

# Missouri NBS Sample Storage Implementation

Combining the “Right Thing to Do” with “Doing it Right”



Patrick Hopkins; Newborn Screening Laboratory Manager

# New Statute: RSMo 191.317

- The newborn screening samples will be stored for five (5) years after the State Public Health Laboratory has completed its screening (*In the past, samples were destroyed one month after the screening was completed*).
- The law allows the leftover samples to be used for anonymous research.
- The law states that parents shall be informed about this at the time of sample collection and be given the opportunity to opt-out/dissent from the sample storage and/or research.
- The law provides parents three (3) opt-out options.

## Parents Can Opt-Out of the Storage or Research

If they choose to do so, the parents may direct the State Public Health Laboratory to:

1. Give the leftover newborn screening sample back to them.
2. Destroy the leftover newborn screening sample after the newborn tests are done.
3. Store the leftover newborn screening sample for 5 years but do not release it for research.

## **Implementation: Decisions and Actions**

- We conducted 6 focus group sessions around the state with parents.
- The general consensus was that parents were fine with their child's NBS sample being stored and used for anonymous research as long as they were informed about it and were given the opportunity to opt-out.

## **Implementation: Decisions and Actions**

- We contacted all the state laboratories that were storing their NBS samples for 5 years or longer.
- Asked several key questions about their protocols.
- Asked what their Do's and Don'ts would be in hindsight.

# Implementation: Decisions and Actions

- We discussed the law with our Department heads and legal counsel and considered our options.
- Decided we would require the parent or legal guardian to write the State Laboratory to opt-out of the storage and/or release.
- We would allow the opt-out at anytime during the 5-year storage.
- If the parents do nothing, the NBS sample will automatically be stored and be available for anonymous research after 3 months of storage time.

## **Implementation: Decisions and Actions**

- We did not want to have a check-off box on the NBS collection form.
- We did not want to force the parent into making a decision while in the hospital when they are exhausted and they are bombarded with so many other things.
- We would provide an information sheet that would be detached from the NBS collection form and handed to the mother.
- We would also provide the same information in the take-home NBS brochure.

# Implementation: Decisions and Actions

- Realized an opportunity for NBS education.
- Spent almost a year preparing this document.
- It was a combined effort of:
  - NBS Laboratory
  - NBS Follow-up
  - Genetics Advisory Committee
  - Health Department Legal Counsel
  - Health Department Governmental Liaison
  - Health Department Office of Public Information
  - Health Literacy Committee



INITIAL NEWBORN SCREENING  
MO 880-0879 (1-03)

2014-01  
LOT 0120201 / 1101327

### Detach This Copy and Give to Mother of Newborn!

Dear Parents of Newborn Baby:



To help give your baby a good start, Missouri law requires your baby's blood to be tested for more than 50 disorders. A few small drops of blood taken from the baby's heel are put on special paper and then sent to the State Public Health Laboratory for testing.

Many disorders are not noticed at birth. Yet they can put the baby at risk for disability or death if not found early. If results from this screening test are not normal, your doctor will tell you about more testing that needs to be done. Please make sure the hospital staff gives you a Newborn Screening pamphlet.

Once the newborn screening test is done, the Missouri State Public Health Laboratory will store the remaining newborn screening sample for five (5) years. The storage is secure. Missouri state law allows for the stored sample to be used for research. The research may help improve methods for spotting illnesses. The research may also find better ways to test, treat and cure major childhood diseases. Your baby is not identified to the researcher in any way. After five years, the rest of the newborn screening sample will be destroyed.

The law allows the parent or legal guardian the option of not having their baby's extra newborn screening sample stored or studied. You may ask the State Laboratory to:

- Give the extra newborn screening sample back to you
- Destroy the newborn screening sample after the newborn tests are done
- Store the extra newborn screening sample for 5 years but do not release it for study

If you choose NOT to allow your baby's extra newborn screening sample to be studied, select one of the above three options. Then write to the Laboratory Director at:

Missouri State Public Health Laboratory  
Newborn Screening Laboratory  
P.O. Box 570  
Jefferson City, MO 65102-0570

Give this information:

- Baby's name
- Baby's date of birth
- Mother's first and last name
- Place where baby was born
- The option you selected from above
- State if you are the parent and legal guardian
- Your current address
- Your signature and current date (See other side)



If you have questions or need assistance, please contact the Newborn Screening Laboratory at 573-751-2662.



LABORATORY COPY

BN

B 1 1 7 0 0 0 1 5

\*



SUBMITTER COPY

BN B117000015

Ahstrom 226  
LOT 0120201 / 102010

FILL CIRCLES FROM ONE SIDE ONLY



## **Detach This Copy and Give to Mother of Newborn!**

Dear Parents of Newborn Baby:



To help give your baby a good start, Missouri law requires your baby's blood to be tested for more than 50 disorders. A few small drops of blood taken from the baby's heel are put on special paper and then sent to the State Public Health Laboratory for testing.

Many disorders are not noticed at birth. Yet they can put the baby at risk for disability or death if not found early. If results from this screening test are not normal, your doctor will tell you about more testing that needs to be done. Please make sure the hospital staff gives you a Newborn Screening pamphlet.

Once the newborn screening test is done, the Missouri State Public Health Laboratory will store the remaining newborn screening sample for five (5) years. The storage is secure. Missouri state law allows for the stored sample to be used for research. The research may help improve methods for spotting illnesses. The research may also find better ways to test, treat and cure major childhood diseases. Your baby is not identified to the researcher in any way. After five years, the rest of the newborn screening sample will be destroyed.

The law allows the parent or legal guardian the option of not having their baby's extra newborn screening sample stored or studied. You may ask the State Laboratory to:

- Give the extra newborn screening sample back to you
- Destroy the newborn screening sample after the newborn tests are done
- Store the extra newborn screening sample for 5 years but do not release it for study

If you choose NOT to allow your baby's extra newborn screening sample to be studied, select one of the above three options. Then write to the Laboratory Director at:

Missouri State Public Health Laboratory  
Newborn Screening Laboratory  
P.O. Box 570  
Jefferson City, MO 65102-0570

Give this information:

Baby's name  
Baby's date of birth  
Mother's first and last name  
Place where baby was born  
The option you selected from above  
State if you are the parent and legal guardian  
Your current address  
Your signature and current date (See other side)



If you have questions or need assistance, please contact the Newborn Screening Laboratory at 573-751-2662.

## **Benefits of storing newborn screening samples:**

There are many reasons why newborn screening samples are kept, many of which benefit your family and other Missouri families.

- In some cases, samples are requested by the family or the baby's health care team.
- The baby's sample is available to you for other health-related testing within five years of storage.
- The baby's sample is available to help identify a missing or deceased child within five years of storage.
- If your child has an illness and is enrolled in a research study, parents may request that their baby's newborn screening sample be returned to them in order that they may send it to the researcher within five years of storage.

For research purposes, all identifying information is removed from the samples (baby's name, parent's name, parent's address, hospital of birth, etc.). The researcher does not know who the baby is. These samples may be used to:

- Provide quality assurance in the screening.
- Do public health studies and research to help develop newborn screening tests and better understand diseases for the benefit of the general public.
- Search for new markers for chronic diseases such as childhood leukemia, sickle cell disease, autism and diabetes.

Only those research projects that undergo careful scientific and ethical review will be given approval to use newborn screening samples.

# Training Process

- Framed it as “A New Step in Newborn Screening” beginning July 1, 2011.
- Conducted a webinar with OB Directors and nurses from all over the state.
- Circulated a Notice to all submitters of NBS’s.
  - Sent out on our NBS submitter notification listserv.
  - Mailed out will all NBS lab reports for 6 weeks.
- Placed it on the “What’s New” tab on our NBS website along with the Mother’s Info sheet.



Missouri Department of Health and Senior Services  
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010  
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466  
Margaret T. Donnelly  
Director



Jeremiah W. (Jay) Nixon  
Governor

June 21, 2011

## IMPORTANT NOTICE

### A New Step in Newborn Screening Sample Collection!

**Beginning July 1, 2011** a new step will be required in the newborn screening (NBS) sample collection process. This new step requires that the mother of the baby be given an information sheet provided by the Department of Health and Senior Services informing her that her child has been screened for certain disorders mandated by state law and that after the testing has been completed, the leftover NBS sample will be stored at the State Public Health Laboratory for five years. This storage is now also mandated by state statute (RSMo 191.317). In the past, NBS samples were destroyed one month after the screening was completed.

This is NOT a consent process but simply a way to provide important information that explains why the NBS sample is being stored, what the parent's options are and how they request them if they choose to do so (see attached information sheet). If the parents do nothing, the leftover NBS sample will be stored by the State Public Health Laboratory for five years and will eventually be made available for anonymous research. If the parents wish to opt-out of this process, they can write a letter to the state laboratory requesting one of three opt-out options:

- Give the extra newborn screening sample back to them
- Destroy the newborn screening sample after the newborn tests are done
- Store the extra newborn screening sample for five years but do not release it for study

With the storage of the NBS sample there are benefits for the child and child's family, benefits for the Newborn Screening Laboratory regarding quality assurance, and benefits for public health research. These benefits are stated on the back of the information sheet. The sample storage is secure and the anonymity and privacy of the family will be protected. The parents may opt-out at any time during the five year storage process. After five years the samples will be destroyed.

**In order for this process to be successful, the DHSS needs your assistance.** What we are requiring of you is for the information sheet to be given to the mother of the baby at the time of the NBS sample collection and to verbally provide her some information pertaining to it:

- Tell her that it is information about the NBS test that is being done on her child and what will happen to the sample after it is screened.
- Tell her there is information on both sides of the sheet.
- Tell her if she has any questions she can call the phone number on the sheet.

We have provided the attached copy of the information sheet for you to photo copy and hand out until your current inventory of collection cards is used up. With future shipments of NBS collection cards, this information sheet will be included as a tear off copy that can be detached and handed to the mother of the newborn at the time of sample collection.

If you have questions, please contact Patrick Hopkins, Newborn Screening Laboratory Manager, by telephone at 573-751-2662 or email [Patrick.Hopkins@health.mo.gov](mailto:Patrick.Hopkins@health.mo.gov)

[www.health.mo.gov](http://www.health.mo.gov)

Healthy Missourians for life.

The Missouri Department of Health and Senior Services will be the leader in promoting, protecting and partnering for health.

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER: Services provided on a nondiscriminatory basis.

# What Did We Ask of Them?

- Begin this new step on July 1<sup>st</sup> 2011.
- Detach and hand the top sheet of the newborn screening collection form to the mother of baby after the sample is collected *(but use copies of the pdf we provided until current card inventory is used up)*.
- Verbally provide the mother some information pertaining to this information sheet.

## **Suggestions on What to Say to Mother:**

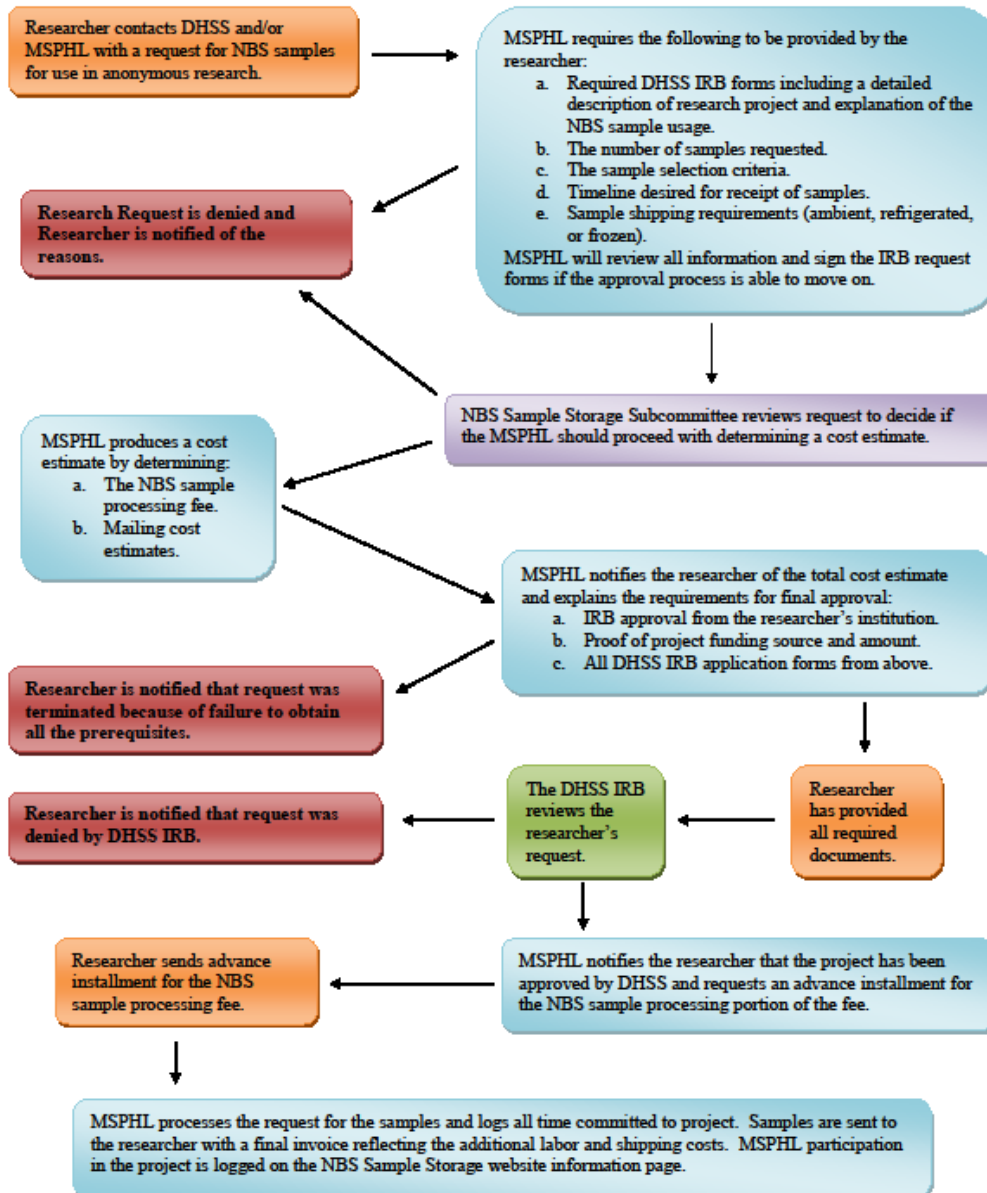
- Tell her that it's information about the NBS test that is being done on her child and what will happen to the sample after it is screened.
- Tell her there is information on both sides of the sheet.
- Tell her that if she has any questions she can call the phone number on the information sheet (the NBS lab).

# What About Research Requests?

- We created a NBS Sample Storage and Release Subcommittee of the Genetics Advisory Committee.
- This committee was charged with:
  - Giving guidance on determining priorities for the types of research we would allow.
  - Reviewing all research requests before involving the IRB.
  - Assuring that only anonymous research is conducted.
  - Continual monitoring and guidance of the process.



## Research Request Protocol for NBS Samples



## Missouri Newborn Screening Sample Storage and Release Policy

The Missouri Newborn Screening (NBS) Sample Storage Process was implemented on July 1<sup>st</sup>, 2011. Missouri State Law (Section 191.317) requires the Missouri State Public Health Laboratory (MSPHL) to retain the NBS samples for five (5) years after the testing has been completed and then to destroy them after the 5 years of storage has ended. The law allows the department to release the samples for the purpose of anonymous research, and allows the department to charge a reasonable fee for the use of such samples for anonymous research and for preparing and supplying samples for anonymous research proposals approved by the department.

This same law provides three (3) opt-out/dissent options for the parents or legal guardian if they do NOT wish the department to release their child's leftover NBS sample for anonymous research. These options are provided to parents at the time of sample collection in an information sheet that is detached from the NBS sample collection card and provided to the mother of the newborn by the hospital staff. This information sheet is available in English, Spanish, Bosnian and Vietnamese.

The three (3) opt-out options available to the parents after their child's NBS testing is completed are:

- 1). Return the leftover sample to the parents
- 2). Destroy the leftover sample in a scientifically acceptable manner
- 3). Store the leftover sample for 5 years but do not release it for anonymous research.

To opt-out of the sample storage and/or release, the parent must write the MSPHL and request the opt-out choice in writing, and they may do so at any time during the 5-year storage process. If the parent does not choose one of these options, the specimen will automatically be stored at the MSPHL and may be released for approved anonymous research after the first three months storage time has transpired and until an opt-out letter is received by the MSPHL. When the MSPHL receives a letter from parents requesting one of the opt-out selections, their request is immediately granted. The MSPHL sends a letter back to the parents stating that their request was fulfilled along with a copy of their original opt-out letter. The MSPHL keeps both electronic and hard copy records of all opt-out cases.

There are numerous benefits to public health in retaining residual NBS samples. Residual NBS samples are the only available opportunity for a complete population study to be conducted since there is a sample received on virtually every baby born. In addition to this, the NBS sample is sometimes the only remaining evidence available to the family from their child if their child becomes missing. The main benefits to NBS sample storage are:

- Quality assurance and improvement for the NBS laboratory.
- Research for new technologies and for detecting new disorders.
- Research for new treatments and cures for major childhood diseases.
- Population incidence research on disorders and environmental contaminant exposures.
- Parents can recall the specimens to help determine the cause of an unexplained death of their child (SIDS).
- Parents can recall the specimens to aid law enforcement in identifying their missing child.

The NBS Sample Storage and Release Subcommittee, a subcommittee of the Missouri Genetics Advisory Committee, reviews all research requests for stored NBS samples, determines priorities for the types of research proposals to be considered, and assures that only anonymous research is conducted. This committee determines if the MSPHL should proceed with sending the request through the Department of Health and Senior Services (DHSS) Institutional Review Board (IRB) for review and final approval.

If the research request is approved by the DHSS IRB, the MSPHL will contact the researcher that made the request and provide an estimate of the cost for processing their research request. The MSPHL will provide approved researchers with small punches from the samples, and no records will be kept of which samples were used for any particular research request. No samples will be provided for research projects until they have been stored for at least 3 months to allow time for parents who wish to write the MSPHL to opt-out.

The DHSS will maintain an information page on the NBS website displaying all the anonymous research projects that were granted approval for using stored NBS samples, the parent opt-out process and other related information regarding NBS sample storage and release.

# Logistics of Storing Samples

- We use upright, manual defrost, kitchen freezers.
  - The freezers only cost about \$550 each.
  - Maintain constant temperature of – 20 to – 30° C.
  - They are very reliable and very quiet.
  - Can store 3 months of samples in each one.
- We keep electronic and hardcopy records of opt-outs.
- We send a letter to parents confirming that we complied with their request, and include a copy of their original opt-out letter.

# Status of the Process to Date

- Feedback from hospitals reveals that the process is working fine for them.
- We have had 9 opt-out letters to date:
  - 3 for destroy
  - 3 for store but don't release
  - 3 for send back to parents
- All opt-outs have been home births.

# Universal Recycling: An Opt-Out Analogy





## THE MURDER THAT NEVER WAS

Wrongly imprisoned for her baby's death, a Missouri mother is finally freed



▲ "I will never forget," says Patricia Stallings of the day her son Ryan was taken fatally ill and the family's ordeal began.

**L**YING ON A PINK-AND-PURPLE-STRIPED beanbag, 22-month-old David Stallings Jr., stout, chubby-faced and cooing contentedly, is enjoying his morning meal. For his mother, Patricia, 26, feeding him is no ordinary task. She pours formula into a tube connected to David's stomach through an opening in his abdomen and waits patiently as the liquid drips slowly down. David, or D.J., requires meticulous care because of a disease that makes it difficult for his body to digest proteins. But Patti isn't complaining. David is alive, and extraordinary as it may seem, if it weren't for the diagnosis of his genetic illness, she would still be serving a life sentence—for murder.

"I want to move on, so I try to act like nothing ever happened," says Patti, cradling D.J. in her arms as she

sifts through the terrible memories of all she has been through.

It was five years ago that she met David Stallings, a plate engraver, while working at a 7-Eleven in St. Louis. They married in 1988, and after having a son, Ryan, in April 1989, they moved to nearby Hillsboro. But Ryan was never quite well. He could not hold down his formula and soon began vomiting once a week. "We kind of got used to it," Patti remembers. "He looked so normal." Then, on the morning of July 7, when Ryan was 3 months old, Patti found him listless in his crib, staring at the ceiling, his breathing heavy, his lips shut tight. She set out with Ryan to meet her physician at Children's Hospital in St. Louis, but in her panic turned off the freeway too soon and arrived at Cardinal Glennon Children's Hospital instead.

Ryan was immediately placed on a

respirator. For three anguished days, Patti and David waited as doctors tried to figure out what was wrong. It wasn't until police detectives began questioning the Stallingses at the hospital that the couple understood they were under suspicion: Tests indicated the presence of ethylene glycol—an active ingredient in antifreeze—in Ryan's blood. Police believed the Stallingses had poisoned their own son.

But the nightmare had just begun. At the station, investigators relentlessly pounded the couple with questions: Did they have fights? Was Patti jealous of the baby? "They even told me Patti had failed her lie detector test," says David. In fact the results had been inconclusive, but a seed of doubt had been planted. "It was just for a second," recalls David. "Then my senses came back, and I said, 'They're crazy.'" After Ryan spent his 12th day in

# St. John's Hospital - Joplin, MO

May 23, 2011



# Acknowledgements

- Dr. Sharmini Rogers and Julie Raburn-Miller; Bureau of Genetics and Health Childhood.
- The Missouri NBS Laboratory Senior Staff.
- The Missouri DHSS Office of General Counsel.
- Our NBS colleagues from around the country who gave us valuable advice.