



Storage and Secondary Use of the Newborn Screening Samples

STORAGE

For the purpose of newborn screening, a small sample of a baby's blood is collected on filter paper and sent to Newborn Screening Ontario (NSO). The dried blood spot sample (DBS) is used to screen for the diseases on the NSO panel. For approximately 6 months following the use of the DBS for screening, any residual sample is stored in NSO at the Children's Hospital of Eastern Ontario (CHEO). After this time, the DBS is stored by NSO in a secure facility off-site.

Dried blood spot samples are stored for 19 years, as they are a part of a child's medical record. After 19 years, the samples are destroyed. The samples for babies born before April 2006 are stored by the Public Health Laboratory in Toronto, Ontario, also for 19 years.

PURPOSE OF STORAGE

The primary reason to store the residual samples is to use them for screening and assuring the quality of screening provided by NSO. NSO strives to ensure that every baby is offered the newborn screening test, and to maximize the identification of babies affected with one of the diseases targeted on the screening panel to allow early treatment and prevention of morbidity or mortality. Conversely, the number of babies with a false positive screening result must be minimized. The stored samples can be used in a number of ways to help improve screening services. For example:

- If a baby has a positive screen but diagnostic testing proves the baby is not affected, it is sometimes necessary to re-run the tests on the original sample to make sure the original results are accurate. Sometimes a second sample is needed from the baby to complete the screening.
- NSO regularly checks the screening cutoffs and the normal ranges for the chemicals measured in the blood; the stored samples assist NSO in performing this task.
- If a baby with a negative newborn screen is later diagnosed with a targeted disease, the baby's stored sample (if one was received) can be tested again. This helps NSO and the baby's other health care providers determine why the baby was missed in the newborn period. If a preventable root cause is discovered, this allows corrective action to be taken to prevent a recurrence of the problem.
- NSO is constantly working to improve existing testing and develop new tests to provide better screening for the targeted diseases. Testing stored samples is the only way to validate these new or improved tests for use in the screening system.

SECONDARY USES

The residual DBS may be also be used for the following purposes:

1. Provision of Health Care. Examples include:
 - i) Retesting the sample to help establish a diagnosis
 - ii) Release of part of the sample to another laboratory for other testing
2. Sharing anonymized samples with other Canadian screening laboratories to provide external quality assurance for all Canadian newborn screening labs, including Ontario's.
3. Use under a Legal Warrant or Court Order. Examples include:
 - i) Use by the Coroner's office if the baby has died unexpectedly
 - ii) Use in a forensic investigation.
4. Research (see below)





POLICIES FOR RESEARCH USE OF SAMPLES

There are two ways that a baby's sample can be used for research:

1. Research that needs the baby's sample linked with the baby's identity.
 - This is only permitted with written consent from the child (if they are old enough to give consent) or from their surrogate decision maker (a parent or guardian).
 - The study must be approved by a research ethics board.
 - The parent/ guardian/ child must be fully informed of the purpose of the research as well as the pros and cons of participating in the research.
 - The parent/ guardian/ child must have the ability to choose to participate or decline to participate in such a research study.
 - If the parent/ guardian/ child declines – the child's sample will NOT be used in the research.

2. Research that requires a baby's sample may be allowed without obtaining the parent's/ guardian's/ child's consent **ONLY IF:**
 - The baby's sample is fully de-identified, meaning that the portion of the child's sample used for such a study can NOT be traced back to the child in any way (e.g. ALL identifying information is removed from the sample: name, date of birth, health card number, address, postal code, mother's name, birth hospital, etc.).
 - The study has been approved by a research ethics board.
 - The study has been scientifically reviewed and approved by NSO.

DESTRUCTION OR RELEASE OF SAMPLE

To request destruction or release of sample from NSO, the parents/ legal guardian/ or child must complete a notarized request form or must attend NSO offices with originals of the required identifying documents to complete the forms in person.

- An original copy of the notarized form is required to complete the request.
- The parents will be notified of the recommendation to store samples until a child is five years of age. If the parents still wish destruction or release of the sample, this request will be honored. If they wish to have the sample destroyed after the child's fifth birthday, they will be asked to make this request at that time.
- The preferred method for releasing the sample is destruction versus returning the sample to the family however, requests to send the sample to the family will be honored.
- If the request form is not completed appropriately, a letter will be sent back to the family informing them of what further action they need to take to process their request.
- If the request arrives when there is a Legal Warrant or Court Order already in place, the request will not be processed until the Legal Warrant or Court Order are complete. The parents will be informed of the Legal Warrant or Court Order, and the relevant authorities will be informed of the parent's request.

