

Agreement ID:

<b>Attachment 2</b> Data Transfer and Use Agreement Data-specific Terms and Conditions: Personally Identifiable Information - HIPAA
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**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.
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.