

I. Introduction

Effective as of July 10, 2024, New York State has promulgated amended regulations (the SHIN-NY Regulations) requiring that the New York State Department of Health (the Department) “provide, either directly or through contract, [the Statewide Data Infrastructure (the SDI)] and any other SHIN-NY services that the [the Department] deems necessary to effectuate the purposes of [the SHIN-NY Regulations].”¹

The SDI, which includes a secure statewide Primary Document Repository (PDR) as well as centralized systems operated or directed by New York eHealth Collaborative (NYeC), supports increased interoperability, provides flexibility for the SHIN-NY to adapt in a constantly evolving technological environment, and facilitates the secure exchange of data among SHIN-NY participants, including the Department.

NYeC, as the State Designated Entity (SDE) for the SHIN-NY, will maintain the technical and administrative resources which comprise the SDI, either directly or through contract. The Statewide Data Use Committee (SDUC), a standing committee of the SHIN-NY Statewide Collaboration Process (SCP), will provide stakeholder engagement and governance support for the use of data within the SDI. In these roles, NYeC and the SDUC will administer requests for use of SDI Data, manage the provision of SDI Data to Permitted Requesters, and uphold a transparent and open governance model for data use, in each case in accordance with and pursuant to the Statewide Data Infrastructure (SDI) Data Use Approval Process Standard Operating Procedure (SOP).

II. Purpose, Scope, Limitations, and Intended Audience

a. Purpose

The PDR is a centralized, statewide clinical document store within the SDI that contains Continuity of Care Documents (CCDs), discharge summaries, and other structured clinical documents contributed by SHIN-NY participants.

This SOP establishes the process by which Permitted Requesters submit requests for data access through the SHIN-NY PDR, and by which NYeC reviews, adjudicates and, upon approval, directs the PDR operator to operationalize authorized access.

b. Scope

This SOP is a subsidiary of the SHIN-NY SDI Data Use Approval Process SOP and should be read in conjunction with it. The SDI Data Use Approval Process SOP establishes the authoritative framework under which any disclosure or use of SDI Data must be evaluated. That process is

¹ 10 N.Y.C.R.R. § 300.2(c).

governed by the SDUC.

This SOP applies to:

- All Permitted Requestors seeking to initiate, expand, or modify access to SDI Data from the PDR;
- NYeC staff responsible for receiving, reviewing, and adjudicating PDR Data Access Requests;
- NYeC staff and contractors that need access to SDI Data from the PDR to perform required functions (e.g., monitoring, quality assurance, data quality);
- The PDR operator (the entity contracted by NYeC to operate the Primary Document Repository), responsible for implementing and monitoring approved access configurations; and
- The Department, in its role as the regulatory authority over the SHIN-NY.

c. Limitations

The PDR Data Access Request process described in this SOP is designed to be consistent with and subordinate to the standards, purposes, and data protections established in the parent SDI Data Use Approval Process SOP. Where this SOP is silent on a governance question, the parent SOP and the SDUC's determinations shall govern. If a PDR access request involves a use case that has not yet been adjudicated under the SDI Data Use Approval Process SOP, NYeC will refer the request to the SDUC prior to completing the PDR-level review.

This SOP does not extend to issues of access to other components of the SDI, which are subject to the SDI Data Use Approval Process SOP and SDUC adjudication.

This SOP does not apply to the use, disclosure or re-disclosure of data from QE Platforms, unless such data has been obtained from the PDR. In those cases, the use, disclosure or re-disclosure of such data is subject to the provisions of this SOP.

d. Audience

The audience for this SOP includes QEs, required and voluntary SHIN-NY participants, New York state and local public health authorities, health care consumers, and all other stakeholders with an interest in the SHIN-NY and the SDI.

III. Definitions

Term	Definition
Data Use Request	A request for use, disclosure and re-disclosure of Core SDI Data for Public Health Permitted Purposes, Medicaid Permitted Purposes, as well as any future SDI Permitted Purposes that the SDUC may review and approve.
Material Modification	A modification to a PDR Data Access Request that would alter the nature and/or scope of the request by changing the scope of the SDI Permitted Purpose(s) or the intended use(s) for which the SDI Data was approved to be used, disclosed, or re-disclosed.
Non-Material Modification	A modification to a PDR Data Access Request that would provide access to additional SDI Data element(s) or change the type of data requested (i.e., identified, limited data set or de-identified).
Permitted Requester	Designated staff of QEs, NYeC, or the Department and designated staff of such other entities as may be approved by the SDUC.
Primary Document Repository (PDR)	The centralized, secure, statewide clinical document repository operated under contract with NYeC that stores and provides query/retrieval access to structured clinical documents (including CCDs and discharge summaries) contributed by SHIN-NY participants.
PDR Access Approval Notice	The written notice issued by NYeC authorizing the PDR operator to operationalize a specific PDR access configuration, including any applicable conditions and limitations.
PDR Data Access Request	A formal submission by a Permitted Requester to NYeC requesting authorization for new, modified, or expanded access to SDI Data within the PDR.
PDR Operator	The entity contracted by NYeC to operate the PDR infrastructure, responsible for technical implementation of access configurations authorized through this SOP.
Qualified Entity (QE)	A not-for-profit regional health information organization or other entity that has been certified by the Department of Health under the SHIN-NY Regulations.
Statewide Common Participation Agreement (SCPA)	A statewide common participation agreement established pursuant to the SHIN-NY Regulations.
Statewide Data Infrastructure (SDI)	The data infrastructure maintained by NYeC that includes (i) a secure statewide repository (sometimes referred to as a “Data Lake”) that includes Core SDI Data, and (ii) data infrastructure used by NYeC to deliver services required under the NYS DOH Contract, such as maintaining and operating the “Statewide Master Patient Index” and

	the “Statewide Patient Record Lookup,” each defined by or described in the SHIN-NY SOPs, and facilitating statewide reporting.
SDI Permitted Purposes	The purposes for which SHIN-NY Data maintained in the SDI may be used or disclosed in accordance with the SCPA and the SHIN-NY SOPs.
Statewide Data Use Committee (SDUC)	An SCP standing committee with responsibility for the development and amendment of SHIN-NY SOPs concerning disclosures and uses of data contained in the SDI.

IV. Roles and Responsibilities

Role	Entity	Responsibilities Under This SOP
QE	Qualified Entity	Initiates/submits PDR Data Access Request; ensures completeness of submission; coordinates with participants; signs applicable agreements; assists in operationalization testing.
NYeC - Permitted Requester	State Designated Entity responsible for SHIN-NY operation	Initiates/submits PDR Data Access Request; ensures completeness of submission; signs applicable agreements; assists in operationalization testing.
NYeC - Intake & Review	NYeC Data Governance Team	Receives and logs PDR Data Access Requests; conducts policy, legal, and technical sufficiency review; coordinates SDUC referral if required; issues approval or denial decision; notifies Permitted Requester and PDR operator.
NYeC - Oversight	NYeC Policy and Legal	Final approval authority for PDR access decisions that do not require SDUC referral; escalation point for contested determinations.
SDUC	Statewide Data Use Committee	Adjudicates requests involving novel or expanded use cases not previously approved under the SDI Data Use Approval Process. May establish conditions or limitations on access.
PDR Operator	Contracted entity operating the PDR infrastructure through contract with NYeC	Receives NYeC approval notification; configures and operationalizes authorized access; confirms implementation; maintains access logs for audit purposes.

NYSDOH	NY State Department of Health	Regulatory and oversight authority; receives notification of access configurations per regulatory requirements.
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V. Procedures

a. PDR Data Access Request Types

Permitted Requesters may submit PDR Data Access Requests in the following categories. The category determines the applicable review pathway and whether SDUC referral is required.

Category	Description	SDUC Referral Required?
A. Standard Access	PDR access for SDI Permitted Purposes, consistent with SCPA obligations and SHIN-NY policies and procedures. Access uses approved, established configurations.	No
B. Program or Population-Level Access	PDR access for a population-level or program-level use case (e.g., population health, public health program, care coordination). Must align with an existing SDUC-approved use case.	Only if use case not previously approved
C. New or Expanded Use Case	Access for a use case or purpose not previously approved by the SDUC, or requests for access that would require approval of a new SDI Permitted Purpose or a new class of Permitted Requester.	Yes
D. Access Modification	Modification to an existing, approved PDR Data Access Request (e.g., change in data elements, user population, or technical access method).	No, if the modification is a Non-Material Modification Yes, if the modification is a Material Modification

b. PDR Data Access Request Submission

- i. Permitted Requester Submission of PDR Data Access Request
 - 1. Permitted Requester submits a complete PDR Data Access Request via NYeC electronic ticketing system²

² PDR Data Access Request Required Elements are detailed in Attachment A to this SOP.

c. PDR Data Access Request Review

i. NYeC Intake and Completeness Review

1. Upon receipt of the PDR Data Access Request, NYeC will:
 - a. Send an automated acknowledgment to the Permitted Requester confirming receipt and providing a reference number
 - b. Conduct a completeness check within five (5) business days of receipt, confirming that all required elements in Section 6, Step 1 are present and sufficiently detailed
 - c. If the submission is incomplete: notify the Permitted Requester in writing identifying the deficiencies; return the request to the Permitted Requester for correction; and restart the review clock upon receipt of the corrected submission
 - d. If the submission is complete: advance the request to the substantive review stage and notify the Permitted Requester that substantive review has commenced

ii. NYeC Substantive Review

1. NYeC's Data Governance team, in coordination with legal and technical teams as appropriate, shall conduct a substantive review of the PDR Data Access Request. This review shall evaluate the request against the following criteria:

Review Criterion	Evaluation Questions
Legal Compliance	Is the requested access consistent with 10 NYCRR Part 300, applicable provisions of the Public Health Law, and other applicable laws and regulations? Does the request fall within a permitted purpose under HIPAA and applicable state law?
SHIN-NY Policy Alignment	Is the use case consistent with the SCPA and the SHIN-NY SOPs? Is the request consistent with an existing SDUC-approved use case under the SDI Data Use Approval Process? If not, is SDUC referral required?
Consent Framework Compliance	Does the request comply with New York's consent requirements? Has the Permitted Requester demonstrated a credible, reliable method for verifying consent status prior to accessing each patient's records?
Data Minimization	Is the request limited to the minimum data elements and patient population necessary to accomplish the stated use case? Are additional restrictions appropriate?

Security Posture	Does the Permitted Requester meet applicable privacy and security requirements, including but not limited to those in the SCPA and SHIN-NY SOPs? Are downstream data handling obligations clearly defined and documented?
Technical Feasibility	Is the proposed technical access method compatible with current PDR infrastructure and operator capabilities? Can the PDR operator implement the requested configuration as described?
Data Quality Risk	Are there known data quality issues in the PDR that would affect the intended use case? Should data quality conditions be attached to the approval?

- iii. NYeC shall document its substantive review findings in the PDR Data Access Request tracking record and note any issues requiring resolution, conditions to be attached to any approval, or matters requiring SDUC referral.
 - 1. SDUC Referral (Category C Requests)
 - a. For Category C requests (novel or expanded use cases) and for any request that NYeC determines raises policy questions appropriate for SDUC deliberation, NYeC shall refer the request to the SDUC for adjudication consistent with the SDI Data Use Approval Process SOP.
 - b. Upon SDUC referral, the following applies:
 - i. NYeC shall notify the Permitted Requester that the request has been referred to the SDUC and provide an estimated timeline for SDUC deliberation.
 - ii. The SDUC shall review the PDR Data Access Request in accordance with the procedures set forth in the SDI Data Use Approval Process SOP, applying the same standards for permitted purpose, patient protection, and data governance.
 - iii. The SDUC may approve the request (with or without conditions), deny the request, or request additional information from the QE or NYeC.
 - iv. The SDUC's determination shall be documented in a formal Decision Memo and provided to NYeC, the QE, and NYSDOH.
 - v. A favorable SDUC determination establishes an approved use case that may be applied to future similar PDR Data Access Request submissions without requiring additional SDUC referral, subject to NYeC's discretion.

d. PDR Data Access Request Determinations

1. NYeC Approval Decision

Following completion of the substantive review (and SDUC adjudication, if applicable), NYeC shall issue one of the following determinations:

Determination	Description and Next Step
Approved	The PDR Data Access Request meets all applicable requirements. NYeC issues a PDR Access Approval Notice to the Permitted Requester and the PDR operator, authorizing the PDR operator to proceed with implementation. The Approval Notice specifies any conditions, limitations, data quality caveats, or audit requirements applicable to the authorized access.
Approved with Conditions	The PDR Data Access Request is approved subject to specific conditions that the Permitted Requester must satisfy prior to or concurrent with operationalization. NYeC shall specify the conditions in writing. The PDR operator shall not operationalize access until NYeC confirms conditions are satisfied.
Returned for Revision	The PDR Data Access Request raises issues that can be remediated by the Permitted Requester. NYeC returns the request with written explanation of required revisions. The Permitted Requester may resubmit a revised PDR Data Access Request, which will be reviewed as a new submission.
Denied	The PDR Data Access Request does not meet applicable requirements and cannot be approved as submitted or revised. NYeC issues a written denial with explanation. The Permitted Requester may appeal the denial to the SDUC within 30 calendar days by submitting a written request to NYeC.

2. NYeC shall notify the Permitted Requester in writing of any determination, including the basis for approval, conditions, or denial.

VI. PDR Operator Operationalization

- a. Upon issuance of a PDR Data Access Approval Notice, the PDR operator shall implement the authorized access configuration. This phase includes the following activities:
- i. NYeC transmits the PDR Access Approval Notice to the PDR operator, including the full PDR Data Access Request submission, the conditions of approval (if any), and any technical specifications developed during the review process.
 - ii. The PDR operator reviews the Approval Notice and confirms to NYeC within five (5) business days that implementation is technically feasible

- within the specified timeframe, or requests a timeline adjustment with written justification.
- iii. The PDR operator and Permitted Requester coordinate on technical implementation details, including configuration of access credentials, role-based access controls, consent verification integration, and audit logging. NYeC may participate in implementation coordination calls as needed.
 - iv. The PDR operator implements the access configuration in a test/staging environment and conducts testing with the Permitted Requester to confirm that: (a) only authorized data are accessible; (b) consent verification is functioning correctly; (c) access is limited to the authorized user population; and (d) audit logs are capturing access events as required.
 - v. Upon successful testing, the Permitted Requester certifies to NYeC and the PDR operator in writing that testing is complete and the access configuration functions as approved.
 - vi. The PDR operator promotes the access configuration to the production environment and notifies NYeC and the Permitted Requester of the go-live date.
 - vii. NYeC records the go-live date in the PDR Data Access Request tracking record and updates the registry of active PDR access configurations.

The PDR operator shall not implement any access configuration prior to receiving a PDR Access Approval Notice from NYeC. Implementation of unauthorized or pre-approval access configurations is a material violation of the PDR operator's contract with NYeC and may constitute a violation of 10 NYCRR Part 300.

VII. Standard Conditions Applicable to All Approved PDR Access

All approved PDR access configurations, regardless of category, are subject to the following standard conditions unless expressly modified by NYeC in the Approval Notice:

a. Consent Verification

The Permitted Requester and PDR operator must confirm that a valid SHIN-NY patient consent is on file in the Statewide Consent Registry before a patient's PDR records are accessed in any individual-level query. Consent verification must be integrated into the technical access workflow; manual consent review is not an acceptable substitute for automated consent checking except where technically infeasible and approved as a temporary exception by NYeC.

b. Minimum Necessary Data

Access is authorized only for the data elements, document types, and patient population specified in the PDR Access Approval Notice. Permitted Requesters shall not configure access to broader data sets or patient populations than approved, and the PDR operator shall implement technical controls to enforce these limitations.

c. **Audit and Access Logging**

The PDR operator shall maintain comprehensive logs of all access events under each approved configuration, including user identity, timestamp, patient identifier, data element(s) accessed, and the purpose code or access reason. Logs shall be retained in accordance with SHIN-NY Privacy & Security Policy requirements and made available to NYeC upon request.

d. **User Training**

Permitted Requesters shall ensure that all users with access to PDR data under an approved configuration have completed applicable SHIN-NY training requirements and have executed user-level confidentiality agreements or attestations as required by the Permitted Requesters access program.

e. **Incident Reporting**

The Permitted Requester shall notify NYeC of any suspected or confirmed unauthorized access, data breach, or misuse of PDR data within 24 hours of becoming aware of the incident, consistent with SHIN-NY Privacy & Security Policy and SHIN-NY Incident Response requirements.

f. **Annual Review and Revalidation**

All active PDR access configurations are subject to annual review by NYeC. The Permitted Requester shall confirm continued need for access and compliance with all conditions of approval on an annual basis. NYeC reserves the right to modify, suspend, or revoke access configurations that no longer comply with applicable policy, law, or the conditions of the original approval.

VIII. Access Modification, Suspension, and Revocation

NYeC may modify, suspend, or revoke an approved PDR access configuration at any time for the following reasons:

- Material change in the use case, user population, or data access scope without prior NYeC approval;
- Failure to satisfy or maintain the conditions of the PDR Access Approval Notice;
- Discovery of unauthorized access, data breach, or misuse of PDR data;
- Change in applicable law, regulation, or SDUC policy that renders the approved use case impermissible;

- Material data quality concerns that make continued access inappropriate pending remediation; or
- Termination or expiration of the Permitted Requester’s DUCA or other foundational agreements with NYeC.

Revocation or suspension shall be communicated to the Permitted Requester and PDR operator in writing. Except in the case of emergency suspension (which may take effect immediately), NYeC shall provide the Permitted Requester with a minimum of 10 business days' notice before revoking access, during which time the Permitted Requester may submit a written response.

The Permitted Requester may appeal a revocation or suspension decision to the SDUC within 30 calendar days by submitting a written request to NYeC. A pending appeal does not automatically stay a revocation or suspension.

IX. Document History

Version	Effective Date	Description of Change	Revised By
1.0	6/11/26	Approved by Statewide Data Use Committee	N/A
	6/25/26	Approved by NYeC Board	N/A
	7/6/2026	Approved NYS Department of Health	N/A

Attachment A

PDR Data Access Request Required Elements

#	Required Element	Description / Instructions
1	Requesting QE and Authorized Representative	Full legal name of the QE, authorized signatory name and title, and contact information for the designated point of contact for this request.
2	Requesting Organization (if applicable)	If the PDR access is being enabled on behalf of a specific participant or downstream organization, identify that entity and describe its relationship to the QE.
3	Request Category	Identify the applicable request category (A, B, C, or D) per Section 5 of this SOP.
4	Use Case Description	Detailed narrative description of the intended purpose for which PDR data will be accessed, including the clinical or programmatic workflow in which data will be used.
5	Data Elements Requested	Identify the specific PDR data elements or document types to which access is sought (e.g., CCDs, discharge summaries, specific structured fields). Requests should be limited to the minimum data necessary.
6	Patient Population	Describe the patient population whose records will be accessed, including any criteria used to define the population (e.g., patients attributed to a care management program, patients with a specific diagnosis).
7	Consent Verification Method	Where SHIN-NY consent is required, describe how the QE will verify that each patient record accessed has valid SHIN-NY consent on file, consistent with all applicable law and SHIN-NY policies and procedures.
8	Users / Access Controls	Identify the users or user roles who will access PDR data, the access controls that will govern their access, and training requirements applicable to those users.
9	Data Security Attestation	Attestation that the QE meets SHIN-NY Privacy & Security Policy requirements for handling PDR data and that any downstream entity receiving PDR data has executed an appropriate agreement.
10	SDUC Use Case Alignment	Identify the existing SDUC-approved use case under the SDI Data Use Approval Process to which this request aligns, or explain why SDUC referral is sought (for Category C requests).
11	Technical Implementation Details	Describe the technical method by which PDR data will be accessed (e.g., CCD query via SHIN-NY Statewide Patient Record Lookup, direct PDR API access), including any interfaces, applications, or third-party tools involved.
12	Audit and Monitoring Approach	Describe how the QE and/or downstream entity will log, monitor, and report on PDR data access for audit and compliance purposes.
13	Supporting Documentation	Attach relevant supporting materials, including executed or proposed Data Use Agreement (DUA), participant attestations, applicable program authorizations, or prior SDUC determinations.