

Data Use Agreement for Limited Data Set

This **Data Use Agreement for a Limited Data Set** ("DUA") is effective on the ____ day of _____, 20____, ("Effective Date") by and between **East Carolina University** ("Covered Entity") and _____("Recipient").

1. **DEFINITIONS.** Except as otherwise defined herein, any and all capitalized terms in this DUA shall have the definitions set forth in HIPAA. In the event of any inconsistency between the provisions of this DUA and mandatory provisions of HIPAA, as amended, the HIPAA provisions shall control. Where provisions of this DUA are different from those provided in HIPAA, but are permitted by HIPAA, the provisions of this DUA shall control.
 - 1.1. **Limited Data Set** shall have the same meaning as that term is defined in the Privacy Standards. 45 C.F.R. § 164.514(e)(2).
 - 1.2. **Privacy Standards** shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 C.F.R. Parts 160 and 164, as may be amended from time to time, promulgated pursuant to the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA").
 - 1.3. **Required by Law** shall have the same meaning as that term is defined in the Privacy Standards. 45 C.F.R. § 164.103.
 - 1.4. **Secretary** shall mean the Secretary of the Department of Health and Human Services or his designee.
 - 1.5. **Protected Health Information (PHI)** shall have the same meaning as the term is defined at, 45 C.F.R. § 160.103, limited to the information created or received by the Recipient from or on behalf of the Covered Entity.

2. Terms of the Agreement.

- 2.1. Pursuant to this Agreement Covered Entity shall provide Recipient with PHI in the form of a Limited Data Set for the sole purpose of:

(check as appropriate)

Research: [Further Describe: _____]

Public Health Activities: [Further describe: _____]

Health Care Operations: [Further describe: _____]

- 2.2. Recipient shall not use or further disclose the Limited Data Set in a manner that would violate the Privacy Standards if done by the Covered Entity.

- 2.3. Recipient agrees to the following:

- 2.3.1. Recipient agrees that it, and any employees, agents and subcontractors to whom it discloses the PHI, will not use or further disclose the PHI other than as permitted by this DUA, or as otherwise required by law or regulation.

- 2.3.2. Recipient shall use appropriate safeguards to protect the PHI from misuse or inappropriate disclosure and to prevent any use or disclosure of the PHI other than as provided in this DUA or as otherwise required by law or regulation.
- 2.3.3. Recipient shall not attempt to identify the individuals to whom the PHI pertains, or attempt to contact such individuals.
- 2.3.4. Recipient shall report to Covered Entity any use or disclosure of the PHI not provided for in this DUA of which Recipient becomes aware. Recipient will take reasonable steps to limit any further such use or disclosure.

3. TERM AND TERMINATION.

- 3.1. Term. The Term of this DUA shall be effective as of the date first written above, and shall terminate when all of the PHI provided by Covered Entity to Recipient is destroyed or returned to Covered Entity, or, if it is infeasible to return or destroy PHI, protections are extended to such information, in accordance with the termination provisions in this Section.
- 3.2. Termination for Cause. Should Recipient commit a material breach of this DUA, which is not cured within thirty (30) days after Recipient receives notice of such breach from the Covered Entity, then the Covered Entity will discontinue disclosure of PHI and will report the breach to the Secretary, Department of Health and Human Services.
- 3.3. Effects of Termination.
 - 3.3.1. Except as provided in paragraph (ii) of this subsection, within ten (10) days upon termination of this DUA, Recipient shall return or destroy all PHI received from Covered Entity. This provision shall apply to PHI that is in the possession of subcontractors or agents of Recipient. Recipient shall retain no copies of the PHI.
 - 3.3.2. In the event that Recipient determines that returning or destroying the PHI is infeasible, Recipient shall provide to Covered Entity notification of the conditions that make return or destruction infeasible. Upon mutual agreement of the Parties that return or destruction of PHI is infeasible, Recipient shall extend the protections of this DUA to such PHI and limit further uses and disclosures of such PHI to those purposes that make the return or destruction infeasible, for so long as Recipient maintains such PHI.
- 4. **Mitigation.** Recipient agrees to mitigate, to the extent practicable, any harmful effect that is known to Recipient of a use or disclosure of PHI or the Limited Data Set by Recipient or by any person to whom Recipient has disclosed PHI or the Limited Data Set pursuant to Section 2 in violation of the requirements of this Agreement.
- 5. **Indemnification.** Recipient agrees to indemnify and hold harmless and defend Covered Entity from and against any claim, action, suit, right, damage, loss, expense, or cost (including, but not limited to, reasonable attorney's fees and court costs) arising out of an act, or omission to act, on the part of the Recipient, its agents, or employees pursuant to this Agreement. This agreement to indemnify and hold harmless Covered Entity shall apply to both third-party claims and second-party claims, including, but not limited to, claims, actions, damages, losses, expenses, or costs (including, but not limited to, reasonable attorneys' fees and court costs) incurred by Covered Entity as a result of an

act, or omission to act, on the part of Recipient, its agents, or employees pursuant to this Agreement.

6. **Ownership of Health Information.** Recipient agrees that all PHI or the Limited Data Set related to this Agreement is exclusive property of the Covered Entity.
7. **Response to Service of Process.** If Recipient receives a request to disclose all or any part of the PHI or Limited Data Set received under the Agreement under the terms of a subpoena or other order issued by a court of competent jurisdiction or by a government agency, Recipient shall: (i) promptly notify Covered Entity of the existence, terms, and circumstances surrounding such a request; (ii) if disclosure of that PHI or the Limited Data Set is required, furnish only such portion of the PHI or Limited Data Set as Recipient is advised by counsel is legally required to be disclosed; and (iv) cooperate with Covered Entity in its efforts to obtain an order or other reliable assurance that confidential treatment will be accorded to that portion of the PHI or the Limited Data Set that is required to be disclosed.
8. **Remedies.** Recipient acknowledges that if Section 2 is breached, Covered Entity could not be made whole by monetary damages. Accordingly, Covered Entity, in addition to monetary damages and any other remedy to which it may be entitled by law or in equity, shall be entitled to an injunction to prevent breaches of this Addendum, and to an order compelling specific performance of this Agreement. Recipient shall reimburse Covered Entity for all costs and expenses, including reasonable attorneys' fees, incurred by Covered Entity if it successfully enforces the obligations of Recipient. All rights and remedies of a party hereunder shall be cumulative and in addition to such rights and remedies as may be available to a party at law or equity.
9. **Counterparts.** This Agreement may be executed in multiple counterparts which, when taken together constitute a single agreement.

IN WITNESS WHEREOF, the parties have caused this Agreement to be duly executed and delivered on the Effective Date.

Date

For Covered Entity

Printed Name and Title

Date

For Recipient

Printed Name and Title