHS IRB will be provided with written evidence of the *Recipient* IRB’s approval or the institution’s determination that the proposed research activity is either exempt from IRB approval or non-human subjects research before release of the data.
13. **Data Ownership**
14. VA retains all ownership rights to the data, including original data and any derived data generated from the original data, provided to the *Recipient* under this RDUA.
15. **Publication of Data**
16. Identifiable, Individual-level human subject data shall not be published.
17. The VAPHS Research Office shall be informed of any manuscripts or presentations resulting from the data upon acceptance for publication or presentation.
18. All manuscripts and presentations resulting from, and reporting analyses of the data, will acknowledge the Department of Veterans Affairs as well as the *Sender (VAPHS Investigator and Study Name)*, and will indicate that all statements, opinions, or views are solely of the author(s) and do not reflect official views of VA.
19. **Data Management**
20. **Transfer**
21. Any transfer of VA data by must be transmitted securely in accordance with VA-approved standards.
22. **Storage**
23. The *Recipient* shall not make copies of VA data except as authorized and necessary to execute the terms of this RDUA, as detailed in Section II.
24. Physical copies of the VA data, such as paper forms, compact discs (CDs) or digital versatile discs (DVDs), provided to The *Recipient,* under this RDUA, as detailed in Section I, must be kept in a locked cabinet or desk when not in use and electronic records must be maintained securely.
25. **Access**
26. Access to VA data shall be restricted to the *Recipient,* who requires access to perform their official duties in accordance with the uses of the data as authorized in this RDUA. Such personnel shall be advised of:(a) the confidential nature of the data; (b) safeguards required to protect the data; and (c) the administrative, civil, and criminal penalties for noncompliance contained in applicable Federal laws.
27. The *Recipient* agrees not to disclose, release, reveal, show, sell, rent, lease, loan, or otherwise grant access to VA data or any data extracted or derived from these data to other parties other than as permitted by this RDUA.
28. Notwithstanding the provision above, the *Recipient* shall not release VA records protected by Title 38 U.S.C. 5705, confidentiality of medical quality assurance records, and/or Title 38 U.S.C. 7332, confidentiality of certain health records pertaining to drug addiction, sickle cell anemia, alcoholism or alcohol abuse, or infection with human immunodeficiency virus. If the *Recipient* is in receipt of a court order or other requests for the above-mentioned information, the *Recipient* shall immediately refer such court orders or other requests to the VAPHS point of contact, identified in Section I.
29. VA reserves the right to allow authorized representatives of VA and the VA Office of Inspector General to be granted access to premises where the data are kept by the *Recipient* for the purpose of confirming that the *Recipient* is in compliance with all security and data use requirements associated with this RDUA.

**iv. Retention**

1. The parties mutually agree that the VA data, and any derivative data or file(s) that are created from the original data, may be retained by the *Recipient* until the data destruction or return date as specified in Section I.

**v. Return**

1. If applicable, the *Recipient* agrees to return to VA the data, including the original VA data received, and any derivative data or file(s) that were created from the original data, and any data repositories created from the original data, by the return date as indicated in Section I.

 **vi. Destruction**

1. All data residing at VAPHS must follow the VA Records Control Schedule. For all data residing outside of VAPHS, the institution must follow the records control governed by that facility. Self-certification by the *Recipient* that the data destruction requirements have been met must be sent to the VAPHS Principal Investigator by the Disposition/Return Date as defined in Section I.
2. **Compliance**
3. The *Recipient* will protect the privacy and confidentiality of any individually identifiable information contained in the VA data, consistent with the Privacy Act of 1974 and, to the extent applicable, standards promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 38 U.S.C. 5701(f), and other applicable laws, regulations, and policies.
4. The *Recipient* agrees that no attempt will be made to re-identify VA data that is de-identified or to obtain identifiable subject information that was not otherwise provided or known. If scrambled Social Security numbers (SSNs) are provided, no attempt to “unscramble” them will be made to reveal the real SSNs.
5. The *Recipient* agrees to immediately report any theft, loss, or compromise of the VA data to the appropriate administrative/law enforcement officials and to the VAPHS point of contact as designated in Section I. As appropriate, this includes INSERT NAME OF COLLABORATING INSTITUTION’s local Information Security Officer, Privacy Officer, IRB, Security Service, or others as required. In the event that VA determines or has reasonable cause to believe that the *Recipient* disclosed or may have used or disclosed any part of VA data other than as authorized by this RDUA or other written authorization, VA in its sole discretion may require INSERT NAME OF COLLABORATING INSTITUTION to: (a) promptly investigate and report to VA INSERT NAME OF COLLABORATING INSTITUTION’s determinations regarding any alleged or actual unauthorized use or disclosure; (b) promptly resolve any problems identified by the investigation; (c) if requested by VA, submit a formal response to an allegation of unauthorized disclosure; and (d) if requested, return VA data files to VA. If VA reasonably determines or believes that unauthorized disclosures of its data in the possession of the *Recipient* have taken place, VA may refuse to release further data to the *Recipient* for a period of time to be determined by VA, or may terminate this RDUA.
6. The *Recipient* agrees to report to the VAPHS Principal Investigator any use or disclosure of data not provided for in this RDUA or any noncompliance with this RDUA as soon as the *Recipient* becomes aware of it.
7. **Other Provisions**
8. The *Recipient* shall not hold VAPHS employees responsible in any liabilities, claims, actions, and suits arising from the *Recipient*’s use of VA data.
9. The terms of this RDUA can be changed only by a written modification of the RDUA by the signatories (or their designated representatives) to this RDUA, or by the parties adopting a new agreement in place of this RDUA.
10. The VAPHS Principal Investigator shall be notified by the *Recipient*, at minimum, within 15 business days prior to any change in the *Recipient*’s status.
11. This RDUA may be terminated by either party at any time for any reason upon 30 days written notice to the VAPHS Principal Investigator. Upon such notice, VAPHS will notify the *Recipient* to destroy or securely return such VA data at the *Recipient*’s expense using the same procedures stated in Section I. (see also items 20 and 21).
12. All questions of interpretation or compliance with the terms of this RDUA should be referred to the VAPHS Principal Investigator.
13. **Execution**
14. Upon execution of this RDUA and written evidence of the *Recipient* IRB’s approval or the institution’s determination that the activity is exempt or non-human subjects research, VA data may be transferred.
15. **SIGNATORIES OF THE AGREEMENT**

The following signatures are required to execute the RDUA. Signatures should be obtained chronologically starting with section A. The RDUA is considered executed upon the date of the last VA signature.

1. **Recipient Signatures**
2. ***Recipient/Collaborator***

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*Printed Name*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Signature*

*\*If the Recipient/Collaborator is affiliated with a Non-VAPHS VA facility, the Associate Chief of Staff for Research & Development of that facility must also sign below.*

* 1. ***Non-VAPHS VA Facility Associate Chief of Staff for Research and Development***

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Printed Name*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Signature*

**B. VAPHS Signatures**

1. ***VAPHS Principal Investigator***

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Printed Name*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Signature*

1. ***VAPHS Privacy Officer***

*(Select one)* [ ] Concur [ ] Do Not Concur\*

*\*if you do not concur please communicate reasons to the VAPHS Principal Investigator*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Printed Name*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Signature*

1. ***VAPHS Information Security Officer***

*(Select one)* [ ] Concur [ ] Do Not Concur\*

*\*if you do not concur please communicate reasons to the VAPHS Principal Investigator*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Printed Name*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Signature*

1. ***Associate Chief of Staff for Research and Development***

*(Select one)* [ ] Concur [ ] Do Not Concur\*

*\*if you do not concur please communicate reasons to the VAPHS Principal Investigator*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Signature*

*Steven H. Graham, MD, PhD*

*Associate Chief of Staff for Research and Development*

*VA Pittsburgh Healthcare System*