**TEMPLATE**

**Grey fields should be filled in with specific agency information and project details, adapted for project purposes, or deleted if not applicable.**

Data Use Agreement

between the

[Urban Indian Health Organization]

and the [Other agency]

for the Collection of Data for [Project Name], and the Sharing of These Data with the Named Groups Disclosed in the Document

Background and Project Scope

Pursuant to Section 164.514 of the Privacy Rule of the Health Insurance Portability and Accountability Act of 1996, the above referenced parties agree to enter into a Data Use Agreement to permit the Use or Disclosure or Acceptance of Protected Health Information by means of a [if applicable include the term “Limited”] Data Set as set forth below.

This agreement is entered into by and between the [UIHO] (herein after “Covered Entity”) located at [address], and the [Other agency] (herein after “Data Recipient”) located at [address], for the [Project Name]. This project will study [INSERT an overview about the scope of project]. The purpose of this project is to [INSERT goals or objectives of the project].

[Some DUAs include background information about the parties entering into the agreement and state the mission and services of the organizations as well as the organizations’ specific roles on the project.]

Definitions

1. “Protected Health Information” or “PHI” means individually identifiable health information regardless of the form in which it is maintained or transmitted and has the same meaning as “protected health information” in 45 CFR Sect. 164.501 of the Privacy Rule, to the extent such information is created or received by the Data Recipient from the Covered Entity.
2. “Individual” means the person who is the subject of the PHI and shall have the same meaning as the term “individual” in 45 CFR Sect. 164.501 of the Privacy Rule and shall include a person who qualifies as a personal representative in accordance with 45 CFR Sect. 164.502(g) of the Privacy Rule.
3. “Confidential information” means the disclosing party's proprietary data, PHI, research documents and information provided to the receiving party for Purposes of this DUA.
4. The “Limited Data Set” means the information and data listed in the data obtained from [insert where and how the data will be collected]. The “Limited Data Set” shall have the same meaning as the term “Limited Data Set” in 45 CFR 164.514(e) of the Privacy Rule.

Specifically the variables collected for the study include [list variables here or include in an attached appendix or exhibit]. The data from these variables will be combined into a Limited Data Set for analysis. Therefore HIPAA-designated PHI will not be included in the study Data Set. The excluded HIPAA-designated PHI for a Limited Data Set are:

1. Name
2. Postal address information, (although city, State, and zip codes may be included);
3. Telephone numbers;
4. Fax numbers;
5. Electronic mail addresses;
6. Social security numbers;
7. Medical record numbers;
8. Health plan beneficiary numbers;
9. Account numbers;
10. Certificate/license numbers;
11. Vehicle identifiers and serial numbers, including license plate numbers;
12. Device identifiers and serial numbers;
13. Web Universal Resource Locators (URLs);
14. Internet Protocol (IP) address numbers;
15. Biometric identifiers, including finger and voice prints; and full face photographic images and any comparable images.

[If applicable include any exceptions to the exclusion of HIPPA-designated PHI here. For example: In order to perform study analyses, the Limited Data Set may include full dates for birth, and services, as well as geographical subdivisions such as zip code.] The Limited Data Set includes the complete Limited Data Set and any portion, part or subset of the Limited Data Set and any and all copies thereof.

* + 1. The “De-identified Data Set” means clinical and/or administrative data that have removed all of the elements that could be used to identify the individual or the individual's relatives, employers, or household members. The 18 elements that must be removed from a “De-identified Data Set” include all of the above HIPAA-designated PHI (4a-o) plus the following elements (5a-d):
1. Geographic subdivisions smaller than a state
2. All elements of dates (except year) related to an individual (including dates of admission, discharge, birth, death and, for individuals over 89 years old, the year of birth must not be used)
3. Full face photos or comparable images
4. Any unique numbering, characteristic or code.
5. The “Modified Data Set” means the data that is recoded from the Limited Data Set may be altered by the Parties to optimize the data for analysis, including but not limited to revisions such as the addition of summary scores, creation of new variables and application of analysis-specific exclusion criteria to the Limited Data Set.

Data Access, Ownership and Limitations

This Agreement sets forth the terms and conditions pursuant to which the Covered Entity will disclose certain PHI to the Data Recipient for purposes outlined in the [Project Name] Proposal and summarized in the above Background.

1. The Data Recipient may use the Data Set only for the following purposes:
* [INSERT how the project will use the Data here]
1. On behalf of the Data Recipient, the following individuals or classes of individuals are permitted to use or receive the Limited Data Set for the purposes described above:
* [INSERT position titles or names here of people who will have access to the data]
	+ [If you are requiring Confidentiality Agreements for data users, include language about data users providing signed Confidentiality Agreements and include Confidentiality Agreements as attachments to the DUA.]
1. Regarding ownership – [Basic ownership language options for you to adapt.]
	* The Covered Entity retains any and all rights to the proprietary information, confidential information and/or Data Set(s) the Covered Entity provides to the Data Recipient.
	* The Covered Entity shall hold and retain all ownership rights to confidential information, intellectual property, including copyright to all materials, the [Limited Data Set or other Data Set name], and products created by the Covered Entity. Products created by the Data Recipient shall be owned by the Data Recipient. Products jointly created by both the Data Recipient and the Covered Entity shall be jointly owned.
2. The Data Recipient agrees not to use or disclose the Data Set for any purpose or secondary use other than the reporting purposes outlined above or as required by law.
	* [If the parties in the agreement wish to allow for secondary data use or analyses, include the specific parameters under which secondary use is allowed. This could include submitting a proposal for secondary data analyses and obtaining written approval from the Covered Entity or other approving parties.]
3. The Data Recipient agrees to report to the Covered Entity any use or disclosure of the Data Set not provided for by this agreement, of which it becomes aware, including without limitation, any disclosure of PHI to an unauthorized subcontractor, within ten (10) business days of its discovery.
4. The Data Recipient agrees to ensure that any agent, including a subcontractor, to whom it provides the Data Set, agrees to the same restrictions and conditions that apply through this agreement to the Data Recipient with respect to such information.
5. The Data Recipient agrees not to identify the information contained in the Data Set, contact the individual, or publish or disclose publically any PHI.

Security

1. The Data Recipient agrees to use appropriate administrative, physical, and technical safeguards to prevent use or disclosure of the Data Set other than as provided for by this agreement.
	* [If needed, an example of additional data security language is:

All data will be stored in secure storage areas (e.g., locked file cabinets), or on digital media that has been password protected, encrypted, or otherwise secured for storage and transfer.]

Publications and Presentations

1. Organizations will work collaboratively to agree on the plan for analyses and drafting of reports and publications. The authorship and the dissemination of such documents will reflect the collaborative nature of the project between the two organizations. Both the Covered Entity and the Data Recipient will review and approve all information intended for public dissemination of any format prior to the dissemination of the information.
	* [Include specific language about any necessary review or approval by Institutional Review Boards or other authorities.]
	* [Add specific acknowledgement language to community member, funders, or study organizations if needed.]

Additional Terms and Conditions

1. This agreement shall be effective on the date signed by the Covered Entity and the Data Recipient and shall remain in effect until all PHI in the Data Set provided to the Data Recipient is destroyed or returned to the Covered Entity.
2. The Data Recipient agrees to destroy study data according to the following specifications:
	* [Insert any specifications regarding the destruction of data pieces here].
	* Unless otherwise required by federal law, the Data Recipient will destroy Data Set(s) no later than [insert Month Day Year of data destruction here] (i.e., within X year(s) of the study end date on [insert Month Day Year of study end date here]). The Data Recipient will notify the Covered Entity with written confirmation of the destruction via email or other memo.
	* When printed material containing confidential information is discarded, it is loaded, transported and stored under supervision (using a chain of custody control process) until the material can be recycled into paper pulp.
3. The Covered Entity reserves the right to terminate this agreement due to a material breach of this Agreement by the Data Recipient. The Covered Entity may provide an opportunity for the Data Recipient to cure the breach or end the violation. If efforts to cure the breach or end the violation are not successful within the reasonable time period specified by the Covered Entity (typically no more than 30 days), the Covered Entity shall discontinue disclosure of PHI to the Data Recipient and report the breach to [appropriate offices providing project ethics oversight such as the Indian Health Service Institutional Review Board].
4. This Agreement shall not be amended, altered, or changed except by written documentation agreed to and executed by both parties.
5. The Data Recipient acknowledges and agrees that the Covered Entity has relied upon the promises and covenants made in the Agreement and in disclosing the Data Set.

Covered Entity Date: \_\_\_\_\_\_\_\_\_\_\_\_ Data Recipient Date: \_\_\_\_\_\_\_\_\_

By: By:

Name Name:

Title: Title:

Organization:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Organization:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_