Policies and Procedures
NY Care Information Gateway

Policies and Procedures

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Definitions

1. **Access** means the ability of an Authorized User or Certified Application to view Protected Health Information through the RHIO System following the Authorized User’s or Certified Application’s logging on to the RHIO System.

2. **Accountable Care Organization (“ACO”)** means an organization of clinically integrated health care providers certified by the Commissioner of Health under N.Y. Public Health Law Article 29-E.

3. **Advanced Emergency Medical Technician** means a person certified pursuant to the New York State Emergency Services Code at 10 N.Y.C.R.R. § 800.3(p) as an emergency medical technician-intermediate, an emergency medical technician-critical care, or an emergency medical technician-paramedic.

4. **Affiliated Practitioner** means an Authorized User that is (i) a Practitioner employed by or under contract to a Participant to render health care services to the Participant’s patients; (ii) a Practitioner on a Participant’s formal medical staff or (iii) a Practitioner providing services to a Participant’s patients pursuant to a cross-coverage or on-call arrangement.

5. **Affirmative Consent** means the consent of a patient obtained through the patient’s execution of a RHIO Consent Form.

6. **Applicant** means any healthcare facility or provider that wishes to become a Participant of NY Care Information Gateway.

7. **Application for Participation** means an Applicant’s application to become a Participant of NY Care Information Gateway, in the form attached hereto as Attachment A.

8. **Audit Log** means an electronic record of the Disclosure of information via the RHIO System, such as, for example, queries made by Authorized Users, type of information Disclosed, information flows between NY Care Information Gateway and Participants, and date and time markers for those activities.

9. **Authorized User** means an employee or independent contractor of a Participant or a credentialed member of the Participant’s professional staff who meets the criteria set forth in Policy and Procedure 1-4 (Authorization and Authentication) and has been authorized by the Participant to Access Protected Health Information through the RHIO System.

10. **Authorized User Attestation** means the certification form required by NY Care Information Gateway in order to activate an Authorized User in NY Care Information Gateway’s central authentication system, including certification by the Authorized User that he or she has received training and will comply with NY Care Information Gateway Policies and Procedures, in the form attached hereto as Attachment D.

11. **Authorized User Registration Form** means the registration form required by NY Care Information Gateway in order to activate an Authorized User in NY Care Information Gateway.
Gateway’s central authentication system, including the name of the Authorized User and the level of Access to the RHIO System such Authorized User will have, in the form attached hereto as Attachment C.

12. **Authorized Purposes** means authorized uses of the Protected Health Information Accessed via the RHIO System, which are limited to Treatment, Care Management, Insurance Coverage Reviews, and Quality Improvement.

13. **Board of Directors** means the Board of Directors of NY Care Information Gateway.

14. **Breach** means the acquisition, access, use, or disclosure of Confidential Health Information in a manner not permitted under the HIPAA Privacy Rule, which compromises the security or privacy of the Protected Health Information. An acquisition, access, use, or disclosure of Protected Health Information in a manner not permitted under the HIPAA Privacy Rule is presumed to be a Breach unless the Participant or NY Care Information Gateway can demonstrate that there is a low probability that the Protected Health Information has been compromised based on a risk assessment of at least the following factors: (i) the nature and extent of the Protected Health Information involved, including the types of identifiers and the likelihood of re-identification; (ii) the unauthorized person who used the Protected Health Information or to whom the disclosure was made; (iii) whether the Protected Health Information was actually acquired or viewed; and (iv) the extent to which the risk to the Protected Health Information has been mitigated. Breach excludes: (i) any unintentional acquisition, access, or use of Protected Health Information by a workforce member or person acting under the authority of NY Care Information Gateway or a Participant, if such acquisition, access, or use was made in good faith and within the scope of authority and does not result in further use or disclosure in a manner not permitted under the HIPAA Privacy Rule; (ii) any inadvertent disclosure by a person who is authorized to access Protected Health Information at NY Care Information Gateway or a Participant to another person authorized to access Protected Health Information at NY Care Information Gateway or the same Participant, or organized health care arrangement in which a Participant participates, and the information received as a result of such disclosure is not further used or disclosed in a manner not permitted under the HIPAA Privacy Rule; or (iii) a disclosure of Protected Health Information where NY Care Information Gateway or a Participant has a good faith belief that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain such information.

15. **Break-the-Glass** means the ability of an Authorized User to Access a patient’s Protected Health Information without obtaining an Affirmative Consent in accordance with the provisions of Policy and Procedure 1-3 (Patient Consent and Privacy).

16. **Business Associate Agreement** means a written signed agreement meeting the HIPAA requirements of 45 CFR § 160.504(e).

17. **Care Management** means (i) assisting a patient in obtaining appropriate medical care, (ii) improving the quality of health care services provided to a patient, (iii) coordinating the provision of multiple health care services to a patient or (iv) supporting a patient in following a plan of medical care. Care Management does not include utilization review
or other activities carried out by a Payer Organization to determine whether coverage should be extended or payment should be made for a health care service.

18. **Certified Application** means a computer application certified by NY Care Information Gateway that is used by a Participant to Access Protected Health Information from the RHIO System on an automated, system-to-system basis without direct Access to the RHIO System by an Authorized User.

19. **Certification Requirements** means the minimum requirements for participation in the SHIN-NY and certification as a Qualified Entity, as set forth in the SHIN-NY Policy Standards.

20. **Covered Entity** has the meaning ascribed to this term in 45 C.F.R. § 160.103 and is thereby bound to comply with the HIPAA Privacy Rule and HIPAA Security Rule.

21. **Data Provider** means a Participant that makes clinical data available through the RHIO System.

22. **Data Recipient** means a Participant that uses the RHIO System to Access clinical data of other Participants.

23. **De-Identified Data** means data 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. Data may be considered de-identified only if it (i) satisfies the requirements of 45 C.F.R. § 164.514(b) and (ii) does not contain DNA variation information derived from sequencing, genotyping or other such technologies.

24. **Demographic Information** means a patient’s name, gender, address, date of birth, social security number, and other personally identifiable information, but shall not include any information regarding a patient’s health or medical treatment or the names of any Data Providers that maintain medical records about such patient.

25. **Disaster Relief Agency** means (i) a government agency with authority under federal, state or local law to declare an Emergency Event or assist in locating individuals during an Emergency Event or (ii) a third party contractor to which such a government agency delegates the task of assisting in the location of individuals in such circumstances.

26. **Disclosure** means the release, transfer, provision of access to, or divulging in any manner of information outside the entity holding the information. NY Care Information Gateway engages in a Disclosure of information if NY Care Information Gateway (i) provides a Participant with Access to such information and the Participant views such information as a result of such Access, or (ii) Transmits such information to a Participant or other third party.

27. **Emancipated Minor** means a minor who is emancipated on the basis of being married or in the armed services, or who is otherwise deemed emancipated under New York law or other applicable laws.

28. **Emergency Event** means a circumstance in which a government agency declares a state
of emergency or activates a local government agency incident command system or similar crisis response system.

29. **Executed RHIO Consent Form** means a RHIO Consent Form which has been completed and executed by a patient.

30. **Failed Access Attempt** means an instance in which an Authorized User or other individual attempting to Access the RHIO System is denied Access due to use of an inaccurate login, password, or other security token.

31. **Health Home** means an entity that is enrolled in New York’s Medicaid Health Home program and that receives Medicaid reimbursement for providing care management services to participating enrollees.

32. **Health Information Exchange Organization** means an entity that facilitates and oversees the exchange of Protected Health Information among Covered Entities, Business Associates, and other individuals and entities.

33. **Health Home Member** means an entity that contracts with a Health Home to provide services covered by New York’s Medicaid Health Home program.

34. **HIPAA** means the Health Insurance Portability and Accountability Act of 1996, and the privacy and security regulations issued thereunder.

35. **HIPAA Privacy Rule** means the federal regulations at 45 C.F.R. Part 160 and Subparts A and E of Part 164.


37. **HITECH** means the Health Information Technology for Economic and Clinical Health Act.

38. **Independent Practice Association** (“IPA”) means an entity that is certified as an independent practice association under 10 N.Y.C.R.R. § 98-1.5(b)(6)(vii).

39. **Insurance Coverage Reviews** means the use of information by a Participant (other than a Payer Organization) to determine which health plan covers the patient or the scope of the patient’s health insurance benefits.

40. **Limited Data Set** means Protected Health Information that excludes the 16 direct identifiers set forth at 45 C.F.R. § 164.514(e)(2) of an individual and the relatives, employers or household members of such individual.

41. **Minor Consent Information** means Protected Health Information relating to medical treatment of a minor for which the minor provided his or her own consent without a parent’s or guardian’s permission, as permitted by New York law or other applicable laws for certain types of health services (e.g., reproductive health, HIV testing, sexually transmitted disease, mental health or substance abuse treatment) or services consented to
by an Emancipated Minor.

42. **NY Care Information Gateway Policies and Procedures** means this Policies and Procedures document, as amended from time to time in accordance with Policy 1-1 (Adoption of Policies and Procedures).

43. **NY Care Information Gateway Research Committee** means the NY Care Information Gateway committee that is organized to review and approve Research proposals. NY Care Information Gateway will ensure that the committee meets the requirements set forth at 45 C.F.R. § 164.512(i)(1)(i)(B), meaning that the committee (1) has members with varying backgrounds and appropriate professional competency as necessary to review the effect of the Research protocol on individuals’ privacy rights and related interests; (2) includes at least one member who is not an employee, contractor, officer or director of NY Care Information Gateway or any entity conducting or sponsoring the research, and is not related to any person who meets any of the foregoing criteria; and (3) does not have any member participating in a review of any project in which the member has a conflict of interest.

44. **NYS DOH** means the New York State Department of Health.

45. **NYS Policies and Procedures** means the Privacy and Security Policies and Procedures for Qualified Entities and their Participants in New York State under 10 NYCRR § 300.3(b)(1) as developed through the Statewide Collaboration Process.

46. **One-to-One Exchange** means a Transmittal of Protected Health Information originating from a Participant which has a relationship with a patient to one or more other Participants with the patient’s knowledge and implicit or explicit consent where no records other than those of the Participants jointly providing health care services to the patient are Transmitted. Examples of a One-to-One Exchange include, but are not limited to, information provided by a primary care provider to a specialist when referring to such specialist, a discharge summary sent to where the patient is transferred, lab results sent to the Practitioner who ordered the laboratory test or a claim sent from a Participant to the patient’s health plan.

47. **Organ Procurement Organization ("OPO")** means a regional, non-profit organization responsible for coordinating organ and tissue donations at a hospital that is designated by the Secretary of Health and Human Services under section 1138(b) of the Social Security Act (42 USC § 1320b-8(b); see also 42 C.F.R. Part 121).

48. **Participant** means a Provider Organization, Payer Organization, Practitioner, Independent Practice Association, Accountable Care Organization, Public Health Agency, Organ Procurement Organization, Health Home, Health Home Member, PPS Partner, PPS Lead Organization, PPS Centralized Entity, Social Services Program or Disaster Relief Agency that has directly or indirectly entered into a Participation Agreement and Accesses Protected Health Information through the RHIO System.

49. **Participation Agreement** is the agreement made by and between NY Care Information Gateway and each Participant, which sets forth the terms and conditions governing the operation of the RHIO System and the rights and responsibilities of the Participants and
NY Care Information Gateway with respect to the RHIO System.

50. **Patient Care Alert** means an electronic message about a development in a patient’s medical care, such as an emergency room or inpatient hospital admission or discharge, a scheduled outpatient surgery or other procedure, or similar event, which is derived from information maintained by NY Care Information Gateway and is Transmitted by NY Care Information Gateway to subscribing recipients but does not allow the recipient to Access any Protected Health Information through the RHIO System other than the information contained in the message. Patient Care Alerts may contain demographic information such as patient name and date of birth, the name of the Participant from which the patient received treatment, and limited information related to the patient’s complaint or diagnosis but shall not include the patient’s full medical record relating to the event that is the subject of the electronic message.

51. **Payer Organization** means an insurance company, health maintenance organization, employee health benefit plan established under ERISA or any other entity that is legally authorized to provide health insurance coverage.

52. **Personal Representative** means a person who has the authority to consent to the Disclosure of a patient’s Protected Health Information under Section 18 of the New York State Public Health Law and any other applicable state and federal laws and regulations.

53. **PPS** means a Performing Provider System that has received approval from NYS DOH to implement projects and receive funds under New York’s Delivery System Reform Incentive Payment Program (DSRIP).

54. **PPS Centralized Entity** means an entity owned or controlled by one or more PPS Partners that has been engaged by a PPS to perform Care Management, Quality Improvement or Insurance Coverage Reviews on behalf of the PPS.

55. **PPS Lead Organization** means an entity that has been approved by NYSDOH and CMS to serve as designated organization that has assumed all responsibilities associated with DSRIP program per their project application and DSRIP award.

56. **PPS Partner** means a person or entity that is listed as a PPS Partner in the DSRIP Network Tool maintained by NYS DOH.

57. **Practitioner** means a health care professional licensed under Title 8 of the New York Education Law, or an equivalent health care professional licensed under the laws of the state in which he or she is practicing, or a resident or student acting under the supervision of such a professional.

58. **Protected Health Information** means individually identifiable health information (e.g., any oral or recorded information relating to the past, present, or future physical or mental health of an individual; the provision of health care to the individual; or the payment for health care) of the type that is protected under the HIPAA Privacy Rule.

59. **Provider Organization** means an entity such as a hospital, nursing home, home health
agency or professional corporation legally authorized to provide health care services.

60. **Public Health Agency** means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, the New York State Department of Health, a New York county health department or the New York City Department of Health and Mental Hygiene, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate and that has signed a Participation Agreement with NY Care Information Gateway and Accesses Protected Health Information through the RHIO System.

61. **Qualified Health IT Entity (“Qualified Entity” or “QE”)** means a not-for-profit entity that has been certified as a QE under 10 N.Y.C.R.R. Section 300.4 and has executed a contract pursuant to which it has agreed to be bound by SHIN-NY Policy Standards.

62. **Quality Improvement** means activities designed to improve processes and outcomes related to the provision of health care services. Quality Improvement activities include but are not limited to outcome evaluations; development of clinical guidelines; population based activities relating to improving health or reducing health care costs; clinical protocol development and decision support tools; case management and care coordination; reviewing the competence or qualifications of health care providers, but shall not include Research. The use or Disclosure of Protected Health Information for quality improvement activities may be permitted provided the Accessing and Disclosing entities have or had a relationship with the individual who is the subject of the Protected Health Information.

63. **Record Locator Service or Other Comparable Directory** means a system, queriable only by Authorized Users, that provides an electronic means for identifying and locating a patient’s medical records across Data Providers.

64. **Research** means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge, including clinical trials.

65. **Retrospective Research** means Research that is not conducted in connection with Treatment and involves the use of Protected Health Information that relates to Treatment provided prior to the date on which the Research proposal is submitted to an Institutional Review Board.

66. **RHIO Consent** means the standard NY Care Information Gateway Consent Form in the form attached hereto as Appendix B, or a document substantially similar to such form approved by NY Care Information Gateway in accordance with the NYS Policies and Procedures.

67. **RHIO Edge Server** is an electronic data storage system in which the Protected Health Information being shared by a Participant through the RHIO System is maintained.

68. **RHIO Staff** means those individuals who are employed or contracted by NY Care
Information Gateway for the purpose of carrying out the functions of NY Care Information Gateway.

69. **RHIO System** means the clinical information data exchange operated by NY Care Information Gateway.

70. **Sensitive Health Information** means any Protected Health Information subject to special privacy protection under state or federal law, including but not limited to HIV/AIDS, mental health, alcohol and substance abuse, reproductive health, sexually-transmitted disease and genetic testing information.

71. **SHIN-NY** means the technical infrastructure (SHIN-NY Enterprise) and the supportive policies and agreements that make possible the electronic exchange of clinical information among QEs, Participants, and other individuals and entities for authorized purposes, including both the infrastructure that allows for exchange among Participants governed by the same QE and the infrastructure operated by the State Designated Entity that allows for exchange between different QEs. The goals of the SHIN-NY are to improve the quality, coordination and efficiency of patient care, reduce medical errors and carry out public health and health oversight activities, while protecting patient privacy and ensuring data security.

72. **SHIN-NY Enterprise** means the information technology (IT) infrastructure inclusive of the QEs and the statewide SHIN-NY Hub that supports the electronic exchange of patient health information across New York State.

73. **SHIN-NY Hub** means the information technology (IT) infrastructure operated by the State Designated Entity that allows for the exchange of information between QEs.

74. **SHIN-NY Policy Standards** means the set of policies and procedures, including technical standards and SHIN-NY services and products, that are developed through the Statewide Collaboration Process and adopted by NYS DOH as provided in 10 N.Y.C.R.R. Section 300.3, including the SHIN-NY Policy Standards incorporated by reference in subdivision (c) of that section.

75. **SHIN-NY Portal** means the secure online website that gives patients and their Personal Representatives access to the Protected Health Information about them that is available through the SHIN-NY.

76. **Social Services Program** means a program within a social services district (as defined by New York Social Services Law, § 2) which has authority under applicable law to provide “public assistance and care” (as defined by New York Social Services Law § 2), Care Management, or coordination of care and related services.

77. **Stakeholder** includes but is not limited to parties interested in providing or obtaining information from the SHIN-NY and includes consumers/patients, caregivers, physicians and clinicians, hospitals, payers including Medicaid and Medicare, public health, care coordination organizations.

78. **State Designated Entity (“SDE”)** means the public/private partnership in New York
State that has been designated by the New York State Commissioner of Health as eligible to receive federal and state grants to promote health information technology.

79. **Statewide Collaboration Process ("SCP")** means an open, transparent process to which multiple SHIN-NY stakeholders contribute for the development of the SHIN-NY Policy Standards as provided in 10 N.Y.C.R.R. Section 300.3.

80. **Training** means the instructions in the use of the RHIO Policies and Procedures and the RHIO System, as more fully described in Policy and Procedure 1-10 (Training).

81. **Transmittal** means NY Care Information Gateway’s transmission of Protected Health Information, a Limited Data Set, or De-identified Data to a recipient in either paper or electronic form, other than via the display of such information through the RHIO System or through a Certified Application.

82. **Treatment** means the provision, coordination, or management of health care and related services among health care providers or by a single health care provider, and may include providers sharing information with a third party. Consultation between health care providers regarding a patient and the referral of a patient from one health care provider to another also are included within the definition of Treatment.

83. **Unsecured Protected Health Information** means Protected Health Information that is not rendered unusable, unreadable, or indecipherable to unauthorized individuals through the use of a technology or methodology specified by the U.S. Department of Health and Human Services in guidance issued under section 1 3402(h)(2) of HITECH (42 USC 1 7932(h)(2)).
NY Care Information Gateway, Inc.  
Policy and Procedure  
1-1  
Adoption of Policies and Procedures  

Adopted March 26, 2010; updated December 15, 2016

I. Policy

It is the policy of NY Care Information Gateway to bring all new NY Care Information Gateway Policies and Procedures, or material changes to existing NY Care Information Gateway Policies and Procedures, to the Board of Directors for review and approval by a majority vote.

II. Responsible Parties

The Executive Director is responsible for the development and/or amendment of NY Care Information Gateway Policies and Procedures. The Executive Director will be responsible for determining whether amendments to the NY Care Information Gateway Policies and Procedures are material. The Executive Director will be responsible for bringing all new NY Care Information Gateway Policies and Procedures, or material changes to existing NY Care Information Gateway Policies and Procedures, to the Board of Directors for review and approval by a majority vote. The Executive Director is responsible for making any non-material changes to the NY Care Information Gateway Policies and Procedures, and for reporting such changes to the Board of Directors at the next meeting of the Board.

Committees of the Board may participate in the review of draft Policies and Procedures and in the development of recommendations to the Board of Directors as to whether such Policies and Procedures should be adopted by the Board.

The Board of Directors is responsible for reviewing draft Policies and Procedures and determining if they should be adopted by the Board of Directors as official NY Care Information Gateway Policies and Procedures.

Participants are responsible for complying with the NY Care Information Gateway Policies and Procedures once they are adopted by a majority vote of the Board of Directors.

III. Procedure

A. The Executive Director, working with staff or Board or Committee members as necessary, will develop draft Policies and Procedures for NY Care Information Gateway. If an amendment to an existing Policy or Procedure is developed, the Executive Director will be responsible for determining whether such amendment is material.

B. The new or materially amended draft Policies and Procedure may be presented to a Committee if they are relevant to the charge of that Committee for review and recommendation for action to the Board, or may be brought directly to the Board
C. The new or materially amended draft Policies and Procedures will be circulated to the Board and Committee members no less than one week prior to the scheduled date of the meeting where voting will take place, except in the event that more immediate action is required to comply with applicable laws and regulations, or under other circumstances where more immediate action is required to protect the interests of NY Care Information Gateway, one or more Participants, or the individuals whose Protected Health Information is exchanged through the RHIO.

D. The new or materially amended NY Care Information Gateway Policies and Procedures will not be adopted other than by majority vote of the Board of Directors at a meeting where a quorum is present.

E. Non-material amendments to the NY Care Information Gateway Policies and Procedures may be made upon approval by the Executive Director. At each meeting of the Board of Directors, the Executive Director will be responsible for providing a list of any non-material changes made to the NY Care Information Gateway Policies and Procedures since the prior meeting of the Board.

F. Once a Policy and Procedure is adopted it will be deemed to be incorporated into the Participation Agreement in accordance with and subject to the provisions regarding the establishment of Policies and Procedures set forth in the Participation Agreement.

G. NY Care Information Gateway Policies and Procedures may only be materially amended or repealed by majority vote of the Board of Directors at a meeting where a quorum is present.
NY Care Information Gateway, Inc.
Policy and Procedure
1-2
Participation in NY Care Information Gateway

Adopted March 26, 2010; updated December 15, 2016

I. Policy

It is the policy of NY Care Information Gateway to obtain the approval of the NY Care Information Gateway Executive Director of the Application for Participation of each prospective Participant prior to permitting such Participant to engage in the exchange of Protected Health Information through the RHIO System.

II. Responsible Parties

The Executive Director of NY Care Information Gateway is responsible for assuring that each Participant has submitted its Application for Participation and that such Application for Participation has received the appropriate approval prior to permitting such Participant to engage in the exchange of Protected Health Information through the RHIO System.

Prospective Participants are responsible for completing the Application for Participation.

III. Procedures

A. Prior to engaging in the exchange of Protected Health Information through the RHIO System, each Participant must complete and submit to the Executive Director of NY Care Information Gateway an Application for Participation (Attachment A).

B. Prior to engaging in the exchange of Protected Health Information through the RHIO System, each Participant’s Application for Participation must be approved by the Executive Director.

C. Simultaneously with submitting an Application for Participation to the Executive Director, each Participant must sign and submit a Participation Agreement.

D. Each Participant must identify its Authorized User Manager, as described in Policy 1-4 (Authorization & Authentication), in its Application for Participation.

E. Each Participant must agree to properly train all of its Authorized Users, as described in Policy and Procedure 1-10 (Training), in its Application for Participation.
NY Care Information Gateway, Inc.
Policy and Procedure
1-3
Patient Consent and Privacy

Adopted March 26, 2010

Updated February 24, 2015; updated December 15, 2016; updated May 10, 2018

I. Policy

It is the policy of NY Care Information Gateway to require that all Participants comply with this Patient Consent and Privacy Policy when exchanging Protected Health Information through the RHIO System.

It is the policy of NY Care Information Gateway to ensure that the NY Care Information Gateway Patient Consent and Privacy Policy complies with the NYS Policies and Procedures.

It is the policy of NY Care Information Gateway to require Participants to safeguard Protected Health Information obtained through NY Care Information Gateway in the same way as they are required by existing federal and state laws and regulations to safeguard any Protected Health Information contained in records within their facility.

II. Responsible Parties

The Board of Directors of NY Care Information Gateway will have primary responsibility for overseeing the execution and revision of this Patient Consent and Privacy Policy.

The Executive Director will oversee the activities of NY Care Information Gateway to evaluate compliance by Participants with this Patient Consent and Privacy Policy and enforce its terms.

Participants will have responsibility for ensuring compliance with this Patient Consent and Privacy Policy at their sites.

III. Procedure

A. Except as outlined in Section III.B of this Policy, NY Care Information Gateway will not Disclose a patient’s Protected Health Information via the RHIO System to a Participant unless the patient has provided an Affirmative Consent authorizing the Participant to Access or receive such Protected Health Information.

B. An Affirmative Consent is not required under the circumstances set forth in this Section III.B. Disclosures of Protected Health Information without Affirmative Consent shall comply with applicable federal, state and local laws and regulations, including 42 C.F.R. Part 2. Protected Health Information subject to 42 C.F.R. Part 2 shall not be Disclosed without Affirmative Consent unless 42
C.F.R. Part 2 specifically allows for such Disclosure.

1. An Affirmative Consent is not required for Transmittal of a patient’s Protected Health Information originating from one Participant to another Participant if such Transmittal meets all the requirements of a One-to-One Exchange (including the requirement that the Transmittal occur with the patient’s implicit or explicit consent) provided the Participants comply with existing federal and state laws and regulations requiring patient consent for the Disclosure and re-disclosure of information by health care providers. If Protected Health Information is Transmitted to a Payer Organization under a One-to-One Exchange, such exchange must comply with Section III.F.18.a which allows an individual to request a restriction on the Disclosure of Protected Health Information.

2. Emergency Disclosures of PHI When Treating a Patient with an Emergency Condition or “Breaking the Glass”.

   a. An Affirmative Consent is not required for NY Care Information Gateway to Disclose Protected Health Information to a Practitioner, an Authorized User that is acting under the direction of a Practitioner, or an Advanced Emergency Medical Technician and those individuals may Break the Glass when the following conditions are met.

      (i) The Practitioner, an Authorized User that is acting under the direction of a Practitioner, or an Advanced Emergency Medical Technician is an Authorized User with Break-the-Glass Access.

      (ii) In the Practitioner’s or Advanced Emergency Medical Technician’s judgment, an emergency condition exists and the patient is in immediate need of medical attention and an attempt to secure consent would result in delay of treatment which would increase the risk to the patient’s life or health.

      (iii) The Practitioner or Advanced Emergency Medical Technician determines, in his or her reasonable judgment, that information that may be available through the RHIO System may be material to emergency treatment.

      (iv) No denial of consent to Access or receive the patient’s information is currently in effect with respect to the Participant with which the Practitioner, Authorized User acting under the direction of a Practitioner or Advanced Emergency Medical Technician is affiliated.

      (v) In the event that an Authorized User acting under the direction of a Practitioner Breaks the Glass, such Authorized User must record the name of the Practitioner
providing such direction.

(vi) The Practitioner, an Authorized User acting under the direction of a Practitioner, or an Advanced Emergency Medical Technician attests that all of the foregoing conditions have been satisfied and NY Care Information Gateway maintains a record of this Disclosure.

b. Break the Glass Access by an Authorized User acting under the direction of a Practitioner must be granted by the Practitioner on a case by case basis.

c. Participants shall ensure that Break-the-Glass Disclosures of Protected Health Information via the RHIO System do not occur after completion of the emergency treatment.

d. Notwithstanding anything to the contrary set forth in these policies, NY Care Information Gateway and its Participants shall not be required to exclude any Sensitive Health Information from Disclosure where the circumstances set forth in this Section III.B.2 are met.

e. If NY Care Information Gateway includes data protected under 42 C.F.R. Part 2, NY Care Information Gateway shall promptly notify Data Providers that are federally–assisted alcohol or drug abuse programs when Protected Health Information from the Data Provider’s records is Disclosed under this Section III.B.2. This notice shall include (i) the name of the Participant that received the Protected Health Information; (ii) the name of the Authorized User within the Participant that received the Protected Health Information; (iii) the date and time of the Disclosure; and (iv) the nature of the emergency.

f. Upon a patient’s discharge from a Participant’s emergency room, if emergency Disclosure of PHI occurred during the emergency room visit, the Participant shall notify the patient of such incident and inform the patient how he or she may request an Audit Log in accordance with Section III.D.2 of Policy 1-6 (Audit). In lieu of providing such notice, Participants that are hospitals may notify all patients discharged from an emergency room that their Protected Health Information may have been Disclosed during a Break the Glass incident and inform patients how they may request an Audit Log to determine if such Disclosure occurred. The notice required by this Section III.B.2.f shall be provided by the Participant within ten days of the patient’s discharge.

3. NY Care Information Gateway does not require an Affirmative RHIO Consent for the uploading of Protected Health Information to the RHIO
System or a RHIO Edge Server.

4. QE Access for Operations and Other Purposes

a. Affirmative Consent is not required for NY Care Information Gateway, government agencies that demonstrate any necessary legal authority or their contractors to Access or receive Protected Health Information for the purpose of evaluating and improving QE operations. Consistent with HIPAA, Disclosure of Protected Health Information shall be limited to the minimum amount necessary to accomplish the intended purpose of the Disclosure.

b. Affirmative Consent is not required for NY Care Information Gateway or its contractors to Access or receive Protected Health Information via the SHIN-NY to enable NY Care Information Gateway to perform system maintenance, testing and troubleshooting and to provide similar operational and technical support.

c. Affirmative Consent is not required for NY Care Information Gateway or its contractors to Access or receive Protected Health Information via the SHIN-NY at the request of a Participant in order to assist the Participant in carrying out activities for which the Participant has obtained the patient’s Affirmative Consent. Such Access or receipt must be consistent with the terms of the Business Associate Agreement entered into by the Participant and NY Care Information Gateway.

5. Public Health Reporting and Access

a. NY Care Information Gateway may Disclose Protected Health Information to a Public Health Agency without Affirmative Consent for public health activities authorized by law, including:

   (i) To investigate suspected or confirmed cases of communicable disease (pursuant to PHL § 2(1)(1) and 10 N.Y.C.R.R. Part 2);

   (ii) To ascertain sources of infection (pursuant to 10 N.Y.C.R.R. Part 2);

   (iii) To conduct investigations to assist in reducing morbidity and mortality (pursuant to 10 N.Y.C.R.R. Part 2);

   (iv) As authorized by PHL § 206(1)(d) to investigate the causes of disease, epidemics, the sources of mortality, and the effect of localities, employments and other conditions, upon the public health, and by PHL § 206(1)(j) for scientific studies and research which have for their purpose
the reduction of morbidity and mortality and the improvements of the quality of medical care through the conduction of medical audits;

(v) For purposes allowed by Article 21, including Article 21, Title 3 and 10 N.Y.C.R.R. Part 63 (HIV) and Article 21, Title 6 and 10 N.Y.C.R.R. Part 66 (immunizations);

(vi) For purposes allowed by PHL § 2(1)(n), Article 23 and 10 N.Y.C.R.R. Part 23 (STD);

(vii) For purposes allowed by PHL § 2401 and 10 N.Y.C.R.R. § 1.31 (cancer);

(viii) For the activities of the Electronic Clinical Laboratory Reporting System (ECLRS), the Electronic Syndromic Surveillance System (ESSS) and the Health Emergency Response Data System (HERDS);

(ix) For purposes allowed by PHL § 2004 and 10 N.Y.C.R.R. Part 62 (Alzheimer’s);

(x) For purposes allowed by PHL § 2819 (infection reporting);

(xi) For quality improvement and quality assurance under PHL Article 29-D, Title 2, including quality improvement and quality assurance activities under PHL § 2998-e (office-based surgery);

(xii) For purposes allowed under 10 N.Y.C.R.R. Part 22 (environmental diseases);

(xiii) To investigate suspected or confirmed cases of lead poisoning (pursuant to 10 N.Y.C.R.R. § 67);

(xiv) For purposes allowed by 10 N.Y.C.R.R. Part 69 (including newborn disease screening, newborn hearing screening and early intervention);

(xv) For purposes allowed under 10 N.Y.C.R.R. § 400.22 (Statewide Perinatal Data System);

(xvi) For purposes allowed under 10 N.Y.C.R.R. § 405.29 (cardiac data); or

(xvii) For any other public health activities authorized by law. “Law means a federal, state or local constitution, statute, regulation, rule, common law, or other governmental action having the force and effect of law, including the Charter,
Administrative Code and Rules of the City of New York.

b. A patient’s denial of consent for all Participants in NY Care Information Gateway to Access the patient’s Protected Health Information shall not prevent or otherwise restrict NY Care Information Gateway from Disclosing to a Public Health Agency the patient’s Protected Health Information through NY Care Information Gateway for the purposes set forth in Section III.B.5.a(i)-(xvii) of this Policy.

c. If a Data Provider or Participant is permitted to Disclose Protected Health Information to a government agency for purposes of public health reporting, including monitoring disease trends, conducting outbreak investigations, responding to public health emergencies, assessing the comparative effectiveness of medical treatments (including pharmaceuticals), conducting adverse drug event reporting, and informing new payment reforms, without patient consent under applicable state and federal laws and regulations, NY Care Information Gateway may make that Disclosure on behalf of the Data Provider or Participant without an Affirmative Consent.

d. NY Care Information Gateway may Disclose the reports and information subject to 10 NYCRR §63.4 (HIV clinical laboratory test results), for purposes of linkage to and retention in care, to Participants engaged in Care Management that have a clinical, diagnostic, or public health interest in the patient, to the extent permitted under 10 NYCRR §63.4(c)(3). Participants engaged in Care Management with a clinical, diagnostic, or public health interest in a patient may include, but are not limited to, Provider Organizations or Practitioners with a Treatment relationship with a patient, Health Homes, and Payer Organizations providing Care Management to their enrollees. NY Care Information Gateway shall work in consultation with the New York State Department of Health, AIDS Institute, prior to implementing any program under this provision.

6. De-Identified Data. An Affirmative Consent is not required for NY Care Information Gateway to Disclose De-identified Data for specified uses as set forth in Section III.F.14 of this Policy.

7. Organ Procurement Organization Access. NY Care Information Gateway may Disclose Protected Health Information to an Organ Procurement Organization without an Affirmative Consent solely for the purposes of facilitating organ, eye or tissue donation and transplantation. A patient’s denial of an Affirmative Consent for all Participants in NY Care Information Gateway to Access the patient’s Protected Health Information shall not prevent or otherwise restrict an Organ Procurement Organization from
Accessing or receiving the patient’s Protected Health Information through NY Care Information Gateway for the purposes set forth in this Section III.B.7.

8. Disclosures for Disaster Tracking

a. For the purpose of locating patients during an Emergency Event, NY Care Information Gateway may Disclose to a Disaster Relief Agency the following information without Affirmative Consent:

   (i) Patient name and other demographic information in accordance with the principles set forth in Section III.D of Policy 1-5 (Access);

   (ii) Name of the facility or facilities from which the patient received care during the Emergency Event; dates of patient admission and/or discharge.

b. NY Care Information Gateway may Disclose information under this Section III.B.8 during an Emergency Event only.

c. Information Disclosed under this Section III.B.8 shall not reveal the nature of the medical care received by the patient who is the subject of the Disclosure unless the Governor of New York, through executive order, temporarily suspends New York State health information confidentiality laws that would otherwise prohibit such Disclosure, as authorized under N.Y. Executive Law Section 29-a.

d. A patient’s denial of consent for all Participants in NY Care Information Gateway to Access or receive the patient’s Protected Health Information shall not restrict NY Care Information Gateway from Disclosing information to a Disaster Relief Agency as permitted in this Section III.B.8.

9. Disclosures to NYSDOH Regarding Medicaid beneficiaries. Affirmative Consent shall not be required for NY Care Information Gateway to Disclose Protected Health Information of Medicaid beneficiaries to NYSDOH or a Business Associate of NYSDOH to the extent such Disclosure is necessary to (i) calculate performance under quality measures adopted by the New York State Medicaid program; or (ii) determine payments to be made under the New York State Medicaid program.

C. Sensitive Health Information

1. An Affirmative Consent will authorize the Participant(s) listed on the consent form to Access or receive all Protected Health Information
referenced on the consent form, including Sensitive Health Information.

2. An Authorized User will have Access to a patient’s Sensitive Health Information if an Affirmative Consent of the patient is in effect with respect to the Participant with which the Authorized User is affiliated.

3. Participants shall implement systems to identify and denote Sensitive Health Information in order to ensure compliance with applicable state and federal laws and regulations governing re-disclosure of Sensitive Health Information, including, but not limited to, those applicable to HIV/AIDS, alcohol and substance abuse information, and records of facilities licensed or operated by the New York State Office of Mental Health or the New York State Office for People With Developmental Disabilities.

4. NY Care Information Gateway shall meet the following requirements with respect to warning statements:

   a. If it includes data protected under 42 C.F.R. Part 2, a warning statement that is viewed by Authorized Users whenever they are obtaining Access to or receiving Transmittals of records of federally-assisted alcohol or drug abuse programs regulated under 42 C.F.R. Part 2 that contains the language required by 42 C.F.R. § 2.32. NY Care Information Gateway may satisfy this requirement by placing such a re-disclosure warning on all records that are Accessed through or Transmitted by the RHIO.

   b. A warning statement that is viewed by Authorized Users whenever they are obtaining Access to or receiving Transmittals of HIV/AIDS information protected under Article 27-F of the N.Y. Public Health Law that contains the language required by Article 27-F (see Public Health Law § 2782(5)). NY Care Information Gateway satisfies this requirement by placing such a re-disclosure warning on all records that are Accessed through or Transmitted by the RHIO.

   c. A warning statement that is viewed by Authorized Users whenever they are obtaining Access to or receiving Transmittals of records of facilities licensed or operated by the New York State Office of Mental Health or the New York State Office for People With Developmental Disabilities that contains language notifying the Authorized User that such records may not be re-disclosed except as permitted by the New York Mental Hygiene Law. NY Care Information Gateway may satisfy this requirement by placing such a re-disclosure warning on all records that are Accessed through or Transmitted by the RHIO.

D. Form of Patient Consent and Recording Consent
1. The RHIO Consent form is attached as Appendix B.

2. No Participant may modify the terms of the RHIO Consent without the prior written approval of the Executive Director of NY Care Information Gateway.

3. Once a Participant’s patient has executed the RHIO Consent, the Participant will be responsible for updating the Patient Authorization Record in the RHIO System to reflect the level of consent, if any, the patient provided.

4. Participants may not deny or restrict Treatment to a patient due to the patient’s refusal to execute a RHIO Consent.

5. Participants must maintain a copy of all patients’ Executed RHIO Consent Forms. Executed RHIO Consent Forms must be kept indefinitely or, if revoked, for six years after revocation.

6. RHIO Consents may not designate that some Sensitive Health Information will be Accessed through the RHIO System while other information will not.

E. Minors’ Consent Information

1. At this time NY Care Information Gateway does not have a mechanism to enable the Disclosure of Minor Consent Information in accordance with the NYS Policies and Procedures. Until such mechanism is defined, Disclosure of Minor Consent Information will be prohibited via the RHIO System, except for One-to-One Exchange provided the Participants comply with existing federal and state laws and regulations requiring patient consent for the disclosure and re-disclosure of information by health care providers.

2. To ensure that Minor Consent Information is not Disclosed via the RHIO System, Protected Health Information for Patients 10 years old or greater, and less than 18 years old may not be Accessed through the RHIO System, except for One-to-One Exchange as described in Section III.B.1 of this Policy.

F. Other Privacy Practices

1. Participants shall adopt and implement any other privacy and security policies and procedures relating to the use, maintenance and disclosure of Protected Health Information Accessed or received via the RHIO System that are necessary to assure the Participant’s compliance with HIPAA and all other applicable confidentiality laws and regulations.

2. An Executed RHIO Consent Form of a patient obtained by a Participant shall apply to an Affiliated Practitioner of the Participant provided that (i) such Affiliated Practitioner is providing health care services to the patient
at the Participant’s facilities; (ii) such Affiliated Practitioner is providing health care services to the patient in his or her capacity as an employee or contractor of the Participant or (iii) such Affiliated Practitioner is providing health care services to the patient in the course of a cross-coverage or on-call arrangement with the Participant or one of its Affiliated Practitioners.

3. An Executed RHIO Consent Form may be obtained electronically provided that there is an electronic signature that meets the requirements of the federal ESIGN statute, 15 U.S.C. § 7001 et seq., or any other applicable New York State or federal laws or regulations. See Electronic Signatures and Records Act (State Technology Law Article III, 9 NYCRR Part 540, New York State Office of Information Technology Services ESRA Guidelines NYS-G04-001).

4. The RHIO Consent form gives patients the option of granting or affirmatively denying consent for individual Participants to Access or receive Protected Health Information about the patient via the RHIO System. A patient’s decision not to sign a consent form shall not be construed as a “denial of consent” under section III.B.2.a.iv of this Policy. Each Participant shall ensure that patients have the option, through the use of a single paper or electronic form, to affirmatively deny consent for all Participants in the RHIO System to Access or receive the patient’s information, except as set forth in Section III.B.5 or III.B.6 of this Policy. Participants shall provide the patient with a description of how patients may deny consent – through use of a single paper or electronic form - for all Participants to Access or receive their Protected Health Information through NY Care Information Gateway.

5. The RHIO Consent does not have to be time-limited.

6. Patients are entitled to revoke an Affirmative Consent at any time. Any Participant that has Accessed or received Protected Health Information via the RHIO System prior to such revocation and incorporated such Protected Health Information into its records may retain such information in its records.

7. Participants will

   a. Provide each patient with a list of or reference to all Data Providers at the time the Participant obtains the patient’s Affirmative Consent and an acknowledgement that Data Providers may change over time; and

   b. Provide each patient with notice – in a manner easily understood by patients – that their Protected Health Information is being uploaded to NY Care Information Gateway.

8. NY Care Information Gateway will maintain and make available on the
NY Care Information Gateway Website a complete and accurate updated list of Data Providers.

9. NY Care Information Gateway shall not use or Disclose Protected Health Information in any manner that violates the RHIO’s Business Associate Agreements with Data Providers.

10. NY Care Information Gateway, acting under the authority of a Business Associate Agreement with its Participants, may Disclose Protected Health Information to vendors that assist in carrying out the RHIO’s authorized activities provided (i) the RHIO requires the vendors to protect the confidentiality of the Protected Health Information in accordance with the RHIO’s Business Associate Agreements with its Participants and (ii) the vendor does not make such information available to a Participant, unless such Participant has attested that it has obtained an Affirmative Consent from the patient to whom such information relates.

11. All Access to Protected Health Information via the RHIO System shall be consistent with applicable federal, state and local laws and regulations. If applicable law requires that certain documentation exist or that other conditions be met prior to Accessing or receiving Protected Health Information for a particular purpose, Participants shall ensure that they have obtained the required documentation or met the requisite conditions and shall provide evidence of such as applicable.

12. The RHIO shall not Disclose Protected Health Information without an Affirmative Consent in response to requests from government agencies for health oversight purposes, such as Medicaid audits, professional licensing reviews, and fraud and abuse investigations, unless such Disclosure is required by law. This Section III.F.12 does not cover Disclosure of Protected Health Information to Public Health Agencies under Section III.B.5 of this Policy.

13. Consent for Access by ACOs and IPAs. An Affirmative Consent authorizing Access by an ACO or IPA shall cover only the ACO or IPA entity itself and not the health care providers participating in the ACO or IPA.


(i) Affirmative Consent shall not be required for NY Care Information Gateway to Disclose De-Identified Data for Research in accordance with Section III.F.16.a of this Policy.

(ii) Affirmative Consent shall not be required for NY Care Information Gateway, a Participant, or a government agency to Access or receive De-Identified Data via the
RHIO System for any purpose for which NY Care Information Gateway, Participant, or government agency may lawfully Access or receive Protected Health Information under these Policies and Procedures.

(iii) Affirmative Consent shall not be required for NY Care Information Gateway to Disclose De-Identified Data via the RHIO System for Quality Improvement, provided that a specially designated committee appointed by NY Care Information Gateway reviews and approves the Quality Improvement activity in accordance with standards. Participants must make available to the committee the methodology of any proposed Quality Improvement project, which NY Care Information Gateway shall make accessible to other Participants and the general public.

(iv) Affirmative Consent shall not be required for NY Care Information Gateway to perform an evaluation of the economic or other value of NY Care Information Gateway provided that the methodology and results of any such evaluation are posted on the NY Care Information Gateway’s website.

(v) Affirmative Consent shall not be required for NY Care Information Gateway to Transmit to a third party that is designing a clinical trial or other clinical research study a count of the number of patients who appear to meet the inclusion and/or exclusion criteria being considered for such clinical trial or study, so long as there is no reasonable basis to believe that the count, when combined with the qualifying criteria, can be used to identify an individual.

b. Creation of De-Identified Data for Specified Uses. NY Care Information Gateway may Access Protected Health Information to create and validate the accuracy of De-Identified Data that is used in accordance with Section III.F.14.a of this Policy.

c. Other Requirements.

(i) All other uses of De-Identified Data shall require Affirmative Consent.

(ii) NY Care Information Gateway shall not condition a patient’s participation in the RHIO on the patient’s decision to consent or deny Access to De-Identified Data for purposes other than those set forth in Section III.F.14.a of this Policy.

(iii) NY Care Information Gateway and Participants must
comply with standards for the de-identification of data set forth in 45 C.F.R. § 164.514.

(iv) NY Care Information Gateway, Participants and government agencies must subject any use of De-Identified Data to adequate restrictions on the re-identification of such data.

15. Patient Care Alerts.

a. A Patient Care Alert may be Transmitted to a Participant without Affirmative Consent provided that the recipient of such Patient Care Alert is a Participant that provides, or is responsible for providing, Treatment or Care Management to the patient. Such categories of Participants may include, but are not limited to, Practitioners, Accountable Care Organizations, Health Homes, Payer Organizations, PPS Centralized Entities, PPS Partners, and home health agencies who meet the requirements of the preceding sentence. If a patient or a patient’s Personal Representative affirmatively denies consent to a Participant to Access the patient’s information, then Patient Care Alerts shall not be Transmitted to such Participant.

b. Patient Care Alerts may be Transmitted from facilities subject to the New York Mental Hygiene Law without Affirmative Consent only if such alerts are sent to Payer Organizations, Health Homes, or other entities authorized by the New York State Office of Mental Health and the sending of such alerts otherwise complies with Mental Hygiene Law § 33.13(d).

c. Patient Care Alerts shall be Transmitted in an encrypted form that complies with U.S. Health and Human Services Department Guidance to Render Unsecured Protected Health Information Unusable, Unreadable, or Indecipherable to Unauthorized Individuals.

16. Research

a. Research Involving De-Identified Data. Affirmative Consent shall not be required for NY Care Information Gateway to Disclose De-Identified Data for purposes of Research, provided that NY Care Information Gateway has adopted policies that inform Data Providers about the circumstances under which De-Identified Data may be Disclosed. The Disclosure of De-Identified Data under this section is subject to NY Care Information Gateway’s compliance with policies adopted by NY Care Information Gateway, which set forth criteria that will be utilized to determine when a proposed Disclosure under this section must be approved by an Institutional Review Board or the NY Care Information Gateway Research
b. Research Involving a Limited Data Set. Affirmative Consent shall not be required for NY Care Information Gateway to Disclose a Limited Data Set for purposes of Research, provided that (i) NY Care Information Gateway has adopted policies that inform Data Providers about the circumstances under which a Limited Data Set may be Disclosed; and (ii) NY Care Information Gateway enters into a data use agreement with the researcher prior to Disclosing the Limited Data Set in accordance with the HIPAA Privacy Rule. The Disclosure of a Limited Data Set under this section is subject to NY Care Information Gateway’s compliance with policies adopted by NY Care Information Gateway, which set forth criteria that will be utilized to determine when a proposed Disclosure under this section must be approved by an Institutional Review Board or the NY Care Information Gateway Research Committee.

c. Research Involving Protected Health Information.

(i) Use of Protected Health Information for Patient Recruitment for Research. Affirmative Consent shall not be required for NY Care Information Gateway to review Protected Health Information on behalf of a researcher to determine which individuals may qualify for a Research study. In addition, Affirmative Consent shall not be required for NY Care Information Gateway to Disclose the name and other identifying information of an individual who may qualify for a Research study to a Participant that has a treating relationship with such individual so that the Participant may contact the individual to determine his or her willingness to participate in such study, provided that all of the following requirements are met:

(A) an Institutional Review Board has approved of such Disclosure;

(B) the NY Care Information Gateway Research Committee has approved of such Disclosure;

(C) the Data Provider(s) that are the source of the Protected Health Information have agreed to allow for the Disclosure of their Protected Health Information for purposes of Research; and

(D) the Disclosure does not include any mental health clinical information governed by Section 33.13 of the Mental Hygiene Law, unless the recipient of the Disclosure is a facility as defined in the Mental
Hygiene Law.

(ii) Use of Protected Health Information for Retrospective Research. Affirmative Consent shall not be required for NY Care Information Gateway to Disclose Protected Health Information to a researcher conducting Retrospective Research if: (1) an Institutional Review Board has approved of such Disclosure; (2) the NY Care Information Gateway Research Committee has approved of such Disclosure; and (3) the Data Provider(s) that are the source of the Protected Health Information have agreed to allow for Disclosures of their Protected Health Information for purposes of Research.

d. Other Requirements Relating to Research. NY Care Information Gateway shall not allow a Participant to opt out of having its Protected Health Information de-identified or converted into a Limited Data Set and used for Research that complies with paragraphs a or b, above.

17. NY Care Information Gateway may use Affirmative Consents that apply to more than one Participant, subject to the following conditions:

a. The Participant offering the multi-Participant consent to the patient must inform the patient that the patient has an option to sign a consent form that applies only to that Participant.

b. If the multi-Participant consent allows a Participant to Access or receive any patient records that are subject to the rules governing federally-assisted alcohol or drug abuse programs at 42 C.F.R. Part 2, the consent form must comply with all relevant restrictions in 42 C.F.R. Part 2.

c. An Affirmative Consent may apply to Participants who join NY Care Information Gateway after the date the patient signs the consent form, provided that: (i) NY Care Information Gateway maintains a list of its Participants on the NY Care Information Gateway website and updates that list within 24 hours of when a new Participant is granted Access to patient information via the SHIN-NY; (ii) NY Care Information Gateway mails a hard copy list of its Participants without charge to any patient who requests that list within 5 business days of the request; (iii) the consent form notifies patients that the list of Participants will be regularly updated on the NY Care Information Gateway website and that patients have the right to obtain a hard copy of the list, free of charge, upon request, and (iv) Access to any patient records that are subject to the rules governing federally-assisted alcohol or drug abuse programs complies with 42 C.F.R. Part 2.
18. In the event that a patient requests, in accordance with the HIPAA Privacy Rule and HITECH, that a Provider Organization that has created Protected Health Information about the patient not Disclose it to the patient’s Payer Organization, then:

a. Upon a Provider Organization’s receipt of a patient’s request that Protected Health Information created by the Provider Organization not be Disclosed to a Payer Organization, any Affirmative Consent previously granted to such Payer Organization shall be revoked and such revocation shall remain in effect permanently unless and until the patient's request is withdrawn; and

b. Upon receipt of an Affirmative Consent covering a Payer Organization, the Payer Organization shall notify the patient in writing that his or her provision of the Affirmative Consent will revoke any prior request for a restriction on the Disclosure of Protected Health Information by any Provider Organization to the Payer Organization, and the Affirmative Consent shall be rejected if the patient indicates he or she does not agree to the revocation of his or her prior request.

19. Transmittals to Non-Participants

a. Transmittals to Business Associates. In any case where a Participant has a right to Access or receive Protected Health Information under the NY Care Information Gateway Policies and Procedures, the Participant may request that NY Care Information Gateway Transmit such information to a Business Associate of the Participant, and NY Care Information Gateway may comply with such request, so long as the conditions set forth in subsections (i) through (vi) are met. Nothing in this section shall allow NY Care Information Gateway to treat a Business Associate as a Participant unless the Business Associate otherwise meets the definition of a Participant.

(i) The Participant and the Business Associate have entered into a Business Associate Agreement under which the Business Associate agrees to protect the confidentiality of the Protected Health Information being Transmitted to the Business Associate.

(ii) The Participant represents to NY Care Information Gateway in writing that its Business Associate is seeking the Participant’s information in accordance with the terms of the Business Associate Agreement between the two parties.

(iii) The Business Associate and the Participant agree to provide a copy of their Business Associate Agreement to NY Care
Information Gateway upon request.

(iv) NY Care Information Gateway reasonably believes that the Transmittal is in accordance with state and federal law and the terms of the Business Associate Agreement.

(v) NY Care Information Gateway either enters into an agreement with the Business Associate requiring the Business Associate to comply with the NY Care Information Gateway Policies and Procedures or the Participation Agreement between the Participant and NY Care Information Gateway holds the Participant responsible for the actions of the Business Associate.

(vi) The Business Associate agrees not to further Disclose the Protected Health Information except where the NY Care Information Gateway Policies and Procedures allow for such Disclosure.

b. Transmittals to Other Non-Participants. NY Care Information Gateway may Transmit a patient’s Protected Health Information from NY Care Information Gateway (or any other QE that has agreed to such Transmittal) to a health care provider or other entity that is not a Participant or a Business Associate of a Participant only if all of the following conditions are met:

(i) The patient has granted Affirmative Consent for the Transmittal, provided that Affirmative Consent shall not be required if the Transmittal is provided to a public health authority, as defined at 45 C.F.R. § 164.501. The Affirmative Consent shall meet all the requirements of a Level 2 Consent (as such term is defined in the NYS Policies and Procedures), even if the Protected Health Information is being Transmitted for a Level 1 Use (as such term is defined in the NYS Policies and Procedures), provided that the time limitation otherwise applicable under the NYS Policies and Procedures shall not apply if the Protected Health Information is being Transmitted for a Level 1 Use. For the avoidance of doubt, none of the exceptions to the Affirmative Consent requirement set forth in this Policy other than Section III.B.5 of this Policy shall apply to Transmittals under this section.

(ii) The recipient of the Transmittal is not a Participant and is one of the following:

(A) A Covered Entity that does not operate in New York State, or a Business Associate of such
Covered Entity.

(B) A Health Information Exchange Organization that does not operate in New York State.

(C) A public health authority, as defined at 45 C.F.R. § 164.501, that is not located in New York State.

(D) A health care facility that is operated by the United States Department of Veteran Affairs or the United States Department of Defense.

(E) A disability insurer or life insurer that has (1) issued a disability or life insurance policy to the patient; (2) received an application from the patient for such a policy; or (3) received a claim for benefits from the patient.

(iii) NY Care Information Gateway takes reasonable measures, or requires the recipient to take reasonable measures, to authenticate that the person who has granted the Affirmative Consent is the patient or the patient’s Personal Representative.

(iv) NY Care Information Gateway takes reasonable measures to authenticate that the recipient is the same individual or entity authorized in the patient’s Affirmative Consent to receive the patient’s Protected Health Information.

(v) NY Care Information Gateway enters into an agreement with the recipient that requires the recipient to:

(A) Obtain the Affirmative Consent of the patient that is the subject of the Protected Health Information, or ensure that another entity or organization has obtained such consent;

(B) Abide by the terms of patients’ Affirmative Consents and applicable law (e.g., health privacy laws for a Covered Entity, insurance laws for life and disability insurers), including any restrictions on re-disclosure;

(C) Notify NY Care Information Gateway in writing and in the most expedient time possible if the recipient becomes aware of any actual or suspected Breach of Unsecured Protected Health Information; and
(D) Represent that the recipient is not excluded, debarred, or otherwise ineligible from participating in any federal health care programs.

(vi) Special requirements applicable to Transmittals to life or disability insurers.

(A) If the recipient is a life or disability insurer that is not a governmental entity, then the agreement specified above must also require such insurer to warrant that it has not, and will not in the future, condition the granting of a disability or life insurance policy, the continuation of such policy, the payment of a claim, or a particular premium rate on the patient’s agreement to sign an Affirmative Consent that allows NY Care Information Gateway to Transmit the patient’s Protected Health Information to such insurer.

(B) When NY Care Information Gateway receives a query from a life or disability insurer seeking a patient’s Protected Health Information, NY Care Information Gateway shall notify the applicable patient, via email or otherwise, of the patient’s option to rescind his or her Affirmative Consent to the insurer and/or request a list of the Data Providers that are the sources of the patient’s Protected Health Information. NY Care Information Gateway shall abide by a patient’s request to rescind Affirmative Consent or provide a list of Data Providers if such request is received within 72 hours of NY Care Information Gateway’s notification of the patient. If NY Care Information Gateway does not receive a request from a patient to rescind Affirmative Consent within the 72-hour period, NY Care Information Gateway may Transmit the patient’s Protected Health Information to the life or disability insurer.

Nothing in this section III.F.19.b shall be construed to prohibit a patient from Disclosing any of the patient’s Protected Health Information the patient has received from NY Care Information Gateway under Section III.D of Policy 1-8 (Patient Engagement and Access) to an individual or entity of the patient’s choice.
NY Care Information Gateway, Inc.
Policy and Procedure
1-4

Authorization and Authentication
Adopted March 26, 2010

Updated February 24, 2015; updated December 15, 2016

I. Policy

It is the policy of NY Care Information Gateway to allow only Authorized Users and Certified Applications to Access information through the RHIO System. Authorization is based on role-based Access standards that take into account an individual’s job function and the information needed to successfully carry out a role within the Participant organization.

It is the policy of NY Care Information Gateway to allow only Authorized Users whose identities have been authenticated in accordance with this Authorization and Authentication Policy to Access data through the RHIO System.

II. Responsible Parties

Each Participant will be responsible for designating its Authorized Users and establishing the level of Access each Authorized User will have based, at a minimum, on the Authorized User’s job function and relationship to patients of the Participant.

The Participant will be responsible for designating an individual(s) who will serve as Authorized User Manager(s), with responsibility for reviewing and approving the Authorized User Attestation of each of the Participant’s Authorized Users and submitting to NY Care Information Gateway an Authorized User Registration Form or list for each of the individuals the Participant wishes to authorize Access to the RHIO System.

NY Care Information Gateway will be responsible for activating those Authorized Users in the NY Care Information Gateway system.

The Participant will be responsible for authenticating each Authorized User’s identity prior to including such Authorized User on the Authorized User Registration Form.

III. Procedure

A. NY Care Information Gateway has established the following categories of Authorized Users.

1. Practitioner with Access to clinical and non-clinical information and Break the Glass authority;

2. Practitioner with Access to clinical and non-clinical information but no
Break the Glass authority;

3. Practitioner with Access to non-clinical information;

4. Advanced Emergency Medical Technician with Access to clinical and non-clinical information and Break the Glass authority;

5. Advanced Emergency Medical Technician with Access to clinical and non-clinical information but no Break the Glass authority;

6. Advanced Emergency Medical Technician with Access to non-clinical information;

7. Non-Practitioner acting under the direction of a Practitioner with Access to clinical and non-clinical information and Break the Glass Authority;

8. Non-Practitioner with Access to clinical and non-clinical information;

9. Non-Practitioner with Access to non-clinical information;

10. RHIO administrators with Access to non-clinical information;

11. RHIO administrators with Access to clinical information in order to engage in public health reporting, in accordance with Section III.B.5 of Policy and Procedure 1-3 (Patient Consent and Privacy) or other activities authorized under these Policies and Procedures; and

12. RHIO or Participant administrators with Access to clinical and non-clinical information for purposes of system maintenance and testing, troubleshooting and similar operational and technical support purposes, including audits.

B. The Participant will designate an individual(s) who will serve as Authorized User Manager(s), with responsibility for reviewing and approving the Authorized User Attestation of each of the Participant’s Authorized Users as described in Policy 1-10 and submitting to NY Care Information Gateway an Authorized User Registration Form for each of the individuals the Participant wishes to activate as an Authorized User. Each Participant must establish and enforce a Policy for User Authentication that is consistent with these NY Care Information Gateway Policies and Procedures and:

1. Determines who may Access clinical data through the RHIO System and assigns an Authorized User Category (as outlined in Section III.A of this Policy) to each Authorized User. The Authorized User Category will determine the level of Access granted to such Authorized User and must be based, at a minimum, on the individual’s job function and relationship to the patient.
2. Includes identity-proofing procedures as approved by NY Care Information Gateway that require Authorized Users to provide identifying materials and information to the Authorized User Manager prior to being included on the Authorized User Registration Form.

3. Provides that each Authorized User shall complete Training prior to activation of the Authorized User’s Access to the RHIO System, as outlined in Policy and Procedure 1-10 (Training).

4. Requires the Participant’s Authorized User Manager to submit to NY Care Information Gateway an Authorized User Registration Form for each of the individuals it wishes to activate as an Authorized User. The Authorized User Registration Form can be found in Appendix C and will include:
   a. A list of proposed Authorized Users, their Authorized User Category, and their job function,
   b. Certification by the Authorized User Manager that all proposed Authorized Users have been appropriately identified and have provided identifying material to the Authorized User Manager,
   c. Certification by the Authorized User Manager that all proposed Authorized Users will undergo NY Care Information Gateway training prior to Accessing data through the RHIO System, as outlined in Policy and Procedure 1-10 (Training),
   d. Requires the Participant to notify NY Care Information Gateway of the termination of Authorized Users in accordance with Policy and Procedure 1-5 (Access).

5. On receipt of the Authorized User Registration Form, NY Care Information Gateway will activate the Authorized Users listed on that form in NY Care Information Gateway central authentication system.

C. NY Care Information Gateway and its Participants shall identify individuals whose Access to data may bypass or enable circumvention of activity logging, Access controls, or other security controls. These Authorized Users shall be subject to heightened scrutiny both in hiring and in ongoing auditing and monitoring of their activities. Such heightened scrutiny may include pre-employment (or pre-engagement for contractors) background checks; mandatory privacy and security training and annual retraining; a formal termination procedure more stringent and timely than that set forth for other Authorized Users; regular review of Access privileges, user accounts; or other measures as NY Care Information Gateway or Participant may deem appropriate given their security risk assessment.

D. Should NY Care Information Gateway include Payer Organizations as Participants, it will ensure that a Payer Organization may not Access Protected
Health Information through the RHIO System if a patient has requested, in accordance with the HIPAA Privacy Rule and HITECH, that the Participant creating such information not disclose it to the Payer Organization.

E. NY Care Information Gateway may permit Certified Applications to Access Protected Health Information via the RHIO System in accordance with the terms of these Policies and Procedures. NY Care Information Gateway’s certification process for Certified Applications shall satisfy all encryption and other security standards incorporated into the SHIN-NY Policy Standards.

F. If, at any time, NY Care Information Gateway, permits Access to the RHIO System by Participants through Certified Applications, the RHIO shall implement systems consistent with the SHIN-NY Policy Standards for authenticating a Certified Application’s credentials in connection with each Access request.

G. A Participant Accessing Protected Health Information through a Certified Application must authenticate the Participant’s users in a manner consistent with these Policies and Procedures.
NY Care Information Gateway, Inc.
Policy and Procedure
1-5
Access

Adopted March 26, 2010
Updated February 24, 2015; updated December 15, 2016

I. Policy

It is the policy of NY Care Information Gateway to allow only trained Authorized Users and Certified Applications to Access information via the RHIO System, in accordance with patient consent and with other requirements that limit their Access to information which is relevant to a patient’s treatment. This Access Policy, coupled with informed patient consent, is designed to reduce unauthorized Access and ensure information is used for Authorized Purposes.

II. Responsible Parties

NY Care Information Gateway will be responsible for activating Access for Authorized Users who are identified by the Participant in accordance with Policy 1-4 (Authorization and Authentication).

NY Care Information Gateway will be responsible for maintaining the RHIO System so that it complies with this Access Policy.

Participants will be responsible for ensuring compliance with this Access Policy at their sites.

Authorized Users will be responsible for managing their user names and passwords in accordance with this Access Policy.

III. Procedure

A. NY Care Information Gateway will:

1. Ensure that each Authorized User is assigned a unique user name and password to the RHIO System.

2. Require passwords to meet the password strength requirements set forth in NIST SP 800-63 (e.g. the probability of success of an online password guessing attack shall not exceed 1 in 16,384 over the life of the password).

3. Prohibit group or temporary user names.

4. Require Authorized Users to change their passwords every 90 calendar days, and prohibit Authorized Users from reusing passwords for a minimum
of five iterations of password changes.

5. Ensure that user names and passwords are not under any circumstances conveyed using any electronic method (including email) unless adequate security measures have been put into place to ensure that the user names and passwords will not be intercepted or otherwise accessed by anyone other than the person to whom such user names and passwords are intended to be conveyed.

6. Limit consecutive Failed Access Attempts by an Authorized User so that upon a fifth Failed Access Attempt, said Authorized User’s Access to the RHIO System is disabled by locking the account until release by a RHIO administrator or designee.

7. Provide for an Authorized User to be automatically logged out of the RHIO System after a maximum period of inactivity of 20 minutes by such Authorized User, which termination shall remain in effect until the Authorized User reestablishes Access using appropriate identification and authentication procedures.

8. Ensure that each Authorized User complies with any other authentication requirements developed through the SCP, or require Participants to ensure that each Authorized User complies with any other authentication requirements developed through the SCP.

B. Participants shall:

1. Require their Authorized Users to sign the Authorized User Attestation.

2. Prohibit Authorized Users from Accessing Protected Health Information in any manner inconsistent with these NY Care Information Gateway Policies and Procedures.

3. Notify the RHIO (i) of termination of an Authorized User’s employment or affiliation with the Participant immediately or as promptly as reasonably practicable but in any event within one business day of termination, and (ii) of a change in an Authorized User’s role with the Participant that renders the Authorized User’s continued Access to the RHIO System inappropriate under the role-based Access standards as promptly as reasonably practicable.

4. Notify the RHIO upon of any change in Authorized User Category of an Authorized User immediately or as promptly as reasonably practicable but in any event within one business day of such change.

5. Prohibit Authorized Users from sharing their user names, passwords or other authentication tools (e.g., tokens), with others and from using the user names, passwords or other authentication tools of others.
C. An Authorized User’s right to Access data through the RHIO System will be terminated or altered as follows:

1. Access to the RHIO System will be terminated immediately or as promptly as reasonably practicable but in any event within one business day of termination of the Participation Agreement of the Participant with which the Authorized User is affiliated.

2. Access to the RHIO System will be terminated immediately or as promptly as reasonably practicable but in any event within one business day of notification of termination of an Authorized User’s employment or affiliation with the Participant.

3. Access to the RHIO System will be altered immediately or as promptly as reasonably practicable but in any event within one business day of notification of change in Authorized User Category of an Authorized User.

4. Access to the RHIO System will be terminated in the event of a Breach in accordance with the provisions of Policy 1-7 (Breach).

5. During the process of identifying a patient and locating a patient’s medical records through a Record Locator Service or other comparable directory, NY Care Information Gateway and each Participant will (i) implement reasonable safeguards to minimize unauthorized incidental Disclosures of Protected Health Information, (ii) include the minimum amount of Demographic Information reasonably necessary to enable Authorized Users to successfully identify a patient through the Record Locator System, and (iii) prohibit Authorized Users from Accessing Protected Health Information in any manner inconsistent with these Policies and Procedures and with the NYS Privacy and Security Policies and Procedures. NY Care Information Gateway may note whether a patient has signed a Medical Order for Life Sustaining Treatment (“MOLST”) or other advance directive in a Record Locator Service or other comparable directory without an Affirmative Consent.

D. Access by Certified Applications

1. Notwithstanding anything to the contrary in this Section, NY Care Information Gateway may allow a Certified Application to Access Protected Health Information through the RHIO System in accordance with the terms of these Policies and Procedures.

2. If NY Care Information Gateway grants such Access, the Participant Accessing the Protected Health Information through the RHIO System through a Certified Application must:

   a. Provide NY Care Information Gateway with (i) the name and contact information of the individual responsible for requesting
Access through the Certified Application on the Participant’s behalf and (ii) a certification signed by such individual acknowledging that he or she is personally responsible for the use of the Certified Application for this purpose. The Participant must update this information and provide a new certification prior to changing the individual responsible for the use of the Certified Application.

b. Limit Access to any Protected Health Information obtained through the Certified Application to individual users of the Participant’s information system who would be eligible to be Authorized Users of the Participant under these Policies and Procedures if they were Accessing Protected Health Information directly through the RHIO System.

c. Credential, train and otherwise manage the Access of such users to Protected Health Information obtained through the RHIO System in accordance with the provisions of this Policy 1-5 (Access) applicable to Authorized Users.
I. Policy

It is the policy of NY Care Information Gateway to maintain Audit Logs documenting all Access to and receipt of Protected Health Information through the RHIO System.

It is the policy of NY Care Information Gateway to require that all Participants participate in audits on a regular basis in order to ensure that the RHIO System is being used only for purposes authorized by the Participation Agreement and these NY Care Information Gateway Policies and Procedures, and that each individual who Accesses Protected Health Information through the RHIO System is doing so in a manner consistent with the Participation Agreement and these NY Care Information Gateway Policies and Procedures, including but not limited to Policy 1-3 (Patient Consent and Privacy).

It is the policy of NY Care Information Gateway to require that all Participants cooperate with NY Care Information Gateway and/or other Participants with respect to any audits.

II. Responsible Parties

The Audit Committee of NY Care Information Gateway is responsible for recommending to the Board of Directors the audits to be performed, the specific controls to be audited and the frequency and sample size for each audit. The Audit Committee is also responsible for reviewing the results of the audits and any corrective action to be taken as a result of problems uncovered during the audits. The Audit Committee will make recommendations to the Board of Directors as to whether the specified corrective action should be accepted.

The RHIO Staff is responsible for assembling the list of cases to be sampled for each audit, for maintaining the audit schedule, for notifying Participants when audits are due and for keeping the Audit Committee informed of all audit activity.

The Participants are responsible for carrying out audits on the sample of cases given to them by the RHIO Staff in accordance with this Audit Policy. In addition, each Participant is responsible for reviewing the results of its audits and determining whether corrective action is necessary, and reporting such results and any required corrective action plans to the Audit Committee.
III. Procedure

A. NY Care Information Gateway will maintain Audit Logs that document all Disclosures of Protected Health Information through the RHIO System.

1. Audit Logs will, at a minimum, include the following information regarding each instance of Access to Protected Health Information:

   a. The identity of the patient whose Protected Health Information was Accessed;

   b. The identity of the Authorized User Accessing the Protected Health Information;

   c. The identity of the Participant with which such Authorized User is affiliated;

   d. The type of Protected Health Information or record Accessed (e.g., pharmacy data, laboratory data, etc.);

   e. The date and time of Access;

   f. The source of the Protected Health Information (i.e., the identity of the Participant from whose records the Accessed Protected Health Information was derived);

   g. Unsuccessful Access (log-in) attempts; and

   h. Whether Access occurred through a Break the Glass incident.

2. Audit Logs will, at a minimum, include the following information regarding each Transmittal by NY Care Information Gateway of Protected Health Information through the RHIO System:

   a. The identity of the patient whose Protected Health Information was Transmitted;

   b. The identity of the recipient of the Protected Health Information in the case of a Transmittal;

   c. The type of Protected Health Information or record Transmitted (e.g., pharmacy data, laboratory data, etc.);

   d. The date and time of Transmittal; and

   e. The source of the Protected Health Information (i.e., the identity of the Participant from whose records the Accessed Protected Health Information was derived).

3. Other Requirements Regarding Audit Logs and Access
a. With respect to Access to Protected Health Information through the RHIO System by a Certified Application, the Audit Log will include each instance in which such Protected Health Information was Accessed (i) by the Certified Application through NY Care Information Gateway and (ii) by an individual user of the Participant through the Participant’s system.

b. With respect to Access to Protected Health Information through the RHIO System by an Authorized User of a Public Health Agency, NY Care Information Gateway shall track at the time of Access the reason(s) for each Authorized User’s Access of Protected Health Information.

4. Other Requirements Regarding Audit Logs and Transmittals

a. NY Care Information Gateway shall not be required to include a Transmittal within an Audit Log in cases where NY Care Information Gateway Transmits Protected Health Information from one Participant to another Participant, or to a Business Associate of another Participant, in accordance with written instructions from the recipient and without modification to the data being Transmitted (as may occur in the case of a One-to-One Exchange).

b. In the case where NY Care Information Gateway performs analytics on behalf of a Participant by running queries on a data set, if a patient’s Protected Health Information is returned in response to such query then such result shall not be considered a Transmittal, and NY Care Information Gateway shall not be required to include a record of such query in the patient’s Audit Log. If the analytics process results in the production of a data set which is Transmitted by NY Care Information Gateway to the Participant and such data set includes Protected Health Information of a patient that is derived from the records of any Data Provider other than the Participant receiving the data set, NY Care Information Gateway shall record such Transmittal in the patient’s Audit Log.

5. General Audit Log Requirements

a. Audit Logs will be immutable. An immutable Audit Log requires either that log information cannot be altered by anyone regardless of Access privilege or that any alterations are tamper evident.

b. Audit Logs will be maintained for a period of at least six years from the date on which information is Accessed.
B. NY Care Information Gateway will conduct, or will require each of its Participants to conduct, periodic audits to monitor use of the RHIO System by Participants and their Authorized Users and ensure compliance with the NY Care Information Gateway Policies and Procedures and all applicable laws, rules and regulations.

1. At a minimum, NY Care Information Gateway will audit, or require its Participants to audit, the following:
   a. That Affirmative Consents are on file for patients whose Protected Health Information is Disclosed through NY Care Information Gateway, other than in Break the Glass situations;
   b. That Authorized Users who Access Protected Health Information through the RHIO System do so for Authorized Purposes; and
   c. That applicable requirements were met where Protected Health Information was Disclosed through the Break the Glass function.

2. If a Participant Accesses Protected Health Information via the RHIO System through a Certified Application, the audits described in Section III.B.1 of this Policy shall include Access by the Participant’s users through the Participant’s system.

3. The activities of all or a statistically significant subset of NY Care Information Gateway’s Participants will be audited.

4. Periodic audits will be conducted at least on an annual basis, except for audits of Break the Glass Access, which will be audited monthly.

5. Periodic audits will be conducted using a statistically significant sample size.

6. Notwithstanding the foregoing, all Break the Glass incidents will be audited.

7. If audits are conducted by Participants rather than by NY Care Information Gateway, Participants will:
   a. conduct the audit within such time period as reasonably requested by NY Care Information Gateway; and
   b. report the results of the audit to NY Care Information Gateway within such time period and in such format as reasonably requested by NY Care Information Gateway.
C. Participant Access to Audit Logs.

1. NY Care Information Gateway will provide the Participant, upon request, with the following information regarding any patient of the Participant whose Protected Health Information was Disclosed through the RHIO System:

   a. The name of each Authorized User who Accessed such patient’s Protected Health Information in the prior 6-year period;

   b. The identity of the Participant with which such Authorized User is affiliated;

   c. The time and date of Disclosure; and

   d. The type of Protected Health Information or record that was Disclosed (e.g., clinical data, laboratory data, etc.).

2. A Participant shall only be entitled to receive Audit Log information for patients who have provided an Affirmative Consent for that Participant to Access his or her Protected Health Information.

3. NY Care Information Gateway shall provide such information as promptly as reasonably practicable but in no event more than 10 calendar days after receipt of the request.

D. Patient Access to Audit Information.

1. NY Care Information Gateway will, or will require its Participants to, provide patients, upon request, with the following information:

   a. The name of each Participant that Accessed or received the patient’s Protected Health Information through the RHIO System in the prior 6-year period;

   b. The time and date of the Disclosure(s); and

   c. The type of Protected Health Information or record that was Disclosed (e.g., clinical data, laboratory data, etc.).

2. If a patient requests the name(s) of the Authorized User(s) who Accessed his or her Protected Health Information through a specific Participant in up to the prior 6-year period, NY Care Information Gateway and that Participant shall take the following actions:

   a. NY Care Information Gateway will inform the Participant of the request and will provide the Participant with the list of the Participant’s Authorized User(s) who Accessed the patient’s Protected Health Information through the RHIO System in up to
the prior 6-year period.

b. The Participant shall either provide the list of Authorized User(s) to the patient or undertake an audit to determine if the Authorized User(s) on the list appropriately Accessed the patient’s Protected Health Information for Authorized Purposes.

c. If the Participant chooses to undertake an audit of its Authorized User Access and determines that all of the Authorized User(s) Accessed the patient’s information for Authorized Purposes, the Participant shall inform the patient of this finding and need not provide the patient with the names of the Authorized User(s) who Accessed that patient’s information.

d. If the Participant chooses to undertake an audit of its Authorized User Access and determines that one or more of the Authorized User(s) did not Access the patient’s information for Authorized Purposes, the Participant shall (i) inform the patient of this finding; (ii) provide the patient with the name(s) of the Authorized User(s) who inappropriately Accessed the patient’s information unless the Participant has a reasonable belief that such disclosure could put the Authorized User at risk of harm, in which case the Participant shall provide the patient with an opportunity to appeal this determination to a representative who is more senior to the individual(s) who made the original determination; and (iii) inform NY Care Information Gateway of the inappropriate Access and otherwise comply with the requirements of this Section III.D.2.

3. NY Care Information Gateway will, or will require its Participants to provide such information as promptly as reasonably practicable but in no event more than ten calendar days after receipt of the request.

4. If requested, NY Care Information Gateway will, or will require its Participants to, provide such information to patients at no cost once in every 12-month period. NY Care Information Gateway may establish a reasonable fee for any additional requests within a given 12-month period; provided that such fee shall be waived where such additional request is based on a reasonable suspicion of unauthorized Access to the patient’s Protected Health Information through the RHIO System.

E. NY Care Information Gateway will make the results of its periodic audit available on NY Care Information Gateway’s public website. Such results shall be made available as promptly as reasonably practicable, but in any event not more than 30 days after completion of the audit.

F. Each Participant will carry out the audits required by this Audit Policy and Procedure, as well as any additional audits that may be recommended by the Audit Committee and approved by the Board of Directors. Such audits will be performed in accordance with the schedule of audits recommended by the Audit
Committee and approved by the Board of Directors. Each Participant will report the result of all such audits to the Audit Committee in the format specified by the Audit Committee. If any audit identifies any non-compliance with the Participation Agreement or any of the NY Care Information Gateway Policies and Procedures, the Participant will submit a corrective action plan to the Audit Committee along with the audit report.

G. The Audit Committee will review the audit reports and any corrective action plans, and will report to the Board of Directors any findings of non-compliance. With respect to each corrective action plan, the Audit Committee shall recommend to the Board of Directors whether the corrective action plan be accepted as presented, be revised as per agreement reached at the Audit Committee meeting or be rejected. If a corrective action plan is rejected, depending on the nature of the problem uncovered in the audit, the Board may vote to suspend Access to the RHIO System for either the Participant or one or more Authorized Users of such Participant until the problem is adequately addressed.

H. In the most expedient time possible, NY Care Information Gateway will investigate the scope and magnitude of any data inconsistency or potential error that was made in the course of NY Care Information Gateway’s data aggregation and exchange activities and, if an error is determined to exist, identify the root cause of the error and ensure its correction. NY Care Information Gateway will log all such errors, the actions taken to address them and the final resolution of the error. NY Care Information Gateway will also make reasonable efforts to identify Participants that Accessed or received such erroneous information and to notify them of corrections. This provision does not apply to updates to data that are made by Data Providers in the ordinary course of their clinical activities nor does it apply to updates to Demographic Information.

I. Weekly Audit Reports by Organ Procurement Organizations That Are Participants of NY Care Information Gateway. Organ Procurement Organizations that are Participants shall provide NY Care Information Gateway with weekly confirmation that all instances in which Protected Health Information was Accessed through the RHIO System by the Organ Procurement Organization’s Authorized Users were consistent with the terms of these Policies and Procedures (based upon a listing sent by NY Care Information Gateway).

J. Additional Requirements Related to Auditing of Access by Public Health Agencies That Are Participants of NY Care Information Gateway. NY Care Information Gateway shall use special safeguards with respect to audits of Access to the RHIO System by Public Health Agencies, which shall include at least the following:

1. NY Care Information Gateway shall create, on a regular basis, an audit report of Authorized User activity for each Public Health Agency workgroup that will include, at a minimum, the patient names, times, dates and reason for Access for each Authorized User.
2. The name of the particular Public Health Agency shall be listed in the patient Audit Logs.

3. NY Care Information Gateway shall follow-up with workgroup manager(s) if approval of an audit report is not received. If the attempt to contact the workgroup manager(s) is unsuccessful, NY Care Information Gateway may suspend all Authorized User accounts associated with that particular workgroup until the situation is resolved.
I. Policy

It is the policy of NY Care Information Gateway that Participants be responsible for immediately investigating and mitigating to the extent possible, any Breach that they become aware of, and for reporting the Breach to the Executive Director of NY Care Information Gateway for any needed investigation or mitigation.

It is the policy of NY Care Information Gateway that NY Care Information Gateway is responsible for reporting any Breach NY Care Information Gateway becomes aware of to any Participants affected by such Breach, and for assisting Participants in the investigation and mitigation of any such Breach.

It is the policy of NY Care Information Gateway that Participants be responsible for Breach notification of individuals affected as required by the New York State Information Security Breach Notification Act (New York General Business Law § 899-aa) and by HIPAA, with the assistance, if necessary, of NY Care Information Gateway if the Breach involves more than one Participant.

It is the policy of NY Care Information Gateway that Participants and NY Care Information Gateway cooperate with each other in the investigation and mitigation of any Breach that they become aware of.

II. Responsible Parties

Each Participant is responsible for investigation, mitigation and reporting of any suspected or actual Breach that such Participant becomes aware of, and for cooperating with NY Care Information Gateway and the other Participants in the investigation and mitigation of any suspected or actual Breach involving the Participant.

The Executive Director of NY Care Information Gateway is responsible for reporting any actual Breach the Executive Director becomes aware of to any Participants that may be affected by such Breach, for assisting Participants in the investigation and mitigation of any Breach, and for coordinating the investigation and mitigation of any actual Breach that involves more than one Participant.

III. Procedure

A. In the event that a Participant becomes aware of a suspected or actual Breach, the Participant shall immediately:
1. Investigate the scope and magnitude of the Breach in the most expedient time possible and without unreasonable delay.

2. Mitigate the Breach to the extent possible.

3. Notify the Executive Director of NY Care Information Gateway of the Breach in writing. Notification shall be made in the most expedient time possible and without unreasonable delay.

4. Cooperate with the Executive Director and the RHIO Staff on any investigation of the potential impact of the Breach on NY Care Information Gateway and any other Participants.

5. In the event that the Breach involves or may involve more than one Participant, cooperate with NY Care Information Gateway and the other Participant(s) in investigating and mitigating the Breach, including but not limited to sharing any information that may be necessary in connection with such investigation and/or mitigation, subject to all applicable laws and regulations.

6. Notify the patient and any applicable regulatory agencies as required by and in accordance with all applicable state and federal laws, rules, and regulations.

7. If the Breach is covered under HITECH or the New York State Information Security Breach Notification Act, meet with NY Care Information Gateway and all affected entities to develop a plan for the response. Each response will be different according to the situation.

B. In the event that the Executive Director becomes aware of a suspected or actual Breach, the Executive Director shall determine whether an actual Breach has occurred and, if so, identify the root case. The Executive Director shall then:

1. Report such Breach to any Participants that may be affected by such Breach.

2. Assist the Participants in the investigation and mitigation of any Breach, including but not limited to sharing any information that may be necessary in connection with such investigation and/or mitigation, subject to all applicable laws and regulations.

3. Coordinate the investigation and mitigation of the Breach should it involve more than one Participant.

4. Assure that all proper notifications have been made by the entities involved.

5. Provide a report of any Breach and mitigation actions taken to the Board.
of Directors

C. In the event of a Breach, the RHIO shall, or shall require the Participant to, impose such sanctions as may be determined by the Board of Directors.
NY Care Information Gateway, Inc.
Policy and Procedure
1-8
Patient Engagement and Access

Adopted March 26, 2010

Updated February 24, 2015; updated December 15, 2016

I. Policy

It is the policy of NY Care Information Gateway to ensure that NY Care Information Gateway Patient Education Program complies with any patient education program standards included in the NYS Policies and Procedures.

It is the policy of NY Care Information Gateway to ensure that patients are able to understand what information exists about them and how that information is used and Disclosed, and how they can access such information, including whether and how they can access such information directly through NY Care Information Gateway.

II. Responsible Parties

It is the responsibility of NY Care Information Gateway to develop patient education materials for use by Participants during the patient education process. NY Care Information Gateway will also maintain a public website which will include patient education material and a list of all Data Providers and information that will enable patients to contact said Data Providers.

It is the responsibility of the Participants to educate patients about NY Care Information Gateway prior to obtaining the consent of such patients to the Disclosure of their Protected Health Information through the RHIO System.

III. Procedure

A. NY Care Information Gateway shall ensure meaningful patient/consumer input and participation in QE operations and decision making.

B. NY Care Information Gateway will develop patient education material with respect to the consent process, the terms and conditions upon which patients’ Protected Health Information may be Disclosed through the RHIO System.

C. Participants will educate patients and/or their Personal Representatives with respect to the consent process, the terms and conditions upon which patients’ Protected Health Information may be Disclosed through the RHIO System, and patients’ right to access their own Protected Health Information. Participants will also inform patients or their Personal Representatives of the benefits and risks of providing an Affirmative Consent for the patients’ Protected Health Information to be Disclosed through the RHIO System.
D. NY Care Information Gateway will facilitate the access of patients and their Personal Representatives to the patient’s Protected Health Information by (i) providing a paper or electronic copy of information maintained about the patient by NY Care Information Gateway; and (ii) one of the following mechanisms:

1. Through the SHIN-NY Portal if operational;

2. Through its own web-based portal or through Participants’ patient web-based portals, provided that each such portal enables access to information maintained by NY Care Information Gateway on behalf of all of its Participants or all Protected Health Information in the SHIN-NY; or

3. Through a web-based portal established by or maintained by a third party on behalf of a patient, provided, to the extent required by applicable law, the patient or his or her Personal Representative authorizes NY Care Information Gateway to release Protected Health Information in the SHIN-NY to such portal.

NY Care Information Gateway may also provide patients or their Personal Representatives with access to Protected Health Information through any means compliant with applicable law. Each patient has the right to indicate which of these mechanisms offered he or she prefers to utilize to obtain access to his or her information.

If patient access to their Protected Health Information is not available directly through NY Care Information Gateway, NY Care Information Gateway shall inform the patient and/or their Personal Representative that they may access their Protected Health Information by contacting their health care providers.

E. NY Care Information Gateway and its Participants may (but are not required to) allow patients to grant access to their Protected Health Information to family members, informal caregivers and friends of the patient who are not Personal Representatives, provided such access is in accordance with any privacy and security standards.

F. Patient education must be conducted by the Participant with respect to each patient or Personal Representative prior to collection of an Executed RHIO Consent Form from that patient. At a minimum, patient education must include delivery to the patient of

1. the RHIO Consent Form;

2. the list of or reference to NY Care Information Gateway Participants;

3. notice – in a manner easily understood by patients – that their Protected Health Information is being uploaded to NY Care Information Gateway;

4. a description of how patients may deny consent for all Participants to
Access their Protected Health Information through the RHIO System.

G. Upon request, Participants shall provide patients with information about how their Protected Health Information was Disclosed by NY Care Information Gateway.

H. NY Care Information Gateway will maintain a publicly available list of all Data Providers and information that will enable patients to contact said Data Providers.

I. NY Care Information Gateway and its Participants shall participate in any applicable patient education programs developed by the State Designated entity through the Statewide Collaboration Process for the purpose of educating patients about the uploading of their Protected Health Information.

J. Patient Access to Information through NY Care Information Gateway

1. If NY Care Information Gateway chooses to provide patients with access to their Protected Health Information, NY Care Information Gateway shall provide such access to a patient’s Personal Representative upon request.

2. If NY Care Information Gateway provides patient access to Protected Health Information, NY Care Information Gateway shall inform the patient as to all material terms and conditions relating to such access. Access of patients or their Personal Representatives to Protected Health Information must be in accordance with all applicable laws and regulations, including but not limited to PHL §18, MHL § 33.16 and 10 NYCRR § 58-1.8.

3. NY Care Information Gateway shall direct patients to the appropriate Participants who can assist them in a timely fashion to resolve an inquiry or dispute over the accuracy or integrity of their Protected Health Information, and to have erroneous information corrected or to have a dispute documented if their request to revise data is denied.

4. Participants and Data Providers shall notify NY Care Information Gateway if, in response to a request by a patient, the Participant or Data Provider makes any corrections to the patient’s erroneous information.

5. NY Care Information Gateway shall make reasonable efforts to provide its Participants with information indicating which other Participants have Accessed or received erroneous information that the Participant has corrected at the request of patients.
NY Care Information Gateway, Inc.
Policy and Procedure
1-9
Participant Termination

Adopted March 26, 2010

Updated February 24, 2015; updated December 15, 2016

I. Policy

It is the policy of NY Care Information Gateway that upon termination of a Participant’s participation in NY Care Information Gateway (in accordance with the Terms and Conditions and the Participation Agreement), whether such termination is initiated by the Participant or by NY Care Information Gateway, the Participant and NY Care Information Gateway shall cooperate to ensure that clinical data from the terminating Participant is no longer Disclosed via the RHIO System as of the termination date.

It is the policy of NY Care Information Gateway that upon termination of a Participant’s participation in NY Care Information Gateway, whether such termination is initiated by the Participant or by NY Care Information Gateway, the Participant and NY Care Information Gateway shall cooperate to ensure that the Participant and their affiliated Authorized Users no longer have Access to or receive data via the RHIO System as of the termination date.

II. Responsible Parties

The Board of Directors will have primary responsibility for overseeing the execution of this Termination Policy.

The Executive Director will oversee the activities of NY Care Information Gateway and its agents to complete the tasks defined in this Termination Policy and enforce its terms.

The Participants will have responsibility for ensuring compliance with this Termination Policy at their sites.

III. Procedure

A. For Participants That Are Data Providers:

1. Upon receipt of notice of a Participant’s intent to terminate the Participation Agreement and its participation in NY Care Information Gateway, or concurrent with notice by NY Care Information Gateway to a Participant of termination of such Participant’s Participation Agreement and participation in NY Care Information Gateway, NY Care Information Gateway or its agent shall schedule and complete a Termination Planning Meeting to determine termination process and timeline. During the Termination Planning Meeting:
a. NY Care Information Gateway and the Participant will agree to the date of disconnection of the Participant’s interface to the RHIO System, except in the event that immediate disconnection is required by law or a regulatory agency or is deemed appropriate by the Board of Directors, and provided that the date of disconnection shall be the same as, or prior to, the date of termination of the Participant’s Participation Agreement.

b. If the Participant is using a RHIO Edge Server to participate in the RHIO, NY Care Information Gateway and the Participant will agree to the date of deletion of the Participant’s clinical data residing on the RHIO Edge Server.

2. On the date determined during the Termination Planning Meeting, the interface between the Participant and NY Care Information Gateway will be disconnected. No additional data will be provided from the Participant to the RHIO System.

3. If the Participant is using a RHIO Edge Server to participate in the RHIO, NY Care Information Gateway will arrange for all clinical data previously contributed to the RHIO Edge Server to be deleted on the date determined during the Termination Planning Meeting. The clinical data previously stored on the RHIO Edge Server will no longer be available for Disclosure to other Participants.

4. Any demographic data contributed by the Participant to the RHIO System and integrated into NY Care Information Gateway Enterprise Master Patient Index will remain at the RHIO and will not be deleted.

5. NY Care Information Gateway will update its website and other materials in a timely manner to remove the name of the terminating Participant.

6. The Participant will pay for the out-of-pocket expenses incurred by NY Care Information Gateway for the update of the RHIO System.

B. For Participants That Are Data Recipients As Well As Data Providers:

1. The procedures set forth in Section III.A of this Policy shall apply; and

2. Effective as of the date of termination of such Participant’s Participation Agreement, the Access of all of such Participant’s Authorized Users to the RHIO System will be terminated.

C. For Participants That Are Data Recipients But Not Also Data Providers:

1. Effective as of the date of termination of such Participant’s Participation Agreement, the Access of all such Participant’s Authorized Users to the RHIO System will be terminated.
2. NY Care Information Gateway will update its website and other materials in a timely manner to remove the name of the terminating Participant.
NY Care Information Gateway, Inc.
Policy and Procedure
1-10
Training

Adopted March 26, 2010
Updated February 24, 2015; updated December 15, 2016

I. Policy

It is the policy of NY Care Information Gateway that all Authorized Users of the RHIO System will be appropriately educated about the policies and procedures for Accessing Protected Health Information via the RHIO System.

II. Responsible Parties

NY Care Information Gateway will develop minimum training requirements and basic training tools for educating individuals about NY Care Information Gateway Policies and Procedures. Such training may be tailored to reflect the purposes for which an Authorized User is authorized to Access Protected Health Information through the RHIO System as well as the nature and scope of the Protected Health Information Accessed.

NY Care Information Gateway will provide each Participant with information about the minimum training requirements and access to the basic training tools.

Participants will develop and implement a training program within their organization to ensure that all Authorized Users affiliated with such Participant complete the minimum training requirements prior to being granted access to the RHIO System.

Participants will develop and implement a program for ongoing training within their organization to ensure that each affiliated Authorized User undergoes continuing training on a periodic basis as a condition of maintaining authorization to Access Protected Health Information via the RHIO System.

III. Procedures

A. NY Care Information Gateway will develop minimum training requirements for educating individuals about NY Care Information Gateway Policies and Procedures and the operation of the RHIO System.

B. NY Care Information Gateway will make information about the minimum training requirements and basic training material available to Participants.

C. Participants will provide either on-site training, web-based training, or comparable training tools to their Authorized Users to ensure that the Authorized Users are familiar with the NY Care Information Gateway Policies and Procedures and the operation of the RHIO System.
D. Participants will ensure that each Authorized User undergoes such training prior to being granted Access to information via the RHIO System.

E. Participants will ensure that each Authorized User signs an Authorized User Attestation, in the form attached as Appendix D, certifying that he or she has received training and will comply with NY Care Information Gateway Policies and Procedures, prior to being granted Access to information via the RHIO System.

1. Such Authorized User Attestation shall be obtained from an Authorized User by the Participant prior to requesting Access to the RHIO System for said Authorized User.

2. Such Authorized User Attestation shall be retained by the Participants until 6 years after termination of the employee as an Authorized User.

3. No Participant may modify the terms of the Authorized User Attestation without the prior written approval of the Executive Director of NY Care Information Gateway.

F. Participants will ensure that each Authorized User undergoes continuing and/or refresher training on an annual basis and will maintain records of such training for audit for a period of at least six years.
NY Care Information Gateway, Inc.  
Policy and Procedure  
1-11  
Insurance  

Adopted March 26, 2010

I. Policy

It is the policy of NY Care Information Gateway that NY Care Information Gateway and each of the Participants maintain such insurance coverage as is reasonable and necessary with respect to its use of the RHIO System and its obligations under the Participation Agreement.

II. Responsible Parties

NY Care Information Gateway will have responsibility for obtaining insurance coverage for NY Care Information Gateway in accordance with the requirements of this policy.

Each of the Participants will have responsibility for obtaining insurance coverage for such Participant in accordance with the requirements of this policy.

III. Procedure

A. NY Care Information Gateway shall obtain and maintain the following insurance coverage:

1. General liability insurance coverage and/or errors and omissions insurance coverage in such amounts as shall be approved by majority vote of the Board of Directors.

2. Directors and officers liability insurance in the minimum amount of one million dollars.

B. Each Participant shall obtain and maintain the following insurance coverage:

1. Professional liability insurance coverage in the minimum amounts of 1.3 million dollars per claim and 3.9 million dollars in the aggregate. In lieu of this insurance coverage, a Participant may provide evidence of Federal Tort Claims Act coverage of the Participants and its physicians and other professional staff.

2. Comprehensive general liability insurance coverage in the minimum amount of one million dollars per occurrence and three million dollars in the aggregate.

C. In the event that a Participant obtains any of the insurance coverage required by this policy on a “claims made” or similar basis, such Participant shall, in the event of termination of Participant’s participation in NY Care Information Gateway,
obtain and maintain a tail policy providing equivalent coverage for a period of at least three years after such termination.

D. All insurance coverage required by this policy shall be provided under valid and enforceable policies issued by insurance companies legally authorized to do business in the State of New York.

E. Upon request of NY Care Information Gateway, Participants shall provide NY Care Information Gateway with certificates of insurance evidencing such coverage.

F. In lieu of obtaining the insurance coverage required in this policy, a Participant may, subject to the approval of the Board of Directors, self-insure its professional liability or its commercial general liability. Participant shall maintain a separate reserve for its self-insurance. If a Participant will use the self-insurance option described in this paragraph, the Participant will provide to NY Care Information Gateway a statement verified by an independent auditor or actuary that its reserve funding levels and process of funding appears adequate to meet the requirements of this Section and fairly represents the financial condition of the fund. The Participant will provide a similar statement during the term of this Agreement upon NY Care Information Gateway’s request, which will be made no more frequently than annually. The Participant will assure that its self-insurance fund will comply with applicable laws and regulations.

G. Notwithstanding the foregoing, the New York City Health and Hospitals Corporation (“HHC”) shall be exempt from obtaining the insurance coverage required in this policy based upon HHC’s representation that it shall be responsible for the acts or omissions of HHC and its constituent facilities in connection with the Participation Agreement, which representation is based upon and limited to the obligation of the City of New York to defend, indemnify and hold harmless its officers, employees, agents and contracted affiliates from any and all liability and damages arising from or in connection with the provision and delivery of health services.
I. Policy

It is the policy of NY Care Information Gateway that Participants that are Data Providers coordinate with the RHIO to provide non-clinical and clinical data to the RHIO System and make reasonable efforts to ensure information accurately reflects associated data maintained by the Participant.

II. Responsible Parties

NY Care Information Gateway will have responsibility for working with its participating Data Providers and, where deemed appropriate by NY Care Information Gateway, the vendors of its participating Data Providers to determine the type of information that will be made available and the means for accomplishing data exchange.

Each Participant will have the responsibility to make reasonable efforts to ensure that information provided accurately reflects associated data maintained by the Participant.
NY Care Information Gateway, Inc.
Policy and Procedure
1-13
Support

Adopted April 01, 2018

Policy

It is the policy of NY Care Information Gateway that Participants that are clinical viewer users or interfaced with the organization shall be afforded the following service levels in support of their utilization of the services provided by NYCIG.

Support Definitions

- Non urgent – Individual user issue such as can’t login or cannot locate patient etc...
- Urgent – Loss of interface connectivity, loss of system for more than one user etc…

Normal Working Hours

- Non urgent -NY Care Information Gateway will respond to requests for support within 2 hours between the hours of 9:00AM and 5:00PM Monday through Friday (excluding holidays).
- Urgent - NY Care Information Gateway will respond to requests for support within 1 hour between the hours of 9:00AM and 5:00PM Monday through Friday (excluding holidays).

Off Hours

- Non urgent - Outside of Normal Business hours calls will be responded to upon the commencement of the next business day. For clients who work outside of our normal business hours, a call will be scheduled that fits their needs.
- Urgent – Clients will be responded to within 2 hours.
I. Policy

While it is anticipated that most Participants will be Covered Entities and thus subject to the HIPAA Privacy Rule and HIPAA Security Rule, there may be some Participants that are not Covered Entities. The provisions of this Policy 1-14 are designed to ensure that entities that are not Covered Entities, other than a public health authority or a health oversight agency under HIPAA (45 CFR Sections 164.501 and 164.512(b) and (d)), Accessing Protected Health Information through the RHIO System abide by the same applicable HIPAA requirements as Covered Entities even if they are not otherwise legally obligated to do so.

II. Responsible Parties

The Executive Director will ensure NY Care Information Gateway’s compliance with this policy.

The Participants will have responsibility for complying with the applicable requirements of the HIPAA Privacy and Security Rules.

III. Procedure

A. Each Participant that is a Covered Entity shall comply with the HIPAA Privacy Rule and HIPAA Security Rule.

B. Each Participant that is not a Covered Entity, other than a public health authority or a health oversight agency under HIPAA (45 CFR Sections 164.501 and 164.512(b) and (d)), shall adopt/address all of the applicable administrative, physical and technical safeguards set forth in the HIPAA Security Rule as well as the restrictions on the use and Disclosure of Protected Health Information set forth in the HIPAA Privacy Rule.
NY Care Information Gateway, Inc.
Policy and Procedure
1-15
Sanctions

Adopted February 24, 2015

I. Policy

Sanctions are an important mechanism for ensuring that Participants and Authorized Users comply with these Policies and Procedures. The provisions in this Policy 1-15 are designed to provide guidelines for the imposition of sanctions by NY Care Information Gateway and its Participants while leaving flexibility for NY Care Information Gateway and its Participants to determine appropriate sanctions on a case by case basis.

II. Responsible Parties

The Participant Oversight Committee will ensure NY Care Information Gateway’s compliance with this policy.

The Participants will have responsibility for determining sanctions for individual Authorized Users in consultation with NY Care Information Gateway as appropriate.

III. Procedure

A. Each Participant shall inform its Authorized Users about NY Care Information Gateway’s sanctions policies.

B. NY Care Information Gateway Participant Oversight Committee will apply sanctions to Participants in the event of violation by a Participant of these Policies and Procedures, an NY Care Information Gateway Participation Agreement or of the NYS Policies and Procedures. Sanctions may include retraining, suspending or terminating a Participant's participation in the RHIO and/or the assessment of fines or other monetary penalties. When determining the type of sanction to apply, the Participant Oversight Committee shall take into account the following factors: (i) whether the violation was a first time or repeat offense; (ii) the level of culpability of the Participant, e.g., whether the violation was made intentionally, recklessly or negligently; (iii) whether the violation constitutes a crime under state or federal law; and (iv) whether the violation resulted in harm to a patient or other person.

C. Each Participant will apply sanctions to its Authorized Users in the event of violation of these Policies and Procedures, the Participation Agreement or the NYS Policies and Procedures. Sanctions may include (i) requiring an Authorized User to undergo additional training with respect to participation in NY Care Information Gateway; (ii) temporarily restricting an Authorized User's Access to the RHIO System; or (iii) terminating the Access of an Authorized User to the RHIO System. When determining the type of sanction to apply, the Participant shall
take into account the following factors: (i) whether the violation was a first time or
repeat offense; (ii) the level of culpability of the Authorized User, e.g., whether the
violation was made intentionally, recklessly or negligently; (iii) whether the
violation constitutes a crime under state or federal law; and (iv) whether the
violation resulted in harm to a patient or other person.
NY Care Information Gateway, Inc.
Policy and Procedure
1-16
Monitoring and Enforcement of SHIN-NY Compliance

Adopted February 24, 2015; updated December 15, 2016

I. Policy

NY Care Information Gateway is required to comply with applicable federal and state law and with the Certification Requirements that Qualified Entities must satisfy to participate in the SHIN-NY. NY Care Information Gateway is also required to establish policies and procedures for receiving complaints from Participants and SHIN-NY Stakeholders regarding possible non-compliance by NY Care Information Gateway or its Participants with applicable federal and state law and with the Certification Requirements; to investigate instances of non-compliance; and to make reports to the oversight agency responsible for overseeing compliance by Qualified Entities with federal and state laws and with the Certification Requirements (the “Oversight Entity”). This policy sets forth a process by which NY Care Information Gateway will comply with these obligations.

II. Responsible Parties

NY Care Information Gateway will ensure NY Care Information Gateway’s compliance with this policy, including ensuring that Participants are notified of the existence of this Monitoring and Enforcement Policy.

NY Care Information Gateway will also notify the entity designated by NYS DOH to oversee the certification process (the “Certification Body”) of changes in this Policy in accordance with the SHIN-NY Policy Standards (i.e., Section 7.11 of the Qualified Entity Organizational Characteristics Requirements).

The Participants will be responsible for complying with this policy.

III. Procedure

A. Self-Audit

1. NY Care Information Gateway will perform, or will cause a third-party to perform, an audit (a “Self-Audit”) at least once per year, as required by the Oversight Entity and as stated in the NYS Privacy & Security Policies and Procedures Section 6.2.4 and in Policy 1-6 (Audit) of these NY Care Information Gateway Policies and Procedures.

2. The scope of the Self-Audit will include a review of NY Care Information Gateway’s compliance with applicable federal and state laws and with the Certification Requirements and a review of Participants’ compliance with
B. Process for Accepting Complaints

1. NY Care Information Gateway will receive, investigate and respond to complaints from SHIN-NY stakeholders, including Participants.

2. Any SHIN-NY stakeholders, including any Participant, may file with NY Care Information Gateway a complaint of any suspected non-compliance by NY Care Information Gateway or its Participants with applicable federal or state laws or with the Certification Requirements. The complaint (the “Non-Compliance Complaint”) must be in writing and must include the following information if known:
   a. the suspected non-compliance;
   b. the acts or omissions believed to constitute non-compliance;
   c. the name of the Participant involved, if any;
   d. all dates related to the suspected non-compliance; and
   e. all locations related to the suspected non-compliance, if any.

3. A Non-Compliance Complaint related to NY Care Information Gateway or a Participant must be filed within 180 days from the date the complainant knew or should have known that non-compliance occurred for the Non-Compliance Complaint to be subject to investigation under this Policy.

4. If a Non-Compliance Complaint related to NY Care Information Gateway or a Participant is filed with NY Care Information Gateway, the RHIO will conduct an Internal Investigation in accordance with Section III.C of this Policy.

5. If a complaint is not a non-compliance issue, it will be addressed in a manner deemed appropriate by NY Care Information Gateway’s Executive Director.

C. Internal Investigation Process

1. If NY Care Information Gateway becomes aware of potential non-compliance or receives notice of a Non-Compliance Complaint, NY Care Information Gateway will conduct an internal investigation (an “Internal Investigation”) of such complaint to determine whether non-compliance has occurred.

2. NY Care Information Gateway will begin the Internal Investigation within 30 days after becoming aware of potential non-compliance or receiving
notice of a Non-Compliance Complaint.

3. NY Care Information Gateway will complete the Internal Investigation as soon as reasonably practicable but in any event no later than 60 days after becoming aware of potential non-compliance or receiving notice of a Non-Compliance Complaint.

D. Reporting to Oversight Entity

1. Following an Internal Investigation conducted pursuant to Section III.C of this Policy, NY Care Information Gateway will report to the Oversight Entity in writing the existence of any non-compliance immediately after NY Care Information Gateway determines that non-compliance has occurred. The report (the “Non-Compliance Report”) will describe the non-compliance and any harmful effects known to NY Care Information Gateway (including a list of Participants harmed, if any) resulting from non-compliance.

2. If instructed by the Oversight Entity to perform an Internal Investigation (rather than if NY Care Information Gateway chose to undertake the investigation voluntarily under Section III.C of this Policy), NY Care Information Gateway will report the results of such investigation to the Oversight Entity. If NY Care Information Gateway did not detect non-compliance as a result of such Internal Investigation, NY Care Information Gateway will provide to the Oversight Entity a statement that no non-compliance was detected and a summary of the Internal Investigation conducted outlining the investigation findings.

E. Participant Cooperation with Investigations

1. Participants shall cooperate with the RHIO in connection with any Internal Investigation performed by the RHIO or with any external investigation performed by the Oversight Entity, including by providing to the RHIO or the Oversight Entity the information requested and access to its books, records, accounts and other sources of information related to the scope of the investigation.
APPLICATION FOR PARTICIPATION IN NY CARE INFORMATION GATEWAY

1. Name and address of Applicant (each licensed entity must apply separately)

   Name of licensed entity: ____________________________________________

   Address: (If multiple sites list all locations. Attach extra sheet if necessary)
   ____________________________________________
   ____________________________________________
   ____________________________________________

   Primary Contact:

   Phone: __________________ e-mail: ________________________________

2. Participant type: (check all that apply)

   _____ General hospital
   _____ Diagnostic and treatment center as defined under Article 28 of the PHL
   _____ Home care services agency as defined under Article 28 of the PHL
   _____ Nursing home or residential health care facility as defined under Article 28 of the PHL
   _____ Individual or group private medical practice
   _____ Clinical laboratory as defined under Article 5 of the PHL
   _____ Pharmacy as defined under Article 137 of the NY State Education Law
   _____ Other, define: ____________________________________________

3. Applying to be (choose one)

   _____ Data Recipient
   _____ Data Provider
   _____ Data Provider and Data Recipient

4. Anticipated number of users _____________

5. Volume for the last calendar year

   Admissions ___________
   Visits _____________
   Unique patients seen ___________
   Other _____________

6. Professional Liability Insurance Coverage

   Per Claim Coverage: ____________________________
   Aggregate Coverage: __________________________
Appendix A

Data Recipient Site

Applicant agrees to meet minimum requirements for Data Recipient sites:
Yes ______

**User authentication:** Each Data Recipient site must follow the user authentication procedure of NY Care Information Gateway.

**Authorized User Manager:** Each Data Recipient site must identify an Authorized User Manager with responsibility for reviewing and approving the Authorized User Attestation of each of the Participant’s Authorized Users and submitting the Authorized User Registration Form(s).

**Training:** All Authorized Users must be trained prior to receiving access to the system. NY Care Information Gateway will provide basic training tools. Each Applicant must make provision for ongoing training.

**Authorized User Attestation:** Each Authorized User must have on file a signed attestation to use the RHIO System as defined in the training.

Data Provider Site

Applicant agrees to meet minimum requirements for Data Provider sites:
Yes ______

**Staff (Note, staff requirements do not apply to Community Members):**
A project manager for coordinating the process of data analysis and mapping to NY Care Information Gateway. Staff to do data mapping.

Staff to resolve duplicate record issues.

_________________________  _______________________
CE0 of Facility           Date
Authorization for Access to Patient Information  
Through a Health Information Exchange Organization

New York State Department of Health

<table>
<thead>
<tr>
<th>PATIENT NAME:</th>
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<tr>
<td>PATIENT ADDRESS:</td>
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<tr>
<td>DATE OF BIRTH:</td>
<td></td>
</tr>
<tr>
<td>PATIENT IDENTIFICATION NUMBER:</td>
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<tr>
<td>PROVIDER ORGANIZATION:</td>
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</table>

I request that health information regarding my care and treatment be accessed as set forth on this form. I can choose whether or not to allow the Provider Organization named above to obtain access to my medical records through the health information exchange organization called NY Care Information Gateway. If I give consent, my medical records from different places where I get health care can be accessed using a statewide computer network. NY Care Information Gateway is a not-for-profit organization that shares information about people’s health electronically and meets the privacy and security standards of HIPAA and New York State Law. To learn more visit NY Care Information Gateway’s website at www.NYCIG.org.

The choice I make in this form will NOT affect my ability to get medical care. The choice I make in this form does NOT allow health insurers to have access to my information for the purpose of deciding whether to provide me with health insurance coverage or pay my medical bills.

My Consent Choice. ONE box is checked to the left of my choice. I can fill out this form now or in the future. I can also change my decision at any time by completing a new form.

- [ ] 1. I GIVE CONSENT for the Provider Organization named above to access ALL of my electronic health information through NY Care Information Gateway to provide health care.
- [ ] 2. I DENY CONSENT for the Provider Organization named above to access my electronic health information through NY Care Information Gateway for any purpose.

If I want to deny consent for all Provider Organizations and Health Plans participating in NY Care Information Gateway to access my electronic health information through NY Care Information Gateway, I may do so by visiting NY Care Information Gateway’s website at www.NYCIG.org or calling NY Care Information Gateway at 718-334-5844.

My questions about this form have been answered and I have been provided a copy of this form.

<table>
<thead>
<tr>
<th>Signature of Patient or Patient’s Legal Representative</th>
<th>Date</th>
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<tbody>
<tr>
<td>Print Name of Legal Representative (if applicable)</td>
<td>Relationship of Legal Representative to Patient (if applicable)</td>
</tr>
</tbody>
</table>
Details about the information accessed through NY Care Information Gateway and the consent process:

1. **How Your Information May Be Used.** Your electronic health information will be used only for the following healthcare services:
   - **Treatment Services.** Provide you with medical treatment and related services.
   - **Insurance Eligibility Verification.** Check whether you have health insurance and what it covers.
   - **Care Management Activities.** These include assisting you in obtaining appropriate medical care, improving the quality of services provided to you, coordinating the provision of multiple health care services provided to you, or supporting you in following a plan of medical care.
   - **Quality Improvement Activities.** Evaluate and improve the quality of medical care provided to you and all patients.

2. **What Types of Information about You Are Included.** If you give consent, the Provider Organization(s) and/or Health Plan(s) listed may access ALL of your electronic health information available through NY Care Information Gateway. This includes information created before and after the date this form is signed. Your health records may include a history of illnesses or injuries you have had (like diabetes or a broken bone), test results (like X-rays or blood tests), and lists of medicines you have taken. This information may include sensitive health conditions, including but not limited to:
   - Alcohol or drug use problems
   - Birth control and abortion (family planning)
   - Genetic (inherited) diseases or tests
   - HIV/AIDS
   - Mental health conditions
   - Sexually transmitted diseases

3. **Where Health Information About You Comes From.** Information about you comes from places that have provided you with medical care or health insurance. These may include hospitals, physicians, pharmacies, clinical laboratories, health insurers, the Medicaid program, and other organizations that exchange health information electronically. A complete, current list is available from NY Care Information Gateway. You can obtain an updated list at any time by checking NY Care Information Gateway’s website at www.NYCIG.org or by calling 718-334-5844.

4. **Who May Access Information About You, If You Give Consent.** Only doctors and other staff members of the Organization(s) you have given consent to access who carry out activities permitted by this form as described above in paragraph one.

5. **Public Health and Organ Procurement Organization Access.** Federal, state or local public health agencies and certain organ procurement organizations are authorized by law to access health information without a patient’s consent for certain public health and organ transplant purposes. These entities may access your information through NY Care Information Gateway for these purposes without regard to whether you give consent, deny consent or do not fill out a consent form.

6. **Penalties for Improper Access to or Use of Your Information.** There are penalties for inappropriate access to or use of your electronic health information. If at any time you suspect that someone who should not have seen or gotten access to information about you has done so, call the Provider Organization; or visit NY Care Information Gateway’s website: www.NYCIG.org; or call the NYS Department of Health at 518-474-4987; or follow the complaint process of the federal Office for Civil Rights at the following link: http://www.hhs.gov/ocr/privacy/hipaa/complaints/.

7. **Re-disclosure of Information.** Any organization(s) you have given consent to access health information about you may re-disclose your health information, but only to the extent permitted by state and federal laws and regulations. Alcohol/drug treatment-related information or confidential HIV-related information may only be accessed and may only be re-disclosed if accompanied by the required statements regarding prohibition of re-disclosure.

8. **Effective Period.** This Consent Form will remain in effect until the day you change your consent choice or until such time as NY Care Information Gateway ceases operation (or until 50 years after your death whichever occurs first). If NY Care Information Gateway merges with another Qualified Entity your consent choices will remain effective with the newly merged entity.

9. **Changing Your Consent Choice.** You can change your consent choice at any time and for any Provider Organization or Health Plan by submitting a new Consent Form with your new choice. Organizations that access your health information through NY Care Information Gateway while your consent is in effect may copy or include your information in their own medical records. Even if you later decide to change your consent decision they are not required to return your information or remove it from their records.

10. **Copy of Form.** You are entitled to get a copy of this Consent Form.
## Authorized User Registration Form

**Instructions:**
1. List the requested NY Care Information Gateway Authorized Users below. The Authorized User Manager must ensure that all proposed users have completed training and have provided appropriate proof of identity prior to inclusion on this form.
2. Physically sign the form.
3. Return completed form to the NY Care Information Gateway.

I certify that:
1. I am the Authorized User Manager designated by my organization, the Participant(s) listed on this form.
2. All proposed Authorized Users listed on this form have provided identifying materials and information to me as required by the NY Care Information Gateway's Policy for User Authorization and Authentication.
3. All proposed Authorized Users listed on this form have or will completed training as required by the NY Care Information Gateway's Training Policy and have completed and executed the Authorized User Training Attestation.
4. I will maintain the supporting documentation required by the NY Care Information Gateway Policies & Procedures and the Policies & Procedures of my organization.

---

**User Category Key:**
- Practitioner defined as a health care professional licensed under Title 8 of the New York Education Law.
- Practitioner with access to clinical and non-clinical information but no Break the Glass authority
- Practitioner with access to non-clinical information
- Non-Practitioner with access to clinical and non-clinical information
- Non-Practitioner with access to non-clinical information
- Administrators with access to clinical and non-clinical information for purposes of system maintenance and testing, troubleshooting and similar operational and technical support purposes, including audits.

<table>
<thead>
<tr>
<th>User Action (Add, Delete, Edit)</th>
<th>Requested Eides</th>
<th>First Name</th>
<th>Last Name</th>
<th>Gender</th>
<th>Job Title</th>
<th>Email</th>
<th>NPI</th>
<th>User Category (drop-down menu)</th>
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<td>Practitioner (Non-Break the Glass)</td>
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<td>Non-Practitioner (Non-Break the Glass)</td>
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<td>Administrator</td>
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**Signature**

**Date**
# Appendix D

## AUTHORIZED USER ATTESTATION

*To be completed by the Authorized User*

<table>
<thead>
<tr>
<th>Participant Name: (Organization)</th>
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</thead>
<tbody>
<tr>
<td>Name of Authorized User:</td>
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<tr>
<td>Job Function:</td>
<td></td>
</tr>
</tbody>
</table>

**Authorized User Category:** *(check one only)*

- Practitioner with access to clinical and non-clinical information and Break the Glass authority;
- Practitioner with access to clinical and non-clinical information but no Break the Glass authority;
- Practitioner with access to non-clinical information;
- Non-Practitioner with access to clinical and non-clinical information; Non-Practitioner with access to non-clinical information;
-  

### Authorized User Certification

I certify that I am the Authorized User listed above.

I have completed the required training required by my organization to obtain access to the NY Care Information Gateway System. I understand my obligations under the RHIO Policies and Procedures, including but not limited to the Privacy and Security Policies.

I recognize and understand the requirement to keep my NY Care Information Gateway System User Name and Password secret and the prohibition on sharing this information.

I agree to access a patient’s Protected Health Information via the NY Care Information Gateway System only for purposes consistent with a patient’s Affirmative Consent. Affirmative Consent allows for use of the data for Treatment, Care Management, and Insurance Coverage Reviews only.

I understand that in the performance of my duties, I must hold medical information in confidence. I understand that the medical condition and medical records of patients are confidential and must be treated as such. I am familiar with the obligations imposed by the statutes, rules and regulations governing confidentiality and the disclosure of AIDS or human immune deficiency virus related information. I further understand that any unauthorized disclosure of confidential medical and patient information may result in legal and/or disciplinary action against me, including dismissal.

**Signature**

**Date**