

DATA USE AND INDIVIDUAL INVESTIGATOR AGREEMENT

The Partners HealthCare System, Inc. (“Partners”) and the undersigned parties agree to the following terms of this Limited Data Set Data Use and Individual Investigator Agreement (“Agreement”), effective as of the date of last signature to this Agreement (“Effective Date”).

Partners is hosting an AI/Machine Learning Data Analytics Competition where investigators are challenged to build machine learning algorithms to determine a patient’s true disease phenotypes from raw electronic health record data (as described more fully below, the “Research”). The below signed individuals (the “Participating Investigators”) is a staff member or employee of the undersigned institution (“Participating Institution”) and are participating in the Research. Partners will provide access to Data to the Participating Investigators for purposes of the Research.

A. Data Use

1. For purposes of this Agreement, the “Data” refers to any and all data provided by Partners to Participating Investigators through the secure computing environment (the “Data Enclave”) for purposes of the Research that constitute a Limited Data Set within the meaning of the United States Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and its accompanying regulations, including but not limited to the Standards for Privacy of Individually Identifiable Health Information (“Privacy Rule”), at 45 CFR 160 and 45 CFR 164:
2. Partners represents that the Data is the minimum necessary to achieve the following Purpose:
 - Research: Requestor requests the Data in connection with Research conducted under the following protocol: “Biobank Disease Challenge”
 - Health Care Operations: _____
 - Public Health: _____
3. Only the Participating Investigators who have signed below will have access to the Data.
4. In consideration of Partners making available the Data to the Participating Investigators, Participating Institution and each Participating Investigator agrees as follows:
 - a. To use and disclose the Data only as permitted by this Agreement and the IRB approval or as otherwise required by law, and to not use or further disclose the Data in a manner that would violate the Privacy Rule if done by Partners;
 - b. To comply with the rules provided regarding participation in the Research (the “Rules for Partners HealthCare Biobank Disease Challenge”);
 - c. To permit only the Participating Investigators to use or access the Data;
 - d. To use appropriate safeguards to prevent use or disclosure of the Data other than as provided for by this Agreement;
 - e. To report to Partners any use or disclosure not provided for by this Agreement of which it becomes aware;
 - f. To ensure that the Data is not disclosed to anyone other than the Participating Investigators, including not disclosing to any agents and subcontractors;

- g. To refrain from using the Data to identify or to contact individuals;
- h. To not copy, transfer, or in any way remove Data from Partners or from the Data Enclave and to only access the Data through the Data Enclave and only for purposes of the Research; and
- i. In the event of a breach or violation of this Agreement, Partners has the right to report the problem to the Secretary of Health and Human Services and to take other appropriate action, including but not limited to terminating this Agreement.

B. Individual Investigator Agreement

- 1. Each of the Participating Investigators agrees to the following:
 - a. To participate in the above-referenced Research in accordance with the terms of this Agreement, the Rules, and the IRB approval.
 - b. That the Research is subject to legal requirements and ethical principles, including with respect to the protection of human subjects, and to applicable policies of Partners for the conduct of human subject research, and each Participating Investigator agrees that s/he will abide by any requirements of Partners or Partners Institutional Review Board (“IRB”) that are communicated to the Participating Investigator with respect to the Research in order to ensure compliance with such laws, principles, and policies and the protection of the rights and welfare of the Research participants. Each Participating Investigator will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this Agreement, including but not limited to HIPAA and its regulations. The provisions of this section shall survive any expiration or termination of this Agreement.
 - c. The Participating Investigator will abide by all determinations and requirements of the Partners IRB(s) and will accept the final authority and decisions of the Partners IRB(s) with respect to the Research. Without limiting the foregoing, each Participating Investigator will cooperate in the Partners IRB(s)’ responsibility for initial and continuing reviews and for recordkeeping, reporting and certification for the Research, and will cooperate with any inquiry by the Partners IRB(s) and/or the Institution into research compliance with respect to the Protocol, including but not limited to providing all information required by the Partners IRB(s) or Partners in a timely fashion and meeting with Partners’ research representatives upon request. The provisions of this section shall survive any expiration or termination of this Agreement.
 - d. Each Participating Investigator acknowledges that s/he is responsible for safeguarding the rights and welfare of each research subject, and that the subject’s rights and welfare must take precedence over the goals and requirements of the research.

C. Miscellaneous

- 1. This Agreement shall become effective on the last date signed below and shall continue until completion of the Research (as determined by the Partners IRB(s)), provided it is not earlier terminated as provided below. In the event of the Participating Investigator’s noncompliance with applicable federal regulations, IRB decisions, Partners’ or the Partners IRB(s)’ policies, or the Participating Investigator’s responsibilities under this Agreement, the Partners IRB(s) and/or Partners may terminate the Participating Investigator’s participation in the Research and this Agreement and recommend or take other further action as appropriate.

2. The Participating Investigator will maintain records of all human subjects research and related activities conducted under this Agreement for at least six years, and longer if required by law, after completion of the Research. Upon request, the Participating Investigator shall provide a copy of such records to the Partners IRB(s), and to others if legally required. The provisions of this section shall survive any expiration or termination of this Agreement.
3. This Agreement has been executed and delivered in and shall be governed by and construed and interpreted in accordance with the laws of the Commonwealth of Massachusetts. This Agreement may be amended only by a written agreement signed by the parties. If any provision of this Agreement shall be held to be invalid, illegal, or unenforceable, the validity, legality and enforceability of the remaining provisions shall not be affected thereby. This Agreement is not assignable in whole or in part, and any attempt to do so shall be void. The provisions of this section shall survive any expiration or termination of this Agreement. This Agreement may be executed in one or more counterparts, and counterparts may be exchanged by electronic or facsimile transmission, each of which will be deemed an original, but all of which together constitute one and the same instrument.

[Remainder of page intentionally left blank; signature page to follow.]

Partners HealthCare System, Inc.

By: _____
Name: _____
Title: _____
Date: _____

Participating Institution

By: _____
Name: _____
Title: _____
Date: _____

Names and signatures of Participating Investigators:

Signature: _____
Print Name: _____
Date: _____

Signature: _____
Print Name: _____
Date: _____

Signature: _____
Print Name: _____
Date: _____

Signature: _____
Print Name: _____
Date: _____