Attachment 2

Data Use Agreement

Data-Specific Terms and Conditions:

Personally Identifiable Human Data – HIPAA

Additional Terms and Conditions:

1. The Data is Protected Health Information (“PHI”) as that term is defined by HIPAA, in 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 will authorize the Recipient to use or further disclose the Data in a manner that would violate the requirements applicable to the Provider under 45 CFR 164.514.

3. Notwithstanding any term to the contrary in this Agreement, the Provider 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, that the Provider has obtained from individuals who are the subjects of the Data.

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

5. The 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 IRB approval, specific written approval from the Provider, and informed consent and authorization from the subject or a waiver, if required.

6. The Recipient will 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.

7. The 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, the 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 the Recipient’s use of the Data. Upon the Provider’s written request to the Recipient’s Contact for Formal Notices identified in the signature block of this Agreement, the Recipient will provide documentation of its IRB approved Protocol.