

## Informational Guide for the NewSTEPS Data Repository



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### Summary of Facts

- Data sharing within the NewSTEPS Data Repository is governed by Memorandums of Understanding (MOUs) with each State.
  - Insomniac Design, Inc. will serve as an honest broker of the data, with no ability to share or identify data, newborns or families.
  - Insomniac Design, Inc. will calculate date differences providing epidemiologic information to NewSTEPS staff, per signed Data Sharing Agreements/MOUs.
  - No information identifying newborns and states will ever be shared.
  - All data shared with investigators will be approved by the NewSTEPS Steering Committee and held to a “Rule of 5” (no data will be shared if there are few than 5 newborns in a given category or cell).
  - All data requests will be shared with and approved by the Data Review Workgroup.
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### WHAT IS THE NEWSTEPS DATA REPOSITORY?



The NewSTEPS data repository is a centralized and secure database that is designed for state newborn screening (NBS) programs to explore data to meet local program needs.

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#### **WHAT OVERSIGHT IS BEING PROVIDED FOR NEWSTEPS?**

The Colorado Multiple Institutional Review Board (COMIRB) has deemed the NewSTEPS data repository to be non-human subject research as defined by their policies and current regulations and in accordance with the Office of Human Research Protections (OHRP) and the Food and Drug Administration (FDA) guidelines.

Specifically, in a [letter](#) regarding NewSTEPS activities, the COMIRB noted that the determination to designate NewSTEPS Data Repository activities as **not human subject research** was made because source data submitted from each state will be collected by a contracted data manager that is not engaged in the research by OHRP guidance, and that the data received from the data manager will not contain sufficient information to render the data identifiable.

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#### **WHAT DATA IS BEING COLLECTED?**

- State profile and programmatic information (e.g., disorders screened, newborn screening fees, annual births, policies, adding to the NBS panel, program structure, program contact information, advisory committee information, health information technology elements and Information Technology support).
  - Case level data for infants diagnosed with a condition (e.g., biological sex, race, gestational age, birth weight, ethnicity, time elapsed for different NBS services, type of disorder).
  - NBS Surveillance Case Definitions, (includes basic criteria for a diagnostic workup) as defined by the medical community, for most of the core Recommended Uniform Screening Panel (RUSP) NBS disorders.
  - Eight Quality Indicators (e.g., percent of dried blood spots specimens missing essential information, percent of eligible newborns not receiving valid NBS test, timeliness of NBS activities).
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#### **WHY IS THIS DATA BEING COLLECTED?**

The collection of data at the national level allows for analysis of information to support quality improvement in the newborn screening system. State newborn screening programs will be able to compare outcomes and trends from their state or region to the national summary data. These data will also provide the ability to accurately calculate the prevalence of the rare disorders as detected by newborn screening. Additionally, reports will provide comparisons between states with similar birth rates and screening methodologies.

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#### **HOW DID NEWSTEPS DECIDE WHAT DATA TO COLLECT?**

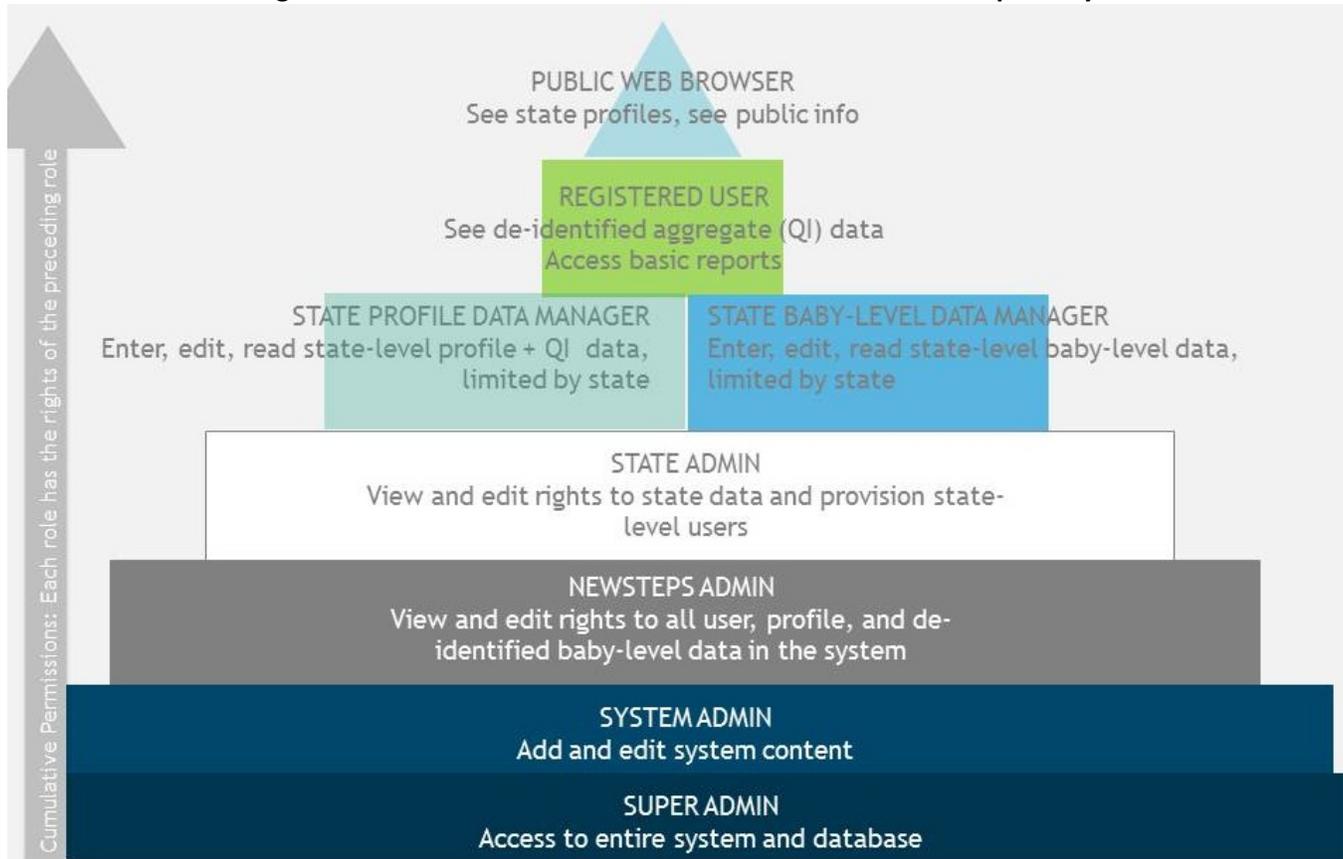
The NewSTEPS steering committee and workgroups made up of dozens of members of the newborn screening community spent more than a year developing data elements, case definitions and quality indicators. Careful consideration was put into the selection of these elements to ensure that they were both beneficial and feasible to collect by newborn screening programs.

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**WHO IS ABLE TO SEE THE DATA?**

Access to the NewSTEPS data repository is structured using well defined user roles (see Figure 1 below). Each State NBS program will have a state administrator role, one that will manage all users for their state. NBS programs that enter data into the NewSTEPS data repository will have access to their own data, including baby level data, case definitions, and quality indicators. They will be able to see aggregate data from other participating NBS programs. Public access is limited to the state profiles on the NewSTEPS website.

**Figure 1: User Roles delineated within the NewSTEPS Data Repository**



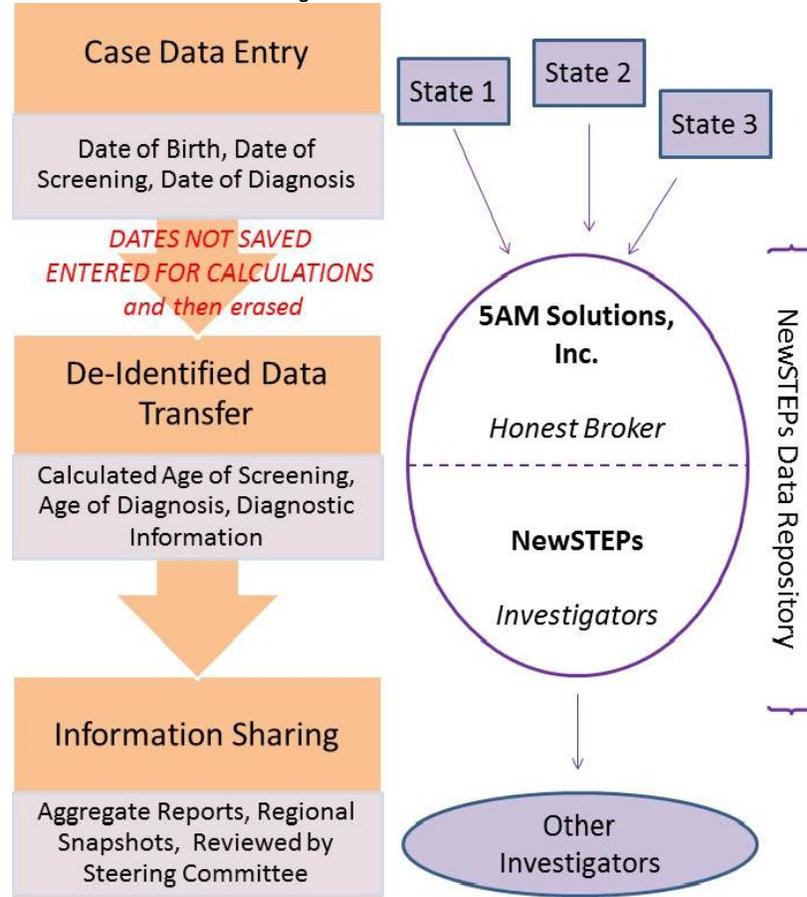
**HOW IS THE DATA BEING SECURED?**

NewSTEPS works closely with its Information Technology (IT) vendor, Insomniac Design, Inc. in order to ensure that data is secure. The NewSTEPS Data Repository is a centralized and secure application that can be accessed by authorized users from anywhere (via the Internet and a web browser). The web application itself is available through web browsers via 128-bit secure socket layer (SSL) encryption. Information in the web application 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 NewSTEPS 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 NewSTEPS team. The NewSTEPS staff has a coded information agreement with Insomniac Design, Inc. as part of their contract for services. The NewSTEPS and Insomniac Design Solutions, Inc. staff and will make no effort to re-identify any individual

babies. No parties involved in the project have access to records that would allow re-identification of newborns.

**Figure 2: Flow of Information within the NewSTEPS Data Repository**

\*Please note that Insomniac Design is the NewSTEPS IT vendor



**IS PARENTAL CONSENT FOR THIS DATA NEEDED?**

Parental consent is **not needed** for this repository because most of the data collected by NewSTEPS is aggregate data about the state newborn screening program. Some of the data elements are related to the infants identified by newborn screening in an individual state, however this **information is de-identified and no personal identifiable information is being stored**. The Colorado Multiple Institutional Review Board has reviewed the policies and privacy plans proposed by NewSTEPS and have commended NewSTEPS on the measures in place to ensure appropriate and ethical treatment of individual data. Further, the Office of Human Research Protection (OHRP) has determined that NewSTEPS is taking all of the necessary proactive measures to safeguard this information.

**WHAT IS THE BENEFIT OF MY ENTERING DATA INTO THE NEWSTEPS DATA REPOSITORY?**



- The NewSTEPS data repository is a centralized and secure database that can be accessed by authorized users from anywhere and allow each NBS program to explore data to meet local program needs.
  - NBS programs that enter data into the NewSTEPS repository have access to their own data plus aggregate data from other participating NBS programs.
  - NBS programs are able to generate standardized reports and run queries in real time.
  - NewSTEPS provides users with real time interactive data visualizations for quality improvement purposes. Visualizations are constantly expanding based on user needs.
  - Technical assistance by the NewSTEPS program is a free service to users of the repository and is complementary to our annual reports.
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#### **WHEN CAN I ENTER DATA AND HOW DO I GET ACCESS?**

Your state NBS program must have a signed Memorandum of Understanding with APHL in order to enter data and access the data repository. You may contact Careema Yusuf ([careema.yusuf@aphl.org](mailto:careema.yusuf@aphl.org)) or Sari Edelman ([sari.edelman@aphl.org](mailto:sari.edelman@aphl.org)) from NewSTEPS in order to establish your program administrator(s) and get your user name and password. Data repository overviews are available upon request.

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#### **WHAT WILL THE MEMORANDUM OF UNDERSTANDING (MOU) ENTAIL?**

The MOUs were developed in accordance with guidance provided by a HIPAA attorney, APHL's in house legal counsel, and State public health laboratories. They include information regarding the following aspects of Data sharing within the NewSTEPS Data Repository.

- Data ownership
  - Data reporting
  - Data security
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