

DATA USE AGREEMENT
between
COVERED ENTITY
and
ACADEMIC INSTITUTION

This Data Use Agreement (including all Attachments attached hereto, as the same may be amended from time to time, the “Data Use Agreement” or “Agreement”) is made as of [date] (the “Effective Date”) by and between [name of academic institution], a [state of incorporation] [legal entity type] with offices at [address of principal offices] (“**Academic Institution**”) and [name of covered entity] a [state of incorporation] [legal entity type] with offices at [address of principal office] (“**Covered Entity**”).

WHEREAS, Covered Entity lawfully has access to healthcare information in connection with conducting its business; and

WHEREAS, Academic Institution wishes to retain the services of/collaborate with Covered Entity to conduct; and

WHEREAS, in the context of conducting such research, Covered Entity may share with Academic Institution a Limited Data Set as defined by the HIPAA privacy rule at 45 CFR §164.514(e)

NOW THEREFORE, for and in consideration of the mutual promises contained herein, the parties agree as follows:

1. Study. Covered Entity and Academic Institution agree to collaborate in conducting the Study, the general terms of which are summarized in the collaboration proposal attached as Attachment A (the “Proposal”) and incorporated into this Data Use Agreement. Representatives of Covered Entity and Academic Institution shall serve as co-principal investigators with respect to the Study. The parties agree that the Proposal shall serve as a guideline for the Study to the extent it is not inconsistent with the terms of this Data Use Agreement. In case of any inconsistency between the Proposal and this Data Use Agreement, the terms of this Data Use Agreement will control.
2. Covered Entity Responsibilities. Covered Entity shall have the following responsibilities in connection with the Study: [**customize, some ideas for terms included**]
 - a. Query its database(s) and extract eligibility, demographic, medical and pharmacy records concerning individuals selected for the study.
 - b. Provide a limited data set to Academic Institution by [certain date], as indicated in Attachment B hereto and made a part hereof (the “Limited Data Set”).
 - c. Collaborate with Academic Institution on the design of the Study (including statistical analyses) to address Study questions.
 - d. Throughout the [time period] and until the termination or expiration of this Data Use Agreement, collaborate with Academic Institution when Academic Institution prepares manuscripts and reports describing the Study.

OR

- a. Analyze administrative data files to identify individuals appropriate for inclusion in either (i) a baseline patient cohort and/or (ii) a follow-up patient cohort.
- b. Identify the primary care providers of these individuals.

- c. Collaborate with Academic Institution on design of study and statistical analyses to measure the effectiveness of the study interventions.
- d. Identify and contact study patients, including obtaining consent.
- e. Collect survey data from patients and providers.

3. Academic Institution Responsibilities. Academic Institution shall have the following responsibilities in connection with the Study:

- a. Collaborate with Covered Entity on design of the Study and statistical analyses to address the Study questions.
- b. Participate in regularly scheduled meetings with Covered Entity to refine the Study questions and discuss interim results.
- c. Provide reports of progress of Study to Covered Entity at regularly scheduled meetings.
- d. During the [time period], conduct statistical analyses of the Limited Data Set to address the Study questions.
- e. Prepare and deliver to Covered Entity, no fewer than sixty (60) days prior to submission, manuscripts and reports describing the Study during the [time period] and prior to the termination or expiration of this Data Use Agreement.
- f. Collaborate with Covered Entity on writing manuscripts and reports describing the Study.

OR

- a. Obtain IRB approval.
- b. Develop materials for mailing by Covered Entity, quality measures for Study, computerized quality algorithms, pilot quality measures, feedback report, and achievable benchmarks of care.
- c. Define performance indicators and develop provider mailing materials.
- d. Collaborate with Covered Entity on design of study and statistical analyses to measure the effectiveness of these interventions.
- e. Collaborate with Covered Entity on writing manuscripts and reports describing the Study.

4. Confidentiality. In exchange for Covered Entity providing it with Confidential Information (as defined below), Academic Institution hereby agrees as follows:

- a. Academic Institution acknowledges and agrees that “Confidential Information” includes, without limitation, (i) information concerning covered individuals, participating providers, and/or non-participating providers, (ii) information concerning any of Covered Entity’ and/or its affiliates’ customers, clients, or vendors, including but not limited to the Limited Data Set; (iii) information referring to, discussing, or in any way related to Covered Entity’ and/or its affiliates’ business condition, strategies or initiatives, systems, processes, and/or policies; and (iv) any other information that Covered Entity designates as confidential. Academic Institution further acknowledges and agrees that “Confidential Information” includes any reports, notes, summaries, abstracts, or drafts of, or containing, Confidential Information or of oral presentations, reports, or discussions referring to, describing, elaborating upon, or otherwise relating to Confidential Information, whether prepared by or on behalf of Covered Entity or Academic Institution or any of their respective affiliates, trustees, directors, officers, employees, or other representatives.
- b. Academic Institution acknowledges that Covered Entity has provided, while negotiating the terms of the collaboration and otherwise discussing the Study, and from time to time during the term of this Data Use Agreement will continue to provide Academic Institution with

Confidential Information in confidence and solely for Academic Institution's use in developing and collaborating with Covered Entity on the Study. Academic Institution represents and warrants that it has and will continue to treat any and all Confidential Information it receives as confidential and secret. Academic Institution acknowledges and agrees that it is granted only a limited and non-transferable right of use of the Confidential Information as specified in this Data Use Agreement which right is revocable at will by Covered Entity and not coupled with any interest in the Confidential Information. In the event of such revocation, Academic Institution shall immediately return to Covered Entity all Confidential Information in Academic Institution's possession, custody, or control (including without limitation the possession, custody, or control of any of Academic Institution's affiliates, officers, directors, trustees, employees, agents, or other representatives (collectively, the "Institution-Related Parties")).

- c. Academic Institution agrees (i) to protect any and all Confidential Information from unauthorized use or disclosure with at least the same degree of care Academic Institution uses to protect its own confidential information of a similar nature; (ii) to use the Confidential Information only for the purpose(s) expressly set forth in, and in accordance with, the terms of this Data Use Agreement; (iii) not to record, copy, or reproduce any Confidential Information in any form, except to the extent necessary to fulfill its obligations under this Data Use Agreement; (iv) not to disclose to or otherwise permit any third person or entity access to any Confidential Information except with Covered Entity's prior written consent, which may be withheld in Covered Entity's sole discretion; (v) to limit disclosure of Confidential Information to those Institution-Related Parties who are necessary for and involved in Academic Institution's performance of its obligations under this Data Use Agreement; (vi) to ensure that any Academic Institution-Related Parties who receive or obtain Confidential Information are advised of the nature of the Confidential Information and of the obligations Academic Institution has undertaken with respect to such information under this Data Use Agreement; (vii) to take any and all other steps necessary to safeguard Confidential Information against unauthorized access or disclosure; and (viii) not to identify or make any efforts to identify the individuals who are the subjects of the Confidential Information or to contact or make any effort to contact such individuals. Academic Institution shall disclose to Covered Entity any breach of the provisions of this Section 4 as soon as reasonably possible, but in no event more than ten (10) business days after such breach.
 - d. Upon expiration or termination of this Data Use Agreement, Academic Institution shall voluntarily surrender to Covered Entity all Confidential Information in Academic Institution's possession, custody, or control (including without limitation the possession, custody, or control of any Institution-Related Parties).
 - e. Academic Institution acknowledges and agrees that Covered Entity operates in a highly regulated and competitive environment; and that the unauthorized disclosure or use of Confidential Information will cause irreparable harm and significant injury to Covered Entity which will be difficult to measure with certainty or to compensate through money damages. Accordingly, Academic Institution agrees that injunctive or other equitable relief shall be appropriate in the event of any breach by Academic Institution of any part or parts of this Section 4, in addition to such other remedies as may be available at law or in equity.
5. Non-Disclosure of Certain Information. Covered Entity shall not disclose to Academic Institution any information related to the rates, costs, or expenses of Covered Entity or any affiliate of Covered Entity. Academic Institution represents and warrants that the data requested,

as specified in Attachment B hereto, is the minimum necessary for the performance of Academic Institution's obligations hereunder, including conducting the Study.

6. Staffing. Each party shall devote such number of employees to the Study as may be necessary to enable the party to properly and efficiently perform its responsibilities under this Data Use Agreement. All matters pertaining to the employment, supervision and compensation of any employee shall be the sole responsibility of the party employing such employee. This Data Use Agreement shall in no way create an employment relationship between (i) an employee of one party and (ii) the other party.
7. Books and Records. Each party shall keep accurate books and records evidencing its participation in the Study and the performance of its responsibilities under this Data Use Agreement, and shall make such books and records available to the other party for inspection upon reasonable prior notice, subject to the restrictions of Sections 4 and 5 above.
8. Study Modifications; Dissemination; Use of Study Results. Academic Institution agrees that Covered Entity's express, written consent shall be required prior to (i) adding, deleting, or modifying Study objectives, hypotheses, or methodologies; or (ii) using any data from the Limited Data Set for any purpose other than performing the Study, drafting publications discussing, referring to, or related to the Study or the Limited Data Set, or preparing presentations discussing, referring to, or related to the Study or the Limited Data Set; or (iii) making any presentation or disseminating any article, report, publication, or document discussing, referring to, or relating to the Study or Limited Data Set in any manner to any third party. Academic Institution and Covered Entity agree that all study results, including any patentable product, shall be joint work product and the rights thereto shall be jointly owned by Covered Entity and Academic Institution. Academic Institution acknowledges and agrees that Covered Entity may use the Study methodologies and/or results in its business in any manner determined by Covered Entity in its sole discretion to be appropriate.
9. Co-Authorship of Publications. Covered Entity and Academic Institution shall be co-authors (and listed as such) on any and all articles and/or other publications related to or resulting from the Study. Each party shall be authorized to exercise all rights and prerogatives of a co-author, including without limitation the right to review any material before it is submitted for publication. Academic Institution shall not submit for publication or otherwise publish or distribute any material containing Confidential Information or all or a part of the Limited Data Set that has not been reviewed by Covered Entity. The parties shall jointly own the copyright on any and all articles and other publications derived from or otherwise related to the Study or Limited Data Set.
10. Term; Termination. The term of this Data Use Agreement shall commence on the date first set forth above (the "Effective Date") and, unless sooner terminated in accordance with this Section 10, shall terminate upon completion of the Study and in any event no more than twenty-four (24) months after the Effective Date. Each party shall have the right to terminate this Data Use Agreement and its rights and obligations hereunder upon thirty (30) days' written notice to the other party of the other party's alleged breach of one or more of its obligations under this Data Use Agreement. The notice shall specify the effective date of the early termination (the "Early Termination Date"). If the other party cures the specified breach to the terminating party's satisfaction before the Early Termination Date, the Data Use Agreement shall remain in full force and effect. Notwithstanding the foregoing, in the case of any breach by Academic Institution of the provisions of Section 4(c) above, Covered Entity shall have the right to terminate this Data Use Agreement immediately upon notice. In the event of any such breach, Academic Institution shall make all efforts to mitigate the effects of such breach, including accommodating every

reasonable request by Covered Entity towards such efforts. Notwithstanding any other provision of this Data Use Agreement to the contrary, Sections 4-9, 11, 16, 19 and this Section 10 of this Data Use Agreement shall survive any expiration or termination, regardless of the reason(s) giving rise to such expiration or termination.

11. Indemnification. Academic Institution shall indemnify, defend, and hold Covered Entity and all Covered Entity-Related Parties (as defined below) harmless from any actual or threatened legal or administrative action, claim, liability, penalty, fine, assessment, lawsuit, litigation, or other loss, expense, or damage (together “Liability”), including but not limited to any reasonable attorneys’ fees and costs, that Covered Entity or Covered Entity’ affiliates, officers, directors, employees, agents, or other representatives (collectively, the “Covered Entity-Related Parties”) may incur arising out of or relating to any actual or alleged breach by Academic Institution or any Institution-Related Parties of any applicable law, regulation, or other legal mandate, or of any provision of this Data Use Agreement.
12. Costs and Expenses. Each party shall assume and pay all costs and expenses associated with the performance of its own responsibilities in connection with the Study.
13. Notices. All notices and other communications hereunder shall be in writing and shall be delivered (a) in person, (b) by registered or certified mail, postage prepaid, and return-receipt requested; or (c) by a nationally recognized overnight courier service, addressed as follows:

If to Covered Entity: _____

ATTN: _____

If to Academic Institution: _____

ATTN: _____

Either party may, in its sole discretion and judgment, designate new person(s) or address(es) for the receipt of notices, by giving notice to the other in accordance with this Section 13.

14. Entire Agreement. This Data Use Agreement contains the entire understanding between the parties with respect to the Study and the subject matter hereof and supersedes all prior or contemporaneous agreements and understandings, whether oral or written, with respect thereto.
15. Relationship Between the Parties. The relationship between the parties is that of independent contractors. Nothing in this Data Use Agreement shall be construed to create a partnership or joint venture between the parties and neither party shall have the right to bind the other to any contracts, agreements, or other obligations without the express, written consent of an authorized representative of such party.
16. Controlling Law; Consent to Jurisdiction. This Data Use Agreement shall be construed in accordance with, and its validity, construction and interpretation shall be governed by, the laws of the Commonwealth of Pennsylvania, without regard to conflict of laws principles. The United States District Court for the Eastern District of Pennsylvania and the Court of Common Pleas, Montgomery County, Pennsylvania shall be the exclusive sites of venue for actions arising under

or relating to this Data Use Agreement, it being acknowledged that Covered Entity is a Pennsylvania corporation that maintains its headquarters in Montgomery County, Pennsylvania and Covered Entity will execute this Data Use Agreement in said county. The parties hereby irrevocably consent to the personal jurisdiction of the courts of Pennsylvania.

17. Amendment. This Data Use Agreement may be modified or amended only by a written agreement signed by authorized representatives of Covered Entity and Academic Institution.
18. Assignment. Covered Entity shall be permitted to assign part or all of its rights and/or obligations under this Data Use Agreement to any successor in interest to Covered Entity or purchaser of all or substantially all of Covered Entity's assets or the assets of any Covered Entity parent, subsidiary, or other affiliate. Academic Institution shall not assign any of its rights or obligations to any third party without the express, written consent of a duly authorized officer of Covered Entity.
19. Use of Names. Academic Institution shall not use the names, symbols, logos, and/or trademarks of Covered Entity or any of its related entities or affiliates without the express, written consent of a duly authorized officer of Covered Entity. Likewise, Covered Entity shall not use the names, symbols, logos, and/or trademarks of Academic Institution without the express, written consent of a duly authorized officer of Academic Institution.

IN WITNESS WHEREOF, the parties, through their authorized representatives, have executed this Agreement as of the Effective Date.

COVERED ENTITY

ACADEMIC INSTITUTION

Signature: _____

Signature: _____

By: _____

By: _____

Title: _____

Title: _____

Date: _____

Date: _____

ATTACHMENT A
STUDY PROPOSAL

ATTACHMENT A
DATA ELEMENTS COMPRISING THE LIMITED DATA SET