

# TEXAS CONSENT METHODOLOGY FOR SAMPLE STORAGE & RESEARCH

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Laboratory Operations Unit Manager

# OUTLINE

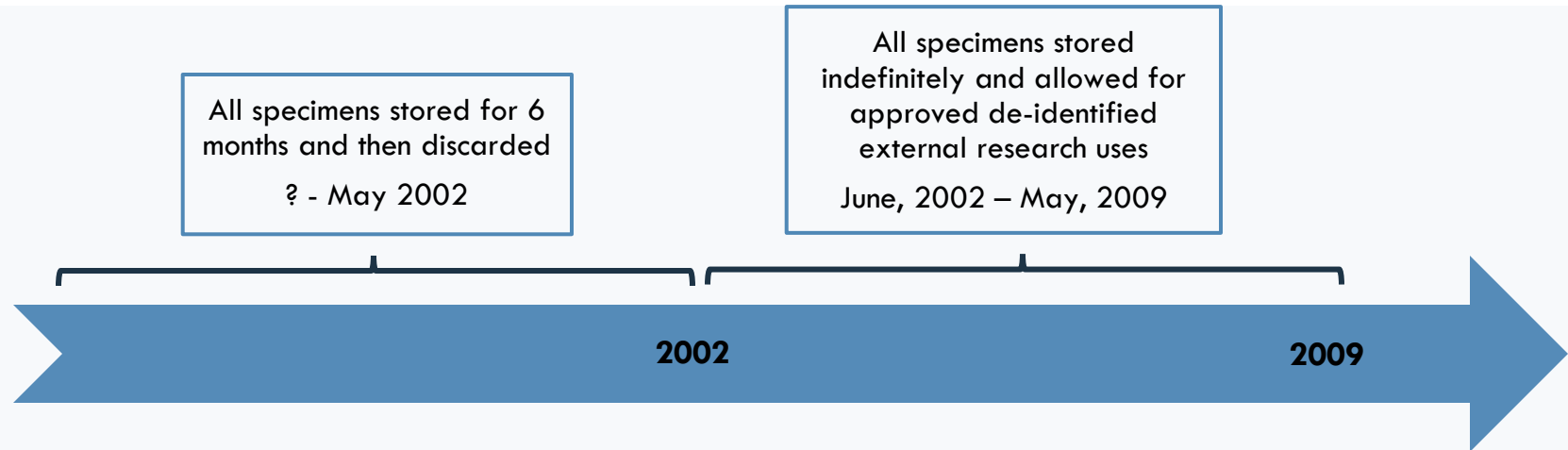
- Background
- Specimen Retention in Texas
  - ▣ Historical
  - ▣ Opt out
  - ▣ Opt in
- Moving forward

# NEWBORN SCREENING IN TEXAS

- Administered by Dept. of State Health Services (DSHS)
- ~400,000 births annually at 399 birthing facilities
- Two screen state
  - 24-48 hours of life
  - 1-2 weeks of life
- ~780,000 specimens screened in 2014
- 2153 providers submitted at least 1 specimen in 2014

# EARLY SPECIMEN RETENTION

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2002 – Changed specimen retention from 6 months to indefinite

- No specific policy
- De-identified specimens allowed for external research uses with DSHS IRB approval

# HISTORY OF STORAGE AND USE IN TEXAS

- 2006 – Entered into MOU with Texas A&M for long-term storage
- 2009 Legislative Session – HB 1672 filed
  - Added provisions to allow use of residual newborn screening specimens for quality assurance & quality control, quality improvement and research use (de-identified)
  - DSHS suggested language to preserve most important uses

# BEGINNINGS OF AN 'OPT-OUT' SYSTEM

- February 2009 – Local newspaper ran story about residual NBS specimen storage and use
- March 2009 – Lawsuit filed against DSHS & Texas A&M
  - ▣ Alleged that Texas Law violated the US Constitution
    - Unlawful search and seizure – 4<sup>th</sup> Amendment
    - Alleged violations of right to liberty and privacy – 14<sup>th</sup> Amendment
  - ▣ Started receiving parental requests for specimen destruction
- April 2009 – Posted specimen destruction request/disclosure form on the DSHS website

# HB 1672 – OPT OUT

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All specimens stored indefinitely and allowed for approved de-identified external research uses  
June, 2002 – May, 2009

HB 1672  
(Opt Out)

2008

2009



2010

2011

2012

2013

- HB 1672 signed into law – May 27, 2009
  - ▣ Added provisions to allow use of residual newborn screening specimens for quality assurance & quality control, quality improvement and research use
  - ▣ Added disclosure requirement and provision to allow parents to request specimen destruction
  - ▣ Unless parent Opts out:
    - Specimens stored up to 25 years
    - De-identified specimens and data allowed for approved external research purposes



# IMPLEMENTATION OF 'OPT-OUT'

- Disclosure/Destruction request form distributed to providers in August 2009 (Separate from NBS kit)
- Providers required to:
  - ▣ Distribute form to parents upon each NBS collection
  - ▣ Return form to DSHS if requested by parent
- DSHS required to destroy specimens within 60 days of request receipt



# HB 1672 – OPT OUT

- TX DSHS developed kit-based Directive to Destroy form
- June 2010 – New specimen kits available for providers that included disclosure/request to destroy form

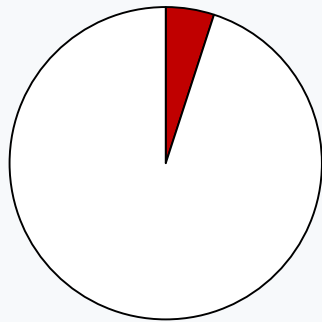
 <p style="text-align: center; font-weight: bold; font-size: 24px;">7</p> <p style="text-align: center; font-weight: bold; font-size: 18px;">TX 11-200001</p>	<p style="text-align: center;"><b>Use and Storage of Newborn Screening Blood Spot Cards</b></p> <p style="text-align: center; background-color: yellow;"><b>PARENT / MANAGING CONSERVATOR / LEGAL GUARDIAN PLEASE READ CAREFULLY</b></p> <p><b>What is newborn screening (NBS)?</b> The Texas Newborn Screening Program checks Texas babies for a list of serious medical conditions. These conditions can cause death or severe disability. Finding a medical problem during newborn screening can help prevent problems and may save your baby's life.</p> <p><b>How does your baby get screened?</b> A small amount of your baby's blood is placed on a special blood spot card. The blood spot card is sent to the state laboratory and tested.</p> <p><b>What happens after the blood is tested?</b> After testing, blood spot cards are safely stored by the Texas Department of State Health Services (DSHS) because they still have important public health uses. The main uses are: 1) quality assurance/quality control, such as making sure that testing equipment continues to produce accurate newborn screening test results for Texas babies, and 2) medical research (see <i>Texas Health and Safety Code Sec. 33.017(b)-(c)</i> for a complete list of uses allowed by law). Specific information that could identify your child and connect him/her to a particular blood spot card is not allowed outside of DSHS without permission from the child's parent, managing conservator, or legal guardian unless otherwise provided by law.</p> <p>You can have your baby's blood sample destroyed if you do not want it to be used after the newborn screening tests are completed. <u>If you are okay with the sample being stored and used, as described above, then there are no further steps for you to take.</u></p> <p>If you want your baby's blood sample to be destroyed, YOU must fill out ALL of the information on this form and send it back to DSHS at the address given below (DSHS will also accept the form from your healthcare provider, once you have completed and signed the form). If the newborn screening blood spot card is destroyed, the blood sample will not be available for any future needs you may have for the sample.</p> <p><b>To request to have your child's blood spot(s) destroyed:</b></p> <ol style="list-style-type: none"> <li>1. Fill out the entire attached form. Do not leave any fields blank.</li> <li>2. Mail original to:             <ul style="list-style-type: none"> <li>Texas Department of State Health Services</li> <li>Newborn Screening Laboratory, MC 1947</li> <li>PO Box 149347</li> <li>Austin, Texas 78714-9347</li> </ul> </li> <li>3. For additional information, call 1(888) 963-7111 ext. 7333 or visit web site: <a href="http://www.dshs.state.tx.us/lab/newbornscreening.shtml">http://www.dshs.state.tx.us/lab/newbornscreening.shtml</a></li> </ol> <p style="text-align: right; font-size: 10px;">  </p>	<p style="text-align: center;"><b>Directive to Destroy Newborn Screening Blood Spot Card Following Testing</b></p> <p style="text-align: center; color: green;"><b>Fill out this form ONLY if you WANT your baby's blood sample destroyed after newborn testing is complete</b></p> <p>I, _____ (please print full name) hereby certify that I am the (check one) <input type="checkbox"/> parent, <input type="checkbox"/> managing conservator, or <input type="checkbox"/> legal guardian of the child named below, and I further certify that there is no court order in effect which restricts my legal ability to make this request.</p> <p>As parent, managing conservator, or legal guardian, I am telling DSHS to destroy my child's blood spot card(s) after the newborn screen testing is finished.</p> <p>Full Name of Child: _____</p> <p>Child's Date of Birth: _____</p> <p>Full Name of Mother: _____</p> <p>Contact Information: _____ (Telephone number, e-mail address)</p> <p>_____ (Mailing address)</p> <p>_____ (City, State, Zip)</p> <p>Check here <input type="checkbox"/> to instruct DSHS to destroy NBS specimens from the child named above.</p> <p>_____ (Signature) _____ (Date)</p> <p style="font-size: 8px;">I hereby certify under penalty of law that all the information I have provided here in is true and accurate. I understand that providing false information on this form constitutes a crime in Texas under Penal Code Sec. 37.09.</p>
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Provider: Detach this Page and Give to Parent for Review

# OPT OUT STATISTICS

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## Form Return Rate





- Directive to Destroy
- No Response

Process	Estimated Response Rate
TX Opt Out	5%

- ~62,000 requests to destroy specimens
- ~122,000 specimens destroyed

# HB 1672 – OPT OUT

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- June 2010 – New specimen kits available for providers that included disclosure/request to destroy form

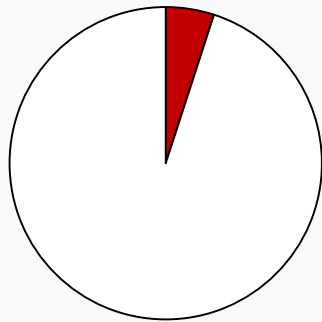
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# OPT OUT STATISTICS

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## Form Return Rate



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# ISSUES WITH “OPT OUT”

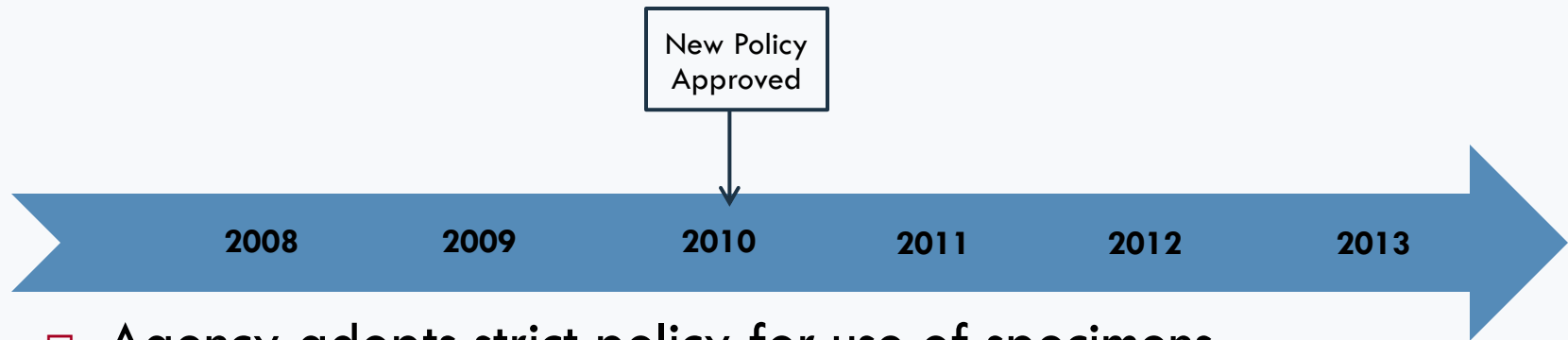
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- Parents
  - Did not understand form
  - Wrote “DO Not Destroy” on form
  - Did not know what newborn screening was
  - Often did not remember they had completed the form
- Healthcare providers
  - No requirement to explain
  - Often did not distribute form
  - Just had parents sign w/o explanation
- TX NBS Lab
  - Need time to prepare
    - Policy, procedure and form preparation
    - Stakeholder / Staff education
    - Update kits
  - Non Information System processing
    - Labor intensive and error prone
    - Difficult to identify non-compliant facilities
    - Difficult to track specimen status
  - 60 day destruction timeframe
    - Impractical for 2 screen state
    - Impedes QA/QC activities
    - Does not allow parents to change their mind



# AGENCY POLICY

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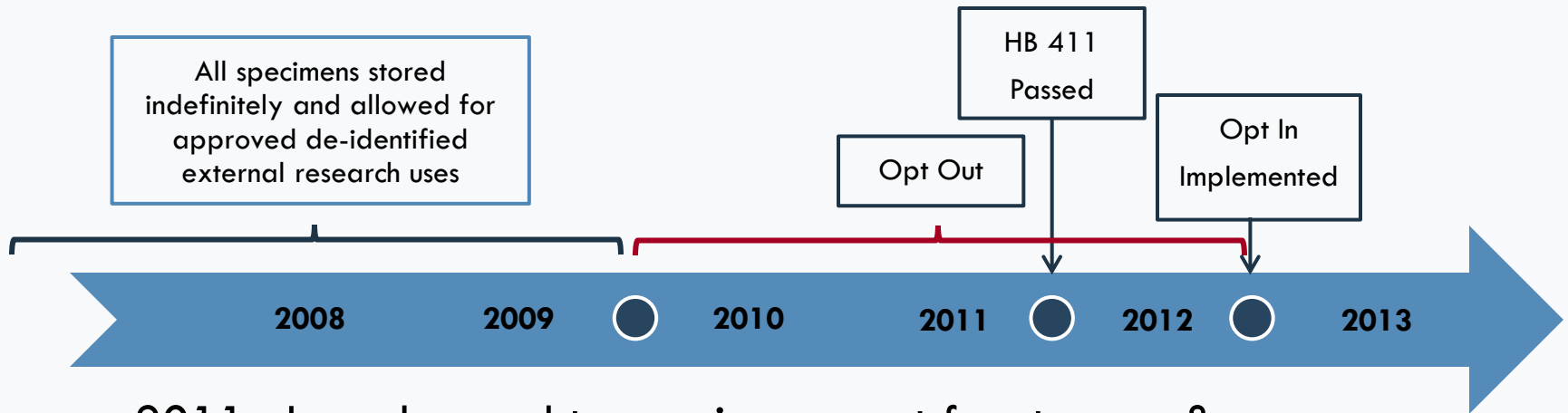
- Agency adopts strict policy for use of specimens
  - Management of Newborn Screening Specimens and Data
  - Includes table of uses with cross-reference to statutory authority and required approvals
  - Lays out approval process

# 2<sup>ND</sup> LAWSUIT FILED – HIGGINS *ET. AL*

- Lawsuit filed Oct 2010
  - ▣ alleged violations of 4th amendment search and seizure, and 14th amendment liberty and privacy rights in connection with DSHS's sale or barter of the specimens to researchers
- Lawsuit dismissed July 2011
  - ▣ DSHS had not utilized the plaintiff's specimens for external uses
  - ▣ Parents had not requested destruction of children's specimens though a mechanism was in place to do so

# HB 411 – OPT IN

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- 2011– Law changed to require consent for storage & use
  - ▣ Without consent, all specimens stored for up to 2 years and not allowed for external research uses (certain internal uses including QA/QC allowed)
  - ▣ With consent, specimens stored up to 25 years AND can be used for internal/external research
  - ▣ Codified existing policy on DSHS IRB and management approval requirements
  - ▣ New form, collection kits, and processes required
  - ▣ Effective date of opt-in provision – June 1, 2012



# OPT IN – IMPLEMENTATION GOALS

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- Parent
  - **Ensure parents understand their choices**
  - Be sensitive to parent / patient privacy concerns
  - Improve general Newborn Screening education
- Healthcare Providers
  - **Ensure understand legal requirements**
  - **Streamline distribution**
  - Maximize return rates of forms
- Texas DSHS
  - **Ensure compliance with parental choices**
  - Streamline processing & document in LIMS
  - Request enough information to match forms to specimens



LESS “OPT IN” THAN “DECISION” – MAKE A CHOICE

# HB 411 – OPT IN

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## Parent Information Form

- ❑ Distributed to parent upon collection of each specimen
- ❑ English / Spanish – Front / Back
- ❑ Available online in Vietnamese
- ❑ Target of 5<sup>th</sup> grade reading level

Information about specimen storage / use and Decision form

MM/DD/YYYY Serial Number [SN] TX 11- #####

Baby's Last Name Baby's First Name Baby's Date of Birth

**Texas Newborn Screening Parent Information** PROVIDER: Fill out baby's information above. Give this form to a parent.

**Parent,**  
Congratulations on your new baby!  
Take your baby to your baby's doctor when your baby is 7 to 14 days old. **Also, take this form!** This is important. This will help the doctor get the newborn screening test results.

**What is newborn screening?** It is a simple blood test to look for some diseases. These diseases can cause a baby to get really sick or die.

**Why should my baby be tested?** If we find and treat these diseases early, we can keep babies from getting sick or dying.

**When is my baby tested?** In Texas, babies have a newborn screening test when they are 1 to 2 days old. This test is done again at 7 to 14 days old. The test is done in accordance with Texas law.

**How is newborn screening done?** A little blood from your baby's foot is put on a blood spot card. The cards are sent to be tested at the Department of State Health Services (DSHS).

**How do I get results?** You can get the test results from your baby's doctor. The results are sent to the doctor from DSHS in one to two weeks.

**Is more testing available?** DSHS screens for many but not all diseases your baby may have. More tests can be done. Ask your baby's doctor and see [www.babysfirsttest.org/find-condition](http://www.babysfirsttest.org/find-condition).

**What happens to the blood spot card after testing?**  
Starting June 1, 2012:

- DSHS keeps the blood spot cards in a safe and secure place for up to two years. The blood spot cards may be used to:
  - o Make sure the newborn screening tests are working right;
  - o Develop new newborn screening tests; and/or
  - o Study diseases that affect public health.
- If you give your OK, your baby's blood spot cards will be stored for up to 25 years, and they may be used for public health research outside of DSHS.

**Complete, sign, and return the "Parental Decision for Storage and Use of Newborn Screening Blood Spot Cards" form to make your choice.**  
You can change your mind at any time. Call the information number below to get details.

No matter your choice, no information that identifies you or your child can be released outside DSHS without your additional written OK. There are a few exceptions, as provided by law.

**For more information, call 1(866) 963-7111 ext. 7333 or visit: [www.dshs.state.tx.us/lab/newbornscreening.shtml](http://www.dshs.state.tx.us/lab/newbornscreening.shtml)**

**INSURANCE / SELF-PAY**

07-060002

Texas Department of State Health Services - Newborn Screening Program  
P.O. Box 14 9341, Austin, Texas 78714 - 9341 (800) 252-0023

PARENT COPY Kit Expires MMDDYYYY

TEXAS Department of State Health Services

Vea el reverso para Español

Expanded general Newborn Screening information

# HB 411 – OPT IN

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## Parental Decision for Storage Form

- ▣ Parents inform DSHS of their decision one way or the other
- ▣ Providers required to:
  - Distribute to parent upon each NBS collection
  - Return form to DSHS if requested by parent

Explanation of Choices

Barcode to streamline processing in LIMS

**Parental Decision for Storage and Use of Newborn Screening Blood Spot Cards** Effective: June 1, 2012

Please read below to decide what you would like DSHS to do with your baby's blood spot card when the Newborn Screening tests are finished.

**If you check the 'OK' box AND sign this form:**

- All of your baby's blood spot cards will be kept safe and secure for up to 25 years.
- The blood spot cards may be used for public health research. The research may take place outside of DSHS. This research would study public health problems like cancer, birth defects, or other diseases.
- If a card is used for research, DSHS will keep at least one blood spot. This is in case it is needed for your child's medical care.
- You can change your mind at any time. Call DSHS (see number below) for details.

**If you check the 'NO' box OR do not sign OR do not fill out OR do not return this form:**

- The Newborn Screening tests will still be done in accordance with Texas law.
- Your baby's blood spot cards will be kept safe and secure. They will be destroyed within two years.
- The blood spot cards will NOT be used for public health research outside DSHS.

**Can information about me or my child be released without my OK?** No matter your choice on this form, no information that identifies you or your child can be released outside DSHS without your additional written OK. There are a few exceptions, as provided by law.

**I've already sent this form. Do I need to send it again?** NO. One form applies to all of your baby's newborn screening blood spot cards.

**For questions or more information:** Call 1(888) 963-7111 ext. 7333 or visit the web site: [www.dshs.state.tx.us/lab/newbornscreening.shtm](http://www.dshs.state.tx.us/lab/newbornscreening.shtm)

DSHS Laboratory/Sentinel Section NBS Form EF14-13629 (June 2012)

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**PARENT:** Please read this form. Select an option. Sign and return.

**1. FILL OUT** the form below.

Baby's First and Last Name: \_\_\_\_\_  
Baby's Date of Birth: \_\_\_\_\_  
Parent Phone Number: \_\_\_\_\_  
Mother's First and Last Name: \_\_\_\_\_

**2. CHECK** one box only and SIGN below.

**'OK'** I give my **OK** for my baby's blood spot cards to be kept by DSHS after the Newborn Screen tests are complete. They may be used for public health research outside of DSHS.

**'NO'** I do **NOT** give my ok for my baby's blood spot cards to be used for any research outside of DSHS after the Newborn Screen tests are complete. I understand the blood spot cards will be destroyed by DSHS within 2 years.

\_\_\_\_\_  
(Parent Signature) \_\_\_\_\_  
(Date)

**3. RETURN** this form to hospital or doctor's office staff. They will send it in with the blood spot cards. Or, you may **MAIL** it to:

Texas Department of State Health Services (DSHS)  
Newborn Screening Laboratory, MC 1947  
P.O. Box 140341  
Austin, Texas 78714-0341

**Vea el reverso para Español**

PROVIDER: Give form to parent & Return with blood spot cards if requested.

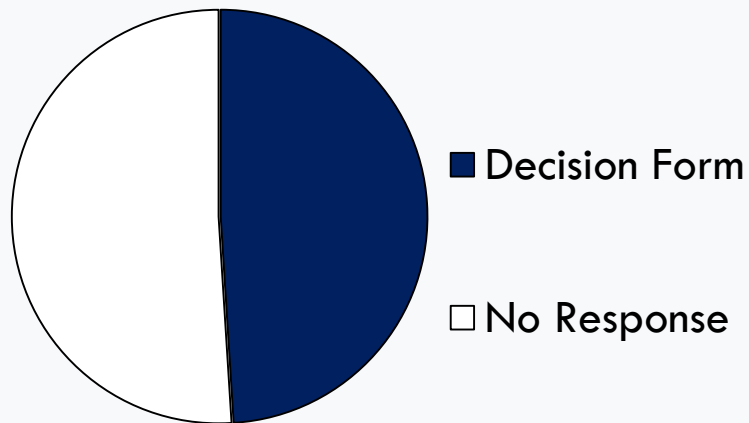
Parents select 1 of 2 options

Selection and Signature only required fields

Forms without a signature or a selection will default to 'No'

# OPT-IN STATISTICS

### Opt In Form Return Rate



- 2014 – 45.14% of all specimens received, had a decision form.
- Form received for ~49% of all babies screened.

Month	Decision Forms Received	Daily Average	% YES	% NO	% Invalid
Dec-14	23279	931	71.0	23.3	5.7

# CONSIDERATIONS FOR OPT-IN

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## Providers:

- ❑ Minimal legal requirements.
- ❑ No consequence for non-compliance.
- ❑ May not understand requirements completely.
- ❑ Disincentives to provider compliance
  - Explanation of the form may be time consuming.
  - Parents may have questions about the form that may be difficult for providers to answer.
  - Waiting for parent to fill out the form may be time consuming.
  - Language and/or education barriers.

## Parents:

- ❑ Form not received.
- ❑ Forms may be given as part of the “discharge packets” with no explanation.
- ❑ Not made aware of option to return completed form to provider.
- ❑ Low priority to complete and return when caring for newborn.



# MOVING FORWARD

- ▣ DSHS IRB follows Common Rule for all research projects
- ▣ In DSHS policy
  - Requesting temporary waiver for non-Federally funded NBS research
  - Follow Texas statute for non-federally funded research until Common Rule is updated.
- ▣ To ensure availability for research use, must conform to required elements of informed consent
  - Currently revising form for broad consent
  - Required by law to have form as part of collection kit

# BROAD CONSENT APPROACH

More information on what types of research are permissible.

Very low potential risk of data release.

## Parent Decision Form for Consent to Store and Use Newborn Screening Blood Spot Cards

Please read below. Then you can decide what you would like DSHS to do with your baby's blood spot card when the Newborn Screening tests are finished.

If you check the 'OK' box **AND** sign this form:

- All of your baby's blood spot cards will be kept safe and secure for up to 25 years.
- The blood spot cards may be used for public health research on:
  - cancer
  - infectious diseases
  - birth defects
  - environmental exposures
  - chronic diseases
  - newborn screening
- We will remove all personal information from blood spot cards that are shared for research outside of DSHS.
- We take steps to protect personal information. There is very low risk that any personal information will be released. We review requests for research to ensure the privacy and welfare of you and your baby.
- All research projects will be listed on the DSHS website. Results from research can benefit public health. Results may not directly benefit you or your baby.
- This is your choice. You can change your mind at any time. Call DSHS (see number below) for details.

If you check the 'NO' box **OR** do not sign **OR** do not fill out **OR** do not return this form:

- The Newborn Screening tests will still be done as required by Texas law.
- Your baby's blood spot cards will be kept safe and secure. We will destroy the blood spot cards within 2 years.
- The blood spot cards will not be used for public health research outside DSHS.

For questions or more information: Call 1(888)963-7111 ext. 7333 or visit the web site: [www.dshs.state.tx.us/nb/newbornscreening.shtm](http://www.dshs.state.tx.us/nb/newbornscreening.shtm)

PARENT: Please read this form, Check a box, Sign, and return.

1. **FILL OUT** the information below.

Baby's First and Last Name: \_\_\_\_\_

Baby's Date of Birth: \_\_\_\_\_

Parent Phone Number: \_\_\_\_\_

Mother's First and Last Name: \_\_\_\_\_

2. **CHECK** one box only and **SIGN** below.

'OK' I give my **OK** for my baby's blood spot cards to be kept by DSHS after the Newborn Screen tests are complete. The blood spots may be used for public health research.

'NO' I do **NOT** want my baby's blood spot cards to be used for any research outside of DSHS. I understand the blood spot cards will be destroyed within 2 years.

(Parent Signature) \_\_\_\_\_

Date: \_\_\_\_\_

3. **RETURN** this form to hospital or doctor's office staff. They will send it in with the blood spot cards. Or, you may **MAIL** it to:

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Austin, Texas 78714-3941



Vea el reverso para Español

# ANY QUESTIONS?

Contact Information:

[susan.tanksley@dshs.state.tx.us](mailto:susan.tanksley@dshs.state.tx.us)