

Statewide Data Infrastructure (SDI) Data Use Request Form for the New York State Department of Health

Request # Project Name: DG-63 NYS Birth Defects Registry Chromosomal Anomaly Surveillance

Project Name: NYS Birth Defects Registry Chromosomal Anomaly Surveillance	
Tracking ID: DG-63	
A. Request Overview	
Item	Response
<p>1) <b>Authorized Requester Information Description</b>                      Identification of the Requester's Organization and a brief description of the requester type (e.g., public health authority (PHA); PHA contractor; government agency (specify) etc.)</p>	<p>The NYS Birth Defects Registry (BDR) is located within the NYS Department of Health's Center for Environmental Health and is mandated by NYS Public Health Law (Environmental Diseases Program) to collect information on birth defects cases in NYS.</p>
<p>2) <b>Project Description</b>                      Summary of the project including how this data will be used.</p>	<p>The BDR is seeking access to data from within the Statewide Data Infrastructure to modernize and supplement our approach to case identification as part of our overall birth defect surveillance activities. Currently the BDR utilizes the SHIN-NY and participating Qualified Entities to look up medical records of cases identified through our existing hospital reporting system.</p> <p>While most types of birth defects are diagnosed by a physician using pertinent clinical information, a subset can be diagnosed through a laboratory test. Through this project with the SDI, we are hoping to supplement the data we currently collect through our existing surveillance program by obtaining laboratory test results for cases with chromosomal anomalies reported to the BDR. Currently, hospitals can report this information, but it is not required and often not available at the time of report. Also, laboratories can report to the BDR through the Department's Electronic Clinical Laboratory Reporting System (ECLRS) but the current mechanism is manual data entry. Manual data entry is a barrier to larger laboratory systems that rely on HL7 protocols for most of their public health reporting.</p> <p>We envision this being a recurring request, at a frequency of twice per year.</p>

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<p><b>3) Permitted Purpose Description</b></p>	<p><input checked="" type="checkbox"/> Public Health Activity Permitted Purpose</p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Data Use Request with Individually Identifiable Health Info (e.g. PHI)</li> <li><input type="checkbox"/> Narrow Data Use Request (e.g. de-identified; LDS). If this box is checked, Requester must complete attestation below in Section D(3)(c).</li> <li><input type="checkbox"/> Data Use Request for Urgent Public Health Surveillance</li> </ul> <p><input type="checkbox"/> Medicaid Permitted Purpose</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Data Use Request</li> <li><input type="checkbox"/> Narrow Data Use Request (e.g., de-identified; LDS) If this box is checked, Requester must complete the attestation below in D(3)(c).</li> </ul> <p><input type="checkbox"/> Other: <a href="#">Click or tap here to enter text.</a></p>
<p><b>4) Description of Intended Use</b> Describe the intended use of data, including any intended disclosure or re-disclosure, and the basis on which the intended use, disclosure or re-disclosure is for a Public Health Activity Permitted Purpose or a Medicaid Permitted Purpose and otherwise in compliance with the Statewide Common Participating Agreement (SCPA), the Data Use and Contribution Agreement (DUCA), the SHIN-NY Regulations and SHIN-NY Standard Operating Procedures (SOPs) and applicable law.</p>	<p>The information obtained through this project will be used to supplement the NYS BDR's existing surveillance methodologies for identifying cases and obtaining accurate diagnostic information which include hospital reporting of cases through the Health Commerce System, identification of cases through the Statewide Planning and Research Cooperative System (SPARCS), and ECLRS. The data obtained through the SDI will be matched to our existing cases using case identifiers (names, sex/gender, dates of birth, dates of discharge, facility ID, medical record number, addresses, patient and parental demographics etc.). Matched data will be used to confirm the presence of a chromosomal anomaly in a given case through the test results obtained from the SDI. The BDR will not disclose or re-disclose any of the information obtained from the SDI, except as part of de-identified, aggregate surveillance reports on select defects.</p>
<p><b>5) Target Population Inclusion</b> Specify the criteria used for the dataset. Typical inclusion criteria are: demographic, clinical, and geographic characteristics.</p>	<p>Newborns (birth to age 1) born or residing in NYS with an inpatient or outpatient record containing a diagnostic laboratory test result indicating a chromosomal anomaly (karyotype, in situ-hybridization, chromosomal micro-array).</p>
<p><b>6) Target Population Exclusion</b> Specify the criteria that would exclude the case/data from being included in the dataset. (For example, if you are looking at residents of certain counties or only looking for persons over the age of 65.)</p>	<p>Records of newborns that were not born in or do not reside in NYS at the time of birth are to be excluded, records pertaining to tests performed on samples obtained from mothers (amniocentesis, chorionic villus sampling, etc. or from products of conception), results from screening tests (cell free DNA, or other non-invasive prenatal screening tests)</p>

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<p>7) <b>What law, regulation, rule or agreement grants the authority to obtain this information?</b> Identify, in detail, the laws, regulations, contracts, SHIN-NY SOPs and other governing documents that allow and authorize access to the data requested.</p>	<p>Part 22.3 of the NYS Sanitary Code stipulates that every physician and hospital in attendance on an individual diagnosed within two years of birth as having one or more congenital anomalies, shall file a supplementary report with the State Commissioner of Health within 10 days of diagnosis. Data collected by the BDR are, by law, to be used for surveillance and to facilitate epidemiologic research into the prevention of environmental diseases, as prescribed by Public Health Law §§ 225(5)(t), and 2730 <i>et. seq.</i>. Public Health Law 206(1)(j) provides for scientific research and research to reduce morbidity and mortality. Confidentiality of all data reported to the Registry is strictly maintained by Department of Health staff and rigorously safeguarded by Section 206 (1)(j), which specifically prohibits the release of personal identifiers. In addition, the NYS BDR has an existing SHIN-NY Access and Implementation Plan with NYSDOH Executive Deputy Commissioner Clearance approval to obtain necessary clinical information on cases reported to our Registry. Our access has been approved for all six Qualified Entities through the Clinical Viewer and Transmittals/Data Lake.</p>
<p>8) <b>Is this data currently being supplied to Requester from another source? *</b> (yes/no)</p>	<p>Yes</p>
<p>9) *If Yes, explain where data is being supplied from and why Statewide Data Infrastructure (SDI) Data is being requested. (SDI data is data held in the “statewide repository” referred to in 10 NYCRR §300.2(f)(5))</p>	<p>While hospitals and laboratories can report test results for chromosomal anomalies, they often do not for various reasons. Since they often report the child with the diagnosis but not all of the additional information, the hospitals are still complying with the law, additional enforcement is a challenge.</p> <p>The SDI offers a streamlined approach to obtaining this information. With modern interoperability technology as the basis of the SDI, clinical information birth defect cases are being accumulated much faster than in the BDR using our existing reporting technologies.</p>

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10) <b>What is the expected start date of this project?</b> The date when the project work is expected to begin (Mo/Day/Yr.).	6/1/2026
11) <b>Is this request time-sensitive and/or critical? *</b> (yes/no)	No
12) *If time-sensitive or critical, explain	n/a
13) <b>When is this information needed?</b> The date by which Requestor would need the report/data (Mo/Day/Yr.).	12/1/2026
14) <b>What is the expected end date of this project?</b> The date when the project is expected to end (Mo/Day/Yr.).	Not applicable, project is ongoing
<b>(B) Technical Specifications Data Use Request</b>	
1) <b>What data elements are needed?</b> Describe all the data fields required for your project (example: Date of birth, diagnosis codes, etc.)	names, dates of birth, sex/gender, dates of discharge, facility ID, medical record number, address, diagnosis codes, LOINC codes for test and sample, test result value. (see Appendix A)
2) <b>Is the data being requested</b> <b>1) individually identifiable health data,</b> <b>2) limited data set (LDS)* or</b> <b>3) de-identified*?</b> *If the data requested is a Limited Data Set (LDS) or de-identified data, Requester must complete attestation below in Section D(3)(c).	1) Individually Identifiable Health Info
3) <b>Proposed delivery method*</b> (select from drop-down)	Secure File Transfer through the Health Commerce System
4) *If selected "other" above for delivery method, please explain the proposed delivery method. Only methods with secure encryption mechanisms will be accepted.	n/a
5) <b>What is the requested format for the data?</b> (examples include XLS, txt, CSV)	CSV
6) <b>What safeguards will you put in place to protect the data?</b>	We will follow our existing protocols for protecting all data reported to or collected by the BDR. This involves storing the data on behind the NYS firewall

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<p>7) <b>How will files be handled/stored/deleted at the end of the project?</b></p>	<p>Chromosomal result information will be appended to case records in the NYS BDR Database, which will be stored indefinitely per the NYS record retention policy. The specific raw files obtained from the SDI will be destroyed after the pertinent data have been entered into the BDR Database.</p>
<p>8) <b>Select "Yes" to indicate adherence to the standard of minimum necessary data requests. (This field cannot be blank.)</b></p>	<p>Yes</p>
<p><b>(C) Program/Project Contact Information</b></p>	
<p><b>1. Program Lead Contact Information</b></p>	
<p>Name (First, Last):</p>	<p>Sarah Fisher</p>
<p>Bureau/Unit:</p>	<p>Birth Defects Registry, Bureau of Environmental &amp; Occupational Epidemiology, Center for Environmental Health, NYSDOH</p>
<p>Email:</p>	<p>Sarah.fisher@health.ny.gov</p>
<p>Phone Number:</p>	<p>518-402-7978</p>
<p><b>2. Other Project Team Members</b></p>	
<p>a) Team Member 1 (Name, Employer, Contact Info)</p>	<p>Adrian Michalski, Birth Defects Registry, Bureau of Environmental &amp; Occupational Epidemiology, Center for Environmental Health, NYSDOH, <a href="mailto:Adrian.michalski@health.ny.gov">Adrian.michalski@health.ny.gov</a>, 518-402-7766</p>
<p>b) Team Member 2 (Name, Employer, Contact Info)</p>	<p>Click or tap here to enter text.</p>
<p>c) Team Member 3 (Name, Employer, Contact Info)</p>	<p>Click or tap here to enter text.</p>
<p>d) Team Member 4 (Name, Employer, Contact Info)</p>	<p>Click or tap here to enter text.</p>
<p>e) Team Member 5 (Name, Employer, Contact Info)</p>	<p>Click or tap here to enter text.</p>

<p><b>(D) Data Use Request Authorized Requester Attestation &amp; Agreement Form</b></p>	
<p><b>1) Name of Requester's Organization: New York State Birth Defects Registry</b></p>	
<p><b>2) Authorized Requester Information</b></p>	
<p>Name: Sarah Fisher</p>	
<p>Title: Click or tap here to enter text.</p>	
<p>Email: Sarah.fisher@health.ny.gov</p>	

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Phone Number: 518-402-7978	
<b>3) Attestations: Authorized Requester attests to the following:</b>	
<b>a) This Data Use Request meets the following criteria:</b>	
i. Request is for a <b>Public Health Activities</b> by Public Health Authority.	<input checked="" type="checkbox"/>
<b>OR</b>	<input type="checkbox"/>
Request is for a <b>Medicaid Permitted Purpose</b>	
ii. Request is in compliance with the SCPA, DUCA, SHIN-NY Regulations and SHIN-NY SOPs.	<input checked="" type="checkbox"/>
iii. Request is in compliance with applicable law.	<input checked="" type="checkbox"/>
iv. Data elements requested meet the standard of minimum necessary.	<input checked="" type="checkbox"/>
<b>b) Safeguards and Protections Attestation:</b>	
Appropriate safeguards and internal controls will be used for data access and use, security and privacy.	<input checked="" type="checkbox"/>
<b>c) Data Classification and Use Attestation (for Narrow Data Requests)</b>	
<i>(select one or both, or neither)</i>	
<b>HIPAA Limited Data Set 45 C.F.R. 164.514(e)</b>	<input type="checkbox"/>
<b>De-Identified Data (45 C.F.R. 164.514(b)(2))</b>	<input type="checkbox"/>
<p><b>Based on the Data Classification(s) identified above, the Authorized Requester attests and agrees to the following:</b></p> <ul style="list-style-type: none"> <li>The data will be used solely for the <b>permitted purpose(s)</b> described in this approved SDI Data Use Request and as authorized under the SCPA, DUCA, SHIN-NY Regulations, and SHIN-NY SOPs and applicable law.</li> <li>Requester may use and disclose a Limited Data Set solely for the purpose(s) expressly described in, and approved through this SDI Data Use Request, and only to the extent such use or disclosure is permitted under applicable law and consistent with 45 C.F.R. § 164.514(e). Requester shall not use or further disclose the Limited Data Set in any manner that would violate the HIPAA Privacy Rule if done by a covered entity.</li> <li>Access to and receipt of a Limited Data Set shall be <b>limited to those workforce members, agents, contractors, and other specifically authorized persons</b> identified by Requester as having a need to know the information for the approved purpose(s), and no other person or entity may use or receive the Limited Data Set except as expressly permitted by this SDI Data Use Request and applicable law.</li> <li>The data will <b>not be re-identified</b>, and no third party will be permitted to re-identify or attempt to re-identify individuals whose information is included in the data. If the Requester becomes aware of any actual or attempted re-identification of individuals or data, Requester will notify NYeC immediately.</li> <li>No individual whose information is included in the data may be contacted in association with the use case described and approved in this SDI Data Use Request., nor will any third party be permitted to contact or attempt to contact such individuals based solely on SDI Data.</li> <li>Any <b>agents, contractors, or downstream recipients</b> with access to the data will agree and be subject to use, disclosure, and safeguard obligations no less protective than those set forth in this Data Use Request, the Statewide Common Participation Agreement, and applicable law.</li> <li>Appropriate <b>administrative, technical, and physical safeguards</b> will be used to</li> </ul>	

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<p>prevent any use or disclosure of the data not permitted by this Data Use Request or applicable law, and any unauthorized use or disclosure of which Requester becomes aware will be reported to NYeC in accordance with the SCPA, and SHIN-NY SOPs.</p> <ul style="list-style-type: none"> <li>• The data will not be used for marketing purposes or sold, licensed, or otherwise disclosed in exchange for remuneration, except as permitted by HIPAA and applicable law, and only with prior written consent of NYeC.</li> <li>• The Requester will not, and will not permit any third parties to use de-identified data for any purpose other than those permitted in this Data Use Request or otherwise as permitted by law.</li> <li>• Requester shall otherwise comply in full with 45 C.F.R. § 164.514(e)(4)(ii).</li> <li>• Upon expiration, suspension or termination of this Data Use Request, Requester shall immediately cease all use and disclosure of all SDI Data and comply with any instructions from NYeC regarding continued retention, return, destruction, or other handling of the data, in accordance with this Data Use Request, the SCPA, DUCA, SHIN NY Regulations, SHIN NY SOPs, and applicable law.</li> </ul>	
<p><b>d) Attestations Regarding Potential Violation of this Data Use Request</b></p>	
<p>i. The New York State Department of Health in coordination with NYeC, reserves the right to investigate any actual or suspected breach, or improper access, use, or disclosure of data by Requester or any person acting on Requester’s behalf stemming from this Data Use Request.</p>	<input checked="" type="checkbox"/>
<p>ii. Requester acknowledges and agrees that NYeC may, following notice to and consultation with the Department, suspend, terminate, or revoke Requester’s access to SDI Data immediately upon notice, or immediately without prior notice where NYeC determines prompt action is necessary, if NYeC determines in its reasonable discretion that Requester has violated this Data Use Request, the SCPA, DUCA, SHIN-NY Regulations, SHIN-NY SOPs, or applicable law. Requester shall cooperate with the Department and NYeC in investigating and mitigating any such violation.</p>	<input checked="" type="checkbox"/>
<p><b>4. Authorized Requester Signature:</b></p>	
<p>Deirdre Depew</p>	<p><b>Date of Signature:</b> Click or tap to enter a date.</p>



**Department  
of Health**

# Appendix A - Data Elements

Data Element Class	Data Element
Patient Demographics/Information	First,Last Name
Patient Medical Record	Medical Record Number
Patient Demographics/Information	Date of Birth
Patient Demographics/Information	Patient Address
Patient Demographics/Information	Discharge Date
Hospital Name	Birth Hospital Facility Name
Provider Name	
Laboratory	Laboratory Name
Laboratory test	Chromosomal Analysis (result)
Patient Demographics/Information	Sex

Patient Medical Record	Diagnosis Codes
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Notes: \*The 'Data Standard Code Values' column is optional.

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Data Element Standard	Data Standard Code Values*
	-
LOINC	8649-6
LOINC	62330-6, LP111263-2
LOINC	68994-3, 65652-0
LOINC	62389-2 (master panel, includes many other LOINC codes, which should be queried separately),57802-1, 50659-2, 29770-5
SNOMED CT U.S. Edition	<a href="#">248152002 (Female)</a> , <a href="#">248153007 (Male)</a>

ICD-10 CM/ SNOMED

Q90.0-Q99.9 737542000, 205616004,  
254264002, 205624009, 254266000,  
205620000, 254268004, 21111006, 254262003,  
254270008, 133849008, 205666005,  
270520003, 718226002, 17122004, 70173007,  
76880004, 699310000, 767263007, 63247009,  
401315004, 254276002, 205672005,  
205673000, 205674006, 205676008,  
254275003, 38804009, 205686009, 35111009,  
254282004, 254283009, 8234004, 254277006,  
22053006, 405769009, 254285002, 254286001,  
254284003, 205718006, 95219002, 205720009,  
57838006, 232057003, 232058008



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## SDI Data Use Request: Summary Decision Memo

### Administrative Data:

Title: NYS Birth Defects Registry Chromosomal Anomaly Surveillance

Tracking Number: DG-63

Date of Data Use Request Receipt: May 28, 2026

Date NYeC Evaluation Completed: May 28, 2026

Date of NYeC Determination (if applicable): N/A

Date of NYeC Recommendation (if applicable): 5/28/2026

Date of SDUC Decision (if applicable):

***Note: Attached to this Summary Decision Memo is the Data Use Request (and any supporting documentation) provided to NYeC by the NYS Department of Health Authorized Requester***

### Overview and Description of Request:

This request was submitted by the New York State Birth Defects Registry (“BDR”) within the Center for Environmental Health of the New York State Department of Health, acting in its stated capacity as a public health authority conducting statewide birth-defect surveillance. The request seeks access to Statewide Data Infrastructure data for the limited purpose of supplementing the Registry’s existing surveillance methodologies by identifying and confirming cases involving chromosomal anomalies through relevant laboratory test results.

As described in the request, the BDR currently relies on hospital reporting, SPARCS, ECLRS, and SHIN-NY-based record review to identify and develop cases, but laboratory-confirmed chromosomal anomaly information is not always reported in a timely or complete manner through those channels. The requested SDI data would be used to match records to existing cases using identifying information, confirm the presence of a chromosomal anomaly through diagnostic test results, and support the Department’s ongoing surveillance activities on a recurring basis, anticipated at twice per year.

### NYeC Review

Based on NYeC’s review, the Data Use Request is found to be:

I. Procedure

Made by an Authorized Requester

Authorized Requester Name: Sarah Fisher

Authorized Requester Title: Program Lead, Birth Defects Registry



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Authorized Requester’s Organization/Entity Name: New York State Birth Defects Registry, Bureau of Environmental & Occupational Epidemiology, Center for Environmental Health, NYS Department of Health

Not made by an Authorized Requester

Requester Name: \_\_\_\_\_

Requester Title: \_\_\_\_\_

Requester’s Organization/Entity Name: \_\_\_\_\_

II. Purpose

Public Health Permitted Purpose

Data Use Request

Narrow Data Use Request

Data Use Request for Urgent Public Health Surveillance

Medicaid Permitted Purpose

Data Use Request

Narrow Data Use Request

Other (brief description: \_\_\_\_\_)

III. Compliance

	Compliant	Not Compliant	Not Applicable
Statewide Common Participation Agreement (SCPA)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Data Use and Contribution Agreement (DUCA) *	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SHIN-NY Regulations & Applicable SHIN-NY SOPs	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Applicable Law	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Justification for Compliance Findings:

The Department’s authority to access the requested SDI information for this use case is established under its role as a Public Health Authority (45 C.F.R. § 164.501 and § 164.512(b)). The Department is the



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State agency responsible for birth defects surveillance in New York State, pursuant to its general public health authority (NYS Public Health Law § 201), Public Health Law §§ 225(5)(t), 2730-2733 (which establishes the Birth Defects Registry and authorizes the use of Registry data for surveillance investigation and research designed to reduce morbidity and mortality), and §22.3 of the New York State Sanitary Code (10 NYCRR Part 22) (which mandates physician and hospital reporting of congenital anomalies including chromosomal anomalies diagnosed within two years of birth, with a supplementary report to the Commissioner of Health within 10 days of diagnosis). Confidentiality of Registry data is strictly maintained by the Department's staff and safeguarded by PHL 206(1)(a). The Birth Defects Registry is located within the Center for Environmental Health and is a State designated registry for the collection of information on birth defects cases.

The data subject to this request will be accessed only by Birth Defects Registry personnel. The data will be used for public health surveillance purposes, specifically to supplement the Registry's existing case-identification methodologies by identifying confirmed chromosomal anomaly cases ascertained through laboratory test results that are not consistently captured through existing hospital reporting, or SPARCS or ECLRS channels. The requested SDI data will be used to match records to existing BDR cases identifying confirmed chromosomal anomaly cases for inclusion in the Registry. Identified data will not be disclosed or redisclosed outside the Department. The disclosure of identifiable SHIN-NY data without authorization for the case identification and Registry-augmentation purposes described herein falls within surveillance activity authorized by PHL §225(5)(t) and §22.3 of the Sanitary Code. It also falls within the SDI Data Use Approval Process SOP, which governs the disclosure, use, and re-disclosure of SDI Data for approved public health permitted purposes, including to conduct investigations to assist in reducing morbidity and mortality. See SDI Data Use Approval Process SOP, p 6; see also SHIN-NY Privacy and Security SOP, Section 1.2.2 (iii).

As stated in the request, identified data obtained pursuant to this request will be accessed only by the Birth Defect Registry personnel and will be incorporated into the Registry database, which operates under existing confidentiality protocols and access controls applicable to BDR data. The transmittal will occur through secure file transfer and the data will be maintained behind the New York State firewall under existing Department protocols. SDI data files received pursuant to this request will be destroyed after being incorporated into the Registry database, in accordance with the Department's record handling procedures.

For clarity, this Summary Decision Memo addresses only the Department's request for identified SHIN-NY data for the public health surveillance purposes described in the Data Use Request. Information incorporated into the Birth Defects Registry through this approval becomes part of the Registry's protected dataset and is governed by confidentiality provisions of PHL § 206(1)(a) and § 225(5)(t), as well as by the ongoing obligations of the SCPA, DUCA, and the SHIN-NY SOPS.

For the foregoing reasons, NYeC recommends approval of this use case by the SDUC.



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### NYeC Determination: Narrow Data Use Request

Approved

Denied (description of reason[s]):

\_\_\_\_\_  
\_\_\_\_\_

### NYeC Determination: Urgent Public Health Surveillance Data Use Request

Approved

Denied (description of reason[s]):

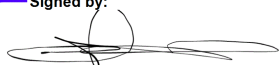
\_\_\_\_\_  
\_\_\_\_\_

### NYeC Recommendation to SDUC: Data Use Request

Approval

Denial (description of reasons[s]):

\_\_\_\_\_  
\_\_\_\_\_

Signed by:  
  
1C1BB9F6120346A...

5/28/2026

NYeC Legal

Date

DocuSigned by:  
  
0CADF6980C7C420...

5/28/2026

NYeC Privacy & Compliance Officer

Date



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## SDUC Determination

Approved

Denied (description of reason[s]):

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Signed by:

*Laura Alfredo*

D00C24318260488...

6/26/2026

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SDUC Chair

Date