



ROY COOPER
Governor

KEITH WERNER
*Secretary of Information Technology
State Chief Information Officer*

North Carolina Health Information Exchange Authority

Privacy & Security Policies for NC HealthConnex



North Carolina Health Information Exchange Authority Privacy & Security Policies for Use of NC HealthConnex

Introduction

The North Carolina Health Information Exchange Authority (“NC HIEA”) is an agency of the State of North Carolina, housed within the Department of Information Technology’s Government Data Analytics Center (GDAC). The NC HIEA was created by the NC General Assembly in N.C.G.S. 90-414.1, *et seq.*, and NC Session Law 2015-241 §§12A.4 and 12A.5. The NC HIEA has been directed to establish an electronic state-wide health information exchange network, known as NC HealthConnex, to facilitate the exchange of health information among health care providers, health plans and other health industry stakeholders. The goal of NC HIEA is to assist health care organizations in improving the quality and controlling the cost of health care services through enhanced access to medical information and other clinical support. To support that goal, the legislation requires all Medicaid providers to be connected to NC HealthConnex by February 1, 2018, and all other entities that receive state funds for the provision of health services, including managed care organizations and local management entities, to be connected by June 1, 2018.

In addition, the Medicaid Transformation bill requires all prepaid health plans, Medicaid providers, and NC Health Choice providers to submit data to NC HealthConnex in order to ensure effective systems and connectivity to support clinical coordination of care, the exchange of information, and the availability of data to the NC Department of Health and Human Services and the Division of Health Benefits to manage the Medicaid and NC Health Choice programs for the state.

The NC HIEA is committed to health information exchange that is secure and private. Accordingly, the NC HIEA has adopted these Privacy and Security Policies (“Policies”), which govern the use, disclosure, and maintenance of health information available through NC HealthConnex. All individuals and entities that have access to health information through, or otherwise utilize, NC HealthConnex must agree to these Policies.

These Policies do not supersede any applicable state or federal laws or regulations, all of which continue to apply to any activities described in these Policies. These Policies may be amended from time to time by the NC HIEA staff in consultation with the NC HIEA Advisory Board. Definitions include references to laws or regulations as appropriate to illustrate the context and intent of this Policy.

These Policies are effective as of September 29, 2016.



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SECTION 1: DEFINITIONS

- 1.1 Applicable Law** means all applicable statutes and regulations of the State in which the Participant operates, as well as all applicable Federal statutes, regulations, standards and policy requirements.
- 1.2 Authorization** means and includes the requirements set forth at 45 CFR § 164.508 of the HIPAA Regulations and include any similar but additional requirements under Applicable Law.
- 1.3 Authorized User** means an employee or independent contractor of a Participant, or a credentialed member of a Participant's medical or other professional staff, who has been authorized by the Participant to be a user of NC HealthConnex.
- 1.4 Breach, Security Breach** have the meanings assigned in 45 C.F.R. §164.402 and N.C.G.S. 75-61, *et seq.*, as applied in Section 8 of this Agreement.
- 1.5 Business Associate** has the meaning assigned to this term in 45 C.F.R. § 160.103.
- 1.6 Business Associate Agreement** means the written agreement required by 45 C.F.R. §§ 164.502(e) containing the terms set forth in 45 C.F.R. § 164.504(e).
- 1.7 Covered Entity** has the meaning assigned to this term in 45 C.F.R. § 160.103.
- 1.8 De-identified Data** means information that does not identify an Individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an Individual.
- 1.9 Designated Institutional Review Board** means one or more institutional review boards or privacy boards constituted in accordance with 45 C.F.R. § 164.512(i)(1) that have been designated by the NC HIEA, in consultation with the NC HIEA Advisory Board, to review and approve requests by researchers for access to Protected Health Information available through NC HealthConnex for Research.
- 1.10 Disclose, Disclosed, and the noun form, Disclosure** means the release, transfer, provision of access to, or divulging in any other manner of Protected Health Information.
- 1.11 Dispute** means any controversy, dispute, or disagreement arising out of or relating to the Transaction of Messages over the eHealth Exchange through NC HealthConnex.
- 1.12 Dispute Resolution Process** means the process to resolve Disputes arising out of activity transacted over the eHealth Exchange through Participants' use of NC HealthConnex, as described in Section 15.2 of these Policies.
- 1.13 Dispute Resolution Subcommittee** means the standing subcommittee of the eHealth Exchange Coordinating Committee that is established pursuant to the DURSA and performs the tasks described in Section 15.2 of these Policies.
- 1.14 Data Use and Reciprocal Support Agreement or DURSA** means the legally enforceable multi-party trust agreement that the NC HIEA will or has entered into with the eHealth Exchange Coordinating Committee that provides for the secure exchange of electronic health information with other participating entities using an agreed upon set of national standards, services, and policies. The current version of the agreement is called the Restatement I of the Data Use and Reciprocal Support Agreement and was last updated on September 30, 2014.



- 1.15 eHealth Exchange** means the national Health Information Exchange that allows for the secure exchange of electronic Protected Health Information between participants and their participant users who have executed the DURSA and other agreements as required by the eHealth Exchange Coordinating Committee.
- 1.16 eHealth Exchange Coordinating Committee or Coordinating Committee** means the body that oversees the operation of the national eHealth Exchange through the execution of the Data Use and Reciprocal Support Agreement with participants nationwide and through its Operating Policies and Procedures and its Performance and Service Specifications.
- 1.17 Emergency Medical Condition** has the meaning assigned to this term in N.C.G.S. § 90-414.3.
- 1.18 Health Care Operations** has the meaning assigned to this term in 45 C.F.R. § 164.501.
- 1.19 Health Plan** has the meaning assigned to this term in 45 C.F.R. § 160.103.
- 1.20 Health Care Provider** has the meaning assigned to this term in 45 C.F.R. § 160.103.
- 1.21 HIPAA** means the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, as amended, and the implementing regulations at 45 C.F.R. Parts 160 through 164.
- 1.22 Individual** has the meaning assigned to this term in 45 C.F.R. § 160.103.
- 1.23 Message** means an electronic transmission of Message Content Transacted between Participants using the eHealth Exchange Specifications. Messages are intended to include all types of electronic transactions as specified in the Performance and Service Specifications, including the data or records transmitted with those transactions.
- 1.24 Message Content** means that information contained within a Message or accompanying a Message using the Specifications. This information includes, but is not limited to, Protected Health Information (PHI), de-identified data (as defined in the HIPAA Regulations at 45 C.F.R. § 164.514), individually identifiable information, pseudonymized data, metadata, Digital Credentials, and schema.
- 1.25 NC HealthConnex** means the electronic health information exchange network overseen and administered by the NC HIEA.
- 1.26 NC HIEA** means the North Carolina state agency – North Carolina Health Information Exchange Authority - created to operate the statewide electronic health information exchange network pursuant to N.C.G.S. § 90-414.7.
- 1.27 NC HIEA Advisory Board** means the Advisory Board established by N.C.G.S 90-414.8 tasked with providing consultation to the NC HIEA with respect to the advancement, administration, and operation of NC HealthConnex and on matters pertaining to health information technology and exchange.
- 1.28 Notify and the noun form Notice or Notification** means the written communication sent to one or more of a Participant’s representatives identified in the Participation Agreement, the NC HIEA staff, or the eHealth Exchange Coordinating Committee.
- 1.29 Opt Out** has the meaning assigned to this term in N.C.G.S. § 90-414.3(13).



- 1.30 Opt Out Form** means the written or electronic document that records the decision by an Individual or his or her Personal Representative to Opt Out. Individuals can select “Opt Out” on the Opt Out Form to Opt Out. The Opt Out Form is available here: <http://hiea.nc.gov>.
- 1.31 Opt Out Rescission** means the decision communicated in writing by an Individual to allow his or her Protected Health Information maintained by the NC HIEA to be disclosed to other Covered Entities or entities through NC HealthConnex following an earlier decision to Opt Out.
- 1.32 Opt Out Rescission Form** means the written or electronic document that records the decision by an Individual or his or her Personal Representative to rescind or revoke his or her decision to Opt Out. Individuals can select “Rescind Opt Out” on the Opt Out Form to rescind an Opt Out. The Opt Out Rescission Form is available here: <http://hiea.nc.gov>.
- 1.33 Participant** means a Covered Entity, a Provider that is not a Covered Entity, a Business Associate of a Covered Entity or the North Carolina Department of Health and Human Services or a division thereof that has executed the Participation Agreement with NC HIEA.
- 1.34 Participation Agreement** means the written agreement entered into by at least one Participant and NC HIEA governing Participants’ use of NC HealthConnex.
- 1.35 Payment** has the meaning assigned to this term at 45 C.F.R. § 164.501.
- 1.36 Performance and Service Specifications** means the Validation Plan and the Specifications, as well as any implementation guidance, migration plans and other technical materials and resources approved by the Coordinating Committee of the eHealth Exchange in accordance with Section 10.03 of the DURSA. These specifications and other eHealth Exchange are available here: <http://sequoiaproject.org/ehealth-exchange/onboarding/>.
- 1.37 Personal Representative** is a person who is permitted to act on behalf of an Individual with respect to the Individual’s Protected Health Information pursuant to 45 C.F.R. § 164.502(g).
- 1.38 Protected Health Information or PHI** has the meaning assigned to this term in 45 C.F.R. § 160.103.
- 1.39 Provider** means (i) an entity such as a hospital, nursing home, home health agency, adult care home, mental health facility or professional corporation legally authorized to provide health care services in North Carolina, (ii) a health care provider referenced in N.C. General Statutes § 90-21.11 or a resident or student acting under the supervision of such a professional, (iii) a local health department as defined in N.C. General Statutes § 130A-2 or (iv) mental health, developmental disabilities, and substance abuse facilities as referenced in N.C. General Statutes § 122C-3.
- 1.40 Psychotherapy Notes** has the meaning assigned to this term at 45 C.F.R. § 164.501.
- 1.41 Public Health** means the activities and purposes described in 45 C.F.R. § 164.512(b) and in N.C.G.S. Chapter 130A.
- 1.42 Public Health Authority** has the meaning assigned to this term at 45 C.F.R. § 164.501.
- 1.43 Qualified Organization** has the meaning assigned to this term at N.C.G.S. § 90-414.3(16).
- 1.44 Recipient** means the Participant(s) that receives Message Content through a Message from a Submitter for a Permitted Purpose. For purposes of illustration only, Recipients include, but are



not limited to, Participants who receive queries, responses, subscriptions, publications or unsolicited Messages.

- 1.45 Required by Law** means a mandate contained in law that compels an entity to make a use or Disclosure of Protected Health Information and that is enforceable in a court of law. Required by law includes, but is not limited to, court orders and court-ordered warrants; subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.
- 1.46 Research** has the meaning assigned to this term at 45 C.F.R. § 164.501.
- 1.47 Specifications** means the specifications adopted by the eHealth Exchange Coordinating Committee pursuant to the DURSA to prescribe the data content, technical, and security requirements to enable the Participants to Transact Message Content. Specifications may include, but are not limited to, specific Network standards, services and policies. The Specifications may be amended from time to time by the eHealth Exchange Coordinating Committee in accordance with the DURSA and are available at the eHealth Exchange website here: <http://sequoiaproject.org/ehealth-exchange/onboarding/>.
- 1.48 Submitter** means the Participant(s) who submits Message Content through a Message to a Recipient for a Permitted Purpose. For purposes of illustration only, Submitters include, but are not limited to, Participants or Authorized Users who push Messages with Message Content, send Messages seeking Message Content, send Messages in response to a request, send subscription Messages, or publish Messages with Message Content in response to subscription Messages.
- 1.49 Substance Abuse Treatment Records** means the records of federally assisted drug or alcohol abuse treatment facilities and programs that are subject to protection under 42 C.F.R. Part 2.
- 1.50 Transact** shall mean to send, request, receive, assert, respond to, submit, route, subscribe to, or publish Message Content through the eHealth Exchange using the Performance and Service Specifications.
- 1.51 Treatment** means the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another.
- 1.52 Workforce** has the meaning assigned to this term in 45 C.F.R. 160.103.



SECTION 2: ELIGIBLE PARTICIPANTS

- 2.1 Restrictions on Use of NC HealthConnex.** Except as specified in Sections 2.7, 6, 12, and 13, NC HIEA may permit only Participants and their Authorized Users to access or Disclose Protected Health Information through NC HealthConnex.
- 2.2 Covered Entities and Other Providers.** The following persons or entities are eligible to be Participants:
- 2.2.1** Any Covered Entity.
 - 2.2.2** Any Provider that is not a Covered Entity.
 - 2.2.3** Business Associates that are approved by NC HIEA in consultation with the NC HIEA Advisory Board under Section 2.3.
- 2.3 Business Associates.** Pursuant to N.C.G.S. § 90-414.7(b)(9), a Business Associate of a Covered Entity is not eligible to be a Participant unless each of the following requirements is satisfied:
- 2.3.1** A Participant notifies the NC HIEA in writing that it has contracted with a Business Associate that needs access to NC HealthConnex in order to perform functions for the Participant that fall within the scope of the Business Associate Agreement between the Participant and the Business Associate.
 - 2.3.2** The Participant must provide the Business Associate Agreement and any associated data sharing agreements entered into between the Participant and the Business Associate to the NC HIEA.
 - 2.3.3** Any agreement between Participant and the Business Associate shall not contain terms that place limitations or obligations on the NC HIEA or that cause the NC HIEA to incur additional costs.
- 2.4 Contractual Obligations.** Each Participant must enter into the Participation Agreement and a Business Associate Agreement with the NC HIEA to obtain authorization to access or Disclose Protected Health Information through NC HealthConnex.
- 2.5 Participating Affiliates.** Entities that control one another or are under common control may elect to participate in NC HealthConnex as a single Participant or multiple Participants. One entity controls another entity if the first entity has the power to appoint a majority of the members of the second entity's governing body. A Participating Affiliate of a Participant may also be a person or entity with whom the Participant has a direct or indirect business or employee relationship, including any person or entity provided a license or right to access and use any of a Participant's electronic health record system, software and/or services, unless such relationship exists for the primary purpose of providing such person or entity with access to and use of NC HealthConnex.
- 2.6 Qualified Organizations**
- 2.6.1** NC HIEA may designate entities as Qualified Organizations pursuant to N.C.G.S. §90-413.4. Any agreement between the NC HIEA and a Qualified Organization must authorize the NC HIEA or its designees to conduct off-site and on-site audits of the Qualified Organization and its Participants to evaluate compliance with the Policies and any contractual obligations. Such agreement must also require the Qualified Organization to abide by the Policies.



- 2.6.2 The form of a Qualified Organization's Participation Agreement must be approved by the NC HIEA.
- 2.6.3 Each Qualified Organization must enter into a Business Associate Agreement acceptable to the NC HIEA with each of the Qualified Organization's Participants.

2.7 Arrangements with In- and Out-of-State Exchanges and Participants.

- 2.7.1 The NC HIEA may enter into agreements with nationwide, statewide, regional or local electronic health information exchanges operating in or outside the State of North Carolina under which Covered Entities or other health care providers participating in the exchange are granted the right to use NC HealthConnex.
- 2.7.2 Entities operating out-of-state exchanges must agree to (i) abide by the Policies and (ii) require any Covered Entities or other health care providers that gain access to NC HealthConnex through the exchange to abide by the Policies, except as expressly set forth otherwise in the agreement between the exchange and the NC HIEA. For example, application of the Policies may be waived by the NC HIEA if the out-of-state exchange imposes more stringent requirements on its participants or a provision of the Policies is designed to comply with a North Carolina law to which an out-of-state entity is not subject.
- 2.7.3 The NC HIEA is not required to directly enter into a Participation Agreement or Business Associate Agreement with any Covered Entity or other health care provider that gains access to NC HealthConnex through an out-of-state exchange.



SECTION 3: ACCESS TO PROTECTED HEALTH INFORMATION FOR TREATMENT, PAYMENT AND HEALTH CARE OPERATIONS; NATIONAL EHEALTH EXCHANGE REQUIREMENTS

- 3.1 Purposes for Access.** Except as specified in Sections 10 and 12, Authorized Users may access Protected Health Information through NC HealthConnex only to carry out Treatment, Payment or Health Care Operations, or for the Permitted Purposes as outlined in the Participation Agreement. Each user accessing NC HealthConnex will have a defined role. The NC HIEA User Access Policy ensures each user will only have access to information necessary to conduct activities associated with that role.
- 3.2 Need for Relationship with Individual.** An Authorized User may access an Individual's Protected Health Information through NC HealthConnex to carry out Treatment, Payment or Health Care Operations only in the following circumstances:
- 3.2.1** The Authorized User has obtained access to NC HealthConnex through a Participant that is a Provider and the Provider has a Treatment relationship with the Individual.
- 3.2.2** The Authorized User has obtained access to NC HealthConnex through a Participant that is a Health Plan and the Individual is receiving or has received health benefits from the Health Plan.
- 3.3** The NC HIEA and its participating providers will have responsibilities related to access. The NC HIEA will make this policy known through the publication of these Policies, the NC HIEA User Access Policy, and through participant outreach and education. The NC HIEA can enforce these obligations pursuant to the Participation Agreement and/or Business Associate Agreement.
- 3.4 National eHealth Exchange.** Participation by the NC HIEA in the national eHealth Exchange, through execution of the DURSA, requires that the NC HIEA replicate terms and policies included in the DURSA in the NC HIEA Participation Agreements or governance policies. The following requirements shall apply solely when Participants, through NC HealthConnex, acquire, access, or Disclose Protected Health Information over the national eHealth Exchange.
- 3.4.1 Permitted Purposes.** The following are the Permitted Purposes for Transacting Messages and otherwise requesting, retrieving, and sending data over the eHealth Exchange:
- a. Treatment of the individual who is the subject of the Message;
 - b. Payment activities of the Health Care Provider for the individual who is the subject of the Message which includes, but is not limited to, Transacting Message Content in response to or to support a claim for reimbursement submitted by a Health Care Provider to a Health Plan. **Please note: Participants are not permitted to send Payment Card Industry ("PCI") data through NC HealthConnex.**
 - c. Health Care Operations of either
 - i. The Submitter if the Submitter is a Covered Entity;
 - ii. A Covered Entity if the Submitter is Transacting Message Content on behalf of such Covered Entity; or
 - iii. The Recipient if (i) the Recipient is a Health Care Provider who has an established Treatment relationship with the individual who is the subject of the Message or the Recipient is Transacting Message Content on behalf



of such Health Care Provider; and (ii) the purpose of the Transaction is for those Health Care Operations listed in paragraphs (1) or (2) of the definition of Health Care Operations in 45 C.F.R. § 164.501 or health care fraud and abuse detection or compliance of such Health Care Provider;

- d. Public health activities and reporting as permitted by Applicable Law, including the HIPAA Regulations at 45 C.F.R. § 164.512(b) or 164.514(e);
- e. Any purpose to demonstrate meaningful use of certified electronic health record technology by the (i) Submitter, (ii) Recipient or (iii) Covered Entity on whose behalf the Submitter or the Recipient may properly Transact Message Content in compliance with these Policies and the DURSA, provided that the purpose is not otherwise described in 3.4.1a-d of this Section 3.4 and the purpose is permitted by Applicable Law, including but not limited to the HIPAA regulations. “Meaningful use of certified electronic health record technology” shall have the meaning assigned to it in the regulations promulgated by the Department of Health and Human Services under the American Recovery and Reinvestment Act, Sections 4101 and 4102; and
- f. Uses and disclosures pursuant to an Authorization provided by the individual who is the subject of the Message or such individual’s personal representative as described in 45 C.F.R. § 164.502(g) of the HIPAA Regulations.

3.4.2 Specific Duties of a Participant When Submitting a Message. Whenever a Participant acts as a Submitter by submitting a Message to another Participant, the Submitter shall be responsible for:

- a. Submitting each Message in compliance with Applicable Law, this Agreement, the applicable Performance and Service Specifications, and Operating Policies and Procedures including, but not limited to, representing that the Message is:
 - i. for a Permitted Purpose;
 - ii. submitted by a Submitter who has the requisite authority to make such a submission;
 - iii. supported by appropriate legal authority for Transacting the Message Content including, but not limited to, any consent or Authorization, if required by Applicable Law; and
 - iv. submitted to the intended Recipient.
- b. Representing that assertions or statements related to the submitted Message are true and accurate, if such assertions or statements are required by the eHealth Exchange Performance and Service Specifications or Operating Policies and Procedures;
- c. Submitting a copy of the Authorization, if the Submitter is requesting Message Content from another Participant or Participant User based on the Permitted Purpose described in Section 3.4.1f. Nothing in this Section shall be interpreted as requiring a Submitter who is requesting Message Content to obtain or transmit an Authorization for a request based on a Permitted Purpose other than the one described in Section 3.4.1f, even though certain other Participants or Participant Users require such Authorization to comply with Applicable Law.



- 3.4.3 Additional Requirements.** All Participants must do the following when Transacting Messages over the eHealth Exchange through NC HealthConnex:
- a.** Comply with all Applicable Law;
 - b.** Reasonably cooperate with the NC HIEA on issues related to the DURSA;
 - c.** Use Message Content received from another eHealth Exchange Participant in accordance with the terms and conditions of the DURSA;
 - d.** Respond to all Messages received from eHealth Exchange Participants that request Message Content for Treatment by either (i) responding to the Message with the requested Message Content or, (ii) responding with a standardized response that indicates the Message Content is not available or cannot be exchanged;
 - e.** As soon as reasonably practicable after determining that a Breach occurred, report such Breach to the NC HIEA (see Section 8 Breach);
 - f.** Refrain from disclosing to any other person any passwords, certificates, or any other security measures issued to the Participant by the NC HIEA, SAS, or the eHealth Exchange; and
 - g.** Appropriately discipline Authorized Users who fail to act in accordance with these Policies or the DURSA.
- 3.4.4** Participants must Transact Message Content over the eHealth Exchange in accordance with the terms of the DURSA and must comply with the eHealth Exchange Performance and Service Specifications and the Operating Policies and Procedures. These policies are available at the eHealth Exchange website available here: <http://sequoiaproject.org/ehealth-exchange/onboarding/>.



SECTION 4: MINIMUM NECESSARY REQUIREMENT AND LIMITATIONS ON USE AND DISCLOSURE OF DATA

- 4.1 Obligations of Authorized Users.** Subject to Section 4.1.1, Authorized Users must make reasonable efforts to use or Disclose only the minimum amount of Protected Health Information available through NC HealthConnex that is necessary to carry out the authorized purpose for which such Protected Health Information is used or Disclosed.
- 4.1.1 Minimum Necessary Policies and Criteria.** Pursuant to 45 C.F.R. §§ 164.502(b) and 164.514(d), each Participant must limit the amount of Protected Health Information used or Disclosed by its Authorized Users for recurring and routine purposes to the minimum amount necessary to carry out the authorized purpose. Each Participant must establish criteria governing the amount of Protected Health Information accessed, used, and Disclosed by its Authorized Users for other purposes that are designed to limit such access to the amount of Protected Health Information necessary to carry out the authorized purpose.
- 4.1.2 Treatment Exception.** Pursuant to 45 C.F.R. 164.514(d) (2), obligations set forth in this Section 4 do not apply to the use or Disclosure of Protected Health Information by a Provider for Treatment.
- 4.2 Reliance on Access Requests.** A Participant making a Disclosure of Protected Health Information through NC HealthConnex may rely on compliance with this Section 4 by Participants accessing Protected Health Information through NC HealthConnex. A Participant making such a Disclosure is not required to take any additional steps to restrict the availability of its own Protected Health Information through NC HealthConnex, except as expressly required by other provisions of the Policies or Applicable Law.
- 4.3 Record Searches.** When searching any master patient index, record locator service or other similar system made available by the NC HIEA to locate records about an Individual through NC HealthConnex, an Authorized User must follow any search guidelines established by the NC HIEA and make reasonable efforts to minimize instances in which the Protected Health Information of the wrong Individual is inadvertently accessed by the Authorized User. The minimum required search criteria are listed in the NC HIEA User Access Policy.
- 4.4 Additional Limitations of Access, Disclosure, and Use**
- 4.4.1 Psychotherapy Notes.** Pursuant to 42 C.F.R. 164.508, Participants shall not include Psychotherapy Notes in the Protected Health Information made available through NC HealthConnex unless (i) the Individual or his or her Personal Representative has signed an authorization form that complies with Applicable Law permitting the Disclosure of such information and (ii) the information is identified in NC HealthConnex as subject to restrictions on re-disclosure absent additional authorization. Participant must retain a copy of all authorization forms as required by Applicable Law and may be required to present such form to demonstrate compliance with HIPAA.
- 4.4.2 Substance Abuse Information.** Pursuant to 42 C.F.R. Part 2, Participants shall not include Substance Abuse Treatment Records in the Protected Health Information made available through NC HealthConnex unless (i) the Individual or his or her Personal Representative has signed an authorization form that complies with Applicable Law permitting the Disclosure of such information and (ii) the information is identified in NC HealthConnex as subject to restrictions on re-disclosure absent additional authorization. Participant must retain a copy of all authorization forms as required by Applicable Law and may be required to present such form to demonstrate compliance with 42 C.F.R. Part 2.



SECTION 5: OPT OUT RIGHTS

- 5.1 Right of Individuals to Opt Out.** In accordance with 45 C.F.R. § 164.522 and N.C.G.S. § 90-414.10, an Individual may elect to Opt Out of having his or her information disclosed through NC HealthConnex at any time. A Personal Representative may Opt Out on behalf of an Individual.
- 5.2 Use of Opt Out Form.** The NC HIEA's Opt Out form is available at <http://hiea.nc.gov>. The Opt Out Form may be amended by the NC HIEA from time to time.
- 5.3 Contents of Opt Out Form.**
- 5.3.1** The Opt Out Form shall include the following information:
- a.** A notice that Participants are authorized to Disclose an Individual's Protected Health Information through NC HealthConnex unless and until the Individual elects to Opt Out by completing and submitting the Opt Out Form.
 - b.** A notice that an Individual's decision to Opt Out will not prevent Participants from Disclosing an Individual's Protected Health Information through NC HealthConnex for Public Health, Research, or other purposes as Required by Law.
 - c.** A notice that an Individual's decision to Opt Out will not affect the Individual's right to receive health care services or benefits from Participants.
 - d.** An explanation of:
 - i.** The purpose and basic functions of NC HealthConnex.
 - ii.** The types of Protected Health Information that are exchanged through NC HealthConnex.
 - iii.** The types of Participants that may Disclose and access Protected Health Information through NC HealthConnex.
 - iv.** The purposes for which Protected Health Information is exchanged through NC HealthConnex.
 - v.** The effect of a decision to Opt Out on access to Protected Health Information to treat an Emergency Medical Condition.
 - vi.** How to submit an Opt Out Form.
 - vii.** Where to obtain additional information about NC HealthConnex.
- 5.3.2** The Opt Out Form shall contain the following elements:
- a.** A field in which the Individual may indicate that he or she is electing to prohibit all Participants from accessing his or her Protected Health Information through NC HealthConnex.
 - b.** The demographic information determined by the NC HIEA to be necessary for accurate matching of Individuals in NC HealthConnex.



5.4 Processing of Opt Out Requests by the NC HIEA.

5.4.1 The NC HIEA shall post the Opt Out Form prominently on its website and will make it publicly available to all Individuals and Participants. The NC HIEA shall permit Individuals or their Personal Representatives to complete and submit the Opt Out Form by mail.

5.4.2 Upon receipt of an Opt Out Form by mail, the NC HIEA will contact the patient to confirm the request via phone or by mail. The NC HIEA shall maintain records of all Opt Outs for six (6) years.

5.5 Opt Out Notification by Participants.

5.5.1 Provider Participants that provide face-to-face Treatment to Individuals shall update their practice privacy statements to include language around the electronic exchange of clinical information through NC HealthConnex and Individuals' rights to Opt Out.

5.6 Implementation of Opt Outs. The NC HIEA shall employ technical measures to prevent the Disclosure of any Protected Health Information through NC HealthConnex that is subject to an Opt Out. Such measures shall be implemented within fifteen (15) calendar days of the completion of the Opt Out verification process described in this Section 5. Notwithstanding the foregoing, the NC HIEA may permit Protected Health Information subject to an Opt Out to be Disclosed through NC HealthConnex to provide Treatment for a Medical Emergency Condition in accordance with Section 7 in response to court orders, subpoenas or discovery requests in accordance with Section 11, for Public Health in accordance with Section 12, or for Research in accordance with Section 13.

5.7 Opt Out Rescission Process.

5.7.1 An Individual or his or her Personal Representative may rescind his or her decision to Opt Out at any time.

5.7.2 Within the Opt Out Form, NC HIEA shall include a field where an Individual or Personal Representative can signify his or her decision to rescind their previous Opt Out. The submission of an Opt Out Rescission Form in accordance with this Section 5 shall be the sole means by which an Individual may rescind his or her decision to Opt Out. No Participant shall use any other mechanism to rescind an Individual's decision to Opt Out. The Opt Out Rescission Form may be amended by the NC HIEA from time to time.

5.7.3 The Opt Out Rescission Form shall include the elements relating to the Individual included in Section 5.3 and shall be distributed and collected according to the methods set forth in Section 5.4.

5.8 Maintenance of Protected Health Information in NC HealthConnex. A Participant may maintain a copy of its Protected Health Information in a computer system operated by the NC HIEA without regard to whether an Individual has elected to Opt Out.

5.9 Restrictions on the Disclosure of Certain Information. If Protected Health Information is not subject to an Opt Out, such information may be Disclosed through the NC HIEA for any purpose permitted by the Policies, except that Participants shall not include Psychotherapy Notes, Substance Abuse Treatment Records, or other information that may not be Disclosed without a patient's authorization under federal law in the Protected Health Information made available through NC HealthConnex unless (i) the Individual or his or her Personal Representative has signed an authorization form that complies with Applicable Law permitting the Disclosure of such information and (ii) the information is identified in NC HealthConnex as subject to restrictions on



re-disclosure absent additional authorization. See Section 4.6 of these Policies for additional information on these limitations.

5.10 Education and Awareness.

5.10.1 By the NC HIEA. Pursuant to N.C.G.S. 90-414.7, the NC HIEA shall engage in public awareness to educate North Carolina residents and Providers about NC HealthConnex, including the right of Individuals and their Personal Representatives to Opt Out.

5.10.2 By Participants. Pursuant to N.C.G.S. 90-414.7 and the Participation Agreement, Participants are required to educate their patients about NC HealthConnex, including the right of Individuals and their Personal Representatives to Opt Out. At a minimum, Participants' notices of privacy practices must include language surrounding the disclosure of PHI to NC HealthConnex pursuant to 45 C.F.R. 164.520 and must make the notice available to all affected Individuals.



SECTION 6: ACCESS RIGHTS OF THE NC HIEA WORKFORCE; SECURITY CONTROLS

- 6.1 Authorized Purposes.** The NC HIEA, and its technology vendor SAS Institute, may authorize their respective Workforces to access Protected Health Information through NC HealthConnex only to the extent consistent with the terms of the NC HIEA's Business Associate Agreements with Participants and only for one or more of the following purposes:
- 6.1.1** To facilitate the Disclosure of Protected Health Information to Participants or for Public Health purposes as permitted by the Policies;
 - 6.1.2** To process or otherwise implement Opt Out requests;
 - 6.1.3** To perform patient identity or patient records maintenance;
 - 6.1.4** To conduct or assist in the performance of audits permitted or required by the Policies, including audits of Emergency Access required by Section 5;
 - 6.1.5** To perform data analysis on behalf of and at the request of one or more Participants, to the extent consistent with HIPAA and the Policies;
 - 6.1.6** To evaluate the performance of or develop recommendations for improving the operation of NC HealthConnex;
 - 6.1.7** To conduct technical system support and maintenance on NC HealthConnex; or
 - 6.1.8** To engage in any other activities reasonably related to the operation of NC HealthConnex that are authorized by the NC HIEA staff, and are consistent with Applicable Law.
- 6.2 Role-Based Access.** The NC HIEA and SAS shall establish role-based access standards reasonably designed to enable each Workforce member to access only such Protected Health Information that is necessary for the performance of his or her authorized activities. These standards shall ensure that the NC HIEA Workforce members access and use only the minimum necessary amount of Protected Health Information reasonably required to carry out the authorized purpose. These role-based access standards are provided in the NC HIEA User Access Policy.
- 6.3 Training.** Each NC HIEA and SAS Workforce member must review these Policies and receive training on HIPAA before being granted access to Protected Health Information through NC HealthConnex and at least annually thereafter.
- 6.4 Discipline for Non-Compliance.** The NC HIEA and SAS shall discipline Workforce members who violate the Policies or engage in any other unauthorized or inappropriate behavior that undermines the privacy or security of Protected Health Information available through NC HealthConnex or through the eHealth Exchange. Depending on the circumstances, disciplinary measures may include verbal and written warnings, retraining, demotion, suspension or termination of employment.
- 6.5 Reporting and Non-Retaliation.** The NC HIEA and SAS shall require all Workforce members to report any actual or suspected violation of the Policies of which they become aware. No Workforce member may be subject to retaliation of any kind for reporting a violation in good faith.
- 6.6 Business Associates.** The NC HIEA and SAS may authorize its own Business Associates to access Protected Health Information for a purpose that is consistent with Section 6.1, provided that



the NC HIEA or SAS has entered into a Business Associate Agreement with the Business Associate.

6.7 NC HIEA Security Controls

- 6.7.1 **Statewide Security Policies.** The NC HIEA, its technology vendor, and any agency of the State of North Carolina that has access to NC HealthConnex must abide by the Department of Information Technology's Statewide Information Security Manual.
- 6.7.2 **HIPAA Safeguards.** The NC HIEA will ensure that all required administrative, physical, and technical safeguards are implemented in the hosting and operation of NC HealthConnex as required by the HIPAA Security Rule found at 45 CFR Parts 160 and 164.



SECTION 7: EMERGENCY ACCESS TO RECORDS OF OPTED OUT INDIVIDUALS

- 7.1 Standards for Emergency Access.** In accordance with 45 C.F.R. §164.522(a)(1)(iii) and N.C.G.S. § 90-414.10, Authorized Users may access Protected Health Information maintained by Participants about an Individual who has exercised his or her right to Opt Out of Disclosures by such Participants if all of the following requirements are satisfied:
- 7.1.1** The reasonably apparent circumstances indicate to the Authorized User that (i) the Individual has an Emergency Medical Condition; (ii) a meaningful discussion with the Individual or his or her Personal Representative about whether to rescind a previous decision to Opt Out is impractical due to the nature of the Individual's Emergency Medical Condition; and (iii) information available through NC HealthConnex could assist in the diagnosis or Treatment of the Individual's Emergency Medical Condition.
- 7.1.2 IMPORTANT NOTE.** Currently, only an NC HIEA or SAS staff member who occupies an authorized administrator or privacy officer role can Opt In an Opted Out Individual in order for an Authorized User to access and use the Individual's clinical data through NC HealthConnex during an emergency.
- 7.2 Attestation.** The NC HIEA shall ensure that the Protected Health Information of Individuals who have exercised their right to Opt Out is not accessible to Authorized Users under this Section 7 unless the Authorized User seeking such access provides an attestation electronically through NC HealthConnex at the time he or she requests access stating that all of the conditions specified in Section 7.1 are satisfied. All such attestations shall be stored electronically by the NC HIEA for a period of at least six (6) years.
- 7.3 Termination of Emergency Access.** Authorized Users shall cease emergency access of an Individual's Protected Health Information under this Section 7 promptly upon (i) stabilization of the Individual's Emergency Medical Condition or (ii) a request by the Individual or his or her Personal Representative to cease such access.
- 7.4 Audit Trail.** The NC HIEA shall conduct periodic audits to evaluate whether Authorized Users are engaging in emergency access of Protected Health Information through NC HealthConnex in accordance with this Section 7. The NC HIEA may delegate the responsibility for conducting such audits to SAS, Participants, Qualified Organizations or other parties if (i) the NC HIEA approves the audit protocols used by SAS, the Participant, Qualified Organization or other party for each audit and (ii) the results of each audit are provided in writing to the NC HIEA. All audit findings must be maintained by the NC HIEA for a period of six (6) years.



SECTION 8: BREACH

- 8.1 Security Breach** shall have the meaning assigned in N.C.G.S. 75-61: the incident of unauthorized access to and acquisition of unencrypted and unredacted records or data containing personal information where illegal use of the personal information has occurred or is reasonably likely to occur or that creates a material risk of harm to an individual. Any incident of unauthorized access to and acquisition of encrypted records or data containing personal information along with the confidential process or key shall constitute a security breach. Good faith acquisition of personal information by an employee or agent of the business for a legitimate purpose is not a security breach, provided that the personal information is not used for a purpose other than a lawful purpose of the business and is not subject to further unauthorized disclosure.
- 8.1.1 Responsibilities of Participants.** Participants must Notify the NC HIEA and all affected Individuals if the Participant becomes aware of a Security Breach. Notification shall be made as expediently as possible and without unreasonable delay after learning of the actual or suspected Security Breach in accordance with N.C.G.S. § 75-65.
- 8.1.2 Responsibility of the NC HIEA.** The NC HIEA must comply with the Department of Information Technology Incident Reporting Policy and the Security Breach Notification requirements outlined in N.C.G.S. § 75-65.
- 8.2 HIPAA Breach or Breach** shall have the meaning assigned in 45 C.F.R. 164.402: the acquisition, access, use, or Disclosure of Protected Health Information in a manner not permitted under 45 CFR 164 subpart E which compromises the security or privacy of the protected health information.
- 8.3** The term “Breach”, under this subsection 8.2, shall not include any unintentional acquisition, access, Disclosure, or use of Protected Health Information by an employee or individual acting under the authority of the NC HIEA or a Participant or Authorized User if:
- 8.3.1** Such acquisition, access, Disclosure, or use was made in good faith and within the course and scope of the employment or other professional relationship of such employee or individual, respectively, with the NC HIEA, a Participant or an Authorized User, and
- 8.3.2** Such Protected Health Information is not further acquired, accessed, used, or Disclosed by such employee or individual.
- 8.3.3** The term Breach also shall not include any acquisition, access, Disclosure or use of Protected Health Information contained in or available through the Participant’s system where such acquisition, access, Disclosure or use was not directly related to Disclosure of Protected Health Information through NC HealthConnex.
- 8.4 HIPAA Breach Notification.**
- 8.4.1 Responsibilities of Participants.** Participants must Notify the NC HIEA and all affected Individuals if the Participant becomes aware of any actual or suspected Breach through NC HealthConnex. Notification shall be made as expediently as possible and without unreasonable delay after learning of the actual or suspected Breach. Participants must also comply with obligations to report Breaches or security incidents as required by Applicable Law.
- a. eHealth Exchange Breach:**
- i.** Within one (1) hour of discovering information that leads the Participant to reasonably believe that a Breach may have occurred involving data



Transacted over the eHealth Exchange, it shall alert the NC HIEA and all Participants whose Message Content may have been Breached.

- ii. As soon as reasonably practicable, but no later than twenty-four (24) hours after determining that a Breach has occurred involving data Transacted over the eHealth Exchange, the Participant shall provide a Notification to the NC HIEA and all Participants likely impacted by the Breach.
- iii. Participant shall assist the NC HIEA and the eHealth Exchange Coordinating Committee in alerting or Notifying the potentially affected Participants whose PHI may have been or was actually Breached over the eHealth Exchange.

8.4.2 Responsibilities of the NC HIEA

- a. If the NC HIEA becomes aware of any actual or suspected Breach, either through Notification by a Participant or otherwise, the NC HIEA must, at a minimum, Notify any Participants whose HIE Data is affected by the Breach. Such Notification shall be made as expediently as possible and without unreasonable delay. The NC HIEA must also comply with obligations to report Breaches or security incidents as required by Applicable Law.
- b. **eHealth Exchange Breach:**
 - i. Within one (1) hour of discovering information that leads the NC HIEA to reasonably believe that a Breach may have occurred involving data Transacted over the eHealth Exchange, it shall alert other Participants whose Message Content may have been Breached and the Coordinating Committee.
 - ii. As soon as reasonably practicable, but no later than twenty-four (24) hours after determining that a Breach has occurred involving data Transacted over the eHealth Exchange, the NC HIEA shall provide a Notification to all Participants likely impacted by the Breach and the Coordinating Committee.
 - iii. The NC HIEA shall assist the eHealth Exchange Coordinating Committee in alerting or Notifying the potentially affected Participants whose PHI may have been or were actually Breached over the eHealth Exchange.

8.4.3 Contents of Notification. The Notification required by this Section 8 shall include sufficient information for the NC HIEA, impacted Participants and Individuals, and, if applicable, the eHealth Exchange Coordinating Committee, to understand the nature and extent of the Breach. For instance, such Notification should include, to the extent available at the time of the Notification, the following information:

- a. A brief description of what happened, including the date of the Breach and the date of discovery of the Breach, if known;
- b. The identification of each Individual whose Protected Health Information has been, or is reasonably believed to have been, accessed, acquired, used, or Disclosed during the Breach;
- c. Description of the roles of the people involved in the Breach (e.g., employees, Authorized Users, service providers, unauthorized persons, etc.);
- d. Description of the types of Protected Health Information that were involved in the Breach (whether full name, Social Security number, date of birth, home address, account number, diagnosis, disability code, or other types of information were involved);



- e. List of Participants likely impacted by the Breach;
- f. Number of Individuals or records impacted/estimated to be impacted by the Breach;
- g. Description of actions taken to investigate the Breach, to mitigate harm to Individuals, and to protect against any further Breach;
- h. Current status of the Breach (under investigation or resolved);
- i. Contact procedures for Individuals to ask questions or learn additional information, which shall include a telephone number, an e-mail address, web site, or postal address; and

Corrective action taken and steps planned to be taken to prevent a similar Breach.

- 8.4.4** The Notifying party shall have a duty to supplement the information contained in the Notification as it becomes available and to cooperate with other Participants, the NC HIEA, and, if applicable, the eHealth Exchange Coordinating Committee, in mitigating the effects of the Breach. Except as provided for in Section 8.4.3b, the notification required by this Section 8 shall not include any Protected Health Information.
- 8.4.5** The NC HIEA will provide, in a timely manner, a summary of the Breach to such Participants that does not identify any of the Participants or Individuals involved in the Breach.
- 8.4.6** This Section 8 shall not be deemed to supersede or relieve a party's reporting obligations (if any) under relevant security incident, breach notification or confidentiality provisions of Applicable Law, including, but not limited to, those related to Individuals.
- 8.4.7** The parties shall use all reasonable efforts to coordinate any notification to Individuals, any applicable regulatory agencies, and any public announcement regarding the Breach that may be required by Applicable Law or the policies of a party. Notwithstanding the foregoing, the party that is legally required to make the notification and/or public announcement shall have final approval of the contents of any such notification or announcement.



SECTION 9: ACCOUNTINGS OF DISCLOSURES

9.1 Tracking of Disclosures by the NC HIEA. In accordance with 45 C.F.R. § 164.528, the NC HIEA shall ensure that NC HealthConnex has the capacity to track all Disclosures of each Participant's Protected Health Information made through NC HealthConnex. Disclosures shall be tracked in accordance with the following standards:

9.1.1 If the Disclosure is from the NC HIEA to another party for Public Health, Research or any other purpose permitted by the Policies or HIPAA, a record of the Disclosure must be maintained by the NC HIEA for six (6) years from the date of the Disclosure. The information tracked for each such Disclosure shall include:

- a. The date of the Disclosure;
- b. The name of the entity or person who received the Protected Health Information and, if known, the address of such entity or person;
- c. A brief description of the Protected Health Information disclosed; and
- d. A brief statement of the purpose of the Disclosure that reasonably informs the Individual of the basis for the Disclosure.

9.1.2 If the NC HIEA Discloses the Protected Health Information of fifty (50) or more Individuals for Research, the information tracked shall be sufficient to enable a Participant to provide an accounting to the Individual that includes:

- a. The name of the protocol or other Research activity.
- b. A description, in plain language, of the Research protocol or other Research activity, including the purpose of the Research and the criteria for selecting particular records.
- c. A brief description of the type of Protected Health Information that was Disclosed.
- d. The date or period of time during which such Disclosures occurred, or may have occurred, including the date of the last such Disclosure during the accounting period.
- e. The name, address, and telephone number of the entity that sponsored the Research and of the researcher to whom the information was Disclosed.
- f. A statement that the Protected Health Information of the Individual may or may not have been Disclosed for a particular protocol or other Research activity.

9.1.3 Disclosures Excluded from HIPAA Accounting. Certain disclosures are excluded from the HIPAA accounting requirement. Participants and Individuals do not have a right under HIPAA to obtain an accounting of disclosures made:

- a. To carry out treatment, payment and health care operations as provided in 45 C.F.R. §164.506;
- b. To individuals of Protected Health Information about them as provided in 45



C.F.R. §164.502;

- c. Incident to a use or Disclosure otherwise permitted or required by this subpart, as provided in 45 C.F.R. §164.502;
- d. Pursuant to an authorization as provided in 45 C.F.R. §164.508;
- e. For the facility's directory or to persons involved in the individual's care or other notification purposes as provided in 45 C.F.R. §164.510;
- f. For national security or intelligence purposes as provided in 45 C.F.R. §164.512(k)(2);
- g. To correctional institutions or law enforcement officials as provided in 45 C.F.R. §164.512(k)(5);
- h. As part of a limited data set in accordance with 45 C.F.R. §164.514(e); or
- i. Prior to March 1, 2016, the date that NC HealthConnex became operational and subject to HIPAA.

9.2 Requests for Accountings by Participants.

- 9.2.1** A Participant may request that the NC HIEA provide the Participant with an accounting of Disclosures of an Individual's Protected Health Information made through NC HealthConnex to enable the Participant to respond to a request for an accounting by the Individual or his or her Personal Representative under HIPAA. Participants must make such requests in accordance with these procedures and utilizing forms adopted by the NC HIEA.
- 9.2.2** The NC HIEA shall respond to all requests for accountings by Participants within 60 days of the NC HIEA's receipt of the request. The NC HIEA's response shall include, for each Disclosure for which an accounting must be provided, all of the information that the NC HIEA is obligated to track under Section 9.1 and as required by HIPAA.

9.3 Requests for Accounting by Individuals.

- 9.3.1** Upon the receipt of accounting requests from Individuals or their Personal Representatives, the NC HIEA shall forward the request to all Participants whose Protected Health Information is subject to the request and notify the Individual or Personal Representative that such Participants will be preparing a response. In those cases where Individuals or Personal Representatives prefer not to receive a response from the Participants, Individuals may complete an Accounting of Disclosure Request form found here: <https://HIEA.nc.gov>.
- 9.3.2** The NC HIEA shall respond to all requests for accountings by Individuals within 60 days of the NC HIEA's receipt of the request. The NC HIEA's response shall include, for each Disclosure for which an accounting must be provided, all of the information that the NC HIEA is obligated to track under Section 9.1 and as required by HIPAA.



SECTION 10: RESTRICTIONS ON ACCESS BY HEALTH PLANS

- 10.1 Acceptance of Restriction Requests by Providers.** All Providers must have a process for accepting written requests by Individuals or their Personal Representatives that Protected Health Information relating to the Individual's receipt of a particular health care item or service from the Provider not be Disclosed by the Provider to a Health Plan for Payment or Health Care Operations. Providers are obligated to grant such requests if the Individual or his or her Personal Representative agrees to pay the Provider in full for the health care items or services subject to such restriction.
- 10.2 Notifying the NC HIEA of Restriction Requests.** Providers agreeing to restriction requests under Section 10.1 must notify the NC HIEA of all such restrictions in a manner and time period that will enable the NC HIEA to implement the restriction in accordance with 45 C.F.R. § 164.522. Notification may be provided in either of the following ways:
- 10.2.1** The Provider may electronically tag, segregate or otherwise identify the records subject to the restriction request in its electronic health record system in accordance with technical standards approved by the NC HIEA designed to ensure that such records are not Disclosed to Health Plans through NC HealthConnex.
- 10.2.2** The Provider may notify the NC HIEA of the restriction in writing.
- 10.3 Implementation of Restrictions on Disclosures to a Health Plan.** The NC HIEA shall employ technical measures to implement the restrictions transmitted by Providers under Section 10.2. These measures shall ensure that any Protected Health Information subject to a restriction is not accessible to any Health Plan through NC HealthConnex.



SECTION 11: RESPONDING TO SUBPOENAS AND DISCOVERY REQUESTS

- 11.1 Disclosures in Response to Court Orders.** Pursuant to 45 C.F.R. § 164.512(e) and (f), the NC HIEA may Disclose Protected Health Information in its possession in response to a court order or for law enforcement purposes provided that the NC HIEA Discloses only the Protected Health Information expressly authorized by such order or request.
- 11.2 Disclosures in Response to Subpoenas and Discovery Requests.**
- 11.2.1** Subject to Section 11.3, the NC HIEA may Disclose Protected Health Information in response to a subpoena, discovery request or other lawful process that is not accompanied by an order of a court only if the subpoena, discovery request or other lawful process is accompanied by a written authorization from the Individual who is the subject of the requested Protected Health Information.
- 11.2.2** The NC HIEA shall respond to subpoenas, discovery requests or other lawful processes that do not satisfy the requirements of Section 11.1 or 11.2.1 by transmitting a written objection to the party requesting the Protected Health Information setting forth the need for either a court order or a written authorization from the Individual in connection with such request.
- 11.3 Opportunity for Participants to Resist Request.** The NC HIEA shall notify all Participants whose Protected Health Information is the subject of pending litigation and is subject to a potential Disclosure under Section 11.2 of the NC HIEA's intention to make the Disclosure no less than five (5) days prior to the anticipated date of the Disclosure. The NC HIEA shall not Disclose any Participant's Protected Health Information if (i) the Participant notifies the NC HIEA within such five-day period of the Participant's intention to move to quash the subpoena or otherwise resist the request and (ii) the Participant takes such action within the time period necessary to prevent the NC HIEA from failing to comply with any legal duty to which it is subject. The NC HIEA shall not make any Disclosure under this Section 11 to the extent any request for Protected Health Information is withdrawn by the requesting party or rejected by a court or administrative tribunal in response to an objection by a Participant.
- 11.4 No Obligation to Search Participant Records.** Under this Section 11, the NC HIEA shall Disclose only those records under its custody and control. The NC HIEA shall not Disclose any records that the NC HIEA may be capable of obtaining by conducting searches through NC HealthConnex of the records maintained by Participants in their own record systems.
- 11.5 Consultation with Counsel.** The NC HIEA shall consult with its counsel regarding its authority to Disclose Protected Health Information under this Section 11 prior to making any such Disclosure.
- 11.6 Minimum Necessary.** The NC HIEA shall Disclose only the minimum necessary Protected Health Information in response to requests covered by this Section 11.
- 11.7 Verification of Identity.** The NC HIEA shall verify the identity and authority of the requesting party prior to Disclosing Protected Health Information under this Section 11.
- 11.8 Accounting of Disclosures.** The NC HIEA shall maintain a record of Disclosures made under this Section 11 in accordance with Section 9.1.1 of the Policies.



SECTION 12: ACCESS TO DATA BY GOVERNMENT AGENCIES

- 12.1 Disclosures Required by Law.** The NC HIEA may Disclose Protected Health Information to a government agency or its representatives or agents when the Disclosure is Required by Law. Nothing in this Section 12.1 shall be construed as obligating the NC HIEA to Disclose Protected Health Information to a government agency on behalf of a Participant when the Participant, rather than the NC HIEA, is Required by Law to make the Disclosure.
- 12.2 Disclosures for Public Health Purposes.** Pursuant to 45 C.F.R. § 164.512(b), N.C.G.S. Chapter 130A, and other Applicable Law, the NC HIEA may Disclose Protected Health Information to Public Health Authorities or other government agencies for Public Health purposes. The NC HIEA shall approve the general types of Public Health purposes for which Protected Health Information may be Disclosed under this Section 12.2.
- 12.3 Minimum Necessary.** The NC HIEA shall Disclose only the minimum necessary Protected Health Information for the purposes specified in Section 12.1 or 12.2. The NC HIEA may rely on a public health official's or other government official's determination that the information requested represents the minimum necessary for the requested purpose.
- 12.4 Verification.** The NC HIEA shall verify the identity and authority of the representative or agent of the government agency making the request prior to Disclosing Protected Health Information for the purposes specified in Section 12.1 or 12.2.
- 12.5 Accounting of Disclosures.** The NC HIEA shall maintain a record of Disclosures made under Section 12.1 or 12.2 in accordance with Section 9.1.1 of the Policies.
- 12.6 Participant Notification.** Except as restricted by Applicable Law, the NC HIEA shall promptly notify Participants whose Protected Health Information has been Disclosed by the NC HIEA under Section 12.1.
- 12.7 Other Disclosures Not Permissible.** The NC HIEA shall not Disclose Protected Health Information to government agencies or their representatives or agents for any purpose not permitted by Applicable Law or these Policies.



SECTION 13: ACCESS TO DATA FOR RESEARCH

- 13.1 Requirements for Disclosure for Research.** The NC HIEA may Disclose Protected Health Information to appropriately qualified researchers for Research if one of the following requirements is satisfied:
- 13.1.1** All Individuals whose Protected Health Information is being Disclosed have signed a written authorization for the Disclosure that complies with HIPAA.
 - 13.1.2** The Research has been approved by a Designated Institutional Review Board (IRB), which has waived the requirement of obtaining Individuals' authorization for the Disclosure in accordance with 45 C.F.R. § 512(i)(2).
 - 13.1.3** The Protected Health Information is limited to that of decedents, the deaths of the relevant Individuals have been documented by the researcher requesting the information and the researcher represents to the NC HIEA in writing that the information is necessary for Research.
 - 13.1.4** The Protected Health Information requested constitutes a limited data set, as defined at 45 C.F.R. § 164.514(e), and a data use agreement, as described under 45 C.F.R. § 164.514(e), has been executed by the researcher and the NC HIEA.
- 13.2 Appointment of Designated IRB.** The NC HIEA shall enter into a written agreement with each Designated IRB to carry out the functions contemplated by this Section 13. Such agreement shall ensure that the Designated IRB performs its obligations in accordance with 45 C.F.R. §164.512(i).
- 13.3 Minimum Necessary.** Except for Research carried out pursuant to Section 13.1.1, the NC HIEA shall Disclose only the minimum necessary Protected Health Information for the permitted Research purpose.
- 13.4 Verification.** The NC HIEA shall verify the identity and authority of any researcher requesting access to Protected Health Information for Research prior to Disclosing such information to the researcher.
- 13.5 Accounting.** The NC HIEA shall maintain a record of all Disclosures for Research in accordance with Section 9 of the Policies.
- 13.6 Fees.** The NC HIEA may charge fees to researchers seeking access to Protected Health Information available through NC HealthConnex, provided that such fees must be reasonably related to the costs incurred by the NC HIEA in connection with reviewing and complying with the Research request, including but not limited to, the cost of review by a Designated IRB.
- 13.7 eHealth Exchange Research Use Prohibition.** The NC HIEA and Participants are prohibited from accessing or using Protected Health Information received through the eHealth Exchange or Disclosing PHI through the eHealth Exchange for Research purposes.



SECTION 14: DE-IDENTIFIED DATA

14.1 Creation of De-Identified Data. Pursuant to 45 C.F.R. § 164.514, the NC HIEA may access Protected Health Information through NC HealthConnex to create De-Identified Data in accordance with this Section 14.

14.2 Standards for De-Identification. Data will be deemed De-identified Data only if one of the following standards is satisfied:

14.2.1 A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and rendering information not individually identifiable determines that the that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information. The methods and results of the analysis that justify such determination must be documented.

14.2.2 The following identifiers are removed from the data:

- a. Names;
- b. All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of Census (1) the geographic units formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) the initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000;
- c. All elements of dates (except year) for dates directly related to the individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
- d. Telephone numbers;
- e. Fax numbers;
- f. Electronic mail addresses;
- g. Social security numbers;
- h. Medical record numbers;
- i. Health plan beneficiary numbers;
- j. Account numbers;
- k. Certificate/license numbers;



- i. Vehicle identifiers and serial numbers, including license plate numbers;
- m. Device identifiers and serial numbers;
- n. Web Universal Resource Locators;
- o. Internet Protocol address numbers;
- p. Biometric identifiers, including finger and voice prints;
- q. Full face photographic images and any comparable images; and
- r. Any other unique identifying number, characteristic, or code, except as permitted for re-identification purposes provided certain conditions are met, as set forth under HIPAA.

14.2.3 Notwithstanding Sections 10.2.1 and 10.2.2, information will not be deemed De-identified Data if the NC HIEA has actual knowledge that the information could be used, alone or in combination with other information, to identify an Individual who is a subject of the information.

14.3 Re-identification. The NC HIEA, in consultation with the NC HIEA Advisory Board, shall develop guidelines that specify when the NC HIEA will assign a code or employ other means of record identification to allow De-Identified Data to be re-identified in the event appropriate for clinical or other valid purposes. If such a code is assigned or other means of record identification is established:

14.3.1 The code or other means of record identification must not be derived from or related to information about the Individual and may not otherwise be capable of being translated so as to identify the Individual; and

14.3.2 The NC HIEA may not use or disclose the code or other means of record identification for any other purpose, and may not disclose the mechanism for re- identification.

14.4 Uses of De-Identified Data. The NC HIEA may use or make available to other parties De-identified Data for any purpose approved by the NC HIEA, in consultation with the NC HIEA Advisory Board. The NC HIEA may charge a fee to Participants or other parties requesting De-identified Data to the extent consistent with Applicable Law. No Participant shall have the right to restrict the NC HIEA's use or transmission of De-identified Data.

SECTION 15: ADDITIONAL EHEALTH EXCHANGE REQUIREMENTS

- 15.1** Participation by the NC HIEA in the national eHealth Exchange, through execution of the DURSA, requires that the NC HIEA replicate terms and policies included in the DURSA in the NC HIEA Participation Agreements or governance policies. Participants shall comply with the following requirements, which shall apply solely when the parties, through NC HealthConnex, acquire, access, use, or Disclose Protected Health Information over the eHealth Exchange:
- 15.1.1** Except to the extent prohibited by Applicable Law, Participants shall provide information that is reasonably requested of it by the NC HIEA or by the eHealth Exchange Coordinating Committee for the following purposes, as described in Section 4.03 of the Restatement I to the DURSA. Such purposes include for the Coordinating Committee: to determine whether Participant may exchange Protected Health Information over the eHealth Exchange; to receive and act upon reports of eHealth Exchange Breaches; to suspend or terminate the right of the NC HIEA or Participant to exchange Protected Health Information over the eHealth Exchange; to resolve disputes pertaining to the eHealth Exchange; or to fulfill other responsibilities delegated to the Coordinating Committee. Participant shall not be required to disclose PHI to the Coordinating Committee in violation of Applicable Law. Any information other than Protected Health Information provided to the Coordinating Committee shall be labeled as confidential business information.
 - 15.1.2** To the extent that Participant uses technology partners other than the NC HIEA and SAS in exchanging Protected Health Information over the eHealth Exchange, it shall maintain valid and enforceable agreements with such technology partners, including health information service providers, requiring them to (a) protect the privacy and security of Protected Health Information, and (b) as soon as reasonably possible after determining that a eHealth Exchange Breach has occurred, report such Breach to the Participant. Please refer to Section 8 for further requirements on reporting Breaches involving Message Content Transacted over the eHealth Exchange.
 - 15.1.3** The NC HIEA may voluntarily suspend or terminate, or the Coordinating Committee may suspend or terminate, the NC HIEA's right to exchange Protected Health Information over the eHealth Exchange. If any such suspension or termination occurs, the NC HIEA will notify Participant of the action as soon as reasonably possible. If an act or omission of Participant is the reason such suspension or termination occurs, Participant shall cooperate with the NC HIEA to submit an appeal or a plan of correction to the Coordinating Committee, as applicable, as quickly as practicable.
- 15.2 Required Alternative Dispute Resolution.** Participants shall submit any disputes related to their exchange of Protected Health Information over the eHealth Exchange to the non-binding Dispute Resolution Process as required by the DURSA and outlined below. If all of the parties involved in the dispute accept a proposed resolution of the dispute, Participant shall implement the terms of the resolution in the agreed upon time frame. Following the Dispute Resolution Process, Participant may pursue alternative remedies if it believes that the Dispute Resolution Process failed to adequately resolve the dispute.
- 15.2.1** When a Dispute arises, a Participant shall send written Notice, in accordance with the Notice provision in the DURSA, to the other Participant(s) involved in the Dispute. The notice must contain a summary of the issue as well as a recommendation for resolution. The Participant must send a copy of the notice to the Dispute Resolution Subcommittee (see below) for informational purposes.
 - 15.2.2** Within thirty (30) calendar days of receiving the notice, the Participants are obligated to

meet and confer with each other, at least once in good faith and at a mutually agreeable location (or by telephone), to try to reach resolution (the "Informal Conference"). If the Participants reach a resolution at the Informal Conference, they shall provide Notification to that effect to the Dispute Resolution Committee.

15.2.3 If the Participants are unable to participate in an Informal Conference during the thirty (30) calendar day period or to reach resolution at the Informal Conference, they have ten (10) business days following the end of the thirty (30) calendar day period or the Informal Conference, respectively, in which to escalate the Dispute to the Dispute Resolution Subcommittee in writing.

a. The Dispute Resolution Subcommittee (the "Subcommittee") will be a five (5) member standing subcommittee of the Coordinating Committee. The Coordinating Committee shall appoint each member of the Subcommittee for a definite term. The members must be representative of the Participants, have diverse skill sets, and be able to help facilitate and reach resolution on conflicts between the Participants. The Subcommittee must have access to legal counsel to advise it on the law relevant to matters before it.

b. In addition to appointing the five (5) members of the Subcommittee, the Coordinating Committee must also appoint three (3) to five (5) alternates for the Subcommittee. Alternates will serve on the Subcommittee should any of the members have a conflict on a particular Dispute or in the event that a member(s) is unavailable. Subcommittee members are required to declare any conflicts in accordance with the Coordinating Committee's conflict of interest policy. Once a Subcommittee member declares a conflict, the remaining Subcommittee members shall decide amongst themselves whether such member must withdraw from the Subcommittee for the dispute in question.

c. The Subcommittee must also have access to panels of subject matter experts, as identified by the Coordinating Committee, for a variety of topics that may be implicated by a Dispute. Each subject matter expert panel must have at least three (3) experts on it who will rotate as advisors to the Subcommittee.

15.2.4 Once a Participant escalates a Dispute to the Subcommittee, the Subcommittee will have thirty (30) calendar days in which to convene a meeting of the involved Participants ("Committee Meeting"). During this meeting, each Participant shall be able to present its version of the Dispute and any information that it believes is pertinent to the Subcommittee's decision.

15.2.5 The Subcommittee shall have the ability to request additional information from the Participants to help it make its determination. The Subcommittee, however, shall not have the authority to compel a response or the production of testimony or documents by the Participants. To the extent that the Participants do respond to requests of the Subcommittee by producing documents, Participants shall have the ability to mark the documents produced as "Confidential Participant Information" and the Subcommittee shall treat those documents in accordance with Section 16 of the DURSA.

15.2.6 The Subcommittee is encouraged to develop an appropriate and equitable resolution of each submitted Dispute, considering all available evidence, the goals of the Agreement and other relevant considerations. The Subcommittee must also have the authority to recommend sanctions for the breaching Participant. These sanctions include developing corrective action plans, suspension of participation rights, and termination of participation rights. The type of sanction will depend on the nature and severity of the

breach.

- 15.2.7** Within fifteen (15) calendar days of the Subcommittee Meeting, the Subcommittee shall issue a written recommendation for resolution, including an explanation of the basis and rationale of its recommendation. If either Participant is dissatisfied with the Subcommittee's recommendation for resolution, it shall have five (5) business days in which to escalate the Dispute to the Coordinating Committee.
- 15.2.8** Within twenty (20) calendar days of receiving notice of escalation from a Participant, the Coordinating Committee shall review the Subcommittee's recommendation along with the information on which such recommendation was based and issue a final resolution. The Coordinating Committee may seek additional information from the Participants to aid its resolution of the Dispute.
- 15.2.9** Within seven (7) calendar days of receiving the final resolution from the Coordinating Committee, the Participants shall determine whether to accept or reject the resolution and so notify the Coordinating Committee.
- 15.2.10** The Coordinating Committee shall send a written summary of the resolution of the Dispute to all Participants. The summary will not identify the Participants involved, but will contain sufficient detail about the resolution to serve as an instructive resource for other Participants.
- 15.2.11** In no case shall a Participant be required to disclose PHI in violation of Applicable Law as part of its participation in the Dispute Resolution Process. The decision to not disclose PHI shall not be held against a Participant in the Dispute Resolution Process.