DATA USE AGREEMENT

This Data Use Agreement ("Agreement") is made and entered into by and between Texas Tech University Health Sciences Center at El Paso ("Covered Entity"), a public institution of higher education in the State of Texas, and _____ ("Data Recipient"), a [insert description of legal status (public / private / profit / non-profit / company incorporated in what state, LLP or LLC or other entity incorporated or registered in what state)]. Both Covered Entity and Data Recipient are also referred to herein as "Party" or, collectively as the "Parties."

Background

- 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.

- Covered Entity and Data Recipient are committed to compliance with the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), the Health Information Technology Act of 2009 ("HITECH"), and regulations promulgated there under including, but not limited to, the Privacy Rule as provided in 45 CFR Part 160 and 164, and as these may be amended.

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

Agreement

Now therefore, the Parties hereby agree as follows.

Article 1
Definitions

1.1   Terms used but not otherwise defined in this Agreement shall have the same meaning as those terms in the Privacy Rule, as it may be amended or renumbered.

   1.1.1   HIPAA Regulations is defined as the regulations promulgated under HIPAA by the United States Department of Health and Human Services, including, but not limited to, 45 CFR Part 160 and 45 CFR Part 164.

   1.1.2   Disclosure or Disclose is defined in 45 CFR 160.103 as "the release, transfer, provision of, access to, or divulging in any other manner of information outside the entity holding the information."

   1.1.3   Individual is defined in 45 CFR 160.103 as "the person who is the subject of protected health information." For purposes of this Agreement, "Individual" shall include a person who qualifies as a personal representative in accordance with 45 CFR 164.502(g)."

   1.1.4   Covered Entity is defined as a health plan, a health care clearinghouse, or a healthcare provider who transmits any health information in electronic form in connection with a transaction covered by the HIPAA Regulations. 45 CFR 160.103.

   1.1.5   Limited Data Set defined in 45 CFR 164.514(e) as "protected health information that excludes direct identifiers" listed in Article 3 below.

   1.1.6   Privacy Rule means the Standards for Privacy of Individually Identifiable Information at 45 CFR Part 160 and Part 164, Subparts A and E, and as may be amended from time to time.

   1.1.7   Protected Health Information ("PHI") is defined in 45 CFR 164.501 as "individually identifiable health information that is transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium" [excluding education and employment records].

   1.1.8   Required by Law is defined in 45 CFR 164.103 as "a mandate contained in law that compels an entity to make a use or disclosure of protected health information and that is enforceable in a court of law."

1.1.9 <u>Use</u> is defined in 45 CFR 160.103 as "with respect to individually identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information."

Article 2
Scope and Purpose of Disclosure of Limited Data Set

2.1 For the purpose of this Agreement, Covered Entity will Disclose a Limited Data Set to Data Recipient:
_____
_____

2.2 Data Recipient may use and disclose the Limited Data Set received from Covered Entity only in connection with the performance of the: [check appropriate box(es)]:

☐ Research Activities

☐ Public Health Activities

☐ Health Care Operations

Data 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:
_____
_____

2.3 Except as otherwise specified herein, Data Recipient may make all Uses and Disclosures of the Limited Data Set necessary to conduct research activities, public health activities, or healthcare operations as described below. [*Insert a brief description of the applicable activity and/or the TTUHSC research protocol number.*]:
_____
_____

Article 3
Limited Data Set

3.1 A Limited Data Set, as defined above, excludes the direct identifiers listed below which must be removed for the individual and relatives, employers, or household members of the individual. 45 CFR 164.514.

3.1.1 Names
3.1.2 Postal address information, other than town or city, State, and zip code
3.1.3 Telephone numbers
3.1.4 Fax numbers
3.1.5 Electronic mail addresses
3.1.6 Social Security numbers
3.1.7 Medical record numbers
3.1.8 Health plan beneficiary numbers
3.1.9 Account numbers
3.1.10 Certificate/license numbers
3.1.11 Vehicle identifiers and serial numbers, including license plate numbers
3.1.12 Device identifiers and serial numbers
3.1.13 Web Universal Resource Locators (URLs)
3.1.14 Internet Protocol (IP) address numbers
3.1.15 Biometric identifiers, including finger and voice prints
3.1.16 Full face photographic images and comparable image
3.1.17 Any other unique identifying number, characteristic, or code unless allowed by 45 CFR 164.514(c) for re-identification

Article 4
Obligations and Activities of Data Recipient

4.1 Data Recipient shall not use or further disclose the Limited Data Set except as permitted or required by this Agreement.

4.2   Data Recipient shall not disclose the Limited Data Set to any non-employee agent or subcontractor of Data Recipient except with the express prior written consent of Covered Entity. Data Recipient shall ensure that any agents, including subcontractors, to whom it provides the Limited Data Set agree in writing to be bound by the same restrictions and conditions that apply to Data Recipient with respect to such Limited Data Set.

4.3   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.

4.4   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 seventy-two (72) hours of Data Recipient becoming aware of any Use or Disclosure of the Limited Data Set in violation of this Agreement or applicable law.

4.5   Data Recipient agrees to ensure that any agent, including a subcontractor, to whom it provides the Limited Data Set agrees in writing to the same restrictions and conditions that apply through this Agreement to the Data Recipient with respect to Use or Disclosure.

4.6   Data Recipient agrees not to identify the information contained in the Limited Data Set or contact the individual whose PHI is included in the Limited Data Set.

4.7   Data Recipient will indemnify, defend, and hold harmless Covered Entity, its Regents, officers, employees, agents, and 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 or who made unauthorized Use or Disclosure of the Limited Data Set which is the subject of this Agreement. [*This clause is not applicable if Data Recipient is a governmental entity.*]

4.8   The respective rights and obligations of Data Recipient under this Article 4 shall survive termination of this Agreement.

Article 5
Obligations and Activities of Covered Entity

5.1   The Covered Entity may Use or Disclose a Limited Data Set upon execution of this Agreement by the Data Recipient.

5.2   The Covered Entity is exempt from the accounting of Disclosure of a Limited Data Set in accordance with 45 CFR 164.528(a).

5.3   The Covered Entity may Use or Disclose a Limited Data Set only for the purposes or research, public health, or health care operations.

Article 6
Term and Termination; Disposition of Limited Data Set

6.1   The term of this Agreement shall start _____ ("Effective Date").

6.2   Covered Entity may terminate this Agreement:

6.2.1   immediately if Data Recipient is named as a defendant in a criminal proceeding for a violation of HIPAA or the HIPAA Regulations;

6.2.2   immediately if a finding or stipulation that Data Recipient has violated any standard or requirement of HIPAA, the HIPAA Regulations, or any other security or privacy laws is made in any administrative or civil proceeding in which Data Recipient has been joined;

6.2.3   immediately if Covered Entity determines that Data Recipient has breached or violated a material term of this Agreement; or

6.2.4   immediately if it is in the best interest of Covered Entity, as deemed by Covered Entity in its sole discretion to do so; or pursuant to Article 7 of this Agreement.

6.3   Upon termination of this Agreement for any reason, including, but not limited to Data Recipient's decision to cease use of the Limited Data Set, Data Recipient agrees to return or destroy all Limited Data Set data, including copies and derivative versions. If it is not feasible to return or destroy the Limited Data Set, Data Recipient shall give Covered Entity written notice of the conditions preventing return or destruction. Upon mutual written agreement through an amendment to this Agreement, Data Recipient shall continue to extend the protections of this Agreement to the Limited Data Set for as long as Data Recipient holds the Limited Data Set. If Data Recipient later elects to destroy the Limited Data Set, Data Recipient shall notify Covered Entity in writing that the Limited Data Set has been destroyed within three (3) business days.

Article 7
Enforcement

7.1   From time to time upon reasonable notice, or upon a reasonable determination by Covered Entity that Data Recipient has breached this Agreement, Covered Entity may inspect the facilities, systems, books, and records of Data Recipient to monitor compliance with this Agreement. The fact that Covered Entity inspects, or fails to inspect, or has the right to inspect Data User's facilities, systems, and procedures does not relieve Data Recipient of its responsibility to comply with this Agreement, nor does Covered Entity's (1) failure to detect or (2) detection of, but failure to notify Data Recipient or require Data User's remediation of, any unsatisfactory practices constitute acceptance of such practice or a waiver of Covered Entity's enforcement or termination rights under this Agreement. The Parties' respective rights and obligations under this Article 7 shall survive termination of the Agreement.

Article 8
General Provisions

8.1   **Amendment**. The Parties agree to take such action as is necessary to amend this Agreement as mutually agreed in writing from time to time as is necessary for Covered Entity to comply with the requirements of the Privacy Rule and HIPAA. 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.

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

8.3   **No Third Party Beneficiaries**. 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.

8.4   **Breach of Agreement**. If the Covered Entity or the Data Recipient knows of a pattern of activity or practice that constitutes a breach or violation of this Agreement, and such violations cannot be cured or such violation ended by reasonable measures, both Parties agree to the discontinued disclosure of PHI and agree to report the problem as required by law.

8.5   **Reporting.** If any breach or violation is not cured, and if termination of this Agreement is not feasible, Covered Entity shall report Data User's breach or violation to the Secretary of the United States Department of Health and Human Services, and Data Recipient agrees that it shall not have or make any claim(s), whether at law, in equity, or under this Agreement, against Covered Entity with respect to such report(s).

8.6   **Conflict**. 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.

8.7   **Notices**. All notices, approvals, demands, requests, or other communications required or permitted to be given under this Agreement shall be given in writing to the respective Parties personally or by registered or certified mail, return receipt requested, at the following addresses unless a party shall otherwise designate a change of address by notice provided in accordance herewith. Any and all notices or other communications required or permitted by this Agreement or by law to be served on or given to either party to this Agreement shall be in writing and shall be deemed served when personally delivered to the party to whom they are directed, or in lieu of personal service, when deposited in the United States mail, first-class postage prepaid, addressed as follows.

Data Recipient Name   Texas Tech University Health

Attention: _____   Sciences Center at El Paso
Title   Department
Address   Department or ATTN
Address   Address
                                                     Address

8.8 **Independent Contractor.** Nothing in this Agreement is intended nor shall be construed to create an employer/employee relationship between the Parties. The sole interest and responsibility of the Parties is that the services covered by this Agreement shall be performed and rendered in a competent, efficient, and satisfactory manner. Neither Party shall have the authority to represent or otherwise bind the other Party, nor shall any of their respective agents, employees, or representatives be construed to be the agent, employee, or representative of the other.

8.9 **Force Majeure**. "Event of Force Majeure" means an event beyond the control of Parties which prevents or makes a party's compliance with any of its obligations under this Agreement illegal or impracticable, including but not limited to: act of God (including, without limitation, fire, explosion, earthquake, tornado, drought, and flood); war, act or threats of terrorism, hostilities (whether or not war be declared), invasion, act of enemies, mobilization, requisition, or embargo; rebellion, insurrection, military or usurped power, or civil war; contamination or destruction from any nuclear, chemical, or biological event; riot, commotion, strikes, go slows, lock outs, or disorder; epidemic, pandemic, viral outbreak, or health crisis; or directive of governmental authority. No party will be considered in breach of this Agreement to the extent that performance of their respective obligations is prevented or made illegal or impracticable by an Event of Force Majeure that arises during the term (or after execution of the Agreement but prior to the beginning of the term). A party asserting an Event of Force Majeure hereunder ("Affected Party") will give reasonable notice to the other party of an Event of Force Majeure upon it being foreseen by, or becoming known to, Affected Party. In the event of an Event of Force Majeure, Affected Party will endeavor to continue to perform its obligations under the Agreement only so far as reasonably practicable.

8.10 **Severability**. If one or more provisions of this Agreement, or the application of any provision to any party or circumstance, is held invalid, unenforceable, or illegal in any respect, the remainder of this Agreement and the application to other parties or circumstances will remain valid and in full force and effect.

8.11 **Assignment.** Neither Party shall have the right to assign or transfer their rights to any third parties under this Agreement without prior written consent of the non-transferring Party.

8.12 **Venue; Governing Law.** This Agreement and all of the rights and obligations of the Parties and any claims arising from this Agreement will be construed, interpreted, and governed by the laws of the State of Texas. Venue will be in accordance with the Texas Civil Practices and Remedies Code and any amendments thereto.

8.13 **Compliance**. The Parties acknowledge that each is subject to applicable federal and state laws and regulations, and policies and requirements of various accrediting organizations. Accordingly, each Party will enforce compliance with all applicable laws, regulations, and requirements, and will make available such information and records as may be reasonably requested in writing by the other Party to facilitate its compliance, except for records that are confidential and privileged by law.

8.14 **Warranty of Authority**. The person(s) executing this Agreement on behalf of the Parties, or representing themselves as executing this Agreement on behalf of a Party, warrant and guarantee that each has been duly authorized by the appropriate Party to execute this Agreement on behalf of the Party and to validly and legally bind the Party to all of its terms, performances, and provisions.

[*Signature page follows.*]

Covered Entity   **Data Recipient**

Texas Tech University   <mark>Name</mark>
Health Sciences Center <mark>at El Paso</mark>

_____   _____
Signature   Signature

_____   _____
Name   Name

_____   _____
Title   Title

_____   _____
Date   Date