# Iowa

## Newborn Genetic Testing & Surveillance System

<table>
<thead>
<tr>
<th>State</th>
<th>Statute/Rule</th>
<th>Language Specific to Genetic Testing and Surveillance System</th>
<th>Exemption</th>
<th>Research Authority</th>
<th>Consent Required?</th>
<th>Dissent Allowed?</th>
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| IA    | STATUTE: Title IV, Subtitle 2, Chapter 136A | **136A.1 PURPOSE**
To reduce and avoid adverse health conditions of inhabitants of the state, the Iowa department of public health shall initiate, conduct, and supervise screening and health care programs in order to detect and predict congenital or inherited disorders. The department shall assist in the translation and integration of genetic and genomic advances into public health services to improve health outcomes throughout the life span of the inhabitants of the state. | **136A.5 NEWBORN METABOLIC TESTING...3.**
This section does not apply if a parent objects to the screening. If a parent objects to the screening, the attending health care provider shall document the refusal in the newborn's medical record and shall obtain a written refusal from the parent. | **641-4.3(7) Sharing of information and confidentiality. ...(b.)**
The program shall not release confidential information except to the following persons or entities, under the following conditions:...
(4) A researcher, upon documentation of parental consent obtained by the researcher, and only to the extent that the information is necessary to perform research authorized by the department and the state board of health. | NO | YES |
| 641-4.3(1) Newborn screening policy | and report the refusal to the department as provided by rule of the department. | 641-4.7(6) Access to information in the IRCID. | The IRCID and the department shall not release confidential information except to the following, under the following conditions:

(c.) Researchers, in accordance with the following:

(1) All proposals for research using the IRCID data to be conducted by persons other than program staff shall first be submitted to and accepted by the researcher’s institutional review board. Proposals shall then be reviewed and approved by the department and the IRCID’s internal advisory committee before research can commence. |

...c. The center may monitor individuals identified as having a genetic or metabolic disorder for the purpose of conducting public health surveillance or intervention and for determining whether early detection, treatment, and counseling lead to the amelioration or avoidance of the adverse outcomes of the disorder. Birthing hospitals or birth centers and health care providers shall provide patient data and records to the center upon request to facilitate the monitoring. Any identifying information provided to the center shall remain confidential pursuant to Iowa Code section 22.7(2). |

**136A.3 ESTABLISHMENT OF CENTER FOR CONGENITAL AND INHERITED DISORDERS -- DUTIES.**

A center for congenital and inherited disorders is established within the department. The center shall do all of the following:

1. Initiate, conduct, and supervise statewide screening programs for congenital and inherited disorders amenable to population screening.
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<th>2.</th>
<th>Initiate, conduct, and supervise statewide health care programs to aid in the early detection, treatment, prevention, education, and provision of supportive care related to congenital and inherited disorders.</th>
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<td>3.</td>
<td>Develop specifications for and designate a central laboratory in which tests conducted pursuant to the screening programs provided for in subsection 1 will be performed.</td>
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<td>4.</td>
<td>Gather, evaluate, and maintain information related to causes, severity, prevention, and methods of treatment for congenital and inherited disorders in conjunction with a central registry, screening programs, genetic health care programs, and ongoing scientific investigations and surveys.</td>
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**641-4.3 (2) Neonatal metabolic screening procedure for facilitators and providers.**

a. **Educating parent or guardian.** Before a specimen from an infant is obtained, a parent or guardian shall be informed of the type of specimen, how it is obtained, the nature of the disorders for which the infant is being screened, the consequences of treatment and nontreatment, and the

**641-4.7(5) Confidentiality and disclosure of information.** Reports, records, and other information collected by or provided to the IRCID relating to a person known to have or suspected of having a congenital or inherited disorder are confidential records pursuant to Iowa Code sections 22.7 and 136A.7…

*The IRCID shall submit to the IRCID’s internal advisory committee for approval a protocol describing any research conducted by the IRCID in which the IRCID deems it necessary to contact case subjects and controls.*
5. Perform surveillance and monitoring of congenital and inherited disorders to determine the occurrence and trends of the disorders, to conduct thorough and complete epidemiological surveys, to assist in the planning for and provision of services to children with congenital and inherited disorders and their families, and to identify environmental and genetic risk factors for congenital and inherited disorders.

6. Provide information related to severity, causes, prevention, and methods of treatment for congenital and inherited disorders to the public, medical and scientific communities, and health science disciplines.

7. Implement public education programs, continuing education programs for health practitioners, and education programs for trainees of the health science disciplines related to genetics, congenital disorders, and inheritable disorders.

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641-4.3(8) Retention, use and disposition of residual neonatal metabolic screening specimens.

a. A neonatal metabolic screening specimen collection form consists of a filter paper containing the dried blood spots (DBS) specimen and the attached requisition that contains information about the infant and birthing hospital, birth center, or drawing laboratory. The DBS specimen can be separated from the information contained in the requisition form.

1. The residual DBS specimen shall be held for five years in a locked area at the UHL [University Hygienic Laboratory].

2. The residual DBS specimen forms shall be stored for the first year at -70 degrees C.
8. Participate in policy development to assure the appropriate use and confidentiality of genetic information and technologies to improve health and prevent disease.

9. Collaborate with state and local health agencies and other public and private organizations to provide education, intervention, and treatment for congenital and inherited disorders and to integrate genetics and genomics advances into public health activities and policies.

136A.5 NEWBORN METABOLIC TESTING.
1. All newborns born in this state shall be screened for congenital and inherited disorders in accordance with rules adopted by the department.
2. An attending health care provider shall ensure that every newborn under the provider's care is screened for congenital and inherited disorders in accordance with rules adopted by the department…

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<td>(3) After one year, the residual DBS specimen shall be archived for four additional years at room temperature. (4) The residual DBS specimen shall be incinerated after completion of the retention period.</td>
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b. Research use.
(1) Investigators shall submit proposals to use residual DBS specimens to the center. Any intent to utilize information associated with the requested specimens as part of the research study must be clearly delineated in the proposal. (2) Before research can commence, proposals shall be approved by the researcher’s institutional review board, the congenital and inherited disorders advisory committee, and the department.
| 136A.6 CENTRAL REGISTRY. The center for congenital and inherited disorders shall maintain a central registry, or shall establish an agreement with a designated contractor to maintain a central registry, to compile, evaluate, retain, and disseminate information on the occurrence, prevalence, causes, treatment, and prevention of congenital disorders. Congenital disorders shall be considered reportable conditions in accordance with rules adopted by the department and shall be abstracted and maintained by the registry. | (3) Personally identifiable residual specimens or records shall not be disclosed without documentation of informed parental consent obtained by the researcher. (4) Research on anonymized or identifiable residual specimens shall be allowed in instances where research would further: neonatal metabolic screening activities; the health of an infant or child for whom no other specimens are available or readily attainable; or general medical knowledge for existing public health surveillance activities. |
| 641-4.7. Iowa registry for congenital and inherited disorders. [IRCID] The central registry provides active statewide surveillance for selected congenital and inherited disorders… | |

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### 641-4.7(3) Central registry activities

**a.** The center shall establish an agreement with the University of Iowa to implement the activities of the central registry.

**c.** The central registry staff shall review hospital records, clinical charts, physician’s records, vital records and prenatal records pursuant to 641-1.3 (139A) and any other information that the central registry deems necessary and appropriate for birth defects surveillance.

### 641-4.1 Program explanation

The center for congenital and inherited disorders within the department of public health provides administrative oversight to the following: Iowa neonatal metabolic screening program, expanded maternal serum alphafetoprotein screening program, regional genetic consultation service, neuromuscular and related genetic disease program **and Iowa registry for congenital and inherited disorders.** [emphasis added]

### 641-4.2 Definitions

**“Anonymized specimen”** means a specimen that cannot be traced back to or linked with the particular infant from whom the specimen was obtained. Specimens shall be anonymized by removing the dried blood spot portion from the infant information portion of the specimen collection form…