CONSENT REQUIRED? COMMON USES OF RESIDUAL SPECIMENS IN PUBLIC HEALTH PROGRAMS

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Overview

- When is consent required for an activity?
  - Examples of activities
  - Implementation of a new test
- Texas DSHS Laboratory
  - Current status
  - Future plans

When is consent required?

- Is the activity research or not?
- Does the activity involve human subjects?
- How is the activity funded?
- Does the activity involve newborn screening specimens?

- **Research** = A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

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When is consent required?

- Is the activity research or not?
- Does the activity involve human subjects?
- How is the activity funded?
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- **Human subject** – living person from which an investigator obtains, uses, studies, analyzes or generates identifiable private information
- In general, research on **Human Subjects** requires consent, but….
  - The definition of Human Subject may change.
  - There are 'Exclusions' & 'Exemptions'.

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“Exclusions” in NPRM

- Categories of activities that are free from coverage under the Common Rule
  - Not research
  - Low risk research
  - Research that doesn’t reveal new information about an individual

- These activities do NOT require consent.

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Quality Assurance & Improvement

- Quality Assurance & Improvement activities involving implementation of an accepted practice
  - Activities necessary for maintaining laboratory certification under CLIA/CAP
  - Use of residual specimens as quality control material to monitor the accuracy, precision and validity of laboratory tests
  - Inter-laboratory exchange for proficiency testing
  - Troubleshooting technical issues associated with existing methods and test systems
- Sharing materials to provide training and technical support associated with test method

Public Health Surveillance

- The collection, analysis and use of data to target public health prevention.
  - State has established registries to monitor the number of children diagnosed with disorders included in the state newborn screening panel and cases missed by screening.
  - Collection of information for purpose of evaluation of the availability and effectiveness of preventive follow-up interventions (i.e. long-term follow-up).
  - Activities designed to enable public health authority to identify changes in incidence or prevalence in a geographic region.
    - US Influenza Surveillance Program

Low-Risk Research

- Secondary use of de-identified data
  - Evaluating the efficacy of the routine second newborn screen in identifying cases of congenital hypothyroidism and congenital adrenal hyperplasia by evaluating retrospective data

- Exclusions do not apply if research includes collection or analysis of biospecimens

Research that doesn't reveal new information about an individual

- Development of a new assay for a condition using specimens from individuals known to have (or not have) the condition
  - Development of ARMS-PCR for mutational analysis of GALT

When is consent required?

- Is the activity research or not?
- Does the activity involve human subjects?
- How is the activity funded?
- Does the activity involve newborn screening specimens?

- The Common Rule applies to federally funded human subjects research.
- However, many IRB's apply the Common Rule regardless of funding source.

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When is consent required?

- Is the activity research or not?
- Does the activity involve human subjects?
- How is the activity funded?
- Does the activity involve newborn screening specimens?

- Amendment 12 of NBS Saves Lives Act declares federally-funded research on NBS specimens to be human subjects research.

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Public Health Research

- Research to evaluate the link between prenatal lead exposure and infant blood lead levels.
- Evaluation of the link between hydrocephalus and infection with Cytomegalovirus (CMV), Lymphocytic Choriomeningitis Virus (LCMV), and Toxoplasmosis gondii.
- West Nile clinical specimens are investigated to compare against a Rabies-profile

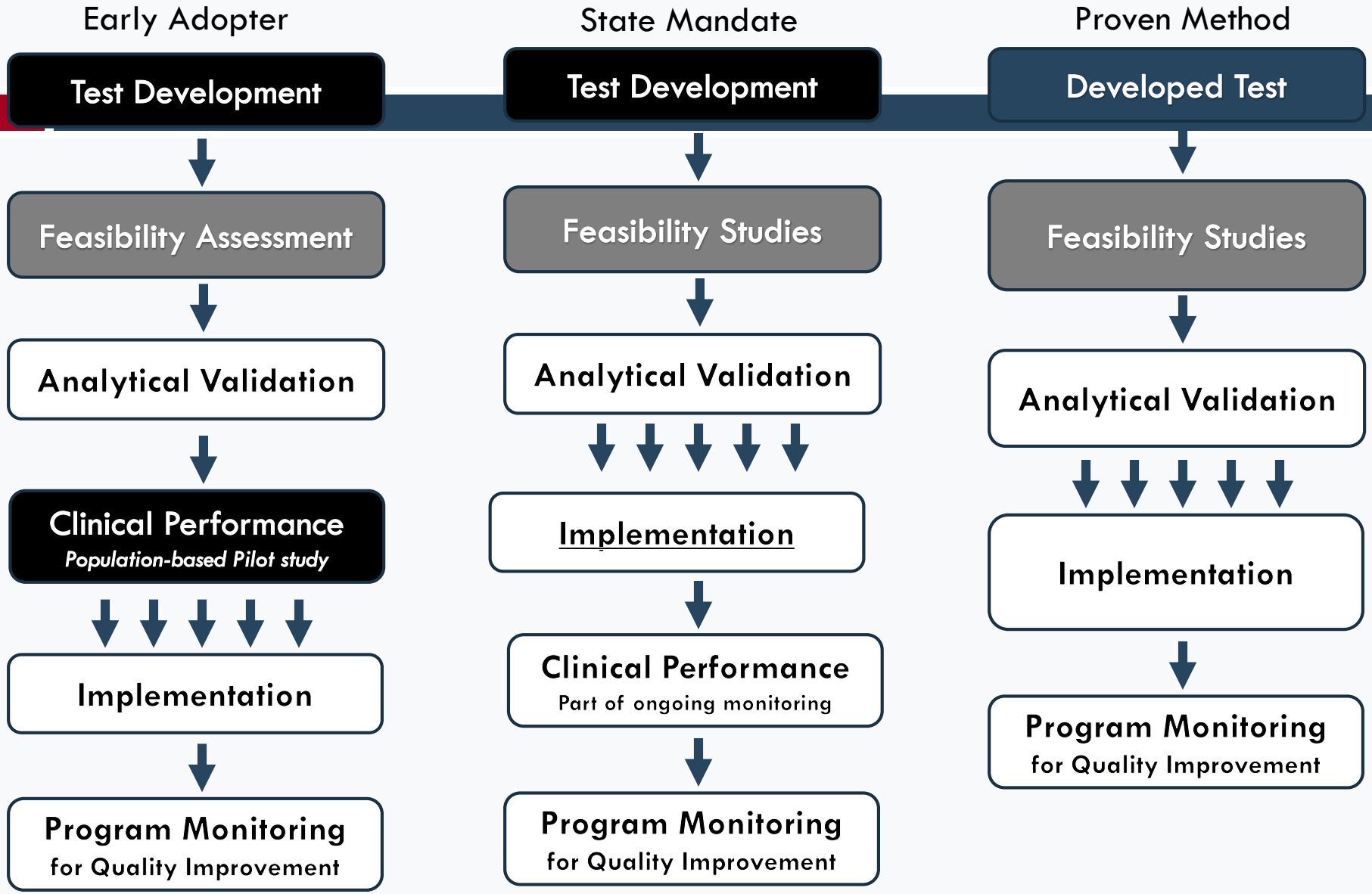
Dear Grey Area,
Why do you have to make everything so messingly complicated.

Sincerely,
Fan of Black-or-White.

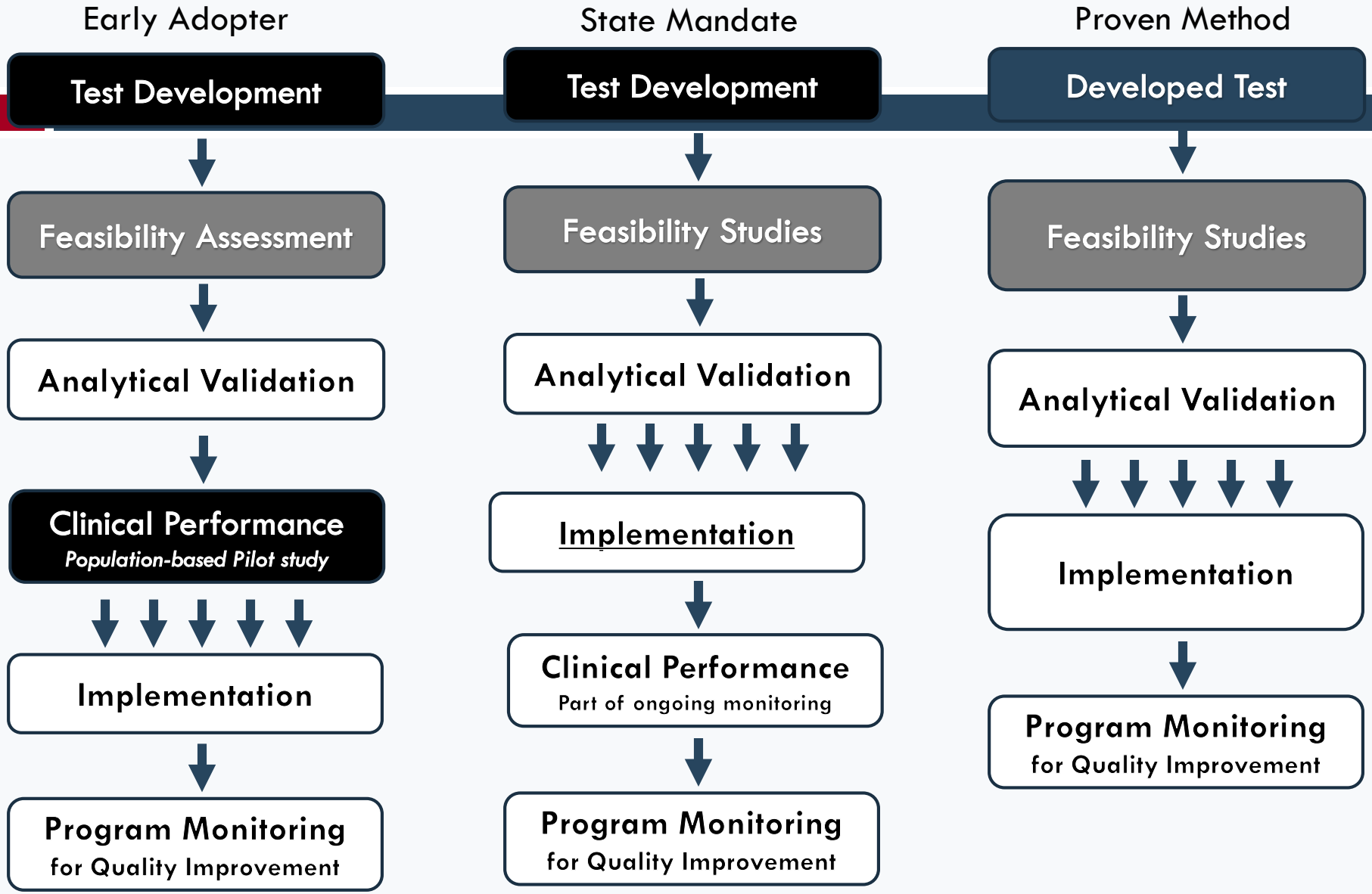
Critical Steps Leading to the Implementation of a New Condition

Stage	Description
Initial Development	To show proof of concept, to develop or to evaluate a biological marker, to determine optimal test conditions, test interferences or assess other performance.
Feasibility Assessment	To make modifications an existing (often published) research method to develop a robust, automated method with sufficient performance characteristics that would be appropriate for high-throughput screening in a public health environment. Question addressed is "Can I screen?"
Analytical Validation	Establishment of performance specifications of a new method as per CLIA/CAP requirements. E.g. Accuracy, precision, analytical sensitivity, reportable range, reference intervals
Clinical Performance	To determine whether the test is able to effectively screen for the specific condition. E.g. Clinical sensitivity and specificity; positive and negative predictive values; clinical utility. Question addressed is "Should I screen?"
Implementation	There is evidence that the test has met the threshold requirements from analytical validation and clinical performance studies. State-wide screening can be initiated.
Program Monitoring and Surveillance	To assess all components of the Newborn Screening system and provide information to ensure that program is achieving goals. To identify opportunities for quality improvement.

Implementation of a Screening Test



Implementation of a Screening Test

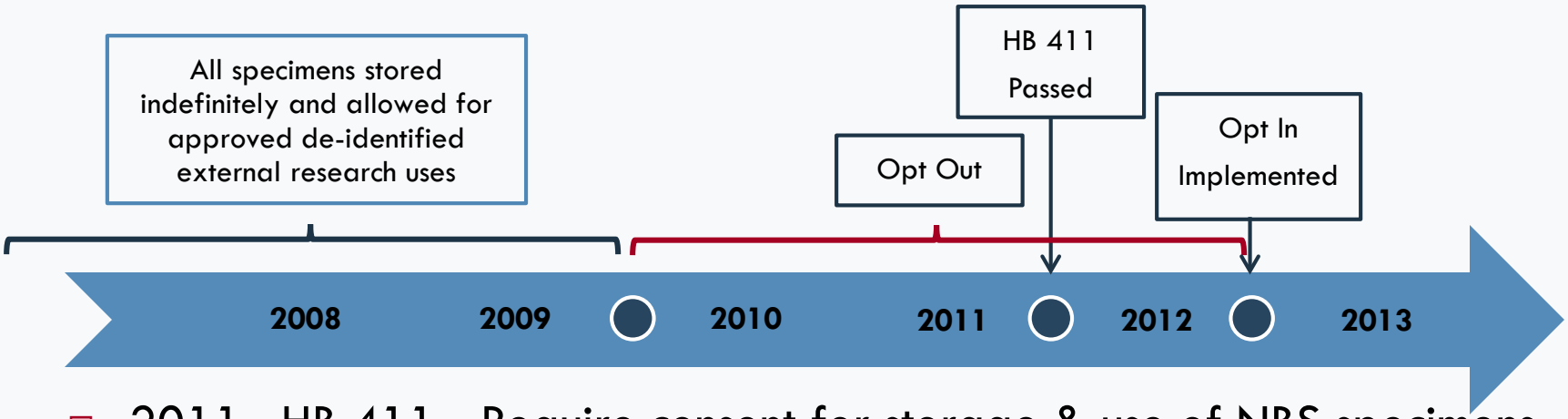


Ultimately, when it's not clear cut, consult your local IRB.

Texas DSHS Laboratory

Current Status & Future Direction

Statutory Requirement for Opt In



- 2011– HB 411 - Require consent for storage & use of NBS specimens
  - 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
  - Effective date of opt-in provision – June 1, 2012

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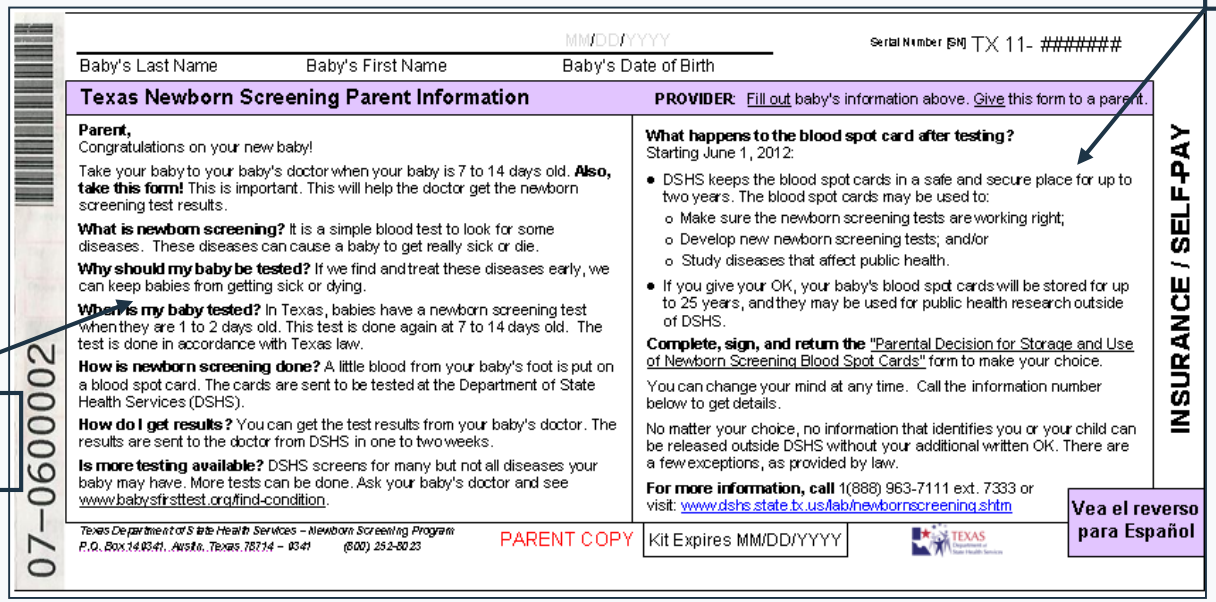
Newborn Screening Parent Information Sheet

- Goal – Inform parents about NBS as well as specimen retention option
- First page of NBS Kit
- Provider distributes to parent upon collection of each specimen
- English / Spanish – Front / Back
- Target of 5th grade reading level

Information about specimen storage / use and Decision form

General Newborn Screening information



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.

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:
  - Make sure the newborn screening tests are working right;
  - Develop new newborn screening tests; and/or
  - 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(888) 963-7111 ext. 7333 or visit: www.dshs.state.tx.us/lab/newbornscreening.shtm

INSURANCE / SELF-PAY

Vea el reverso para Español

07-0600002

Texas Department of State Health Services – Newborn Screening Program
P.O. Box 149041, Austin, Texas 78714 – 9041 (800) 252-8023

PARENT COPY | Kit Expires MM/DD/YYYY

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Parental Decision for Storage and Use

- 2nd Page of NBS kit (tear off)
  - Form also available on website (English, Spanish, Vietnamese)
- Providers required to:
  - Distribute to parent upon each NBS collection
  - Return form to DSHS if requested by parent
- Parents make choice to inform DSHS of their decision

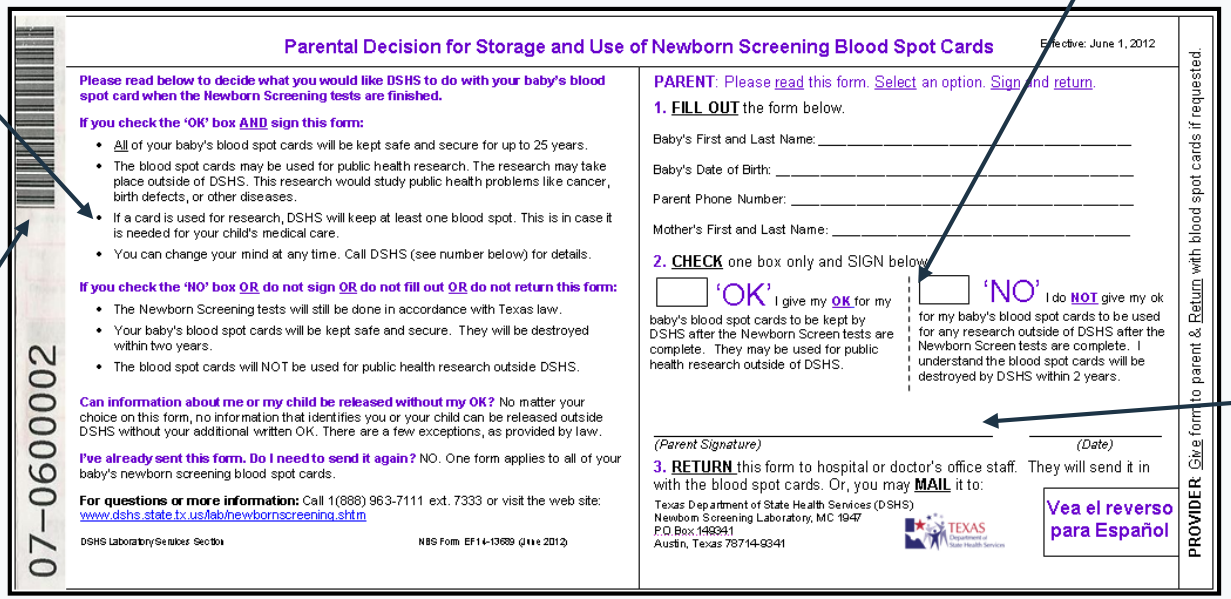
Parents select 1 of 2 options

Explanation of Choices

Barcode to streamline processing in LIMS

Selection and Signature only required fields

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



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

DSHS Laboratory Services Section NBS Form EF14-13689 (June 2012)

07–0600002

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 149341
Austin, Texas 78714-9341

Vea el reverso para Español

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

TEXAS Department of State Health Services

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Impact to Texas NBS Program of Amendment 12 & NPRM (if adopted)

- DSHS IRB follows Common Rule for all research – regardless of funding
  - Received a waiver from agency IRB policy to only apply the consent provisions in Chapter 12 of the Newborn Screening Saves Lives Reauthorization Act of 2014 to federally funded research.
- Need to adapt current decision form to meet elements of broad consent once finalized
- Submit finalized broad consent form and procedures for IRB review
- Need to adapt policy on management of NBS specimens and data to ensure adherence to state law and Common Rule
- Need to finalize policy on use of other residual specimens to ensure adherence to Common Rule
  - Are isolates biospecimens?

Any questions?

Contact Information:

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