

**SINAI HEALTH SYSTEM
DATA USE AGREEMENT
LIMITED DATA SETS**

This Agreement is made effective the _____ of _____, 200_, by and between _____, hereinafter referred to as “Covered Entity”, and _____, hereinafter referred to as “User”, (individually, a “Party” and collectively, the “Parties”).

WITNESSETH:

WHEREAS, Sections 261 through 264 of the federal Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, known as “the Administrative Simplification provisions,” direct the Department of Health and Human Services to develop standards to protect the security, confidentiality and integrity of health information; and

WHEREAS, pursuant to the Administrative Simplification provisions, the Secretary of Health and Human Services has issued regulations modifying 45 CFR Parts 160 and 164 (the “HIPAA Privacy Rule”); and

WHEREAS, User performs certain [research] [public health] [health care operations] functions (the “Activities”) and desires to obtain a Limited Data Set from Covered Entity; and

WHEREAS, Covered Entity agrees to disclose such Limited Data Set to User for use by User in performance of the Activities; and

WHEREAS, User agrees to limit its use of the Limited Data Set and protect the Limited Data Set in accordance with the terms of this Agreement and the HIPAA Privacy Rule.

THEREFORE, in consideration the mutual agreements, covenants, terms and conditions herein contained, the Covered Entity and the User agree as follows:

I. DEFINITIONS

Except as otherwise defined herein, any and all capitalized terms in this Agreement shall have the definitions set forth in the HIPAA Privacy Rule.

The term “Protected Health Information” means individually identifiable health information including, without limitation, all information, data, documentation, and materials, including without limitation, demographic, medical and financial information, that relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and that identifies the

individual or with respect to which there is reasonable basis to believe the information can be used to identify the individual.

II. COORDINATION WITH HIPAA PRIVACY RULE

In the event of an inconsistency between the provisions of this Agreement and mandatory provisions of the HIPAA Privacy Rule, as amended, the HIPAA Privacy Rule in effect at the time shall control. Where provisions of this Agreement are different than those mandated in the HIPAA Privacy Rule, but are nonetheless permitted by the HIPAA Privacy Rule, the provisions of this Agreement shall control.

III. DISCLOSURE OF LIMITED DATA SET TO USER

(a) *Activities.* User will perform only the following Activities:

(b) *Limited Data Set.* User agrees to use and Covered Entity agrees to disclose Protected Health Information to User in the form of a Limited Data Set for use only in accordance with 42 CFR § 164.514(e).

IV. OBLIGATIONS OF USER

(a) User may use or disclose the Limited Data Set only for the Activities specified above or as required by law, but shall not otherwise use or disclose the Limited Data Set in a manner that would constitute a violation of the HIPAA Privacy Rule if used by Covered Entity.

(b) User is permitted to share the Limited Data Set with its directors, officers, employees, contractors and agents as necessary to perform the activities. No other uses or disclosures are permitted, unless required under this Agreement or by law.

(c) User agrees to not use or further disclose the Limited Data Set other than as permitted or required by this Agreement or as required by law.

(d) User agrees to use appropriate safeguards to prevent use or disclosure of the Limited Data Set other than as provided for by this Agreement.

(e) User agrees to report to Covered Entity any use or disclosure of the Limited Data Set not provided for by this Agreement of which it becomes aware.

(f) User agrees to ensure that any agents, including a subcontractor, to whom it provides the Limited Data Set agrees to the same restrictions and conditions that apply through this Agreement to User with respect to such information.

(g) User agrees not to identify the information contained in the Limited Data Set or contact the individuals to whom the information refers.

V. TERM AND TERMINATION

(a) Term. The Term of this Agreement shall be effective as of the date first written above, and shall terminate on the first to occur of the following: (i) when all of the Protected Health Information provided by Covered Entity to User is destroyed or returned to Covered Entity; or (ii) if it is not feasible to return or destroy the Limited Data Set, protections are extended to such information, in accordance with Section V(c)(ii) of this Agreement.

Termination for Cause. Upon Covered Entity's knowledge of a material breach by User, Covered Entity shall have the right to immediately terminate this Agreement.

(b) Effect of Termination.

(i) Except as provided in paragraph (ii) of this subsection, upon termination of this Agreement or upon request of Covered Entity, whichever occurs first, User shall return or destroy the Limited Data Set received from Covered Entity. This provision shall apply to a Limited Data Set that is in the possession of subcontractors or agents of User. User shall retain no copies of the Limited Data Set.

(ii) In the event that User determines that returning or destroying the Limited Data Set is not feasible, User shall provide to Covered Entity notification of the conditions that make return or destruction not feasible. Upon mutual agreement of the Parties that return or destruction of the Limited Data Set is infeasible, User shall extend the protections of this Agreement to such Limited Data Set and limit further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction not feasible, for so long as User maintains such Limited Data Set.

VI. MISCELLANEOUS

(a) No Rights in Third Parties. Except as expressly stated herein or the HIPAA Privacy Rule, the Parties to this Agreement do not intend to create any rights in any third parties.

(b) Survival. The obligations of User under this Section shall survive the expiration, termination, or cancellation of this Agreement and shall continue to bind User, its agents, employees, contractors, successors, and assigns as set forth herein.

(c) Amendment. This Agreement may be amended or modified only in a writing signed by the Parties. The Parties agree that this Agreement will be automatically amended to conform to any changes in the HIPAA Privacy Rule as is necessary for a Covered Entity to comply with the current requirements of the HIPAA Privacy Rule and the Health Insurance Portability and Accountability Act, Public Law 104-191.

(d) Assignment. No Party may assign its respective rights and obligations under this Agreement without the prior written consent of the other Party.

(e) Independent Contractor. None of the provisions of this Agreement are intended to create, nor will they be deemed to create any relationship between the Parties other than that of independent parties contracting with each other solely for the purposes of effecting the provisions of this Agreement and any other agreements between the Parties evidencing their business relationship.

(f) Governing Law. This Agreement will be governed by the substantive laws of the State of _____.

No Waiver. No change, waiver or discharge of any liability or obligation hereunder on any one or more occasions shall be deemed a waiver of performance of any

(g) continuing or other obligation, or shall prohibit enforcement of any obligation, on any other occasion.

(h) Interpretation. Any ambiguity of this Agreement shall be resolved in favor of a meaning that permits Covered Entity to comply with the HIPAA Privacy Rule.

(i) Severability. In the event that any provision of this Agreement is held by a court of competent jurisdiction to be invalid or unenforceable, the remainder of the provisions of this Agreement will remain in full force and effect.

(j) Notice. Any notification required in this Agreement shall be made in writing to the representative of the other Party who signed this Agreement or the person currently serving in that representative's position with the other Party.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the day and year written above.

COVERED ENTITY:

USER:

By: _____

By: _____

Title: _____

Title: _____