

 <p>Management of Newborn Screening Specimens and Data</p>	Policy Number	CD-2010.01
	Effective Date (<i>original issue</i>)	August 6, 2010
	Revision Date (<i>most recent</i>)	
	Subject Matter Expert (<i>title</i>)	Manager, Laboratory Operations Unit
	Approval Authority (<i>title</i>)	Commissioner
	Signed by David L Lakey	

1.0 Purpose

The purpose of this policy is to provide guidance for obtaining appropriate Department of State Health Services (DSHS) management review and approval of proposed residual uses of newborn screening (NBS) residual specimens and associated data which are otherwise allowable under Texas Health and Safety Code, Chapter 33, Subchapter B.

2.0 Policy

When looking at proposed residual uses that are allowable but not mandatory under the statute, 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 (*PA-4002 Institutional Review Boards*).

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)].

This policy is not applicable to residual uses that are at the express written instruction of the parent/managing conservator/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).

3.0 Definitions

- 3.1 **Affiliated with a Health Agency.** A person who is an employee or former employee of a health agency.
- 3.2 **De-identified.** Specimens or 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.

- 3.3 **Clinical Laboratory Improvement Act Of 1988 (CLIA).** Federal law, which establishes standards for clinical laboratory testing, that DSHS must follow in order to be CLIA-certified. An objective of CLIA is to ensure the accuracy, reliability and timeliness of laboratory test results.
- 3.4 **Identified.** Specimens or associated data which contain any information that directly or could reasonably be said to indirectly allow the linkage of a NBS blood spot or data derived from the blood spot back to the child or the parents of the child from which the specimen was collected.
- 3.5 **Institutional Review Board (IRB).** A specially constituted review body established or designated by an entity to protect the welfare of “human subjects” (which includes the specimens referenced in this policy) in a research context. The DSHS IRB operates in accordance with federal IRB law. By policy, DSHS has chosen to have the DSHS IRB review all research projects regardless of funding source (PA-4002 Institutional Review Boards). In addition, Code Sec. 33.018 currently requires DSHS IRB review of specific proposed uses of NBS specimens and/or associated data.
- 3.6 **Newborn screening (NBS).** One or more tests to identify a newborn that 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. This screening is conducted under Chapter 33 of the Texas Health and Safety Code.
- 3.7 **Newborn screening data (data).** Includes demographic information received on the NBS specimen collection form, NBS 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).
- 3.8 **Newborn Screening Program.** The Texas Newborn Screening Program includes the laboratory and clinical care coordination functions that enable early detection and treatment to prevent serious complications in infants with congenital and heritable conditions.
- 3.9 **Newborn screening specimen.** Dried blood spot (DBS) 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. Other equivalent terms used include dried blood spot specimen or blood spot.
- 3.10 **Parent.** For purposes of this policy, the term refers to a parent, managing conservator or legal guardian.
- 3.11 **Proficiency testing.** A quality assurance process in which unknown samples, provided by an external source, are tested in order to verify the performance (e.g. accuracy and/or precision) of laboratory testing. In order for the DSHS Laboratory to remain federally certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), the State of Texas Newborn Screening Program must participate in ongoing proficiency testing. Such testing is also required to ensure ongoing reliability of NBS test results.
- 3.12 **Public health purpose.** A “public health purpose,” for purposes of this policy, relates to cancer, a birth defect, an infectious disease, a chronic disease, environmental exposure, or newborn screening. The term is defined in Code Sec. 33.018(a), and is used to limit agency discretion in these scenarios at Code Sec. 33.018(f)(1).
- 3.13 **Quality assurance and quality control (QA/QC).** Quality assurance consists of multiple processes and measures, including quality control, to monitor a system and identify successes as well as potential problems before they adversely affect the final product. As used in the Texas Newborn Screening Program, quality assurance is used to monitor the entire testing process, from the time the specimen

is collected until the results are reported to the healthcare provider. Quality control is a specific check designed to ensure that the final test result is valid. For example, quality control in the Texas Newborn Screening Program includes checks to ensure the specimen is acceptable for testing, that the instruments and chemicals operate correctly, and that the results being reported to the healthcare provider are consistently accurate. The Texas Newborn Screening Laboratory must adhere to federal CLIA requirements for laboratory certification, including ongoing QA/QC and proficiency testing.

- 3.14 **Research.** Research is as defined in federal regulations related to Institutional Review Boards, found at 45 CFR Chapter 46.
- 3.15 **Research Executive Steering Committee (RESC).** Committee comprised of DSHS managers including the General Counsel, State Epidemiologist, Chief Operating Officer and one or more Assistant Commissioners (RESC is also referenced in PA-4002 Institutional Review Boards).
- 3.16 **Residual use.** Use of a specimen(s) and/or associated data that occurs after newborn screening is completed.
- 3.17 **Retention period.** The minimum time that must pass after the creation, recording, or receipt of a record, or the fulfillment of certain actions associated with a record, before it is eligible for destruction. DSHS is bound by its approved records retention schedule under the Texas Government Code. Both NBS data and the blood spot specimens themselves are “state records” under the Texas Government Code Chapter 441 (a specimen becomes a state record once it is received at DSHS for testing).

4.0 Persons affected

Persons affected by this policy include

- Employees working in the Newborn Screening Program, which includes:
 - Staff in the Laboratory Services Section of the Disease Control and Prevention Services Division of DSHS; and
 - Staff in the Newborn Screening Unit of the Family and Community Health Division of DSHS
- DSHS staff in program areas outside of the Newborn Screening Program who will be conducting substantive reviews of residual use proposals;
- DSHS management and leadership, who will be involved in reviewing proposed residual usages under this policy;
- Members of the DSHS IRB; and
- Those parties (internal or external) who submit a request for residual use.

5.0 Responsibilities

- 5.1 The Laboratory Services Section is responsible for ensuring that proposed residual uses are processed in accordance with this policy, DSHS IRB policy (PA-4002 Institutional Review Boards), as well as with applicable law. DSHS Laboratory Services Section managers must conduct reviews of proposed residual uses, as outlined in this policy.
- 5.2 The Specialized Health Services Section (i.e. the portion of the Newborn Screening Program that assists with coordination of clinical care) is responsible for ensuring that proposed residual data uses are processed in accordance with this policy, DSHS IRB policy (PA-4002 Institutional Review Boards), as well as with applicable

law. DSHS Specialized Health Services Section managers must conduct reviews of proposed residual uses, as outlined in this policy.

- 5.3 A DSHS program representative will serve as the Program Contact when DSHS receives requests from external parties for residual use that are relevant to that particular DSHS Program (e.g. Birth Defects Program). The Program Contact must conduct the initial review of such proposals, and must work with the Laboratory Services Section Point of Contact to aid in determining the overall DSHS response to the request. The Program Contact must submit a written review of the proposal to the Laboratory Services Section Point of Contact. The analysis should include a diligent review of the proposal from a public health perspective as well as from a legal perspective. That analysis must indicate whether the program does or does not recommend that the proposal be approved, and must indicate the policy and legal reasoning behind the recommendation. The Program Contact must consult the appropriate DSHS program attorney as part of preparing the analysis. The analysis must be consistent with this policy, including Table 1. When the request for residual use comes from a DSHS program, it must have sign-off from the section director over that program area.
- 5.4 The DSHS IRB must act consistently with legal requirements, with DSHS IRB policy (PA-4002 Institutional Review Boards), and with this policy when considering proposed residual research or external QA/QC-under Code Section 33.018 regarding NBS confidentiality. Note that this statutory provision puts additional areas of responsibility on the DSHS IRB by requiring review of research with de-identified specimens and/or data as well as review of certain non-research proposals such as those for external QA/QC.
- 5.5 The DSHS Office of General Counsel (OGC) will be consulted as needed in order to assure compliance with the law and this policy.
- 5.6 Under Code Sec. 33.018 and this policy, the RESC will provide DSHS executive review of all research proposals (described in Table 1: Section 3) and of external QA/QC-related requests (described in Table 1: section 1.7), to determine whether the proposal should be approved, denied, or sent to the DSHS Commissioner for further review and approval. When the proposed use requires DSHS IRB review under law or agency policy that review happens prior to the RESC review.
- 5.7 The DSHS Commissioner or designee must act consistently with the law, with DSHS IRB policy (PA-4002 Institutional Review Boards), and with this policy when considering proposed residual research and QA/QC uses under Code Section 33.018 regarding NBS confidentiality. The statute requires commissioner or designee approval for specific types of proposed uses of residual blood spots and/or associated data.

6.0 Procedures

6.1 Uses of NBS Specimens and/or Associated Data

Code Section 33.018 regarding Confidentiality, mandates that NBS specimens and/or associated data can only be used or disclosed in certain circumstances, for specific purposes and with appropriate levels of review and approval. Included in these allowable purposes are certain QA/QC and research uses. However, the fact that a certain QA/QC or research use is permissible under the statute does not mean that DSHS must allow such a use. Table 1 specifies the process for how such decisions are made. A proposal must be approved at each level before moving onto the next level for approval.

Please note, for purposes of this policy, individuals that are part of DSHS or entities contracted to act on the behalf of DSHS for the stated purpose are considered "internal".

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	<p>DSHS QA/QC, related to its Laboratory's newborn screening activities, necessary for maintaining federal certification under CLIA. Involves identified and/or de-identified specimens and/or associated data, but no external parties.</p>	<ul style="list-style-type: none"> ▪ Validation, verification, or evaluation of testing methods, modified protocols, instrumentation, or reagents. ▪ Use of blood spots as quality control material to ensure validity/accuracy of each laboratory test. 	<ul style="list-style-type: none"> ▪ Authorized by Section 33.018(b)(7). ▪ Authorized by this policy (no further approval needed).
1.2	<p>DSHS QA/QC, related to its Laboratory's newborn screening activities, necessary for maintaining federal certification under CLIA. Involves sharing of de-identified specimens and/or associated data with: other state newborn screening laboratories as part of the required proficiency testing exchanges; and with the DSHS newborn screening contractors who supply equipment and supplies, to troubleshoot issues that arise in the Texas screening processes.</p>	<ul style="list-style-type: none"> ▪ 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. 	<ul style="list-style-type: none"> ▪ Authorized by Section 33.018(c)(2)(A). ▪ Authorized by this policy (no further approval needed).
1.3	<p>DSHS NBS Program evaluation of existing processes for NBS internal review and quality assurance, involving identified or de-identified specimens and/or associated data.</p>	<ul style="list-style-type: none"> ▪ Evaluating newborn screening system performance measures to identify areas in need of improvement (e.g. turnaround time and percentage of specimens unsatisfactory for testing). 	<ul style="list-style-type: none"> ▪ Authorized by Section 33.018(b)(6). ▪ Authorized by this policy (no further approval needed).
1.4	<p>DSHS NBS Program reports de-identified newborn screening data for federal initiatives to evaluate national trends related to newborn screening. Access to the federal compilation of data facilitates improvement of the Texas NBS Program.</p>	<ul style="list-style-type: none"> ▪ Reporting de-identified data to Newborn Screening Technical Assistance and Evaluation Program (NewSTEPS) to compare the DSHS NBS Program to that of other state NBS programs. ▪ Evaluating the efficacy of the routine second 	<ul style="list-style-type: none"> ▪ Authorized by Section 33.018(c)(1) and 33.018(b)(8). ▪ Approval by Biochemistry and Genetics Branch Manager, acting as DSHS Commissioner designee when laboratory data or specimens are involved. ▪ Approval by Newborn Screening Unit Director,

Ref. No.	Use	Examples	Approval Requirements
		newborn screen in identifying cases of congenital hypothyroidism and congenital adrenal hyperplasia by evaluating retrospective data.	acting as DSHS Commissioner designee when clinical care coordination data are involved.
1.5	Changes to the existing DSHS NBS Program to improve testing and/or follow-up services.	<ul style="list-style-type: none"> ▪ Improvement of DSHS NBS Program processes including evaluation and development of alternative methods/algorithms, second tier testing and/or addition of new disorders to the NBS panel. 	<ul style="list-style-type: none"> ▪ Authorized by Section 33.018(b)(8). ▪ Approval by Laboratory Services Section Director, as DSHS Commissioner designee. ▪ Approval by Specialized Health Services Section 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 remain CLIA-compliant referenced at 1.2 above), related to monitoring and enhancing their processes. Releases only involve de-identified specimens and/or associated data.	<ul style="list-style-type: none"> ▪ Validating, troubleshooting, and evaluating NBS laboratory tests at CDC or in another state's NBS Program. ▪ Training personnel from another state's NBS Program on testing methodologies. 	<ul style="list-style-type: none"> ▪ Authorized by Section 33.018(c)(2)(B). ▪ Approval by Laboratory Services Section Director, as DSHS Commissioner designee. ▪ Approval by Specialized Health Services Section Director, when Clinical Care Coordination data are requested.
1.7	QA/QC purposes related to public health testing equipment and/or supplies. This use involves identified specimens and/or associated data when work is performed by DSHS or its contractor, or de-identified specimens and/or associated data when sent to other external entities.	<ul style="list-style-type: none"> ▪ 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. 	<ul style="list-style-type: none"> ▪ Authorized by Section 33.018(c)(3). ▪ Approval by DSHS program director, when applicable. ▪ Approval by Laboratory Services Section Director. ▪ Approval by DSHS IRB. ▪ Approval by RESC, as Commissioner designee.
2	Statistical Reports		

Ref. No.	Use	Examples	Approval Requirements
2.1	Statistical purposes, involving de-identified specimens and/or associated data.	<ul style="list-style-type: none"> ▪ Responding to legislative requests for aggregate data such as number of infants diagnosed with a particular condition in a certain time period. 	<ul style="list-style-type: none"> ▪ Authorized by 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.		
3.1	Research conducted by DSHS public health programs, involving identified or de-identified specimens and/or associated data.	<ul style="list-style-type: none"> ▪ Research like the Evaluation of a Second-Tier Congenital Adrenal Hyperplasia Screening method, to develop new tests for the Texas Newborn Screening Program. ▪ Research to evaluate the link between prenatal lead exposure and infant blood lead levels. 	<ul style="list-style-type: none"> ▪ Authorized by Section 33.018(b)(5). ▪ Approval by DSHS Program director, when applicable. ▪ Approval by Laboratory Services Section Director. ▪ Approval by Specialized Health Services Section Director, when Clinical Care Coordination data are requested. ▪ Approval by DSHS IRB. ▪ Approval by RESC, as DSHS Commissioner designee.
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.	<ul style="list-style-type: none"> ▪ Research to implement a pilot newborn screening test for severe combined immunodeficiency (SCID). ▪ Research to evaluate the link between hydrocephalus and infection with Cytomegalovirus (CMV), Lymphocytic Choriomeningitis Virus (LCMV), and Toxoplasmosis gondii. 	<ul style="list-style-type: none"> ▪ Authorized by Section 33.018(c-1) (Involvement of the external co-researcher requires consent via the <i>Parental Decision for Storage and Use of Newborn Screening Blood Spot Cards</i> form sent to DSHS after the infants birth). ▪ Approval by DSHS Program Section Director, when applicable. ▪ Approval by Laboratory Services Section Director ▪ Approval by Specialized Health Services Section 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	Research conducted by external entities, involving de-identified specimens and/or associated data.	<ul style="list-style-type: none"> ▪ Development of a test to measure polyfluoroalkyl compounds in blood spots to determine perinatal exposure and its effects on newborns. ▪ Development of a newborn screening test for biotinidase deficiency. 	<ul style="list-style-type: none"> ▪ Authorized by Section 33.018(c-1) (Involvement of the external researcher requires consent via the <i>Parental Decision for Storage and Use of Newborn Screening Blood Spot Cards</i> sent to DSHS after the infants birth). ▪ Approval by DSHS Program Section Director, when applicable. ▪ Approval by Laboratory Services Section Director. ▪ Approval by Specialized Health Services Section Director, when Clinical Care Coordination data are requested. ▪ Approval by DSHS IRB. ▪ Approval by RESC, as DSHS Commissioner designee.
4	<ul style="list-style-type: none"> ▪ Non-public Health Purpose: Certain uses are otherwise specifically prohibited by Section 33.018(f)(2). 		
4.1	Non-public health purpose use.	<ul style="list-style-type: none"> ▪ For forensic science use. ▪ For health insurance underwriting use. 	<ul style="list-style-type: none"> ▪ Only authorized pursuant to specific advance written directives from the parent (or from the grown child, as an adult) after approval by Office of General Council [see Code Sec. 38.018(f)].

6.2 Request and Approval Process For Uses That Require IRB and RESC Reviews

The procedures to request NBS specimens and/or associated data for the residual uses that are described in Table 1: Sections 1.7 and Section 3 are listed below:

1. The requestor must submit a detailed written request to the appropriate DSHS Program Contact using the Request For Residual Newborn Screening (NBS) Specimens and/or Associated Data Form.
2. The DSHS Program Contact will review the request for scientific merit and to ensure the usage fits within the definition of public health purpose. If the DSHS Program Contact approves the initial proposal, the DSHS Program Contact shall notify the NBS Program Contact of their approval and forward him/her the proposal and associated documents for further review. If the proposal is approved by the NBS Program Contact, the request and associated documents will be submitted for further management review as listed in Table 1.

3. If approved by the NBS Program Contact, the requestor will then be asked to complete the required DSHS IRB documents and submit to the DSHS Program Contact. Preparation of required IRB documentation will be the responsibility of the requesting party.
4. A proposal must be approved at each level before moving onto the next level for approval (as specified in Table 1).
5. The proposal and IRB documents will be submitted to the DSHS IRB after appropriate DSHS management approvals are given.
6. The DSHS IRB will review proposed uses under the requirements of Code Sec. 33.018 and of this policy, while also making sure the study is consistent with federal IRB criteria, including HIPAA regulations on the use and disclosure of protected health information for research purposes [Title 45 Code of Federal Regulations Section 164.512(i)]. (Also see DSHS policy, PA-4002, Institutional Review Board.) Substantive changes in the proposal at this IRB review stage will require re-review of the revised proposal from a policy standpoint. Please note that approval of the project from a policy perspective does not guarantee subsequent approval of the project by the DSHS IRB, the RESC or the Commissioner.
7. The DSHS RESC must review each DSHS-IRB approved proposal and determine whether the proposal should be approved or sent to the DSHS Commissioner for further review and approval. (Upon request of executive leadership, the RESC may review any other proposed residual use.)
8. If the request is approved according to the process specified in Table 1, DSHS may then release NBS specimens and/or associated data for use only as provided in the approved written proposal.
9. For uses by external entities, DSHS shall document the public health purpose of the use, and the external entity shall agree to sufficient controls to ensure that the public health purpose is achieved (e.g. contract or memorandum of understanding provisions that restrict the use to that represented to DSHS, and links to the effective date of any applicable IRB approval and/or data use agreement).
10. The DSHS Program Contact will be responsible for following up with the researcher or external entity to ensure required documentation is submitted to the DSHS IRB at the conclusion of the approved project and to confirm final disposition of residual use.

The approval process for requests requiring approval of the Commissioner and IRB may take approximately three months after receipt of the complete request.

6.3 Notifications of Approval

1. For proposals that were approved for the residual uses that are described in Table 1: Sections 1.7, 3.2, and 3.3, a notice that the agency has approved a request will be posted on the DSHS NBS website.
 - a. The Biochemistry and Genetics Branch Manager or the Laboratory Operations Unit Manager of the Laboratory Services Section will ensure that the notice is posted in a timely manner.
 - b. The Biochemistry and Genetics Branch Manager or Laboratory Operations Unit Manager of the Laboratory Services section will notify appropriate DSHS Leadership, DSHS Press Office, Office of Government Affairs and Office of General Counsel when notices of approved proposals have been posted on the DSHS NBS website.

2. The Laboratory Services Section Director or designee will submit a summary report of all residual uses that required approval by the Commissioner or designee to the DSHS Commissioner every six months.

7.0 Revision History

Date	Action	Section
07/01/13	Revised policy to be in compliance with HB411 of the 82 nd Texas Legislative Session	All
08/06/10	New policy	All