# VCULogotypeB



# DATA USE AGREEMENT FOR RESEARCH

**45 CFR 164.514 (e)**

This Data Use Agreement (“Agreement”) effective the       day of      , 20      (“Effective Date”) by and between The Virginia Commonwealth University Affiliated Covered Entity (“Covered Entity”) and      , the Limited Data Set recipient (“Recipient”).

The Covered Entity is willing to provide the Recipient with a Limited Data Set of Protected Health Information (“PHI”) as defined by 45 CFR 164.514(e)(2) for research purposes; and

The Recipient warrants that it shall use or disclose the Limited Data Set exclusively for the purposes set forth herein:

1. **Permitted Users.** Recipient agrees that Recipient will allow access to the Limited Data Set only to the following individuals and classes of individuals (attach separate page if necessary):
2. **Permitted Uses.** The Recipient agrees to use and allow access to the Limited Data Set solely as described in the attached Research Plan and Appendix A for the study titled:
3. **Other Use or Disclosure.** Recipient agrees that Recipient will not disclose, or allow access to the Limited Data Set to anyone other than Permitted Users except as required by law.
4. **Safeguards.** The Recipient agrees to and shall ensure that all Permitted Users use appropriate safeguards to prevent use, access to, or disclosure of the Limited Data Set other than as provided by this Agreement.
5. **Reporting.** The Recipient agrees to report in writing to the Institutional Review Board (IRB) of the Covered Entity any unauthorized use or disclosure of the Limited Data set that it becomes aware of within one (1) business day of its discovery.
6. **Agents and Subcontractors.** The Recipient agrees to ensure that its agents and subcontractors to whom it provides the Limited Data Set agree in writing to adhere to the same restrictions and conditions contained herein regarding its use and disclosure. Recipient will notify in writing the IRB of the Covered Entity when Limited Data Set is made available to agents and subcontractors.
7. **Contact/Identification**. The Recipient agrees to and shall ensure that all Permitted Users shall agree to not identify the information in the Limited Data Set or contact any individual who is a subject of the Limited Data Set or his/her relatives, employers or household members. The Recipient further agrees to not attempt to link any information in the Limited Data Set with personally identifiable records from any other source.
8. **Indemnification.** The Recipient shall indemnify, hold harmless and defend the Covered Entity from and against any and all claims, losses, liabilities, costs and other expenses resulting from or relating to the acts or omissions of the Recipient in connection with the Protected Health Information (PHI) provided to the Recipient under this Agreement.
9. **Term.** This Agreement shall become effective on the Effective Date of the Agreement and shall continue in effect until the associated research study is closed with the IRB of Record. Upon completion of the Agreement, the Limited Data Set shall be either destroyed or returned to the Covered Entity. The terms and conditions of this Agreement shall survive the expiration or termination of the Agreement.
10. **Termination.** Either party may terminate this Agreement upon thirty (30) days notice to the other. Either party may terminate this Agreement immediately in the event that the other party is in material breech of its terms.
11. **Publication.** Recipient shall have the right to publish, present, or use Limited data Set for their own instruction, research or publication provided that all identifiers as outlined in 45 CFR 164.514(b)(2)(i) are removed
12. **Publicity.** Neither party will use the name of the other party in any publicity, advertising, or news release without the prior written approval of the authorized representative of the other party.
13. Covered Entity in no way guarantees Limited Data Set pursuant to this Agreement and makes no warranties, express or implied, regarding the quality of any product produced under this Agreement. Recipient agrees to indemnify and hold harmless Covered Entity against any claims arising out of Recipient’s commercial sale or distribution of products or processes developed under this Agreement, or its reliance upon the Limited Data Set provided.
14. **No Third Party Beneficiaries.** Nothing express or implied in this Agreement is intended or shall be deemed to confer upon any person other than the Covered Entity and the Recipient, and their respective successors and assigns, any rights, obligations, remedies or liabilities.
15. In the event the Covered Entity becomes aware of a pattern of activity or practice that constitutes a material breach or violation of this Data Use Agreement, the Covered Entity may take reasonable steps to cure the breach and/or end the violation. In the event such steps are unsuccessful, the Covered Entity may discontinue disclosure of Protected Health Information to the Recipient and report the problem to the Secretary of the Department of Health and Human Services.
16. In the event the Recipient violates the terms of this Data Use Agreement, the Recipient and the Covered Entity may be found noncompliant with 45 CFR 164.514 (e) and subject to civil or criminal penalties.

**AGREED AND ACCEPTED:**

**By Recipient:**

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| --- | --- |
| Name:       | Title:       |
| Signature: | Date: |

**By Covered Entity’s Authorized Representative:**

The VCU IRB

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| --- | --- |
| Name:       | Title:       |
| Signature: | Date: |