

DATA USE AGREEMENT FOR USE WITH NON-UNIVERSITY OF WASHINGTON RECIPIENTS

This Data Use Agreement is entered into between the University of Washington (“UW”) and _____ (hereinafter “Recipient”), effective as of the date of last signature (“Effective Date”) _____ to (“End Date”) _____.

The University of Washington is a hybrid entity and has designated its healthcare components and non-healthcare components as described in COMP.101 [Patient Information Privacy and Security Compliance Program and Administrative Requirements](#). These entities are Affiliated Entities as described in 45 CFR Section 164.105(b)(1). For purposes of this Agreement UW and Recipient may hereinafter be collectively referred to as the “Parties”.

I. PURPOSE OF ACTIVITIES

Recipient will only use or disclose data for the following limited purposes:

- Sharing a UW Medicine Limited Data Set for one of the following purposes:
 - Research
 - Public Health
 - UW Medicine Healthcare Operations
- Sharing UW Medicine Clinical Data for Research Purposes with Commercial Entity
- Sharing UW Medicine Clinical Data for Research Purposes with Non-Commercial Entities
- Sharing UW Research Data

Description of data (may attach reference document that describes the data):

II. DEFINITIONS

2.1 “Authorization” means a written detailed document that gives the UW permission to use and/or disclose PHI for research purposes, which are generally other than treatment, payment or healthcare operations (TPO), or to disclose PHI to a third party specified by the individual.

2.2 “Clinical Data” refers to healthcare delivery records and associated clinical data, including protected health information (“PHI”), de-identified healthcare data, Quality Improvement (“QI”) data, registry data, repository data, data contained in Peer Systems, financial data, and other forms of confidential or sensitive data within UW Medicine healthcare records.

2.3 “Commercial Entities”: A “commercial entity” is a private, generally technology industry organization that UW Medicine collaborates with to develop and test predictive and related models e.g., using AI tools. For this policy, “commercial entity” *does not* include private, pharmaceutical, medical device or related organizations that UW collaborates with to conduct interventional clinical trials.

2.4 “De-identified PHI” refers to healthcare information that has been de-identified in accordance with [COMP.103 Use and Disclosure of PHI, Section VI.B](#). See also [102.G4 PHI Guidance](#).

2.6 "Individually Identifiable Health Information" means a subset of health information, including demographic information collected from an individual, and (i) is created or received by a healthcare provider, health plan, employer or healthcare clearinghouse and (ii) relates to past, present or future physical or mental health or condition of an individual; and (a) identifies the individual, or (b) with respect to which there is a reasonable basis to believe that the information can be used to identify an individual.

2.7 "IRB" refers to the Institutional Review Board that reviewed and approved the research and provided a waiver of authorization, to the extent required under applicable laws and UW Medicine policy.

2.8 "Limited Data Set" is Protected Health Information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual: names; postal address information, other than town or city, state, and ZIP code; telephone numbers; fax numbers; electronic mail addresses; Social Security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers, including license plate numbers; device identifiers and serial numbers; web universal resource locaters (URLs); Internet Protocol (IP) address numbers; biometric identifiers, including finger and voice prints; and full face photographic images and any

comparable images.

2.9 "Protected Health Information" means Individually Identifiable Health Information that is (i) transmitted by electronic media, (ii) maintained in any medium constituting electronic media, or (iii) transmitted or maintained in any other form or medium. "Protected Health Information" shall not include (i) education records covered by the Family Educational Right and Privacy Act ("FERPA"), as amended, 20 U.S.C. Section 1232g(a)(4)(B)(iv).

2.10 "Research Data" means information, records, and tangible products arising from or associated with research conducted at, under the auspices of, or using the resources of the UW. Research Data includes both intangibles (e.g., information and copyrighted works such as software and expressions of information) and tangibles (e.g., cell lines, biological samples collected for research purposes, synthetic compounds, organisms, and originals or copies of laboratory notebooks).

2.11 "Security Review": Process by which the UW Medicine Principal Investigator sets up a meeting with the UW Medicine Chief Security Information Officer, Senior Director of Enterprise Records & Health Information, and the Director of Research IT to ensure the UW Medicine data set for projects involving a large language model will be protected and secure.

2.12 "Use" means the sharing, employment, application, utilization, examination, analysis, canonization, or commingling with other information.

III. OBLIGATIONS OF RECIPIENT

3.1 Use or Disclosure of Data. Recipient shall not use or disclose the above-referenced data in any manner that is not specifically authorized by this Agreement or that would constitute a violation of any applicable laws and regulations, including specifically the Health Insurance Portability and Accountability Act of 1996 and any regulations enacted pursuant to its provisions ("HIPAA Standards"), Washington state law, or any other data privacy obligations agreed to by either Party such as representations to the IRB or research study sponsor. Recipient shall ensure all directors, officers, employees, contractors, and agents use or disclose the data in accordance with the provisions of this agreement and federal and state law. Recipient shall not disclose, release, sell, rent, lease, loan or otherwise grant access to the Data to any third party except as may be authorized under this agreement under Section 3.6 or otherwise. Recipient must obtain specific authorization in the form of another written data Use Agreement to use or disclose the data for any purpose other than that specifically authorized herein.

3.2 Minimum Necessary. Recipient represents that it has obtained appropriate IRB authorization to conduct the research project identified in this agreement. In addition, Recipient represents that the data contains only the minimum necessary information to accomplish the purpose identified.

3.3 Safeguards Against Unauthorized Use of Disclosure of Data. Recipient agrees to implement all safeguards appropriate to prevent the unauthorized use or disclosure of the data. If UW Medicine de-identified or identified patient data will be used in conjunction with a Large Language Model or AI algorithm, a Security Review is required prior to sharing the data. The Security Review can be requested by following this link <https://redcap.iths.org/surveys/?s=A4M3H37JTK>

3.4 Reporting of Unauthorized Use of Disclosure of Data. Recipient shall report in writing any unauthorized use or disclosure of data not provided for in this Agreement within five (5) working days of becoming aware of an unauthorized use or disclosure. Recipient shall take immediate steps to stop the unauthorized disclosure and cure the breach of confidentiality. Written notification will be made to the following: UW Medicine Compliance, Box 358049, Seattle, Washington 98195-9210, 206.543.3098, comply@uw.edu.

3.5 Oversight and Monitoring. Recipient agrees that UW Medicine retains oversight of this data sharing arrangement and may monitor Recipient's access or use of the Data and audit compliance with the terms of this Data Use Agreement.

3.6 Agreements with Third Parties. Recipient agrees to ensure that any agent, including subcontractors, to whom the Recipient intends to provide the Data will, prior to receiving the Data, enter into a written data use agreement with UW such as this Agreement and be bound by the same restrictions and conditions that apply to Recipient.

3.7 Contact with Individuals. If applicable, Recipient agrees it will not: a) attempt to identify the information contained in the data, either directly or indirectly through linking with other sources of information, b) contact any patient(s) who are the subject of the data, or c) disclose individual subject results when or if the data are presented or published.

3.8 Publication. Recipient acknowledges that UW reserves the right to review any and all publications that result from the use of the Data prior to any manuscript submission. In addition, Recipient agrees to acknowledge the source of the Data in any publications reporting use of the Data.

3.9 Term and Termination. This Agreement shall remain in effect until the End Date. Where either party violates the terms of this Agreement, the party must take immediate steps to stop the unauthorized use or disclosure and cure any resulting breach of confidentiality. Either party may terminate this Agreement immediately upon written notice in the event that: (1) UW determines that Recipient has violated a material provision of this Agreement; (2) the Recipient or any of its employees, officers, or agents is convicted of a crime relating to, or is excluded, debarred or otherwise ineligible to participate in, any government healthcare program, including but not limited to Medicare, Medicaid, CHAMPUS, Tricare; (3) The Recipient or any employee, officer, or agent is named as a defendant in a criminal proceeding for the violation of state or federal privacy and confidentiality laws. Either party may terminate the Agreement for any reason upon 30 days written notice to the other parties.

3.10 Return or Destruction of Information. Unless terminated earlier in accordance with Section 3.9 or extended via a modification in writing and executed by duly-authorized representatives of both parties, this Agreement shall expire as of the End Date set forth above. Either party may terminate this Agreement with thirty (30) days written notice to the other party's Authorized Official as set forth below. Upon expiration or early termination of this Agreement, Recipient shall follow the disposition instructions provided in Attachment 1, provided, however, that Recipient may retain one (1)

copy of the Data to the extent necessary to comply with the records retention requirements:

- I. under any law, regulation, or Recipient institutional policy, and
- II. for instances where Data disposal is infeasible, and

The restrictions set forth in this Agreement (as applicable) shall survive and apply to such archival copy so long as Recipient holds the Data. Recipient shall not use data received from UW in a manner other than those permitted or required by state and federal laws or for the purposes described herein.

3.11 Use of Parties' Names. Neither party shall use the other party's name, trademarks or other logos in any publicity, advertising, or news release without the prior written approval of an authorized representative of that party.

3.12 Cost Reimbursement. Recipient agrees to reimburse UW for its costs in providing data under this Agreement as follows:

IV. GENERAL TERMS AND CONDITIONS

4.1 Ownership. UW shall retain ownership of any and all rights it has in the data and Recipient does not obtain any rights in the data other than as set forth in this agreement.

4.2 Indemnification. To the extent permitted by law, the Parties agree to defend (if requested), indemnify, and hold each other harmless from and against any loss, claim, or damage arising from the negligent acts or omissions of their own officers, employees, students, or agents in the performance of their duties under this Agreement.

4.3 Assignment; Successors and Assigns. The Recipient cannot assign its rights or obligations under this Agreement without the prior written consent of the UW. Subject to the foregoing, this Agreement shall apply to, be binding in all respects upon and inure to the benefit of the Parties hereto and their respective successors and assigns.

4.4 Severability. If any provision of this Agreement, or any other agreement, document, or writing pursuant to or in connection with this Agreement, is found to be wholly or partially invalid or unenforceable; the remainder of the agreement is unaffected.

4.5 Waiver. No term or provision of this Agreement shall be deemed waived and no breach excused unless waiver or excuse of breach is in writing and signed by the party against whom such waiver or excuse is claimed.

4.6 Entire Agreement. This Agreement constitutes the entire agreement between the Parties with respect to the subject matter hereof, and supersedes and replaces all prior agreements, understandings, commitments, communications, and representations made between the Parties whether written or oral, with respect to the subject matter hereof. No modification or amendment to this agreement shall be valid unless in writing and executed by the duly authorized representatives of both parties.

[Signature page follows.]

UW Medicine Representative

Data Set Recipient

Signature

Signature

Date

Name

Title

Read and Understood

Date

Signature

Name of UW PI

Title

Date