

DATA SHARING AGREEMENT

This DATA SHARING AGREEMENT (“Agreement”) is entered into as of the last date of authorized signatory hereto (“Effective Date”), by and between [DATA RECIPIENT NAME] (hereinafter "Recipient") and [DATA PROVIDER NAME] (hereinafter "Provider"), collectively referred to as the “Parties” and individually as a “Party.”

RECITALS

WHEREAS, Provider desires to share its data (“Data”) with Recipient for academic and research purposes (the “Purpose”) described in attachment A;

WHEREAS, Recipient will store the Data in a Recipient generated and maintained database (“Registry”), subject to the terms of this Agreement;

NOW, THEREFORE, the Parties, each in consideration of the foregoing, and intending to be legally bound, mutually agree as follows:

1. This Agreement sets forth the terms and conditions pursuant to which Provider will disclose and provide its Data to Recipient in accordance with the Purpose to conduct research as defined in Attachment A (“Research”).
2. Data may consist of Personally Identifiable Information (“PII”), as PII is defined in the OMB Memorandum M-07-16, in which PII refers to information, which can be used to distinguish or trace an individual's identity, including without limitation their name, social security number, and biometric records, alone, or when combined with other personal or identifying information which is linked or linkable to a specific individual, including without limitation date and place of birth, mother’s maiden name, address, etc. For purposes of this Agreement PII is not covered under HIPAA, FERPA, or similar laws or regulations governing personal information that require the addition of special terms beyond those included herein.
3. Provider shall obtain all required permissions from its institutional review board (“IRB”) or equivalent or other relevant regulators, as applicable, which may be required in order to submit Data for inclusion into the Registry. Notwithstanding any statement herein to the contrary, Provider represents that it has full authority to share its Data with Recipient and has confirmed that the Purpose is consistent with such consents as Provider has obtained from individuals who are the subjects of the Data, as applicable.
4. Recipient will be the custodian of the Data and will observe all conditions for use and for establishment and maintenance of security arrangements to prevent unauthorized use as specified in this Agreement. Recipient shall comply with all applicable state and federal laws and regulations governing the use of such Data.
5. Data will be maintained by Recipient on an encrypted server with appropriate security controls and physical, administrative and technical safeguards employed at all times to protect the Data and to ensure that only those persons authorized by Recipient have access to the Data.
6. In the event Recipient becomes aware of any unauthorized use or disclosure of Data, including any case where Data may have been transmitted or obtained by an unapproved third-party due to a security breach, Recipient shall take 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.
7. Recipient will not use Data, either alone or in concert with any other information to make any effort to contact individuals who are the subjects of the Data.

8. This Agreement shall be effective for a term of five (5) years from the Effective Date but may be terminated by either Party within sixty (60) days of written notice. This Agreement may be terminated by either Party for default upon the defaulting Party's failure to cure a material breach within thirty (30) days after receipt of notice from the non-defaulting Party specifying with sufficient detail the nature of the default. In the event of the termination of the Agreement, Recipient shall (i) securely destroy or return, as directed by the Provider, the part or parts of the Data that identifies individuals at the earliest time at which removal and destruction or return can be accomplished and (ii) retain the De-Identified Data included in the Registry to satisfy the Purpose. Termination of this Agreement shall not relieve either Party of the obligations arising hereunder.

9. Provider permits Recipient the right to use Data, alone or in conjunction with other data from Third Party providers, consistent with the Research, and to solely use its Data in the generation of the Registry that will be accessed by Authorized Researchers, as further described below and in Attachment A.

10. Recipient shall grant access to the Registry to authorized external researchers ("Authorized Researchers") who have submitted a Study proposal, which has been vetted and approved by Recipient, and entered into a Researcher Access Agreement.

11. All access to the Registry by Authorized Researchers shall be pursuant to the following conditions: (i) accessibility of Data in the Registry by Authorized Researchers shall be solely for academic, educational and research purposes consistent with the Research and Purpose hereunder and the Researcher Access Agreement, (ii) accessibility by Researchers shall be via encrypted access to the servers, and (iv) Researchers will not be permitted to download case-level data. Recipient shall receive written authorization from Provider, not to be unreasonably withheld, before providing Data to Third Parties other than Authorized Researchers.

12. Recipient shall allow Provider to access its Data in the Registry. To access data made available by other providers, Provider will have to apply for access and enter into a data access agreement consistent with Recipient's governance model.

13. Unless otherwise required by law or legal process, Recipient shall not use or further disclose the Data or any key that can be used to re-identify the Data to any Third Party. If Recipient 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.

14. Legal title to the Data will remain with Provider. To the extent Provider has rights in the Data, Provider grants Recipient a royalty-free, non-exclusive, non-commercial license to use Provider Data solely for conducting the Research hereunder in furtherance of the Purpose and under the terms and conditions of this Agreement. Provider grants no rights to the Data other than those specifically set forth in this Agreement. Nothing in this Agreement shall prohibit Provider from retaining its unrestricted right to further use, disclose, transfer or license its Data for any other purpose or to other Third Parties at its discretion. Provider acknowledges that Recipient shall be the owner of all rights in and to the Registry, and all trademarks associated with Recipient or the Registry ("Recipient's Intellectual Property") with the exception of Provider's Data (identified and de-identified), including subsets thereof. Inventorship of any intellectual property that may be conceived, developed or discovered hereunder shall be determined under the principles of United States Intellectual Property Law, and ownership shall follow inventorship. In consideration for the use of Provider Data herein, Recipient hereby grants Provider a royalty-free, non-exclusive, non-commercial license to access the Registry and use results from the Research for its internal academic and/or educational non-commercial research purposes.

15. PROVIDER DATA AND THE REGISTRY ARE PROVIDED "AS-IS" WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ACCURACY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR THAT THE USE OF THE LIMITED DATA SET WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

16. Recipient shall notify Provider of publications arising from use of the Data contained within the Registry every six months. Publications using Data provided through this Agreement must be referenced using the following citation standard: Provider,

Date, Digital Object Identifier (DOI) link. Recipient will assist with obtaining the DOI and inform Third Party Registry users of this requirement.

17. Neither Party shall use the name, insignia, trademark, trade name, logo, abbreviation, nickname, or other identifying mark or term of the other Party for any purpose, except as required by law, without the prior written consent of the other Party, provided however, that the Parties may use the name of the other Party without prior written consent in its routine listings of sponsored research, as required on grant applications, and as may be required by scientific journals for publication.

18. Except to the extent prohibited by law, each Party shall be liable to the other Party for any loss, claim, damage, or liability, of any kind or nature (“Loss”), that may arise from a breach of a Party’s obligations hereunder or its use of Data, except to the extent such Loss is caused by the gross negligence or willful misconduct of the other Party. No indemnification for any Loss is intended or provided by either Party under this Agreement.

19. Notices under this Agreement shall be in writing and sent by public courier, or email, and addressed to the following:

To Recipient:

[RECIPIENT POINT OF CONTACT]

To Provider:

[PROVIDER POINT OF CONTACT]

20. This Agreement shall be governed by the laws of New York State, excluding conflict-of-law provisions.

21. Neither Party may assign or transfer this Agreement or any of the rights, duties or obligations hereunder without the prior written consent of the other Party, whose consent shall not be unreasonably withheld. Any attempted assignment without such consent shall be null and void.

22. This Agreement embodies the entire understanding between the Parties and supersedes all prior understandings and agreements, whether written or oral, relating to the subject matter hereof. This Agreement may not be amended or modified except by a written document signed by duly authorized representatives of both Parties.

23. This Agreement may be executed in two or more counterparts, each of which will be deemed an original and all of which together will constitute the same agreement, and delivery of an executed copy of this Agreement by any Party via electronic transmission will be as effective as delivery of a manually executed copy of the Agreement.

IN WITNESS WHEREOF, the duly authorized representatives of the Parties hereby execute this Agreement as of the Effective Date.

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 respective institutions:

By an Authorized Official of Provider:

x _____
Date: _____
Name: _____
Title: _____

By an Authorized Official of Recipient:

x _____
Date: _____
Name: _____
Title: _____

Contact Information for Formal Notices:

Name: _____
Address: _____

Email: _____
Phone: _____

Contact Information for Formal Notices:

Name: _____
Address: _____

Email: _____
Phone: _____

ATTACHMENT A

DATA DESCRIPTION:

[DESCRIPTION OF DATA]

PURPOSE:

[PURPOSE OF DATA]

RESEARCH:

[DESCRIPTION OF RESEARCH]