



Newborn Screening Program Manual



This program manual serves as a reference for professionals who have a role in Indiana's state-mandated Newborn Screening Programs and its best practices and procedures.

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Indiana Newborn Screening Program and Goals

The Indiana Department of Health (IDOH) Genomics and Newborn Screening Program envisions a state that values and acknowledges genetics in healthcare by offering Hoosier newborns, children, and their family's equitable resources and opportunities to reach their health potential.

Newborn screening started in the United States in the 1960s with the creation of the Guthrie card (newborn screening card) and the screen for phenylketonuria (PKU). Newborn screening slowly expanded to include endocrine conditions, galactosemia, sickle cell disease, and Biotinidase deficiency. Rapid expansion of the heel stick occurred with the advancement of tandem mass spectrometry in the early 2000s. The hearing screen was added in 2000, and Indiana was the second state to implement the CCHD screen through pulse oximetry in 2012. Conditions continue to be added to Indiana's newborn screening panel. Indiana now screens for over 50 conditions.

View the most up to date [Newborn Screening Program History Timeline](#).

What is the Genomics and Newborn Screening (GNBS) Program?

The GNBS program is a state-mandated program within the Maternal and Child Health (MCH) division of IDOH that houses both the [Indiana Birth Defects and Problems Registry \(IBDPR\)](#) and the [Newborn Screening Program](#). The GNBS Program is responsible for ensuring every Hoosier infant receives timely and quality newborn screening.

Newborn screening is mandated by [Indiana Code 16-41-17](#) and [Indiana Administrative Code 410 IAC 3-3](#). Every infant born in Indiana is required by state law to complete newborn screening. The GNBS Program is responsible for the oversight of the heel stick and CCHD screens, while working closely with our sister program, the Early Hearing Detection and Intervention (EHDI) program, for the newborn hearing screen.

What is Newborn Screening?

Newborn screening (NBS) is a set of three health screens that identify at-risk infants for over 50 conditions. These three screens are:

1. **Heel stick**—To detect a variety of serious genetic conditions before symptom onset.
 - o View the conditions currently screened for in Indiana on the [Newborn Screening Conditions List](#).
 - o View the [Screening Methods and Targets](#) for each condition.
2. **CCHD**—To detect critical congenital heart defects (CCHDs) via pulse oximetry.
3. **Hearing**—To detect congenital hearing loss.

All birthing facilities and midwives must ensure the three screens listed above are performed for each newborn. Primary care providers and other physicians who see infant patients must ensure all their infant patients received the three screens.

Why is Newborn Screening Important?

Newborn screening has been credited as a public health success as it plays a vital role in reducing infant mortality and morbidity. Infants born with conditions may look and act like healthy newborns but may have a medical condition that could cause serious illness, developmental delay, disability, or even death. Completion of timely and accurate newborn screening will ensure the best outcomes for infants and their families.

Newborn Screening Goals

Our mission is to promote, protect, and improve the health of identified Hoosier newborns with genetic conditions and birth defects. When performing the three screens, it is important to remember the goals of newborn screening:

1. Early diagnosis (before symptom onset) and treatment of screened conditions
2. Avoidance of associated disability, morbidity, and mortality

Health Professional Roles and Responsibilities

Individuals who play a part in ensuring that all infants born in Indiana receive valid and timely newborn screening and any necessary follow-up are important to the GNBS program. Indiana has over 80 birthing hospitals and birth centers throughout the state. In addition, a large portion of home births occur in Indiana. Nurses, physicians, midwives, pediatricians, primary care providers, OB/GYN offices, health departments, geneticists, genetic counselors, and other sub-specialists all have a role in newborn screening. It is important to recognize the work and maintenance that goes into ensuring that every family receives timely education, screening, and follow-up services. Everyone has a crucial role to play in the early detection and intervention of these severe conditions. The picture below represents roles within the newborn screening system.



Birthing Facility, Birth Center, and Midwife/Home Birth Attendant Responsibilities

All birthing facilities, birthing centers, and midwives are responsible for performing the heel stick, CCHD, and hearing screens for each infant. Each facility is also responsible for educating parents prior to newborn screening and ensuring the NBS cards are completely filled out with accurate documentation and a completed consent for dried blood spot (DBS) storage card for each infant. Each birth facility, birth center, and midwife/home birth attendant are required by law to keep a newborn screening log. To learn more about the birthing facility's or birth center's specific duties and appropriate reporting to the GNBS program, please see [Appendix E](#). To learn more about the role of the midwife or home birth attendant, please see [Appendix G](#).

Primary Care Provider (PCP) Responsibilities

All primary care providers are responsible for obtaining, communicating, and explaining newborn screening results with families. PCPs are also responsible for facilitating initial screens, rescreens, or confirmatory testing when needed. PCPs will be contacted by the NBS laboratory if rescreens are needed. PCPs may also be contacted by our care coordination partners for any follow-up to presumptive positive results. PCPs are responsible for reviewing the Act Sheet provided to them by the NBS laboratory including collaboration with the listed care coordination partner for guidance. To learn more about the primary care provider role and specific duties, please see [Appendix F](#).

Care Coordination Partner Responsibilities

The GNBS program awards funding to clinical partners who provide care coordination services to ensure that all infants who have presumptive positive or abnormal heel stick results receive confirmatory testing, follow-up care, and genetic counseling when appropriate. All care coordination partners are responsible for collaborating with PCPs and the NBS laboratory regarding abnormal results. Care coordination partners will consult with the PCP for appropriate rescreen or confirmatory testing. In addition, they will verify that identified infants receive timely medical intervention.

Newborn Screening Lab Responsibilities

The newborn screening lab is responsible for distributing NBS cards to birthing facilities and midwives, entering CCHD and hearing results, screening all initial and subsequent heel stick specimens, and initiating short-term follow-up on all presumptive positive screens by contacting PCPs, submitters, and care coordination partners. The NBS lab will also contact the submitting facility for all specimens that are quantity not sufficient (QNS) or missing information on the NBS card. The NBS laboratory contact information can be found on our [Contact Us](#) webpage.

Newborn Screening Log

The NBS log (paper or electronic*) is required to be maintained by every hospital, birthing center, and midwife or physician attending a home birth. The NBS log must document the following information for all infants born, transferred in, or otherwise screened:

- Name of newborn or infant
- Attending physician or midwife (follow-up PCP is recommended)
- Medical record number
- NBS card number of sample sent
- Date each screen was performed
- Date NBS card sent to NBS lab
- Date heel stick results received
- Results of each newborn screen:
 - Heel Stick - Normal, Abnormal, or Quantity Not Sufficient (QNS)
 - CCHD – Oxygen saturation % for right hand and foot, and whether it was Pass or Fail (if failed, list echo date and normal/abnormal result)
 - Hearing – Pass, Fail, or Refer
- Name of person notified of abnormal results and the date and time of notification

The NBS log should be reviewed daily to ensure that every infant has been screened and the results have been received and recorded within 14 days—**if results are not received within 14 days, the submitter must contact the NBS laboratory by telephone to confirm receipt of the specimen.**

*Facilities and midwives are encouraged to utilize the **Microsoft Excel NBS log templates** located on our [Resources for Providers](#) webpage to ensure all required fields are included in the log.

All information that is documented in the NBS log should also be documented in the facility's electronic medical record (EMR). This includes results received from the NBS lab. The facility should scan and upload the results into each child's EMR or otherwise retain the child's results.

NBS logs and related newborn screening information must be kept on file, either physically or electronically:

- NBS logs must be kept for a minimum of one year after the most recent birth listed. If organizational policy requires them to be kept longer, please follow the organizational policy.
- Newborn screening results must be scanned into the EMR or stored in the medical chart and kept indefinitely.

Newborn Screening Card

The newborn screening card is used to capture information about all three screens. The white part of the card is a special filter paper used to collect the blood specimen for the heel stick screen. There are two carbon copies behind the front card—a yellow and a pink copy. The yellow copy is intended for record keeping by the hospital, birth center, or midwife. The pink copy may be removed and held back if the CCHD or hearing screen results will be delayed more than 3 hours after the heel stick is performed. Once the CCHD or hearing results are available, the pink slip may be sent to the NBS lab through the normal method for NBS card submission.

Storing and Handling New/Unused Newborn Screening Cards

- ✔ Store new cards upright, not flat or laying on top of each other. This helps to keep the fibers within the filter paper from becoming compressed. Compressed fibers lead to quality issues like uneven saturation of the blood.
- ✔ Store cards in a cool, dry location away from direct sunlight or heat.
- ✔ Always check the expiration date prior to performing the heel stick. NBS cards can be used through the last day of the month of the expiration date printed on the card. Expired cards submitted for screening will be considered unsatisfactory and another screen will be requested, which could delay diagnosis and treatment. It is essential to review NBS card expiration dates regularly to help manage inventory.
- ✘ Do not photocopy cards. If you need a copy for your own reference, simply detach the yellow carbon copy.

Requesting NBS Cards and/or Envelopes

If your facility needs additional newborn screening cards or envelopes, contact the Newborn Screening Laboratory by calling 1-800-245-9137.

Change of Information

If the information written on the newborn screening card needs to be updated after the card has already left your facility, complete a [Lab Change of Information Form](#) and fax it to the NBS Laboratory at 317-321-2495 as soon as possible.

Completing the NBS Card

All fields on the NBS card must be filled out in their entirety to allow for timely screening, follow-up, and confirmatory testing if needed. When information is not completed, screening is delayed because staff from the NBS lab will need to contact the submitter before testing the specimen. Never submit an NBS card if there is no blood applied. If a heel stick screen is refused, complete the appropriate religious refusal, and submit to GNBS program. Review the [Refusals of Newborn Screening](#) section in this document for more information regarding religious refusals. The following pages explain how to complete the NBS card.

Front of NBS Card – Demographic and Screening Information:

Does not print

Use Ball Point Pen. Press Hard. Instructions on Back. Print Legibly

10534578 REF Rev. AF
XXXXXX
XXXXXX
LOT

PLEASE PRINT: Complete Entire Form

Infant's Last Name **1** First Name **2** Multiple Birth: (A, B, C, etc.) **3**

Infant's Previous Last Name **4** Infant's Medical Record # **18**

Infant's Birthdate **4** Type of Feeding: **5** Collection Date **6**

Time (Military) **7** Sex: Male Female Unknown/Ambiguous

Mother's Full Name **8** Mother's Phone **8**

Mother's DOB **8** Address **9** City / State / Zip **9**

Hospital **9** Submitting **9** Birth (if Different) **9**

Infant's Physician **10** Address **10** City / State / Zip **10**

Birthweight in grams **11** Race: White Black American Indian Asian Other **12**

Ethnicity: Hispanic Non-Hispanic Unknown **13**

Status: 1. Normal 2. NICU 3. Meconium ileus 4. Transfused (gest. age ___ wks.) Yes No Yes No

Date of last RBC Transfusion ___/___/___

BLOOD DRAWER ID **14** PREVIOUS REQUISITION # **15** Submitter Label **16**

Initial Screen **17** Repeat Screen Prev. Abn Prev. QNS

18 Newborn Lab Use Only

19 Hearing Screening Initial Rescreen

Date of Screen ___/___/___ Final Screen Left ___/___/___ Final Screen Right ___/___/___

Results Pass Refer Pass Refer

Risk Factors Yes No

Intrauterine Infection Jaundice Craniofacial anomalies Family History

20 Pulse Oximetry Screening

Performed NICU Nursery Exempt

1st Reading Date ___/___/___ Time ___:___

21 Right Hand ___/___/___ Foot ___/___/___

Pass Did Not Pass

2nd Reading Date ___/___/___ Time ___:___

Right Hand ___/___/___ Foot ___/___/___

Pass Did Not Pass

Echo Date ___/___/___ **22**

Normal Abnormal

SN LXXXXXX

HOSPITAL COPY

Back of NBS Card – Consent for Storage of Dried Blood Spots (DBS):

Storage and Use of Newborn Screening Dried Blood Spots (DBS)

NOTES:

- Parent(s) or legal guardian(s) must indicate whether they accept or decline participation in research & sign bottom of form.
- If participation is declined, child's DBS will be destroyed after 6 months in storage.
- If participation is accepted, child's DBS will be stored in freezer w/ humidity control & allowed to be used for research (samples will be de-identified for research use). Child's DBS will be destroyed after 3 years in storage.

23

You should have been given the brochure called "After Newborn Screening." This brochure describes how your child's blood sample from newborn screening (also called a dried blood spot, or DBS) could be used for medical research after newborn screening is complete. Please read this brochure. If you did not receive a copy, please ask your child's nurse or primary care provider for one.

As your child's parent(s) or legal guardian(s), you have the right to decide whether your child's DBS will be used for medical research after newborn screening is complete. Please read the information below. Once you decide whether your child's DBS can be used for medical research after newborn screening, check "YES" or "NO" and then sign the bottom of this form.

- It is important for parent(s)/guardian(s) to understand that participating in medical research is completely voluntary.
- There is no penalty for declining to have your child's DBS used for medical research after newborn screening.
- If you agree to have your child's DBS used for medical research now, but change your mind later, you can call the Indiana State Department of Health Newborn Screening Program & ask that your child's DBS not be used for research.

I/we have read the brochure called "After Newborn Screening" and the information above. My/our decision about my/our child's DBS is below. My/our permission applies to this specific sample only.

PLEASE CHECK EITHER YES OR NO.

24

YES. I/we agree that my/our child's dried blood spot (DBS) can be used for medical research after newborn screening is complete. My/our child's DBS will be stored for use in future medical research. My/our child's DBS will be destroyed after 3 years.

NO. I/we decline the use of my/our child's dried blood spot (DBS) in medical research after newborn screening is complete. My/our child's DBS will be destroyed after 6 months.

If you have more questions about dried blood spots & medical research, please contact the Indiana State Department of Health Newborn Screening Program at (888) 815 – 0006.

25

Parent/legal guardian signature _____

Date _____

SN



LXXXXXX

NBS Card Field Information:

The table below lists the corresponding numbered NBS card fields from page 10 to provide additional information and tips for completing the NBS card.

<p>1 Infant's Name fields – Write the infant's names and ensure spelling is correct and handwriting is legible.</p> <ul style="list-style-type: none"> - Write the infant's current last name and first name at the time of screening. - Infant's Previous Last Name: If this is a repeat screen, write the infant's previous last name on the "Infant's Previous Last Name" line. This helps the NBS lab identify all screens each infant has had. - If any names are unknown, write the name that is used in the patient's medical record. As soon as the name has become known, fill out a Lab Change of Information Form and fax it to the NBS lab immediately. This will assist follow-up of any abnormal results. 	<p>2 Infant's Medical Record # – Write the infant's medical record number.</p> <ul style="list-style-type: none"> - The number that is written in this field will be listed on the final newborn screen results report. - Ensure the correct MRN is included so it can be used to identify the patient in the event of uncommunicated name changes.
<p>3 Multiple birth field – Complete this section only if there is a multiple birth.</p> <ul style="list-style-type: none"> - Enter the birth order from first to last using letter values (A, B, C, etc.). 	<p>4 Birthdate and Time of Birth – Write the birthdate and time of birth of the infant.</p> <ul style="list-style-type: none"> - Use the date format MM/DD/YY. - Use the military time format oooo. - Including the accurate date and time of birth helps the NBS lab to know whether the heel stick was collected during the appropriate timeframe, between 24 and 48 hours after time of birth. - Collecting before this timeframe will result in an invalid heel stick result and will require an additional screen.
<p>5 Type of Feeding – Check the appropriate box to indicate the infant's current feeding type at time of collection.</p> <ul style="list-style-type: none"> - Lactose 	<p>6 Collection Date & Time – Write the date and time when the heel stick was performed, and the blood was dropped onto the filter paper.</p> <ul style="list-style-type: none"> - Use the date format MM/DD/YY.

<ul style="list-style-type: none"> - Breast - Lactose Free - NPO: Infants who are NPO may not have adequate protein challenge to cause the analyte increases the NBS lab looks for during testing. Knowing that the infant is NPO helps to identify false negative results. - Soy: Infants on soy are unable to yield valid Total Galactose results, which can be needed to appropriately screen for galactosemia. Total Galactose is used as a reflex test when the GALT is abnormal or when the infant has been transfused. GALT is in red blood cells, so transfusion invalidates this test. Knowing an infant is on soy helps to identify possible false negative galactosemia results. - Hyperal (TPN): Infants who are on Hyperal (TPN) may flag during lab testing for various amino acids because they may be present in the formula. Knowing that the infant is on TPN helps to identify false positive results. 	<ul style="list-style-type: none"> - Use the military time format 0000. - Be sure this date is accurate because it can tell the NBS lab a few things: <ul style="list-style-type: none"> - This can indicate whether the screen was performed during the appropriate timeframe between 24 and 48 hours. - This can also indicate if there is a delay in transit from the facility to the lab. Specimens greater than 10 days old will be too old to yield valid results.
<p>7 Sex – Check the box that indicates the biological sex of the infant.</p> <ul style="list-style-type: none"> - Male - Female - Unknown/Ambiguous: Ambiguous genitalia can be associated with congenital adrenal hyperplasia (CAH). 	<p>8 Mother’s Full Name, DOB, Phone & Address – Write the mother’s first name, middle initial, last name, date of birth, telephone number, and address in the appropriate fields.</p> <ul style="list-style-type: none"> - Use the date format MM/DD/YY. - Please ensure all information is up-to-date and current. This allows for timely follow-up of abnormal results. - If the birth mother is a surrogate or the infant will be placed for adoption, include the name and information of the adoptive guardian. This ensures the correct

	guardian will be contacted in the case of abnormal results.
<p>9 Hospital (Submitting) – Write the name of the facility where the heel stick was performed.</p> <ul style="list-style-type: none"> - Including this information allows the NBS lab to know where to send the results and helps when addressing heel stick timeliness and quality concerns. <p>Hospital (Birth) – Write the name of the facility where the infant was born if it is different from the Submitting Facility name.</p> <ul style="list-style-type: none"> - All births and heel sticks performed in a home setting should include the name of the midwife as the birth facility or submitting facility name. 	<p>10 Infant's Physician – Write the full name and mailing address of the attending physician, or PCP, who will be caring for the infant.</p> <ul style="list-style-type: none"> - If the PCP has not yet been identified, include the name of the attending physician or other healthcare professional who will be able to relay results to the family and assist in follow-up of abnormal results. - Once the correct PCP's information is available, fill out a Lab Change of Information Form and fax it to the NBS lab immediately. This will assist follow-up of any abnormal results.
<p>11 Birthweight – Write the infant's birthweight in grams.</p> <ul style="list-style-type: none"> - Include only one digit in each of the slots. <div data-bbox="391 1129 607 1289" style="text-align: center;"> </div>	<p>12 Race & Ethnicity – Check the boxes to indicate the infant's race(s) and ethnicity.</p> <ul style="list-style-type: none"> - If the infant is multiracial, check every box that applies. - If the infant is of a race that is not listed, check the "Other" box, and write the correct race on the line next to "Other". - For ethnicity, check the box to indicate whether the infant is of Hispanic origin or if this is unknown.
<p>13 Infant's Status – Indicate the status of the infant at time of collection.</p> <ul style="list-style-type: none"> - Normal: Check this box if infant is in the newborn nursery. - NICU: Check this box if infant is in the NICU. <u>Include the infant's gestational age in weeks.</u> NOTE: Infants in the NICU may follow a special screening schedule. See Appendix C to learn more. - Meconium Ileus: <u>ALWAYS</u> check <u>YES</u> or <u>NO</u> to indicate whether infant 	<p>14 Blood Drawer ID – Write the identifying number or initials of the person performing the heel stick.</p> <ul style="list-style-type: none"> - The ID written on the NBS card will be listed in the quality reports sent from the NBS lab. - If there are any quality concerns with the specimen, knowing the ID of the person who performed the heel stick will allow for targeted education efforts.

<p>has meconium ileus. DO NOT check Yes for meconium stool or meconium stain. Meconium ileus is a bowel obstruction in the small intestine. This field is vital for appropriate cystic fibrosis screening.</p> <ul style="list-style-type: none"> - Transfused: Check the box if infant is a whole red blood cell transfusion. <u>Include the date when the most recent whole red blood cell transfusion occurred in MM/DD/YY format.</u> - NOTE: Infants who have been transfused will follow a special screening schedule. See Appendix C to learn more. 	
<p>15 Previous Req. Number – If this is a repeat/subsequent screen, list the requisition (req.) number of the previous screen.</p> <ul style="list-style-type: none"> - Locate this number on the front of the NBS card, directly underneath the barcode. - Include the letter and all six numbers. (ex. L#####) - The requisition number allows the NBS lab to reference previous results and guide follow-up actions. 	<p>16 Submitter label – Use this area to place the infant's medical record label.</p> <ul style="list-style-type: none"> - This reduces the chance of missing information, which would lead to delayed screening and follow-up.
<p>17 Heel Stick Screen Type – Check the correct box to describe whether the heel stick screen is the initial or a repeat screen. Each of the screen types will help the NBS lab determine the follow-up actions that need to take place:</p> <ul style="list-style-type: none"> - Initial Screen: Check this box if this is the first heel stick screen that has been performed and submitted for this infant. - Repeat Screen: Check this box if this is NOT the first heel stick screen that has been performed and submitted for this infant. 	<p>18 Hearing Screening – Check the correct box to indicate whether the hearing screen results are from an "initial" or "rescreen".</p> <ul style="list-style-type: none"> - Initial Screen: Check this box if this is the first hearing screen that has been performed on this infant. - Repeat Screen: Check this box if this is NOT the first hearing screen that has been performed on this infant.

<ul style="list-style-type: none"> - Prev. Abn: Check this box if the previous screen for this infant had a presumptive positive/abnormal result. - Prev. QNS: Check this box if the previous screen had the quality error "quantity not sufficient" (QNS). 	
<p>19 Hearing Screen Date, Results & Risk Factors – Write the date in the format MM/DD/YY to indicate when each hearing screen was performed. Check each appropriate box with the infant's results, whether there were risk factors, and what the risk factors were.</p> <ul style="list-style-type: none"> - Hearing screen results and risk factors should also be entered in the EMR and NBS log. 	<p>20 Pulse Oximetry Screening Performed – Check the appropriate box to indicate the location where the CCHD screen was performed.</p> <ul style="list-style-type: none"> - NICU: Check this box if the CCHD screen(s) was performed while the infant was admitted to a NICU or other unit with a higher level of care than the well-baby nursery. - Nursery: Check this box if the CCHD screen(s) was performed while the infant was in the well-baby nursery. - Exempt: Check this box if the initial or repeat CCHD screen was not performed due to one of the exemptions on the Pulse Oximetry Exceptions Guide or a Religious Refusal. All exemptions must be reported to GNBS through the MSR.
<p>21 Pulse Oximetry 1st & 2nd Readings – <i>Include the date and time of each screen, oxygen saturations for both extremities in each reading, and CCHD screen result.</i></p> <ul style="list-style-type: none"> - <i>Use the date format MM/DD/YY.</i> - <i>Use the military time format 0000.</i> - <i>Include oxygen saturation percentages for the right hand and foot for all screens performed.</i> - <i>Indicate whether the scores resulted in a Pass or Did Not Pass result.</i> - <i>If the infant Did Not Pass the 1st and 2nd CCHD screen, information about the echocardiogram must be included.</i> 	<p>22 Echo Date & Result – Include the date when the echocardiogram was performed and the result.</p> <ul style="list-style-type: none"> - Use the date format MM/DD/YY. - Check the appropriate box to indicate whether the echo had normal or abnormal findings. - Be sure to document the echocardiogram results in the required NBS log.

<p>- <i>Be sure to include all saturations and results in the required NBS log.</i></p>	
<p>23 Consent for Storage of Dried Blood Spots (DBS) Information –</p> <p>After heel stick screening, there will be leftover dried blood on the NBS card. According to Indiana statute, the remaining DBS can be made available for epidemiological research to identify new conditions, treatments, and preventive measures. All research is required to be deidentified per Indiana Code 16-41-17-10. Leftover DBS may also be requested by the child's physician to be used for additional testing.</p> <p>IDOH requires consent from parents or guardians of infants if they would like to make their child's DBS available for research purposes. Parents or guardians must indicate their DBS storage timeline preference by checking the corresponding box and signing the DBS consent card. All DBS are stored for six months regardless of consent and then destroyed.</p> <p>Within the six months, parents or legal guardians who previously did not consent to storage can request that their child's DBS be stored for three years for research purposes by completing and submitting state form 55651 Request for Storage of Dried Blood Spot to the GNBS Program. Parents or legal guardians who initially consented to storage may request that their child's DBS be destroyed within the three years by completing and submitting state form 55650 Request for Destruction of Dried Blood Spot to the GNBS Program.</p>	
<p>24 Dried Blood Spot Storage Consent</p> <ul style="list-style-type: none"> - Yes: If the parent checks "YES", consent to storage is granted. <p>The infant's DBS will be screened and destroyed in three years. The DBS will be made available for deidentified epidemiological research until it is destroyed.</p> <ul style="list-style-type: none"> - No: If the parent checks "NO", consent to storage is not granted. The infant's DBS will be screened and then destroyed in six months. <p>The infant's DBS will not be made available for research. The DBS will be kept for six months to ensure all screening has been completed and then will be destroyed.</p>	<p>25 Signature of Parent – Parent must check the box AND sign the card to validate the consent.</p> <ul style="list-style-type: none"> - IDOH requires hospitals, birthing centers, midwives, and attending physicians to ensure that every heel stick DBS consent card is fully completed, including a checked "YES" or "NO" box and a parent's signature. - Failure to submit completed consent cards will lead to an audit by the GNBS Program.

Refusals of Newborn Screening

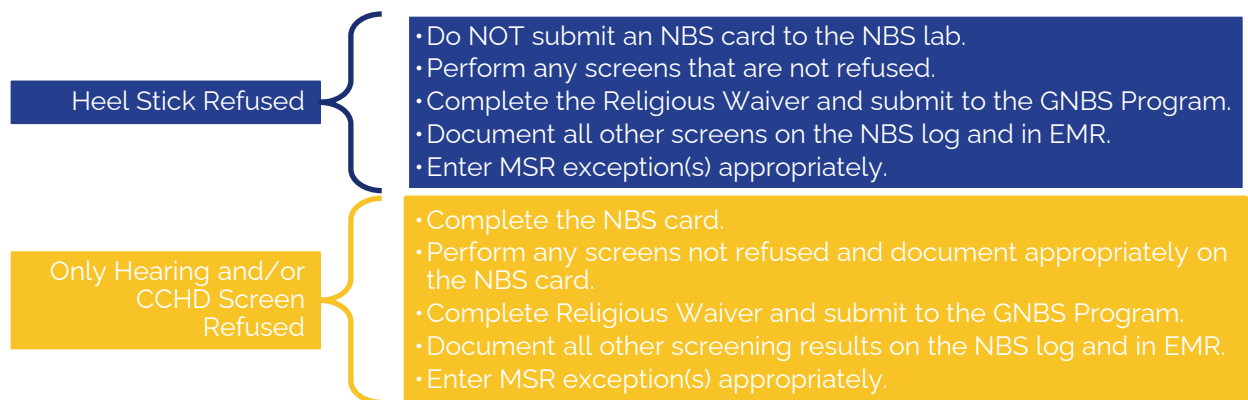
Indiana has mandated that all infants receive newborn screening unless it does not align with their religious beliefs.

Per Indiana Code (IC 16-41-17-2), a family can refuse one, two, or all three parts of newborn screening due to religious beliefs. To refuse any or all parts of newborn screening, the parent must complete the [Religious Waiver form 54102](#). This waiver is also available in [Spanish](#).

How to Document a Religious Refusal

The parent must complete the form by indicating which screen(s) they are refusing to be performed on the infant. The parent must write the infant's name, infant's date of birth, mother's name, and mother's date of birth. The parent must sign and date the completed form. A witness from the birthing facility or the midwife/attending physician must also sign and date the waiver on the line labeled "Witness".

If one screen is refused, the other two screens should be performed and documented. **If the heel stick screen is refused, do not submit an NBS card to the NBS laboratory.** Instead, complete the religious waiver form and document the CCHD screening and hearing screens appropriately on the religious waiver.



Always report religious refusals by completing the appropriate exception in the [Monthly Summary Report \(MSR\)](#) to the GNBS Program and attaching the [Religious Waiver form 54102](#) into the MSR exception. If you do not have the capability to upload the completed Religious Waiver into the MSR exception, it is still required to submit the waiver to the GNBS Program. This can be submitted to the GNBS Program via [email](#) or fax to 317-234-2995.

Note: There are no guidelines to verify a religious affiliation. The birthing facility or midwife must obtain a completed and signed copy of the Religious Waiver. The birthing facility or midwife must immediately submit this document to the GNBS Program and maintain a copy of this refusal. Submitting a completed and signed [Religious Waiver form 54102](#) precludes hospitals, birthing facilities, or midwives from the risk of legal issues should the infant be diagnosed with a newborn screening condition after symptom onset.

Monthly Summary Reporting (MSR)

All Indiana birthing facilities, birth centers, midwives, and other entities overseeing births are required by Indiana law to submit timely and accurate Monthly Summary Reports to the GNBS and EHDI programs. The purpose of MSRs is to ensure that the GNBS and EHDI programs are provided with information of all infants born in Indiana who are not screened so they may fulfill their responsibility of ensuring each infant born in the state of Indiana receives timely newborn screening.

MSRs for heel stick and pulse oximetry (CCHD) screens must be submitted through [INSTEP](#). Hearing screen MSRs and diagnostic results must be submitted through EARS (EHDI Alert Response System). See the [EHDI Hospital Policy Manual](#) for information about how to sign up and report to EARS.

All MSRs are Due by 5PM EST on the 15th of Every Month

Heel Stick MSR

- . Total # births
- . Total # home births/walk-ins
- . Total # infants screened
- . Details of infants not screened

Pulse Oximetry MSR

- . Total # births
- . Total # home births/walk-ins
- . Total # infants screened
- . Details of infants not screened

Hearing MSR

- . Total # births
- . Total # infants screened
- . Details of infants who did not pass
- . Details of infants not screened

Submit online through INSTEP to GNBS Program. GNBS Program will review reports and follow up with infants who were not screened.

Submit online through EARS to EHDI Program. EHDI Program will follow up with infants who did not pass.

Helpful Tips:

- . Ensure all information from the [NBS log](#) is made available for the MSR reporters to view and utilize.
- . Enter information into the MSR daily because it allows for timely follow-up by the GNBS Program.
- . Ensure all MSR reporters receive [MSR training](#) and are assigned periodic refresher trainings.
- . Identify a backup MSR reporter who can be trained and assigned reporting access to INSTEP and/or EARS. This reduces the risk of missing reports in the case of vacations, illnesses, and turnover.
- . Visit the [GNBS Monthly Summary Reporting](#) webpage for additional MSR resources.

Indiana Newborn Screening Tracking and Education Program



INSTEP is the online application for reporting newborn heel stick and CCHD screen information to newborn screening to the GNBS Program and to retrieve newborn screening results. The INSTEP application is housed within the IDOH Gateway portal, which can be accessed through an Access Indiana account.

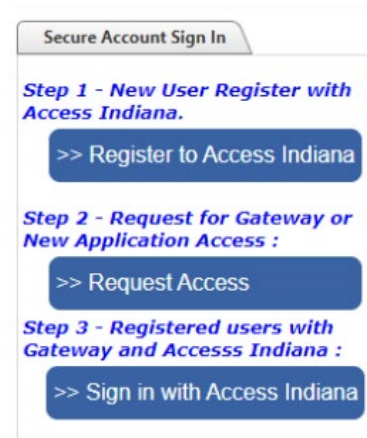
Who needs access to INSTEP?

- **Birth facility staff** who will report MSRs (a minimum of two staff for each facility is recommended to have access in case of time off or turnover). **If the MSR reporter for your facility changes, please notify the GNBS Program with updated contact information as soon as possible.** To learn more about MSR reporting, view the [MSR reporting](#) section of this manual.
- **Midwives/attending physicians** who will report MSRs and retrieve NBS results.
- **Healthcare providers and support staff** are granted access to retrieve newborn screening results. Healthcare providers are encouraged to obtain and review all pediatric patients' newborn screening results during the infant's first well-child check.

How to obtain access?

Visit the [IDOH Gateway](#) and follow the three steps to set up your account for Access Indiana and INSTEP. **Each person accessing INSTEP is required to have their own account.**

1. Register for an [Access Indiana Account](#). For assistance registering for an Access Indiana account, visit the [Access Indiana Getting Started](#) webpage.
2. Request [Access to INSTEP Application](#) through Gateway. Complete all required fields of the form that appears in the web browser.
 - In the Request Type drop-down, select the option that pertains to you.
 - If you do not have a Gateway account, select "New User Request for the Gateway Access".
 - If you have a Gateway account for another purpose (EARS, lead reporting, perinatal levels of care, etc.), select "Existing User Requesting for New Application Access"..
 - In the Application drop-down menu, select INSTEP.
3. After completing steps 1 and 2, visit the [IDOH Gateway](#) and click the blue button under step 3 to sign in with your Access Indiana account to get to INSTEP.



For Access Indiana assistance, please call 1-866-960-3023 between 8 a.m. and 9 p.m. Monday through Friday or between 9 a.m. and 1 p.m. on Saturday.

Heel Stick Overview

The newborn heel stick is a quick and simple method of obtaining a small sample of a newborn's blood to allow screening for over 50 rare, life-threatening genetic conditions. Each of these conditions may cause severe morbidity or mortality if left untreated. Heel stick screening allows for early identification and treatment, which lead to improved health outcomes for the identified infants.

Heel Stick Basics and Special Cases:

All newborns in the healthy newborn nursery are required to have the heel stick collected between 24 and 48 hours after birth. Infants who are in the neonatal intensive care unit, preterm, low birthweight, or receiving whole blood transfusions will follow a special heel stick screening schedule. The special schedules assist the lab with identifying false positive and false negative cases. See [Appendix C](#) for more information about the special cases schedule.



Collect at least 24 hours after birth and not later than 48 hours after birth. Always collect before patient is discharged home.

Collect prior to transfer and whole blood cell transfusion regardless of time elapsed since birth.



There are multiple reasons subsequent screens may be needed. Follow the established rescreen protocol in [Appendix C](#).

Infants Transferring Out Prior to 24 Hours:

If an infant will be transferred out of the birth facility to another healthcare facility prior to 24 hours after birth, **the birth facility must ensure a heel stick is performed before the infant is transferred.** A second heel stick must then be performed between 24 and 48 hours after birth. The initial collection prior to 24 hours ensures the infant will not miss their heel stick, while the second collection between 24 and 48 hours will help to validate results from the early collection.

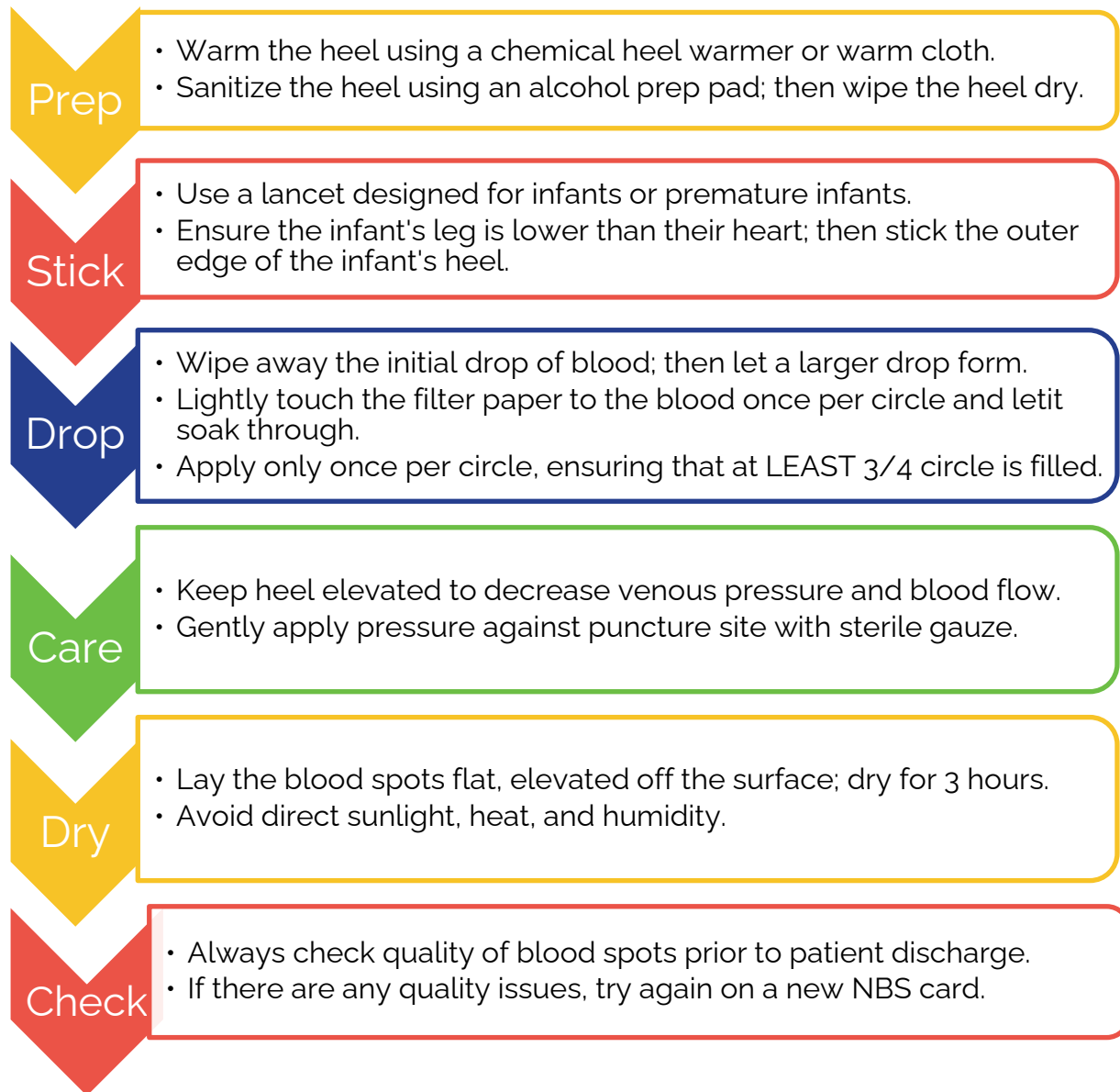
Infants Discharged Prior to 24 Hours:

If an infant will be discharged prior to 24 hours after birth, the birthing facility is required to collect a heel stick before the infant leaves the facility. The birthing facility must collect a repeat heel stick between 48 and 120 hours after birth. The parents must be provided with a written notice, at or before time of discharge, of the need for a repeat heel stick between 48 and 120 hours after birth.

An infant should never be discharged home before performing a heel stick. In the rare event that a heel stick is not collected prior to discharge nor a [religious waiver](#) signed, the birthing facility must enter the infant as an [MSR exception](#) and immediately notify GNBS via phone call at 888-815-0006.

How to Perform the Heel Stick

Follow the six steps to assist the collection of excellent quality dried blood spots:



View and print the [Blood Specimen Collection Handout](#) that displays step-by-step instructions for performing the heel stick.

Complete the [Heel Stick Quality Training](#) in IN-TRAIN, which explains how to collect a good quality heel stick specimen.

Contact the GNBS Program at 888-815-0006 with questions about heel stick collection procedure and technique.

Heel Stick Results and Recommended Actions

If all testing has been successfully completed at the lab, a **Patient (Final) Report** will be generated and sent from the NBS lab to the submitter listed on the NBS card. If an abnormal result for a time-critical condition is generated before all testing has been completed at the lab, a **Partial Report** will be generated and sent to the submitter, as well as the physician listed on the NBS card.

Physicians must sign up for INSTEP access to retrieve NBS results for their patients. See the [INSTEP section](#) for additional information. If the results are presumptive positive or abnormal, the results will also be submitted to the physician on the NBS card. The following table details the process and recommended actions based on the results.

Normal, Valid Results	Invalid (QNS) Results	Presumptive Positive or Abnormal Results
<ul style="list-style-type: none">• Results will be sent back to the submitting facility only, within 10-14 days of collection.• Results should then be documented in the NBS log.• No further action needs to be taken when a heel stick result is normal and valid.	<ul style="list-style-type: none">• QNS results will be sent back to the submitting facility as soon as the specimen is identified as being unfit for screening.• Results must then be documented in the NBS log.• A rescreen will be required to be performed within 48 hours after notification of the invalid specimen.• Repeat the heel stick as soon as possible to reduce delays in follow-up and intervention.	<ul style="list-style-type: none">• Results will be sent back to the submitter as soon as testing is completed, within 5-7 days after collection.• Results must then be documented in the NBS log.• The NBS lab will call and fax follow-up information and recommended actions to the submitting facility. The physician on the NBS card will receive a copy of the results.

NOTE: It is imperative for the submitting facility and infant's physician or midwife to take immediate action when heel stick results are invalid (QNS) or presumptive positive/abnormal to ensure the best health outcomes for the infant!

Heel Stick Quality Assurance

The purpose of newborn screening is timely diagnosis and early intervention. Ensuring quality heel stick collection can reduce the need for recollection, which delays timely diagnosis and early intervention. Heel stick quality assurance starts with proper storage of the NBS cards and ends with the last quality check.

What is the last quality check?

Review the NBS card, including the information on the front of the card, the blood collected, and the consent on the back. Ensure all fields on the NBS card are completed and legible. Ensure the NBS card is not expired.

Who should perform it?

Different for each facility. Identify individuals responsible for completing this step to ensure quality.

When should it be performed?

Before the infant is discharged and before the NBS card is sent to the NBS lab.

How should it be performed?

Utilize the **Simple Spot Check** handout as a guide to ensure blood was collected and dried appropriately. Ensure blood is not clotted, there are not multiple spots in one circle, and blood is soaked through the filter paper.

Why does it need to be performed?

Identifies quality issues before the NBS card is sent to the NBS lab and prevents delays in screening, diagnosis, and treatment.

How is specimen quality tracked and reported?

Quality Assurance (QA) Reports

The NBS lab generates quality assurance (QA) reports for all specimens that are sent to the lab. Specimens that are poor quality are logged and reported back to the submitting facility in the QA report. The QA reports break down the specimens by the ID of who collected them. This allows for targeted education efforts.

Quality Indicator (QI) Reports

The GNBS Program also prepares reports for select facilities that meet the requirement of 25 or more specimens per month and an average quality indicator rate greater than 25%. This report includes a breakdown of the types of quality indicators (QIs) each facility is receiving, as well as recommendations for addressing the quality issues.

Simple Spot Check Handout

The [Simple Spot Check](#) is a visual aid that displays what good-quality and poor-quality dried blood spots look like. We recommend keeping this visual aid close to where blood spots are drying for use during the last quality check.

Lab Courier Process and Contact Information

NOW Courier is the statewide courier service used to transport newborn screening specimens from all birthing facilities in Indiana to the NBS lab in Indianapolis. NOW's mission is to provide the most efficient, cost-effective, and value-added courier services through quality service, people, and proven technology while developing long-term partnerships with customers. NOW serves high-volume Indiana birthing hospitals with daily stops six days a week to ensure all NBS cards are delivered in a timely manner to the NBS lab. It is best to become aware of your facility's NOW courier service route and times to ensure your daily pickup is made with no delay.



View [NOW Courier's website](#) more information about their service.

Midwives, PCPs, local health departments, or other clinics that do not have a standard pickup schedule should take the specimen to a nearby birthing facility that does have a scheduled courier pickup. If assistance is needed with locating the nearest birthing facility, call the NBS lab at 800-245-9137. In certain scenarios the lab will provide a prepaid envelope for midwives/PCPs to submit specimens.

Low-volume birthing facilities that would like NOW Courier service on an "as-needed" basis Monday through Friday should email Barb Lesko at bglesko@iupui.edu.

The following lists the regional numbers to call in case your facility needs information about a scheduled route or if an error has occurred.

NOW Courier Contacts	
Email: NewbornScreening@nowcourier.com	
Web: http://nowcourier.com	
Regional Contacts Listed Below	
Cincinnati, OH Phone: 317-709-0170	Indianapolis, IN Phone: 317-762-9143
Fort Wayne, IN Phone: 260-747-2393	Louisville, KY Phone: 502-895-4777
Evansville, IN Phone: 812-474-0400	Merrillville, IN Phone: 219-736-6066
South Bend, IN Phone: 574-233-1838	

NBS Care Coordination Partners

Care coordination partners are a group of specialists who are responsible for ensuring follow-up and confirmatory testing for all patients identified with abnormal and presumptive positive newborn screening heel stick results. This follow-up includes confirmatory testing, genetic counseling, social services, nutrition services, and public and academic education. NBS care coordination partners are awarded funds through a competitive grant process to perform these activities.

Care Coordination Partner	NBS Condition(s) Served
Indiana Hemophilia & Thrombosis Center	Hemoglobinopathies
IU Medical & Molecular Genetics	Inborn Errors of Metabolism, Lysosomal Storage Conditions, Adrenoleukodystrophy, Severe Combined Immunodeficiency (SCID), and Spinal Muscular Atrophy (SMA)
IU Riley Endocrine	Congenital Hypothyroidism (CH) and Congenital Adrenal Hyperplasia (CAH)
IU Cystic Fibrosis	Cystic Fibrosis
Parkview	Congenital Hypothyroidism (CH), Congenital Adrenal Hyperplasia (CAH), and Cystic Fibrosis
Community Health Clinic	Inborn Errors of Metabolism, Adrenoleukodystrophy, SCID, and SMA

Critical Congenital Heart Disease (CCHD) Screening

Critical congenital heart disease (CCHD) represents a group of heart defects that cause serious, life-threatening symptoms and require intervention (typically surgery) soon after birth. A heart defect occurs when an infant's heart does not develop correctly. CCHD can involve abnormal or absent chambers, holes in the heart, abnormal connections in the heart, and abnormalities in the function of the heart. If an infant has CCHD and does not receive treatment shortly after birth, the infant has a higher chance of developing serious health outcomes, including death.

Indiana became the second state to have CCHD screening added to the state newborn screen in 2012. Since then, every infant born in Indiana has been required to have a valid CCHD screening, unless the infant's parents object to newborn screening based on their religious beliefs.

CCHD screening is a quick, noninvasive, gentle way to measure how much oxygen an infant's blood is carrying. Infants who have low oxygen levels in their blood may have CCHD. Screening for CCHD in newborns is important because CCHDs are not always detected in utero. This screening can alert providers of possible CCHDs before major signs and symptoms occur, therefore avoiding life-threatening symptoms and treatment delays that could lead to death before leaving the hospital. It is important for parents to know that CCHD screening only detects seven of the 12 CCHDs. Therefore, it is important for parents

to know the signs of CCHD list below. Encourage a family to contact their infant's doctor if they notice any of these signs.

7 Targets of CCHD Screening

Hypoplastic Left Heart Syndrome

Pulmonary Atresia

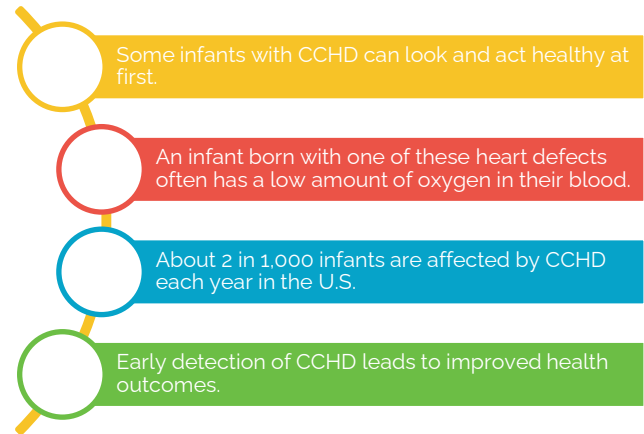
Tetralogy of Fallot

Total Anomalous Pulmonary Venous Return (TAPVR)

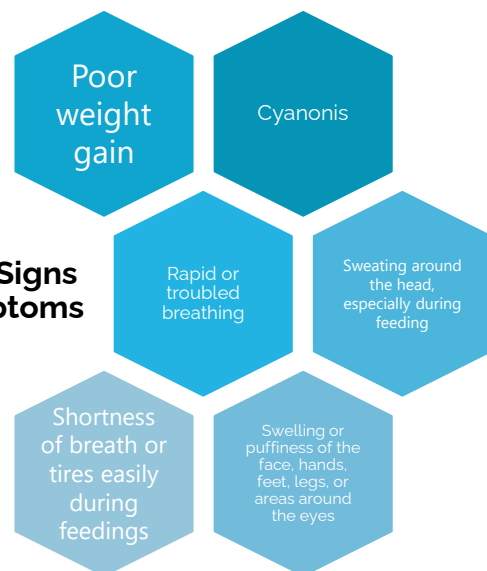
Transposition of the Great Arteries

Tricuspid Atresia

Truncus Arteriosus



CCHD Signs & Symptoms



How to Perform CCHD Screening

CCHD screening must take place between the first 24 to 48 hours after birth. The only reason a newborn can be exempt from receiving CCHD screening is if they meet one of the exemptions listed on the [Pulse Oximetry Exceptions Guide](#) or a [Religious Waiver](#) is submitted to the GNBS Program.



A pulse oximeter is used to measure the percentage of hemoglobin in the blood that is saturated with oxygen. Best practice is to obtain hand and foot readings simultaneously. However, this is only possible by using an oximeter with two probes or two separate oximeter devices. If you only have access to one single-probed oximeter, it is acceptable to first perform the right-hand reading and then immediately switch it over to perform the foot reading. **This screen can occur a maximum of two times, with a minimum of one hour between screens, before an echocardiogram is required before discharge.**

If the infant passes the screen, it means the infant did not show signs of a low level of oxygen in the blood. An infant who passes the screen is unlikely to have a CCHD. However, not all infants with a CCHD will have a low level of oxygen in the blood that is detected during newborn screening. Thus, it is possible for an infant who passes the screen to still have a CCHD or other CCHD.

If the infant fails the screen, it means that the infant showed low levels of oxygen in the blood. Low oxygen saturation levels do not always mean that the infant has a CCHD but means that more testing is needed. **An infant who does not pass the CCHD screen is required by law to receive an echocardiogram prior to discharge to confirm or rule out CCHD.** There may be other causes, such as breathing problems or sepsis, for low levels of oxygen in the blood.

A [flow chart](#) and [table](#) were developed to show the steps in CCHD screening. Print them to display in the location where screening is most likely to occur.

An infant should never be discharged home without CCHD screening unless the infant qualifies as an [exception to CCHD screening](#). In the rare event that CCHD screening is not performed prior to discharge nor a [religious waiver signed](#), the birthing facility must enter the infant as an [MSR exception](#) and immediately notify GNBS via phone at 888-815-0006.

Early Hearing Detection and Intervention (EHDI)

Why Universal Newborn Hearing Screening (UNHS)?

Each year in the United States, approximately three of every 1,000 infants are born with permanent hearing loss. Congenital hearing loss is considered a neurodevelopmental emergency that requires timely identification and intervention.

The Importance of Universal Newborn Hearing Screening

Hearing Loss in Newborns

- Hearing loss is one of the most common conditions present at birth.
- If left undetected, hearing loss can have long-lasting effects on a child's ability to develop speech and language.

UNHS and Early Diagnosis

- Prior to universal newborn hearing screening (UNHS), the average age of identification of a child with hearing loss was **30 months of age**.
- In early 2000, UNHS became mandated by law.
- Since that time, the age of identification of permanent congenital hearing loss has decreased to less than **6 months of age**.

Improved Patient Outcomes

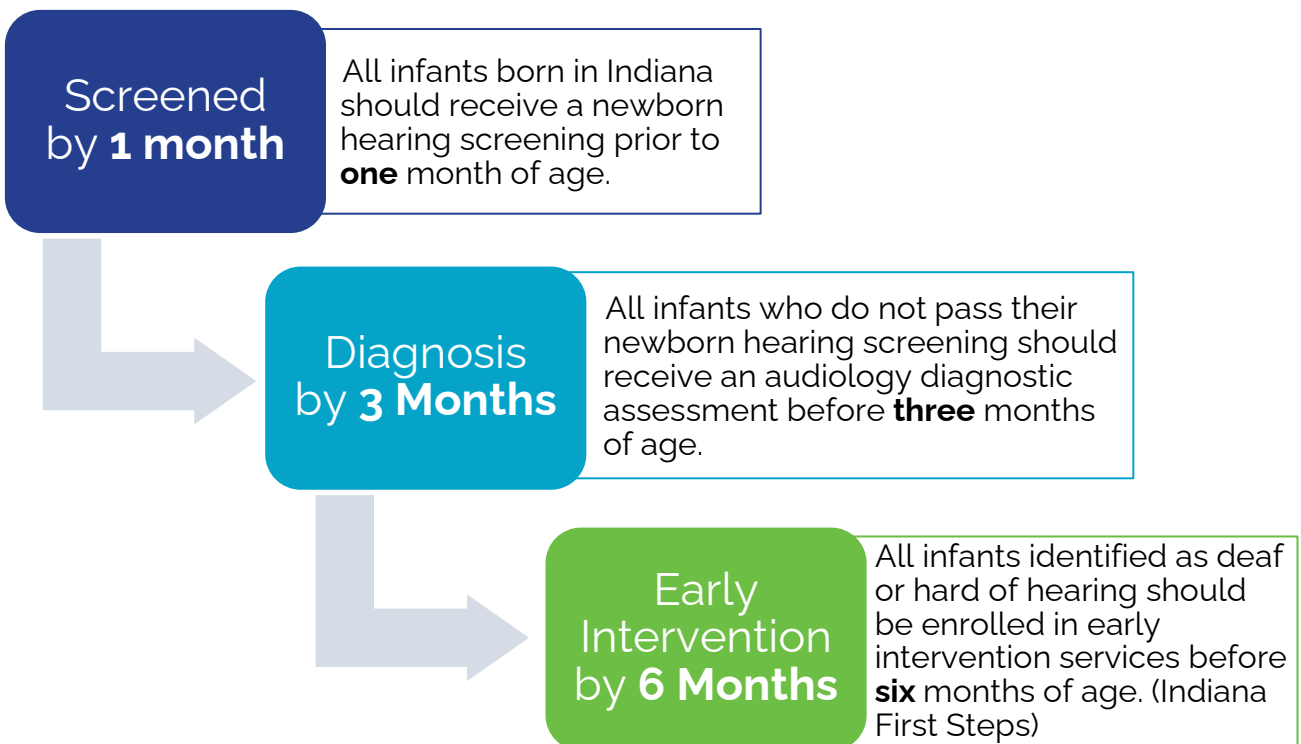
- Through the dedication and hard work of our birthing facilities, audiologists, physicians, and parents, we can continue to ensure early diagnosis and intervention.
- Through UNHS, infants are identified with hearing loss as early as possible to maximize their outcomes.

Indiana Early Hearing Detection and Intervention Mission

The Indiana EHDI Program is housed in the Indiana Department of Health, under the Genomics Newborn Screening program of the Maternal and Child Health Division. It is the mission of the Indiana EHDI Program to monitor the newborn hearing screening program including monitoring newborn hearing screening procedures at birthing facilities, follow-up audiological testing, identification of hearing loss, enrollment in early intervention services, and support of the medical home for deaf and hard of hearing children in Indiana. Our goals and procedures are evidence based and are designed to maximize outcomes for deaf and hard of hearing children in the state of Indiana. We will

provide data surveillance on the incidence and prevalence of hearing loss in Indiana and provide public and professional education about issues related to deaf and hard of hearing children. We also provide free parent-to-parent support to families with deaf and hard of hearing children for one year after diagnosis through the Guide by Your Side program. Visit the EHDI webpage at hearing.in.gov for additional hearing screening information and resources.

EHDI “**1-3-6**” goals are mandated by state and federal law. These goals are based on evidence-based best practice guidelines to maximize communication and developmental outcomes for deaf and hard of hearing children.



Ensure that every infant with hearing loss has a medical home.

According to the American Academy of Pediatrics (AAP), a medical home is an approach to providing comprehensive primary care that facilitates partnership between patients, physicians, and families. A medical home should include patient- and family-centered partnership, community-based systems, transitions, and value.

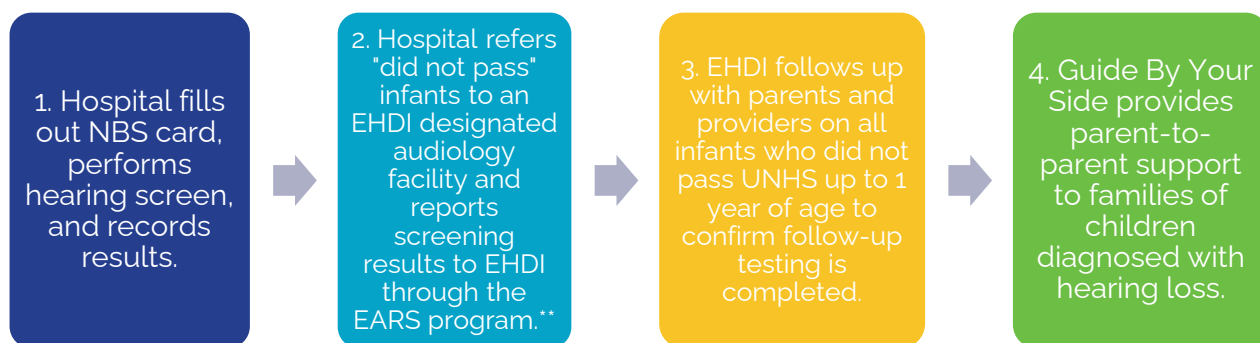
Indiana EHDI Program and Procedures

Legal Mandate

Mandated by Indiana Statute IC 16-41-17-2, the Universal Newborn Hearing Screening (UNHS) can be performed as early as six hours after birth, and it is best practice that no more than two inpatient hearing screens are done. Like the heel stick and CCHD screening, the hearing screening needs to be completed prior to discharge.

Indiana Code 16-41-17-2 states that "...every infant shall be given a physiologic hearing screening examination at the earliest feasible time for the detection of hearing loss."

1. Under Public Law 91-1999, screening for hearing loss began on July 1, 2000.
2. Birthing facilities and hospitals are required to report screening results and referral



information to the EHDI department in the Indiana Department of Health each month. Reporting of newborn hearing screening is done through the EARS (EHDI Alert Response System) program.

Newborn Hearing Screening Procedures:

** See EHDI Hospital Manual or MSR training for more details www.hearing.in.gov

1. Several types of situations warrant reporting "exceptions" in EARS to EHDI. When required to be reported, data entered EARS should include newborn demographic information, hearing screen information, and risk factors (if indicated) that are documented when the hearing screen is performed at the hospital.
 - a. When the hearing screen is not done prior to the DBS being sent to the lab, the pink carbon copy titled "Hearing Screen" should be removed from the card and sent to the lab with the second screening results with the next set of NBS cards to be picked up by the courier. See the [NBS Card section](#) for more information about hearing screen documentation.
2. When an infant does not pass newborn hearing screening, the hospital enters that information within five days to the EHDI "EARS" database collection system and, consequently, Indiana EHDI staff receives an alert. The hospital should also refer the family to a designated audiology facility listed on the [Comprehensive and Limited Audiology Provider Facilities List](#) for diagnostic testing. Letters are sent to parents and primary care physician of that child regarding the infant's hearing results and reminds them of the importance and need for further audiology diagnostic testing.

3. Parents of infants who did not pass receive a phone call from an Indiana EHDI parent consultant to answer questions and offer support in the process. Infants who did not pass the newborn hearing screening and do not have a documented diagnosis are followed by the EHDI program until one year of age to confirm a diagnosis is achieved.
4. When an infant is identified as deaf or hard of hearing, a tool kit is sent to the parents and the physician, a referral is made to our early intervention program, and they are assigned a parent guide from the Guide by Your Side Program. The Guide by Your Side program provides free and local parent-to-parent support to help guide the family into early intervention that reflects their choices and desires for their child for one year after diagnosis. Parent-to-parent support is provided to a family of any newly identified deaf and hard of hearing child, regardless of the child's age at diagnosis.

For more information regarding newborn hearing screening or Indiana EHDI, please visit the Indiana EHDI webpage at hearing.in.gov.

Genomics and Newborn Screening Education Materials

The purpose of newborn screening education is to raise awareness about newborn screening, help families understand the newborn screening process, and assist healthcare professionals with educating families about NBS.

Requesting Education Materials for Families

All healthcare facilities, adoption agencies, local health departments, and related organizations are welcome to FREE printed educational materials:

1. Go to the GNBS webpage and click on the "Information for Providers" tab.
2. Once you click on the "Information for Providers" tab, click on the "GNBS Materials Request Form".
3. Complete the [GNBS Materials Request Form](#). Fill it out in its entirety and email the complete form to ISDHNBS@isdh.in.gov.

Requesting Keepsakes, After NBS Brochures, and NBS Cards

If your facility needs additional newborn screening cards or envelopes, directly contact the Newborn Screening Laboratory by calling 1-800-245-9137.

Genomics and Newborn Screening Training

Indiana **TRAIN**

Genomics and newborn screening training modules are available online 24/7 on [IN-Train.org](https://www.in-train.org)!

Each training module has been developed with various newborn screening partners in mind. Through these training modules, GNBS aims to provide education to various healthcare professionals ranging from birthing facility staff, primary care providers, midwives, and any other health professionals who wish to learn more about newborn screening.



Follow the instructions outlined in the [Creating an Account](#) document. See the list below for descriptions and links to each of the free online training modules. Additional training modules will be posted on the [Training Modules webpage](#) as they become available! [Sign up to receive email updates](#) to know when additional modules are released.

Indiana Newborn Screening Policy Guidelines Training (Course ID 1095965)

- **Description:** This training is designed to educate hospital leadership, nurses, physicians, and other stakeholders about the policies and guidelines for Indiana newborn screening.
- **Purpose:** This training exists to provide stakeholders with an overview of the policies and guidelines that must be met to fulfill state mandates for Indiana newborn screening.
- **Note:** This training does not cover the policies and guidelines for the hearing screen. Please contact the Early Hearing Detection and Intervention (EHDI) program for assistance.

Indiana Heel Stick Quality Training (Course ID 1095935)

- **Description:** This training is designed to educate newborn heel stick collectors about heel stick collection best practices. This training will discuss the basics of the newborn heel stick screening, heel stick collection protocol, and heel stick quality indicators.
- **Purpose:** This training exists to educate heel stick collectors about the best practices and protocols for collecting good-quality heel stick specimens from newborns.

Indiana After Heel Stick Training (Course ID 1095970)

- **Description:** This training is designed to educate newborn screening stakeholders about the process after completing the heel stick screening.

- **Purpose:** This training exists to provide guidance about what role you play in newborn screening and to improve the timeliness and effectiveness of the newborn screening process.

Indiana INSTEP Monthly Summary Reporting (MSR) Training (Course ID 1095938)

- **Description:** This training is designed to educate monthly summary report (MSR) submitters about how to complete heel stick and pulse oximetry newborn screening MSRs.
- **Purpose:** This training exists to increase MSR reporter knowledge of monthly summary reporting for heel stick and pulse oximetry newborn screening exceptions in INSTEP.
- **Note:** This training does not cover MSRs for the newborn hearing screen within EARS. Please contact the EHDI program for assistance with MSRs for the newborn hearing screen.

Indiana Newborn Screening Process Training (Course ID 1095990)

- **Description:** This training is designed to educate hospital staff, midwives, primary care physicians, and other newborn health professionals about the newborn screening process in Indiana. This training will discuss the IDOH Genomics and Newborn Screening Program, give an overview of what must be done prior to newborn screening, give the guidelines for performing the three newborn screens (heel stick, pulse oximetry and hearing screen) and discuss what must be done once the screenings have been completed.
- **Purpose:** This training exists to provide stakeholders with an overview of the newborn screening process in Indiana to improve the timeliness and quality of newborn screening.

Indiana Newborn Screening Pulse Oximetry Updates Webinar (Course ID 1095991)

- **Description:** Webinar to discuss the changes that will be made to the pulse oximetry screening protocol that went into effect on July 1, 2021. This webinar walks through current pulse oximetry protocol, describes the changes that have been made, and educates about the resources that are available to help implement the new process.
- **Purpose:** To provide pulse oximetry screening staff education about the impending changes to pulse oximetry screening protocol prior to the implementation date. This will allow staff time to adapt to the new protocol.

If you experience any technical issues while registering or using IN-Train, please reach out to the IN-Train admin at IN-Train@isdh.in.gov.

Contacts and Communications

GNBS Contact Information

Have questions that need to be answered? Please do not hesitate to reach out to the GNBS team! We are here to help and provide resources and opportunities to all Hoosiers along with our various healthcare partners.

Genomics & Newborn Screening Program

View the [GNBS Contacts page](#) to view GNBS and NBS lab contact information.

Visit the [GNBS website](#) to access all NBS resources and forms and view updates.

Sign up for [GNBS email updates](#) to stay informed on various newborn screening updates, webinars, conferences and more!

View the [GNBS quarterly newsletters](#) for news and updates about the program.

Early Hearing Detection & Intervention Program

View the [EHDI Contacts page](#) for phone number, fax and email contact information.

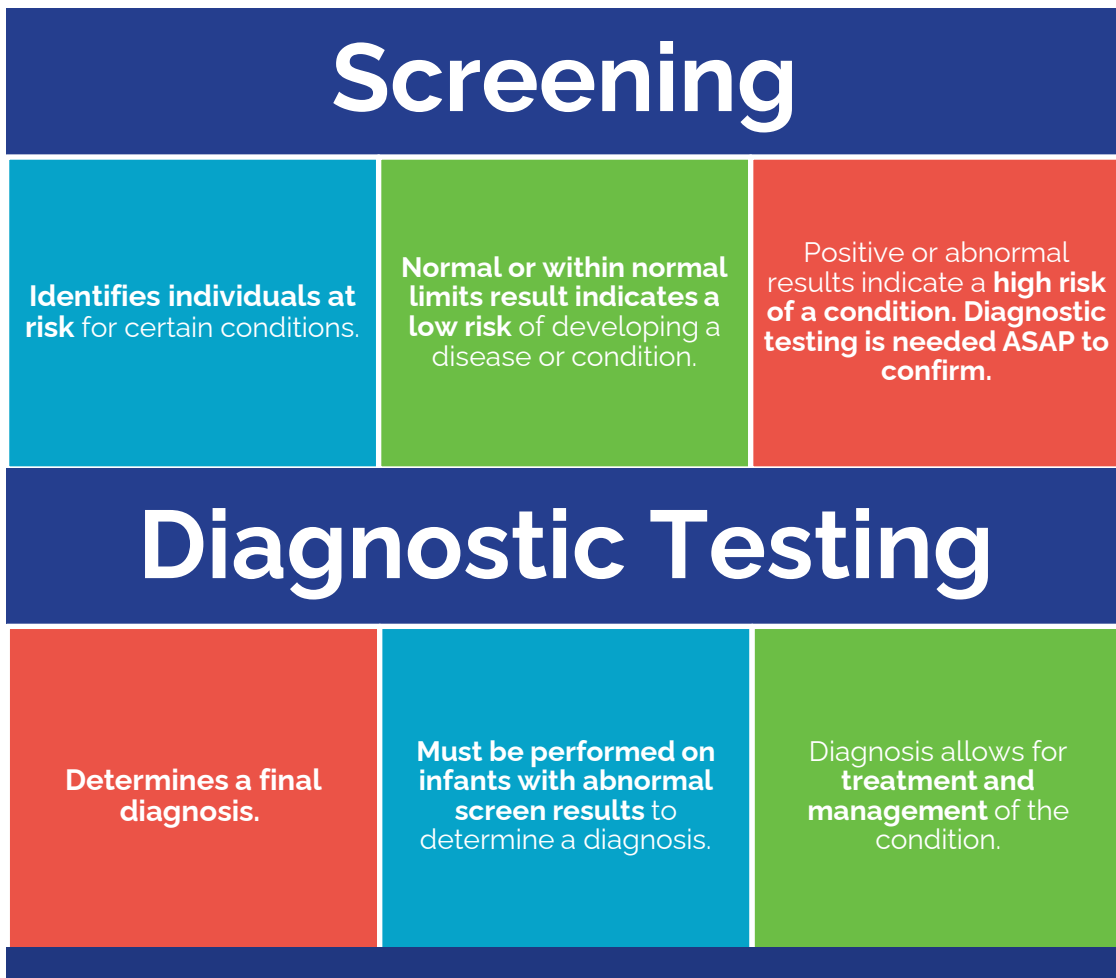
The [EHDI website](#) lists additional resources for the public and healthcare staff.

Appendix A

Screening vs. Testing

The purpose of this document is to provide newborn screening partners with talking points to assist in educating families about the difference between screening versus testing and understanding screening results.

It is important to note the difference between screening and diagnostic testing. The primary purpose of screening is to identify individuals who are at risk of developing certain conditions, while the primary purpose of diagnostic testing is to determine the presence or absence of disease or a condition.



Appendix B

NBS Results Explained

Birthing facility staff, primary care physicians, pediatricians and midwives are responsible for communicating all NBS results to the infant's family.

Heel Stick Report Types

Partial Report

If a time-critical condition is detected before screening is finished for all 50+ conditions, the NBS lab will send a partial report.

Facility staff must complete the recommended actions.

Facility staff should await the final report to ensure no additional action is needed for the condition's previously pending results.

Patient (Final) Report

All infants screened will receive a Patient Report.

Lists the results of each screen.

Lists recommended actions for any abnormal or positive results. **Facility staff must complete recommended actions to ensure proper follow-up is completed.**

Heel Stick Result Types

Normal, Valid Results

- Results will be sent back to the submitting facility only, within 10-14 days of collection.
- Results should then be documented in the NBS log.
- No further action needs to be taken when a heel stick result is normal and valid.

Invalid (QNS) Results

- QNS results will be sent back to the submitting facility as soon as the specimen is identified as being unfit for screening.
- Results must then be documented in the NBS log.
- A rescreen will be required to be performed within 48 hours after notification of an invalid specimen.
- Repeat the heel stick as soon as possible to reduce delays in follow-up and intervention.

Presumptive Positive or Abnormal Results

- Results will be sent back to the submitter as soon as testing is completed, within 5-7 days after collection.
- Results must then be documented in the NBS log.
- The NBS lab will call and fax follow-up information and recommended actions to the submitting facility. The physician on the NBS card will receive a copy of the results.

CCHD Screen Results

Pass

- Indicates blood oxygen saturation levels are normal.
- Indicates low risk of CCHD.
- Parents should be educated about the signs and symptoms of CCHD.

Did Not Pass

- If the infant did not pass the initial screen, a second CCHD screen must be performed 1 hour after the initial screen.
- If the infant does not pass the second screen as well, an echocardiogram must be performed before discharge to evaluate for CCHD.

Hearing Screen Results

Pass

- Indicates the infant did not show signs of congenital hearing loss.
- No further hearing testing will be needed during the newborn period.

Did Not Pass

- Indicates the infant may have hearing loss.
- Confirmatory testing will be needed to verify if hearing loss is present in the infant.
- The hospital staff should refer the family to an audiology specialist to have the confirmatory testing done.

Appendix C

Special Cases Heel Stick Schedule

The purpose of this document is to highlight the newborn heel stick rescreen protocol specific to each given scenario. The protocols listed below outline the minimum required collections according to 410 IAC 3-3. Additional collections may be required upon notification from the NBS lab. **The protocols listed within this document are currently under review and subject to change. [Sign up to our email listserv](#) to receive GNBS Program updates.**

*

Transfer Out Before 24 Hours

1st - Collect before infant is transferred, even if <24 hours.
2nd - Collect between 24 and 48 hours after birth.

*Note: If infant also has another special case listed below, follow its specific schedule after collecting 2nd (24-48 hour) specimen.

Preterm <37 completed weeks of gestation

1st - Collect between 24 and 48 hours after birth.

2nd - Collect on day 14 after birth.

3rd - Collect on day 30 after birth, or day of discharge, whichever comes first.

Low Birthweight <2,000g at birth

1st - Collect between 24 and 48 hours after birth.

2nd - Collect on day 14 after birth.

3rd - Collect on day 30 after birth, or day of discharge, whichever comes first.

Extended Stay in NICU >2 weeks

1st - Collect between 24 and 48 hours after birth.

2nd - Collect on day 14 after birth.

3rd - Collect on day 30 after birth, or day of discharge, whichever comes first.

Total Parenteral Nutrition

1st - Collect between 24 and 48 hours after birth.

2nd - Collect on day 14 after birth.

3rd - Collect on day 30 after birth, or day of discharge, whichever comes first.

Transfusion

ALWAYS COLLECT PRE-TRANSFUSION IF IT DOES NOT INTERFERE WITH LIFE-SAVING MEASURES:

1st - Collect prior to transfusion even if <24 hours.

Note: A collection at 24-48 hours is not needed unless the results of the 1st are presumptive positive or abnormal. In that case, follow the recommendations from the NBS lab on recollection.

2nd - Collect on day 14 after birth.

3rd - Collect on day 30 after birth, or day of discharge, whichever comes first.

IF 1ST COLLECTION IS POST-TRANSFUSION:

1st - Collect at 24-48 hours after birth.

2nd - Collect on day 14 after birth.

3rd - Collect on day 30 after birth, or day of discharge, whichever comes first.

4th - Collect final specimen 2-4 months after last transfusion.

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.

Appendix E

Roles and Responsibilities of Hospitals and Birth Centers

The chart below explains the responsibilities of birthing facilities and birth centers for newborn screening. Indiana has over 80 birthing hospitals and birth centers throughout the state. It is important to recognize the work and maintenance that goes into ensuring all families are educated, screened, and followed up with quickly and appropriately. **A delay at any point during this process causes a delay for timely diagnosis and treatment!**

Complete all NBS trainings	<ul style="list-style-type: none"> • Online NBS training is available 24/7 through Train.org.
Educate the family	<ul style="list-style-type: none"> • Provide the Newborn Screening Keepsake and After Newborn Screening Brochure. • Answer any questions the family may have.
Complete the Consent for Storage	<ul style="list-style-type: none"> • Have the family read the Consent for Storage card. • Ask them to check the appropriate box "Yes" or "No" and sign and date the card.
Complete the front of the NBS card	<ul style="list-style-type: none"> • ALL fields must be completed. Not completing all fields can result in delays for treatment.
Conduct 3 screens	<ul style="list-style-type: none"> • Perform heel stick 24-48 hours after birth. • Perform CCHD screen 24-48 hours after birth. • Perform hearing screen before the infant goes home. • If a family refuses newborn screening, complete a religious refusal.
Explain results	<ul style="list-style-type: none"> • CCHD: <u>Pass</u> indicates normal oxygen saturation levels in the blood. <u>Low risk for CCHD.</u> <u>Did Not Pass</u> indicates low oxygen saturation levels and increased risk for CCHD. • Hearing: <u>Pass</u> indicates normal hearing. <u>Did Not Pass</u> indicates at risk for congenital hearing loss. • Heel Stick: Tell parents that results should be <u>explained at the first well-baby visit.</u>
Document results	<ul style="list-style-type: none"> • Document all results on the NBS card/religious waiver, in the NBS log and in the EMR.
Submit samples	<ul style="list-style-type: none"> • Send all dried blood spot samples to the NBS lab.
Report to IDOH	<ul style="list-style-type: none"> • Complete MSRs for all 3 screens: hearing, CCHD and heel stick. • Submit any religious waivers to IDOH.
Follow up	<ul style="list-style-type: none"> • Ensure any infant with an abnormal heel stick result obtains the recommended testing from the Patient Report. • Ensure any infant who did not pass the CCHD screen receives an echocardiogram prior to discharge. • Ensure any infant who did not pass the hearing screen is referred to an audiologist specialized in confirmatory testing before discharge.

Appendix F

Roles and Responsibilities of Primary Care Providers

The chart below explains the responsibilities of birthing primary care providers or other physicians who see pediatric (infant) patients. Physicians play a vital role in ensuring that all families receive their infant's heel stick screen results and actions are taken urgently with any abnormal results. A delay in follow-up actions, including repeat or confirmatory testing, could result in severe disabilities or death.

Complete all NBS trainings	<ul style="list-style-type: none">• Online NBS training is available 24/7 through Train.org.
Obtain all NBS results	<ul style="list-style-type: none">• Obtain access to the online portal, INSTEP, if you or someone from your office does not already have access.• All results are available to be printed from INSTEP.
Explain all results to the family	<ul style="list-style-type: none">• Discuss CCHD, hearing and heel stick results with the family at the first well-child visit.• Make sure to explain all abnormal results in detail.
Perform follow-up	<ul style="list-style-type: none">• Ensure any infant who did not pass the CCHD screen received an echocardiogram prior to discharge from the hospital. Explain any abnormal findings from the echocardiogram.• Ensure any infant who did not pass the hearing screen has been referred to an audiologist specialized in confirmatory testing of infants.• For any abnormal heel stick results, follow instructions from the NBS lab and the Physician Act Sheet. Consult with the appropriate care coordination group. Do NOT delay any additional testing. It could be severely detrimental to the infant.
Coordinate care	<ul style="list-style-type: none">• Coordinate care and treatment for patients with confirmed diagnoses (congenital hearing loss, critical congenital heart disease or one of more than 50 inherited conditions).

Appendix G

Roles and Responsibilities of Midwives and Home Birth Attendants

The chart below explains the roles and responsibilities of midwives and home birth attendants. Midwives and home birth attendants play a vital role in ensuring that all families receive education, screening, and follow-up for any abnormal results of newborn screening. Midwives and home birth attendants are also required by law to report monthly summary reports to the GNBS Program. **A delay in any of these actions, including repeat or confirmatory testing, could result in severe disabilities or death for the infant.**

Complete all NBS trainings	<ul style="list-style-type: none"> • Online NBS training is available 24/7 through Train.org.
Educate the family	<ul style="list-style-type: none"> • Provide the Newborn Screening Keepsake and After Newborn Screening Brochure to the family. • Answer any questions the family may have.
Complete the Consent for Storage	<ul style="list-style-type: none"> • Have every family read the Consent for Storage card. • Ask them to check the appropriate box "Yes" or "No" and sign and date the card.
Complete the front of the NBS card	<ul style="list-style-type: none"> • ALL fields must be complete and accurate. List the child's pediatric provider as the "Physician". • Not completing all fields can result in delays for treatment.
Conduct 3 screens	<ul style="list-style-type: none"> • Perform heel stick and CCHD screens between 24 and 48 hours after birth. • Perform or schedule hearing screen prior to leaving the family. • If a family refuses newborn screening, complete a religious refusal waiver and submit it to IDOH.
Explain results	<ul style="list-style-type: none"> • CCHD: <u>Pass</u> indicates normal oxygen saturation levels in the blood. Low risk for CCHD. <u>Did Not Pass</u> indicates low oxygen saturation levels and increased risk for CCHD. • Hearing: <u>Pass</u> indicates normal hearing. <u>Did Not Pass</u> indicates at risk for congenital hearing loss. • Heel Stick: Tell parents that results should be <u>explained at the first well-baby visit.</u>
Submit samples	<ul style="list-style-type: none"> • Let dried blood spots dry for 3 hours; then send to NBS lab.
Document results	<ul style="list-style-type: none"> • Send all dried blood spot samples to the NBS lab.
Complete reporting	<ul style="list-style-type: none"> • Complete MSRs for all 3 screens: hearing, CCHD and heel stick. • Submit any religious refusals to IDOH.
Follow up	<ul style="list-style-type: none"> • Ensure any infant with an abnormal heel stick result obtains the recommended testing from the Patient Report. • Ensure any infant who did not pass the CCHD screen receives an echocardiogram prior to discharge. • Ensure any infant who did not pass the hearing screen is referred to an audiologist specialized in confirmatory testing before discharge.