Policy Number	AP-1000
Policy Title	Management of Residual Newborn Screening Specimens and Data
Effective Date	8/6/2010
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Subject Matter Expert	Director, Medical Screening Unit, Public Health Laboratory
Policy Owner	Deputy Commissioner Public Health Laboratory Division
Signed by:	Grace Kubin

1.0 Purpose

1.1 This policy provides the Public Health Laboratory Division ("Division") guidance for obtaining appropriate review and approval of proposed uses of residual newborn screening (NBS) specimens and associated data which are otherwise allowable under Texas Health and Safety Code, Chapter 33, Subchapter B.

1.2 When looking at proposed residual uses that are allowable but not mandatory under the statute, the Department of State Health Services (DSHS) management will weigh the potential public health benefits against any possible harm when deciding whether such a use will be allowed. This policy works in tandem with DSHS IRB policy (AP-900 Institutional Review Board).

1.3 This policy is not applicable to residual uses that are at the express written instruction of the parent, managing conservator, or legal guardian under Code Sec. 33.018(b)(2), nor those directed by court order under Code Sec. 33.018(b)(3) (which should be sent to the Office of General Counsel for review), nor those requested by a medical examiner under Code Sec. 33.018(b)(4). This policy also does not apply to the Newborn Screening Program clinical care coordination (follow-up) functions related to newborn screening under Code Sec. 33.018(b)(1).

2 Definitions

2.1 **Affiliated with a Health Agency:** A person who is an employee or former employee of a health agency.

2.2 **Clinical Laboratory Improvement Amendments Of 1988 (CLIA):** Federal legislation enacted to establish standards and certification credentials for clinical laboratory testing; the Division must maintain its CLIA certification. CLIA's purpose, in part, is to

ensure the accuracy, reliability and timeliness of laboratory test results.

2.3 **Data Request Inbox:** NBSDataRequest@dshs.texas.gov.

2.4 **De-identified:** Specimens or associated data that neither identify nor provide a reasonable basis to identify the child or the parents of the child from which the specimen was collected.

2.5 **Identified:** Specimens or associated data which contain any information that directly or could reasonably be said to indirectly allow linkage of a NBS blood spot or associated data back to the child, relatives, or household members of the child from which the specimen was collected.

2.6 **Institutional Review Board (IRB):** An administrative body established by the DSHS to protect the rights and welfare of human subjects involved in research. It reviews and approves research proposals to ensure compliance with federal and state laws regarding human subjects. Additionally, research involving human subjects or their identifiable personal records must be reviewed and approved by an IRB per legal requirements.

2.7 **Newborn screening (NBS):** Testing and follow-up performed by the NBS Program in accordance with Title 2 Texas Health and Safety Code Chapter 33. The NBS Program tests one or more specimens to identify a newborn who may be at risk of having a genetic condition like phenylketonuria, other heritable conditions, or hypothyroidism which can cause severe debilitation or death if not identified and treated early.

2.8 **Newborn screening data (data):** Includes demographic information received on the NBS collection form, test results, and case data compiled as part of the clinical care coordination of individual children (i.e., with "out-of-range" NBS test results).

2.9 **Newborn Screening Program:** The Texas Newborn Screening Program includes laboratory and clinical care coordination functions that enable early detection and treatment to prevent serious complications in infants with congenital and heritable conditions.

2.10 **Newborn screening specimen:** Dried blood spot (DBS, "dried blood spot specimen", or "blood spot") sample used for newborn screen testing that consists of drops of blood collected on a specialized filter paper, which is an FDA-approved medical device for specimen collection.

2.11 **Parent:** Parent, managing conservator, or legal guardian of a newborn screened as part of the NBS Program.

2.12 **Parental consent:** For the purpose of this policy, parental consent can manifest itself in three ways: 1) DSHS receives express-written

consent from the parent, with instructions to send their child's sample/data to a certain study [allowable under Texas Health & Safety Code (Code) Sec. 33.018(b)(2)]; 2) DSHS receives a signed "Parental Decision for Storage and Use of Newborn Screening Blood Spot Cards" form with the check box 'OK' selected [allowable under Code Sec. 33.018(c-1); or 3) DSHS receives a research proposal from requestor(s) external to DSHS who wish to conduct research on identified residual samples/data, and the study protocol includes obtaining informed parental consent. If DSHS management and IRB approve the study under this policy and the DSHS IRB policy, samples/data would be released once the signed parental consent forms are received from the researchers [allowable under Code Sec. 33.018(b)(2)].

2.13 **Proficiency testing:** A quality assurance process in which unknown samples, provided by an external source, are tested in order to verify the performance (i.e. accuracy and precision) of laboratory test. Proficiency testing is performed in accordance with CLIA certification requirements.

2.14 **Program Contact:** A member of a program who serves as a point of contact with a data or specimen requestor. The Program Contact may or may not be engaged in collaborative research with the requestor.

2.15 **Program Review Group:** A group of subject matter experts from the NBS Program and Division that reviews data requests and may communicate with requestors about requests.

2.16 **Public health purpose:** A purpose that relates to cancer, a birth defect, an infectious disease, a chronic disease, environmental exposure, or newborn screening, as defined in Title 2 Health and Safety Code § 33.018(5).

2.17 **Quality Assurance (QA):** A part of the Division's Quality Management System designed to ensure the Division's activities (i.e., specimen collection, testing, and reporting procedures), policies, and procedures are implemented according to quality standards and regulatory requirements. CLIA certification and CAP accreditation, requirements for testing, outline these QA standards that the Laboratory must follow.

2.18 **Quality Control (QC):** A set of measures and processes implemented as part of the Division's Quality Management System to detect and mitigate potential irregularities or deficiencies found in the Division's analytical processes. QC activities also ensure accuracy and reliability of results produced by the Division.

2.19 **Research:** A systematic investigation (i.e., the gathering and analysis of information) designed to develop or contribute to generalized knowledge as defined in 45 Code of Federal Regulations,

Part 46. Research involving newborn screening specimens, data, or both must be approved by the DSHS IRB, even when deidentified.

2.20 **Research Executive Steering Committee (RESC):** An executive body whose membership includes agency leadership. Its policy is to consider public health purpose and benefit when reviewing and approving proposed research applications.

2.21 **Residual use:** Use of a specimen(s), associated data, or both after newborn screening is completed.

3 Persons Affected

3.1 Employees working in the NBS Program, including:

3.1.1 Staff in the Division; and

3.1.2 Staff in the DSHS Community Health Improvement Division Newborn Screening Unit.

3.2 DSHS staff in program areas outside of the NBS Program tasked with conducting substantive reviews of residual use proposals.

3.3 DSHS management and leadership tasked with reviewing proposed residual uses in accordance with agency policy.

3.4 Members of the DSHS IRB.

3.5 Entities requesting specimens or associated data (internal or external to the agency).

4 Responsibilities

4.1 The Division's Program Contact

4.1.1 Provides an initial review of the proposal for completeness.

4.1.2 Contacts requestor for clarification of details in the proposal.

4.1.3 Coordinates review of proposal by Program Review Group.

4.1.4 Communicates logistical, legal, or other issues with the requestor.

4.1.5 Consults with program attorney to ensure the initial application meets all the legal requirements for the program to release the requested specimens, data, or both.

4.2 The Division's IRB Contact

4.2.1 Consults with program attorney to ensure the renewal application or a substantial change to the application meets all the legal requirements for the program to release the requested specimens, data, or both.

4.2.2 Ensures the application includes all the required signatures, including:

4.2.2.1.1 Program Attorney

4.2.2.1.2 Laboratory Director

4.3 The Division's Program Review Group

4.3.1 Conducts an initial scientific review of the proposal's validity.

4.3.2 Reviews the request to assess whether specimen or data use applications are in alignment with:

4.2.2.1 All federal and state statutes, rules, and guidelines; and

4.2.2.2 DSHS and HHS policies.

4.3.3 Ensures the data or specimens are in the possession of DSHS.

4.3.4 Ensures the program has sufficient resources to meet the time commitments of the request without compromising agency functions.

4.3.5 Meets, as needed, with a data requestor(s) to provide guidance regarding data feasibility, availability, and permissibility of data requests.

4.3.6 Determines acceptability of research and QA/QC requests.

4.4 Medical Screening Director

4.4.1 Ensures approved uses are published online.

4.4.2 Ensures data use report is sent to the Commissioner, and all necessary parties.

4.4.3 May serve as Laboratory Director designee.

4.5 Newborn Screening Clinical Care Coordination Director

4.5.1 May review proposed request to determine if proposal is in alignment with:

4.4.1.1 All federal and state statutes, rules, and guidelines; and

4.4.1.2 DSHS and HHS policies.

4.5.2 May conduct an initial scientific review of the proposal's validity.

4.2.3 If applicable, may provide approval of requests.

4.6 Laboratory Director (or designee):

4.6.1 Serves as policy owner.

4.6.2 Ensures data use applications are in alignment with:

4.5.2.1 All federal and state statutes, rules, and guidelines; and

4.5.2.2 DSHS and HHS policies.

4.5.3 Provides executive review of initial data requests and substantial changes to existing data requests.

4.5.4 May approve requests, as allowed by law.

4.7 Program Attorney

4.7.1 Reviews residual use proposals for compliance with the law and agency policy.

4.8 DSHS Institutional Review Board

4.8.1 Ensures data use applications are in alignment with:

4.7.1.1 All federal and state statutes, rules, and guidelines; and

4.7.1.2 DSHS and HHS policies.

4.8.2 Meets regularly to review applications.

4.9 RESC

4.9.1 After DSHS IRB review, RESC ensures data use applications are in alignment with:

4.8.1.1 All federal and state statutes, rules, and guidelines; and

4.8.1.2 DSHS and HHS policies.

4.9.2 Provides approval, denial, or recommend escalating approval to the DSHS Commissioner.

4.10 DSHS Commissioner

4.10.1 Ensures applications that require DSHS Commissioner approval are in alignment with:

4.9.1.1 All federal and state statutes, rules, and guidelines; and

4.9.1.2 DSHS and HHS policies.

5 Procedures

5.1 Residual use request.

5.1.1 Requestor submits a data request form (Form F14-14058) to the Data Request Inbox.

5.1.2 The Division Program Contact receives the request, replies to the requestor with confirmation of receipt, and provides

initial review; contacts the requestor for clarification, as needed; and determines if the Program Review Group is needed to help determine project eligibility in accordance with all applicable policies, rules, guidance, and laws.

5.1.2.1 Routine daily quality assurance and quality control activities such as reagent lot changes, post preventive maintenance, post equipment or instrument repair runs, internal troubleshooting, cut-off evaluations, and internal data review are authorized under Code Sec. 33.018(b)(6) and 33.018(b)(7) and do not need further review or approval.

5.1.2.2 Routine reports that do not identify a child or family, such as for legislative performance measures for the Laboratory and Clinical Care Coordination, consultant meetings, posters, presentations, and the NBS annual report are authorized under Code Sec. 33.018(c)(1) and do not need further review or approval.

5.1.2.3 Table 1 specifies how requests are categorized, which determines the approval process for each. A proposal must be approved at each level before moving onto the next level for approval.

5.1.3 The Program Review Group thoroughly assesses the proposal.

5.1.4.1 Completes initial scientific review of the request's validity.

5.1.4.2 Assesses alignment with state and federal law.

5.1.6.3 Ensures the request will not disrupt program operations (i.e., competing priorities, logistics, funding and other resources).

5.1.6.4 If approved by the Program Review Group and determined to require IRB review, a representative of the Program Review Group submits its recommendation via form F14-14058 and routes for approval.

5.1.6.5 Recommendation includes authority support and required approvals from Appendix A.

5.1.7 The Requestor is notified of the Division's decision and begins the DSHS IRB application process, if applicable.

5.1.8 If DSHS IRB approves the request or the request was otherwise approved if IRB review is not required, NBS Program staff coordinate with the requestor regarding transport of data, specimens, or both, as applicable.

5.1.9 For IRB-approved studies, once the approved use is complete, the requestor confirms specimen and data destruction plan is executed by submitting a confirmation email with a completed Certificate of Data Destruction to the Data Request Inbox.

5.2 Notifications of approval for the residual uses.

5.2.1 The Division posts a notice of the approved request on the NBS Program website for any IRB-approved research or QA/QC uses.

5.2.2 The Medical Screening Quality Improvement and Testing Support Branch Manager or the Division's Medical Screening Director, ensures the information is posted on the website in a timely manner.

5.2.3 The Laboratory Director (or designee) submits a summary report of all residual uses that require approval by the Commissioner (or designee) to the DSHS Commissioner every six months.

5.2.4 The Medical Screening Quality Improvement and Testing Support Branch Manager or the Division's Medical Screening Director, notifies the following offices of the notice on the website:

5.2.4.1 Appropriate DSHS Leadership

5.2.4.2 DSHS Press Office

5.2.4.3 Office of Government Affairs

5.2.4.4 Office of General Counsel

6 History

Date	Action	Section
09/19/2023	Commissioner's Directive 2010.01 Revised to become an Agency Policy due to Agency reorganization.	All
07/01/13	Revised Commissioner's Directive to be in compliance with HB411, Texas 82nd Legislative Session.	All
08/06/10	Commissioner's Directive 2010.01 created	All

7 Associated Policies

Policy or Directive Number	Policy or Directive Name
AP-900	DSHS Institutional Review Board

8 Associated Requirements and Documentation

Requirements and Document Name
F14-14058: Requests for Residual Newborn Screening Specimens and/or Data – Research and QA/QC Purposes.
F14-13561: Request for Release of an Individual's Newborn Screening Specimens.
Data Use Agreement - Attachment 2 SECURITY AND PRIVACY INQUIRY (SPI)

Table 1. QA/QC and Research Uses of NBS Specimens and/or Associated Data

Ref. No.	Use	Examples	Approval Requirements
1	Quality Assurance, Quality Control, Quality Improvement		
1.1	DSHS QA/QC, related to its Laboratory's newborn screening activities, necessary for maintaining federal certification. Involves identified and/or de-identified specimens and/or associated data, but no external parties.	▪ Validation or verification of testing methods, modified protocols, instrumentation, reagents, or software applications. ▪ Use of blood spots as quality control material to ensure validity/accuracy of each laboratory test.	▪ Authorized by HSC Section 33.018(b)(7). ▪ Authorized by this policy (no further approval needed).
1.2	DSHS QA/QC, related to its Laboratory's newborn screening activities, necessary for maintaining federal certification. Involves sharing of de-identified specimens and/or associated data with other state newborn screening laboratories as part of the required proficiency testing exchanges or with the DSHS newborn screening contractors who supply equipment and supplies, to troubleshoot issues that arise in the Texas screening processes.	▪ Inter-laboratory exchange for proficiency testing. ▪ Troubleshooting equipment, supplies, reagent issues, and specimen quality (which may occur at DSHS or at location of the DSHS equipment/supply/reagent vendor) to resolve issues identified in the newborn screening process.	▪ Authorized by HSC Section 33.018(c)(2)(A). ▪ Authorized by this policy (no further approval needed).

Ref. No.	Use	Examples	Approval Requirements
1.3	DSHS NBS Program evaluation of existing processes for NBS internal review and quality assurance, involving identified or de-identified specimens and/or associated data. No disclosure outside of the NBS Program is permitted.	▪ Evaluating newborn screening system performance measures to identify areas in need of improvement (e.g. turnaround time, percentage of specimens unsatisfactory for testing, or review of diagnosed cases).	▪ Authorized by HSC Section 33.018(b)(6). ▪ Authorized by this policy (no further approval needed).
1.4	DSHS NBS Program reports de-identified newborn screening data for evaluation of trends related to newborn screening. Access to the compilation of data facilitates improvement of the Texas NBS Program.	▪ Reporting de-identified data to a national newborn screening resource center or roster to compare the DSHS NBS Program to that of other state NBS programs.	▪ Authorized by HSC Section 33.018(c)(1) and 33.018(b)(8). ▪ Approval by Medical Screening Unit Director, acting as DSHS Commissioner designee when laboratory data or specimens are involved. ▪ Approval by Newborn Screening Unit Director, acting as DSHS Commissioner designee when clinical care coordination data are involved.

Ref. No.	Use	Examples	Approval Requirements
1.5	Changes to the existing DSHS NBS Program to improve testing and/or follow-up services.	▪ Improvement of DSHS NBS Program processes including evaluation and development of alternative methods/ algorithms, higher tiered testing, laboratory developed tests, and/or addition of new disorders to the NBS panel.	▪ HSC Section 33.018(b)(8). ▪ Approval by Public Health Laboratory Director, as DSHS Commissioner designee. ▪ Approval by Newborn Screening Unit Director, when proposed program improvement would impact NBS clinical care coordination, as DSHS Commissioner designee.
1.6	QA/QC purposes related to another public health laboratory (i.e. not part of inter-laboratory exchanges needed for DSHS Laboratory to maintain its federal certification referenced at 1.2 above), related to monitoring and enhancing their processes. Releases only involve de-identified specimens and/or associated data.	▪ Validating, troubleshooting, and evaluating NBS laboratory tests at another NBS Program. ▪ Training personnel from another state's NBS Program on testing methodologies. ▪ Evaluating internal QA/QC practices from submitting facilities requesting data from their own submitted specimens.	▪ Authorized by HSC Section 33.018(c)(2)(B). ▪ Approval by Public Health Laboratory Director, as DSHS Commissioner designee. ▪ Approval by Newborn Screening Unit Director, when Clinical Care Coordination data are requested.

Ref. No.	Use	Examples	Approval Requirements
1.7	Other quality assurance purposes related to public health testing equipment and/or supplies. This use involves de-identified specimens and/or associated data.	▪ Use of blood spots to evaluate newborn screening test kits at DSHS in which de-identified data will be submitted to FDA by the manufacturer, where FDA approval may lead to DSHS use of the test kits. ▪ Newborn screening test kit manufacturer uses de-identified blood spots to evaluate their newborn screening test kits as part of their QA/QC process before a particular lot of kits is released.	▪ Authorized by HSC Section 33.018(c)(3). ▪ Approval by Public Health Laboratory Director. ▪ Approval by DSHS IRB. ▪ Approval by RESC, as DSHS Commissioner designee.
2	Statistical Reports		
2.1	Statistical purposes, involving de-identified specimens and/or associated data	▪ Responding to legislative requests for aggregate data such as number of infants diagnosed with a particular condition in a certain time period. ▪ Requests for aggregate data from reporters, specialists or other stakeholders.	▪ Authorized by HSC Section 33.018(c)(1). ▪ Authorized by this policy (no further approval needed).
3	Public Health Research: Must satisfy "public health purpose" definition in Section 33.018(a)(5)—"Public health purpose" means a purpose that relates to cancer, a birth defect, an infectious disease, a chronic disease, environmental exposure, or newborn screening.		

Ref. No.	Use	Examples	Approval Requirements
3.1	Research conducted by DSHS public health programs, involving identified or de-identified specimens and/or associated data.	▪ Research evaluating links between NBS markers and specific disorders/ diseases.	▪ Authorized by HSC Section 33.018(b)(5). ▪ Approval by Public Health Laboratory Director. ▪ Approval by Newborn Screening Unit Director, when Clinical Care Coordination data are requested. ▪ Approval by DSHS IRB. ▪ Approval by RESC, as DSHS Commissioner designee.

Ref. No.	Use	Examples	Approval Requirements
3.2	Joint projects between DSHS and an external entity for research purposes in which the identity of the individual is known at DSHS, but specimens and/or associated data are de-identified prior to distribution to the external co- researcher.	▪ Joint research to implement a pilot newborn screening test. ▪ Joint research to evaluate links between diseases	▪ Authorized by HSC Section 33.018(b)(5) and 33.018(c-1) (Involvement of the external co-researcher requires consent via the Parent Decision Form for Storage and Use of Newborn Screening Blood Spot Cards sent to DSHS after the infant's birth). ▪ Approval by Public Health Laboratory Director. ▪ Approval by Newborn Screening Unit Director, when Clinical Care Coordination data are requested. ▪ Approval by DSHS IRB. ▪ Approval by RESC, as DSHS Commissioner designee.

Ref. No.	Use	Examples	Approval Requirements
3.3	Public health research conducted by external entities, involving de-identified specimens and/or associated data.	▪ Development of a test to measure compounds in blood spots to determine perinatal exposure and their effects on newborns. ▪ Development of a newborn screening test by an external entity.	▪ Authorized by HSC Section 33.018(c-1) (Involvement of the external researcher requires consent via the Parent Decision Form for Storage and Use of Newborn Screening Blood Spot Cards sent to DSHS after the infant's birth). ▪ Approval by Public Health Laboratory Director. ▪ Approval by Newborn Screening Unit Director, when Clinical Care Coordination data are requested. ▪ Approval by DSHS IRB. ▪ Approval by RESC, as DSHS Commissioner designee.

Ref. No.	Use	Examples	Approval Requirements
3.4	Any public health research with advanced informed parental consent.		▪ Authorized by HSC Section 33.018(b)(2) (Involvement of the external researcher requires project-specific consent). ▪ Approval by PHLD Deputy Commissioner. ▪ Approval by DSHS IRB. ▪ Approval by RESC, as DSHS Commissioner designee.