

## Appendix D

### Newborn Dried Blood Spot Storage and Use

[Heel stick screening](#) is a quick and simple method of obtaining a sample of a newborn's blood. It is one of [three newborn screenings](#) in Indiana that are performed before the infant goes home from the hospital. The resulting dried blood spot (DBS) from the heel stick is sent to the newborn screening laboratory where it is then analyzed for more than 50 rare, life-threatening genetic conditions.

The purpose of this document is to provide hospital staff with key points to discuss with families when obtaining consent for DBS storage. These talking points were drafted by the [Genomics & Newborn Screening](#) (GNBS) Program at the [Indiana Department of Health](#) (IDOH).

#### Consent for DBS Storage

Remember: **consent for storage is required by law** for all heel stick specimens collected. If, for religious reasons, the family refuses the heel stick screen, consent for storage is not warranted as there will be no dried blood spot to be stored. The religious refusal should be completed, signed, and submitted to the GNBS Program. **DO NOT submit a blank NBS card.**

#### Tips for speaking with families about the storage and use of DBS:

- Be kind, compassionate and sensitive with your delivery and language.
- Explain to families the following benefits of consenting to storage:
  - Additional testing should the child need it
  - Identification of a missing or deceased child
  - Quality assurance to ensure tests, equipment and supplies are working correctly for newborn screening
  - De-identified research for public health (this may include research to better understand newborn screening conditions, treatments for conditions, development of other tests for additional disorders for newborn screening and other public health research).
- Ensure families know that their child's information will be **de-identified** and not disclosed.
- Educate families about the need for all samples to be kept for at least six months, per best practices, in case a test needs to be repeated. After six months, the sample will be destroyed unless the family consents to storage. If the family consents to storage, it will be kept for three years and then destroyed.
- Remind families that consent for storage beyond six months is optional; however, by law, hospital staff must ensure a parent indicates their choice and signs the card for every heel stick specimen obtained from their child.

## Frequently Asked Questions About Dried Blood Spots

### **Q: Why are dried blood spots stored?**

**A:** There are a couple of reasons DBS are stored. First, good laboratory practices require DBS samples to be kept for a period of time after testing is completed, in case a test needs to be checked or repeated. DBS are also used by newborn screening laboratories to help develop new tests for newborn screening and to ensure laboratory equipment is working correctly. Lastly, DBS can be used for de-identified research that may help future children and families.

### **Q: What type of research is performed?**

**A:** Using de-identified DBS for research can provide important information about what may cause a disease or impact a person's health—not just in Indiana, but all over the world. DBS are useful for studying the cause of or treatments for disease. DBS have been used for researching causes of cancer and birth defects and the development of new newborn screening tests, life-saving treatments, cures for conditions and more! The use of DBS for cloning or stem cell research is not permitted.

### **Q: What steps are taken to protect the privacy of the family and child?**

**A:** Indiana's newborn screening law does not allow researchers access to any identifying information about the parents or child. Researchers will only be given a punch from the child's DBS. Every researcher who wants to use DBS from Indiana must submit a written request to the GNBS Program, including their commitment to comply with privacy and confidentiality regulations. No identifying information about the family or child will be published or available to anyone else.

### **Q: How long is the DBS stored?**

**A:** The DBS is stored and made available for de-identified research purposes for a period of three years and then is destroyed. If consent to storage was not given, the DBS is kept for six months to ensure additional screening for the infant is not necessary, and then the DBS is destroyed.

### **Q: Can parents change their minds?**

**A:** Yes! If a parent who previously consented to storage of the DBS wishes to have the DBS destroyed, they may complete and submit [State Form 55650](#) any time within the DBS storage period. The DBS storage period spans three years from the date the DBS was collected, which is usually a day or two after the birth of the child.

If a parent who previously DID NOT consent to storage of the DBS later chooses to have the DBS stored, they must complete and submit [State Form 55651](#) within six months from the date the DBS was collected. If the parent does not enter this request prior to the six-month storage period, the DBS will already have been destroyed.