



NORTH CAROLINA DEPARTMENT OF
INFORMATION TECHNOLOGY



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 North Carolina General Assembly created the NC HIEA and directed it 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. See N.C.G.S. §§ 90-414.1, et seq., and NC Session Law 2015-241 §§ 12A.4 and 12A.5. 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 providers of Medicaid and state-funded services to be connected to NC HealthConnex by specific dates based on provider and services type. Certain health plan and business associates may also be required to connect to or access NC HealthConnex.

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. From time to time the NC HIEA, in consultation with its Advisory Board, may amend these Policies. Definitions include references to laws or regulations as appropriate to illustrate the context and intent of this Policy.

These Policies are effective as of April 5, 2021.

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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 Approved Third Parties** means Covered Entities, Business Associates, government agencies, and other entities that have entered into data sharing agreements with NC HIEA to further the purposes outlined in G.S. § 90-414.2 *et. seq.* and other Applicable Law.
- 1.3 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.
- 1.4 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.
- 1.5 Breach, Security Breach** have the meanings assigned in 45 C.F.R. §164.402 and G.S. § 75-61, *et seq.*, as applied in Section 8 of this Agreement.
- 1.6 Business Associate** has the meaning assigned to this term in 45 C.F.R. § 160.103.
- 1.7 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).
- 1.8 Covered Entity** has the meaning assigned to this term in 45 C.F.R. § 160.103.
- 1.9 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.
- 1.10 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 0 of these Policies.
- 1.13 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 II of the Data Use and Reciprocal Support Agreement and was last updated on August 13, 2019 and executed by NC HIEA on January 28, 2020.
- 1.14 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.

- 1.15 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.
- 1.16 Electronic Health Information or EHI** has the meaning assigned to this term in 45 C.F.R. § 171.102.
- 1.17 Electronic Health Record or EHR** is the technical software system used by health care providers to collect and disseminate patients' digital health records.
- 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 HIE Act** means the Statewide Health Information Exchange Act found in Chapter 29B of Article 90 of the North Carolina General Statutes.
- 1.22 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.
- 1.23 Individual** has the meaning assigned to this term in 45 C.F.R. § 160.103.
- 1.24 Information Blocking** has the meaning assigned to this term in the 21st Century Cures Act at 42 U.S.C. 300jj-52(a)(1).
- 1.25 Information Blocking Rule** collectively refers to 42 U.S.C. § 300jj-52 and its implementing regulations 45 C.F.R. Part 171.
- 1.26 Interoperability Element** means hardware, software, integrated technologies or related licenses, technical information, privileges, rights, intellectual property, upgrades, or services that may be necessary to access, exchange or use EHI; and are controlled by the NC HIEA, which includes the ability to confer all rights and authorizations necessary to use the element to enable the access, exchange, or use EHI.
- 1.27 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.
- 1.28 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.
- 1.29 NC HealthConnex** means the electronic health information exchange network overseen and administered by the NC HIEA.

- 1.30 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 G.S. § 90-414.7.
- 1.31 NC HIEA Advisory Board** means the Advisory Board established by 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.
- 1.32 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.
- 1.33 Opt Out** has the meaning assigned to this term in G.S. §90-414.3(13).
- 1.34 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>.
- 1.35 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.
- 1.36 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>.
- 1.37 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.
- 1.38 Participating Entities** are entities owned, controlled, or under common control with the main Participant listed on a Participation Agreement that the Participant will submit clinical data to NC HealthConnex on behalf of. Participating Entities could be subsidiaries of a larger parent company, additional health care facilities that fall under the control of a Participant, and so forth. Participating Entities could also be individual contractors or separate organizations that the Participant has entered into direct or indirect business or employment relationships with, and the Participant has agreed to submit the clinical data they generate to NC HealthConnex on behalf of the Participating Entity. This could be a small clinic that uses the EHR product of a larger health system that is not owned or controlled by the health system.
- 1.39 Participation Agreement** means the written agreement entered into by a Participant and NC HIEA governing Participants’ use of NC HealthConnex.
- 1.40 Patient Centered Data Home (PCDH)** is an initiative of the Strategic Health Information Exchange Collaborative (SHIEC) that facilitates secure exchange of patient data among health information exchanges across the United States when certain patients receive treatment or care outside their normal care area. Information exchange via the PCDH is based on triggering episode alerts, which notify providers a care event has occurred outside of the patients’ “home” health information exchange and confirms the availability and the specific location of the clinical data, enabling providers to initiate additional data exchanges to access real-time information across state and regional lines and the care continuum. SHIEC is a nonprofit national consortium of statewide, regional, and community health information exchanges and a trade association that assists

member organizations through the exchange of ideas and business practices as well as through public education and advocacy.

- 1.41 Payment** has the meaning assigned to this term at 45 C.F.R. § 164.501.
- 1.42 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 the DURSA. These specifications and other eHealth Exchange are available here: <https://ehealthexchange.org/testing-program/technical-specifications/>.
- 1.43 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).
- 1.44 Protected Health Information or PHI** has the meaning assigned to this term in 45 C.F.R. § 160.103.
- 1.45 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.
- 1.46 Psychotherapy Notes** has the meaning assigned to this term at 45 C.F.R. § 164.501.
- 1.47 Public Health** means the activities and purposes described in 45 C.F.R. § 164.512(b) and in G.S. § Chapter 130A.
- 1.48 Public Health Authority** has the meaning assigned to this term at 45 C.F.R. § 164.501.
- 1.49 Qualified Organization** has the meaning assigned to this term at G.S. §90-414.3(16).
- 1.50 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.
- 1.51 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.
- 1.52 Research** has the meaning assigned to this term at 45 C.F.R. § 164.501.
- 1.53 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: <https://ehealthexchange.org/testing-program/technical-specifications/>.

- 1.54 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.
- 1.55 Substance Use Disorder Treatment Records or Part 2 Data** 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.
- 1.56 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.
- 1.57 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.
- 1.58 Workforce** has the meaning assigned to this term in 45 C.F.R. 160.103.

SECTION 2: ELIGIBLE PARTICIPANTS

- 2.1 Covered Entities and Other Providers.** The following persons or entities are eligible to be Participants of NC HealthConnex:
- 2.1.1** Any Covered Entity licensed to provide health care or other services in the State of North Carolina or in surrounding states.
 - 2.1.2** Any Health Care Provider that is not a Covered Entity licensed to provide health care services in the State of North Carolina or in surrounding states.
 - 2.1.3** Business Associates that are approved by NC HIEA in consultation with the NC HIEA Advisory Board under Section 2.2.
- 2.2 Business Associates.** Pursuant to 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:
- 2.2.1** 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. This could include electronic health record (EHR) vendors.
 - 2.2.2** The Participant has entered into a Business Associate Agreement and any associated data sharing agreements with the Business Associate.
 - 2.2.3** 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.
- 2.3 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.
- 2.4 Participating Entities.** A Participant that owns or controls other entities or that are under common control may elect to participate in NC HealthConnex as a single Participant or as multiple Participants. If a Participant identifies Participating Entities in its agreement with the NC HIEA, then Participant is responsible for ensuring that its organization sends the Participating Entities' required clinical and demographic data to NC HealthConnex, and that the Entities are appropriately accessing and using NC HealthConnex. Further, Participant is responsible for providing the NC HIEA with timely updates regarding any changes to Participant's list of Participating Entities.
- 2.5 G.S. §90-414.7(b)(9) Arrangements with In- and Out-of-State Exchanges and Participants.**
- 2.5.1** 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.
 - 2.5.2** Covered Entities that desire to become full participants in NC HealthConnex and utilize the value-added features offered by the NC HIEA must agree to (i) abide by the Policies and (ii) enter into a full Participation Agreement with NC HIEA.

- 2.5.3** 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, such as through the eHealth Exchange network or the Patient Centered Data Home.

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 organization's 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.** As of January 2020, the following are the Permitted Purposes for Transacting Messages and otherwise requesting, retrieving, and sending data over the eHealth Exchange:
- a.** Treatment, Payment, Health Care Operations, and Authorization based disclosures as defined by HIPAA;
 - b.** Transaction of Message Content related to value-based payment models, alternative payment arrangements or financial risk sharing models of any nature whether for Medicare, Medicaid, other federal programs, commercial payers or employer self-insured arrangements. This could include, but is not limited to, participation in Medicare bundled payments, the Medicare Shared Savings Program, other Medicare Alternate Payment programs, Medicaid Managed Care programs or commercial value-based payment programs;
 - c.** Transaction of Message Content for certain specialized government functions which are necessary to fulfill an agency's statutory obligations for programs the agency administers including, but not limited to: (i) activities deemed necessary by appropriate military command authorities to assure the proper execution of the military mission; (ii) for the purpose of the Department of Veterans Affairs determining the individual's eligibility or entitlement to benefits under the VA upon separation or discharge of the individual from military service; (iii) to determine

eligibility for or entitlement to or provision of other government benefits; (iv) for activities related to eligibility for or enrollment in a health plan that is a government program; (v) for administering a government program providing public benefits, to coordinate covered functions; or, (vi) to improve administration and management relating to the covered functions of such government programs;

- 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 under this Agreement, provided that the purpose is not otherwise described in subsections 1-46 of this definition 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. Transaction of Message Content in support of an individual’s: (i) right to access their health information or (ii) right to direct with whom their information can be shared or where their information should be sent. For the avoidance of doubt, a Participant may be prevented from disclosing information due to Applicable Law even though the individual asserts this Permitted Purpose.

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 7 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: <https://ehealthexchange.org/policies/>.

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 (<https://hiea.nc.gov/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 Use Disorder Information.** Pursuant to 42 C.F.R. Part 2, Participants shall not include Substance Use Disorder Treatment Records in the Protected Health Information disclosed to NC HIEA through NC HealthConnex unless explicitly permitted by the NC HIEA in writing. Participants may share Substance Use Disorder information covered by 42 C.F.R. Part 2 through Direct Secure Messaging when communicating with providers or entities when otherwise permitted by 42 C.F.R. Part 2. 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 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 email 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 five (5) 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 in response to court orders, subpoenas or discovery requests in accordance with Section 10, for other government agencies in accordance with Section 11, or for Research in accordance with Section 12.
- 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 disclose a copy of a patient's Protected Health Information to 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 Use Disorder 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.. See Section 4.4 of these Policies for additional information on these limitations.
- 5.10 Education and Awareness.**

- 5.10.1 By the NC HIEA.** Pursuant to 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 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.
- 5.11 Minor Opt Out.** The NC HIEA shall use an encounter-based opt out process for minors who receive medical services pursuant to circumstances contemplated by G.S. § 90-21.5. That process shall satisfy the requirements of G.S. § 90-414.10 and comport with the following provisions of this Section: 5.3; 5.6; 5.7.1; 5.7.2; 5.8; 5.9; and 5.10.

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** Facilitating exchanges and Transactions of HIE Data and Message Content with eligible Participants and Approved Third Parties for Permitted Purposes.
 - 6.1.2** Processing or otherwise implementing Opt Out requests.
 - 6.1.3** Performing patient identity or patient records maintenance.
 - 6.1.4** Conducting or assisting in the performance of audits permitted or required by the NC HIEA Policies and Procedures, including the performance of audits of emergency access.
 - 6.1.5** Evaluating the performance of or develop recommendations for improving the operation of NC HealthConnex.
 - 6.1.6** Conducting technical system support and maintenance of NC HealthConnex.
 - 6.1.7** Engaging in any other activities as may be required to facilitate the operation of NC HealthConnex that are authorized by NC HIEA and are consistent with this Agreement and 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: BREACH

- 7.1 Security Breach** shall have the meaning assigned in 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.
- 7.1.1 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 G.S. §75-65.
- 7.1.2 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 G.S. §75-65.
- 7.2 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.
- 7.3** The term “Breach”, under subsection 7.2, 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:
- 7.3.1** 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
- 7.3.2** Such Protected Health Information is not further acquired, accessed, used, or Disclosed by such employee or individual.
- 7.3.3** 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.
- 7.4 HIPAA Breach Notification.**
- 7.4.1 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.** 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.

- ii. 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.

7.4.2 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. 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.
 - ii. 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.

7.4.3 Contents of Notification. The Notification required by this Section 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.

- 7.4.4** 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 7.4.3b, the notification required by this Section 7 shall not include any Protected Health Information.
- 7.4.5** 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.
- 7.4.6** This Section 7 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.
- 7.4.7** 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 8: ACCOUNTINGS OF DISCLOSURES

8.1 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:

8.1.1 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.

8.1.2 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.

8.1.3 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.

8.2 Requests for Accountings by Participants.

- 8.2.1** 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.
- 8.2.2** 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 8.1 and as required by HIPAA.

8.3 Requests for Accounting by Individuals.

- 8.3.1** 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>.
- 8.3.2** 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 8.1 and as required by HIPAA.

SECTION 9: RESTRICTIONS ON ACCESS BY HEALTH PLANS

- 9.1 Acceptance of Restriction Requests by Providers.** All Providers must have a process for accepting 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.
- 9.2 Notifying the NC HIEA of Restriction Requests.** Providers agreeing to restriction requests under Section 9.1 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:
- 9.2.1** 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.
- 9.2.2** The Provider may notify the NC HIEA of the restriction in writing.
- 9.3 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 9.2. These measures shall ensure that any Protected Health Information subject to a restriction is not accessible to any Health Plan through NC HealthConnex.

SECTION 10: RESPONDING TO SUBPOENAS AND DISCOVERY REQUESTS

- 10.1 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.
- 10.2 Disclosures in Response to Subpoenas and Discovery Requests.**
- 10.2.1** Subject to Section 10.3, 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.
- 10.2.2** The NC HIEA shall respond to subpoenas, discovery requests or other lawful processes that do not satisfy the requirements of Section 10.1 or 10.2.1 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.
- 10.3 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 10.2 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 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.
- 10.4 No Obligation to Search Participant Records.** Under this Section, 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.
- 10.5 Consultation with Counsel.** The NC HIEA shall consult with its counsel regarding its authority to Disclose Protected Health Information under this Section prior to making any such Disclosure.
- 10.6 Minimum Necessary.** The NC HIEA shall Disclose only the minimum necessary Protected Health Information in response to requests covered by this Section.
- 10.7 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.
- 10.8 Accounting of Disclosures.** The NC HIEA shall maintain a record of Disclosures made under this Section in accordance with Section 8.1.1 of the Policies.

SECTION 11: ACCESS TO DATA BY GOVERNMENT AGENCIES

- 11.1 Disclosures Permitted or Required by Law.** The NC HIEA may Disclose Protected Health Information to a government agency or its representatives or agents when the Disclosure is permitted or Required by Law. Nothing in this Section 11. 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.
- 11.2 Disclosures for Public Health Purposes.** Pursuant to 45 C.F.R. § 164.512(b), 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 11.2.
- 11.3 Minimum Necessary.** The NC HIEA shall Disclose only the minimum necessary Protected Health Information for the purposes specified in Section 11.1 or 11.2. 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.
- 11.4 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 11.1 or 11.2.
- 11.5 Accounting of Disclosures.** The NC HIEA shall maintain a record of Disclosures made under Section 11.1 or 11.2 in accordance with Section 8.1.1 of the Policies.
- 11.6 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 11.1.
- 11.7 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 12: ACCESS TO DATA FOR RESEARCH

- 12.1 Requirements for Disclosure for Research.** The NC HIEA may Disclose Protected Health Information to appropriately qualified researchers for Research. The NC HIEA will follow its research policies and protocols and will require the researcher to enter into one or more agreements that require safeguarding of any HIE Data to be disclosed to or accessed by such researcher. Data may be disclosed to a researcher if one of the following criteria is satisfied:
- 12.1.1** All Individuals whose Protected Health Information is being Disclosed have signed a written authorization for the Disclosure that complies with HIPAA.
 - 12.1.2** The Research has been approved by a researcher's 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).
 - 12.1.3** 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.
 - 12.1.4** The Protected Health Information requested constitutes a limited data set, as defined at 45 C.F.R. § 164.514(e)..
- 12.2 Minimum Necessary.** Except for Research carried out pursuant to Section 12.1.1, the NC HIEA shall Disclose only the minimum necessary Protected Health Information for the permitted Research purpose.
- 12.3 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.
- 12.4 Accounting.** The NC HIEA shall maintain a record of all Disclosures for Research in accordance with Section SECTION 12: of the Policies.
- 12.5 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..
- 12.6 eHealth Exchange Research 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 13: DE-IDENTIFIED DATA

13.1 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.

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

13.2.1 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.

13.2.2 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;

- l. 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.

13.2.3 Notwithstanding Section 13.2, 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.

13.3 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:

13.3.1 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

13.3.2 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.

13.4 Uses of De-Identified Data. The NC HIEA may use or make available to other parties De-identified Data for purposes approved by the NC HIEA, in consultation with the NC HIEA Advisory Board. The Authority shall not allow de-identified data to be used or disclosed by or to any person or entity for commercial purposes or for any other purpose other than those set forth in G.S. § 90-414.4(a) or G.S. § 90-414.2.

SECTION 14: ADDITIONAL EHEALTH EXCHANGE REQUIREMENTS

14.1 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:

14.1.1 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 certain purposes.. 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.

14.1.2 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 SECTION 7: for further requirements on reporting Breaches involving Message Content Transacted over the eHealth Exchange.

14.1.3 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.

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 Second Restatement of the DURSA.

SECTION 15: INDIVIDUALS' ACCESS TO ELECTRONIC HEALTH INFORMATION

- 15.1 Patient Access to Protected Health Information.** An individual may request a copy of his or her Protected Health Information or Electronic Health Information by submitting a request in writing to the NC HIEA in a manner set forth by the NC HIEA. The NC HIEA shall make all necessary forms available to individuals on its website and provide copies of forms to individuals who request them via telephone. At any time, the NC HIEA may encourage a patient to submit a request for Protected Health Information available in NC HealthConnex to a health care provider with whom the individual has an existing patient-medical provider relationship.
- 15.2 Authorization and Verification.** The NC HIEA shall require an individual who seeks a copy of his or her Electronic Health Information to complete an authorization form and provide materials to verify his or her identity. The NC HIEA shall confirm that an individual has a right to access Protected Health Information before processing any request.
- 15.3 Secure Transmission of Electronic Health Information.** When the NC HIEA fulfills an individual's request for Electronic Health Information, it shall transmit the protected health information to the individual via secure means.
- 15.4 No Existing Patient Relationship.** The NC HIEA does not have a patient-provider relationship with any individual and cannot change or amend Protected Health Information within an individual's health record or within NC HealthConnex. If an individual wishes to amend his or her Protected or Electronic Health Information or medical record within NC HealthConnex, then the individual shall contact his or her health care provider. Further, when processing requests for Electronic Health Information, NC HIEA may seek additional information from the individual in order to match the individual with records within NC HealthConnex in order to fulfill the request.
- 15.5 Incomplete or Denied Requests for Electronic Health Information.** From time to time the NC HIEA will be unable to fulfill all or part of an individual's request for Electronic Health Information. If an individual has a right pursuant to HIPAA or other applicable law to receive Electronic Health Information but the NC HIEA cannot fulfill the request completely or in the manner requested, then the NC HIEA shall respond to the request in a manner consistent with the policies herein.
- 15.6 Incorrect Data.** If an individual receives Electronic Health Information from the NC HIEA concerning another person or persons whose data he or she is not authorized to see, then individual shall contact the NC HIEA immediately. The individual shall not review or share the information received in error with anyone else and shall assist the NC HIEA in destroying all copies of the Electronic Health Information,

SECTION 16: REQUESTS TO ACCESS, EXCHANGE, AND USE ELECTRONIC HEALTH INFORMATION; PROHIBITION AGAINST INFORMATION BLOCKING; AND SAFE HARBORS

16.1 NC HIEA's Commitment. The NC HIEA is committed to facilitating the appropriate, lawful, and timely access, exchange, and use of Electronic Health Information (EHI) in compliance with Applicable Law, including the Information Blocking Rule:

16.1.1 NC HIEA is committed to not interfering with timely access to EHI by North Carolina patients or others who have a legitimate right to EHI.

16.1.2 NC HIEA will do its best to not engage in practices that interfere with, prevent, or discourage access, exchange, or use of EHI except as specifically permitted by one of the exceptions identified in the Information Blocking Rule.

16.1.3 NC HIEA will incorporate into its policies and operations measures to assure the NC HIEA complies with its duties arising from the Information Blocking Rule.

16.1.4 Taking into accounts its resources, the NC HIEA will respond in good faith and in a timely manner to requests to retrieve or exchange electronic health information, including from individuals, health care providers (as defined by 42 U.S.C. 300jj(3)), and other persons, regardless of the requestor's affiliation or technology vendor.

16.1.5 NC HIEA will evaluate and process any requests to Access, Use, and Exchange EHI in a consistent, non-discriminatory way.

16.2 NC HIEA Activities that Do Not Constitute Information Blocking. Information Blocking does not include activities that could be perceived as interfering with the Access, Use, or Exchange of EHI when such activities are required by law. In these instances, an entity like NC HIEA does not have to demonstrate that it has met the criteria of one of the eight exceptions to the Information Blocking Rule. The following non-exhaustive list of activities do not meet the definition of Information Blocking because they are required by the HIE Act:

16.2.1 Denying use or disclosure of EHI by or to any person or entity for commercial purposes;

16.2.2 Denying use or access of an opted-out individual's EHI;

16.2.3 Requiring Covered Entities to enter into a Participation Agreement and Business Associate Agreement prior to viewing, accessing, or using EHI in NC HealthConnex unless otherwise provided in these Policies;

16.2.4 Requiring Business Associates of Participants to enter into data sharing agreements with NC HIEA and to follow other criteria in this Policy prior to accessing and using EHI; and

16.2.5 Any other activities that are required by Applicable Law.

16.3 Other Applicable Law. The Information Blocking Rule also does not require the NC HIEA to disclose EHI if doing so would violate other Applicable Law, such as HIPAA and other state or federal privacy laws.

16.4 NC HIEA Staff Training.

16.4.1 The NC HIEA will provide training to NC HIEA and certain DIT staff concerning the

Information Blocking Rule and the NC HIEA's related procedures.

- 16.4.2** As needed, the NCHIEA will discipline staff who violate the Information Blocking Rule and related implementation policies or procedures, including staff who (i) fail to report actual or suspected violations of the Information Blocking Rule, and/or (ii) engage in retaliatory behavior. The level of disciplinary action imposed will depend on the severity of the violation and may include termination of employment.

16.5 Information Blocking Safe Harbors.

16.5.1 From time to time, circumstances may dictate that the NC HIEA cannot fulfill or is unable to fully satisfy a request for access, exchange, or use of EHI over which it has control. On those occasions when the NC HIEA engages in practices that might implicate the Information Blocking Rule, the NC HIEA will endeavor to satisfy at least one of the eight (8) exceptions (collectively, "Safe Harbors") delineated in the Information Blocking Rule that identify reasonable and necessary practices and activities that do not constitute information blocking. The NC HIEA will work to satisfy the regulatory conditions of any applicable Safe Harbor and will act in a manner consistent with the policies outlined below. Importantly, because the Information Blocking Rule is intent based, any failure by or inability of the NC HIEA to satisfy the elements of a regulatory Safe Harbor does not establish a violation of the Information Blocking Rule. The NC HIEA's Safe Harbor policies follow.

16.5.2 The NC HIEA will invoke the following Safe Harbors while evaluating and responding to requests for EHI. In some instances where permitted by the Information Blocking Rule, the NC HIEA may make an individualized determination on how to respond to an EHI request based on (i) the facts and circumstances known or reasonably believed at the time of the request and (ii) the relevant expertise of the NC HIEA in handling such requests.

16.6 Instances Resulting in the Denial of EHI Requests

16.6.1 Preventing Harm Safe Harbor. If during the course of evaluating a request for access, exchange, or use electronic health information the NC HIEA is made aware of a particularized risk of harm to a person's life or physical safety in connection with a requested disclosure of EHI, the NC HIEA may withhold information and evaluate the circumstances of the request on a case-by-case basis.

- a.** The particularized risk of harm to the life or physical safety that the NC HIEA learns of must arise under one of the following circumstances:
 - i.** A licensed health care professional—who has a current or prior clinical-patient relationship with the individual whose EHI is affected—makes the risk-of-harm determination on an individualized basis and in the exercise of professional judgment; or
 - ii.** A risk of harm arises from data that is known or reasonably suspected to be misidentified or mismatched, corrupt due to technical failure, or erroneous for another reason (collectively, "Corrupted Data"). Note: An incomplete medical record or sporadic data entry errors do **not** constitute Corrupted Data.
- b.** Any actions undertaken by the NC HIEA that result in the request not being fully

fulfilled and/or delayed shall be:

- i. documented;
- ii. no broader than necessary in order to substantially reduce the risk of harm to the life or physical safety of a natural person;
- iii. based on facts and circumstances known or reasonably believed by the NC HIEA at the time the determination was made and while the practice remains in use; and
- iv. implemented in a consistent and non-discriminatory manner.

16.6.2 Privacy Safe Harbor

- a. The NC HIEA is committed to protecting the privacy of patient EHI. It will follow its policies and procedures with respect to granting, delaying, or denying requests to access an individual's EHI.
- b. Participants' requests to Access, Use, Exchange HIE Data are subject to respective Participation Agreement, NC HIEA and state policies, and applicable state and federal law.
- c. NC HIEA follows its opt-out policy and will deny requests for opted-out individuals' EHI unless otherwise required by law. See above.
- d. With respect to Individuals seeking access to their own EHI:
 - i. Individuals seeking access to their own EHI must meet authorization and verification requirements. See Section 15. When a requestor submits an authorization or consent that NC HIEA determines is incomplete or invalid, the NC HIEA will use reasonable efforts within its control to provide the requestor with a consent or authorization form that satisfies the requirements or otherwise provide reasonable assistance with respect to the deficiencies. The NC HIEA will not encourage or induce the Individual to withhold consent.
 - ii. NC HIEA will not make information available during those circumstances where denial of the HIPAA right to access is not reviewable or it is not appropriate to treat a person as an individual's personal representative. These include, but are not limited to, situations in which a licensed health care provider determines that providing EHI would endanger the life or physical safety of the patient or someone else; psychotherapy notes; certain records that are involved in civil litigation; requests by inmates; and certain records involved in research studies.
- e. With respect to third parties seeking information on behalf of individual patients:
 - i. **Authorizations/consents.** Depending on who is requesting the EHI and for what purpose, NC HIEA may be required by state or federal privacy laws to obtain a signed authorization or consent from the individual or the individual's personal representative. The state or federal privacy law might require that the authorization or consent used meet certain requirements. When a requestor submits an authorization or consent that the NC HIEA determines is invalid or incomplete, the NC HIEA will use reasonable efforts within its control to provide the requestor with a consent or authorization form that satisfies the

requirements or otherwise provide reasonable assistance with respect to the deficiencies. NC HIEA will not improperly encourage or induce an individual to withhold the authorization or consent.

- ii. **Verification of identity and authority.** The NC HIEA may be required by state or federal privacy laws to verify the identity and authority of a person requesting access to EHI. The NC HIEA will tailor its verification practices to meet legal requirements and health care industry standard security procedures (see the Security Safe Harbor) / or Statewide Security Manual.
- f. The NC HIEA will also follow other applicable Safe Harbors—such as the Content and Manner Safe Harbor or Infeasibility Safe Harbor—in circumstances where the Privacy Safe Harbor applies to only a portion of the EHI requested, but it is not feasible for the NC HIEA to provide access, exchange or use of the rest of the requested EHI due to technical or administrative limitations (such as lacking data segmentation capabilities to sequester only the EHI subject to the Privacy Safe Harbor).

16.6.3 Security Safe Harbor.

- a. In addition to its policies and contractual obligations, the NC HIEA is subject to laws and state-level policies that concern, among other things, the security of EHI over which the NC HIEA has control. The NC HIEA shall abide the requirements of these laws and applicable policies, including the Statewide Information Security Manual.
- b. To the extent security-related directives required by applicable laws and/or state policies impact requests that the NC HIEA receives concerning the access, exchange, or use of EHI, the NC HIEA will implement those directives with practices that are:
 - i. tailored to the specific security risk being addressed; and
 - ii. implemented in a consistent and non-discriminatory manner, as informed by the unique facts/circumstances.

In any event, the NC HIEA will not fulfill requests to access, exchange, or use EHI that conflict with the law or other security-related obligations applicable to the NC HIEA.

- c. Existing security obligations and safeguards applicable to the NC HIEA may not always anticipate or account for changes in the security risk environment. When NC HIEA encounters security risk(s) that may impact its ability to respond fully to a request to access, exchange, or use of EHI, it may engage in a practice related to safeguarding the confidentiality, integrity, and availability of electronic health information that may implicate the information blocking rule if:
 - i. The practice is necessary to mitigate the security risk to electronic health information; and
 - ii. There are no reasonable and appropriate alternatives to the practice that address the security risk that are less likely to interfere with,

prevent, or materially discourage access, exchange or use of electronic health information.

16.6.4 Infeasibility Safe Harbor. Legitimate, practical challenges may limit the NC HIEA's ability to fulfill a request for access, exchange, or use of EHI. For example, it may be infeasible for NC HIEA to fulfill a request for access, exchange or use of EHI under the following circumstances:

- a. **Uncontrollable Events.** NC HIEA may not be able to fulfill an EHI request due to a natural or human-made disaster, public health emergency, public safety incident, war, terrorist attack, civil insurrection, strike or other labor unrest, telecommunication or internet service interruption, or act of military, civil or regulatory authority.
- b. **Data Segmentation.** NC HIEA may not be able to fulfill an EHI request because NC HIEA cannot unambiguously segment the requested EHI from EHI that cannot be disclosed due to an individual's privacy preferences or legal requirements (see, e.g., the Privacy Safe Harbor), or because the EHI may be withheld under the Preventing Harm Safe Harbor in accordance with 45 C.F.R. 171.201.
- c. **Infeasible under the Circumstances.** On other occasions, the NC HIEA may make an individualized determination that fulfilling a request for access, exchange, or use of EHI is infeasible. The NC HIEA shall make such a determination based upon the following factors:
 - i. The type of EHI and the purposes for which it may be needed;
 - ii. The cost of complying with the request in the manner requested;
 - iii. The financial and technical resources available to the NC HIEA;
 - iv. Whether the NC HIEA's practice is nondiscriminatory in its application to others with whom the NC HIEA has a business relationship;
 - v. Whether NC HIEA owns or has control over a predominant technology or platform through which the EHI is Accessed or Exchanged; and
 - vi. Why the NC HIEA could not make the EHI available under the Content and Manner Safe Harbor.

NC HIEA will document its consideration of these factors in writing prior to responding to the EHI request and will apply these factors consistently and in a non-discriminatory manner.

In determining whether a fulfilling a request is infeasible under the circumstances, the NC HIEA shall not consider: (i) Whether complying with the EHI request in the manner requested would facilitate competition with NC HIEA, or (ii) Whether complying with the EHI request would prevent NC HIEA from charging a fee or will result in a reduced fee to NC HIEA.

- d. When the NC HIEA determines that any of the foregoing circumstances make fulfilling a request infeasible, it will provide written notification via letter or email to the requestor of its determination. This writing shall include reason(s) for the infeasibility determination and issue in a timely manner.

16.6.5 Health IT Performance. The NC HIEA routinely conducts technical system support and maintenance, which can include activities and circumstances where suspension or

degradation of services is required to maintain or update the performance of NC HealthConnex.

- a. NC HIEA performs maintenance and upgrades on the third weekend of each month and as needed. Users may experience slower performance of or the inability to access affected HIE Features during these periods.
- b. While taking steps to maintain, support, and improve NC HealthConnex and related ancillary systems, the NC HIEA's actions shall:
 - i. occur for period of time no longer than necessary to complete the maintenance or improvements for which the health IT was made unavailable or the health IT's performance degraded; and
 - ii. be implemented in consistent and non-discriminatory manner.
- c. In the event a third-party application or action negatively impacts the performance of NC HealthConnex and/or any ancillary systems, the NC HIEA may take action to maintain the performance of NC HealthConnex. In taking such actions, the NC HIEA will utilize practices that:
 - i. occur for a period no longer than necessary to resolve negative impact;
 - ii. are implemented in a consistent and non-discriminatory manner; and
 - iii. are consistent with HIEA policies and any applicable agreements.
- d. If the NC HIEA initiates maintenance or improvement efforts in response to a security risk and/or in response to a risk of harm to a patient or another person and such efforts impact a request to Access, Use, or Exchange EHI, then the Security Safe Harbor and/ or Preventing Harm Safe Harbor may apply.

16.7 Instances Resulting in the Complete or Partial Fulfillment of EHI Requests

16.7.1 Content and Manner Safe Harbor. Consistent with its resources and capabilities, the NC HIEA strives to fulfill requests for access, exchange or use of EHI in the manner requested. However, it will not be information blocking if the NC HIEA fulfills an EHI request in an alternative manner, so long as the conditions of the Content and Manner Safe Harbor are met.

- a. If the NC HIEA fulfills an EHI request in the manner it is requested, then any fees charged by the NC HIEA or licensing requirements used are not required to comply with the Fees Safe Harbor or Licensing Safe Harbor.
- b. **Content Limitation.** The NC HIEA may limit its response to an EHI request to only those data elements represented by the data elements in the USCDI (v1) standard until October 6, 2022, or such other date later identified by federal law or regulation.
- c. **Alternative Manner Option.** NC HIEA may respond to an EHI request in an alternative manner than the one requested if one of the following circumstances applies:
 - i. NC HIEA is technically unable to fulfill the request; or

- ii. NC HIEA is unable to reach agreeable terms with the requestor.
- d. If the NC HIEA is technically unable to fulfill the request in the manner requested or cannot reach agreeable terms with the requestor, then the NC HIEA will fulfill the request in an alternative manner and without unnecessary delay, unless it is infeasible for the NC HIEA to do so (see the Infeasibility Safe Harbor). The NC HIEA will notify the requestor within 10 business days of the request if fulfilling the EHI request in the manner requested or in an alternative is infeasible.
- e. If responding in an alternative manner is feasible, NC HIEA will fulfill the request using the technical standards listed below in the following order of priority, only proceeding to the next standard if NC HIEA is technically unable to fulfill the request using the higher priority standard:
 - i. Using certified technology specified by the requestor (e.g., via application programming interface (API), Direct protocol);
 - ii. Using content and transport standards specified by requestor and published by the federal government or standards development organization accredited by the American National Standards Institute (ANSI); or
 - iii. Using an alternative machine-readable format agreed upon with the requestor (e.g., Portable Document Format (PDF), comma-separated value (CSV) files).

NC HIEA may also require the requestor to first agree to licensing terms for the Interoperability Elements and/or fees in accordance with the Licensing Safe Harbors and Fees Safe Harbor. If applicable, NC HIEA will begin negotiating any licensing terms within 10 business days of the request and offer a negotiated license within 30 business days of the request

16.7.2 Fees Safe Harbor.

- a. The NC HIEA will not charge any fees that are prohibited by HIPAA or based in any part on the Electronic Access of an individual's EHI by the individual, their personal representative, or another person or entity designated by the individual.
- b. For requestors other than an individual or personal representative, the NC HIEA may (but is not required to) impose a fee on the access, exchange or use of EHI, so long as the fee is based on the following:
 - i. Objective and verifiable criteria that are uniformly applied for all similarly situated classes of persons or entities and requests, as identified by the NC HIEA;
 - ii. Reasonably related to NC HIEA's costs of providing the type of access, exchange or use of EHI to, or at the request of, the person or entity to whom the fee is charged;

- iii. Reasonably allocated among all similarly situated persons or entities, as identified by the NC HIEA, to whom the technology or service is supplied, or for whom the technology is supported; and
- iv. Costs not otherwise recovered for the same instance of service to a provider and third-party.

16.7.3 Licensing Safe Harbor.

- a. When the NC HIEA responds to a request for EHI in an alternative manner, the NC HIEA may impose terms and conditions (e.g., a license or non-disclosure agreement) on the requestor's use of Interoperability Elements.
- b. In the event the NC HIEA licenses the use of Interoperability Elements to Access, Exchange or Use EHI in an alternative manner, it will:
 - i. Begin license negotiations with a requestor within ten (10) business days of the request; and
 - ii. Negotiate in good faith a license within thirty (30) business days of the request.
- c. The license will meet all of the following requirements:
 - i. Scope of License. It will provide all rights necessary to enable the access, exchange or use of EHI achieve the intended access, exchange or use of EHI via the Interoperability Elements.
 - ii. Royalty. Any royalty assessed by the NC HIEA will be reasonable, non-discriminatory and based solely on the independent value of NC HIEA's technology to the licensee's products. A royalty will not be based on any strategic value stemming from NC HIEA's control over essential means of Accessing, Exchanging, or Using EHI. To the extent the NC HIEA's has licensed an Interoperability Element through a standards developing organization, the NC HIEA may charge a royalty that is consistent with such policies.
 - iii. Non-Discriminatory. The NC HIEA's licensing terms will be based on objective and verifiable criteria that are uniformly apply for all similarly situated classes of persons and requests, as determined by the NC HIEA.

16.8 Information Blocking Reporting

16.8.1 NC HIEA staff, affiliates, agents, and vendors that reasonably believe the NC HIEA is violating the Information Blocking Rule must promptly notify the NC HIEA Executive Director. Anonymous reports may be made to DIT Human Resources. NC DIT and NC HIEA will not retaliate against any individual for reporting a suspected or actual violation of Information Blocking Rule.

16.8.2 DIT leadership will appoint an individual to respond to allegations of information blocking and, where appropriate, investigate such allegations within a reasonable period of time. Investigations will:

- a.** Identify all persons who were involved in the alleged information blocking practice and interview them;
- b.** Identify, review and preserve all relevant documentation, including relevant policies and procedures, e-mails, correspondence, notes, files and other documents that may have been created by those involved in the matter;
- c.** Assess whether the practice complained of implicates the Information Blocking Rule and whether the practice is Required by Law or falls into one or more Safe Harbors;
- d.** Address and mitigate any compliance issues, including but not limited to disciplining any Workforce Members who have violated this No Information Blocking Policy or the Information Blocking Rule; and
- e.** Document all of the above, including the final disposition of the complaint and any disciplinary actions.

User Access Policy Changes

Location or Section	Summary of Changes Made (Policy language – not the summary descriptions below – controls)	Date
Entire Policy Document	Removed old headers and footers; added NC HealthConnex Logo; citation revisions and updates to internal numbering; revise URLs to websites.	4/5/2021
Introduction	Removed statutory deadlines; included reference to health plan participation; updated effective date	4/5/2021
Section 1: Definitions	<p>Added or revised definitions for:</p> <ul style="list-style-type: none"> • Approved Third Parties • Data Use and Reciprocal Support Agreement (DURSA) • Electronic Health Information (EHI) • Electronic Health Record (EHR) • HIE Act • Information Blocking • Information Blocking Rule • Interoperability Element • Participating Entities • Performance and Service Specification • Substance Use Disorder Treatment Records or Part 2 Data <p>Deleted definitions:</p> <ul style="list-style-type: none"> • Designated Institutional Review Board • Dispute Resolution Subcommittee • Emergency Medical Condition 	4/5/2021
Section 2: Eligible Participants	Revised provisions concerning restrictions on use of NC HealthConnex for Covered Entities and Business Associates; clarified responsibilities with respect to Participating Entities, including revisions to harmonize the provision with defined term; deleted provisions concerning Qualified Organizations; clarified terms regarding Out-of-State Exchanges and Participants to reflect HIEA practices	4/5/2021
Section 3: Access to Protected Health Information for Treatment, Payment, and Health Care Operations; National EHealth Exchange Requirements	Revised “Permitted Purposes” for Transacting Messages over the eHealth Exchange	4/5/2021
Section 4: Minimum Necessary Requirement and Limitations on Use and Disclosure of Data	Revised limitations on Access, Disclosure, and Use of Substance Use Disorder Information.	4/5/2021

Section 5: Opt Out Rights	Revised citations; revise provisions concerning the processing and implementation of Opt Out Requests to conform to HIEA practices; clarifying revision concerning maintenance and disclosure of Protected Health Information; reference added regarding minor opt out process.	4/5/2021
Section 6: Access Rights of the NC HIEA Workforce; Security Controls	Clarifying revisions to "Authorized Purposes."	4/5/2021
Section 7: Emergency Access to Records of Opted Out Individuals	Section 7 deleted; subsequent existing sections re-numbered.	4/5/2021
Section 7: Breach	Renumbered; Breach notification responsibilities revised with the deletion provisions concerning alerts occurring within one hour of discovery of information.	4/5/2021
Section 8: Accounting of Disclosures	Renumbered.	4/5/2021
Section 9: Restrictions on Access by Health Plans	Renumbered.	4/5/2021
Section 10: Responding to Subpoenas and Discovery Requests	Renumbered.	4/5/2021
Section 11: Access to Data by Government Agencies	Renumbered; clarifying edit to address "permitted" disclosures.	4/5/2021
Section 12: Access to Data for Research	Renumbered; additional requirements for disclosure of PHI for research; deletion of requirement that HIEA enter agreements with certain institutional review boards, including deletion of related references.	4/5/2021
Section 13: De-Identified Data	Renumbered; statutory reference included regarding permitted uses of deidentified data.	4/5/2021
Section 14: Additional EHealth Exchange Requirements	Renumbered; deletion of provisions concerning dispute resolution and inclusion of updated references to applicable dispute resolution requirements in the Second Restatement of the DURSA.	4/5/2021
Section 15: Individuals' Access to Protected Health Information	New section added.	4/5/2021
Section 16: Requests to Access, Exchange, and Use Electronic Health Information; Prohibition Against Information Blocking; and Safe Harbors	New section added.	4/5/2021