



## Early Steps Data Use Agreement

**Date:** May 15, 2020

### **I. Project Director Information**

**Name of Requestor:** *Jessica Meyer*

**Title:** *Newborn Hearing Screening Program Director*

**Requestor's Organization/Agency:** *Division of Children's Medical Services | Bureau of Early Steps & Newborn Screening / Florida Department of Health*

**Mailing Address:** *4052 Bald Cypress Way, Bin A-06, Tallahassee, FL 32399-1707*

**Telephone Number:** *(850) 245-4673*

**Fax Number:** *(850) 245-4049*

**E-Mail Address:** *Jessica.Meyer@flhealth.gov*

**Does this application update a previous Data Use Agreement?** Yes No

**If yes, provide Study Number of previous Data Use Agreement:**

### **II. Project Summary**

**Provide a brief title for your project or study:** *ESAS Interface to Newborn Screening Records from DOH Newborn Screening Program.*

**Purpose of the Project :** *Develop an interface from the Early Steps Administration System (ESAS), currently under development with the vendor GRM/Visual Vault, to the DOH Newborn Screening Program data system, Specimen Gate, which would allow Early Steps data to be available for comparison and input into the Newborn Screening system when a child is referred to Early Steps and enters the program.*

**Intended Use of the Data :** *The Early Steps enrollment and outcome data will assist the Newborn Screening Program with surveillance and the reporting of early intervention enrollment for hearing loss, as well as provide the ability for the Newborn Screening Program to monitor and receive updated demographic information for children with conditions that require long-term follow-up. The data will be reviewed and validated by the Newborn Screening Program before utilizing and accepting into the Newborn Screening System.*

Please describe your plan for the release of results, including plans for public dissemination, if any: *The Newborn Screening Program has no plans to disseminate this information to the public. Early Intervention data is shared with the Centers for Disease Control and Prevention (CDC), however this data is aggregated and does not contain PHI or is deidentified to mask PHI. The data is solely intended to improve the outcomes for infants and toddlers identified with conditions pertaining to the Newborn Screening Program.*

**The publication must cite the DOH as the data source.** A disclaimer must also be included that "any published findings and conclusions are those of the authors and do not necessarily represent the official position of the Florida Department of Health."

**Family Educational Rights and Privacy Act (FERPA)** The disclosure of PII from education records must be to:

- a. Audit or evaluate a Federal- or State-supported education program; or
- b. Enforce or comply with Federal legal requirements related to the program.

Authorized representatives of the FERPA-permitted entities may only redisclose the PII when expressly authorized in the parties' written agreement (assuming that the redisclosure by the authorized representative on behalf of the FERPA-permitted entity would be permissible under FERPA)

**The Project Director is the Data Custodian for this project; however, there are some circumstances which may allow another person to be the Data Custodian.**

The Data Custodian is responsible for observance of all conditions of use and for establishment and maintenance of physical and electronic security arrangements to prevent unauthorized use. This individual must have the legal authority to keep the information confidential and maintain confidentiality. If the custodian is changed, the organization must promptly notify the DOH, Division of Children's Medical Services, Bureau of Early Steps and Newborn Screening.

**Are you the Data Custodian for this project? Yes No**

**If no, please indicate the name of the Data Custodian and their relationship to the requestor's organization:**

**Is the requested data needed for work being performed under contract with the DOH? Yes No**

**If yes, then please provide the DOH contract manager's name:**

**III. Data Requested and Specifications**

<u>Data Requested</u>	<u>Data Specifications</u>	<u>Data Format</u>
Enrollment	Years	Photocopies
Parent Refusal	(Specify) 3 and all births	Electronic Transfer (Secure FTP)
Moved out of area	moving forward	
Moved out of state	Statewide Data	
Ineligible	County Only	
	(Specify)	

**IV. Variables and/or Linking (Matching) of Data**

List the specific variable names being requested here or in an attachment to the data use agreement: *Please see attached Excel document which list each field to be included and those to be excluded.*

Will the data requested be linked or matched with any other data sources? **Yes No**

If yes, describe in detail any linking of requested Early Steps data with any other data sources. Specify the data sources, the variables which will be used for linking, (SSN, name, etc.), and which variables will be kept in the linked file.

*The Early Steps Records will be matched to the Specimen Gate data as enrollment information is updated. The variables to be used to link/match between ESAS and Specimen Gate will be: First Name, Last Name, DOB, Sex, and possibly Race/Ethnicity (Others may need to be added depending on matching success %). The matching algorithms will also take into account Nicknames, "sounds-like" technology (Soundex), and other methods where possible since hard matches like with SSN are not viable.*

If the applicant will be linking the data, provide a detailed description of the linking methodology to be used. If the requestor will need DOH to match or link records, describe how the data needing to be matched or linked will be provided.

*DOH CMS Newborn Screening will perform the matching to the DOH ESAS, within Specimen Gate, since the data is one way, from ESAS to Specimen Gate.*

**V. Security and Confidentiality**

The release of information that may lead to the identification of individuals or be traced back to an individual record is prohibited. However, statistical and research results based on the data provided by the Early Steps Program pursuant to this Agreement may be released. Any person(s) who access, disclose or use personally identifiable information in a manner or for a purpose not authorized by this agreement may be subject to civil and criminal sanctions contained in applicable federal and state statutes.

Only the listed Data Custodian or authorized users listed on this agreement may access data. Describe where data will be stored and how data will be accessed by authorized users.

*The DOH Early Steps enrollment data that is brought into the Specimen Gate system, via the interface, will be housed in the Specimen Gate® system, which is located within the Florida Department of Health's IT infrastructure. The Specimen Gate® system meets all required security and encryption specifications required by DOH IT.*

Do you agree to each of the following requirements?

- 1) The files will be used only to accomplish the research project described in this agreement. Yes No
- 2) These files, or any files extracted or derived from them, will not be released to other organizations or individuals who have not been named in this agreement. Yes No
- 3) No attempt will be made to link information from any other source to records for specific individuals for whom records are included in these files, unless authorized by this agreement. Yes No
- 4) No listing of information from individual records, with or without identifiers, will be published or otherwise released. Yes No
- 5) No statistical tabulations or research results will be released which reveal information about identifiable individuals. Yes No
- 6) Statistical and research results derived from these files may be published. However, no results may be copyrighted by the author without the permission of the Early Steps Program. Yes No

#### **VI. Data Destruction Schedule**

Consistent with Florida law, applicants must make provisions for the destruction of records at the conclusion of their project, or when the data is no longer required. Maintaining the privacy of the individuals whose personal information is included is required to preserve the integrity of the data sharing process.

Please detail the manner and timeline for destruction. If you are following a data destruction policy set by your organization or agency, please attach that policy to your application.

The records requested are solely utilized for the Newborn Screening Program and will be maintained according to Newborn Screening Program policy in performing its duties in conducting data management and analysis tasks as described in the project summary. Activities support DOH maternal and child health programs by providing information on the connection between Newborn Screening and Early Care and Education Services. The Newborn Screening Program agrees that it will not copy or redistribute the confidential data in any manner, even for its own studies, without separate DUA and DOH IRB approval.

No data will be destroyed as long as a valid data use agreement is in place. If this data use agreement is not renewed, data destruction will occur within 30 days of expiration of this data use agreement. Data destruction requires planning and coordinating efforts with department DOH IT personnel: detaching database monitor data integrity, changing file permissions to allow data destruction, wiping data, and repurposing hardware.

#### **VII. Data Use by Others**

Will any sub-contractors affiliated with this project use the data during the project?

Yes No

If yes, each sub-contractor or other individual will need to complete a separate Data Use Agreement. Please identify the individuals of the sub-contractor who will have access or be using the data and describe the work they will perform.

*The Newborn Screening Program database contractor is PerkinElmer. PerkinElmer will ensure the DOH Early Steps data is loaded into the NBS system as a defined interface.*

#### **VIII. Fees**

Prior to generating the data, the DOH will provide an estimate of the costs incurred in its preparation. Once the request is approved and payment received, the data will be provided. A waiver or reduction of the fees authorized by section 382.0255(1), Florida Statutes, will be considered only if the intended use of the data will have a direct

health-related benefit to Florida citizens. If a waiver or reduction of the fees is requested, describe how use of the data is a direct benefit to Florida citizens.

*A fee waiver is requested because this data is being used via Intra-agency. The DOH CMS Newborn Screening program screens for rare metabolic, endocrine, enzymatic, and other genetic disorders to ensure early identification, treatment, and access to follow-up services of newborns. Early identification and initiation of treatment or intervention can prevent developmental delays, complex medical conditions, massive infections, and even death. The early intervention data will assist by provide outcome data which will assist with long-term follow-up and program evaluation.*

**IX. Contact with Human Subjects**

No contacts of any kind can be made with any person named on a certificate or data file or related persons without the written permission of the Early Steps Program and review by the DOH Institutional Review Board (IRB). If the project requires DOH IRB review, applicants must first submit a signed and notarized Data Use Agreement along with the protocol for review to the Early Steps Program. A Data Use Agreement may be rejected if the research protocol involves intrusive follow-back of research subjects.

**Will the project involve direct contact with individuals or establishments mentioned on the record?**  
 Yes No

**If so, describe the need for such activity and the types of individuals or establishments who will be contacted.**  
 Current routine processes needed to assist the infants, toddlers, and their families with essential public health activities. Contact may also be required for long-term follow-up if needed based on health condition.

**X. All Staff Accessing the Information**

**List name, title, affiliation and role in this project for each authorized user :**

Role	Job Title	First Name	Last Name	Email	Work Phone
Project Director	Newborn Hearing Screening Coordinator	Jessica	Meyer	<a href="mailto:Jessica.Meyer@flhealth.gov">Jessica.Meyer@flhealth.gov</a>	850-245-4673
Project Manager	Newborn Screening Program Director	Dusty	Edwards	<a href="mailto:Dusty.Edwards@flhealth.gov">Dusty.Edwards@flhealth.gov</a>	(850)-245-4674
Subject Matter Expert	Data Manager	Ashley	Bailey	<a href="mailto:Ashley.Bailey@flhealth.gov">Ashley.Bailey@flhealth.gov</a>	(850) 901-6293
Subject Matter Expert	Data Manager	Nikema	Peterson	<a href="mailto:Nikema.Peterson@flhealth.gov">Nikema.Peterson@flhealth.gov</a>	(850) 901-6288

*The interface early intervention data from DOH Early Steps will not be generally available to end users and will only be utilized once reviewed and accepted by the Newborn Screening Program as part of the long-term follow-up process. If a record is matched with DOH Early Steps and if the data is beneficial and accepted by the NBS, then and only then will it be brought into the NBS system as part of the child*

*record. Again, the initial inbound DOH Early Steps data will not be accessible to any end users unless through the referral process detailed above.*

## **XI. Use and Consent of the Data**

Early Steps data may only be used for the specific purpose(s) described in this agreement. All persons with data access must maintain the confidentiality of the data and prevent release to unauthorized parties. All publications, tabular presentations, maps or depictions of cartographic information must aggregate results to protect the identity of individuals and comply with applicable state and federal laws. The Division of Children's Medical Services, Bureau of Early Steps and Newborn Screening, Section of Early Steps shall be notified immediately by phone (850-245-4456) after discovery of any use or disclosure of the data not provided for by this agreement.

As the signatory for this agreement as the Data Custodian, the Data Custodian bears full responsibility for adhering to all data confidentiality, security policies, and the terms of this agreement. The Data Custodian serves as the point of contact for receiving, maintaining, protecting, and ultimately destroying the data provided by DOH. Data may be used by the custodian only for the purpose stated in this agreement and may not be used for any other purpose. No entity with data access may link data with any other source of information without the written authorization of the Bureau of Early Steps and Newborn Screening. Additionally, proper physical, computer and system security safeguards will be maintained by the signatory's requestor's organization/agency pursuant of the agreement.

### Physical Security

The requestor's organization shall ensure that DOH data are used and stored in an area that is physically safe from access by unauthorized persons during working hours and non-working hours. The requestor's organization agrees to safeguard DOH data from loss, theft, or inadvertent disclosure and, therefore, agrees to:

1. Secure all areas of the organization's facilities where employees assist in the administration of the program's use or disclose DOH data. Ensure that authorized individuals only access these secure areas with properly coded key cards, authorized door keys or access authorization; and access to premises is by official identification.
2. Issue identification badges to workers who assist in the administration of the organization's programs and require the organization's workers to wear these badges at organization's facilities where DOH data are stored and used.
3. Store paper records with DOH data in locked spaces, such as locked file cabinets, locked file rooms, locked desks, or locked offices in facilities which are multi-use, meaning that where the requestor's organization and non-requestor's organization functions in one building in work areas that are not securely segregated from each other.
4. Use all reasonable measures to prevent non-authorized personnel and visitors from having access to, control of, or viewing DOH data.

### Computer Security Safeguards

The requestor's organization agrees to comply with the general computer security safeguards, system security controls, and audit controls in this section.

#### General Computer Security Safeguards:

1. Encrypt portable computer devices, such as but not limited to, laptops and notebook computers, that process and/or store DOH data with an encryption solution that is full-disk utilizing a minimum algorithm of 256-bit AES or 3DES (Triple DES) if AES is unavailable.

2. Encrypt workstations where DOH data are stored using an encryption product that utilizes a minimum algorithm of 256-bit AES, or 3DES (Triple DES) if AES is unavailable and is recognized as an industry leader in meeting the needs for the intended solution.
3. Ensure that only the minimum necessary amount of DOH data is downloaded to a laptop or hard drive when necessary for current business purposes.
4. Encrypt all electronic files that contain DOH data when the file is stored on any removable media type device (i.e., USB thumb drives, floppies, CD/DVD, portable hard drives, etc.) using an encryption product that utilizes a minimum algorithm of 256 bit AES, or 3DES (Triple DES) if AES is unavailable, and is recognized as an industry leader in meeting the needs for the intended solution.
5. Ensure that all emails sent outside the requestor's organization's e-mail environment that include DOH data are sent via an encrypted method using an encryption product that is recognized as an industry leader in meeting the needs of the intended solution.
6. Ensure that all workstations, laptops and other systems that process and/or store DOH data have a commercial third-party anti-virus software solution and are automatically updated when a new anti-virus definition/software release is available.
7. Ensure that all workstations, laptops and other systems that process and/or store DOH data have current security patches applied and are up-to-date.
8. Ensure that all DOH data are wiped from all systems and backups when the data is no longer legally required. The requestor's organization shall ensure in writing that the wipe method conforms to the US Department of Defense standards for data destruction.
9. Ensure that any remote access to DOH data are established over an encrypted session protocol using an encryption product that is recognized as an industry leader in meeting the needs of the intended solution. The requestor's organization shall ensure all remote access is limited to the minimum necessary and maintains the principles of least privilege.

#### System Security Controls

In order to comply with the following system security controls, requestor's organization agrees to:

1. Ensure that all systems containing DOH data provide an automatic timeout after no more than 15 minutes of inactivity.
2. Ensure that all systems containing DOH data display a warning banner stating that data is confidential, systems are logged, and system use is for business purposes only. Users shall be directed to log off the system if they do not agree with these requirements.
3. Ensure that all systems containing DOH data log successes and failures of user authentication and authorizations granted. The system shall log all data changes and system accesses conducted by all users (including all levels of users, system administrators, developers, and auditors). The system shall have the capability to record data access for specified users when requested by authorized management personnel. A log of all system changes shall be maintained and be available for review by authorized management personnel.
4. Ensure that all systems containing DOH data uses role-based access controls for all user authentications, enforcing the principle of least privileges.

5. Ensure that all data transmissions over networks outside of the requestor's organization's control are encrypted end-to-end using an encryption product that is recognized as an industry leader in meeting the needs for the intended solution when transmitting DOH data. Encrypt DOH data at the minimum of 256-bit AES or 3DES (Triple DES) if AES is unavailable.
6. Ensure that all systems that are accessible via the Internet or store DOH data interactively use a comprehensive third-party real-time host-based intrusion detection and prevention program or are protected at the perimeter by a network-based IDS/IPS solution.

Any failure of persons listed in this agreement to abide by the terms of this agreement constitutes a breach and may result in legal action and/or the demand for immediate return of all data obtained hereunder and the destruction under the supervision of the DOH of all copies of the data in the requestor's, the organization's, employees, agents, assigns, or subcontractor's possession. All actions brought under this agreement will be in the State of Florida. In any action brought by the DOH under this agreement in which the DOH prevails, the DOH shall be entitled to its attorney's fees and court costs.

\*\*\* All persons who come in direct contact with Early Steps data are required to sign this agreement. If additional signatures are required, please provide them on the last page of this agreement.

Project Director's Name (Please Print): Jessica Meyer

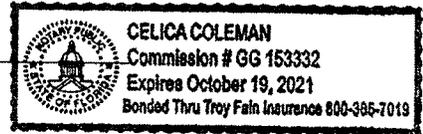
Project Director's Signature (Notarization Required):

*Jessica Meyer*

Attest (If applicant is a corporation): \_\_\_\_\_  
(As Corporate Secretary)

Subscribed and sworn before me Celica Coleman this 28 day of May, 2020.

Notary Public, State of Celica Coleman  
Notary Public Signature (Affix Notary Stamp)



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Fees Waived: Yes No Fees Reduced: Yes No

DOH IRB Recommendation: Yes No

Florida Department of Health Reviewers:

\_\_\_\_\_ (Reviewer 1)

\_\_\_\_\_ (Reviewer 2)

Florida Department of Health, Early Steps Authorization:

*Renee Jenkins*  
\_\_\_\_\_  
Renee Jenkins  
Early Steps Administrator  
Bureau of Early Steps and Newborn Screening

5/15/2020  
Date

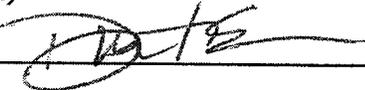
This agreement shall expire one year from the date above. If the agreement is not renewed, all Early Steps data must be handled in accordance with the Data Destruction Plan .



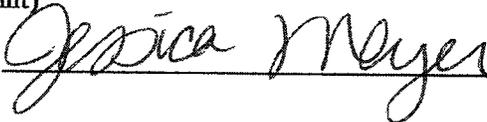
Early Steps Data Use Agreement

Signatures below, by individuals who will access data as authorized users, acknowledging agreement to the terms of this Data Use Agreement.

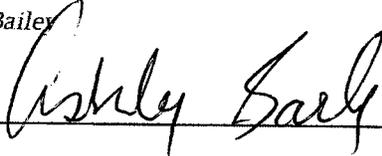
Name *Dusty Edwards*  
(Please Print)

Signature:  \_\_\_\_\_

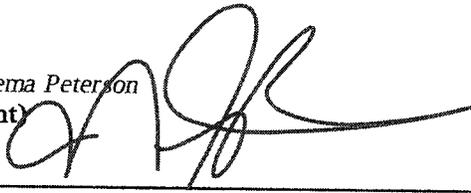
Name: *Jessica Meyer*  
(Please Print)

Signature:  \_\_\_\_\_

Name: *Ashley Bailey*  
(Please Print)

Signature:  \_\_\_\_\_

Name: *Nikema Peterson*  
(Please Print)

Signature:  \_\_\_\_\_

Name:  
(Please Print)

Signature: \_\_\_\_\_

**Demographic Items****Use for Matching**

Child Last Name	X
Child First Name	X
Date of Birth	X
Mother Last Name	X
Mother First Name	X
Address	
City	
State	
Zipcode	
Sex	X

**ES Data Needed**

LES Center  
Residence state of birth (if available)  
Diagnosis (multiple if needed)  
Date of hearing loss diagnosis (if available)  
Provider of diagnosis (if available)  
Eligibility (Y/N)  
Referral Source  
Date of referral  
Enrollment Status  
Enrollment Date  
IFSP Date  
IFSP Services  
IFSP Service Providers  
Closure reasons (parent refused, moved out of the area, moved out of state, ineligible, unable to contact)

Closure Date