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- **Newborn Screening Sample Research Table**

Missouri Newborn Screening Sample Storage and Release Policy

The Missouri Newborn Screening (NBS) Sample Storage Process was implemented on July 1st, 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.