DATA USE AGREEMENT

This Data Use Agreement (“Agreement”), effective as of       (“Effective Date”), is entered into by and between      (“Data Recipient”) and       (“Data Provider”). The purpose of this Agreement is to provide Data Recipient with access to a Limited Data Set (“LDS”) for use in research in accord with the HIPAA and FERPA Regulations.

1. Definitions. Unless otherwise specified in this Agreement, all capitalized terms used in this Agreement not otherwise defined have the meaning established for purposes of the “HIPAA Regulations” codified at Title 45 parts 160 through 164 of the United States Code of Federal Regulations, as amended from time to time.
2. Preparation of the LDS. Data Provider shall prepare and furnish to Data Recipient a LDS in accordance with any applicable HIPAA or FERPA Regulations
3. Data Fields in the LDS. No direct identifiers such as names may be included in the Limited Data Set (LDS). In preparing the LDS, Data Provider shall include the **data fields specified as follows**, which are the minimum necessary to accomplish the research (list all data to be provided in Section 10.).
4. Responsibilities of Data Recipient. Data Recipient agrees to:
	1. Use or disclose the LDS only as permitted by this Agreement or as required by law;
	2. Use appropriate safeguards to prevent use or disclosure of the LDS other than as permitted by this Agreement or required by law;
	3. Report to Data Provider any use or disclosure of the LDS of which it becomes aware that is not permitted by this Agreement or required by law;
	4. Require any of its subcontractors or agents that receive or have access to the LDS to agree to the same restrictions and conditions on the use and/or disclosure of the LDS that apply to Data Recipient under this Agreement; and
	5. Not use the information in the LDS to identify or contact the individuals who are data subjects.
5. Permitted Uses and Disclosures of the LDS. Data Recipient may use and/or disclose the LDS for its Research activities only.
6. Term and Termination.
	1. Term. The term of this Agreement shall commence as of the Effective Date and shall continue for so long as Data Recipient retains the LDS, unless sooner terminated as set forth in this Agreement.
	2. Termination by Data Recipient. Data Recipient may terminate this agreement at any time by notifying the Data Provider and returning or destroying the LDS.
	3. Termination by Data Provider. Data Provider may terminate this agreement at any time by providing thirty (30) days prior written notice to Data Recipient.
	4. For Breach. Data Provider shall provide written notice to Data Recipient within ten (10) days of any determination that Data Recipient has breached a material term of this Agreement. Data Provider shall afford Data Recipient an opportunity to cure said alleged material breach upon mutually agreeable terms. Failure to agree on mutually agreeable terms for cure within thirty (30) days shall be grounds for the immediate termination of this Agreement by Data Provider.
	5. Effect of Termination. Sections 1, 4, 5, 6(e) and 7 of this Agreement shall survive any termination of this Agreement under subsections c or d.
7. Miscellaneous.
	1. Change in Law. The parties agree to negotiate in good faith to amend this Agreement to comport with changes in federal law that materially alter either or both parties’ obligations under this Agreement. Provided however, that if the parties are unable to agree to mutually acceptable amendment(s) by the compliance date of the change in applicable law or regulations, either Party may terminate this Agreement as provided in section 6.
	2. Construction of Terms. The terms of this Agreement shall be construed to give effect to applicable federal interpretative guidance regarding the HIPAA Regulations.
	3. No Third Party Beneficiaries. Nothing in this Agreement shall confer upon any person other than the parties and their respective successors or assigns, any rights, remedies, obligations, or liabilities whatsoever.
	4. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.
	5. Headings. The headings and other captions in this Agreement are for convenience and reference only and shall not be used in interpreting, construing or enforcing any of the provisions of this Agreement.

**Data and/or Records Needed for Research Protocol**

1. Selection Criteria: **(what are you selecting from the de-identified pre-existing data to use in your research-be as detailed as possible)**
2. Dates of required records: from \_\_\_\_\_\_\_\_\_\_\_\_ through \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. Data fields required **(list fields required from an electronic data base, or list fields to be recorded from the paper record by the researcher)**
4. Anticipated sources of information (check all that apply)
5. **☐** Paper Medical Records
6. **☐** Electronic files
7. **☐** Other de-identified appraisal scores ONLY in the AGGREGATED OR SUMMED format; DISTRICT ONLY to run the software and provide the data.
8. Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
9. Email Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
10. Phone Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
11. Co-Principal Investigator(s): \_\_\_(if applicable, delete if no CoPI)\_\_\_\_\_\_\_\_\_\_\_\_
12. Student Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
13. Email Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
14. Phone Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
15. Study Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
16. Number of Records Needed: \_\_\_\_\_\_\_\_\_\_\_≥ 50 \_\_\_\_\_\_\_\_\_\_\_\_\_ < 50
17. The Privacy Rule (45 CFR 164.512) allows the use or disclosure of protected information that has been de-identified to a Limited Data Set, provided that certain criteria are met. Please read the following statements:
18. Limited data Set may **not** include any of the following:
19. Names
20. Addresses other than city, state, zip code
21. Telephone numbers
22. Fax numbers
23. Electronic mail addresses
24. Social Security Numbers
25. Medical Record Numbers
26. Health Plan Beneficiary numbers
27. Account Numbers
28. Certificate/License Numbers
29. Vehicle Identifiers and Serial Numbers
30. Device Identifiers and Serial Numbers
31. Web Universal resource locators (URLs; web site addresses)
32. Internet Protocol (IP) Addresses
33. Biometric Identifiers, including finger and voice prints
34. Full face photographic images and any comparable images
35. This Limited Data Set will be used only for the purposes of research.
36. The requested Limited Data Set constitutes the minimum necessary data to accomplish the goals of the research.

**By submitting this form with a TAMUK IRB application, the PI attests to the following:**

I declare that the requested information constitutes the minimum necessary data to accomplish the goals of the research.

I agree that the protected information will not be re-used or disclosed to any other person or entity, except as required by law, for the authorized oversight of the research study, or for other research for which the use of disclosure of protected health information would be permitted by the Privacy Regulation (45 CFR 164.512)

I agree to abide by the terms of the Data Use Agreement for this study.

IN WITNESS WHEREOF, each of the undersigned has caused this Agreement to be duly executed in its name and on its behalf.

**DATA PROVIDER DATA RECIPIENTS**

Signed: \_\_\_\_\_\_\_\_\_ Signed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_

Printed Name: Printed Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Title: Printed Title:

Date: Date: