# Washington

## Newborn Genetic Testing & Surveillance System

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<tr>
<td>WA</td>
<td>STATUTE: RCW Title 70 Chapter 70.83, RULE: Chapter 246-65-WAC</td>
<td><strong>RCW 70.83.010 Declaration of policy and purpose.</strong> It is hereby declared to be the policy of the state of Washington to make every effort to detect as early as feasible and to prevent where possible phenylketonuria and other preventable heritable disorders leading to developmental disabilities or physical defects. <strong>70.83.023 Specialty clinics – Defined disorders – Fee for infant screening.</strong> The department has the authority to collect a fee of three dollars and fifty cents from the parents or other responsible party of each infant screened for congenital disorders as defined by the state board of health under RCW 70.83.020 to fund specialty clinics that provide treatment</td>
<td><strong>70.83.020 Screening tests of newborn infants.</strong> It shall be the duty of the department of health to require screening tests of all newborn infants before they are discharged from the hospital for the detection of phenylketonuria and other heritable or metabolic disorders leading to intellectual disabilities or physical defects as defined by the state board of health: PROVIDED, That no such tests shall be given to any newborn infant whose parents</td>
<td><strong>246-650-050 Privacy and security of screening specimen/information forms.</strong> … …(4) Release: Dried blood spot samples and specimen information may only be released when required by state or federal law or under the following conditions: (a) A sample from a specimen and copies of associated information (patient information and testing results, if requested) may be released to: … (ii) A researcher with the written, informed consent of the patient or their patient's legal</td>
<td>NO</td>
<td>YES</td>
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services for those with the defined disorders. The fee may also be used to support organizations conducting community outreach, education, and adult support related to sickle cell disease. The fee may be collected through the facility where a screening specimen is obtained.

246-650-050 Privacy and security of screening specimen/information forms. The specimen/information form submitted to the department pursuant to WAC 246-650-020 becomes the property of the state of Washington upon receipt by the Washington state public health laboratory. The department shall protect the privacy of newborns and their families and assure that all specimen/information forms submitted for screening are protected from inappropriate use or access. [emphasis added]

(1) Storage: The specimen/information forms shall be kept at ambient

or guardian object thereto on the grounds that such tests conflict with their religious tenets and practices.

246-650-020 Performance of screening tests. (1) Hospitals providing birth and delivery services or neonatal care to infants shall:

(a) Inform parents or responsible parties, by providing a departmental information pamphlet or by other means, of:

(i) The purpose of screening newborns for congenital disorders,

(ii) Disorders of concern as listed in WAC 246-650-020(2),

(iii) The requirement for newborn screening, and

(iv) The legal right of parents or representative as part of a research project that has been reviewed and approved by the DOH/DSHS human subjects research review board and the secretary or designee of the department of health…

(b) Anonymous samples may be released if the department determines that the intended use has significant potential health benefit and that each of the following criteria have been met:

(i) The investigation design is adequate to assure anonymity will be preserved.

(ii) All newborn screening tests have been completed and the status of the infant is resolved.

(iii) At least one fully adequate spot will remain after the anonymous sample has been taken.

(iv) Sufficient resources
### Privacy and Confidentiality

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<td><strong>(1)</strong></td>
<td>Temperature in secured storage to preserve their confidentiality and prevent access by unauthorized persons.</td>
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<td><strong>(2)</strong></td>
<td>Retention/destruction: The specimen/information form shall be retained until the child is twenty-one years old in accordance with the requirements for hospitals specified in RCW 70.41.190. After this time the form will be destroyed. <strong>EXCEPTION FOR PARENTAL REQUEST</strong>: Upon request of a parent or guardian (or a patient who is over the age of eighteen years), the department will destroy the specimen/information form only after all required screening tests have been performed and if the patient's screening/clinical status related to these tests is not in question.</td>
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<td><strong>(3)</strong></td>
<td>Access: Access to stored specimen/information forms shall be restricted to department employees and those contractors or others approved by the responsible parties to refuse testing because of religious tenets or practices as specified in RCW 70.83.020, and (v) The specimen storage, retention and access requirements specified in WAC 246-650-050…</td>
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<td><em>Note:</em></td>
<td>(personnel) are available for extracting the samples. (v) The DOH/DSHS human subjects research review board has reviewed and approved the investigation. <em>This requirement may be waived by the department for a very small (i.e., less than 100 sample) pilot study</em> where the intent is to evaluate a testing tool, as opposed to an evaluation where the intent is to measure some characteristic of a population. [emphasis added]</td>
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*Updated August 2012. All state statutes and department rules originally accessed online July/Aug 2008.*

*Statute/Rule data not inclusive. For comprehensive or updated language, access complete statute and rules online, at local library or through the state legislature.*

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|   | department as necessary to meet specific program needs. Access is contingent upon compliance with all applicable federal and state laws, regulations, and policies safeguarding the privacy and confidentiality of medical information. The department shall assure that those granted access understand the confidentiality requirements and have a signed confidentiality agreement on file. …

…(5) Notification: The department shall notify parents of the specimen storage, retention/destruction and access requirements through the department's newborn screening informational pamphlet. |   |   |   |