### Utah

**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>
</tr>
</thead>
<tbody>
<tr>
<td>UT</td>
<td>STATUTE: U.C., Title 26, Chapter 10 RULE: R398-1</td>
<td>26-10-6. Testing of newborn infants. (1) Except in the case where parents object on the grounds that they are members of a specified, well-recognized religious organization whose teachings are contrary to the tests required by this section, each newborn infant shall be tested for: (a) phenylketonuria (PKU); (b) other metabolic diseases which may result in mental retardation or brain damage and for which: (i) a preventive measure or treatment is available; and (ii) there exists a reliable laboratory diagnostic test method; and… (c) (i) beginning July 1, 1998, for an infant born in a hospital with 100 or more live births</td>
<td>26-10-6. Testing of newborn infants. (1) Except in the case where parents object on the grounds that they are members of a specified, well-recognized religious organization whose teachings are contrary to the tests required by this section, each newborn infant shall be tested for:…</td>
<td>R398-1-15. Blood Spots. (1) Blood spots become the property of the Department. (2) The Department includes in parent education materials information about the Department's policy on the retention and use of residual newborn blood spots. (3) The Department may use residual blood spots for newborn screening quality assessment activities. (4) The Department may release blood spots for research upon the following: (a) The person proposing to conduct the research applies in writing to the Department for approval to perform the research. The application shall include a written protocol for the proposed research, the person's professional qualifications to perform the proposed research, and other information if needed and requested by the Department. When appropriate, the proposal will then be</td>
</tr>
</tbody>
</table>
annually, hearing loss; and (ii) beginning July 1, 1999, for an infant born in a setting other than a hospital with 100 or more live births annually, hearing loss.

(2) In accordance with Section 26-1-6, the department may charge fees for:
(a) materials supplied by the department to conduct tests required under Subsection (1);
(b) tests required under Subsection (1) conducted by the department;
(c) laboratory analyses by the department of tests conducted under Subsection (1); and
(d) the administrative cost of follow-up contacts with the parents or guardians of tested infants.

R398-1-11. Testing Refusal. A parent or legal guardian may refuse to allow the required testing for religious reasons only. The medical home/practitioner or institution shall file in the newborn's record documentation of refusal, reason, education of family about the disorders, and signed waiver by both parents or legal guardian. The practitioner or institution shall submit a copy of the refusal to the Utah Department of Health, submitted to the Department's Internal Review Board for approval. (b) The Department shall de-identify blood spots it releases unless it obtains informed consent of a parent or guardian to release identifiable samples. (c) All research must be first approved by the Department's Internal Review Board.

R398-1-16. Retention of Blood Spots. (1) The Department retains blood spots for a minimum of 90 days. (2) Prior to disposal, the Department shall de-identify and autoclave the blood spots.

26-25-1. Authority to provide data on treatment and condition of persons to designated agencies -- Immunity from liability. (1) Any person, health facility, or other organization may, without incurring liability, provide the following information to the persons and entities described in Subsection (2):
(a) information as determined by the state registrar of vital records appointed under Title 26, Chapter 2,
R398-1-13. Noncompliance by Parent or Legal Guardian. If the medical home/practitioner or institution has information that leads it to believe that the parent or legal guardian is not complying with this rule, the medical home/practitioner or institution shall report such noncompliance as medical neglect to the Department.

R398-1-17. Reporting of Disorders. If a diagnosis is made for one of the disorders screened by the Department Newborn Screening Program, P.O. Box 144710, Salt Lake City, UT 84114-4710. Utah Vital Statistics Act; (b) interviews; (c) reports; (d) statements; (e) memoranda; (f) familial information; and (g) other data relating to the condition and treatment of any person.

(2) The information described in Subsection (1) may be provided to: (a) the department and local health departments; (b) the Division of Substance Abuse and Mental Health within the Department of Human Services; (c) scientific and health care research organizations affiliated with institutions of higher education; (d) the Utah Medical Association or any of its allied medical societies; (e) peer review committees; (f) professional review organizations; (g) professional societies and associations; and (h) any health facility's in-house staff committee for the uses described in Subsection (3).

(3) The information described in Subsection (1) may be provided for the following purposes: (a) study and advancing medical research, with the purpose of reducing the incidence of disease, morbidity, or mortality; or (b) the evaluation and improvement of hospital and health care rendered.
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>that was not identified by the Department, the medical home/practitioner shall report it to the Department.</td>
<td>by hospitals, health facilities, or health care providers.</td>
</tr>
</tbody>
</table>