

## LIMITED DATA USE AGREEMENT

**THIS LIMITED DATA USE AGREEMENT** ("LDU Agreement") is made and entered into as of this \_\_\_\_ day of \_\_\_\_\_, \_\_\_\_\_ (the "Effective Date") by and between University of South Alabama Hospitals (hereinafter referred to as the "Covered Entity") and \_\_\_\_\_ (hereinafter referred to as the "Recipient").

**WHEREAS**, Recipient desires to obtain certain information from Covered Entity for the limited purposes of performing Recipient (i) Research; (ii) Public Health Activities; or (iii) Health Care Operations and, in connection with those purposes, Recipient will receive from Covered Entity certain Protected Health Information in the form of a Limited Data Set ("LDS") that is subject to protection under the Privacy Rules of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 ("HIPAA");

**WHEREAS**, Covered Entity and Recipient intend to protect the privacy and provide for the security of the LDS in compliance with the Privacy Rules; and

**WHEREAS**, the Privacy Rules require Recipient to enter into a contract containing specific requirements that it must meet in order to receive the LDS from or on behalf of Covered Entity.

**NOW, THEREFORE**, in consideration of the foregoing and of the covenants and agreements set forth herein, the parties, intending to be legally bound, agree as follows:

**Section 1. Definitions.** The terms used, but otherwise not defined, in this LDU Agreement shall have the same meaning as those terms in the Privacy Rules.

(a) "Recipient" shall mean the person or entity designated as such above, as well as his/her/its officers, directors, employees, agents and representatives.

(b) "Health Care Operations" shall have the meaning set forth in 45 CFR 164.501, including, without limitation, the following activities of Recipient: quality assessment and improvement activities, credentialing, accreditation, conducting medical reviews, legal services, business planning and development, business management, and general administrative activities.

(c) "Individual(s)" shall have the meaning set forth in 45 CFR 164.501, including, without limitation, a person who is the subject of the LDS, and shall include an individual or entity who qualifies as a personal, legal representative of the person, as the context requires.

(d) "Limited Data Set" ("LDS") shall mean Protected Health Information that Recipient receives from, or on behalf of, Covered Entity and that excludes the following direct identifiers of the Individual and of relatives, employers or household members of the Individual pursuant to 45 CFR 164.514(e): names; postal address information (other than town or city, state and zip code); telephone and fax numbers; e-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); device identifiers and serial numbers; web universal resource locators (URLs); internal protocol (IP) address numbers; and biometric identifiers, including finger and voice prints and full face photographic images and any comparable images.

(e) "Privacy Rules" shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 CFR Parts 160 and 164, Subparts A and E, as may be amended, modified or superceded, from time to time.

(f) "Protected Health Information" shall have the meaning set forth in 45 CFR 164.501, including, without limitation, any information, whether oral or recorded in any form or medium: (i) that relates to the past, present or future physical or mental condition of an individual; or (ii) the provision of health care to an individual; or (iii) the past, present or future payment for the provision of health care to an individual; and (iv) that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

(g) "Required by Law" shall have the meaning set forth in 45 CFR 164.501, including, without limitation, a mandate contained in law that compels a covered entity to make a use or disclosure of PHI and that is enforceable in a court of law.

(h) "Public Health Activities" shall have the meaning set forth in 45 CFR 164.512(b), including, without limitation: (i) a public health authority that is authorized by law to collect or receive Protected Health Information for the purpose of preventing or controlling disease, injury, or disability, including but not limited to, the reporting of disease, injury, vital events such as birth and death, and the conduct of public surveillance or public health investigations; (ii) a public health authority or other appropriate government authority authorized by law to receive reports of child abuse or neglect; (iii) a person subject to the jurisdiction of the Food and Drug Administration ("FDA") with respect to an FDA-regulated product or activity for which that person has responsibility; or (iv) a public health authority that is authorized by law to notify a person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading a disease or condition.

(i) "Research" shall have the meaning set forth in 45 CFR 164.501, including, without limitation, a systematic investigation, including research development, testing, and evaluation, designated to develop or contribute to generalizable knowledge.

(j) "Secretary" shall mean the Secretary of the U.S. Department of Health and Human Services or his/her designee.

## **Section 2. Obligations of Recipient.**

(a) Limited Data Set. Recipient shall have access only to the following specific LDS information; as set forth in Section 1(d): \_\_\_\_\_  
\_\_\_\_\_. Recipient hereby affirms and acknowledges that his/her/its request for LDS information is the minimum necessary to accomplish his/her/its purpose as set forth in Section 2(b) below.

(b) Permitted Uses. Recipient shall not use LDS except for the express purpose of performing Recipient's (note: specifically describe the particular Research, Public Health Activity or Health Care Operation purpose): \_\_\_\_\_  
\_\_\_\_\_. Recipient shall not use the LDS in any manner that would constitute a violation of the Privacy Rules.

(c) Permitted Disclosures. Recipient shall not disclose LDS except as may be related to the specific purpose(s) as set forth in § 2(b) and shall not disclose LDS in any manner that would constitute a violation of the Privacy Rules.

(d) Appropriate Safeguards. Recipient shall implement appropriate administrative, technical and physical safeguards in compliance with the Privacy Rules as are necessary to prevent the use and/or disclosure of LDS other than as permitted by the terms of this LDU Agreement. Recipient shall maintain a comprehensive written information privacy program that includes administrative, technical and physical

safeguards appropriate to the size and complexity of the Recipient's operations and the nature and scope of his/her/its activities in order to safeguard the LDS.

(e) Recipient's Agents and/or Subcontractors. To the extent Recipient retains any agents or subcontractors that will use or have access to the LDS for the purposes of performing Recipient's (i) Research; (ii) Public Health Activities; or (iii) Health Care Operations in accordance with Exhibit A, Recipient shall require that each agent or subcontractor agree, in writing, to be bound by the terms of this LDU Agreement to the same extent as Recipient. Recipient shall implement and maintain sanctions against agents and subcontractors that violate such restrictions and conditions and shall mitigate the effects of any such violation.

(f) Re-Identify or Contact Individuals. The Recipient agrees not to re-identify or contact the Individual(s) who is/are the subject(s) of the LDS.

(g) Governmental Access to Records. Recipient shall make his/her/its internal practices, books and records relating to the use and disclosure of LDS available to Secretary in a time and manner designated by the Covered Entity or the Secretary, for purposes of the Secretary determining Covered Entity's compliance with the Privacy Rules. Recipient shall provide Covered Entity access to or a copy of any LDS or other information that Recipient makes available to the Secretary concurrently with providing such LDS to the Secretary.

(h) Covered Entity Access to Records. Within five (5) days of a written request by Covered Entity, Recipient shall allow Covered Entity to conduct a reasonable inspection of Recipient's facilities, systems, books, records, agreements, policies and procedures relating to the use and/or disclosure of LDS for the purpose of determining whether Recipient has complied with this LDU Agreement; provided, however, that: (i) Recipient and Covered Entity shall mutually agree in advance upon the scope, timing and location of such an inspection; (ii) Covered Entity shall protect the confidentiality of all confidential and proprietary information of Recipient to which Covered Entity has access during the course of such inspection; and (iii) Covered Entity shall execute a nondisclosure agreement, upon terms mutually agreed upon by the parties, if requested by Recipient. The fact that Covered Entity inspects, or fails to inspect, or has the right to inspect, Recipient's facilities, systems, books, records, agreements, policies, and procedures does not relieve Recipient of his/her/its responsibility to comply with this LDU Agreement. Moreover, Covered Entity's failure to detect or, in the alternative, detection, but failure to notify or require Recipient to remediate any unsatisfactory practices, does not constitute acceptance of such practice or a waiver of Covered Entity's enforcement rights under this LDU Agreement.

(i) Minimum Necessary Use and Disclosure Requirement. Recipient shall only request, use or disclose the minimum amount of LDS necessary to reasonably accomplish the purpose of the request, use or disclosure in accordance with 45 CFR 164.502(b). Further, Recipient will restrict access to LDS to those employees of Recipient or other workforce members under control of Recipient who are actively and directly participating in the request, use or disclosure of LDS in accordance with the purposes set forth in Exhibit A and who need to know such information in order to fulfill such responsibilities.

(j) LDS Ownership. Recipient acknowledges that it has no ownership rights with respect to LDS received by Recipient pursuant to this LDU Agreement.

(k) Notification of Breach; Mitigation. During the term of this LDU Agreement, Recipient shall notify Covered Entity within twenty-four (24) hours of any actual or suspected use and/or disclosure of LDS in violation of the Privacy Rules or this LDU Agreement. Recipient shall take prompt corrective action to mitigate and cure any harmful effect that is known to Recipient of an improper use and/or disclosure of LDS.

**Section 3. Term and Termination.**

(a) Term. This LDU Agreement shall commence on the Effective Date and will remain effective for the entire time Recipient maintains the LDS, unless earlier terminated in accordance with the terms herein.

(b) For Cause Termination Due to Material Breach. In the event of a material breach by Recipient of any of his/her/its obligations hereunder, Covered Entity shall have the right, as specifically recognized by Recipient, to terminate this LDU Agreement at any time by providing Recipient written notice of termination setting forth a description of the breach and the effective date of termination.

(c) Reasonable Steps to Cure Material Breach. If Covered Entity knows of a pattern of activity or practice of Recipient that constitutes a material breach of Recipient's obligations under the provisions of this LDU Agreement and does not terminate this LDU Agreement pursuant to Section 3(b) above, then Recipient shall take reasonable steps to cure such breach. If Recipient's efforts to cure such breach are unsuccessful within thirty (30) days following a written request to cure provided by Covered Entity, Covered Entity shall either: (i) terminate this LDU Agreement, if feasible; or (ii) if termination of this LDU Agreement is not feasible, Covered Entity shall report Recipient's breach to the Secretary.

(d) Judicial or Administrative Proceedings. Either party may terminate this LDU Agreement, effective immediately, if: (i) the other party is named as a defendant in a criminal proceeding for a violation of the Privacy Rules; or (ii) there is a finding or stipulation that the other party has violated any standard or requirement of the Privacy Rules in any administrative or civil proceeding.

(e) Effect of Termination. As of the effective date of termination of this LDU Agreement, neither party shall have any further rights or obligations hereunder except: (a) as otherwise provided herein; (b) for continuing rights and obligations accruing under the Privacy Rules; or (c) arising as a result of any breach of this LDU Agreement, including, but not limited to, any rights and remedies available at law or equity. Upon termination of this LDU Agreement for any reason, Recipient shall return or destroy all LDS (regardless of form or medium), including all copies thereof. The obligation to return or destroy all LDS shall also apply to LDS that is in the possession of agents or subcontractors of Recipient. If the return or destruction of LDS is not feasible, Recipient shall provide Covered Entity written notification of the conditions that make return or destruction not feasible. Upon mutual agreement of the parties that return or destruction of LDS is not feasible, Recipient shall continue to extend the protections of this LDU Agreement to such information, and limit further uses or disclosures of such LDU to those purposes that make the return or destruction of such LDU not feasible, for as long as Recipient maintains such LDU. If Recipient elects to destroy the LDU, Recipient shall notify Covered Entity in writing that such LDU has been destroyed.

**Section 4. Indemnification.** Recipient shall indemnify and hold the Covered Entity, and its employees, officers, directors and independent contractors, harmless from and against all claims, liabilities, judgments, fines, assessments, penalties, awards or other expenses, of any kind or nature whatsoever, including, without limitation, attorneys' fees, expert witness fees, and costs of investigation, litigation or dispute resolution, relating to or arising out of any breach or alleged breach of this LDU Agreement by Recipient. The obligations set forth in this Section 5 shall survive termination of this LDU Agreement, regardless of the reasons for termination.

**Section 5. Disclaimer.** Covered Entity makes no warranty or representation that compliance by Recipient with this LDU Agreement or the Privacy Rules will be adequate or satisfactory for Recipient's own purposes. Recipient is solely responsible for all decisions made by Recipient regarding the safeguarding of its confidential information.

**Section 6. Assistance in Litigation or Administrative Proceedings.** Recipient shall be available to Covered Entity, at no cost to Covered Entity, to testify as a witness, or otherwise provide reasonable assistance, in the event of litigation or administrative proceedings being commenced against Covered Entity, his/her/its directors, officers or employees based upon a claimed violation of HIPAA, the Privacy Rules or other laws relating to LDS security or privacy, except where Recipient is named as an adverse party.

**Section 7. Injunctive Relief.** In the event of a breach by Recipient of any of his/her/its obligations hereunder, Covered Entity shall have, in addition to any other rights and remedies available at law or in equity, the right to obtain injunctive relief without the necessity of proving actual damages or that any irreparable harm would or might result from a failure to obtain injunctive relief, it being acknowledged and agreed to by all parties hereto that any such breach will cause irreparable harm to Covered Entity and that monetary damages alone will not provide an adequate remedy.

**Section 8. Construction.** This LDU Agreement shall be construed as broadly as necessary to implement and comply with the Privacy Rules. The parties agree that any ambiguity in this LDU Agreement shall be resolved in favor of a meaning that complies and is consistent with the Privacy Rules.

**Section 9. Captions.** The captions contained in this LDU Agreement are included only for convenience of reference and do not define, limit, explain or modify this LDU Agreement or its interpretation, construction or meaning and are in no way to be construed as part of this LDU Agreement.

**Section 10. Notice.** All notices and other communications required or permitted pursuant to this LDU Agreement shall be in writing, addressed to the party at the address set forth at the end of this LDU Agreement, or to such other address as either party may designate from time to time in writing in accordance with this Section. All notices and other communications shall be mailed by registered or certified mail, return receipt requested, postage pre-paid; by facsimile with a copy sent by First Class Mail, postage prepaid; or transmitted by hand delivery. All notices shall be effective as of the date of delivery by hand delivery, two (2) days following the date of facsimile, or for certified mail on the date of receipt, whichever is applicable.

**Section 11. Assignment.** This LDU Agreement and the rights and obligations hereunder shall not be assigned, delegated, or otherwise transferred without the prior written consent of the other party and any attempted assignment or transfer without proper consent shall be null and void.

**Section 12. Governing Law and Venue.** This LDU Agreement shall be governed by, and interpreted in accordance with, the Privacy Rules and the laws of the State of Alabama, without giving effect to any conflict of laws provisions. Any action at law, suit in equity, or other judicial proceeding for the enforcement of this LDU Agreement, or any provision hereof, shall take place in the State of Alabama in the County in which Covered Entity has his/her/its place of business. Recipient hereby consents to the personal jurisdiction of the state and federal courts in such County, in any dispute arising from or related to this LDU Agreement.

**Section 13. Binding Effect; Modification.** This LDU Agreement shall be binding upon, and shall enure to the benefit of, the parties hereto and their respective permitted successors and assigns. This LDU Agreement may only be amended or modified by mutual written agreement of the parties; provided, however, that in the event provisions of this LDU Agreement shall conflict with the requirements of the Privacy Rules, this LDU Agreement shall automatically be deemed amended as necessary to comply with such legal requirements.

**Section 14. Waiver.** The failure of either party at any time to enforce any right or remedy available hereunder with respect to any breach or failure shall not be construed to be a waiver of such right or remedy with respect to any other breach or failure by the other party.

**Section 15. Severability.** In the event that any provision or part of this LDU Agreement is found to be totally or partially invalid, illegal, or unenforceable, then the provision will be deemed to be modified or restricted to the extent and in the manner necessary to make it valid, legal, or enforceable, or it will be excised without affecting any other provision of this LDU Agreement with the parties agreeing that the remaining provisions are to be deemed to be in full force and effect as if they had been executed by both parties subsequent to the expungement of the invalid provision.

**Section 16. No Third-Party Beneficiaries.** Nothing express or implied in this LDU Agreement is intended to confer, nor shall anything herein confer, upon any person other than Covered Entity, Recipient and their respective successors or permitted assigns, any rights, remedies, obligations or liabilities whatsoever.

**Section 17. Entire Agreement.** This LDU Agreement constitutes the entire agreement between the parties with respect to the matters contemplated herein and supersedes all previous and contemporaneous oral and written negotiations, commitments, and understandings relating thereto.

[Signatures on the following page.]

**IN WITNESS WHEREOF**, Covered Entity and Recipient have each caused this LDU Agreement to be executed in their respective names by their duly authorized representatives, as of the day and year first above written.

**"COVERED ENTITY"**

**"RECIPIENT"**

**University of South Alabama Hospitals**

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

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

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

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

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

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

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

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