Management of Newborn Screening Specimens and Data	Tracking Number	
	Effective Date	August 6, 2010
	Revision Date	
	Subject Matter Expert	Manager, Biochemistry and Genetics Branch
	Approval Authority	Commissioner
	Signed by David L. Lakey, M.D.	

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 post-screening uses of newborn screening (NBS) specimens and data which are otherwise allowable under Texas Health and Safety Code, Chapter 33, Subchapter B.

2.0 Policy

House Bill 1672, from the 2009 Session of the Texas Legislature, amended Chapter 33 of the Texas Health & Safety Code to provide explicit permissible uses for NBS specimens and data once the newborn screening itself has been completed [see Sec. 33.017]. Those amendments also provided for a disclosure statement regarding the allowable uses to be provided to parents at the time the newborn screening blood spots are collected, along with a blank form which gives the parents the option to instruct DSHS to destroy their child's specimen once newborn screening is completed [see Sec.s 33.0111, 33.0112]. For newborn screening blood spots which are stored by DSHS (because destruction has not been requested), internal and external proposals for Quality Assurance/Quality Control (QA/QC) and research use of the specimens and/or data are occasionally received. Even when such proposed uses are allowable under the statute (see Chapter 33, Subchapter B), a management review of the proposed use from a policy perspective shall be conducted as described in this policy.

This policy is not applicable to post-screening uses that are at the express written instruction of the parent/managing conservator/legal guardian under Sec. 33.017(b)(2) nor those by court order under Sec. 33.017(b)(3) (which will be reviewed by the Office of General Counsel) nor by request of a medical examiner under Sec. 33.017(b)(4). This policy does not apply to the release of de-identified data for statistical purposes under Sec.33.017(c)(1), nor is it applicable to clinical care coordination activities related to the newborn screening under Sec. 33.017(b)(1).

3.0 Definitions

3.1 **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. De-identification must be to the extent required by the Health Insurance Portability and Accountability Act (HIPAA).

3.2 **Health Insurance Portability and Accountability Act (HIPAA)** – The federal Health Insurance Portability and Accountability Act of 1996 and the regulations issued by the United States Department of Health and Human Services under the Act, including the HIPAA security and privacy regulations found at Title 45 Code of Federal Regulations Parts 160 and 164.

3.3 **Identified.** Specimens or data which contain any information that directly or indirectly allows the linkage of a blood spot or data derived from the NBS blood spot back to the child or the parents of the child from which the specimen was collected.

3.4 **Institutional Review Board (IRB).** A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in research. The DSHS IRB operates in accordance with federal IRB law and (for purposes of these types of projects) in accordance with HIPAA, because the NBS Laboratory is a HIPAA-covered entity. In addition, the Texas Health & Safety Code Sec. 33.017 requires DSHS IRB review of proposed QA/QC and research post-screening uses of NBS blood spots, as specified in that law.

3.5 **Newborn screening (NBS).** One or more tests to identify a newborn that may be at risk of having phenylketonuria, other heritable conditions, or hypothyroidism. This screening is conducted under Chapter 33 of the Texas Health & Safety Code.

3.6 **Newborn Screening data (data)**. Includes demographic information received on the NBS specimen collection form, the NBS test results, and case data compiled as part of the clinical coordination of care of individual children (i.e. with positive NBS test results).

3.7 **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 collection device. Other equivalent terms used include blood spot card, dried blood spot specimen, or blood spot.

3.8 **Parent.** For the purpose of this policy, this term means a parent, managing conservator or legal guardian.

3.9 **Proficiency testing.** A regulatory-required QA/QC 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.

3.10 **Provider.** A hospital, birthing facility, healthcare practitioner, midwife, clinic, or laboratory that collects and submits NBS specimens.

3.11 **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.

3.12 **Research.** A systematic investigation (i.e., the gathering and analysis of information) designed to develop or contribute to generalized knowledge.

3.13 **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 include employees working in the Laboratory Services Section of DSHS, DSHS staff in program areas besides the Laboratory who will be conducting substantive reviews of proposals, DSHS management who will be involved in reviewing proposed post-screening blood spot/data usages under this policy, and those parties (internal or external) who submit a request to use blood spots.

5.0 Responsibilities

Laboratory Services Section Responsibilities - The Laboratory Services Section is responsible for ensuring that proposed post-screening blood spot and/or data uses are processed in accordance with this policy, as well as with applicable law. DSHS managers must conduct reviews of proposed post-screening uses, as outlined in this policy.

DSHS Program Responsibilities – A DSHS Program will serve as a Program Contact when requests for NBS specimens and/or data that are relevant to a particular DSHS Program (e.g. Birth Defects Program) are submitted from an external source. The Program Contact will review proposals from external sources as well as any internal requests generated by the DSHS Program prior to submitting the request to the Laboratory Services Section. For specimen and/or data uses requiring Commissioner-level approval, the Program Contact will submit action memos and other requested documentation when required. DSHS managers must conduct reviews of proposed post-screening uses, as outlined in this policy.

IRB Responsibilities – The DSHS IRB must act consistently with this policy when considering proposed post-screening research and QA/QC when applicable under Texas Health and Safety Code Section 33.017 regarding NBS blood spots and data.

OGC Responsibilities – The DSHS Office of General Counsel will be consulted as needed in order to assure compliance with the law and this policy.

Commissioner Responsibilities - The DSHS Commissioner must act consistently with this policy when considering proposed post-screening research and QA/QC when applicable under Texas Health and Safety Code Section 33.017 regarding NBS blood spots and data.

5.1 Uses of NBS Specimens and/or Data

Texas Health and Safety Code Section 33.017(a)-(c) mandates that NBS specimens and data are confidential and can only be used or disclosed for specific purposes. 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 will be made. Note that for any external use of specimens or data in Table 1, the specimens or data will be de-identified unless advance parental consent is obtained.

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

Use	Examples	Approval Requirements

QA/QC for maintaining certification of the DSHS Laboratory to perform newborn screening tests and/or ensuring validity of test results, involving data and/or specimens	▪ QA/QC activities to comply with the Federal Clinical Laboratory Improvement Amendments of 1988 (CLIA)
	  ▪ Validation or verification of testing methods
	  ▪ Inter-laboratory exchange for proficiency testing
	  ▪ Reagent lot evaluations
	  ▪ Instrument validations
	▪ Instrument or reagent comparisons
	▪ Troubleshooting equipment and reagent issues (which
		▪ Authorized by Section 33.017(c)(2)
		▪ Authorized by this policy (no further approval needed)

Use	Examples	Approval Requirements
	may occur at DSHS or at location of the DSHS equipment/supply vendor)	
DSHS NBS Program evaluation (for both internal review and comparison with other state programs), involving data and/or specimens	▪ Reporting data to NBS databases such as the National Newborn Screening Information System (NNSIS) and the Region 4 Genetics Collaborative (both federally funded by Health Resources and Services Administration), and conducting periodic review of information in those databases to compare the Texas NBS Program to that of other states ▪ Retrospective reviews of existing test/analytical or clinical care coordination data ▪ Evaluating newborn screening system performance measures	▪ Authorized by Section 33.017(c)(3) ▪ Authorized by this policy (no further approval needed)
Improvement of current NBS testing methods for DSHS Program, involving data and/or specimens	▪ Improvement of NBS Program processes ▪ Preliminary evaluation of products for possible inclusion into DSHS NBS processes ▪ Development and implementation of alternate screening methods ▪ Development of second-tier testing methods	▪ Authorized by Section 33.017(c)(3) ▪ Approval by Laboratory Services Section Director ▪ Approval by Specialized Health Services Section Director, when proposed program improvement would impact NBS Clinical Care Coordination Group
QA/QC purposes related to other public health newborn screening laboratory (i.e. not part of inter-laboratory exchanges needed for DSHS Laboratory to remain CLIA-compliant), involving data and/or specimens	▪ Validating NBS laboratory tests at CDC or in other state NBS Programs	▪ Authorized by Section 33.017(c)(2) ▪ Approval by Laboratory Services Section Director
QA/QC purposes conducted by an external entity or by DSHS NBS staff on behalf of the external entity (not a laboratory), involving specimens	▪ Evaluation of equipment or supplies for use in newborn screening ▪ QA/QC of commercial equipment or supplies used in public health testing (ex. HIV test kit)	▪ Authorized by Section 33.017(c)(5) ▪ Approval by DSHS program area administrative director ▪ Approval by Laboratory Services Section Director ▪ Approval by DSHS Commissioner

Use	Examples	Approval Requirements
		▪ Approval by DSHS IRB
Public health research purposes conducted by DSHS public health programs, involving data and/or specimens	▪ Clinical, epidemiological, and/or toxicological research related to public health ▪ Pilot testing new tests in NBS Laboratory for potential expansion of NBS panel of disorders	▪ Authorized by Section 33.017(b)(5) ▪ Approval by DSHS Program area administrative director, when applicable ▪ Approval by Laboratory Services Section Director ▪ Approval by DSHS IRB
Joint projects between DSHS and an external entity for public health research purposes in which data and/or specimens are identified internally at DSHS but are de-identified prior to distribution to an external entity	▪ Clinical, epidemiological, and/or toxicological research related to public health	▪ Authorized by Sections 33.017(b)(5) (as to DSHS public health program staff) and 33.017(c)(4) (as to external entities) ▪ Approval by DSHS program area administrative director. when applicable ▪ Approval by Laboratory Services Section Director ▪ Approval by DSHS Commissioner ▪ Approval by DSHS IRB
Research for public health purposes conducted by external entities, alone or in conjunction with DSHS, involving data and/or specimens	▪ Epidemiological evaluation of data for public health purposes (e.g. correlation between NBS analyte levels and a particular disorder) ▪ Participation in national public health studies where only data is shared (e.g. federally funded National Second Screen Study) ▪ Clinical, epidemiological, and/or toxicological research related to public health ▪ Evaluation or development of commercial equipment or supplies related to public health	▪ Authorized by Section 33.017(c)(4) ▪ Approval by DSHS program area administrative director, when applicable ▪ Approval by Laboratory Services Section Director ▪ Approval by DSHS Commissioner ▪ Approval by DSHS IRB
Non-public health research	▪ Law enforcement	▪ Will not be approved

5.2 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).

5.3 Request and Approval Process for the Use of NBS Specimens and/or Data

The procedures to request post-screening QA/QC or research use of NBS specimens and/or data for those activities requiring additional approval levels (see Table 1) are listed below:

1. The requestor must submit a detailed written request to the appropriate DSHS Program Contact. For proposals that require IRB review, the requestor should include the required DSHS IRB submission documents, which will satisfy the "detailed written request" requirement. Preparation of required IRB documentation will be the responsibility of the requesting party.
2. The request will be submitted for management review as listed in Table 1. Please note that management approval of the project from a policy perspective does not guarantee subsequent approval of the project by the DSHS IRB. The management policy review is in addition to the DSHS IRB review, not a substitute for it. Appropriate DSHS program areas shall assist as needed in the management review process, including drafting of an action memo for the Commissioner's signature, when applicable.
3. When approval of the DSHS Commissioner is required, an action memo that summarizes the proposed use, and requests a decision as to whether the use of specimens and/or data should be permitted, will be sent to the DSHS Commissioner by the DSHS Program Contact after approval by the appropriate Assistant Commissioner. The complete DSHS IRB documents should accompany the action memo, if applicable.
4. When DSHS IRB approval is required, the proposal and IRB documents will be submitted to the DSHS IRB after appropriate management approvals are received. At that point in the process, communications will be between the proposing entity and the DSHS IRB. Substantive changes in the proposal at this IRB review stage will require management re-review of the revised proposal from a policy standpoint.
5. The DSHS IRB will review proposed uses under the requirements of Texas Health & Safety Code Sec. 33.017, 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.)
6. If the request is approved according to the appropriate procedure specified in Table 1, DSHS may then release NBS specimens and/or data for use only as provided in the written proposal that was ultimately approved.
7. For proposals that were approved through the Commissioner, 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.
8. The Laboratory Services Section Director or designee will submit a summary report of all approved requests to the DSHS Commissioner every six months.
9. 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 data and/or specimens.

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

6.0 Revision History

Date	Action	Section
	New policy.	