DATA USE AGREEMENT

This Data Use Agreement (“Agreement”) is made and entered into as of this \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_\_\_\_, 20\_\_ (“Effective Date”) by the *Center for Community Health Development at the Texas A&M Health Science Center School of Public Health* (“Covered Entity”), and \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (“Data Recipient”).

**WITNESSETH:**

WHEREAS, Covered Entity may Disclose or make available to Data Recipient, and Data Recipient may use, disclose, receive, transmit, maintain or create from, certain information in conjunction with research; and

WHEREAS, Covered Entity and Data Recipient are committed to compliance with the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and regulations promulgated thereunder; and

WHEREAS, the purpose of this Agreement is to satisfy the obligations of Covered Entity under HIPAA and to ensure the integrity and confidentiality of certain information Disclosed or make available to Data Recipient and certain information that Data Recipient Uses, Discloses, receives, transmits, maintains or creates, from Covered Entity.

NOW, THEREFORE, in consideration of the foregoing recitals and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

1. **DEFINITIONS**

Terms used but not otherwise defined in this Agreement shall have the same meaning as those terms in the Privacy Rule.

1. Individual shall have the same meaning as the term “individual” in 45 CFR Sect. 164.501 of the Privacy Rule and shall include a person who qualifies as a personal representative in accordance with 45 CFR Sect. 164.502(g) of the Privacy Rule.

2. Limited Data Set shall have the same meaning as the term “limited data set” in 45 CFR 164.514(e) of the Privacy Rule.

3. Privacy Rule shall mean the Standards for Privacy of Individually Identifiable Information at 45 CFR Part 160 and Part 164, Subparts A and E, as amended from time to time.

4. Protected Health Information or PHI shall have the same meaning as the term “protected health information” in 45 CFR Sect. 164.501 of the Privacy Rule, to the extent such information is created or received by Data Recipient from Covered Entity.

5. Required by Law shall have the same meaning as the term “required by law” in 45 CFR Sect. 164.501 of the Privacy Rule.

**B. SCOPE AND PURPOSE**

1. This Agreement sets forth the terms and conditions pursuant to which Covered Entity will Disclose certain PHI to the Data Recipient.

2. Except as otherwise specified herein, Data Recipient may make all Uses and Disclosures of the *Insert Project Name/Limited Data Set* (hereinafter referred to as “Limited Data Set”), necessary to conduct the research described herein:

*Describe proposed research activity (include the general areas of research and proposed analytical approach)*

3. In addition to the Data Recipient, the individuals, or classes of individuals, who are permitted to Use or receive the Limited Data Set for purposes of the Research Project, include: None other than the Covered Entity (SPH researchers) and Data Recipient.

**C. OBLIGATIONS AND ACTIVITIES OF DATA RECIPIENT**

1. Data Recipient agrees to not Use or Disclose the Limited Data Set for any purpose other than the Research Project or as Required by Law. (164.514 (e)(4)(ii)(A))

2. Data Recipient agrees to use appropriate safeguards to prevent Use or Disclosure of the Limited Data Set other than as provided for by this Agreement. (164.514 (e)(4)(ii)(C)(1))

3. Data Recipient agrees to report to the Covered Entity any Use or Disclosure of the Limited Data Set not provided for by this Agreement of which it becomes aware, including without limitation, any Disclosure of PHI to an unauthorized subcontractor, *within ten (10) days of its discovery*. (164.514(e)(4)(ii)(C)(2).)

4. Data Recipient agrees to ensure that any agent, including a subcontractor, to whom it provides the Limited Data Set agrees to the same restrictions and conditions that apply through this Agreement to the Data Recipient with respect to such information. (164.514 (e)(4)(ii)(C)(3).)

5. Data Recipient agrees not to identify the information contained in the Limited Data Set or contact the individual. (164.514 (e)(4)(ii)(C)(4).)

6. Data Recipient will indemnify, defend and hold harmless Covered Entity and any of Covered Entity’s affiliates, and their respective trustees, officers, directors, employees and agents (“Indemnitees”) from and against any claim, cause of action, liability, damage, cost or expense (including, without limitation, reasonable attorney’s fees and court costs) arising out of or in connection with any unauthorized or prohibited Use or Disclosure of the Limited Data Set or any other breach of this Agreement by Data Recipient or any subcontractor, agent or person under Data Recipient’s control. (164.514) (4)(ii)(C)(5).)

\_\_\_\_\_\_\_\_

Initial

7. Data Recipient agrees to provide CCHD with an approved certificate and protocol from the TAMU IRB for use of the Limited Data Set prior to its distribution.

\_\_\_\_\_\_\_\_

Initial

8. Data Recipient agrees to include the Statement of Sponsorship for the Limited Data Set provided by Covered Entity in any and all publications, documents, presentations or descriptions of research related to the Limited Data Set.

***“This report was supported by the Center for Community Health Development under the Cooperative Agreement Number 1U48 DP001924 from the Centers for Disease Control and Prevention through the National Center for Chronic Disease Prevention and Health Promotion and the National Center for Injury Prevention and Control.”***

\_\_\_\_\_\_\_\_

Initial

9. Data Recipient agrees to provide Covered Entity with any and all citations of publications related to the Limited Data Set within 90 days of publication.

**D. TERM AND TERMINATION**

The provisions of this Agreement shall be effective as of the Effective Date and shall terminate three years from effective date. Upon that time, all of the Limited Data Set provided by Covered Entity to Data Recipient must be destroyed or returned to Covered Entity, or, if it is infeasible to return or destroy the Limited Data Set, protections are extended to such information, in accordance with the termination provisions in this Section.

Should Data Recipient commit a material breach of this Agreement, which is not cured within thirty (30) days after Data Recipient receives notice of such breach from Covered Entity, the Data Recipient shall discontinue use of the Limited Data Set for any purpose.

**E. MISCELLANEOUS**

1. A reference in this Agreement to a section in the Privacy Rule means the section as amended or as renumbered.

2. 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 HIPAA.

3. The respective rights and obligations of Data Recipient under Section C of this Agreement shall survive termination of this Agreement.

4. Any ambiguity in this Agreement shall be resolved to permit Covered Entity to comply with the Privacy Rule.

5. There are no intended third party beneficiaries to this Agreement. Without in any way limiting the foregoing, it is the parties’ specific intent that nothing contained in this Agreement gives rise to any right or cause of action, contractual or otherwise, in or on behalf of the individuals whose PHI is Used or Disclosed pursuant to this Agreement.

6. No provision of this Agreement may be waived except by an agreement in writing signed by the waiving party. A waiver of any term or provision shall not be construed as a waiver of any other term or provision.

7. The persons signing below have the right and authority to execute this Agreement and no further approvals are necessary to create a binding agreement.

8. In the event of any conflict between the terms and conditions stated within this Agreement and those contained within any other agreement or understanding between the parties, written, oral or implied, the terms of this Agreement shall govern. Without limiting the foregoing, no provision of any other agreement or understanding between the parties limiting the liability of Data Recipient to Covered Entity shall apply to the breach of any covenant in this Agreement by Data Recipient.

9. This Agreement shall be construed in accordance with and governed the laws of the state or jurisdiction of the covered entity

IN WITNESS WHEREOF, the parties have executed this Agreement effective upon the Effective Date set forth above.

|  |  |
| --- | --- |
| **COVERED ENTITY:** | **COVERED ENTITY DATA RECIPIENT:** |
| **TEXAS A&M HEALTH SCIENCE CENTER** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |
| *Departmental Approval* |  |
| *Dept.:* Center for Community Health Development |  |
| *Name:* | *Name:* |
| *Title:* | *Title:* |
| *Signature:* | *Signature:* |
| *Date:* | *Date:* |
| *Phone:* | *Phone:* |
| *Email:* | *Email:* |