**­­­DATA SHARING AGREEMENT (DE-IDENTIFIED DATA)**

This agreement for the provision of de-identified data (this “**Agreement**”), effective as of the date of last signature below (the “**Effective Date**”), is entered into by and between **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_,** with a place of business at **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** (“**Institution**”) with \_\_\_\_\_\_\_\_\_\_\_\_\_ as Institution Principal Investigatorand \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, with a place of business at **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** (“**User**”) with \_\_\_\_\_\_\_\_\_\_\_\_\_ as User Principal Investigator.  User and Institution are individually referred to herein as a "**Party**,” and collectively as the "**Parties**."

**R E C I T A L S**

**WHEREAS**, Institution creates, receives, accesses, and maintains certain information from its patients and is required to protect the confidentiality of such information in accordance with applicable privacy laws, including the Health Insurance Portability and Accountability Act of 1996, Subtitle D of the Health Information Technology for Economic and Clinical Health Act of 2009, and regulations and other guidance promulgated under both laws, as may be amended from time to time (collectively, **"HIPAA"**) and other federal and state privacy laws (hereinafter collectively referred to as **“Privacy Laws”**);

**WHEREAS**, User desires to receive from Institution certain clinical data in Institution’s possession, including data pertaining to patients (referred to herein as “**Data**”) for the purposes described herein; and

**WHEREAS**, Institution is willing to provide such Data to User in accordance with the terms and conditions of this Agreement.

**NOW, THEREFORE**, in consideration of the foregoing, User and Institution agree as follows:

1. Scope. This Agreement contemplates a one-way transfer from Institution to User of Data created, received, accessed or maintained by Institution in accordance with all applicable laws.
2. Provision of Data by Institution. Institution represents that any Data that it provides to User hereunder will not contain any “Protected Health Information” (as that term is defined in the HIPAA privacy rule at 45 C.F.R. §160.103) and shall be de-identified in accordance with 45 C.F.R. §164.514(b) of the HIPAA privacy rule (hereinafter, “**De-Identified**”). The Parties agree that the Data will be completely De-Identified.
3. Use by User. Institution grants to User the right to use the Data provided hereunder for the project entitled “\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_” (“**Research Project**”). The Data shall not be used or further disclosed except as permitted by this Agreement or as otherwise required by law and shall be used only for purposes of internal, non-commercial research.
4. User Obligations. As a condition of receiving the Data for purposes of the Research Project, User agrees to comply with all applicable federal and state laws. User further agrees:
   1. to use all appropriate safeguards to prevent use or disclosure of the Data other than as provided for by this Agreement;
   2. not to re-identify, or make any attempt to re-identify, the Data;
   3. to report promptly to Institution any use or disclosure of the Data not provided for by this Agreement of which User becomes aware;
   4. to ensure that any employees, staff, or agents, to whom it provides the Data agree in writing to the same restrictions and conditions that apply to the User with respect to the Data;
   5. to the extent disclosure of all or a portion of the Data is required by applicable law, rule or order of court, or government regulation, (i) to limit disclosure to required information, and (ii) to provide, to the extent such is not prohibited by law, rule, or order of court or governmental regulations, prompt written notice to Institution to permit Institution to take steps to avoid the need for such disclosure and/or to obtain a protective order; and
   6. to use or disclose to its employees, staff, subcontractors, agents or other third parties, and request from Institution, only the minimum necessary information needed for the Data for performance of the Research Project.
5. Compliance with Laws. User and Institution shall comply with all applicable laws and regulations including, without limitation, Privacy Laws and the Federal Anti-Kickback Statute (42 U.S.C. 1320a-7(b)).
6. Use of Name. Neither Party shall use the names or trademarks of the other Party or of any of the other Party's affiliated entities in any advertising, publicity, endorsement, or promotion unless the other Party has provided prior written consent for the particular use contemplated. The terms of this section survive the termination, expiration, non-renewal, or rescission of this Agreement.
7. No Transfer of Rights. It is expressly agreed that neither Institution nor User transfers by operation of this Agreement to the other Party any right in or license to any patents, copyrights, or other proprietary right owned as of the Effective Date of the Agreement or arising outside of the research conducted under this Agreement.
8. Entire Agreement. This Agreement constitutes the final, complete and exclusive agreement between the parties with respect to its subject matter and supersedes all past and contemporaneous agreements, promises, and understandings, whether oral or written, between the parties.
9. Counterparts. This Agreement may be executed in any number of counterparts which, when taken together, will constitute one original, and photocopy, facsimile, electronic, or other copies shall have the same effect for all purposes as an ink-signed original. Each party hereto consents to be bound by photocopy, facsimile or electronic signatures of such party's representative hereto.
10. Miscellaneous.
    1. Liability. Institution and User shall each be responsible for the negligent acts and omissions of their own employees, officers, staff, students, or agents, as applicable (“Personnel”). User assumes all liability for damages that may arise from its use, storage, or disposal of the Data. In no case will either Party or its Personnel be liable for any incidental, special or consequential damages, resulting from the use or handling of the Data, except for any such claims or damages arising out of gross negligence, recklessness or willful misconduct of the affected Party.

This Section 10(a) shall survive termination or expiration of this Agreement.

* 1. Liability Coverage. During the term of this Agreement, User shall maintain, at its own expense, general liability coverage with minimum limits of $1 million per occurrence and $3 million per annual aggregate, which shall cover User's obligations to Institution under this Agreement. At Institution’s written request, User shall furnish or cause insurance carrier to furnish a certificate of insurance to Institution as evidence of such coverage.
  2. Rights of Proprietary Information. Disclosure by Institution of its Data hereunder does not constitute a grant to User of any right or license to such Data, except as set forth herein. Institution retains any and all rights to the proprietary information, confidential information, and/or Data Institution discloses to User.
  3. Notices. Any notices pertaining to this Agreement shall be given in writing and shall be deemed duly given when personally delivered to a Party or a Party's authorized representative as listed below or sent by means of a reputable overnight carrier, or sent by means of certified mail, return receipt requested, postage prepaid. A notice sent by certified mail shall be deemed given on the date of receipt or refusal of receipt. All notices shall be addressed to the appropriate Party as follows:

If to Institution:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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If to User:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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* 1. Amendments. This Agreement may not be changed or modified in any manner except by an instrument in writing signed by a duly authorized officer of each of the Parties hereto.

**IN WITNESS WHEREOF**, the Parties hereto have caused this Agreement to be executed by their duly authorized officers or representatives.

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| --- | --- |
| **User** | **Institution** |
| By:  Authorized Signature | By:  Authorized Signature |
| Print Name | Print Name |
| Title | Title |
| Date | Date |