NEWBORN SCREENING ONTARIO'S POLICY FOR THE STORAGE AND SECONDARY USE OF NEWBORN SCREENING SAMPLES

Policy Statement:

Newborn Screening Ontario (NSO) retains dried blood spot samples to ensure quality screening for all babies born in Ontario – to make sure that the newborn screening system and laboratory tests are working properly. Dried blood spots may be used for the purpose of risk management, error management or for the purpose of activities to improve or maintain the quality of care or to improve or maintain the quality of any NSO related programs and/or services.

NSO is committed to ensuring that dried blood spot samples and any related or identifying information are used in compliance with the provisions in the Ontario Personal Health Information Privacy Act (PHIPA) 2004 and in accordance with the wishes of parents/legal guardian/or child.

1) 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 is used to screen for the diseases on the NSO panel. For approximately 6 months following the use of the dried blood spot for screening, any residual sample is stored in NSO at the Children's Hospital of Eastern Ontario (CHEO). After this time, the dried blood spot 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.

2) SECONDARY USES

Purpose of Secondary Use

The residual dried blood spot sample may 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. Quality Assurance Purposes

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

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

i) 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.

ii) Research that requires a baby's sample may be allowed without obtaining the consent of the parent/guardian/child **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.

Opting Out of Research and Secondary Use

Parents/guardians wishing to opt out of the use of their infant's sample for research or other secondary purposes may do so by contacting NSO by phone, email, or by signed and dated letter, stating their request that the identified specimen not be used specifically for research purposes, or any secondary use purposes. They must provide NSO with at least two unique identifiers for their infant.

3) DESTRUCTION OR RELEASE OF SAMPLE

In 2008, an Ontario Advisory Committee on Newborn and Childhood Screening task force recommended a minimum storage time of 5 years to facilitate effective screening and quality assurance for the program. Storing samples for 5 years would allow investigation and retesting if an infant /child is later diagnosed with one of the conditions on the screening panel. Storage of the sample would also allow confirmation that a sample was received and tested. The task force also recommended that parents/guardians be able to request the return or destruction of samples after that 5 year period.
Parents/guardians requesting destruction/release of a sample, both prior to or after this 5 year recommended period, may do so and are required to complete a notarized request form or attend the NSO offices with originals of the required identifying documents to complete the forms.