Requests for Residual Newborn Screening Specimens and/or Data—Research and QA/QC purposes

Consistent with Texas state law, DSHS has a strict policy regarding allowable uses of residual newborn screening blood spots and associated data; Title 2 Texas Health and Safety Code § 33.018, AP 1000. This form must be completed for all proposed releases of newborn screening specimens and/or data that are for Quality Assurance/Quality Control (QA/QC) and/or research as the terms defined under Title 2 Texas Health and Safety Code §§ 33.018(b)(5), (c-1),(c)(3).*

- All proposed public health research uses are reviewed by DSHS Program Review Group and the DSHS IRB.** The IRB is tasked with ensuring the protection of the safety, rights, and welfare of human participants involved in the project (human specimens included).
- Quality Assurance/Quality Control uses related to public health testing equipment and supplies (as specified in the policy referenced above) are also reviewed by DSHS Program Review Group and the DSHS IRB.
- If a project is approved, the requester may only use the blood spots and/or data in accordance with the terms and conditions of the IRB-approved application and its proceeding associated documents approved under OneAgeis, in accordance with AP-900, including, but not limited to, associated policies, guidelines, state and federal law.

Overview of Request Review Process:

1. Requestor completes Page 2 of this form.
2. Requestor submits request by email to NBSDataRequest@dshs.texas.gov and the DSHS Program Contact, if applicable.
3. The PHLD Division Program Contact will contact the requestor to verify the receipt of the request and seek clarification, if needed.
4. Program Review Group determines project eligibility in accordance with all applicable policies and law.
5. Program Review Group may contact requestor to better understand how the request can be tailored to meet the project's needs, at the discretion of PHLD, and in accordance with applicable standards, guidance, policies, and law.
6. If approved by Program Review Group and Laboratory Director, requestor is informed to submit for DSHS IRB review.
7. DSHS IRB reviews the request during its monthly meeting.
   a. If the request is not approved by DSHS IRB, the requester is notified by DSHS IRB.
   b. DSHS IRB-approved requests are sent to the Research Executive Steering Committee (RESC) for review and approval. The RESC will also determine if review and approval by the DSHS Commissioner is required.
8. DSHS IRB must notify the requestor of its decision, including changes required to meet data or specimen release terms and conditions.

Notes

* QA/QC uses expressly allowed under HSC Sec. 33.018(b)(6), (b)(7), (b)(8), and (c)(2) are not within the scope of this form.

** Program Review Group's determination is contingent upon approval from the appropriate authority.

Contacts and More Information

- **Email DSHS Newborn Screening Data Request:** NBSDataRequest@dshs.texas.gov
- **Phone:** 512-776-7585
- **Fax:** 512-776-7157
- **DSHS Newborn Screening website:** http://www.dshs.state.tx.us/lab/newbornscreening.shtm
- **DSHS IRB website:** http://www.dshs.state.tx.us/irb/Default.shtm.

Request for Residual Newborn Screening Specimens and/or Data Form

Requestor	**Name & Title:**	
	Mailing Address:	
	City, State, Zip:	
	Phone #:	
	Email Address:	
Project Contact	**Name & Title**:	
	Phone #:	
	Email Address:	
	Organization/Institution Name:	
Program Contact	**Name & Title:**	
	Email Address:	
	DSHS Program/Division:	
Project Overview	**Title of Study** (if available):	
	Funding Source: (Is the project federally funded?)	
	Summary of Project: Include how the project supports a public health** or QA/QC purpose. Explain why newborn screening specimens and or data are necessary.	
Request Information	**Approximate # of residual blood spot specimens requested:** Also include frequency of delivery, if applicable.	
	Sub-population specifications: (e.g., 1st screen 24-48 hours after birth, 2nd screen 7 days after birth or more, etc.)	
	Specific data field(s) requested (if applicable): Include a brief explanation of how each field will be used and/or why each field is critical to the project outcome.	
	Date specimens and/or data are needed:	

For DSHS Use Only:

Please enter your information and assessment below.

Program Review Group Liaison: Click here to enter text.
Title: Click here to enter text.
Telephone: Click here to enter text.
Summary: Click here to enter text.
Program Contact:
Recommendation: Click here to enter text.

PHLD Deputy Laboratory Director Name: Click here to enter text.
Title: Click here to enter text.
Telephone:
Summary: Click here to enter text.
Recommendation: Click here to enter text.

PHLD Laboratory Director Name: Click here to enter text.
Title: Click here to enter text.
Telephone: Click here to enter text.
Summary: Click here to enter text.
Recommendation:

Newborn Screening Director Name (if applicable): Click here to enter text.
DSHS Division & Section: Click here to enter text.
Title: Click here to enter text.
Telephone: Click here to enter text.
Summary: Click here to enter text.
Recommendation: Click here to enter text.