

### STATE OF WASHINGTON

#### DEPARTMENT OF HEALTH

OFFICE OF NEWBORN SCREENING

1610 N.E. 150<sup>th</sup> Street • Shoreline, WA 98155-9701 www.doh.wa.gov/nbs • Phone (206) 418-5410 • Toll Free 1-866-660-9050 • Fax (206) 418-5415

## DATE

## TO: NAME STREET ADDRESS CITY, STATE ZIP CODE

FROM: Lain Knowles, Director Newborn Screening

#### RE: Request to Destroy Residual Newborn Screening Specimen

This information is provided in response to your request for destruction of residual dried blood specimens currently stored at the Washington State Newborn Screening Laboratory. We will honor such requests when made by a parent or legal guardian of a minor patient or the patient, if over 18 years of age. **Upon receipt of a completed copy of the enclosed request form and a photocopy (certified copy is not necessary) of the patient's birth certificate**, the Office of Newborn Screening will make a good faith effort to locate all specimens related to the patient within 60 days. For each specimen located we will:

- Photocopy the front and back of the blood spots.
- Separate the filter paper containing blood spots from the specimen card.
- Destroy the filter paper and blood spots.
- Notify you of all specimens located and destroyed, and the date destroyed.
- File the specimen card with the photocopy of the blood spots, your original written request and, a copy of our notification to you of our action.

Enclosed are forms and a self-addressed, postage-paid envelope for you to use when submitting your request. (You must use a separate form for each patient.) Also enclosed is a copy of Section 246-650-050 Washington Administrative Code (WAC) related to this issue.

If you have questions or require additional information, please feel free to contact me at (206) 418-5470

# **Request to Destroy Residual Newborn Screening Specimens**

Patient's Name
Patient's Date of Birth
Your Name
Your Current Mailing Address: Street City, State, Zip Code
Your Relationship to Patient
I request that the identified patient's remaining Newborn Screening dried blood specimens stored by the Washington State Office of Newborn Screening be destroyed.
"I dealane under nonalty of nonium, under the laws of the State of Washington that the foregoing is true

"I declare under penalty of perjury under the laws of the State of Washington that the foregoing is true and correct":

(Signature)

(Date)

(Place)

Return this form along with a photocopy (a certified copy is not necessary) of the patient's birth certificate to:

Director, Newborn Screening 1610 NE 150<sup>th</sup> Street Shoreline, WA 98155

#### WAC 246-650-050 Privacy and security of screening specimen/information forms.

The specimen/information form submitted to the department pursuant to WAC <u>246-650-020</u> 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.

(1) Storage: The 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 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.

EXCEPTION FOR PARENTAL REQUEST: 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.

(3) Access: Access to stored specimen/information forms shall 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 information (patient information and testing results, if requested) may be released to:

(i) A health care provider at the request of the patient or their 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 their patient's legal 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.

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

#### WAC 246-650-050 Privacy and security of screening specimen/information forms, continued

(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 DOH/DSHS human subjects research 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 of the specimen storage, retention/destruction and access requirements through the department's newborn screening informational pamphlet.

[Statutory Authority: Chapters 70.83, 43.20 RCW. 03-24-026, § 246-650-050, filed 11/24/03, effective 12/25/03.]