

LIMITED DATA SET USE AGREEMENT

Project Title: _____

BG Number: _____

Principal Investigator: _____

This **DATA USE AGREEMENT** (this “Agreement”) is executed this _____ day of _____, 200__ (the “**Execution Date**”), to be effective on the _____ day of _____, 200__ (the “**Effective Date**”), by and between **North Carolina Region I EMS Database** (the “**Covered Entity**”), and _____ (the “**Data User**”).

RECITALS :

WHEREAS, the Data User performs certain [*research, public health or healthcare operations*] functions (the “**Activities**”);

WHEREAS, Covered Entity agrees to disclose a Limited Data Set, as defined herein to Data User for use by Data User in performance of the Activities;

WHEREAS, Data User agrees to limit its use of the Limited Data Set and protect the Limited Data Set according to the terms and conditions of this Agreement and the Health Insurance Portability and Accountability Act and corresponding Privacy Standards, as may be amended from time to time.

NOW, THEREFORE, in consideration of the mutual agreements, covenants, terms and conditions herein contained, the Covered Entity and the Data User agree as follows:

I. DEFINITIONS FOR USE IN THIS AGREEMENT

“**Designated Record Set**” shall mean a group of records maintained by or for the Covered Entity that is (i) the medical records and billing records about individuals maintained by or for the Covered Entity; (ii) the enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or (iii) used, in whole or in part, by or for the Covered Entity to make decisions about individuals. As used herein the term “Record” means any item, collection, or grouping of information that includes Protected Health Information and is maintained, collected, used, or disseminated by or for the Covered Entity.

“**Electronic Media**” shall mean the mode of electronic transmissions. It includes the Internet, extranet (using Internet technology to link a business with information only accessible to collaborating parties), leased lines, dial-up lines, private networks, and those transmissions that are physically moved from one location to another using magnetic tape, disk, or compact disk media.

“**Individually Identifiable Health Information**” shall mean information that is a subset of health information, including demographic information collected from an individual, and
(i) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and
(ii) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual; and (a) identifies the individual, or (b) there is a reasonable basis to believe the information can be used to identify the

individual.

“**Privacy Standards**” shall mean the Standards for Privacy of Individually Identifiable Health Information, 45 C.F.R. Parts 160 and 164.

“**Protected Health Information**” shall mean Individually Identifiable Health Information that is (i) transmitted by electronic media; (ii) maintained in any medium constituting Electronic Media; or (iii) transmitted or maintained in any other form or medium. “Protected Health Information” shall not include (i) education records covered by the Family Educational Right and Privacy Act, as amended, 20 U.S.C. § 1232g and (ii) records described in 20 U.S.C. § 1232g(a)(4)(B)(iv). For instance, Protected Health Information includes information contained in a patient’s medical records and billing records.

“**Secretary**” shall mean the Secretary of the Department of Health and Human Services.

II. DISCLOSURE OF LIMITED DATA SET TO DATA USER

Section 2.1 **Activities**. Data User performs the following Activities: _____

[The Parties should describe the research, public health activities or health care operation activities performed by Data User with enough particularity to provide a rationale for the types of information to be disclosed to Data User under Section 2.2 of this Agreement. For example, if Data User is performing Research, describe generally the type of research to explain why a date of birth may be necessary.]

Section 2.2 **Limited Data Set**. Data User agrees to use and the Covered Entity agrees to disclose the following Protected Health Information to Data User for use by Data User in the performance of the Activities (the “**Limited Data Set**”): _____

[There are two limitations on the types of information that can be disclosed under this Agreement. First, Covered Entities can not disclose any of the following specifically enumerated types of information about an individual who is the subject of Protected Health Information, relatives of an individual, employers of an individual or household members of an individual: names, 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, full face photographic images and comparable images. Second, Covered Entities must limit the information disclosed to the minimum necessary information needed to perform the Activities. For example, date of birth is not one of the enumerated types of information for which disclosure is prohibited. However, date of birth should not be disclosed unless it is needed by the Data User to perform the Activities. Due to these two limitations, the parties should seek to describe the types of information that will be disclosed with particularity.]

III. OBLIGATIONS OF DATA USER

Section 3.1. **Use of Limited Data Set**. The Data User may use and disclose the Limited Data Set only as permitted under the terms of this Agreement or required by law, but shall not otherwise use or disclose the Limited Data Set and shall ensure that its directors, officers, employees, contractors and agents do not use or disclose the Limited Data Set in any manner that would constitute a violation of the Privacy Standards if used by the Covered Entity. Data User agrees not to use the Limited Data Set in such a way as to identify any individual and further

agrees not to contact any individual. Data User 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*. _____.

Section 3.2 **Minimum Necessary Information**. The Data User represents that, to the extent the Data User requests that the Covered Entity disclose Protected Health Information to the Data User as described in Section 2.2, such a request is only for the minimum necessary Protected Health Information for the accomplishment of the Data User's purpose.

Section 3.3. **Safeguards Against Misuse of Information**. The Data User shall use appropriate safeguards to prevent use or disclosure of the Limited Data Set other than as permitted under this Agreement.

Section 3.4. **Reporting of Disclosures of Protected Health Information**. The Data User shall, within thirty (30) days of becoming aware of any use or disclosure of the Limited Data Set in violation of the Agreement by the Data User, its officers, directors, employees, contractors or agents or by a third party to which the Vendor disclosed the Limited Data Set pursuant to Section 3.5, report any such disclosure to the Covered Entity.

Section 3.5. **Agreements by Third Parties**. The Data User shall obtain and maintain an agreement with each agent or subcontractor that has or will have access to the Limited Data Set, which is received by or on behalf of the Data User, pursuant to which agreement such agent or subcontractor agrees to be bound by the same restrictions, terms and conditions that apply to the Data User pursuant to the Agreement with respect to the Limited Data Set.

Section 3.6. **Access to Information** (Required only if the Limited Data Set used and kept by the Data User is part of a Designated Record Set) Within five (5) days of a request by the Covered Entity for access to Protected Health Information about an individual contained in a Designated Record Set, the Data User shall make available to the Covered Entity such Protected Health Information for so long as such information is maintained in the Designated Record Set. In the event any individual requests access to Protected Health Information directly from the Data User, the Data User shall within two (2) days forward such request to the Covered Entity. Any denials of access to the Protected Health Information requested shall be the responsibility of the Covered Entity.

Section 3.7. **Availability of Protected Health Information for Amendment**.(Required only if the Limited Data Set used or kept by the Data User is part of a Designated Record Set). Within ten (10) days of receipt of a request from the Covered Entity for the amendment of an individual's Protected Health Information or a record regarding an individual contained in a Designated Record Set (for so long as the Protected Health Information is maintained in the Designated Record Set), the Data User shall provide such information to the Covered Entity for amendment and incorporate any such amendments in the Protected Health Information as required by 45 C.F.R. § 164.526.

Section 3.8. **Indemnification**. The Data User shall indemnify, defend (if requested by the Covered Entity), and hold the Covered Entity harmless from and against any actual or threatened legal or administrative action, claim, liability, penalty, fine, assessment, lawsuit, litigation, or other loss, expense, or damage, including without limitation any reasonable attorneys' fees and costs that the Covered Entity may incur directly or indirectly resulting from any actions or omissions of Data User, its agents or subcontractors, including failure to perform its obligations under this Agreement, without regard to any limitation or exclusion of damages provision otherwise set forth in the Agreement.

Section 3.9. **Insurance**. The Data User shall obtain and maintain and during the term of the Agreement liability insurance covering claims based on a violation of the Privacy Standards or any applicable state law or regulation concerning the privacy of patient information and

claims based on its obligations pursuant to this Section in an amount not less than \$1 000,000 per claim. Such insurance shall be in the form of occurrence based coverage and shall name the Covered Entity as an additional named insured. A copy of such policy or a certificate evidencing the policy shall be provided to the Covered Provider upon written request. Data User shall provide Covered Entity at least thirty (30) days' advance notice of any cancellation or material modification of said policies.

Section 3.10. **Notice of Request for Data.** The Data User agrees to notify the Covered Entity within five (5) business days of the Data User's receipt of any request or subpoena for Protected Health Information. To the extent that the Covered Entity decides to assume responsibility for challenging the validity of such request, the Data User shall cooperate fully with the Covered Entity in such challenge.

Section 3.11. **Injunction.** The Data User acknowledges and agrees that the Covered Entity will suffer irreparable damage upon the Data User's breach of this Agreement and that such damages shall be difficult to quantify. The Data User acknowledges and agrees that the Covered Entity may file an action for an injunction to enforce the terms of this Agreement against the Data User, in addition to any other remedy the Covered Entity may have.

Section 3.12 **Ownership of Information.** The Data User acknowledges that, as between the Data User and the Covered Entity, all Protected Health Information shall be and remain the sole property of the Covered Entity, including any and all forms thereof developed by the Data User in the course of its fulfillment of its obligations pursuant to the Agreement

IV. TERMINATION

Section 4.1. **Termination Upon Breach of Provisions Applicable to Protected Health Information.** Any other provision of this Agreement notwithstanding, this Agreement may be terminated by the Covered Entity upon five (5) days written notice to the Data User in the event that the Data User breaches any provision contained in this Agreement and such breach is not cured within such five (5) day period. Data User acknowledges and agrees that in the event Data User's efforts to cure the breach are unsuccessful, the Covered Entity has a duty to discontinue disclosure of Protected Health Information and to report the breach to the Secretary, notwithstanding any other provision of this Agreement to the contrary.

Section 4.2. **Return or Destruction of Protected Health Information upon Termination.** Upon termination of this Agreement, the Data User shall either return or destroy all Protected Health Information received from the Covered Entity or created or received by the Data User on behalf of the Covered Entity and which the Data User still maintains in any form. The Data User shall not retain any copies of such Protected Health Information. Notwithstanding the foregoing, to the extent that the Covered Entity agrees that it is not feasible to return or destroy such Protected Health Information, the terms and provisions of this Agreement shall survive termination of the Agreement and such Protected Health Information shall be used or disclosed solely for such purpose or purposes that prevented the return or destruction of such Protected Health Information.

Section 4.3. **The Covered Entity's Right of Cure.** At the expense of the Data User, the Covered Entity shall have the right to cure any breach of the Data Users obligations under this Agreement. The Covered Entity shall give the Data User notice of its election to cure any such breach and the Data User shall cooperate fully in the efforts by the Covered Entity to cure the Data User's breach. All requests for payment for such services of the Covered Entity shall be paid within thirty (30) days.

V. GENERAL PROVISIONS

Section 5.1. **Effect.** The terms and provisions of this Agreement shall supercede any other conflicting or inconsistent agreements between Covered Entity and Data User, including all exhibits or other attachments thereto and all documents incorporated therein by reference. Without limitation of the foregoing, any limitation or exclusion of damages provisions shall not be applicable to this Agreement.

Section 5.2. **Amendment.** The Data User and the Covered Entity agree to amend this Agreement to the extent necessary to allow either party to comply with the Privacy Standards, the Standards for Electronic Transactions (45 C.F.R. Parts 160 and 162) and the Security Standards (45 C.F.R. Part 142) (collectively, the “**Standards**”) promulgated or to be promulgated by the Secretary or other regulations or statutes. The Data User agrees that it will fully comply with all such Standards and that it will agree to amend this Agreement to incorporate any material changes required by the Standards.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed as of the day and year first written above.

Signed: _____ Date: _____
Print or Type Name of Data Recipient: _____
Title: _____
Organization: _____
Address: _____
City: _____ State: _____ ZIP Code: _____
Phone Number: _____ Fax: _____
E-mail: _____