



U.S. Department of  
Health and Human Services  
Centers for Disease  
Control and Prevention

*Print Date: 1/14/26*

**Title:** ED3N Newborn Screening Data Platform - Enhancing Disease-Detection in Newborns PRA Revision 2

**Project Id:** 0900f3eb8261402d

**Accession #:** NCEH-DLS-6/7/21-4d4b6

**Project Contact:** Amy M Gaviglio

**Organization:** NCEH/ATSDR/DLS/NSB

**Status:** **Pending Clearance : PRA Revision**

**Intended Use:** **Project Determination**

**Estimated Start Date:** 09/01/2021

**Estimated Completion Date:** 12/31/2030

**CDC/ATSDR HRPO/IRB Protocol #:**

**OMB Control #:** 0920-1391

**Source System #:** 2020-0102

**OMB Discontinuation Date:**

## Determinations

Determination	Justification	Completed	Entered By & Role
HSC: Does NOT Require HRPO Review	Not Research - Public Health Surveillance <i>45 CFR 46.102(1)(2)</i>	7/10/25	Flores_Sharon (fil4) CIO HSC
PRA: PRA Applies		7/10/25	Flores_Sharon (fil4) CIO OMB / PRA
ICRO: PRA Applies	OMB Approval date: 4/10/23 OMB Expiration date: 4/30/26	7/11/25	Zirger_Jeffrey (wtj5) ICRO Reviewer

## Description & Funding

### Description

Priority: Standard

Date Needed: 12/03/2021

Priority Justification:

CDC Priority Area for this Project: Not selected

Determination Start Date: 12/11/25

This is a request to publish a 30-day Federal Register Notice for a new information collection request (ICR) titled #ED3N." Every year about 3.6 million infants are born in the United States. Almost all newborns are screened by state and territorial newborn screening programs for diseases that can cause severe disability or death when untreated. The Newborn Screening and Molecular Biology Branch (NSMBB) at the CDC supports newborn screening (NBS) programs by creating quality assurance materials, developing new methods, and providing technical assistance and technology transfer for biochemical and molecular techniques aimed at identifying newborns at risk for congenital diseases. Both NSMBB and newborn screening programs are experiencing increased data analytic challenges associated with the continued expansion of the number of newborn diseases screened, the increased complexity of disease phenotype, and the difficulties in correlating disease markers with disease risk. To overcome analytic challenges and harmonize testing and interpretative processes, NSMBB and contractors are developing a Newborn Screening Data Platform. This Data Platform can serve as a secure, central, and national resource for the US and international newborn screening community, containing a data repository and data sharing resources for newborn screening data. The Data Platform will include three functional modules for biochemical, molecular, and clinical data and will support NBS Program best practices through 1) The evaluation of daily routine workflows at the individual patient level to enhance disease detection, 2) The exploration of aggregate data (e.g., pooled analyte, variant, and/or clinical data with potential identifiers removed) to test new workflows based on national normalized trends, and 3) The education of NBS program personnel on data analytic skills and best practices, and through a resource library of peer reviewed literature. Biochemical: Data for this module includes analyte values from tandem mass spectrometry and other biochemical tests, methods and instrumentation used, normalization techniques, and test cutoff values. Benefits of this data may include the harmonization of analytic values across NBS programs, assessment of demographic, analytic, and geographic influences on screening outcomes, comparison of test cutoff values, and the development of

### Description:

novel interpretative algorithms. Molecular: Data for this module includes variants identified through sequencing, the platform used, and the interpretation of the variants assigned by NBS programs. Benefits of this data may include improving variant interpretation, providing consistency around variant interpretation, correlation of biochemical and molecular data, and standardizing variant interpretation changes across programs. Clinical: Data for this module includes clinical information necessary for tracking health outcomes for infants screening positive for and/or afflicted by an NBS disorder. Benefits of this data may include the comparison of case definition algorithms and interpretation, the implementation and refining of public health surveillance case definitions, and creating an urgency index for NBS results. In addition, the data hub will collect demographic information that will crosscut between all three modules. Data for the demographic section include descriptive information about the infant and the mother that is necessary for appropriate interpretation of NBS result

**IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission:** No

**IMS Activation Name:** Not selected

**Submitted through IMS Clearance Matrix:** Not selected

**Primary Scientific Priority:** Not selected

**Secondary Scientific Priority (s):** Not selected

**Task Force Responsible:** Not selected

**CIO Emergency Response Name:** Not selected

**Epi-Aid Name:** Not selected

**Lab-Aid Name:** Not selected

**Assessment of Chemical Exposure Name:** Not selected

**Goals/Purpose**

The NSMBB ED3N Data Platform seeks to be a resource that NBS programs will use to improve and harmonize disease detection in newborn screening (NBS) programs. The state-based nature of NBS has led to a lack of uniformity in how NBS is administered and accomplished throughout the country, especially in the analytical and post-analytical phases of the NBS system. Additionally, the increasingly technological and interpretative complexities of NBS assays and diseases necessitates an innovative solution to compile data and share experiences across the country. National NBS harmonization and improved disease detection will be accomplished through a National Data Platform developed and operated by the CDC's NSMBB, in conjunction with Booz Allen Hamilton and CI International. The Data Platform will serve as a secure, centralized resource for newborn screening partners to analyze and share biochemical and molecular data. It will support laboratory best practices through standardized workflows and robust, validated analytical tools. The Newborn Screening and Molecular Biology Branch (NSMBB) Enhancing Data-driven Disease Detection in Newborns (ED3N) Newborn Screening Data Platform (hereafter called ED3N) will help meet NSMBB's Mission of "Better detection of newborn disorders by implementing advanced technologies and capabilities that improve screening test performance, test result interpretation, quality assurance programs, training and technology transfer and by assisting state programs to expand screening to new conditions of high priority." The purpose of ED3N is to serve as a secure, central, and national resource for the state newborn screening community, containing a data repository and data sharing resources for newborn screening data. ED3N will collect infant and specimen level newborn screening (NBS) data to help overcome analytic challenges and harmonize testing and interpretive processes in order to reduce false positive and negative newborn screening results.

**Objective:**

The completion of the National Data Platform (ED3N) will allow for the NSMBB to meet several of the Branch's priorities and address its congressional mandate. The expected impact of successfully completing this project is a site for sharing and analyzing molecular, biochemical, and clinical data that will enable newborn screening partners to accurately identify and appropriately act on

newborns identified as being at-risk for life and health-threatening diseases.

**Does your project measure health disparities among populations/groups experiencing social, economic, geographic, and/or environmental disadvantages?:** Yes

**Does your project investigate underlying contributors to health inequities among populations /groups experiencing social, economic, geographic, and/or environmental disadvantages?:** Yes

**Does your project propose, implement, or evaluate an action to move towards eliminating health inequities?:** Yes

**Activities or Tasks:**

Secondary Data or Specimen Analysis ; Purchase, Use, or Transfer of Information, Data, Biospecimens or Materials ; Programmatic Work

**Target Populations to be Included/Represented:**

General US Population ; Children ; Neonates

**Tags/Keywords:**

DLS 2020-0102 ; NSMBB ED3N Data Warehouse

**CDC's Role:**

CDC employees or agents will obtain or use identifiable (including coded) private data or biological specimens ; CDC employees will participate as co-authors in presentation(s) or publication(s) ; CDC employees will provide substantial technical assistance or oversight ; CDC is provider of materials/services TO an institution ; CDC is recipient of private data/specimens FROM an institution

**Method Categories:**

Needs Assessment; Public Health Assessment; QA/QI; Surveillance Support; Technical Assistance

**Methods:**

ED3N will be developed in the AWS Gov Cloud using an iterative and phased release approach starting with the Molecular Module and ending with the Clinical Module. Throughout development, beta and pilot testing will be done with select states (less than 9 programs total) utilizing mock data and feedback obtained. Determination for this activity is also requested as part of this submission. Feedback will then be prioritized and additional development conducted prior to next pilot test. Development will utilize an Agile approach with Sprints. Once a Minimal Viable Product is developed, it will be moved to production. Access to the production site and consumption of actual patient data will require SAMS access and signed Data Sharing Agreements. Stakeholder engagement will be accomplished using a series of small discussion groups, update webinars, and a webpage. Small discussion groups will include less than 9 programs and/or will be convened using existing mechanisms through APHL. This activity, along with the webinars and webpage is under a separate STARS entry (0900f3eb81d44942).

**Collection of Info, Data or Biospecimen:**

ED3N will collect, store, or share the following types of information: \* Newborn and parental demographic information (e.g., date of birth, time of birth, sex, birthweight, gestational age, etc.) \* Specimen-specific information (e.g., date and time of collection, site of collection, etc.) \* Newborn screening laboratory values and result interpretations (including all biochemical and molecular screening results) \* Clinical evaluation, diagnostic, and treatment information (only for certain cases, when applicable) \* Geographical information (e.g., zip code, state) User information will not be gathered directly by ED3N, as SAMS will be utilized to authenticate and allow user access. ED3N will consist of three functional modules: 1) Biochemical, 2) Molecular, and 3) Clinical Data sources for ED3N will include Newborn Screening Programs/Departments of Health as well as treating/managing clinicians. This is further delineated below in each module section. Data collected will not contain identifiers such as name, medical record number, or address. Dates (e.g., birth date and testing dates) will be collected. 1) Biochemical: Data for this module will flow from Newborn Screening Programs and include analyte values from tandem mass spectrometry and other biochemical tests, methods and instrumentation used, normalization techniques, and test cutoff values. 2) Molecular: Data for this module flow either from Newborn Screening Programs or from treating clinicians and will include variants identified through molecular analysis and the interpretation of the variants assigned by NBS programs or other diagnostic laboratories 3) Clinical: Data for this module will flow either from

Newborn Screening Programs or from treating clinicians' electronic medical records and will include clinical information necessary for tracking final diagnoses and health outcomes for infants afflicted by an NBS condition.

**Expected Use of Findings/Results and their impact:** The completion of the National Data Platform (ED3N) will allow for the NSMBB to meet several of the Branch's priorities and address its congressional mandate. The expected impact of successfully completing this project is a site for sharing and analyzing molecular, biochemical, and clinical data that will enable newborn screening partners

**Could Individuals potentially be identified based on Information Collected?** Yes

**Will PII be captured (including coded data)?** Yes

**Does CDC have access to the identifiers (including coded data)?:** Yes

**Is this project covered by an Assurance of Confidentiality?** No

**Does this activity meet the criteria for a Certificate of Confidentiality (CoC)?** No

**Is there a formal written agreement prohibiting the release of identifiers?** Yes, *see supporting info*

## Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award	Budget Amount
CDC Funding Intramural	Project Funding and Partners				\$700000

## HSC Review

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## Regulation and Policy

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**Do you anticipate this project will require review by a CDC IRB or HRPO?** No

**Estimated number of study participants**

<b>Population - Children</b>	N/A	Protocol Page #:
<b>Population - Minors</b>	N/A	Protocol Page #:
<b>Population - Prisoners</b>	N/A	Protocol Page #:
<b>Population - Pregnant Women</b>	N/A	Protocol Page #:
<b>Population - Emancipated Minors</b>	N/A	Protocol Page #:

**Suggested level of risk to subjects**

Do you anticipate this project will be exempt research or non-exempt research

**Requested consent process wavers**

<b>Informed consent for adults</b>	No Selection
<b>Children capable of providing assent</b>	No Selection
<b>Parental permission</b>	No Selection
<b>Alteration of authorization under HIPAA Privacy Rule</b>	No Selection

**Requested Waivers of Documentation of Informed Consent**

<b>Informed consent for adults</b>	No Selection
<b>Children capable of providing assent</b>	No Selection
<b>Parental permission</b>	No Selection

**Consent process shown in an understandable language**

<b>Reading level has been estimated</b>	No Selection
<b>Comprehension tool is provided</b>	No Selection
<b>Short form is provided</b>	No Selection
<b>Translation planned or performed</b>	No Selection
<b>Certified translation / translator</b>	No Selection

**Translation and back-translation to/from target language(s)** No Selection

**Other method** No Selection

## Clinical Trial

**Involves human participants** No Selection

**Assigned to an intervention** No Selection

**Evaluate the effect of the intervention** No Selection

**Evaluation of a health related biomedical or behavioral outcome** No Selection

**Registerable clinical trial** No Selection

## Other Considerations

**Exception is requested to PHS informing those bested about HIV serostatus** No Selection

**Human genetic testing is planned now or in the future** No Selection

**Involves long-term storage of identifiable biological specimens** No Selection

**Involves a drug, biologic, or device** No Selection

**Conducted under an Investigational New Drug exemption or Investigational Device Exemption** No Selection

## Institutions & Staff

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### Institutions

Will you be working with an outside Organization or Institution? Yes

Institution	FWA #	FWA Exp Date	Funding	Funding Restriction Amount
Vermont Department of Health				
West Virginia Department of Health and Human Resources				
CI International, Center for Public Health Innovation				

Delaware Health and Human Services				
Guam Department of Public Health & Social Services				
Georgia Department of Public Health	FWA00024279			
Kentucky Department of Health				
North Carolina Department of Health and Human Services				
Alabama Department of Public Health	FWA00003283	01/13/30		
Alaska Division of Public Health	FWA00018306	11/01/29		
Arizona Department of Health Services, Human Subjects Review Board	FWA00002311	12/19/29		
Arkansas Dept of Hlth	FWA00002961	03/25/27		
Booz Allen Hamilton Inc.	FWA00014089	08/25/28		
California Health & Human Services Agency	FWA00000681	01/23/30		
Colorado Department of Public Health & Environment	FWA00003044	01/22/29		
Connecticut Department of Public Health	FWA00026243	04/24/30		
District of Columbia Dept of Hlth	FWA00003034	07/01/29		
Hawaii State Department of Health	FWA00000118	07/06/28		
Idaho Dept of Hlth & Welfare	FWA00010222	02/13/23		
Illinois Department of Public Health	FWA00002005	07/02/29		
Indiana State Department of Health	FWA00001959	03/18/26		
Iowa Department of Public Health	FWA00027243	08/31/28		
Kansas Department of Health & Environment	FWA00000383	01/18/29		
Louisiana Department of Health	FWA00026681	02/12/29		
Maryland Department of Health	FWA00002813	09/05/30		

Massachusetts Department of Public Health	FWA00000786	08/26/27		
Michigan Department of Health and Human Services	FWA00007331	04/09/29		
Minnesota Department of Health	FWA00000072	07/05/29		
Mississippi State Department of Health	FWA00021429	12/21/26		
Missouri Dept of Hlth & Senior Services	FWA00001948	06/10/29		
Montana Dept Public Hlth & Human Services	FWA00005012	12/21/28		
Nebraska Department of Health and Human Services	FWA00003679	10/01/29		
Nevada State Hlth Division	FWA00009908	05/24/26		
New Hampshire Division of Public Health Services	FWA00004372	04/01/26		
New Jersey Department of Health	FWA00029683	06/24/25		
New Mexico Department of Health	FWA00030150	09/29/25		
New York City Dept of Hlth & Mental Hygiene	FWA00009459	03/18/27		
North Dakota Dept Hlth	FWA00005027	01/06/27		
Ohio Dept of Hlth	FWA00001963	12/20/29		
Oklahoma State Dept of Health	FWA00000183	04/24/29		
Oregon Health Authority - Public Hlth Division	FWA00000520	10/04/29		
Pennsylvania Department of Health	FWA00028491	11/29/29		
Puerto Rico Dept Hlth	FWA00006333	02/17/22		
Rhode Island Department of Health	FWA00006141	03/13/30		
South Carolina Dept Hlth & Environmental Control	FWA00003803	04/11/29		
South Dakota Dept. of Health	FWA00006900	01/13/31		
State of Florida, Dept of Hlth	FWA00004682	04/25/30		
State of Maine Department of Health and Human Services	FWA00016239	01/22/30		

Tennessee Department of Health	FWA00000379	01/18/27		
Texas Dept of State Hlth Services	FWA00008616	11/22/28		
Utah Department of Health	FWA00024843	06/25/30		
Virginia Dept of Health	FWA00000274	06/22/28		
Washington State Department of Health	FWA00000327	10/12/26		
Wisconsin Dept of Health Services	FWA00002517	09/14/28		
Wyoming Dept Hlth	FWA00005562	07/22/27		

<b>Institution</b>	<b>Funding Restriction Percentage</b>	<b>Funding Restriction Reason</b>	<b>Funding Restriction has been Lifted</b>
Vermont Department of Health			
West Virginia Department of Health and Human Resources			
CI International, Center for Public Health Innovation			
Delaware Health and Human Services			
Guam Department of Public Health & Social Services			
Georgia Department of Public Health			
Kentucky Department of Health			
North Carolina Department of Health and Human Services			
Alabama Department of Public Health			
Alaska Division of Public Health			
Arizona Department of Health Services, Human Subjects Review Board			
Arkansas Dept of Hlth			
Booz Allen Hamilton Inc.			
California Health & Human Services Agency			

Colorado Department of Public Health & Environment			
Connecticut Department of Public Health			
District of Columbia Dept of Hlth			
Hawaii State Department of Health			
Idaho Dept of Hlth & Welfare			
Illinois Department of Public Health			
Indiana State Department of Health			
Iowa Department of Public Health			
Kansas Department of Health & Environment			
Louisiana Department of Health			
Maryland Department of Health			
Massachusetts Department of Public Health			
Michigan Department of Health and Human Services			
Minnesota Department of Health			
Mississippi State Department of Health			
Missouri Dept of Hlth & Senior Services			
Montana Dept Public Hlth & Human Services			
Nebraska Department of Health and Human Services			
Nevada State Hlth Division			
New Hampshire Division of Public Health Services			
New Jersey Department of Health			
New Mexico Department of Health			

New York City Dept of Hlth & Mental Hygiene			
North Dakota Dept Hlth			
Ohio Dept of Hlth			
Oklahoma State Dept of Health			
Oregon Health Authority - Public Hlth Division			
Pennsylvania Department of Health			
Puerto Rico Dept Hlth			
Rhode Island Department of Health			
South Carolina Dept Hlth & Environmental Control			
South Dakota Dept. of Health			
State of Florida, Dept of Hlth			
State of Maine Department of Health and Human Services			
Tennessee Department of Health			
Texas Dept of State Hlth Services			
Utah Department of Health			
Virginia Dept of Health			
Washington State Department of Health			
Wisconsin Dept of Health Services			
Wyoming Dept Hlth			

Institution	Institution Role(s)	Institution Project Title	Institution Project Tracking #	Prime Institution
Vermont Department of Health				
West Virginia Department of Health and Human Resources				

CI International, Center for Public Health Innovation				
Delaware Health and Human Services				
Guam Department of Public Health & Social Services				
Georgia Department of Public Health				
Kentucky Department of Health				
North Carolina Department of Health and Human Services				
Alabama Department of Public Health				
Alaska Division of Public Health				
Arizona Department of Health Services, Human Subjects Review Board				
Arkansas Dept of Hlth				
Booz Allen Hamilton Inc.				
California Health & Human Services Agency				
Colorado Department of Public Health & Environment				
Connecticut Department of Public Health				
District of Columbia Dept of Hlth				
Hawaii State Department of Health				
Idaho Dept of Hlth & Welfare				
Illinois Department of Public Health				
Indiana State Department of Health				
Iowa Department of Public Health				
Kansas Department of Health & Environment				
Louisiana Department of Health				
Marvland Department of Health				

Maryland Department of Health				
Massachusetts Department of Public Health				
Michigan Department of Health and Human Services				
Minnesota Department of Health				
Mississippi State Department of Health				
Missouri Dept of Hlth & Senior Services				
Montana Dept Public Hlth & Human Services				
Nebraska Department of Health and Human Services				
Nevada State Hlth Division				
New Hampshire Division of Public Health Services				
New Jersey Department of Health				
New Mexico Department of Health				
New York City Dept of Hlth & Mental Hygiene				
North Dakota Dept Hlth				
Ohio Dept of Hlth				
Oklahoma State Dept of Health				
Oregon Health Authority - Public Hlth Division				
Pennsylvania Department of Health				
Puerto Rico Dept Hlth				
Rhode Island Department of Health				
South Carolina Dept Hlth & Environmental Control				
South Dakota Dept. of Health				
State of Florida, Dept of Hlth				

State of Maine Department of Health and Human Services				
Tennessee Department of Health				
Texas Dept of State Hlth Services				
Utah Department of Health				
Virginia Dept of Health				
Washington State Department of Health				
Wisconsin Dept of Health Services				
Wyoming Dept Hlth				

<b>Institution</b>	<b>Regulatory Coverage</b>	<b>IRB Review Status</b>
Vermont Department of Health		
West Virginia Department of Health and Human Resources		
CI International, Center for Public Health Innovation		
Delaware Health and Human Services		
Guam Department of Public Health & Social Services		
Georgia Department of Public Health		
Kentucky Department of Health		
North Carolina Department of Health and Human Services		
Alabama Department of Public Health		
Alaska Division of Public Health		
Arizona Department of Health Services, Human Subjects Review Board		
Arkansas Dept of Hlth		
Booz Allen Hamilton Inc.		

California Health & Human Services Agency		
Colorado Department of Public Health & Environment		
Connecticut Department of Public Health		
District of Columbia Dept of Hlth		
Hawaii State Department of Health		
Idaho Dept of Hlth & Welfare		
Illinois Department of Public Health		
Indiana State Department of Health		
Iowa Department of Public Health		
Kansas Department of Health & Environment		
Louisiana Department of Health		
Maryland Department of Health		
Massachusetts Department of Public Health		
Michigan Department of Health and Human Services		
Minnesota Department of Health		
Mississippi State Department of Health		
Missouri Dept of Hlth & Senior Services		
Montana Dept Public Hlth & Human Services		
Nebraska Department of Health and Human Services		
Nevada State Hlth Division		
New Hampshire Division of Public Health Services		
New Jersey Department of Health		

New Mexico Department of Health		
New York City Dept of Hlth & Mental Hygiene		
North Dakota Dept Hlth		
Ohio Dept of Hlth		
Oklahoma State Dept of Health		
Oregon Health Authority - Public Hlth Division		
Pennsylvania Department of Health		
Puerto Rico Dept Hlth		
Rhode Island Department of Health		
South Carolina Dept Hlth & Environmental Control		
South Dakota Dept. of Health		
State of Florida, Dept of Hlth		
State of Maine Department of Health and Human Services		
Tennessee Department of Health		
Texas Dept of State Hlth Services		
Utah Department of Health		
Virginia Dept of Health		
Washington State Department of Health		
Wisconsin Dept of Health Services		
Wyoming Dept Hlth		

Institution	Registered IRB	IRB Registration Exp. Date	IRB Approval Status
Vermont Department of Health			
West Virginia Department of Health and Human Resources			
CI International, Center for Public Health Innovation			
Delaware Health and Human Services			
Guam Department of Public Health & Social Services			
Georgia Department of Public Health			
Kentucky Department of Health			
North Carolina Department of Health and Human Services			
Alabama Department of Public Health	Alabama Dept Public Hlth-Panel A IRB #1	06/04/23	
Alaska Division of Public Health	U Alaska Anchorage IRB #1	08/05/24	
Arizona Department of Health Services, Human Subjects Review Board	Arizona Department of Health Services, Human Subjects Review Board IRB #1	01/08/23	
Arkansas Dept of Hlth			
Booz Allen Hamilton Inc.	Advarra, Inc. IRB #1	08/17/24	
California Health & Human Services Agency			
Colorado Department of Public Health & Environment			
Connecticut Department of Public Health			
District of Columbia Dept of Hlth			
Hawaii State Department of Health			
Idaho Dept of Hlth & Welfare			
Illinois Department of Public Health			
Indiana State Department of Health	Indiana Hlth Services IRB #1 (IRB 01)	06/06/23	

Indiana State Department of Health	Indiana U Indianapolis IRB #1A - (IRB-01)	03/02/23	
Iowa Department of Public Health	U of Northern Iowa Graduate Coll IRB #1	11/12/22	
Kansas Department of Health & Environment	Kansas Dept Hlth & Environment IRB #1	02/06/22	
Louisiana Department of Health	Louisiana Department of Health IRB #2	03/29/24	
Maryland Department of Health	Maryland Dept of Hlth & Mental Hygiene IRB #1	03/11/24	
Massachusetts Department of Public Health			
Michigan Department of Health and Human Services			
Minnesota Department of Health			
Mississippi State Department of Health	Mississippi State Department of Health IRB #1	09/22/23	
Missouri Dept of Hlth & Senior Services	Missouri Dept of Hlth & Senior Services IRB #1	03/10/24	
Montana Dept Public Hlth & Human Services			
Nebraska Department of Health and Human Services	U of Nebraska Med Ctr IRB #1	09/21/24	
Nevada State Hlth Division	U Nevada - Reno IRB #1 Biomed	02/12/24	
New Hampshire Division of Public Health Services			
New Jersey Department of Health	Rowan University School of Osteopathic Medicine IRB #1	02/22/24	
New Mexico Department of Health	New Mexico State U IRB #1	07/03/22	
New York City Dept of Hlth & Mental Hygiene	New York City Dept of Hlth & Mental Hygiene IRB #1	08/06/23	
North Dakota Dept Hlth			
Ohio Dept of Hlth	Ohio Dept of Hlth IRB #1	01/15/24	
Oklahoma State Dept of Health	Oklahoma State Dept Hlth IRB #1	08/23/24	
Oregon Health Authority - Public Hlth Division	DHS-Health Svces/Multnomah Co Public Hlth IRB #1	12/11/22	
Pennsylvania Department of Health	Pennsylvania Dept Hlth IRB #1	06/11/22	
Puerto Rico Dept Hlth			

Rhode Island Department of Health	RHODE ISLAND STE DEPT HLTH IRB #1	04/03/22	
South Carolina Dept Hlth & Environmental Control			
South Dakota Dept. of Health	Centers for Disease Control & Prevention IRB #1 - A	10/08/24	
State of Florida, Dept of Hlth			
State of Maine Department of Health and Human Services			
Tennessee Department of Health			
Texas Dept of State Hlth Services			
Utah Department of Health	Utah Dept Hlth IRB #1 - Public Hlth	06/03/24	
Virginia Dept of Health			
Washington State Department of Health			
Wisconsin Dept of Health Services			
Wyoming Dept Hlth	Wyoming Dept Hlth IRB #1	08/05/24	

<b>Institution</b>	<b>IRB Approval Date</b>	<b>IRB Approval Exp. Date</b>	<b>Relying Institution IRB</b>
Vermont Department of Health			
West Virginia Department of Health and Human Resources			
CI International, Center for Public Health Innovation			
Delaware Health and Human Services			
Guam Department of Public Health & Social Services			
Georgia Department of Public Health			
Kentucky Department of Health			
North Carolina Department of Health and Human Services			
Alabama Department of Public Health			

Alaska Division of Public Health			
Arizona Department of Health Services, Human Subjects Review Board			
Arkansas Dept of Hlth			
Booz Allen Hamilton Inc.			
California Health & Human Services Agency			
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Michigan Department of Health and Human Services			
Minnesota Department of Health			
Mississippi State Department of Health			
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Montana Dept Public Hlth & Human Services			

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Oklahoma State Dept of Health			
Oregon Health Authority - Public Hlth Division			
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Puerto Rico Dept Hlth			
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South Carolina Dept Hlth & Environmental Control			
South Dakota Dept. of Health			
State of Florida, Dept of Hlth			
State of Maine Department of Health and Human Services			
Tennessee Department of Health			
Texas Dept of State Hlth Services			
Utah Department of Health			
Virginia Dept of Health			
Washington State Department of Health			
Wisconsin Dept of Health Services			

**Staff**

Staff Member	SIQT Exp. Date	CITI Biomedical Exp. Date	CITI Social & Behavioral Exp. Date	CITI Good Clinical Practice Exp. Date	CITI Good Laboratory Practice Exp. Date	Staff Role	Email	Phone	Organization
Amy Gaviglio	08/26 /2026	05/12/2025				Project Officer		--	NEWBORN SCREENING BRANCH
Carla Cuthbert	11/15 /2026	08/21/2024				Project Officer		770-488-7571	DIVISION OF LABORATORY SCIENCES
Charles Pickens	06/26 /2026	04/08/2027				Program Lead	ogh6@cdc.gov	404-498-5586	NEWBORN SCREENING TEAM 2
Konstantions Petritis	06/29 /2026	03/31/2028				Program Lead	nmo3@cdc.gov	404-498-5248	NEWBORN SCREENING BRANCH
Suzanne Cordovado	06/27 /2026	04/08/2027				Program Lead	snc4@cdc.gov	770-488-4048	NEWBORN SCREENING BRANCH

**Data****DMP**

Proposed Data Collection Start Date: 12/31/21

Proposed Data Collection End Date: 12/31/30

Proposed Public Access Level: Public, Restricted

Restricted Details:

Data Use Type: Data Sharing Agreement

**Data Use Type URL:****Data Use Contact:**

cdced3nsupport@cdc.gov

**Public Access Justification:**

Data is at an individual level and is secondary use from a mandated public health program where consent is not obtained. Access will be restricted to screening programs and clinicians needing to use the data for the purpose of patient care. NBS programs will be involved in determining who has access to their data. Data will be submitted to the NBS Data Hub by NBS programs, PCPs, and clinical specialists. Submitted data includes biochemical, molecular, and diagnostic/clinical information that could potentially identify an individual when combined with certain demographic data points. In addition, NBS programs consider NBS data sensitive in that it has the potential to compare performance between NBS programs. All data sharing at the record level is restricted to the DSA ratified between the CDC and each individual state or territorial NBS program. De-identified, aggregate data will be made available to the public.

**How Access Will Be Provided for Data:**

Aggregate data will be published in both peer-reviewed publications and in the ED3N online evaluate module. Restricted access will be provided through SAMS to individuals identified and authenticated by the data provider (e.g., NBS program) and CDC. ED3N will utilize defined user roles with specific data access rights and functionality and the ability for NBS programs to assign users to each role. In addition to user roles, each user may be assigned to data access groups (DAGs). Once assigned to a DAG the user can only interact with record-level data belonging to that DAG. System Administrators are the only users with the ability to assign and reassign users to jurisdictional DAGs. Both System Administrators and State Administrators can assign and reassign participants to other DAGs described below. The first level of DAG users may be assigned to is the jurisdiction for which the user represents. A user may be assigned to more than one DAG if that individual is a representative of more than one jurisdiction. The second level of DAG users may be assigned to is the program classification for which the user requires read and/or write access: 1) CDC (universal record access), 2) NBS System (state-level record access), 3) NBS Lab (state-level record access), 4) NBS Follow-Up (state-level record access), and 6) Clinicians (patient-level records). It is possible that a single user may be assigned to multiple DAGs from this level. The third level of DAG users may be assigned to is the data module(s) for which the user requires read and/or write access: 1) Biochemical, 2) Molecular, and 3) Clinical. A user may be assigned to more than one data module DAG. Users will not have access to record-level data from DAGs they are not assigned to but will have access to de-identified aggregate data within the ED3N user interface. System Administrator Role: The CDC will provide personnel assigned to the System Administrator role having universal access to all data records. These individuals can add and remove users at any level and assign them into the appropriate DAGs. System Administrators also function as national data quality monitors and are responsible for reviewing and verifying data submitted from each NBS program. Program Administrator Role: NBS programs will identify one or more individuals to serve in the Program Administrator user role (i.e., the individual(s) who manage all users for the jurisdiction). These individuals can assign and edit the rights granted to other jurisdiction-level users within their state or territory. Program Administrators have full read-write access to program-level records submitted by their NBS program. The State Administrators will be assigned to all three data module DAGs. NBS programs must notify the CDC of any change to the individuals identified as the State Administrators in writing. Any change will be effective no more than 30 days after the CDC receives the change request. Program Data Analyst Role: Users assigned to this role generally serve as data analysts for state or territorial NBS programs and require full read-write access rights to state-level records submitted by their state or territorial NBS Program. These users are assigned to all three data module DAGs. Program Data Entry Role: Users assigned to this role can add and edit records only for their assigned state or territorial DAG and data module DAG. Program Data Viewer Role: Users assigned to this role can view records only.

**Plans for Archival and Long Term Preservation:**

Data will be maintained and stored in compliance with the Recipient's security policies and procedures and consistent with applicable law and according to federal record retention standards. Where Data are identifiable or potentially identifiable or are privileged, sensitive, or confidential, such records and data shall be secured in an encrypted, password-protected cloud-based enclave that supports stringent role-based access, data access audit logging, and data encryption at rest and in-transit. Data will be maintained, stored, protected, archived and/or disposed of in accordance with applicable law. Obligations under law to maintain and secure data will survive termination of any Data Use Agreements. An archival copy of the Data may be retained to comply with relevant records retention requirements and/or for the purposes of data integrity and verification. As CDC is governed by the

Federal Records Act and the disposition of records in their custody and control may only be accomplished in accordance with schedules for destruction as provided under law.

## Spatiality

Country	State/Province	County/Region
United States		

## Dataset

Dataset Title	Dataset Description	Data Publisher /Owner	Public Access Level	Public Access Justification	Landing Page URL	Direct Download URL	Type of Data Released	Collection Start Date	Collection End Date
Dataset yet to be added...									

## Supporting Info

Current	CDC Staff Member and Role	Date Added	Description	Supporting Info Type	Supporting Info
	Gaviglio_Amy (pxd9) Project Contact	12/28/2025	Version 3 of ED3N 30 Day FRN Request	Paperwork Reduction Act Form	ED3N 30 Day FRN 2026_v3.zip
	De Leon Salazar_Alfonsina (wvg4) Division Approver Projects	12/22/2025	2026 ED3N 30-day rev by ADS	Other	2026 ED3N 2026 rev ADS.zip
	Gaviglio_Amy (pxd9) Project Contact	12/17/2025	Updated 30D FRN Request Package	Paperwork Reduction Act Form	ED3N 30 Day FRN 2026.zip
Current	Gaviglio_Amy (pxd9) Project Contact	12/11/2025	Paperwork for 30D FRN for ED3N PRA Extension	Paperwork Reduction Act Form	ED3N 30 Day FRN 2025 Extension.zip
	Zirger_Jeffrey (wtj5) ICRO Reviewer	07/11/2025	NOA 0920-1391 (2023)	Notice of Action	NOA 0920-1391_2023.pdf
	De Leon Salazar_Alfonsina (wvg4) Division Approver Projects	06/16/2025	2025 ED3N extension Documents reviewed by DLS ADS team	Other	2025 ED3N Extension_v2_clean.zip
	Gaviglio_Amy (pxd9) Project Contact	06/12/2025	documents review by ADS team	Other	2025 ED3N Extension_rev by ADS.zip
	Gaviglio_Amy (pxd9) Project Contact	06/12/2025	Supplemental 60D FRN documents with track changes	Paperwork Reduction Act Form	2025 ED3N Extension_v2_track changes.zip
	Gaviglio_Amy (pxd9) Project Contact	06/12/2025	Clean 60D FRN supplemental documents	Paperwork Reduction Act Form	2025 ED3N Extension_v2_clean.zip
	De Leon Salazar_Alfonsina (wvg4) Division Approver Projects	06/10/2025	documents review by ADS team	Other	2025 ED3N Extension_rev by ADS.zip
	Gaviglio_Amy				

Current	Gaviglio_Amy (pxd9) Project Contact	05/20/2025	60D FRN publication request package	Paperwork Reduction Act Form	60D ED3N Files to ICRO.zip
Current	Gaviglio_Amy (pxd9) Project Contact	05/20/2025	Request for 60 Day FRN Publication: Extension	Paperwork Reduction Act Form	ED3N 60 Day FRN_2026.zip
Current	Gaviglio_Amy (pxd9) Project Contact	05/20/2025	NOA 0920-1391 (2023).	Notice of Action	NOA 0920-1391_2023.pdf
Current	Gaviglio_Amy (pxd9) Project Contact	05/20/2025	Business Case with AoA	Other-Business Case with AoA	Business Case with AoA_ED3N_20200630.docx
Current	Gaviglio_Amy (pxd9) Project Contact	05/20/2025	Common Data Model (Data Elements) for electronic transfer to ED3N	Data Collection Form	11.8.2021_NBS Common Data Model for ED3N.xlsx
Current	Gaviglio_Amy (pxd9) Project Contact	05/20/2025	Business Needs Statement for ITDG	Other-Business Needs Statement	Business_Needs_Statement_ED3N_FOR ITDG_20210622.docx
Current	Gaviglio_Amy (pxd9) Project Contact	05/20/2025	Data Sharing and Use Agreement	Data Use Agreement	ED3N DSA_Draft 2021_11092021_clean.docx
Current	Gaviglio_Amy (pxd9) Project Contact	05/20/2025	30D FRN publication request and ICR	Paperwork Reduction Act Form	30D ED3N for ICRO.zip
Current	Gaviglio_Amy (pxd9) Project Contact	05/20/2025	Approved PIA	Other	20210915_ED3N PIA.pdf
	Zirger_Jeffrey (wtj5) ICRO Reviewer	05/01/2023	NOA 0920-1391 (2023).	Notice of Action	NOA 0920-1391_2023.pdf
	Davis_Stephanie I. (sgd8) PRA Reviewer	11/10/2022	30D FRN publication request and ICR	Paperwork Reduction Act Form	30D ED3N for ICRO.zip
	Gaviglio_Amy (pxd9) PRA Reviewer	11/07/2022	30D FRN Package	Paperwork Reduction Act Form	ED3N 30D FRN.zip
	Davis_Stephanie I. (sgd8) PRA Reviewer	03/08/2022	30-day ICR with OS comments for PRA clearance	Other	30 day FRN ED3N rev OS.zip

	PIA Reviewer				
	Gaviglio_Amy (pxd9) Project Contact	03/07/2022	30 day FRN package	Paperwork Reduction Act Form	30 day FRN ED3N.zip
	Davis_Stephanie I. (sgd8) CIO OMB / PRA	11/19/2021	60D FRN publication request package	Paperwork Reduction Act Form	60D ED3N Files to ICRO.zip
	Gaviglio_Amy (pxd9) Project Contact	11/19/2021	Updated ED3N 60 day FRN package	Paperwork Reduction Act Form	ED3N 60 day FRN Updated.zip
	Davis_Stephanie I. (sgd8) CIO HSC	11/16/2021	60-day PRA files with OS comments	Paperwork Reduction Act Form	ED3N 60 day FRN rev OS.zip
	Gaviglio_Amy (pxd9) Project Contact	11/09/2021	60-day FRN Package	Paperwork Reduction Act Form	ED3N 60 day FRN.zip
	Gaviglio_Amy (pxd9) Project Contact	11/09/2021	Common Data Model (Data Elements) for electronic transfer to ED3N	Data Collection Form	11.8.2021_NBS Common Data Model for ED3N.xlsx
	Gaviglio_Amy (pxd9) Project Contact	11/09/2021	Data Sharing and Use Agreement	Data Use Agreement	ED3N DSA_Draft 2021_11092021_clean.docx
	Gaviglio_Amy (pxd9) Project Contact	11/09/2021	Approved PIA	Other	20210915_ED3N PIA.pdf
	Gaviglio_Amy (pxd9) Project Contact	07/26/2021	Privacy Impact Assessment	Other-Privacy Impact Assessment	NSMBB ED3N PIA_20201025.pdf
	Gaviglio_Amy (pxd9) Project Contact	07/26/2021	Data Sharing Agreement	Data Use Agreement	ED3N DSA_Draft 2021_05_13_Clean (1).docx
	Gaviglio_Amy (pxd9) Project Contact	07/26/2021	Business Case with AoA	Other-Business Case with AoA	Business Case with AoA_ED3N_20200630.docx
	Gaviglio_Amy (pxd9) Project Contact	07/26/2021	Business Needs Statement for ITDG	Other-Business Needs Statement	Business_Needs_Statement_ED3N_FOR ITDG_20210622.docx

	Gaviglio_Amy (pxd9) Project Contact	07/26/2021	Data Use Agreement	Non Disclosure Agreement	ED3N DSA_Draft 2021_05_13_Clean.docx
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U.S. Department of Health and Human Services  
Centers for Disease Control and Prevention