# Indiana

## Newborn Genetic Testing & Surveillance System

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<td>IN</td>
<td>STATUTE: Title 13 Article 38 (Health Registries) and Title 16, Article 41 (PKU et.al) RULE: 410 IAC Article 3 Rule 3</td>
<td>IC 16-38-1-1. Newborn screening registry; development Sec. 1. The state department shall develop the newborn screening registry under IC 16-41-17-10. IC 16-41-17-10. Follow-up programs; newborn screening fees; waste blood specimen confidentiality Sec. 10. (a) The state department shall develop the following: (1) A registry for tracking and follow-up of all newborns and individuals for screening. (2) A centralized program that provides follow-up, diagnosis, management, and family counseling and support… IC 16-41-17-2. Examinations; religious exemption Sec. 2. …[E]very infant shall be given examinations at the earliest feasible time for the detection of the following disorders: (1) Phenylketonuria. (2) Hypothyroidism.(3) Hemoglobinopathies, including sickle cell anemia. (4) Galactosemia. (5) Maple Syrup urine</td>
<td>IC 16-41-17-2. Examinations; religious exemption (d) If a parent of an infant objects in writing, for reasons pertaining to religious beliefs only, the infant is exempt from the examinations required by this chapter. 410 IAC 3-3-2. Provision of testing information;</td>
<td>IC 16-41-17-1. Waste blood specimen Sec. 1. As used in this chapter, &quot;waste blood specimen&quot; means a blood sample or a solid, liquid, or semiliquid blood product that: (1) has served the intended purpose under section 4 of this chapter; or (2) has served the natural, biological, medical, or intended purpose and has been discarded or accumulated for discard from a use</td>
<td>NO</td>
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disease.  (6) Homocystinuria.  (7) Inborn errors of metabolism that result in mental retardation and that are designated by the state department.  (8) Congenital adrenal hyperplasia.  (9) Biotinidase deficiency.  (10) Disorders detected by tandem mass spectrometry or other technologies with the same or greater detection capabilities as tandem mass spectrometry...(b) Subject to subsection (d), every infant shall be given a physiologic hearing screening examination….

**Rule 3. Examination of Infants for Disorders**

410 IAC 3-3-7. **Follow-up of positive results**...(g) The board shall maintain a **tracking system** for follow-up of newborn screening results, and shall maintain a **confidential registry** of every infant born for whom the diagnosis of phenylketonuria, hypothyroidism, galactosemia, maple syrup urine disease, homocystinuria, or hemoglobinopathy has been confirmed. These records shall be utilized only for the purpose of service delivery and program administration and shall be managed in accordance with the procedures described in 410 IAC 1-2-2.

**religious objection.**

(b) Any parent or guardian who objects to the testing for reasons pertaining to religious beliefs only shall so indicate by signing a statement of informed refusal. Such objection shall become part of the medical record and the infant shall be exempted from the testing.

other than as provided under section 10(a)(5) of this chapter.

IC 16-41-17-10. **Sec. 10**…(5) A system for using, for epidemiological survey and research purposes, any waste blood specimen generated under this chapter.  (f) Waste blood specimens used for the purpose of implementing the system described under subsection (a)(5) may not include the name or other identifying characteristics that would identify the individual submitting the specimen.