

Appendix 1



DATA USE AGREEMENT  
45 CFR 164.514 (e)

This Data Use Agreement (“Agreement”) effective the \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_ (Effective Date”) by and between Indian Health Service (IHS) (collectively 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 Code of Federal Regulations (CFR) 164.514 (e) (2) for public health, health care operations or research purpose; 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 to allow access to the Limited Data Set only to the following individuals and classes of individuals (Name the individuals):
- 2. Permitted Uses.** The Recipient agrees to use and allow access to the Limited Data Set solely as described in the research protocol attached as Exhibit A and entitled: (Attach the research protocol and title of the proposed research)
- 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. Recipient shall protect the confidentiality of the Limited Data Set with the same level of care it used to protect its own confidential information.
- 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 five (5) business days 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 Agreement in writing to adhere to the same restrictions and conditions contained herein regarding its use and disclosure. Recipient will notify 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 or her relatives, employers, or household members.
8. **Publication.** Recipient shall have the right to publish, present, or use Limited Data Set for his or her own instruction, research or publication. Provided however, all identifiers as outlined in 45 CFR 164.514 (b)(2)(i) are removed, and

Check all that apply:

Recipient is not intending to publish.

Recipient is intending to publish. Any proposed publication or presentation shall be provided to the Covered Entity for review at least sixty (60) days prior to the submission. Any publication of any materials by person or entity affiliated in any manner to any training and/or clinical experiences obtained by virtue of this Agreement is strictly prohibited except by prior approval by the IHS. In the event approval is obtained, published materials shall clearly state that the opinions or assertions contained therein are those of the author and do not reflect any official or unofficial view or opinion of the IHS. Additionally, no such materials shall infringe upon, violate, or otherwise compromise patient's rights to privacy under the Privacy Act, the Health Insurance Portability and Accountability Act (HIPAA) Privacy or any applicable Federal or State statute or regulation.

9. **Publicity.** Neither party will use the name of the other party in any publicity, advertising, or new release without the prior written approval of the authorized representative of the other party.
10. **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 PHI provided to the Recipient under this Agreement.

- 11. No Guarantees or Warranties.** 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 processed developed under this Agreement, or its reliance upon the Limited Data Set provided.
- 12. No Third Party Beneficiaries.** Nothing express or implied in this Agreement is intended or shall be deemed to confer upon any individual or entity other than the Covered Entity and the Recipient, any rights, obligations, remedies or liabilities. Neither party shall have the right to assign or transfer their rights to any third party under this Agreement.
- 13. Term.** This Agreement shall become effective on the Effective Date of the Agreement and shall continue in effect for a period of five years or until all obligations of the Parties have been met. Upon completion of the Agreement, the limited Data Set shall be returned to the Covered Entity. The terms and conditions of this Agreement shall survive the expiration or termination of the Agreement.
- 14. 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 breach of its terms. Upon termination of this agreement, the Limited Data Set shall be returned to the Covered Entity.
- 15. Law.** The parties agree that the laws of the United States shall apply to any problem or dispute arising out of this Agreement.
- 16. Entirety of Agreement.** It is expressly agreed that this written agreement represents the entire understanding between the parties and supersedes any prior agreements or understanding with respect to the subject matter herein. Any changes or modifications to this Agreement must be in writing and be signed by both parties.

**AGREED AND ACCEPTED:**

<p><b>By Authorized Representative of Recipient:</b></p> <p>Name: _____</p> <p>Title: _____</p> <p>Signature: _____</p> <p>Date: _____</p>	<p><b>By Covered Entity's Authorized Representatives:</b> Indian Health Service</p> <p>By: (Name) _____</p> <p>Title: _____</p> <p>Signature: _____</p> <p>Date: _____</p>
<p><b>Read and Understood by Recipient's Investigator:</b></p> <p>Name: _____</p> <p>Title: _____</p> <p>Signature: _____</p> <p>Date: _____</p>	<p><b>Read and Understood by Covered Entity's Investigator:</b></p> <p>Name: _____</p> <p>Title: _____</p> <p>Signature: _____</p> <p>Date: _____</p>