



**Form of
Memorandum of Understanding
Regarding the NewSTEPs Data Repository
Between
The Association of Public Health Laboratories, Inc. and
[State NBS Program]**

This Memorandum of Understanding (the “Memorandum”) is entered into as of December ___, 2013 by and between the Association of Public Health Laboratories, Inc. (“APHL”), a nonprofit corporation organized under the laws of the District of Columbia, and [State NBS Program] (the “State NBS Program”), [an administrative unit]/[a governmental agency]/[an executive agency] of the State of [_____] (the “State”). APHL and the State 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 State 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 state-based public health newborn screening and other genetics programs (as appropriate) through technical assistance, resource development, state education and training, policy initiatives, disorder surveillance, evidence-based data collection, evaluation, and collaborative efforts with stakeholders, 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 state NBS programs to explore data to meet local program needs.

Both the Colorado Institutional Review Board (“COMIRB”) and HHS’ Office of Human Research Protection (“OHRP”) have deemed that the data being collected through the Data Repository is Non-Human Subject Research. A link to the letter from the COMIRB chair outlining its decision can be found in Exhibit A.

The State NBS Program will to share the selected NBS data with APHL through the Data Repository program, and APHL will provide the State 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 State 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 State NBS Program will submit or update, and APHL will collect, the following information and data as part of the Data Repository:

- State profile information, including disorders screened, newborn screening fees, annual births, program contact information, and dried blood spot storage conditions and retention time;
- De-identified baby-level data for individual cases identified on Exhibit B attached to this Memorandum including NBS Surveillance Case Definitions, as defined by the medical community, for most of the core Recommended Uniform Screening Panel (RUSP) NBS disorders;
- Select quality indicators identified on Exhibit C attached to this Memorandum; and
- Overall Programmatic Information (such as policies, health information technology, advisory committee practices).

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 states to APHL at any time in the future.

The State NBS Program will have the option to stop entering data into the Data Repository at any time, and may request retroactive withdrawal of any State 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 withdraw the State data from the Data Repository within 30 days of its receipt of the written request (for clarification, APHL will be unable to withdrawal State 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 State data from information shared with HRSA prior to its receipt of the withdrawal request).

C. Access to Data.

The State NBS Program will identify one individual to serve in the state administrator (the “State Administrator”) role (*i.e.*, the individual who will manage all users for the State) for the State. This individual will have the ability to create State-level user profiles and to view and edit the rights granted to the State-level users. The State NBS Program must notify APHL of any change to the individual identified as the State Administrator in writing. Any change will be effective no more than 30 days after APHL’s receipt of a change request.

The State-level users identified by the State NBS Program, whose profiles will be administered by the State Administrator, will have the capacity to enter, edit and read the State’s own data, including baby-level data, quality indicators and case definitions, as well as having the ability to edit the State NBS Program profile information. These State-level users will not have access to data from other states. Instead, the State-level users and State 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 state level data, including data from the State NBS Program, to develop aggregate state, regional and national reports. All data reports will be produced to be used for quality improvement efforts within State 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 state profiles, including the State’s profile, on the Data Repository website. Third parties may request more detailed access to the information in the Data Repository through an online application and such requests will be evaluated by APHL’s NewSTEPS program staff and the NewSTEPS Steering Committee, which is and will be comprised of members of the NBS community, as discussed below in Section F (Data Sharing). If an application is approved, the third party requesting access will be required to establish a registered profile and will then have the ability to see de-identified aggregate data and data queries that maintain the confidentiality of the state programs.

APHL has provided a graph showing the various user roles within the Data Repository on Exhibit D.

D. Data Security and Privacy.

APHL solicited bids from third parties to serve as the information technology vendor to the NewSTEPS Data Repository and selected 5AM Solutions, Inc. (“5AM Solutions”) to serve in this capacity. APHL and 5AM Solutions have a formal contract in place which includes provisions regarding data security and data privacy. Under this contract, 5AM Solutions 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 State-level users to input dates of birth and dates that screening services were performed under the State NBS Program. APHL, through 5AM Solutions, 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 system; 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 E.

Actual date differences and de-identified information from the State NBS Program will be shared with APHL's NewSTEPS program staff and faculty identified in APHL's contract with the University of Colorado Denver ("UCD"), with whom APHL has contracted to work on NewSTEPS and the Data Repository. No parties involved in NewSTEPS – whether APHL staff, UCD faculty or 5AM Solutions staff – will have access to records that would allow re-identification of newborns.

E. Services to State NBS Program.

As discussed in Section C of this Memorandum, the State 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 so as to allow the State NBS Program to generate standardized reports and run queries on all information entered into the Data Repository at the time each query is run while maintaining the confidentiality of all states entering data into the system.

APHL will provide the State NBS Program with a free annual report, which the State NBS Program will be able to customize by reasonable request to APHL. This annual report will include graphics and charts for quality improvement purposes and will be prepared with data summaries at the State, regional, and national levels.

APHL will also provide no-cost technical assistance through NewSTEPS to the State 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.

APHL will share the data identified on Exhibit F from each state with the Newborn Screening Clearinghouse, the Newborn Screening Translational Research Network and the National Coordinating Center for the Regional Genetic Service Collaborative, each a federally funded NBS program, and the Centers for Disease Control and Prevention's National Center for Environmental Health. In no event will APHL share state-level quality indicator data or case data with other partners.

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 an APHL subcommittee 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 state 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 Data 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 State 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. Due Authorization.

Each Party represents and warrants to the other Party that individual(s) signing this Memorandum on its behalf has due authority to do so. The State NBS Program also represents

and warrants that it has statutory or regulatory authority from the State to enter into this Memorandum and to enter the State’s data into the Data Repository.

M. 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	State NBS Program
<p>Sikha Singh Manager, NewSTEPS APHL 8515 Georgia Avenue, Suite 700 Silver Spring, MD 20910 T: 240.485.2726 F: 240.485.2700 E: sikha.singh@aphl.org</p> <p><i>With a copy to:</i></p> <p>Troy Willitt In-House Counsel APHL 8515 Georgia Avenue, Suite 700 Silver Spring, MD 20910 T: 240.485.2716 F: 240.485.2700 E: troy.willitt@aphl.org</p>	<p>[To be provided]</p>

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 state 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:

[STATE NBS PROGRAM]

By: _____ Date: _____

Name:

Title:

TEMPLATE

EXHIBIT A

Colorado Multiple Institutional Review Board

Letter of Approval and Application for Review

An electronic copy of the Application for Review is currently available at:

<https://newsteps.org/sites/default/files/IRB%20Application.pdf>

An electronic copy of the COMIRB Letter of Approval is currently available at:

<https://newsteps.org/sites/default/files/Not%20Human%20Research.pdf>

TEMPLATE

EXHIBIT B

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)- *State-level 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)
- Ages at the following, using Date of Birth to calculate age, but not storing Date of Birth or any other dates of service:
 - Date initial NBS was performed, date of initial specimen receipt by lab, date of release for initial 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. Intervention by a medical professional may include changes in care per phone conversation. This does not include additional newborn screen NBS specimen collection.
 - Date of Confirmation of diagnosis. Indicates date newborn was determined to have the disorder indicated.

The Data Repository will collect additional baby-level data specific to each disorder. This additional data will be requested for public health surveillance of each condition in order to categorize the certainty of each disorder across NBS programs. This collected data will allow comparisons of the prevalence as detected by NBS using consistent definitions developed for use in public health surveillance.

EXHIBIT C

Quality Indicators

The Data Repository will collect the following quality indicator data:

- QI 1 Percent of invalid dried blood spot specimens/cards due to improper collection and/or transport.
- QI 2 Percent of dried blood spot specimens/cards missing essential information.
- QI 3 Percent of eligible infants not receiving valid newborn screening test, reported by dried blood spot or point of care test(s).
- QI 4 Percent of loss to follow-up.
- QI 5 Time elapsed from birth to screening, follow-up testing, confirmed diagnosis.
- QI 6 Percent of out of range results.
- QI 7 Frequency of condition detected by newborn screening for each disorder.
- QI 8 Percent of missed cases (false negatives), reported by disorder.

A list of the Quality Indicators data elements that will be collected in the Data Repository is currently available at:

<https://newsteps.org/sites/default/files/QI%20Worksheet%20September%202013.pdf>.

EXHIBIT D

User Roles within the Data Repository

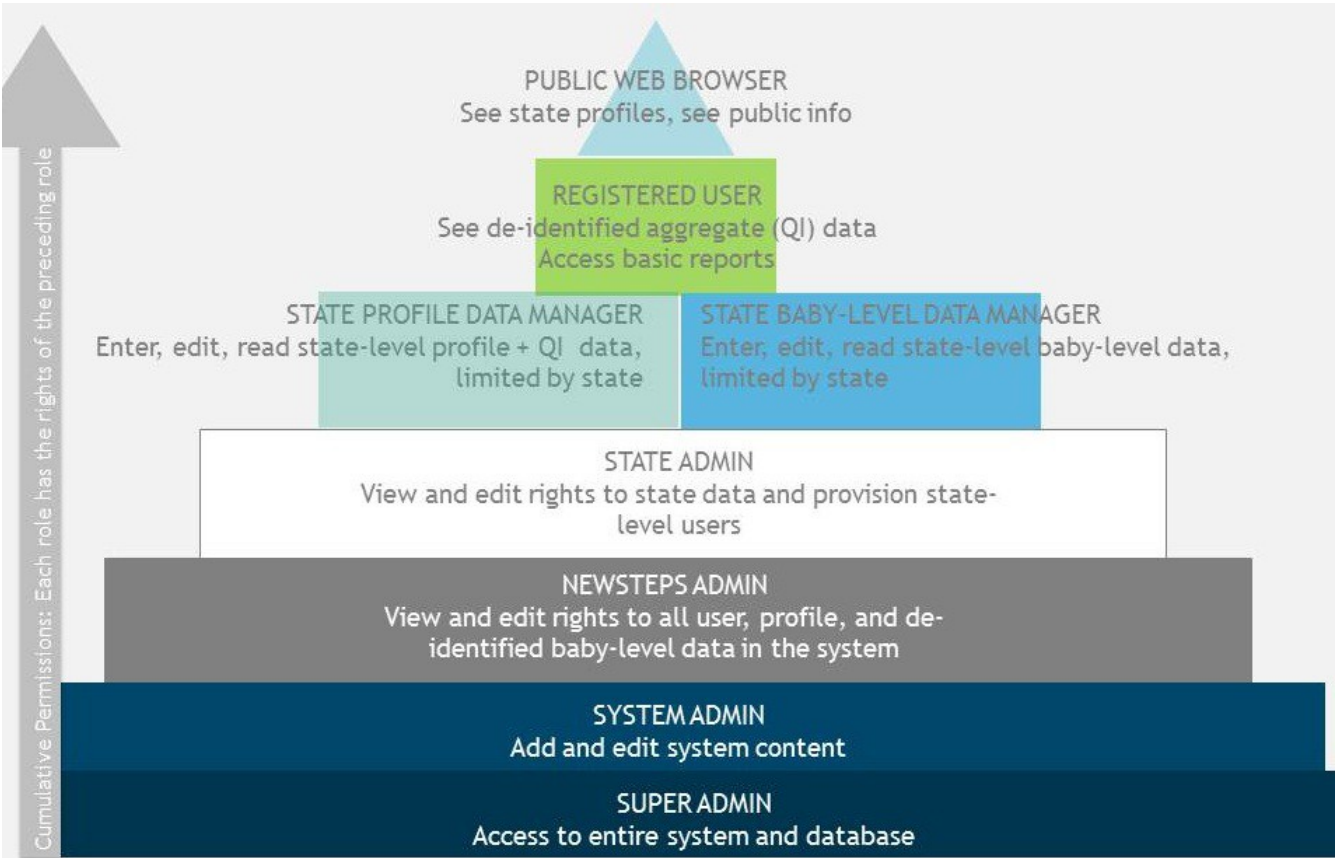


EXHIBIT E

Technical Specifications of Data Security Related to Date of Birth

APHL works closely with 5AM Solutions 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 – state profiles are available to the public, while more detailed data is limited by role-based access control (see section above). For case reporting, the Data Repository web application does require users to input dates of birth 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 and UCD faculty working on the NewSTEPs program. APHL anticipates that will have a supplemental coded information agreement with 5AM Solutions which will be incorporated as part of its contract for services. No parties involved in the project (UCD faculty, APHL staff, nor 5AM Solutions staff) have access to records that would allow re-identification of newborns.

Specifically, for positive cases, State-level users 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 State-level 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 State-level user 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 State-level user 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 State-level user needs to update any of the elapsed times, he or she must have it be recalculated by reentering the corresponding dates.

EXHIBIT F

Data to be shared with other federally funded partners in NBS

The following data will be shared with the Newborn Screening Clearinghouse, the Newborn Screening Translational Research Network, the National Coordinating Center for the Regional Genetic Service Collaboratives and the Centers for Disease Control and Prevention's National Center for Environmental Health:

- State Demographic Data
 - Number of births, by Race, Ethnicity, Sex
 - Number of birthing centers
 - Number of babies screened
- IT & Lab Systems
 - Applications in use in the lab? Follow-up?
 - COOP plans
- HIT Elements
 - Data integration and exchange policies and procedures
- NBS Program Structure
 - NBS program information brochures (PDF)
 - Contact information: lab, follow-up, CCHD, EHDI, HIT
 - NBS Advisory Committee: Make up/ Charge/ by-laws
- NBS Policies on
 - Recommended age at initial/second screening
 - Consent
 - Follow-up services
 - Missed cases
 - Sharing of specimens

The following additional data will be shared with the NCC for the Regional Genetic Service Collaborative:

- Aggregate Quality Indicators data at the state level, with state identities blinded