

This DUA is based on the following HHS DUA for data covered by the Privacy Act of 1974:

<https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS-R-0235D2.pdf>

Any party considering adopting this template agreement should discuss it with their legal counsel.

<Party Specific Substitutions>

<Language for Consideration by Parties>

<Considerations for Parties Negotiating the Agreement>

AGREEMENT FOR THE EXCHANGE OF PERSONALLY IDENTIFIABLE DATA BETWEEN <Sender> and
<Recipient> FOR RESEARCH REQUIRING RECORD LINKAGE USING THE MINDFIRL SOFTWARE

In order to permit appropriate disclosure and use of information maintained by the <Sender> as permitted by law, and in order to ensure the integrity, security, and confidentiality of such data, <Sender> and <Recipient>, hereinafter termed "Recipient," enter into this agreement to comply with the following specific paragraphs.

1. Introduction

a. Definitions:

- i. Parties: <Sender> and <Recipient>
- ii. Covered Data: the data files identified in paragraph 7 below and any derivative data files, including a Coded Dataset but excluding the Linked Data
- iii. Outside Data: data that is not identified under paragraph 7 as Covered Data or a derivative data file of the Covered Data.
- iv. Linked Data: dataset(s) created by linking records pertaining to individuals in the Covered Data with records pertaining to the same individuals in Outside Data.
- v. Direct Identifiers: data values capable of identifying an individual without additional information, including names, identification numbers, and social security numbers.
- vi. Indirect Identifiers: data values that can be used in combination with other information to identify an individual, including but limited to, dates of birth, race, gender, and location data (e.g., zip codes).
- vii. Minimum Necessary Disclosure for Record Linkage (MINDFIRL) v beta.1.0: a software program used to enhance privacy in the record linkage process.
- viii. Coded Dataset: a data file created prior to the record linkage process where Direct Identifiers and some Indirect Identifiers have been removed from each record in the Covered Data (i.e., for record linkage) and replaced with a unique code. <Parties might consider providing a more specific definition or example based on the specific activities covered by the Agreement>

- ix. Re-identify: the process of connecting a Direct Identifier to a record without a direct identifier (i.e., records within de-identified data, Coded Data, or the Linked Data)

b. Background:

- i. <Describe the Mutual Interests of the Parties>
 - ii. The Parties acknowledge that accurate record linkage requires access to direct and indirect identifiers of data subjects.
 - iii. The Parties acknowledge that the MINDFIRL software has demonstrated capability to enable accurate record linkage while reducing disclosures of data subjects' Direct and Indirect Identifiers as compared to standard methods of record linkage.
 - iv. The Parties recognize that the privacy protections provided by MINDFIRL, including segregation of Direct Identifiers, limited disclosure of Direct and Indirect Identifiers during record linkage, and functions for audit and monitoring, are critical to the willingness of <Sender> to permit Recipient to access and use the Covered Data.
 - v. The Parties agree that administrative controls are necessary to limit disclosures using the MINDFIRL software platform to the minimum necessary to enable accurate record linkages.
2. This Agreement addresses the conditions under which <Sender> will disclose and Recipient will obtain and use the data file(s) specified in paragraph 7 (i.e., Covered Data). This Agreement supersedes any and all agreements between the parties with respect to the use of Covered Data and preempts and overrides any instructions, directions, agreements, or other understanding in or pertaining to any grant award or other prior communication from the <Sender> or any of its components with respect to the data specified herein. Further, the terms of this Agreement can be changed only by a written modification to this Agreement or by the Parties adopting a new agreement. The Parties agree further that instructions or interpretations issued to Recipient concerning this Agreement or the data specified herein, shall not be valid unless issued in writing by the <Sender> point-of-contact specified in paragraph .
- <Parties should consider addressing relevant legal authority and describing its applicability for sharing or using the Covered Data here, e.g., Health Insurance Portability and Accountability Act of 1996, The Privacy Act of 1974.>
3. The Parties mutually agree that <Sender> retains all ownership rights to the Covered Data, and that Recipient does not obtain any right, title, or interest in any of the data furnished by <Sender>.
4. <Parties should consider and address the ownership rights to the Linked Data and other derivative files here.>
5. Recipient represents, and in furnishing the Covered Data, <Sender> relies upon such representation, that such data file(s) will be used solely for the Activities described in Attachment A. Recipient represents further that Recipient shall not disclose, release, reveal, show, sell, rent, lease, loan, or otherwise grant access to the data covered by this Agreement to

any person. Exception: Recipient may disclose, release, reveal or show individually identifiable data if required by federal or state law or if permitted by federal or state law and with the approval of <Sender>. Recipient is expected to redact Direct Identifiers or use code identifiers <wherever possible> <Parties might consider more specific requirements for redaction or use of code identifiers>. Recipient further agrees that, within the Recipient organization, access to the data covered by this Agreement shall be limited to the minimum number of individuals necessary to achieve the purpose stated in this section paragraph and Attachment A and to those individuals on a need-to-know basis only.

6. Recipient agrees to use the MINDFIRL software during the record linkage process to reduce the disclosure of Direct Identifiers and Indirect Identifiers to the minimum reasonably necessary to enable accurate record linkage. Recipient agrees not to circumvent any protections provided by MINDFIRL, including circumventing protections to re-identify any individual in the Coded Dataset, Linked Data, or any derivative file, unless the re-identification is necessary for accurate record linkage. <The Parties mutually agree that Recipient will configure MINDFIRL pursuant to the specifications indicated in Attachment B for all record linkage activities covered by this Agreement.> The Recipient further agrees that no effort will be made to re-identify individuals in the Linked Data.
7. Covered Data: The following <Sender> data file(s) is/are covered under this Agreement:

Data File	Values included

8. <The Parties should consider and address record keeping, retention and disposition of records of the Covered Data, Linked Data and any derivative files here. Example language could be: The parties mutually agree that the Covered Data, <Linked Data,> and any derivative file(s) (which includes any file that maintains or continues identification of individuals <but excludes the Linked Data>) may be retained by Recipient no more than 90 days after the date of termination of this Agreement. Recipient agrees to destroy the Covered Data, <Linked Data,> and any derivative file(s) (which includes any file that maintains or continues identification of individuals <but excludes the Linked Data>) after the date of termination of this Agreement. Recipient agrees that no data from <Sender> records, or any parts thereof, shall be retained when the Covered Data are destroyed unless authorization in writing for the retention of such file(s) has been received from the appropriate Systems Manager or the person designated in paragraph 20 of this Agreement. Recipient acknowledges that strict adherence to the aforementioned retention date is required.>

<Parties should consider setting a finite term for the Agreement, i.e., two years.>

The Agreement may be terminated by either party at any time for any reason upon <number> days written notice. Upon such notice, <Sender> will cease releasing data to Recipient under this Agreement and will notify Recipient to destroy all previously released data files. Sections 3, 4, 5, 8, 11, 122, 14, 15 and 166 shall survive termination of this Agreement.

9. Recipient agrees to establish appropriate administrative, technical, and physical safeguards to protect the confidentiality of the Covered Data and to prevent unauthorized use or access to it. The safeguards shall provide a level and scope of security that is not less than the level and

scope of security established by <relevant legal authority or other security standards>. Recipient acknowledges that the use of unsecured telecommunications, including the Internet, to transmit individually identifiable or deducible information derived from the Covered Data is prohibited. Further, Recipient agrees that the data must not be physically moved or transmitted in any way from the site(s) indicated in paragraph 19, except as provided in paragraph 5, without written approval from <Sender>.

10. Recipient agrees that the authorized representatives of <Sender> <or other enforcement entity> will be granted access to premises where the Covered Data are kept for the purpose of inspecting security arrangements confirming whether the Recipient is in compliance with the security requirements specified in paragraph 9.

11. <Parties should describe any conditions for reporting results or public release of data. Example language could be: The Recipient agrees not to disclose direct findings, listings, or information derived from the Covered Data, with or without Direct Identifiers, if such findings, listings, or information can, by themselves or in combination with other data, be used to deduce an individual's identity. Examples of such data elements include, but are not limited to geographic location, age if > 89, sex, diagnosis and procedure, admission/discharge date(s), or date of death.>

The Recipient agrees that any use of <Sender> data in the creation of any document (manuscript, table, chart, study, report, etc.) concerning the purpose specified in paragraph 5 and Attachment A (regardless of whether the report or other writing expressly refers to such purpose, to <Sender>, to the Covered Data, to the Linked Data, or to any data derived from such files) must adhere to <Sender>' current cell size suppression policy. This policy stipulates that no cell (e.g., admittances, discharges, patients) less than <number> may be displayed. Also, no use of percentages or other mathematical formulas may be used if they result in the display of a cell less than <number>. By signing this Agreement you hereby agree to abide by these rules and, therefore, will not be required to submit any written documents for <Sender> review. If you are unsure if you meet the above criteria, you may submit your written products for <Sender> review. <Sender> agrees to make a determination about approval and to notify the user within 4 to 6 weeks after receipt of findings. <Sender> may withhold approval for publication only if it determines that the format in which data are presented may result in identification of individuals. >

12. Recipient understands and agrees that it may not reuse Covered Data, Linked Data, or any derivative data file(s) without prior written approval from the appropriate System Manager or the person designated in paragraph 20 of this Agreement.

13. The Parties mutually agree that the following specified Attachments are part of this Agreement:

<☐ NO ATTACHMENTS>

Attachment A: Description of Permitted Uses

Attachment B: MINDFIRL Configurations

Attachment C: Authorized Personnel

14. Recipient agrees that in the event <Sender> determines or has a reasonable belief that Recipient has made or may have made disclosure of the aforesaid file(s) that is not authorized by this

Agreement or other written authorization from the appropriate System Manager or the person designated in paragraph 20 of this Agreement, <Sender> in its sole discretion may require Recipient to: (a) promptly investigate and report to <Sender> Recipient's determinations regarding any alleged or actual unauthorized disclosure, (b) promptly resolve any problems identified by the investigation; (c) if requested by <Sender>, submit a formal response to an allegation of unauthorized disclosure; (d) if requested by <Sender>, submit a corrective action plan with steps designed to prevent any future unauthorized disclosures; and (e) if requested by <Sender>, return data files to <Sender>. Recipient understands that as a result of <Sender>'s determination or reasonable belief that unauthorized disclosures have taken place, <Sender> may refuse to release further <Sender> data to Recipient for a period of time to be determined by <Sender>.

15. Recipient hereby acknowledges that <Parties should describe the relevant legal or contractual penalties> may apply if it is determined that the Recipient or Custodian, or any individual employed or affiliated therewith, knowingly and willfully obtained the Covered Data under false pretenses.

16. <Parties should describe the specific contractual penalties or terms that apply in the case of an unauthorized disclosure or use of the Covered Data.>

By signing this Agreement, User agrees to abide by all provisions set out in this Agreement for protection of the data file(s) specified in paragraph 7, and acknowledges having received notice of potential criminal, <administrative>, and contractual penalties for violation of the terms of the Agreement.

17. <Parties should consider adding terms for the following issues to the Agreement if relevant or important to the parties:

- a. Responsibilities of Sender and Recipient
- b. Funding, Costs and Reimbursement
- c. Reporting Requirements
- d. Constraints, including Performance standards, DUA Review Procedures, Audit Clause, Liability Issues, Definition of a Breach
- e. Resolution of Conflicts
- f. Concurrences, including Third Party Concurrence

18. On behalf of Recipient the undersigned individual hereby attests that he or she is authorized to enter into this Agreement and agrees to all the terms specified herein.

Name and Title of Recipient (<i>Representative for Provider</i>) (typed or printed)		
Provider Name		
Street Address		
City	State	ZIP Code
Office Telephone (<i>Include Area Code</i>)		E-Mail Address (<i>If applicable</i>)

Signature	Date
-----------	------

19. The parties mutually agree that the following named individual(s) and/or entities is or are designated as Custodian(s) of the file(s) on behalf of Recipient and each person or entity so designated will be responsible for the observance of all conditions of use and for establishment and maintenance of security arrangements as specified in this Agreement to prevent unauthorized use. Recipient is responsible for any non-observance of the conditions of use, and/or failure to establish or maintain security arrangements, on the part of any Custodian. Recipient agrees to notify <Sender> within fifteen (15) days of any change of custodianship. The parties mutually agree that <Sender> may disapprove the appointment of a custodian or may require the appointment of a new custodian at any time. Each Custodian agrees and in his or her capacity as an employee or contractor (including consultant, attorney or other representative) of the Recipient to comply with all of the provisions of this Agreement on behalf of Recipient.

Name of Custodian <i>(typed or printed)</i>		
Company/Organization		
Street Address		
City	State	ZIP Code
Office Telephone <i>(Include Area Code)</i>		E-Mail Address <i>(If applicable)</i>
Signature		Date

20. The parties mutually agree that the following named individual will be designated as point-of-contact for the Agreement on behalf of <Sender>. On behalf of <Sender> the undersigned individual hereby attests that he or she is authorized to enter into this Agreement and agrees to all the terms specified herein.

Name of <Sender> Representative		
Title/Component		
Street Address		
City	State	ZIP Code

Office Telephone <i>(Include Area Code)</i>	E-Mail Address <i>(If applicable)</i>
Signature	Date

ATTACHMENT A: DESCRIPTION OF Permitted Uses

<Parties should clearly describe the specific uses of the Covered Data and Linked Data permitted by this agreement. This should include descriptions of research or other activities covered by this agreement, including:

- Purpose
- Hypotheses
- Outside Data used for record linkage or analysis
- General Research Protocol
- Record Linkage Protocol
 - Specify the Direct Identifiers and Indirect Identifiers to be used in record linkage.
 - Specify the computer system that will operate the MINDFIRL software
 - Specify the Information Technology group that will manage the computer system and MINDFIRL software
- Describe storage, maintenance, and custodianship of Linked Data>

ATTACHMENT B: MINDFIRL CONFIGURATIONS

<Parties should clearly describe the MINDFIRL software configuration:

- Describe the configuration settings for using the KAPR score (K-anonymity privacy risk score) to limit disclosures during record linkage. For example,
 - Plan A: The Recipient will configure MINDFIRL to prevent disclosing information (i.e., revealing information to researchers linking records) that will exceed the recommended KAPR score setting of thirty percent (30%). Recipient may request and <Sender> may approve additional disclosures in writing if the disclosures are appropriate and required for accurate record linkage. However, <Sender> will not approve any disclosure that exceeds a KAPR score of <percent>.
 - Plan B: The Recipient will configure MINDFIRL to prevent disclosing information (i.e., revealing information to researchers linking records) that will exceed the KAPR score setting of <percent>. Recipient may request and <Sender> may approve additional disclosures in writing.
 - Plan C: Recipient will request a KAPR score limit configuration after a preliminary round of record linkage using no more than <percent> of the Covered Data. <Sender> must approve of the KAPR score setting in writing. The agreed KAPR score limit will be based on a review of the preliminary record linkage and the estimated minimum necessary KAPR score needed for accurate record linkage.
- Describe the configuration settings for imposing disclosure restrictions on specific data elements. For example,
 - Only 4 digits of any social security number will be disclosed during the record linkage process (i.e., revealed to researchers linking records).
 - No full or partial social security numbers will be disclosed during the record linkage process (i.e., revealed to researchers linking records). However, information indicating the similarity or differences between two social security numbers may be used for record linkage. See figure 1, pair 3, first column.
 - No full names can be disclosed during record linkage (i.e., revealed to researchers linking records). Partial names may be used during the record linkage process. See figure 1, pair 2.>

Figure 1: The following three pairs depict different levels of disclosure. Pair 1: Full disclosure. Pair 2: Partial disclosure. Pair 3: No disclosure.

Pair	ID	FFreq	First Name	Last Name	LFreq	DoB(M/D/Y)	Sex	Race	Choice Panel
1	199553862	...	WILLIAM	KING JR	...	01/25/1968	F	W	H M L L M H
	?	...	WILLIAM	KING	...	01/25/1968	M	W	Different Same
2	1000563341	∞	***MY	**W***	...	07/03/****	✓	✓	H M L L M H
	1000391562	∞	***	**R***	...	03/07/****	✓	✓	Different Same
3	****@****	①	@@@@@@@	@@@@@	∞	**/**/****	✓	✓	H M L L M H
	****@****	②	@@@@@	@@@@@	①	**/**/****	✓	✓	Different Same

ATTACHMENT C: PERSONNEL WITH ACCESS TO COVERED DATA

a. <Recipient> Organizational Personnel

Name, Title, and Department	Role	Access to PII for linkage	Access to Coded Data (i.e., analysis)	Access to the Key linking PII to coded data	Protocol Responsibilities and Qualifications
Name: Title: Department:		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Name: Degree: Department:		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	

b. Non- Organizational Personnel

Name, Title, and Organization	Role	Access to PII for linkage	Access to Coded Data (i.e., analysis)	Access to the Key linking PII to coded data	Protocol Responsibilities and Qualifications
Name: Title: Organization:		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Name: Title: Organization:		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	