

## Yale University and Yale New Haven Health Data Use Agreement

THIS AGREEMENT is entered into on this \_\_\_\_\_ day of \_\_\_\_\_, year of \_\_\_\_\_, between \_\_\_\_\_

(“COVERED ENTITY”) and \_\_\_\_\_ (“LIMITED DATA SET RECIPIENT”).

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COVERED ENTITY will make available and/or transfer to LIMITED DATA SET RECIPIENT a limited data set of protected health information that is confidential and must be afforded special treatment and protection in accordance with this Agreement and the Standards for Privacy of Individually Identifiable Health Information (45 C.F.R. Parts 160 and 164), hereinafter referred to as the Privacy Rule.

**NOW, THEREFORE,** COVERED ENTITY and LIMITED DATA SET RECIPIENT agree as follows:

1. **Definitions.** The following terms shall have the meaning ascribed to them in this Section. Other capitalized terms shall have the meaning ascribed to them in the context in which they first appear.

**Agreement** shall refer to this document.

**Limited Data Set** shall mean the following protected health information: \_\_\_\_\_

and shall exclude 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 Locators (URLs); Internet Protocol (IP) address numbers; biometric identifiers, including finger and voice prints; and full face photographic images and any comparable images.

**LIMITED DATA SET RECIPIENT** shall mean \_\_\_\_\_

**COVERED ENTITY** shall mean \_\_\_\_\_

**Privacy Rule** shall mean the Code of Federal Regulations (“C.F.R.”) at Title 45, Sections 160 and 164.

**Individual** shall mean the person who is the subject of the Protected Health Information, as defined by 45 C.F.R. 164.501.

**Protected Health Information** shall mean any individually identifiable health information provided and/or made available by COVERED ENTITY to LIMITED DATA SET RECIPIENT, and has the same meaning as the term “protected health information” as defined by 45 C.F.R. 164.501.

**Parties** shall mean LIMITED DATA SET RECIPIENT and COVERED ENTITY.

**Secretary** shall mean the Secretary of the Department of Health and Human Services (“HHS”) and any other officer or employee of HHS to whom the authority involved has been delegated.

2. **Regulatory References.** A Reference in this Agreement to a section in the Privacy Rule means the section as in effect or as amended.

3. **Stated Purposes for Which LIMITED DATA SET RECIPIENT May Use or Disclose Protected Health Information.** Except as otherwise required by law, LIMITED DATA SET RECIPIENT shall use and/or disclose the Limited Data Set of Protected Health Information provided or made available by COVERED ENTITY exclusively for the purpose of:

\_\_\_\_\_ described in Exhibit A attached to this agreement.

*The purpose of the use or disclosure must be limited to research, public health or health care operations and may not authorize LIMITED DATA SET RECIPIENT to use or disclose the information in a manner that would violate the Privacy Rule if done by COVERED ENTITY.*

4. **Permitted Access to Limited Data Set.** LIMITED DATA SET RECIPIENT shall limit the use or receipt of the Limited Data Set to the following individuals or classes of individuals who need the Limited Data Set for the performance of the Activities: \_\_\_\_\_

5. **Limits on Use and Further Disclosure Established by Agreement and Law.** LIMITED DATA SET RECIPIENT hereby agrees that the Protected Health Information provided or made available by COVERED ENTITY shall not be further used or disclosed other than as permitted or required by the Agreement or as required by law. (ref. 45 C.F.R. §164.514(e)(4)(ii)(C)(1)). LIMITED DATA SET RECIPIENT shall not, without the prior written consent of Covered Entity, disclose the Limited Data Set on the basis that such disclosure is required by law without notifying Covered Entity so that Covered Entity shall have an opportunity to object to the disclosure and to seek appropriate relief. If Covered Entity objects to such disclosure, LIMITED DATA SET RECIPIENT shall refrain from disclosing the Limited Data Set until Covered Entity has exhausted all reasonably available alternatives for relief.

6. **Appropriate Safeguards.** LIMITED DATA SET RECIPIENT will establish and maintain appropriate safeguards to prevent use or disclosure of the Protected Health Information provided or made available by COVERED ENTITY other than as provided for by this Agreement. (ref. 45 C.F.R. §164.514(e)(4)(ii)(C)(2)).

7. **Reports of Improper Use or Disclosure.** LIMITED DATA SET RECIPIENT hereby agrees that it shall report to COVERED ENTITY **within two (2) days of discovery** any unauthorized acquisition, access, use or disclosure of the Limited Data Set of Protected Health Information not provided for or allowed by this Agreement or applicable law. (ref. 45 C.F.R. §164.514(e)(4)(ii)(C)(3)). The notification shall include, to the extent possible, and shall be supplemented on an ongoing basis with: (A) the identification of all individuals whose Unsecured PHI was or is believed to have been involved, (B) all other information reasonably requested by Covered Entity to enable Covered Entity to perform and document a risk assessment in accordance with 45 C.F.R. Part 164 subpart D with respect to the incident to determine whether a Breach of Unsecured PHI occurred, and (C) all other information reasonably necessary to provide notice to individuals, HHS and/or the media, all in accordance with the security breach notification requirements set forth in 42 U.S.C. § 17932 and 45 C.F.R. Parts 160 & 164 subparts A, D, & E. Notwithstanding the foregoing, in Yale's sole discretion and in accordance with its directions, LIMITED DATA SET RECIPIENT shall conduct, or pay the costs of conducting, an investigation of any incident required to be reported under this Section 2.1(c)(ii) and shall provide and/or pay the costs of providing, the security breach notifications pursuant to the HITECH Act.

8. **Subcontractors and Agents.** LIMITED DATA SET RECIPIENT shall not disclose the Limited Data Set to any non-employee agent or subcontractor of LIMITED DATA SET RECIPIENT except with the prior written consent of Covered Entity. LIMITED DATA SET RECIPIENT hereby agrees that any time the Limited Data Set of Protected Health Information is provided or made available to any subcontractors or agents, LIMITED DATA SET RECIPIENT must enter into a subcontract with the subcontractor or agent that contains the same terms, conditions and restrictions on the use and disclosure of Protected Health Information as contained in this Agreement. (ref. 45 C.F.R. §164.514(e)(4)(ii)(C)(4)).

9. **Not Identify Information or Contact Individuals.** LIMITED DATA SET RECIPIENT hereby agrees it will not attempt in any manner to identify the information or contact individuals whose Protected Health Information was provided or made available by COVERED ENTITY under this Agreement. (ref. 45 C.F.R. §164.514(e)(4)(ii)(C)(5)).

10. **Mitigation Procedures.** LIMITED DATA SET RECIPIENT agrees to mitigate, to the extent practicable, any harmful effect that is known to LIMITED DATA SET RECIPIENT of a use or disclosure of the Limited Data Set of Protected Health Information by LIMITED DATA SET RECIPIENT in violation of the requirements of this Agreement.

11. **Property Rights.** The Limited Data Set of Protected Health Information shall be and remain the property of COVERED ENTITY. LIMITED DATA SET RECIPIENT agrees that it acquires no title or rights to the Limited Data Set Protected Health Information as a result of this Agreement.

12. **Term.** The term of this Agreement shall be effective as of \_\_\_\_\_ and shall terminate on \_\_\_\_\_. Such term may be terminated earlier terminated by either Party as provided herein or as a result of the fulfillment of the purpose(s) described in Section 3 above.

13. **Termination for Cause.** Upon COVERED ENTITY'S knowledge of a pattern of activity or practice of the LIMITED

DATA SET RECIPIENT that constitutes a material breach or violation of this Agreement, COVERED ENTITY shall:

- a. Provide an opportunity for LIMITED DATA SET RECIPIENT to immediately cure the breach or end the violation, and, if such does not occur
- b. COVERED ENTITY will discontinue disclosure of the Limited Data Set of Protected Health Information and report the violation to the Secretary. (ref. 45 C.F.R. § 164.514(e)(4)(iii)(A)(1) and (2)).

14. **Effect of Termination.** Upon termination of this Agreement, for any reason, LIMITED DATA SET RECIPIENT shall return or destroy all Limited Data Set of Protected Health Information provided or made available by COVERED ENTITY. This provision shall also apply to any Limited Data Set of Protected Health Information that is in the possession of subcontractors or agents of LIMITED DATA SET RECIPIENT. LIMITED DATA SET RECIPIENT shall retain no copies of the Limited Data Set of Protected Health Information.

15. In the event that LIMITED DATA SET RECIPIENT determines that returning or destroying the Limited Data Set of Protected Health Information is infeasible, LIMITED DATA SET RECIPIENT shall provide to COVERED ENTITY notification of the conditions that make return or destruction infeasible. Upon receipt within 10 days of request of that notice that return or destruction of Limited Data Set of Protected Health Information is infeasible, LIMITED DATA SET RECIPIENT shall extend the protections of this Agreement to such Limited Data Set of Protected Health Information and limit further uses and disclosures of such Limited Data Set of Protected Health Information to those purposes that make the return or destruction infeasible, for so long as LIMITED DATA SET RECIPIENT maintains such Protected Health Information.

16. **Governing Law.** This Agreement shall be governed by the law of the state of Connecticut.

17. **Amendment.** The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for COVERED ENTITY to comply with the requirements of the Privacy Rule and the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191.

18. **Survival.** The respective rights and obligations of LIMITED DATA SET RECIPIENT under this Agreement shall survive the termination of this Agreement.

19. **Interpretation.** Any ambiguity in this Agreement shall be resolved to permit COVERED ENTITY to comply with the Privacy Rule and the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191.

20. **Injunctive Relief.** Covered Entity and LIMITED DATA SET RECIPIENT agree that any violation of the provisions of this Agreement may cause irreparable harm to Covered Entity. Notwithstanding any rights or remedies provided for in this Agreement, COVERED ENTITY retains all rights to seek injunctive relief or other decree of specific performance with respect to such violation or explicit threat thereof, without any bond or other security being required and without the necessity of demonstrating actual damages to prevent or stop the unauthorized use or disclosure of Limited Data Set of Protected Health Information by LIMITED DATA SET RECIPIENT or any agent, contractor or third party that received Limited Data Set of Protected Health Information from LIMITED DATA SET RECIPIENT. The parties' respective rights and obligations under this section shall survive termination of the Agreement.

21. **Indemnification.** Data User shall indemnify, hold harmless and defend Covered Entity from and against any and all claims, losses, liabilities, costs and other expenses resulting from, or relating to, the acts or omissions of Data User in connection with the representations, duties and obligations of Data User under this Agreement. The parties' respective rights and obligations under this Section 4.i. shall survive termination of the Agreement.

22. **Binding Nature and Assignment.** This Agreement shall be binding on the Parties hereto and their successors and assigns, but neither Party may assign this Agreement without the prior written consent of the other, which consent shall not be unreasonably withheld.

23. **Notices.** Whenever under this Agreement one party is required to give notice to the other, such notice shall be deemed given if mailed by First Class United States mail, postage prepaid, and addressed as follows:

**COVERED ENTITY:**

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**LIMITED DATA SET RECIPIENT:**

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Either Party may at any time change its address for notification purposes by mailing a notice stating the change and setting forth the new address.

24. **Article Headings.** The article headings used are for reference and convenience only, and shall not enter into the interpretation of this Agreement.

25. **Force Majeure.** LIMITED DATA SET RECIPIENT shall be excused from performance under this Agreement for any period LIMITED DATA SET RECIPIENT is prevented from performing any services pursuant hereto, in whole or in part, as a result of an Act of God, war, civil disturbance, court order, labor dispute or other cause beyond its reasonable control, and such nonperformance shall not be grounds for termination.

26. **Entire Agreement.** This Agreement consists of this document, and constitutes the entire agreement between the Parties. There are no understandings or agreements relating to this Agreement which are not fully expressed in this Agreement and no change, waiver or discharge of obligations arising under this Agreement shall be valid unless in writing and executed by the Party against whom such change, waiver or discharge is sought to be enforced.

27. **State Law.** Nothing in this Agreement shall be construed to require LIMITED DATA SET RECIPIENT to use or disclose the Limited Data Set without a written authorization from an individual who is a subject of the PHI from which the Limited Data Set was created, or written authorization from any other person, where such authorization would be required under state law for such use or disclosure.

**IN WITNESS WHEREOF**, LIMITED DATA SET RECIPIENT and COVERED ENTITY have caused this Agreement to be signed and delivered by their duly authorized representatives, as of the date set forth above.

**LIMITED DATA SET RECIPIENT**

By: \_\_\_\_\_

Print Name: \_\_\_\_\_

Title: \_\_\_\_\_

**COVERED ENTITY**

By: \_\_\_\_\_

Print Name: \_\_\_\_\_

Title: \_\_\_\_\_

**ASSURANCE OF COMPLIANCE WITH  
DATA USE AGREEMENT**

The following individuals are authorized to receive and use the Limited Data Set described in the Data Use Agreement for the purposes described in Section 3 of the Data Use Agreement.

By signing below, we acknowledge the restrictions on our use and disclosure of the Limited Data Set in accordance with the Data Use Agreement.

Name: \_\_\_\_\_ Name: \_\_\_\_\_

Signature: \_\_\_\_\_ Signature: \_\_\_\_\_

Date: \_\_\_\_\_ Date: \_\_\_\_\_

Name: \_\_\_\_\_ Name: \_\_\_\_\_

Signature: \_\_\_\_\_ Signature: \_\_\_\_\_

Date: \_\_\_\_\_ Date: \_\_\_\_\_

Name: \_\_\_\_\_ Name: \_\_\_\_\_

Signature: \_\_\_\_\_ Signature: \_\_\_\_\_

Date: \_\_\_\_\_ Date: \_\_\_\_\_