

# TEXAS OPT-IN METHODOLOGY FOR SAMPLE STORAGE & RESEARCH

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# Outline

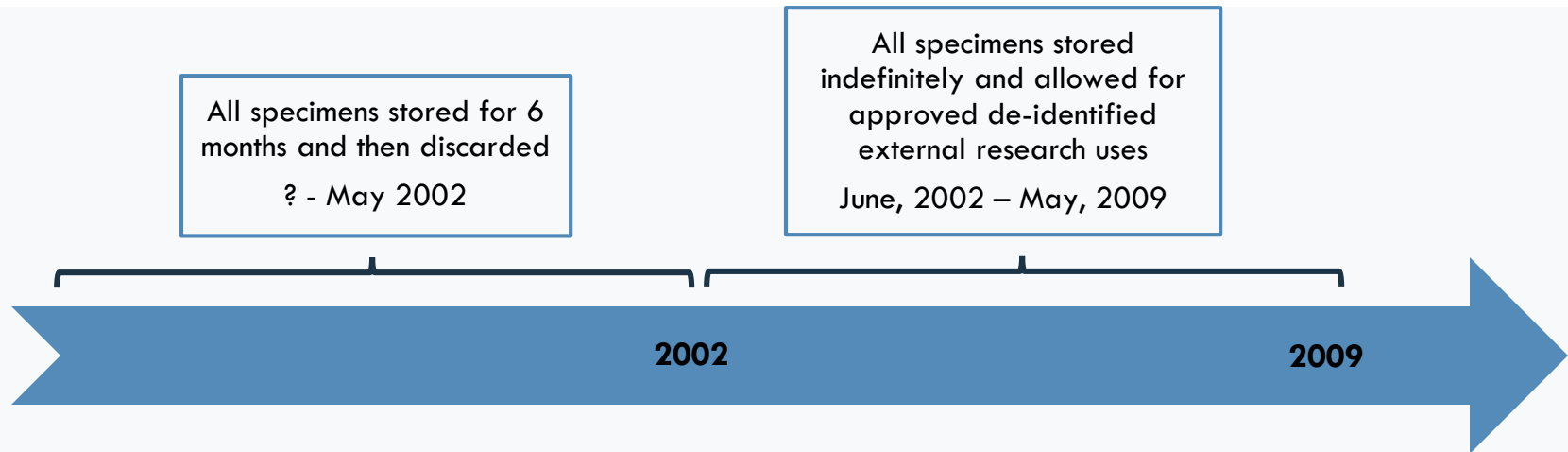
- Background
- Specimen Retention in Texas
  - ▣ Historical
  - ▣ Opt out
  - ▣ Opt in
- Moving forward

# Newborn Screening in Texas

- Administered by Dept. of State Health Services (DSHS)
- ~400,000 births annually
- Two screen state
  - 24-48 hours of life
  - 1-2 weeks of life
- ~780,000 specimens screened in 2014
- One laboratory located in Austin, TX
- Clinical Care Coordination team follows-up on presumptive positive NBS results

# 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

# 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

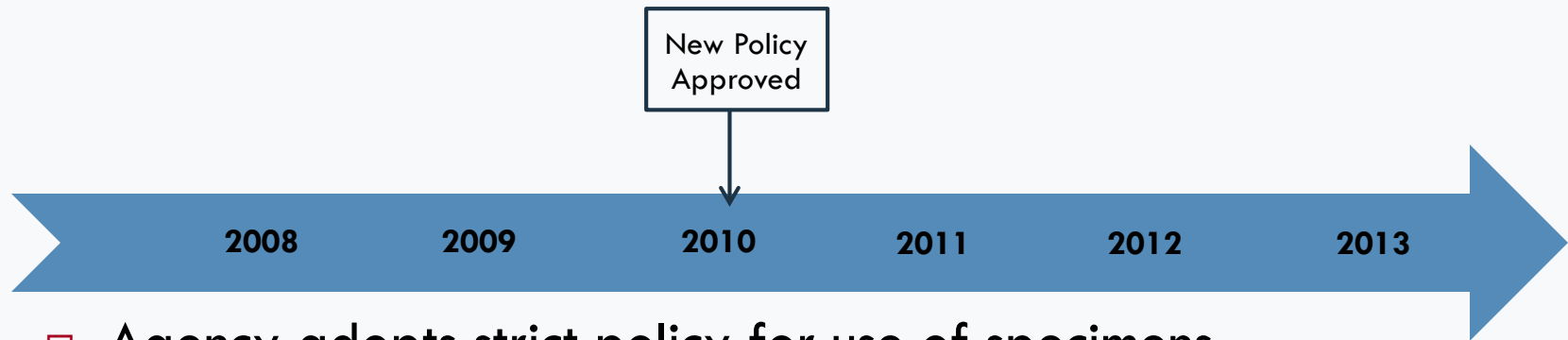
2012

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

# AGENCY POLICY

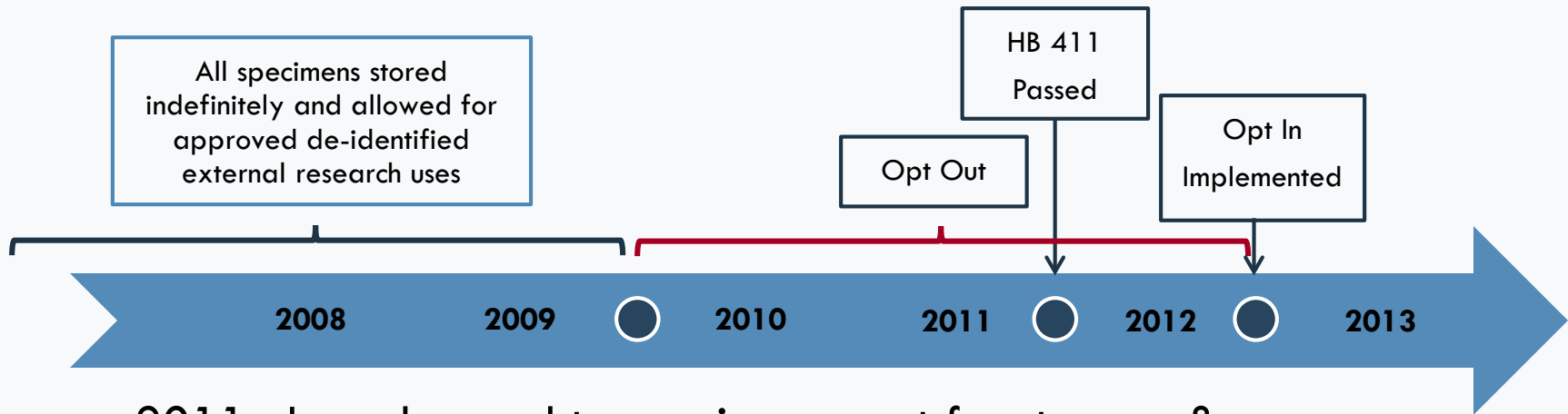
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- Agency adopts strict policy for use of specimens
  - Management of Newborn Screening Specimens and Data
  - Includes table of uses with cross-reference to statutory authority and required approvals
  - Lays out approval process

# 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 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



NOT “OPT IN” – “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
- ❑ Target of 5<sup>th</sup> grade reading level

Information about specimen storage / use and Decision form

07-060002	MM/DD/YYYY		Serial Number (SN) TX 11- #####
	Baby's Last Name	Baby's First Name	Baby's Date of Birth
<b>Texas Newborn Screening Parent Information</b>		<b>PROVIDER:</b> Fill out baby's information above. Give this form to a parent.	
<p><b>Parent,</b> Congratulations on your new baby!</p> <p>Take your baby to your baby's doctor when your baby is 7 to 14 days old. <b>Also, take this form!</b> This is important. This will help the doctor get the newborn screening test results.</p> <p><b>What is newborn screening?</b> It is a simple blood test to look for some diseases. These diseases can cause a baby to get really sick or die.</p> <p><b>Why should my baby be tested?</b> If we find and treat these diseases early, we can keep babies from getting sick or dying.</p> <p><b>When is my baby tested?</b> 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.</p> <p><b>How is newborn screening done?</b> 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).</p> <p><b>How do I get results?</b> 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.</p> <p><b>Is more testing available?</b> DSHS screens for many but not all diseases your baby may have. More tests can be done. Ask your baby's doctor and see <a href="http://www.babyfirsttest.org/find-condition">www.babyfirsttest.org/find-condition</a>.</p>		<p><b>What happens to the blood spot card after testing?</b> Starting June 1, 2012:</p> <ul style="list-style-type: none"><li>• 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:<ul style="list-style-type: none"><li>o Make sure the newborn screening tests are working right;</li><li>o Develop new newborn screening tests; and/or</li><li>o Study diseases that affect public health.</li></ul></li><li>• 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.</li></ul> <p><b>Complete, sign, and return the "Parental Decision for Storage and Use of Newborn Screening Blood Spot Cards" form to make your choice.</b></p> <p>You can change your mind at any time. Call the information number below to get details.</p> <p>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.</p> <p><b>For more information, call 1(888) 963-7111 ext. 7333 or visit: <a href="http://www.dshs.state.tx.us/lab/newbornscreening.shtml">www.dshs.state.tx.us/lab/newbornscreening.shtml</a></b></p>	
Texas Department of State Health Services – Newborn Screening Program P.O. Box 14 9341, Austin, Texas 78714 – 0341 (800) 252-0023		PARENT COPY	
		Kit Expires MM/DD/YYYY	
		INSURANCE / SELF-PAY	
		Vea el reverso para Español	

Expanded general Newborn Screening information

Vea el reverso para Español

# 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.

<input type="checkbox"/> <b>'OK'</b> I give my <b>OK</b> 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.	<input type="checkbox"/> <b>'NO'</b> I do <b>NOT</b> 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.
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\_\_\_\_\_  
(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.

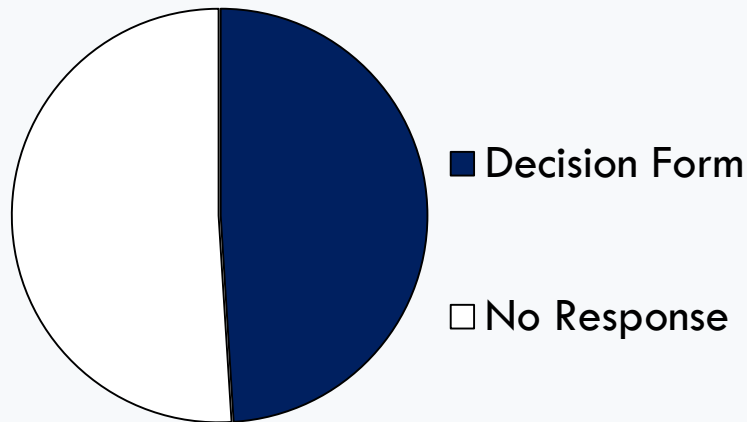
Parents select 1 of 2 options

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

- ▣ Must preserve core program uses
  - Screening
  - QA/QC - regulatory requirement
  - Quality Improvement
- ▣ To ensure availability for research use, must conform to required elements of informed consent
  - Currently revising form for broad consent

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Any questions?

Contact Information:

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