



Campbell University Institutional Review Board
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CUIRB-IRB00009201

DATA USE AGREEMENT

This Data Use Agreement (“Agreement”), effective as of (“Effective Date”), is entered into by and between (“Recipient”) and (“Covered Entity”). The purpose of this Agreement is to provide Recipient with access to a Limited Data Set (“LDS”) for use in its Research and Public Health analyses and for the Health Care Operations of the Covered Entity, in accord with the HIPAA 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.** Covered Entity shall prepare and furnish to Recipient a LDS in accord with the HIPAA Regulations or Covered Entity shall retain Recipient as a Business Associate (pursuant to an appropriate Business Associate Agreement) and direct recipient, as its Business Associate, to prepare such LDS.
3. **Minimum Necessary Data Fields in the LDS.** In preparing the LDS, Covered Entity or its Business Associate shall include the data fields specified by the parties from time to time, which are the minimum necessary to accomplish the purposes set forth in Section 5 of this Agreement.
4. **Responsibilities of Recipient.** Recipient agrees to:
 - a. Use or disclose the LDS only as permitted by this Agreement or as required by law;
 - b. Use appropriate safeguards to prevent use or disclosure of the LDS other than as permitted by this Agreement or required by law;
 - c. Report to Covered Entity any use or disclosure of the LDS of which it becomes aware that is not permitted by this Agreement or required by law;
 - d. 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 Recipient under this Agreement; and
 - e. 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. Recipient may use and/or disclose the LDS for its Research and Public Health activities and the Health Care Operations of the Covered Entity.
6. Term and Termination.
 - a. Term. The term of this Agreement shall commence as of the Effective Date and shall continue for so long as Recipient retains the LDS, unless sooner terminated as set forth in this Agreement.
 - b. Termination by Recipient. Recipient may terminate this agreement at any time by notifying the Covered Entity and returning or destroying the LDS.
 - c. Termination by Covered Entity. Covered Entity may terminate this agreement at any time by providing thirty (30) days prior written notice to Recipient.
 - d. For Breach. Covered Entity shall provide written notice to Recipient within ten (10) days of any determination that Recipient has breached a material term of this Agreement. Covered Entity shall afford 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 Covered Entity.
 - e. 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.
 - a. 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.
 - b. Construction of Terms. The terms of this Agreement shall be construed to give effect to applicable federal interpretative guidance regarding the HIPAA Regulations.
 - c. 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.

- d. 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.
- e. 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.

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

COVERED ENTITY

RECIPIENT

By:

By:

Print Name:

Print Name:

Print Title:

Print Title: