

This Data Submission Agreement ("Agreement") is entered into by and between the party requesting access to neuroHIV Data Ecosystem data ("Data Requestor") and the NeuroHIV Data Ecosystem ("Ecosystem"), a collaborative research infrastructure supporting the sharing and integration of data related to NeuroHIV research.

Description of Data to be Delivered, and Format:

Through this Agreement, the Data to be provided shall include de-identified participant-level data available through the Ecosystem restricted tier. Data will be provided in Excel-readable format.

Data Security

Both Parties must employ government best practices, both technically and procedurally, to protect the Data from unauthorized physical and electronic access.

Compliance with Applicable Laws and Regulations

Both Parties shall comply with all applicable federal, state or local laws and regulations during its performance of this Agreement. The Recipient may receive or create certain health or medical information under this Agreement ("Protected Health Information") as defined in 45 C.F.R. 164.501. Recipient acknowledges that use or disclosure of Protected Health Information is subject to protection under state and federal law, including the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), including the Standards for Security for the Protection of Electronic Protected Health Information, codified at 45 C.F.R. parts 160 and 164, Subpart C ("Security Rule"), and implementing regulations as amended by the "Final Omnibus Rule" (78 Fed. Reg. 5565, Jan. 25, 2013) issued pursuant to HIPAA and the "HITECH Act," and the terms of any data transfer, data sharing, data use, materials transfer, or other similar agreement executed between and the Principal Investigator and/or Sponsor.

Amendments and Alterations to this Agreement

Both Parties may amend this agreement by mutual consent, in writing, at any time.

Constraints on Use of the Data

The Recipient acknowledges, agrees, and represents that, unless otherwise expressly permitted in writing by Emmes:

1. Rights in the Data are retained by Sponsor, Principal Investigator, and Emmes.
2. Emmes and Recipient will agree in writing, subject to mutually agreeable modification from time to time, on what data elements are to be included, the subsets of data and the schedule of transfers of the Data.
3. Emmes may withhold certain information at its discretion with subsequent need of review.
4. Sponsor and Principal Investigator may be invited to participate in developing any analyses.
5. Mutual confidentiality is limited to the content of the Data and not the nature of the collaboration.
6. The Recipient shall not use the Data to identify individuals or personal health identifiers and will not link or combine the Data with other information for the purpose of identifying individuals, unless approved in writing by Sponsor, Principal Investigator, Emmes and the Research Involving Human Subjects Committee.
7. Data supplied by Emmes to Recipient or collected on behalf of Sponsor and/or Principal Investigator in support of the Grant/Contract is the sole property of Sponsor and Principal Investigator and shall not be shared with third parties without the written consent of Emmes, Sponsor, and Principal Investigator. The Data shall not be sold or used, internally or externally, for any purpose not directly related to the scope of work defined in this Agreement without the written consent of Emmes, Sponsor, and the Principal Investigator.

8. The Recipient shall use the Data solely for bona fide research/analysis as described in the purposes set forth above.
9. Only Recipient's employees who have a "need to know" shall access the Data, and all such Recipient employees shall be advised of the terms of this Agreement and the restrictions upon use and disclosure.
10. The Recipient shall keep an accurate written account of all authorized copies of the Data, and of work product derived from the Data, and will furnish such written logs upon request to Emmes, Sponsor, and Principal Investigator, including tiered access levels or data use agreements, as appropriate.

Data Handling Requirements

Data handling requirements may vary depending on the classification of the data shared with each Party. However, it is anticipated that most of the data shared between the Parties will involve a mix of data classes including sensitive and possibly confidential information. Therefore, whenever data elements are aggregated for collection, transmission, or storage, the aggregate data shall be handled using the protocols that apply to the most sensitive data element.

Warranty Disclaimer

ALL DATA FURNISHED TO EITHER PARTY IS PROVIDED ON AN "AS IS" BASIS. THE PARTIES MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO THE DATA, AND EXPRESSLY DISCLAIM ANY AND ALL WARRANTIES OF ANY KIND WITH RESPECT THERETO, INCLUDING ANY WARRANTIES OF MERCHANTABILITY OR FITNESS OF A PARTICULAR PURPOSE.

Publications

1. All results from the Data used for publications shall be in accordance with any applicable publications policy.
2. All publications using the Data must contain the standard disclaimer, if applicable:

"This project has been funded in whole or in part with Federal funds from [SPONSOR] under Grant/Contract Number [GRANT/CONTRACT NUMBER]."

Termination

Either Party may terminate this Agreement for any reason upon thirty (30) days' written notice to the other Party, effective on the date of notice receipt. Either Party may terminate this agreement for cause thirty (30) days after an uncured breach of this Agreement described in a written notification to the breaching Party.

Patents and Inventions

Recipient shall report to Emmes in a timely manner all inventions made and reduced to practice during the course of performing under this Agreement in order that Emmes may comply and carry out any conditions of the sub-award concerning the filing of patent applications and dispositions of patent rights. Any applicable provisions of federal law concerning the rights to inventions made under government grants are made part of this Agreement by reference.

Any inventions or discoveries made or reduced to practice by either Party prior to or independent of this Agreement are each Party's separate property, and are not affected by this Agreement. Any inventions or discoveries made and reduced to practice solely by Recipient without the use of the Data provided to the recipient shall be exclusively owned by the Recipient.

Indemnification

Each Party shall defend, indemnify, and hold the other Party, its officers, employees, affiliates, and agents harmless from and against any and all liability, damages, loss, or expense (including reasonable attorneys' fees), incurred in connection with any third party claims or cause of action arising out of or relation to the performance of this Agreement but only in proportion to the extent such liability, damage, loss, expense, or attorneys' fees are caused by or result from the negligent or willful misconduct or omission or breach of this Agreement by the indemnifying party, its officers, employees, affiliates, and agents.

UNDER NO CIRCUMSTANCES SHALL EITHER PARTY BE ENTITLED TO, OR RESPONSIBLE FOR, ANY INCIDENTAL, INDIRECT, PUNITIVE, SPECIAL OR CONSEQUENTIAL DAMAGES (INCLUDING, WITHOUT LIMITATION, LOSS OF REVENUE OR LOSS OF PROFITS) ARISING IN CONNECTION WITH ANY BREACH OR DEFAULT RELATED TO THIS AGREEMENT.

Insurance

Both Parties shall maintain those amounts or insurance as is customary or considered appropriate with regard to the activities contemplated by this Agreement.

Independent Responsible Party

Both Parties shall be solely responsible for the manner in which they perform this Agreement.

Entire Agreement

This Agreement represents the entire agreement of the parties, and supersedes and replaces any and all prior communications, agreements, understandings, and representations of the parties.

Governing Law; Attorneys' Fees

This Agreement shall be governed by the laws of the State of Maryland without regard to conflict of laws principles. Any action or proceeding seeking to enforce any provision of, or based on any right arising out of, this Agreement may be brought against either of the parties in the courts for the State of Maryland, or if it has or can acquire jurisdiction, in the United States District Court for the District of Maryland and each of the parties consents to the jurisdiction of such courts (and of the appropriate appellate courts) in any such action or proceeding and waives any objection to personal jurisdiction or venue therein. The substantially prevailing party in any legal dispute between the parties shall be entitled to recover its reasonable attorneys' fees and costs.

Severability

If any part, term, or provision of this Agreement shall be held void, illegal, unenforceable, or in conflict with any law of any federal, state, or local government having jurisdiction over this Agreement or its subject matter, the validity of the remaining portions or provisions will not be affected hereby.

Waiver

Waiver of any provision of this Agreement will not be deemed waiver of any other provision of this Agreement, nor will waiver of any breach of this Agreement be construed as a continuing waiver of other breaches of the same or other provisions of this Agreement.

Signature

Name: _____

Organization: _____

Date: _____