CAROLINA COST AND QUALITY INITIATIVE (CCQI)

Restricted Data Use Agreement for a Limited Data Set (BCBSNC) between Data Recipient and User.

This restricted **Data Use Agreement (DUA) for a Limited Data Set (LDS)** is between the Carolina Cost and Quality Initiative (Data Recipient) and the Principal Investigator (User) to specify the obligations applicable to User when accessing, using or disclosing the Limited Data Set (LDS) created from certain data provided by Blue Cross and Blue Shield of North Carolina (BCBSNC) (Data Owner) for purposes of research.

WITNESSETH:

WHEREAS, BCBSNC is a Covered Entity as defined in the Health Insurance Portability and Accountability Act of 1996, as amended (HIPAA); and

WHEREAS, BCBSNC is providing Sheps, and subsequently the Principal Investigator, with a Limited Data Set (LDS) of Protected Health Information (PHI) as defined in 45 Code of Federal Regulations (CFR §164.514(e)(2) pursuant to a Data Use Agreement dated **May 5, 2014** setting forth the terms and conditions of such use of data (the Agreement);and

WHEREAS, the Principal Investigator Is a "Limited Data Set Recipient" as defined In HIPAA and each agrees to abide by the requirements of HIPAA and the provisions of this DUA to protect and safeguard the privacy and security of the PHI provided for purposes of research, public health activities, and, where applicable, health care operations.

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:

1. **DATA USE AGREEMENT DOCUMENTS**. This agreement consists of: (a) this document; (b) Data Request with description/statement of work; and (c) Data Dictionary noting data elements to be provided.

2. **DEFINITIONS.**
   a) Terms used but not otherwise defined in this DUA shall have the same meaning established for purposes of HIPAA and 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. In the event of a discrepancy in definitions in this DUA and HIPAA, HIPAA definitions will apply.

   b) "**Authorized User Personnel"** means an employee, agents, or subcontractors to whom User authorizes access to or to whom User discloses PHI protected by the terms of this Agreement.

   c) **“CCQI Oversight Committee"** shall mean the governing body, consisting of representatives from Data Owner and Data Recipient, authorized by the collaborative partnership between The Data Owner and Data Recipient to assess and approve or deny requests for use of data received by CCQI submitted by researchers at the University of North Carolina at Chapel Hill (University), like User.

   d) **"Limited data set"** or **"LDS"** means PHI that excludes specified identifiers (such as, the patient's name, chart number, social security number, etc.),but that can still potentially be linked to a particular patient because it contains dates (including birth date, admission date, discharge date, and date of death) and/or information about the patient's city, state, or nine-digit zip code.

3. **USE OR DISCLOSURE.** User shall have the right to use all PHI provided to it under this DUA only for the research, public health or health care operations' purposes outlined in the accompanying Data Request, which includes a description/statement of work and has been approved in writing by the CCQI Oversight Committee. ***User agrees that the data shall not be used for any purposes other than the research analysis, and aggregate statistical reporting described in the data request and that such limited permitted purposes never include the use of data for commercial or competitive purposes involving individual or professional providers.*** User represents that his/her request for a research dataset is limited in scope to the minimum information necessary to accomplish the work described in the approved Data Request.

4. **RESTRICTIONS ON USE; AUTHORIZED USER PERSONNEL**. User agrees that he/she and any Authorized User Personnel 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. User shall use appropriate administrative, technical, and physical 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. User shall not attempt to identify the individuals to whom the PHI pertains, or attempt to contact such individuals. User agrees that access to data shall be limited solely to Authorized User Personnel, who shall be made aware of and agree to comply with the terms of this DUA by signing onto this DUA. User agrees that the data protected by this DUA shall not be viewed, "loaned" or otherwise conveyed to anyone other than Authorized User Personnel. User agrees to use all necessary and required administrative, technical and physical safeguards to protect data from being viewed, "loaned," or otherwise conveyed to any individual or party other than Authorized User Personnel. The User agrees to maintain documentation that all Authorized User Personnel working with said PHI have completed the Collaborative IRB Training Initiative (CITI) web-based training package on issues relating to human subjects research.

5. **PROTECTING DATA.** User agrees that CCQI provided datasets that contain PHI will be kept only at _____ for the duration of this DUA. User certifies that the above location is a lockable, non-public area of User's employer, which shall remain locked at all times when not occupied, and that the **PHI will not be stored on a laptop or other device that could be moved from this location**. In the event that User needs to change the designated location above, User agrees to update this DUA with the new location prior to moving PHI. User certifies that all computers storing and accessing these data meet the requirements defined in UNC Information Security policies, specifically that computers are maintained by trained UNC IT staff, receive regular software updates via the UNC AD domain, and receive routine vulnerability scans with remediation.

6. **REPORTING**. User agrees to immediately report to the CCQI any use or disclosure of the PHI that is not provided for in this DUA of which the User becomes aware. User will take reasonable steps to limit any further such use or disclosure and will mitigate any harm associated with such use or disclosure.

7. **VALIDITY CHECKS**. User agrees to provide a copy of his/her IRB approval to CCQI; and CCQI will provide BCBSNC copies of the following (a) User's approved data request and any subsequent modifications and (b) User's IRB approval.

8. **COPY UPON SUBMISSION TO PROPOSED PUBLICATION; VETO RIGHTS.** User agrees to submit to CCQI who will pass on to Data Owner a copy of any proposed publication that contains findings with respect to the LDS covered by this Agreement at the time of its submission to a publisher. Such submission by User shall include the condition that Data Owner has thirty (30) days from the date of submission to review such submission. Further, Data Owner may request, and User shall agree to, delay of such proposed publication for an additional period, not to exceed thirty (30) days, to allow Data Owner to review and comment on the publication for the purpose of ensuring that (i) any findings contained within the proposed publication do not

breach the confidentiality of Data Owner's data, by allowing for the identification of the data's subject individuals, and (ii) any findings contained within the proposed publication do not jeopardize Data Owner's business or relationships with customers. Data Owner's failure to provide, within thirty (30) days of receipt of the proposed publication or sixty (60) if an additional period of review is requested, written notification that Data Owner believes the proposed publication breaches this Section 3, the Agreement or applicable law and regulations will be deemed to constitute approval to publish the proposed publication. If Data Owner determines that (i) any finding or findings contained within the proposed publication breach the confidentiality of the Data Owner's data or (ii) any finding or findings contained within the proposed publication jeopardize Data Owner's business or relationships with customers, or (iii) both (i) and (ii) (individually and collectively, "Disputed Findings"), Data Owner has the right to request that User withdraw such submission and otherwise prohibit the publication relating to Disputed Findings. Data Owner shall provide written notification of such a request to withdraw submission or prohibit publication within thirty (30) days of receipt of the proposed publication from User or sixty (60) days if an additional period of review is requested. Data Owner shall exercise such right by sending a written notification to Data Recipient of Data Owner's request to withdraw the proposed publication.

9. **TERM AND TERMINATION**.

a) Term. The term of this DUA shall be effective as of the date written below, and shall terminate on _____ (date not to exceed three years from effective date below); at which time the PHI shall either be returned to Recipient or destroyed with notification to Recipient.

b) Termination for Cause. Should User commit a material breach of this DUA, which is not cured within thirty (30) days after User receives notice of such breach, then the Data Recipient will discontinue disclosure of PHI and will report the problem to the Data Owner.

10. This Agreement contains all the terms and conditions agreed upon by the parties regarding the subject matter of this Agreement and supersedes any prior agreements, oral or written, and all other communications between the parties relating to such subject matter.

CAROLINA COST AND QUALITY INITIATIVE (RECIPIENT):	**PRINCIPAL INVESTIGATOR (USER):**
_____	_____
(Date)	*(Date)*
Cecil G. Sheps Center for Health Services Research and School of Public Health, UNC-CH	_____
(Organization)	*(Organization)*
_____	_____
(Signature)	*(Signature)*
Sandra Greene, DrPH	_____
(Printed Name)	*(Printed Name)*
Chair, CCQI Oversight Committee	_____
(*Title)*	*(Title)*

All other data users sign on page 4

DATA USER:

(Date)

(Organization)

(Signature)

(Printed Name)

(*Title)*

DATA USER:

(Date)

(Organization)

(Signature)

(Printed Name)

(Title)

DATA USER:

(Date)

(Organization)

(Signature)

(Printed Name)

(*Title)*

DATA USER:

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(Date)

(Organization)

(Signature)

(Printed Name)

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