Memorandum of Understanding
Regarding the NewSTEPs Data Repository

This Memorandum of Understanding (the "Memorandum") is entered into as of [+++Use the dropdown calendar to select the desired date+++] by and between the Association of Public Health Laboratories, Inc. ("APHL"), a nonprofit corporation organized under the laws of the District of Columbia, and [***Type in the full name of the state's NBS program ***] (the "NBS Program"), [+++Select the state's characterization or classification of their NBS program from the dropdown list+++] of the [+++Select state from drowdown menu+++] (the "Jurisdiction"). APHL and the NBS Program are collectively referred to in this Memorandum as the "Parties" and individually referred to as a "Party".

A. Background and Purpose.

APHL works to safeguard the public's health by strengthening public health laboratories in the United States and across the world. In collaboration with members, APHL advances laboratory systems and practices, and promotes policies that support healthy communities.

The NBS Program is responsible for the analysis, interpretation, and follow-up of the newborn screening ("NBS") bloodspot samples and point of care tests collected within the State as part of the State's NBS and for the transmittal of the results as required under law.

Under Grant Number U22MC24078 (CFDA# 93.110) (the "Cooperative Agreement") from the Health Resources and Services Administration ("HRSA") of the U.S. Department of Health and Human Services ("HHS"), APHL administers the Newborn Screening Technical assistance and Evaluation Program ("NewSTEPs"). This program seeks to provide leadership on the implementation of public health newborn screening and other genetics programs (as appropriate) through technical assistance, resource development, education and training, policy initiatives, disorder surveillance, evidence-based data collection, evaluation, and collaborative efforts with partners, including federal and non-federal partners. A key feature of the program is the NewSTEPs data repository (the "Data Repository") which is a centralized and secure database that is designed to allow NBS Programs to explore data to meet local program needs.

The data being collected through the Data Repository have been deemed Non-Human Subject Research by the HHS' Office of Human Research Protection ("OHRP").

The NBS Program will share the selected NBS data with APHL through the Data Repository, and APHL will provide the NBS Program with related services, as set out more fully in this Memorandum.

Accordingly, the Parties enter into this Memorandum to work together to:

- Establish the framework in which the NBS Program will share elements of its NBS data with the Data Repository; and
- Identify each Party's roles and responsibilities with respect to the Data Repository.

B. NBS Data Collection.

The NBS Program will submit or update, and APHL will collect, the following information and data as part of the Data Repository:

- Profile information, including disorders screened, policies, newborn screening fees, program structure, , contact information, advisory committee, IT support, and HIT elements.
- De-identified baby-level data for individual cases identified on Exhibit A attached to this Memorandum, for the core Recommended Uniform Screening Panel (RUSP) NBS disorders;
- Quality indicators identified on Exhibit B attached to this Memorandum

The data reported by each state will not contain sufficient information to render the individual baby-level data identifiable by APHL or its contractors. Further, no identifiers will be released from the NBS Program (or from any other newborn screening program in the country) to APHL at any time in the future.

The NBS Program will have the option to stop entering data into the Data Repository at any time and may request retroactive withdrawal of any NBS Program data previously entered into the Data Repository by submitting a written notice to APHL requesting this retroactive withdrawal. APHL will use its best efforts to retroactively withdrawal the NBS Program's data from the Data Repository within 30 days of its receipt of the written request (for clarification, APHL will be unable to withdrawal the NBS Program data included in any publication that was issued prior to the date APHL received the withdrawal request nor will APHL be able to remove any NBS Program data from information shared with HRSA prior to its receipt of the withdrawal request).

C. Access to Data.

The NBS Program will identify at least one individual to serve in the program administrator (the "Program Administrator") role (*i.e.*, the individual who will manage all users for the NBS Program and the Jurisdiction) for the NBS Program. This individual will have the

ability to create program-level user profiles and to view and edit the rights granted to the program-level users. The NBS Program must notify APHL of any change to the individual identified as the Program Administrator in writing. Any change will be effective no more than 30 days after APHL's receipt of a change request.

The program-level users identified by the NBS Program, whose profiles will be administered by the Program Administrator, will have the capacity to enter, edit and read their own data, including case data and quality indicators, as well as having the ability to edit the NBS Program profile information. These users will not have access to data from other NBS programs. Instead, the users and Program Administrator will only be able to see aggregate, blinded data from other participating NBS programs.

APHL's NewSTEPs program staff will be able to access all data, including data from the NBS Program, to develop aggregate state, regional and national reports. All data reports will be produced to be used for quality improvement efforts within NBS Programs. The data will not be reported to APHL in a manner that would allow identification of an individual infant.

Public access will be limited to the NBS Program and other participating NBS program profiles, on the NewSTEPs website (currently available at https://www.newsteps.org/data-center/state-profiles). Third parties may request more detailed access to the information in the Data Repository through an online data request form and such requests will be evaluated by APHL's NewSTEPs program staff and the NewSTEPs Steering Committee, which are and will be comprised of members of the NBS community, as discussed below in Section F (Data Sharing).

A summary of the various user roles within the Data Repository is available on Exhibit C.

D. Data Security and Privacy.

APHL solicits bids from third parties to serve as the information technology vendor to the Data Repository. APHL and the selected vendor have a formal contract in place which includes provisions regarding data security and data privacy. Under this contract, the selected vendor will host the Data Repository application on a server that has a secure physical location and will have limited physical and remote access. The Data Repository web interface will be made available through web browsers via 128-bit secure socket layer (SSL) encryption to ensure data security.

For case reporting, the Data Repository web application will require case manager users to input dates of birth and dates that screening services were performed under the NBS Program. APHL, through the selected vendor, will ensure that this information will be collected only in the browser for the purpose of calculating differences in dates (*e.g.,* the number of days elapsed between birth and screening). Only the birth year will be stored in the Data Repository

database; the day and month of birth and the dates of NBS screening services will not be stored in the Data Repository. A more detailed description of the technical details of these calculations is provided in Exhibit D.

Actual date differences and de-identified information from the NBS Program will be shared with APHL's NewSTEPs program staff. No parties involved in NewSTEPs – whether APHL staff or the selected vendor (or any replacement third party) staff – will have access to records that would allow re-identification of newborns.

APHL will have the right to conduct one or more competitive bid solicitations in order to procure future hosting services for the Data Repository or to maintain or enhance the repository's data security and data privacy protections. Any competitive bidding process held by APHL would be an open competition, where any qualified third party would be able to submit a bid for full consideration. APHL might use this process prior to the expiration of APHL's contract with the current vendor, in connection with a renewal of the Cooperative Agreement or as needed to comply with applicable legal and regulatory requirements. APHL will publicly announce any bid solicitation and will post details of the bidding process on its procurement website (www.aphl.org\rfp). APHL will also announce the names of the winning bidder(s) on that site.

E. Services to NBS Program.

As discussed in Section C of this Memorandum, the NBS Program will have access to its own data in the Data Repository and will also have access to aggregate data from other participating NBS programs. APHL will ensure that the Data Repository is set up in such a way as to allow the NBS Program to generate standardized reports and dashboards on information entered into the Data Repository while maintaining the confidentiality of all NBS programs entering data into the system.

APHL will provide the NBS Program with free interactive dashboards which the NBS Program will be able to customize by reasonable request to APHL. These online dashboards will include graphics and charts for quality improvement purposes and will be prepared with data summaries at the jurisdictional, regional, and national levels.

APHL will also provide no-cost technical assistance through NewSTEPs to the NBS Program upon reasonable request. The Parties will establish the details and parameters of any technical assistance prior to the start of any work.

F. Data Sharing.

Any data sharing request from a third party of information that is not publically available will be channeled through APHL's governance structure. APHL anticipates that each data sharing request from a third party will be directed to the NewSTEPs Steering Committee formed with state representation specifically to look at all such data sharing requests. APHL will use best efforts to ensure that all requests will follow the same process and will be subject to detailed review. APHL will also ensure that approval from any Newborn Screening Program whose data would be released as part of a data sharing request is obtained prior to any release of such data.

G. Data Ownership.

APHL will own the data entered into the Data Repository. Under the terms of the Cooperative Agreement, APHL must grant a nonexclusive, royalty-free, irrevocable license to HRSA for use of the data in the Date Repository for federal purposes. In the event the Cooperative Agreement is not renewed, HRSA will have the explicit right to request that APHL turn over the Data Repository and its ownership interests in the Data Repository to HRSA or its designee.

H. Term of Memorandum.

This Memorandum will become effective upon the date of signature by the NBS Program 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.

I. Modification.

This Memorandum may only be modified or amended by written agreement by the authorized signatories of both Parties.

J. Assignment.

Neither Party shall, without the prior written consent of the other Party, assignor transfer, totally or partially, its rights and obligations under this Memorandum.

K. Nature.

Nothing in this Memorandum shall be construed as creating a partnership or agency between the Parties.

L. Notices.

Any notice required or permitted by this Memorandum must be given by an express/overnight delivery service to the other Party at the address designated below, or to such other address as may be designated in writing by such other Party.

APHL	**NBS Program**
Jelili Ojodu Senior Director, Newborn Screening and Genetics APHL 7700 Wisconsin Avenue, Suite 1000 Bethesda, MD 20814 T: 240.485.2772 F: 240.485.2700 E: jelili.ojodu@aphl.org *With a copy to:* General Counsel, and Managing Director, Legal & Compliance APHL 7700 Wisconsin Avenue, Suite 1000 Bethesda, MD 20814 T: 240.485.2745 F: 240.485.2700 E: legal@aphl.org	[**Please provide name and title of contact for notices**] [**Please provide overnight/express mail delivery address**] T: [**Please provide contact's phone no.**] F: [**Please provide a fax number**] E: [**Please provide contact's email**]

Notices may be delivered electronically or a physical hard copy. Notices will be considered timely if such notices are received on or before the established deadline date as verifiable by a dated receipt from a commercial carrier or via a confirm or via dated electronic communication. Parties should request and obtain a dated receipt from a commercial carrier. Private metered postmarks will not be acceptable as proof of timely mailing.

(Signatures on the following page)

It is with this Memorandum of Understanding that APHL and the NBS Program establish themselves as collaborative partners who will undertake efforts to solidify linkages between their organizations.

THE ASSOCIATION OF PUBLIC HEALTH LABORATORIES, INC.

By: _____ Date: _____
Name:
Title:

[*TYPE IN THE FULL LEGAL NAME OF THE STATE ENTITY SIGNING THE MOU***]**

By: _____ Date: _____
Name:
Title:

EXHIBIT A

Baby-Level Data for Individual Cases

The Data Repository will collect the following baby-level data to help assess prevalence:

- Biologic sex
- Gestational age as reported with newborn screening essential information
- Race as reported with NBS essential information (may be reported as mother's race in some states)- *users will be allowed to select more than one response*
- Ethnicity as reported with NBS essential information (may be reported as mother's ethnicity in some states)
- Screening information including the NBS result that indicated risk, prenatal testing, family history, etc.
- Ages at the following, using Date of Birth to calculate age, but not storing Date of Birth or any other dates of service:
    - Date first NBS was performed, date of first specimen receipt by lab, date of release for first specimen out-of-range results.
    - Date of subsequent NBS dried blood spot specimen was collected (mandatory second screen or second screen requested due to out of range first screen or unsatisfactory first screen), date of subsequent specimen receipt by lab, date of release for subsequent specimen out-of-range results.
    - Date of intervention by appropriate medical professional. *See Definition for Medical Intervention and Diagnosis*. .
    - Date of Confirmation of diagnosis. Indicates date newborn was determined to have the disorder indicated. *See Definition for Medical Intervention and Diagnosis*.
- Treatment and care out-of-state
- Diagnosis reversed
- Final diagnosis workup as determined by metabolic geneticist or clinician performing the follow-up

The Data Repository will collect additional baby-level data specific to each disorder relative to the confirmation of the disorder. This collected data will allow comparisons of the prevalence as detected by NBS.

EXHIBIT B

Quality Indicators

The Data Repository will collect quality indicator data in aggregate as currently listed on the following website: https://www.newsteps.org/data-resources/quality-indicators

EXHIBIT C

User Roles within the Data Repository

NewSTEPs User Role	User Role Descriptions
User	Users can manage their own account including, password, photo, and email address. All users have access to the resource library and can view NBS Program Profiles reports/dashboards.
Profile Data Manager	Ability to view and edit own state/territorial NBS Program Profile.
Data Viewer	Data viewers can only view their state/territory data provided to NewSTEPs for: • NBS Program Profiles • Individual and aggregate case data • Annual and monthly Quality Indicator (QI) data and reports Data viewers are not able to enter or edit data.
Case Data Manager	Enter, edit, delete, and view their program's individual and aggregate cases data using the webform or CSV import file.
QI Data Manager	Enter, edit, delete, and view any Quality Indicator data, including annual and monthly data, for their assigned state/territory via the webform or CSV import file. Can view QI reports.
Program Administrator	The Program Administrator has access to all data for their state/territory. Further, they can manage users within their state/territory, including adding or editing users, changing user access, and exporting users for their program. The Program Administrator can view, add, edit, and delete their program's data.

EXHIBIT D

Technical Specifications of Data Security Related to Date of Birth

APHL works closely with the selected vendor (identified by APHL through a public and competitive bid solicitation) in order to ensure that data is secure. The Data Repository application is run on a server that is hosted in a secure physical location with strictly limited physical and remote access. The web application itself is available through web browsers via 128-bit secure socket layer (SSL) encryption. Information in the web app has limited access – profiles are available to the public, while more detailed data is limited by role-based access control (see Exhibit C). For case reporting, the Data Repository web application does require users to input birth date and dates of service, which are collected only in the browser for the purpose of calculating differences in dates (i.e., days elapsed between birth and screening) – aside from birth year, no date is stored in the system. Actual date differences, and de-identified information, will be shared with the APHL staff working on the NewSTEPs program. No parties involved in the project (neither APHL staff nor the selected vendor staff) have access to records that would allow re-identification of newborns.

Specifically, for confirmed cases, case managers (see Exhibit C) will be asked to enter specific dates in the Data Repository web interface in order to calculate the time elapsed between significant events in the newborn screening process. The Data Repository will perform the calculations on behalf of the states in order to ensure consistency across all of the cases entered for all of the states.

The elapsed time calculations will be performed on the users' side using Javascript running in the user's web browser as the dates are entered into the form. The data model and corresponding database schema used by the Data Repository are configured to track only the calculated elapsed times and **not** the specific dates. When a case manager submits the form after entering all of the case information, the calculated values are transmitted to the Data Repository server for storage in the appropriate location within the data model. The dates, however, are not transmitted, nor are they saved, because there is not a dedicated place for them in the data model.

When a Case Manager accesses a previously entered case for editing, it is clear that the previously entered dates have not been saved, because all of the date fields on the form do not have a value. On the other hand, the previously calculated elapsed times are still shown. If a user needs to update any of the elapsed times, he or she must have it be recalculated by reentering the corresponding dates.