CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) / NATIONAL CENTER FOR ENVIRONMENTAL HEALTH / NEWBORN SCREENING AND MOLECULAR BIOLOGY BRANCH (NSMBB) / ENHANCING DATA-DRIVEN DISEASE DETECTION IN NEWBORNS (ED3N)

DATA SHARING AND USE AGREEMENT

This data use agreement ("Agreement") is between the following parties:

The Newborn Screening and Molecular Biology Branch (NSMBB) at the National Center for Environmental Health (NCEH) at the Centers for Disease Control and Prevention (CDC) and the [NEWBORN SCREENING PROGRAM].

Data Provider ("Provider"):

[NEWBORN SCREENING PROGRAM]

Data Recipient ("Recipient"):

CDC

These parties will collectively be considered the "Parties," or individually, a "Party". This Agreement will be effective as of the latest date signed below ("Effective Date") by the Provider and Recipient.

PURPOSE AND BACKGROUND

The Newborn Screening and Molecular Biology Branch (NSMBB) at the National Center for Environmental Health (NCEH) at the CDC supports newborn screening (NBS) programs, generally found at the state level, 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 CDC and NBS 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. This Agreement establishes the basic terms and conditions concerning the contribution of data by the NBS Program or Provider to the Enhancing Data-Driven Disease Detection in Newborns (ED3N) platform.

To overcome analytic challenges and to harmonize testing and interpretative processes, CDC and contracted partners are developing ED3N as an NBS data warehouse that resides at CDC. ED3N shall serve as a secure, central, and national platform for the U.S. state and territorial, and the international NBS community, containing a data warehouse and data sharing resources for NBS data. ED3N will include three functional modules for biochemical, molecular, and clinical data and is intended to support NBS program best practices through: 1) the

enhancement of daily routine workflows at the individual observation level to enhance disease detection, 2) the creation of aggregate datasets to help test pre-validated new workflows based on national normalized trends; and 3) the education of NBS program personnel on enhanced data analytic skills and best practices, and through a resource library of peer reviewed published literature.

As part of its role under this Agreement, CDC will provide the cloud-based environment for ED3N either directly or by and through a contract with a vendor ("CDC Contractor") for participating NBS programs to facilitate transmission, receipt, storage, and management of the NBS program's data. NBS programs, and, as relevant, medical providers, that choose to participate will securely transfer minimal demographic, biochemical, molecular and/or clinical data, as further set out in the ED3N Common Data Model (see Attachment A), into ED3N for the purposes set out herein and to enable, in part, the best practice uses set out above. The ED3N Common Data Model is a dynamic document that reflects the current state of NBS at any given time and represents the totality of data elements that may be transferred to ED3N if relevant to an individual case. The Parties acknowledge that the ED3N Common Data Model may change over time. Updates to the ED3N Common Data Model will be published on the ED3N access website.

ED3N is configured to allow NBS programs and their identified staff to have access only to their own data that has been transferred to ED3N at the individual level. Data access by NBS program staff can be further restricted based on role (i.e., role-based access) at the discretion of the NBS program. Within ED3N, NBS programs may analyze and edit their own data, as needed. NBS programs will not have individual-level access to any other programs' data unless access is granted by the other NBS program. Otherwise, NBS programs will have access to de-identified aggregate-level data within ED3N from the other participating NBS programs, to enable the assessment of trends or to perform additional analyses.

The Parties agree that CDC, as the Recipient, will use the data for the general purpose(s) described herein. To that end, CDC staff will have access to all data within ED3N to build and refine the predictive algorithms, assess data integrity, create reports, and add additional functionality. Also, either directly or working with a CDC Contractor, CDC may provide maintenance of and operational support related to the transmission of, use of and access to the data transferred to ED3N to help improve the algorithms and data workflow used by the system. In these cases, CDC staff will utilize transferred data to create, train, and enhance predictive machine learning algorithms, create reports requested and/or needed by participating NBS programs, and assess performance and outcome metrics and correlations. ED3N will contain audit trail functionality.

This Agreement establishes the terms and conditions under which the Provider will provide, and the Recipient will receive and use, the data covered under this Agreement. This Agreement ensures adherence to guiding principles of accountability, privacy and confidentiality, stewardship, scientific practice, efficiency, and equity. Use and disclosure of the data must be consistent with this Agreement and with applicable law.

COVERED DATA

This section will provide information about the data being shared per this Agreement.

The Parties acknowledge that Covered Data are limited to those data specified in the *Attachment A: ED3N Common Data Model*, which identifies the current set of data items that the Recipient will receive and use under this Agreement. The Parties acknowledge that Covered Data also includes analyte data for future disorders added to the Provider's newborn screening panel not yet included in *Attachment A: ED3N Common Data Model.* As of the date of this Agreement, the Parties agree that the Covered Data are being collected for purposes categorized as public health surveillance/program evaluation/program improvement. The Parties agree to coordinate, consistent with applicable law, on potential supplementary non-newborn screening surveillance activities (e.g., assessing birth trends across the country or general issues of health equity), prior to such use. Such use must comply with applicable law and any necessary approvals (e.g., institutional review board approval).

The Parties are permitted to transmit, access, receive, share and/or use any part of the Covered Data as specified in the agreed purpose and uses, as set out in this Agreement:

1) ***Biochemical:*** Data for this module include analyte values from tandem mass spectrometry and other biochemical tests utilized for the purpose of NBS, methods and instrumentation, normalization techniques, and test cutoff values. Benefits of aggregation and/or analysis of these 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 novel interpretative algorithms to improve test accuracy and better predict risk.

2) ***Molecular:*** Data for this module includes variants identified through molecular testing, the platform used, and the interpretation of the variants assigned by NBS programs. Benefits of aggregation and/or analysis of these data may include improving variant interpretation, providing consistency around variant interpretation, correlation of biochemical and molecular data, and standardizing variant interpretation changes across programs.

3) ***Clinical:*** Data for this module includes clinical information necessary for tracking final diagnosis, disease severity, and/or health outcomes for infants screening positive for and/or afflicted by an NBS disorder. Benefits of these 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 Provider will also submit minimal relevant demographic information, included in *Attachment A: ED3N Common Data Model,* that will crosscut between all three modules and allow for the implementation of algorithms to match data from multiple specimens or sources to a single infant across all three data modules. Data for the demographic section include descriptive information about the infant and the mother that are necessary for appropriate interpretation of NBS results. Most of these data fields are populated with demographic

information already collected and utilized by the Provider. These data will help with interpretation, harmonization, and the implementation and refining of public health surveillance case definitions and outcome tracking.

The Parties acknowledge that in a public health emergency (PHE) or if an event is significantly likely to become a PHE, as provided in 42 U.S.C. §247d certain data in the custody and control of CDC may be necessary to respond to the PHE. In that event, CDC may use the Covered Data, consistent with CDC's authorities under applicable federal law. CDC agrees that any such use will be on a need-to-know basis, will be a minimum amount necessary to support a coordinated federal response, and will protect individual privacy and confidential business or financial information to the fullest extent allowed by federal law. CDC further agrees that it will notify the Provider of the need to use the Covered Data as soon as practicable prior to use of the data for this purpose and, where practicable and appropriate, will work collaboratively with the Provider throughout the response to ensure appropriate coordination and access to developed analyses and reports.

AGREEMENT ADMINISTRATION

Unless otherwise designated and agreed upon by Parties, the Recipient will act as the "data custodian" of the Covered Data once the data are transmitted by the Provider and received by the Recipient. As data custodian, the Recipient is responsible for ensuring that the Covered Data are kept secured and that access to and use of the Covered Data is consistent with this Agreement and applicable law.

Where required, the Recipient will ensure that the individuals within the Recipient's organization or deemed authorized to access the Covered Data will receive appropriate security training and be aware of the terms of this Agreement.

The Recipient designates the following individual as the primary Data Custodian point of contact:

Name and Position:	Carla Cuthbert, PhD, FACMG Chief, Newborn Screening and Molecular Biology Branch Division of Laboratory Sciences, NCEH, CDC
Address:	4770 Buford Highway, Mailstop S109-1 Atlanta, GA 30341
Phone:	(770) 488-7571
Fax:	(770) 488-4520
Email:	ccuthbert@cdc.gov

Unless otherwise designated and agreed upon by the Parties, the Provider will act as the "data administrator" of the Covered Data being transmitted. As data administrator, the Provider is responsible for the Covered Data being transmitted to the Recipient and/or granting appropriate access to designated personnel for the Recipient.

To the extent allowed by law, the Provider will ensure that the Covered Data may be transmitted to Recipient's organization consistent with the purposes set forth under this Agreement.

The Provider designates the following individual as the primary Data Administrator point of contact:

[Add DUA Contact (Data Provider)– First Name, Last Name, Position, Address, Phone, Email]

The Provider must notify Recipient in writing of changes to the Data Administrator. Changes will be effective no more than 30 days after receipt of notice.

Processes for Communication

All notices or any other communication provided for herein shall be provided in writing and transmitted by email to the above identified individuals.

Effective Date, Term of Data Use, and Termination Date

The term of this Agreement shall become effective upon the date of signature by Provider and Recipient and will continue in effect until terminated by either party with 60 days advanced written notice to the other Party. Any termination will not affect the completion of those activities that are in progress and the rights and obligations arising from these activities.

Except as otherwise expressly provided herein, this Agreement may be amended only by the mutual written consent of the signatory as the authorized representatives of each Party. Amendments to this Agreement must be requested in writing through the means above and must be signed by all Parties to be effective.

CONFIDENTIALITY, SECURITY, AND LEGAL REQUIREMENTS

The Parties will establish appropriate administrative, technical, procedural, and physical safeguards to assure the confidentiality and security of Covered Data. The safeguards shall provide a level and scope of security that is not less than the level and scope of security established by applicable law for the type of data provided under this Agreement.

Recipient agrees to the following:

> **Confidentiality:** Where Covered Data provided pursuant to this Agreement are identifiable or potentially identifiable, the Recipient agrees to maintain the confidentiality of the Covered Data to the fullest extent required by applicable law. The Recipient further agrees to not disclose such Covered Data, including but not limited to identifying information of persons who are the subject of such Covered Data, either during the term of this Agreement or longer, except as consistent with this Agreement or as may be allowed or required by applicable law.
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> CDC, as Recipient, will protect the privacy and confidentiality of the Covered Data consistent, where applicable, with the following federal laws: the Privacy Act of 1974; to the extent applicable, standards promulgated pursuant to the Health Insurance

Portability and Accountability Act of 1996 (HIPAA), and the Freedom of Information Act (FOIA). Where other more specific federal laws apply to the Covered Data, CDC, as the Recipient, will comply with those laws as well. CDC will seek to assert relevant exemptions to disclosure available under federal law, most critically, where applicable, for personal and/or private information, the disclosure of which would constitute an invasion of privacy; trade secret and commercial or financial information that is private and confidential; or information exempted from release by federal statute.

Except as may be provided for in this Agreement, the Recipient shall not use the information from Covered Data to identify or establish contact with the named person or his/her family without prior written approval from the Provider.

Where required by law and/or where practicable, the Recipient agrees to notify the Provider before releasing Covered Data to a third party pursuant to a judicial, governmental, or other request under law, to allow the Provider the opportunity to state any objection to the disclosure of the Covered Data.

Security: The Recipient will use all reasonable administrative, technical, and physical measures to safeguard Covered Data once transmitted and received, and to protect Covered Data from unauthorized access, disclosure, use, or modification. This includes setting permissions to access or edit data commensurate with the level of sensitivity of the data. Should there be a data breach and unauthorized disclosure of Covered Data, the Recipient shall promptly notify appropriate response teams and the Provider of the incident, consistent with applicable legal requirements.

More specifically, ED3N is hosted by a Federal Risk and Authorization Management Program (FedRAMP) approved provider. FedRAMP is a government-wide program that provides a standardized approach to security assessment, authorization, and continuous monitoring for cloud products and services. ED3N meets CDC certification and accreditation standards to assure that it is Federal Information Security Modernization Act (FISMA) compliant and is supported by the timely maintenance of security updates, anti-virus updates, malware updates, and hardware/application vulnerability reviews and remediation. Servers are housed in access-controlled, physically secured locations. These locations prevent the unauthorized physical and logical access of servers and network devices, ensuring that only those authorized to maintain the servers are allowed access to them.

Transfer: The Provider shall transfer Covered Data to the Recipient via manual data entry or file upload using the ED3N web portal user interface, or via direct automated file and data transfer. Where Covered Data provided pursuant to this Agreement are identifiable or potentially identifiable or are privileged, sensitive, or confidential, transmission of the Covered Data from the Provider to Recipient shall be done in accordance with acceptable practices for ensuring the protection, confidentiality, and integrity of the contents. The Parties may coordinate to implement methods to achieve these outcomes consistent with procedures already in place for similar data exchanges. If encrypted identifiable information is transferred electronically through means such as the Internet, then said transmissions will be consistent with the rules and standards

promulgated by applicable legal requirements regarding the electronic transmission of identifiable information.

Storage: Covered Data will be maintained and stored in compliance with the Recipient's security policies and procedures and consistent with applicable law. Where Covered 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. In general, data access will be restricted to project personnel for purposes as set forth in this Agreement.

Access: Where Covered Data provided pursuant to this Agreement are identifiable or potentially identifiable or are privileged, sensitive, or confidential, the Recipient and its authorized users shall access Covered Data on secured devices only.

Except as may be required by applicable law or as otherwise provided in this Agreement, only the Provider and Recipient will have access to the Provider's Covered Data at the individual, potentially identifiable level. Access to all Covered Data by the Provider and Recipient will be managed by CDC's Secure Access Management System (SAMS), which performs credential and identity authentication and grants authorization to access the ED3N application. SAMS and the CDC ED3N Data Administrator shall collaborate to manage all data access, remove users that no longer require access, and track all attempts to access ED3N in collaboration with the CDC Cloud Task Force. The CDC Cloud Task Force, which resides in CDC's Office of the Chief Information Officer (OCIO), in part provides assistance to programs with migrating information technology (IT) applications and systems to cloud environments to promote increased scalability, flexibility, collaboration, and access to the latest tools and technologies. ED3N defines user roles with specific data access rights and functionality and has the ability to limit user data access using these roles.

The Recipient may provide Covered Data access to appropriate employees, contractors, and other authorized users. The Recipient agrees to establish appropriate administrative, technical, and physical safeguards to prevent unauthorized access to the Covered Data.

Data Maintenance, Deletion or Storage Requirements after Termination

Unless explicitly stated otherwise in the Agreement, ownership of Covered Data shall remain with the Provider. However, the Parties agree that the Covered Data provided under this Agreement and in the custody and control of the Recipient is subject to the laws applicable to the Recipient.

Accordingly, the Recipient agrees to maintain, store, protect, archive and/or dispose of Covered Data in accordance with applicable law. Obligations under law to maintain and secure Covered Data will survive termination of this Agreement. At a minimum, the Provider agrees that an archival copy of the Covered Data may be retained by Recipient to comply with relevant records retention requirements and/or for the purposes of data integrity and verification.

Where CDC is the Recipient, as a federal agency, 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.

APPLICABLE LEGAL AUTHORITIES

Applicable federal and/or state laws that govern the collection, use, disclosure, and maintenance of the Covered Data may be cited as standard authorities related to the Covered Data, which includes project-specific authorities and regulations. Parties acknowledge that CDC, as a federal agency, is not subject to the application of state or local laws or regulations or the internal policies and/or procedures of the other party, except where consistent with federal law.

This Agreement is governed by applicable federal law.

Applicability of HIPAA

As applicable to the Covered Data and the Provider, CDC, as Recipient, is a "public health authority" as defined at 45 C.F.R. §164.501 and as used in 45 C.F.R. §164.512(b), Standards for Privacy of Individually Identifiable Health Information, promulgated under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). CDC as a public health authority, is authorized by 45 CFR 164.512(b) to receive Protected Health Information ("PHI").

REPORTING OF DATA USED IN PUBLICATIONS AND PRESENTATIONS

Notification

Where the Recipient is reporting the data, the Recipient agrees to allow the Provider thirty (30) days to review and provide comments for consideration on papers, reports, publications, or presentations that the Recipient plans to submit for publication or presentation that directly compares Provider data to other NBS programs, names the Provider explicitly, or uses the Provider data exclusively. If publication needs to occur sooner than 30 days to comply with federal requirements, the Recipient agrees to notify the Provider, who will expedite review consistent with the need to publish. However, notification shall not act to prevent the publication of information if there is an emergency need to publish or disseminate meaningful, real-time information for a public health response. Appropriate privacy protections will be considered prior to any such emergency need to publish.

Attribution

The Recipient agrees to factually acknowledge the Provider in any paper, publication or presentation using the Covered Data.

Representation

Where the Recipient is reporting the data, Recipient agrees to assume full responsibility for the analysis, interpretation of the data, and provide a copy of the report, publication, or presentation to the Provider.

Use

Per mutual agreement between the Provider and Recipient, the Provider grants full permission and a royalty-free, non-exclusive, irrevocable license to HHS, CDC to use, reproduce, publish, distribute, and exhibit materials arising from this Agreement for use in education, training, and other purposes consistent with CDC's mission.

Disclaimer

Covered Data provided under this Agreement are provided on an 'as is' basis. Except as expressly set forth herein, the Provider makes no representations, of any kind, either express or implied, with respect to the provided data. The Provider expressly disclaims any and all representations of any kind with respect thereto, including any representations of data quality or fitness for a particular purpose. Intellectual property rights on material arising from the use of the data will be determined by applicable federal law. In addition, interpretations, conclusions, and/or opinions that are reached as a result of analyses of the data are the Recipient's interpretations, conclusions, and/or opinions, and do not constitute the findings, policies, or recommendations of the Provider.

ADDITIONAL TERMS AND CONDITIONS

- Entire Agreement: This Agreement, including any addenda related to data, specifications, or operations incorporating this Agreement by reference, and as amended from time to time, constitutes the entire agreement and understanding between the Parties and supersedes all prior oral or written agreements and understandings between them with respect to such activities.

- Assignment: No Party may assign or transfer any or all of its rights and/or obligations under this Agreement or any part of it, nor any benefit or interest in or under it, to any third party without the prior written consent of all Parties, which shall not be unreasonably withheld.

- Mutual Representations: Each party to this Agreement represents to the other Party that, at all times during the term and at such other times as may be indicated, it shall comply with, and as applicable, shall require its directors, officers and employees to comply with its duties and obligations pursuant to applicable law and this Agreement, including but not limited to duties and obligations which survive the termination of this Agreement.

- Use of Electronic Signatures and Electronic Records: The Parties may elect to establish processes for the use of Electronic Records in the management of and compliance with this Agreement. This may include for the addition of published policies, procedural information, notices, and any other documents arising from or pertaining to this Agreement, including this Agreement itself. Any such process must include the

establishment of a mutually acceptable Electronic Signature process, which complies with applicable federal and state laws.

- Disagreements: Disagreements between the Parties arising under or relating to this Agreement will be resolved by consultation between the Parties and referral of the dispute to appropriate management officials of the Parties whenever possible.

- Public Document: This Agreement may be made publicly available.

- Funding: This Agreement is not an obligation or a commitment of funds, or a basis for the transfer of funds, and does not create an obligation or commitment to transfer data, but rather is a statement of understanding between the parties concerning the sharing and use of covered data. Expenditures by each party are subject to its budgetary processes and to the availability of funds and resources pursuant to applicable laws, regulations, and policies."

- Partner Specific Requirements: [Basic DUA Information – Partner Specific Requirement]

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SIGNATORIES

The undersigned individuals represent that they have competent authority on behalf of their respective agencies to enter into the obligations set out in this Agreement. Signature indicates that an understanding of the terms of this Agreement and an agreement to comply with its terms, to the extent allowed by law.

PROVIDER	RECIPIENT
Signature: (Blank) Printed Name: [Step 3: Add DUA Contact (Provider)- First Name Last Name] Title: [Step 3: Add DUA Contact (Provider) – Signature Title] Organization: [Step 2: Add Agreement Party (Provider)– Agreement Party)] Date:(Blank)	Signature:(Blank) Printed Name: Carla Cuthbert, PhD, FACMG Title: Chief Organization: NSMBB, NCEH, CDC Date: (Blank)

APPENDIX A: DATA USE AGREEMENT DEFINITIONS

- Terms used, but not otherwise defined, in this agreement shall have the same meaning as those terms in applicable laws and regulations, unless specifically stated otherwise.
- “Agreement” means this data use agreement, as amended from time to time in accordance with the terms and conditions set forth below.
- “Effective date” is the date this agreement becomes valid, either on the date specified or the last date of signature.
- “Data Provider” or “Provider” refers to the party providing the data outlined in this Agreement.
- “Data Recipient” or “Recipient” refers to the party receiving the data outlined in this Agreement.
- “Data administrator” is the data provider or recipient’s individual(s) responsible for the data and granting appropriate access to agreement parties.
- “Data custodian” is the organization from a recipient agreement party responsible for the maintenance and protection of the data for their party.
- “Covered Data” shall mean the data provided to the Recipient by the Provider and any associated records, reports, copies, or databases.
- "Applicable law" means all laws, statutes and regulations promulgated by all regulatory authorities and all governmental authorities.
- “Required by law” means as applicable federal laws require.
- “Protected health information (PHI)” is information considered to be individually identifiable information relating to the past, present, or future health status of an individual that is created, collected, or transmitted, or maintained by a HIPAA-covered entity in relation to the provision of healthcare, payment for healthcare services, or use in healthcare operations.
- “Personally identifiable information (PII)” is any information about an individual maintained by an agency, including (1) any information that can be used to distinguish or trace an individual‘s identity, such as name, social security number, date and place of birth, mother‘s maiden name, or biometric records; and (2) any other information that is linked or linkable to an individual, such as medical, educational, financial, and employment information.
- “Agreement party” / “parties” or “signatory” refers to the representative for both the data provider and data recipient with the authority to sign this agreement into place.

LIST OF SUPPORTING DOCUMENTS

1. ED3N Common Data Model (Attachment A)