DATA USE AGREEMENT

*For sharing health data in non-commercial research*

|  |
| --- |
| **CONTEXT: This document is based on the February 2019 FDP DTUA but is not endorsed by FDP.**The Federal Demonstration Partnership (FDP) is a cooperative initiative among 10 federal agencies and 217 institutional recipients of federal funds, and has produced a library of tools, pilots, and guides for its members. We found that its pilot DTUA (see <https://thefdp.org/default/committees/research-compliance/data-stewardship/>) was the most universally-recognized data use agreement for research purposes, but that many institutions did not adopt or accept it without changes. This document provides explanatory notes and proposed amendments to the FDP DTUA to supplement for ease of use particularly in the context of computational medicine: transfer and use of health data for machine learning research purposes. |
| **CONTENT:** We added notes and suggestions as follows:* **The left column** is the body of the agreement, including suggested amendments in red, and alternative or potential provisions in red italics.
* **The right column** includes explanatory notes and alternative provision explanations.
* **Attachments 1 & 3** should be used with all agreements.
* **Choose one Attachment 2** that is appropriate for the data type to be shared for use with your agreement.

Other tools for your toolkit include: [a legal whitepaper on computational medicine](https://drive.google.com/file/d/1LMa0PdhQHkfQxDJ6RdO3kSyZ2ieGMnFJ/view), [Process flow maps and templates for your institution](https://docs.google.com/presentation/d/11Nx1mnHsU2KDAY57KiW8PDhOxAGNXDa3ai__582DrXw/edit?usp=sharing), and a guide for sharing health data for non-commercial research. |
| **INTENDED AUDIENCE:** We designed this Legal Guide for Data Sharing for Non-Lawyers to be used by university contracts managers and in-house counsel.**HOW TO USE: Use this as a reference, and download a clean version of the DUA for use** [**here.**](https://www.chicagobooth.edu/-/media/project/chicago-booth/centers/caai/docs/cmla-template-dua-clean.docx)The clean version incorporates all recommended and suggested changes (red and red italics) noted in this document.***This document should not be construed as legal advice for any particular facts or circumstances.*** |
| **ABOUT: Computational Medicine Research Accelerator**The Computational Medicine Legal Accelerator (CMLA) is working to accelerate machine learning research aimed at improving clinical care through more streamlined legal processes for sharing health data between institutions. Our fundamental goal is to safely get more health data into the hands of machine learning researchers faster, in order to accelerate the development of computational medicine.  |

 Agreement ID:

|  |  |
| --- | --- |
| FDP Data Transfer and Use Agreement (“Agreement”) | Notes and AlternativesThis document is based on the February 2019 FDP DUA (For more information, see <https://thefdp.org/default/committees/research-compliance/data-stewardship/>). It is intended to supplement the FDP DUA for ease of use in the context of computational medicine: transfer and use of health data for machine learning research purposes.**The left-hand column** is the body of the agreement, including suggested amendments to the FDP DUA in red, and alternative or potential provisions in red italics.**This column** includes explanatory notes and alternative provision explanations.A clean version of this DUA (including alternative provisions) is available at [TBD].***This document should not be construed as legal advice for any particular facts or circumstances.*** |
| Provider: | Recipient: |
| Provider Scientist Name: Email: | Recipient Scientist Name: Email: |
| Agreement TermStart Date: Date of last signature belowEnd Date: Three (3) Years after the Start Date | Project Title: |
| Attachment 2 Type:  |
| **Terms and Conditions** |
| 1. **Provision and ownership of data.** Provider shall provide the data set described in Attachment 1 (the “**Data**”) to Recipient for the research purpose set forth in Attachment 1 (the “**Project**”). Provider shall retain ownership of any rights it may have in the Data, and Recipient does not obtain any rights in the Data other than as set forth herein. *Provider shall transfer the Data to Recipient in the manner described in Attachment 1*.
 | **Note on Headers and Bold.** We added headers to each of the provisions to serve as an easy reference and roadmap to the reader. We also chose to bold the defined terms where defined to facilitate cross-reference (this change is unmarked).**Alternative provision on means of transfer:** It is sometimes quite important *how* the Data will be transferred to Recipient. If so, include the following, and insert the relevant information in Attachment 1.  |
| 1. **Cost reimbursement.** If applicable, reimbursement of any reasonable costs associated with the preparation, compilation, and transfer of the Data to the Recipient will be addressed in Attachment 1.
 | **Note on reasonable costs:** If the data to be shared under the agreement include protected health information (“**PHI**”) subject to the Health Insurance Portability and Accountability Act of 1996 (“**HIPAA**”), including PHI in the form of a limited data set, the amount of the fees to be paid under the agreement must be limited to a “limited cost-based fee” to prepare and share the PHI to avoid HIPAA’s prohibition on the “sale” of PHI unless an authorization from the patient has been obtained that permits the sale of PHI. |
| 1. **Intellectual Property.** Subject to the terms and conditions of this Agreement, Provider grants to Recipient a royalty-free, worldwide, non-exclusive license to the Data for the sole and limited purpose of performing the Project. Recipient shall not use the Data except as authorized under this Agreement. The Data will be used solely to conduct the Project and solely by Recipient Scientist and Recipient’s faculty, employees, fellows, students, and agents (“**Recipient Personnel**”) and Collaborator Personnel (as defined in Attachment 3) that have a need to use, or provide a service in respect of, the Data in connection with the Project and whose obligations of use are consistent with the terms of this Agreement (collectively, “**Authorized Persons**”).
 | **Note on intellectual property options generally.** This data sharing agreement contemplates that the Data will be provided to the Recipient on a royalty-free and non-exclusive basis. In some circumstances involving computational medicine, additional provisions to provide further clarity may be desirable. If that is the case, consider reviewing the Ropes & Gray White Paper Appendix at [HTML] for additional drafting notes.**Note on License.** Rather than transferring ownership of data, data providers may confer limited rights to data recipients by granting a license under the data to the data contributors. A license differs from a transfer of ownership in that a license only confers limited, contractual rights in and to the data. We inserted an explicit license to clarify the FDP DUA’s language because of the license’s importance in the computational medicine context. |
| 1. **Third party data access.** Except as authorized under this Agreement or otherwise required by law, Recipient agrees to retain control over the Data and shall not disclose, release, sell, rent, lease, loan, or otherwise grant access to the Data to any third party, except Authorized Persons, without the prior written consent of Provider. Recipient agrees to establish appropriate administrative, technical, and physical safeguards to prevent unauthorized use of or access to the Data and comply with any other special requirements relating to safeguarding of the Data as may be set forth in Attachment 2. Recipient will (a) cause all Authorized Persons to operate in a manner consistent with the terms of this Agreement, and (b) remain responsible for the conduct of all such activities in accordance with the terms and conditions of this Agreement.
 | **Note on authorized persons.** Given the data storage and processing requirements involved in computational medicine, often a data recipient will use third party cloud service providers. In order to facilitate data provider agreement to that use case, we recommend inserting an obligation on the data recipient to ensure that all authorized users operate in compliance with these terms. |
| 1. **Compliance with law.**  Recipient agrees to use the Data in compliance with all applicable laws, rules, and regulations, as well as all professional standards applicable to such research.
 |  |
| 1. **Publication.** Recipient is encouraged to make publicly available the results of the Project. Before Recipient submits a paper or abstract for publication or otherwise intends to publicly disclose information about the results of the Project, the Provider will have thirty (30) days from receipt to review proposed manuscripts and ten (10) days from receipt to review proposed abstracts to ensure that the Data is appropriately protected. Provider may request in writing that the proposed publication or other disclosure be delayed for up to thirty (30) additional days as necessary to protect proprietary information.
 | **Note on publication:** Rights to publish the results of the Project can vary significantly. Factors may include the particular Parties to the Agreement, the purpose of the Project, and the proprietary or sensitive nature of the Data. The approach recommended by the FDP would permit the Recipient to publish the results of the Project, subject to the Recipient granting the Provider the right to review such publication so as to allow the Provider to protect any proprietary or sensitive information included in the data. If a variant of this is the case, consider reviewing the [Ropes & Gray White Paper Appendix at HTML] for additional drafting notes. |
| 1. **Data Contribution Recognition.** *Upon Provider’s request,* Recipient agrees to recognize the contribution of the Provider as the source of the Data in all written, visual, or oral public disclosures concerning Recipient’s research using the Data, as appropriate in accordance with scholarly standards and any specific format that has been indicated in Attachment 1.
 | **Alternative Provision on provider’s request for recognition:** Because section 6 (Publication) requires advance review of publications by the data provider, and the data provider is likely to be particular about its brand usage, it may facilitate a streamlined process for publication to insert that the data recipient will acknowledge data provider only if requested. This also forestalls any required negotiation of the DUA itself if the data provider would prefer to remain anonymous. |
| 1. **Termination.** Unless terminated earlier in accordance with this section or extended via a modification in accordance with Section 13, this Agreement shall expire as of the End Date set forth above. Either party may terminate this Agreement with [thirty (30)] days written notice to the other party’s Authorized Official as set forth below. *In addition, either Party may terminate this Agreement ias a result of the material breach by the other Party of this Agreement, upon giving the other Party written notice identifying specifically the applicable breach, provided that the breaching Party does not cure such breach within thirty (30) days following receipt of such notice, or immediately if the breach is incurable.* Upon expiration or early termination of this Agreement, (a) all licenses and other rights granted by either Party to the other Party under this Agreement shall terminate, and (b) Recipient shall follow the disposition instructions provided in Attachment 1, provided, however, that Recipient may retain one (1) copy of the Data to the extent necessary to comply with the records retention requirements under any law, and for the purposes of research integrity and verification.
 | **Note on termination without cause timing and Alternative Provision on termination for cause:** Termination without cause by the data provider can cut a data recipient’s research short unexpectedly. As such, the parties may agree to a longer timeline for terminations without cause. If a much longer timeline is agreed (90-120 days), it may also be appropriate to add the below alternative provision allowing for a shorter termination period for cause. |
| 1. **Disclaimer and Authority to provide Data.** Except as provided below or prohibited by law, any Data delivered pursuant to this Agreement is understood to be provided “AS IS.” PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE DATA WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Notwithstanding, Provider~~, to the best of its knowledge and belief,~~ has the right and authority to provide the Data to Recipient for use in the Project.
 | **Note on knowledge qualifier:** Particularly in the context of large databases, the Recipient isn’t in a position to be able to make its own determinations about the legality of the data transfer. Given Recipient’s lack of knowledge or control over whether Provider has the right and authority to provide the Data, we believe that the appropriate allocation of risk is to the Provider without a knowledge qualifier. Essentially, the Provider should have known and should be required to take responsibility for any issues arising even without its knowledge. |
| 1. **Liability.** Except to the extent prohibited by law, the Recipient assumes all liability for damages which may arise from its use, storage, disclosure, or disposal of the Data. The Provider will not be liable to the Recipient for any loss, claim, or demand made by the Recipient, or made against the Recipient by any other party, due to or arising from the use of the Data by the Recipient, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the Provider. No indemnification for any loss, claim, damage, or liability is intended or provided by either party under this Agreement.

*Alternative Provision - Section 10 in its entirety:* ***Liability.*** Except to the extent prohibited by law *or otherwise provided in this Agreement*, the Recipient assumes all liability for damages which may arise from its use, storage, disclosure, or disposal of the Data. *Recipient shall defend, indemnify and hold harmless Provider from and against any loss, claim or demand made against Provider by any other party due to or arising from the use of the Data by Recipient, except to the extent caused by, or gross negligence or willful misconduct of, a breach of this Agreement by Provider. Provider shall defend, indemnify and hold harmless Recipient from and against any loss, claim or demand made against Recipient by any other party due to or arising from the provision of the data to Recipient, except to the extent caused by a breach of this Agreement by, or gross negligence or willful misconduct of, Recipient.* | **Alternative Provision on indemnification:** Many institutions are legally prohibited from providing an indemnification. The alternative provision inserted is intended to address two cases where information asymmetry could lead to third party claims appropriately paid for by the other Party. We suggest that these are the only indemnifications that should be sought, and to the extent that one party is requesting an indemnity, the entire alternative provision should be included. |
| 1. **Publicity.** Generally, neither party shall use the other party’s name, trademarks, or other logos in any publicity, advertising, or news release without the prior written approval of an authorized representative of that party. The parties agree that (a) each party may disclose factual information regarding the existence and purpose of the relationship that is the subject of this Agreement for other purposes without written permission from the other party provided that any such statement shall accurately and appropriately describe the relationship of the parties and shall not in any manner imply endorsement by the other party whose name is being used, and (b) Recipient may attribute Provider’s contribution of the Data in a relevant publication, in accordance with section 7 (Data Contribution Recognition).
 | **Note on publicity:** These additions are meant to simply clarify the potential overlap or conflict between a general prohibition on publicity with a requirements for publication attribution. |
| 1. **Entire Agreement.** Unless otherwise specified, this Agreement and the below listed Attachments embody the entire understanding between Provider and Recipient regarding the transfer of the Data to Recipient for the Project:
	1. Attachment 1: Project Specific Information
	2. Attachment 2: Data-specific Terms and Conditions
	3. Attachment 3: Identification of Permitted Collaborators (if any)
 |  |
| 1. **Amendment.** No modification or waiver of this Agreement shall be valid unless in writing and executed by duly- authorized representatives of both parties. *Additional Projects may be appended to this Agreement by amending and re-signing Attachment 1.*
 | **Alternative Provision on Additional Projects:** This alternative provision provides that Attachment 1 can be amended by mutual agreement of the Parties to expand the scope of the Project or to add additional Projects, rather than requiring a new agreement be entered. This can significantly streamline future work, however it will require a second signature (on Attachment 1) and may not be desirable if future projects are very unlikely. |
| 1. **Authorized representative and Accuracy.** The undersigned Authorized Officials of Provider and Recipient expressly represent and affirm that the contents of any statements made herein are truthful and accurate and that they are duly authorized to sign this Agreement on behalf of their institution.
 |  |
| By an Authorized Official of Provider:DateName:Title:Contact Information for Formal Notices:Name:Address:Email:Phone: | By an Authorized Official of Recipient: DateName:Title:Contact Information for Formal Notices:Address:Email:Phone: |  |

 Agreement ID:

|  |
| --- |
| **Attachment 1**Data Transfer and Use AgreementProject Specific Information |

1. Description of Data:

*Instructions to the drafter; delete after completion of this section:*

*This section of this attachment should provide sufficient information such that each party understands the information that will be transmitted under this Agreement.*

*Examples of information that should be provided include:*

* *Whether the data is obtained from human subjects and, if so, a description of the population included in the data.*
* *If the data is from animal subjects, the species of animal the data was obtained using.*
* *If not from human or animal subjects, a description of the focus of the data.*
* *The number of subjects and/or experiments included*
* *Name of the study that the data was obtained under*

*If there is a particular study that needs to be acknowledged/cited as the source of the data, this information should be included here.*

1. Description of Project:

*Instructions to the drafter; delete after completion of this section:*

*This section of this attachment should provide sufficient information such that each party understands the project that the Recipient will perform using the Data. Content of this section will be very similar to the Statement of Work used in other types of Agreements.*

*Examples of information that should be provided include:*

* *Objective or purpose of the Recipient’s work*
* *A general description of the actions to be performed by the Recipient using the Data and possibly the anticipated results*
* *Include whether or not the Recipient is permitted to link the Data with other data sets (If yes, be sure to include any special disposition requirements related to the linked data sets in Section 5 of this attachment).*

*Note: This data sharing agreement contemplates that the Recipient will only have the right to use the Data for the limited purpose of completing the Project. If the Parties would like to allow for a broader, more open-ended scope of use, consider inserting something like “Academic research” as the description of the project.*

1. Provider Support and Data Transmission:

Provider shall transmit the Data to Recipient: (select one) electronically or by mail to:

|  |  |
| --- | --- |
| Name: |  |
| Address: |  |
| Email: |  |
| Phone: |  |

Upon execution of this Agreement, Provider shall send any specific instructions necessary to complete the transfer of the Data to the contact person listed above, if not already included below in this section of Attachment 1.

*Instructions to the drafter; delete after completion of this section.*

*This section of this attachment should also provide sufficient information such that each party understands the level of support the Provider will supply to the Recipient. Examples of information that may be appropriate to include in this section are:*

* *Format of Data*
* *Provision of Data dictionary*
* *Availability of Provider to assist Recipient in understanding the Data structure (e.g. variables, code lists, etc.)*
* *If/how Data will be revised and resent if errors are found by the Recipient*
* *Specific instructions necessary to complete the transfer of the Data, if available/appropriate, and any support supplied by the Provider for the transfer.*
1. Reimbursement of Costs:

 None

 As governed by a separate written agreement between the parties

Reimbursement Agreement Reference # (if required):



As set forth herein:

1. Disposition Requirements upon the termination or expiration of the Agreement:

*Instructions to the drafter; delete after completion of this section:*

*This section of this attachment should provide sufficient information such that each party understands the Recipient’s obligations with regards to the Data upon the expiration or early termination of this Agreement. If the Recipient is permitted to link the Data with other data sets, be sure to include any special disposition requirements related to the linked data sets in this attachment.*

*Note: If the Parties agree to allow for future projects to be added to this same DUA, as contemplated by the alternative provision in Section 13, a signature should be added to this Attachment 1 such that all future projects are signed off by authorized officials of the institutions.*

The undersigned Authorized Officials of Provider and Recipient expressly represent and affirm that the contents of any statements made herein are truthful and accurate and that they are duly authorized to sign this Agreement on behalf of their institution.

|  |  |
| --- | --- |
| By an Authorized Official of Provider:DateName:Title:Contact Information for Formal Notices:Name:Address:Email:Phone: | By an Authorized Official of Recipient: DateName:Title:Contact Information for Formal Notices:Name: Address:Email:Phone: |

 Agreement ID:

|  |
| --- |
| **Attachment 3**Data Transfer and Use AgreementIdentification of Permitted Collaborators (if any) |

For all purposes of this Agreement, the definition of “Collaborator Personnel” checked below will pertain:

 “Collaborator Personnel” means: None. No collaborators are permitted on the Project.

-OR-

 “Collaborator Personnel” means as set forth below and agreed upon between the Parties:

*Sample definition language for the drafter; delete if the first option is checked or after a final definition has been agreed between the Parties:*

*“Collaborator Personnel” means: faculty, employees, fellows, or students of an academic institution, which institution (i) has agreed to collaborate in the Project, (ii) has faculty, employees, fellows, or students who have a need to use or provide a service in respect of the Data in connection with its collaboration in the Project, and (iii) has been made aware of the terms of this Agreement and agreed to comply, and to cause its personnel to comply, with such terms.*

*An alternative option for (iii); “has executed an agreement that is substantially similar to this Agreement”*

Attachment 2 Options: Choose one to use

Four of the Attachment 2 options presented by FDP could be used for computational medicine data sharing:

1. **Fully identified information that originates at a HIPAA covered entity** and is disclosed by the covered entity pursuant to a HIPAA authorization or waiver of authorization;
2. **Personally identifiable information that is governed only by the Common Rule** and not by HIPAA or other regulations;
3. A **limited data set** (“LDS”) by a HIPAA covered entity subject to a data use agreement; and
4. **Completely de-identified data** that fall outside HIPAA.

For use of this agreement, only one of the attachment 2 options should be selected and used - whichever is appropriate to the underlying data. FDP has two further attachments covering educational records and data that does not fit into any other category. We did not address these two attachments.

FDP version February 2019 Agreement ID:

|  |
| --- |
| **Attachment 2**Data Transfer and Use AgreementData-specific Terms and Conditions:Personally Identifiable Information - HIPAA |

**Additional Terms and Conditions:**

1. The Data is Protected Health Information (“PHI”) as that term is defined in the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), at 45 C.F.R. §160.103 (and not a Limited Data Set).

☐ If checked, the Data is covered under a Certificate of Confidentiality, which must be asserted against compulsory legal demands, such as court orders and subpoenas for identifying information or characteristics of a research participant. See https://grants.nih.gov/grants/guide/notice-files/NOT-OD- 17-109.html for further information.

2. Nothing herein shall authorize the Recipient to use or further disclose the Data in a manner that would violate the requirements applicable to Provider under 45 CFR §164.514.

3. Notwithstanding any statement herein to the contrary, Provider represents that it has full authority to share the Data with the Recipient and has confirmed that the Project is consistent with such consents or authorizations, if any, as Provider has obtained from individuals who are the subjects of the Data.

4. Unless otherwise required by law or legal process, Recipient shall not use or further disclose the Data other than as permitted by this Agreement. If Recipient believes it is required by law or legal process to use or disclose the Data, it will promptly notify Provider, to the extent allowed by law, prior to such use or disclosure and will disclose the least possible amount of Data necessary to fulfill its legal obligations.

5. In the event Recipient becomes aware of any use or disclosure of the Data not provided for by this Agreement, Recipient shall take any appropriate steps to minimize the impact of such unauthorized use or disclosure as soon as practicable and shall notify Provider of such use or disclosure as soon as possible, but no later than 5 business days after discovery of the unauthorized use or disclosure. Recipient shall cooperate with Provider to investigate, correct, and/or mitigate such unauthorized use or disclosure. Recipient acknowledges that Provider may have an obligation to make further notifications as set forth in Subpart D of 45 CFR §164 or under applicable state law and shall cooperate with the Provider to the extent necessary to enable Provider to meet all such obligations, and will reimburse Provider for the cost of meeting all such obligations.

6. Recipient will not use the Data, either alone or in concert with any other information, to make any effort to contact individuals who are the subjects of the Data without appropriate Institutional Review Board (IRB) approval, specific written approval from Provider, and informed consent and authorization from the individual or a waiver, if required.

7. Recipient agrees to implement reasonable safeguards, sufficient to meet the standards of 45 CFR

§164.530(c), to limit incidental, and avoid prohibited, uses and disclosures of the Data, and to ensure that only Authorized Persons have access to the Data.

8. Recipient agrees to remove and securely destroy or return, as directed by the Provider in Attachment 1, the part or parts of the Data that identifies the individual who is the subject of the Data at the earliest time at which removal and destruction or return can be accomplished, consistent with the purpose of the Project.

9. The parties agree to take such action as is necessary to amend this Agreement, from time to time, in order for the Provider to remain in compliance with the requirements of the HIPAA Privacy Regulations.

10. By signing this Agreement, Recipient provides assurance that its relevant institutional policies and applicable federal, state, or local laws and regulations (if any) have been followed, including the completion of any IRB review or approval that may be required prior to Recipient’s use of the Data. Upon Provider’s written request to the Recipient’s Contact for Formal Notices identified in the signature block, Recipient shall provide documentation of its IRB-Approved Protocol.

**Notes**

**Section 5:** The cost of breach notifications and related compliance obligations can be significant, and when those are a result of Recipient’s actions, the cost should be passed along to Recipient. Indemnification is sometimes used in these circumstances, but we chose reimbursement to avoid issues for institutions that are statutorily prohibited from providing an indemnity.

FDP version February 2019 Agreement ID:

|  |
| --- |
| **Attachment 2**Data Transfer and Use AgreementData-specific Terms and Conditions:Personally Identifiable Information - Common Rule Only |

**Additional Terms and Conditions:**

1. The Data is Personally Identifiable Information, as that is defined in OMB Memorandum M-07-16, and not covered under HIPAA, FERPA, or similar laws or regulations governing personal information that require the addition of special terms beyond those included in this Attachment 2.

☐ If checked, the Data is subject to the Federal Privacy Act of 1974, as amended, at 5 U.S.C. § 552a.

☐ If checked, the Data is covered under a Certificate of Confidentiality, which must be asserted against compulsory legal demands, such as court orders and subpoenas for identifying information or characteristics of a research participant. See https://grants.nih.gov/grants/guide/notice-files/NOT-OD- 17-109.html for further information.

2. Notwithstanding any statement herein to the contrary, Provider represents that it has full authority to share the Data with the Recipient and has confirmed that the Project is consistent with such consents as Provider may have obtained from individuals who are the subjects of the Data.

3. Unless otherwise required by law or legal process, Recipient shall not use or further disclose the Data other than as permitted by this Agreement. If Recipient believes it is required by law or legal process to use or disclose the Data, it will promptly notify Provider, to the extent allowed by law, prior to such use or disclosure and will disclose the least possible amount of Data necessary to fulfill its legal obligations.

4. In the event Recipient becomes aware of any use or disclosure of the Data not provided for by this Agreement, Recipient shall take any appropriate steps to minimize the impact of such unauthorized use or disclosure as soon as practicable and shall notify Provider of such use or disclosure as soon as possible, but no later than 5 business days after discovery of the unauthorized use or disclosure. Recipient shall cooperate with Provider to investigate, correct, and/or mitigate such unauthorized use or disclosure. Recipient acknowledges that Provider may have an obligation to make further notifications under applicable state law and shall cooperate with the Provider to the extent necessary to enable Provider to meet all such obligations, and will reimburse Provider for the cost of meeting all such obligations.

5. Recipient will not use the Data, either alone or in concert with any other information, to make any effort to contact individuals who are the subjects of the Data without appropriate Institutional Review Board (IRB) approval, specific written approval from Provider, and informed consent from the individual, if required.

6. Recipient agrees to store Data with security controls adequate to protect Personally Identifiable Information, to ensure that only Authorized Persons have access to the Data, and to maintain appropriate control over the Data at all times.

7. Recipient agrees to remove and securely destroy or return, as directed by the Provider in Attachment 1, the part or parts of the Data that identifies the individual who is the subject of the Data at the earliest time at which removal and destruction or return can be accomplished, consistent with the purpose of the Project.

8. By signing this Agreement, Recipient provides assurance that its relevant institutional policies and applicable federal, state, or local laws and regulations (if any) have been followed, including the completion of any IRB review or approval that may be required prior to Recipient’s use of the Data. Upon Provider’s written request to the Recipient’s Contact for Formal Notices identified in the signature block, Recipient shall provide documentation of its IRB-Approved Protocol.

**Notes**

**Section 4:** The cost of breach notifications and related compliance obligations can be significant, and when those are a result of Recipient’s actions, the cost should be passed along to Recipient. Indemnification is sometimes used in these circumstances, but we chose reimbursement to avoid issues for institutions that are statutorily prohibited from providing an indemnity.

FDP version May 2017 Agreement ID:

|  |
| --- |
| **Attachment 2**Data Transfer and Use AgreementData-specific Terms and Conditions:Limited Data Set |

**Additional Terms and Conditions:**

1. Nothing herein shall authorize the Recipient to use or further disclose the Data in a manner that would violate the requirements of Provider under 45 CFR 164.514.
2. Recipient shall not use or further disclose the Data other than as permitted by this Agreement or as otherwise required by law.
3. Recipient shall report to the Provider any use or disclosure of the Data not provided for by this Agreement within 5 business days of when it becomes aware of such use or disclosure.
4. In the event Recipient becomes aware of any use or disclosure of the Data not provided for by this Agreement, Recipient shall take any appropriate steps to minimize the impact of such unauthorized use or disclosure as soon as practicable and shall notify Provider of such use or disclosure as soon as possible, but no later than 5 business days after discovery of the unauthorized use or disclosure. Recipient shall cooperate with Provider to investigate, correct, and/or mitigate such unauthorized use or disclosure. Recipient acknowledges that Provider may have an obligation to make further notifications under applicable state law and shall cooperate with the Provider to the extent necessary to enable Provider to meet all such obligations, and will reimburse Provider for the cost of meeting all such obligations.
5. Provider is a HIPAA Covered Entity, and the Data will be a Limited Data Set as defined by the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”). In accordance with Section 164.514(e)(2) of the HIPAA Privacy Rule, the Data shall exclude the following direct identifiers of the individual or of relatives, employers, or household members of the individual:
	1. Names;
	2. Postal address information, other than town or city, State, and zip code;
	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
	16. Full face photographic images and any comparable images.

If the Data being provided is coded, the Provider will not release, and the Recipient will not request, the key to the code.

1. Notwithstanding any statement herein to the contrary, Provider represents that it has full authority to share the Data with the Recipient.
2. Recipient agrees to store Data with security controls adequate to protect Personally Identifiable Information, to ensure that only Authorized Persons have access to the Data, and to maintain appropriate control over the Data at all times.
3. Recipient will not use the Data, either alone or in concert with any other information, to make any effort to identify or contact individuals who are or may be the sources of Data without specific written approval from Provider and appropriate Institutional Review Board approval, if required pursuant to 45 CFR 46. Should Recipient inadvertently receive identifiable information or otherwise identify a subject, Recipient shall promptly notify Provider and follow Provider’s reasonable written instructions, which may include return or destruction of the identifiable information.
4. By signing this Agreement, Recipient provides assurance that relevant institutional policies and applicable federal, state, or local laws and regulations (if any) have been followed, including the completion of any IRB or ethics review or approval that may be required. Upon Provider’s written request to the Recipient’s Contact for Formal Notices identified in the signature block, Recipient shall provide documentation of its IRB-Approved Protocol.
5. The parties agree to take such action as is necessary to amend this Agreement, from time to time, in order for the Provider to remain in compliance with the requirements of HIPAA.

**Notes**

**New Section 4:** While the ramifications of unauthorized use or disclosure of a Limited Data Set are typically less significant than unauthorized use or disclosure of a fully identifiable dataset, they can still be significant and so an obligation on the recipient to notify provider, minimise impact, and cooperate and pay for breach notifications and legal obligations is appropriate.

**New Section 6:**  Even with a Limited Data Set, placing responsibility to ensure that Provider has necessary authority to provide the data with the Provider is necessary given Recipient’s likely inability to do so.

**New Section 7:** Also copied from other Attachments 2 above, it is still important to carefully consider the security of an environment storing a Limited data Set.

**Section 9:** Provider may need IRB-related documentation, and similar to other Attachments 2 this provides a process by which Recipient can be asked to provide.

FDP version May 2017 Agreement ID:

|  |
| --- |
| **Attachment 2**Data Transfer and Use AgreementData-specific Terms and Conditions:Personally Identifiable Information - HIPAA |

**Additional Terms and Conditions:**

1. Provider represents that:

1. The Data will not include personally identifiable information as defined in NIST Special Publication 800-122. If the Data being provided is coded, the Provider will not release, and the Recipient will not request, the key to the code.
2. If Provider is a Covered Entity, the Data will be de-identified data, as defined by the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”).

2. Notwithstanding any statement herein to the contrary, Provider represents that it has full authority to share the Data with the Recipient.

3. Recipient will not use the Data, either alone or in concert with any other information, to make any effort to identify or contact individuals who are or may be the sources of Data without specific written approval from Provider and appropriate Institutional Review Board (IRB) approval, if required pursuant to 45 CFR 46. Should Recipient inadvertently receive identifiable information or otherwise identify a subject, Recipient shall promptly notify Provider and follow Provider’s reasonable written instructions, which may include return or destruction of the identifiable information.

4. By signing this Agreement, Recipient provides assurance that relevant institutional policies and applicable federal, state, or local laws and regulations (if any) have been followed, including the completion of any IRB or ethics review or approval that may be required. Upon Provider’s written request to the Recipient’s Contact for Formal Notices identified in the signature block, Recipient shall provide documentation of its IRB-Approved Protocol.

5. Recipient shall promptly report to the Provider any use or disclosure of the Data not provided for by this Agreement of which it becomes aware.

**Notes**

**Section 1:** We made original sections 1 and 2 subsections a and b in order to clarify that these statements are representations of the Provider, which is responsible for ensuring their accuracy.

**New Section 2:**  Even with deidentified data, placing responsibility to ensure that Provider has necessary authority to provide the data with the Provider is necessary given Recipient’s likely inability to do so.

**Section 4:** Provider may need IRB-related documentation, and similar to other Attachments 2 this provides a process by which Recipient can be asked to provide.