INSTRUCTIONS TO DATA USER:

1) ENTER THE INFORMATION REQUESTED IN THE AGREEMENT

2) SIGN (If Data User is an organization/institution, signature should be by a duly authorized representative of the organization)

3) RETURN THE SIGNED AGREEMENT BY EMAIL (PDF) TO:
Griffin M Weber, MD, PhD
Associate Professor of Medicine
Department of Biomedical Informatics
Harvard Medical School
E-mail: weber@hms.harvard.edu
DATA USE AND CONFIDENTIALITY AGREEMENT

for access to supporting data from

“Biases in electronic health record data due to processes within the healthcare system: retrospective analysis of observational health data”

Denis Agniel, Isaac S. Kohane, Griffin M. Weber

Research Article | published April 2018 | BMJ.

This Data Use and Confidentiality Agreement (the “Agreement”) is made as of the _____ day of ________, 20____ by and between Partners HealthCare System, Inc., through its i2b2 National Center for Biomedical Computing, and on behalf of itself and its affiliates (collectively, “Partners”) and __________________________________________________________ (“Data User”).

WHEREAS, Partners controls certain patient-level data in the form of patient laboratory values derived from its clinical information systems, which data have been De-Identified within the meaning of the Health Insurance Portability and Accountability Act of 1996 privacy regulations (“HIPAA”) and utilized and analyzed by Partners in the conduct of its published work, "Biases in electronic health record data due to processes within the healthcare system: retrospective analysis of observational health data". Denis Agniel, Isaac S. Kohane, Griffin M. Weber, (the “Study”) and included in Study publications (the “Data”); and

WHEREAS, in connection with such Study publications, Partners has been requested to release the Data, and its Institutional Review Board has approved such release, for the purpose of permitting validation of the Study results by interested academicians (the “Purpose”); and

WHEREAS, Data User wishes to receive the Data for this Purpose under the terms and conditions of access set forth herein;
NOW, THEREFORE, in consideration of the mutual promises and covenants set forth below, the parties hereby agree as follows:

1. **Data User** is either (check one):

   ___ an individual, requesting Data/Datasets under this Agreement on behalf of himself/herself as follows:
   
   Professional Title: ______________________________________
   Address: _______________________________________________
   Telephone: _____________________________________________
   Fax: ___________________________________________________
   E-mail: ________________________________________________

   OR

   ___ an organization / institution, requesting Data/Datasets under this Agreement on behalf of itself and its employees with a principal place of business and primary business contact as follows:
   
   Principal Place of Business: ______________________________
   Contact Name/Title: ______________________________________
   Telephone: _____________________________________________
   Fax: ___________________________________________________
   E-mail: ________________________________________________

2. Any Data provided to Data User under this Agreement will be De-Identified within the meaning of HIPAA. Data User agrees that Data User will not attempt to identify or re-identify any individual patient or group of patients from the Data.

3. Data User agrees that Data User will use the Data solely for the Purpose described above and for no other purpose.

4. Data User understands and agrees that the Data are proprietary and confidential to Partners and agrees that Data User will not disclose, disseminate, or otherwise share the Data to or with any other person or entity, including any subcontractor, for any purpose, without the prior written consent of Partners. To the extent Partners agrees in writing to permit such further access, the Data User will
ensure that such further recipient of the Data agrees in writing to all of the same restrictions, conditions and obligations that apply to Data User with respect to the Data, and will make Partners a third-party beneficiary of such agreement.

5. If the Data User determines that it is Required by Law (as that term is defined in the HIPAA privacy regulations) to use or disclose the Data other than as provided for in this Agreement, Data User shall provide prompt written notice of such determination to Partners so that Partners may have an opportunity to take measures to protect the Data as appropriate.

6. Data User will use appropriate safeguards to prevent use or disclosure of the Data other than as provided for by this Agreement, and Data User will report immediately to Partners in writing any use or disclosure not provided for by this Agreement of which it becomes aware. The Data User acknowledges that any use or disclosure of the Data that is inconsistent with the terms of this Agreement may cause irreparable injury to Partners and agrees that Partners will be entitled to seek injunctive relief with respect to such use and/or disclosure, in addition to seeking any other remedy available at law or in equity.

7. All Data disclosed pursuant to this Agreement, including without limitation all written and tangible forms thereof, shall be and remain the property of Partners and Partners shall at all times retain all rights, title and interest in and to the Data. Upon the expiration or earlier termination of this Agreement as provided in Section 12 below, the Data User shall cease using the Data and shall destroy (or return if so requested by Partners) all of the Data received in tangible form, including notes, reports, and other information to the extent it contains the Data, and shall keep no copies, except to the extent specifically Required by Law(s) made known to Partners by the Data User.

8. THE DATA ARE PROVIDED “AS IS.” PARTNERS MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, CONCERNING THE DATA OR THE RIGHTS GRANTED HEREIN, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT, AND THE ABSENCE OF LATENT OR OTHER DEFECTS, WHETHER OR NOT DISCOVERABLE, AND HEREBY DISCLAIMS THE SAME.

9. IN NO EVENT SHALL PARTNERS OR ANY OF PARTNERS’ RESPECTIVE TRUSTEES, DIRECTORS, OFFICERS, MEDICAL OR PROFESSIONAL STAFF, EMPLOYEES AND AGENTS BE LIABLE TO THE DATA USER FOR DIRECT, INDIRECT, SPECIAL, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES OF ANY KIND ARISING IN ANY WAY OUT OF THIS AGREEMENT OR RIGHTS GRANTED HEREIN, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, INCLUDING WITHOUT LIMITATION, ECONOMIC DAMAGES OR INJURY TO PROPERTY OR LOST PROFITS, REGARDLESS OF WHETHER PARTNERS
SHALL BE ADVISED, SHALL HAVE OTHER REASON TO KNOW, OR IN FACT SHALL KNOW OF THE POSSIBILITY OF THE FOREGOING.

10. Data User agrees not to use the name or logo of Partners or any of its affiliates or any of their respective trustees, directors, officers, staff members, employees, students or agents for any purpose without Partners’ prior written approval; provided, however, that Data User will acknowledge Partners as the source of the Data in any publication or presentation arising from the Purpose.

11. This Agreement shall become effective upon Partners’ release of Data to Data User and shall expire upon Data User’s completion of the Purpose. Partners may terminate the Agreement and Data User’s access to Data hereunder at any prior time and for any reason upon written notice to the Data User.

12. To the extent Data User is permitted under the terms of this Agreement to retain any portion of the Data, or any copies thereof, upon the expiration or termination of the Agreement, the Data User’s obligations under the Agreement with respect to such Data shall survive such expiration or termination for as long as Data User retains the Data.

13. This Agreement may be modified or amended only in a writing signed by duly authorized representatives of both the Data User (where Data User is an organization) and Partners. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts. Any claim or action brought under this Agreement shall be brought in the federal or state courts of Massachusetts.

14. All notices required by this Agreement shall be provided to the signatory for each party at the address identified below.

15. Sections 2 through 10 and Sections 12, 13, and 14 of this Agreement shall survive its expiration or termination.
Agreed to by:

PARTNERS

By (print name): __________________________
Title: ___________________________________
Address: ________________________________
Date: ___________________________________

DATA USER

Signature of Data User (of Data User’s Duly Authorized Representative, if an organization)

By (print name): ________________________
Title:  ________________________________
Address: ______________________________
Date:     _____________________________