Middle Tennessee State University

Data Use Agreement

 This Data Use Agreement (“Agreement”) is made and entered into as of this \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_\_\_\_, 20\_\_ (the “Effective Date”) by and between Middle Tennessee State University (investigator) , and\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ , for purposes of compliance with the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), as it may be amended from time to time.

**WITNESSETH:**

 WHEREAS, MTSU 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, MTSU and Data Recipient are committed to compliance with HIPAA and regulations promulgated there under; and

 WHEREAS, the purpose of this Agreement is to satisfy the obligations of the parties 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 MTSU.

 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:

## 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. A limited data set is protected health information that excludes 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), full face photographic images, and any comparable images.
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 MTSU.
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.
	* 1. **SCOPE AND PURPOSE**
			1. This Agreement sets forth the terms and conditions pursuant to which MTSU will disclose the Limited Data Set to the Data Recipient.
			2. Data Recipient will only use or disclose the Limited Data Set for the limited purposes necessary to conduct the research described herein: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(include a brief description of the research and/or MTSU IRB protocol number)­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (“Research Project”). Data Recipient represents that Data Recipient's request that Covered Entity disclose certain PHI to Data Recipient is limited in scope to the minimum information necessary to accomplish Data Recipient’s purpose in connection with the Research Project.
			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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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1. **OBLIGATIONS AND ACTIVITIES OF DATA RECIPIENT**
	1. Data Recipient agrees to not use or disclose the Limited Data Set for any purpose other than as described in this Agreement or as required by law.
	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.
	3. Data Recipient agrees to report in writing to the Middle Tennessee State University Privacy Official any use or disclosure of any portion of the Limited Data Set not provided for by this Agreement of which it becomes aware, including without limitation, any disclosure to an unauthorized subcontractor or any other individual or entity not named in Section B.3 above, within ten (10) days of its discovery.
	4. Data Recipient agrees that it shall obtain and maintain, for the term of this Agreement, a written agreement with each contractor or with any agent, including a subcontractor, to whom it provides any portion of the Limited Data Set holding them to the same restrictions and conditions that apply through this Agreement to the Data Recipient with respect to such information. Further, upon request, Data Recipient will provide copies of such agreements to MTSU.
	5. Data Recipient agrees not to identify the information contained in the Limited Data Set or contact any individual whose PHI is contained in the Limited Data Set.
	6. Data Recipient will indemnify, defend and hold harmless The Middle Tennessee State University, and its trustees, agents, officers, servants, and employees, and its respective successors, heirs, subcontractors and assigns (“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 failure to perform the obligations hereunder by Data Recipient, its employees, officers, volunteers, assigns or contractors.
	7. Data Recipient agrees to notify MTSU in writing within five (5) business days of Data Recipient’s receipt of any request or subpoena for any portion of the Limited Data Set or any information related to this Agreement. To the extent that MTSU decides to assume responsibility for challenging the validity of such request, Data Recipient will cooperate fully with MTSU in any such challenge.

**TERM AND TERMINATION**

The provisions of this Agreement shall be effective as of the Effective Date and shall terminate when all of the Limited Data Set provided by MTSU to Data Recipient is destroyed or returned to MTSU, 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.

* + - 1. Upon MTSU’s knowledge of a material breach by Data Recipient, MTSU shall:
				1. Provide Data Recipient with written notice of the breach and an opportunity to cure the breach within ten (10) days of receipt of such notice. If Data Recipient fails to cure the breach within the notice period, MTSU may immediately terminate this Agreement; or
				2. Immediately terminate this Agreement (without opportunity to cure) if MTSU determines, in its sole discretion, that Data Recipient has breached a material term of this Agreement; or
				3. MTSU shall report the violation to the Secretary of the Department of Health and Human Services.

**MISCELLANEOUS**

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

The parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for MTSU to comply with the requirements of the Privacy Rule and HIPAA.

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

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

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.

* 1. 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.
	2. The persons signing below have the right and authority to execute this Agreement and no further approvals are necessary to create a binding agreement.
	3. 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 MTSU shall apply to the breach of any covenant in this Agreement by Data Recipient.
	4. This Agreement shall be construed in accordance with and governed by the laws of the State of Tennessee.

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

**APPROVED BY:**

**Middle Tennessee state UNIVERSITY** **DATA RECIPIENT**

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

Title: Title:

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

**RECOMMENDED BY:**

**Principal Investigator: Principal Investigator:**

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

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

Title: Title:

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