

WAC 246-650-050 Privacy and security of newborn screening specimen/information forms. The newborn screening 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. A newborn specimen/information form contains health care information that is confidential under chapter 70.02 RCW.

(1) Storage: The newborn screening specimen/information forms shall be kept at ambient temperature in secured storage to preserve their confidentiality and prevent access by unauthorized persons.

(2) Retention/destruction: The newborn screening 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 department shall destroy the form.

EXCEPTION FOR PARENTAL REQUEST: Upon request of a parent or guardian (or a patient who is over the age of eighteen years), the department shall destroy the newborn screening 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.

(3) Access: Access to stored newborn screening specimen/information forms must be restricted to department employees and those contractors or others approved by the 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.

(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 identifying information (patient information and testing results, if requested) may be released to:

(i) A health care provider at the request of the patient or his or her legal representative after completing and signing a written request form approved by the department. The release form must be provided to the director of newborn screening before the request will be fulfilled.

(ii) A researcher with the written, informed consent of the patient or the patient's legal representative as part of a research project that has been reviewed and approved by the Washington state institutional review board and the secretary or designee of the department.

(iii) A named person in a legally executed subpoena following review and approval of the state attorney general.

(iv) A person to whom release is mandated by order of a court of competent jurisdiction.

(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 (personnel) are available for extracting the samples.

(v) The Washington state institutional review board has reviewed and approved the investigation. This requirement may be waived by the department for a very small (i.e., less than 100 sample) pilot study 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.

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

[Statutory Authority: RCW 70.83.050, 70.83.090 and RCW 70.83.020. WSR 19-20-025, § 246-650-050, filed 9/23/19, effective 10/24/19. Statutory Authority: Chapters 70.83, 43.20 RCW. WSR 03-24-026, § 246-650-050, filed 11/24/03, effective 12/25/03.]