**VA Pittsburgh Healthcare System Research & Development**

**Research Written Agreement**

1. **INTRODUCTION**

This research written agreement (RWA) has been adopted for use by the VA Pittsburgh Healthcare System (VAPHS), which represents the U.S. Department of Veterans Affairs (VA), to establish the terms and conditions under which a VAPHS Investigator will release aggregate or analytic VA research data to a Non-VA Collaborator. The RWA describes the data and scope of the collaboration, and establishes the responsibilities of each party, the ownership of the data, and the reuse of the data for other research, as required by VHA Handbook 1200.05.

This RWA may only be used for the release of aggregate data or other analytic output, unless another agreement is in place governing VA research data for this project. This RWA cannot be used for the release of private health information, individually identifiable information, or de-identified data. Furthermore, this RWA cannot be used for collaborations involving a contracted service.

1. **DEFINITIONS OF DATA TYPES APPLICABLE FOR USE OF THE RWA**
   1. Aggregate Data: Data compiled in such a manner that it cannot be linked to an individual. Aggregate data may also be considered a processed version of raw data, or data combined on a level across more than one individual or data point. Examples include, but are not limited to, tables, figures, summary statistics, etc.
   2. Analytic Data: Data pooled and compiled in a summary manner or data that has been extracted and categorized for further analysis to help identify patterns, correlations and other insights. These data may also be included in summary tables, summary statistics, statistical output, and analytic methodology.
2. **TERMS OF THE RWA**
   1. This agreement is between the VAPHS Research Investigator and individual Non-VA Collaborator, together collectively referred to as “parties,” listed below:

| **VAPHS Research Investigator** | | | |
| --- | --- | --- | --- |
| **Name and Title** | Click here to enter text. | | |
| **Mailing** **Address** | Click here to enter text. | **Phone** | Click here to enter text. |
| **Email** | Click here to enter text. |

| **Non-VA Collaborator** | | | |
| --- | --- | --- | --- |
| **Name and Title** | Click here to enter text. | | |
| **Mailing** **Address** | Click here to enter text. | **Phone** | Click here to enter text. |
| **Email** | Click here to enter text. |

* 1. The VA research data described in this RWA will be used solely in connection with the VAPHS R&D Committee approved research project listed below. This RWA must be consistent with the Institutional Review Board (IRB) reviewed study application/protocol, consent form, and HIPAA authorization.

| **IRB# or MIRB#** | **Full Title of Research Project** |
| --- | --- |
| Click here to enter text. | Click here to enter text. |

* 1. The data will not be disclosed outside of the VA other than as permitted by this RWA and permitted within the protocol for which the data have been disclosed.
  2. Data must be used, stored, and secured according to the requirements of the VHA 1200 series Handbooks, other applicable VA and VHA requirements, and as described in the approved research protocol.
  3. Any non-compliance with the applicable VA and VHA requirements, other applicable Federal regulations, or the research protocol as approved by the R&D Committee and its subcommittee(s), must be reported according to VAPHS policies and procedures and by VHA requirements. It must also be reported to the VAPHS investigator who allowed the data to be transferred.
  4. Any theft, loss, or compromise of the data must be immediately reported to the investigator’s facility’s Information Security Officer, Privacy Officer, the investigator’s supervisor, and others as stipulated in VA, VHA, and local facility’s requirements.
  5. No effort will be made to re-identify data that are de-identified.

1. **RESPONSIBILITIES RELATED TO VHA RESEARCH DATA**
   1. The VA Research Data to be released per this RWA are as follows (describe the data):

| Click here to enter text. |
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* 1. Describe the purpose of this collaboration and scope of interaction that the Non-VA Collaborator will have with VA Research data:

| Click here to enter text. |
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* 1. Describe how the data will be transferred:

| Click here to enter text. |
| --- |

* 1. The Non-VA Collaborator agrees to notify the VAPHS Research Investigator within fifteen (15) days of any known or anticipated change(s) to the collaborating status and/or scope of the collaboration as outlined in this document so that a new written agreement may be established.

* 1. The VAPHS Research Investigator agrees to notify the Non-VA Collaborator of any known or anticipated change(s) to the collaborating status and/or scope of the collaboration as outlined in this document.
  2. The parties agree to maintain the security and confidentiality of all VA research data, and further agree not to release, distribute, disseminate or publish the data or findings except as authorized/outlined by this RWA.
  3. The terms of this RWA can be changed only by a written modification to the agreement by the parties adopting a new agreement in place of this RWA.

1. **SIGNATURES**

The RWA is entered into, and shall be effective on the date of the last signature of the parties involved. The undersigned expressly certify and affirm that the contents of any statements made herein are truthful and accurate. Any false or misleading statements made, present, or submitted to the Government, including any relevant omissions, under this agreement and during the course of negotiation of this agreement are subject to all applicable civil and criminal statues including Federal statutes 31 U.S.C. §§ 3801-3812 (civil liability) and 18 U.S.C. § 1001 (criminal liability including fines(s) and/or imprisonment).

| **VAPHS Investigator** |  | **Non-VA Collaborator** |
| --- | --- | --- |
| **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** Printed Name  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  Signature  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** Date |  | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** Printed Name  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** Signature  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** Date |

1. **WRITTEN AGREEMENT VERSION DATE**

The version date of this agreement is: \_Click here to enter text.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_