Policy #001
Iowa Department of Public Health Center for Congenital and Inherited Disorders

Retention, Storage, and Use of Specimens Residual to Those Collected for Newborn Screening Services

I. Overview

The Iowa Department of Public Health (IDPH) is authorized pursuant to Iowa Code 136A and Iowa Administrative Code (IAC) 641IAC 4.3 to establish a newborn screening program, and directs that all newborns born in the state of Iowa be tested for specific congenital and inherited disorders as determined by the Center for Congenital and Inherited Disorders (CCID) and approved by the State Board of Health. Comprehensive newborn screening services including laboratory, follow-up, consultative, and educational services are provided through the Iowa Newborn Screening Program (INSP), a program of the IDPH.

INSP is a program under the CCID pursuant to Iowa Code chapter 136A and Iowa Administrative Code 614 IAC 4.3. The CCID provides administrative oversight to the INSP for the IDPH. The State Hygienic Laboratory (SHL) at The University of Iowa (UI) is the designated central screening laboratory pursuant to IC chapter 136A and 641 IAC 4.2. SHL tests Iowa newborns as set forth in 641 IAC 4.3 (5) and is the custodian of the residual specimens collected for newborn screening in Iowa on behalf of the INSP. Staff within the UI Departments of Internal Medicine, Pathology, and Pediatrics serves as consultants for the INSP pursuant to 641 IAC 4.3 and provide program coordination, consultation, follow-up, and education activities. IDPH and UI maintain a 28E agreement to ensure the provision of comprehensive newborn screening services for congenital and inherited disorders in the state of Iowa through the INSP.

This policy addresses the rationale for retention of residual newborn screening specimens, retention and storage conditions, notice of storage of specimens to parents, access to and retrieval of residual specimens. It is understood that SHL procedures may address additional technical and implementation matters not covered by this policy. In the event that there is a conflict between this policy and SHL procedures, this policy shall be controlling with respect to residual newborn screening specimens collected for newborn screening services in Iowa.

II. Definitions

Anonymized. Permanently dissociating a specimen or data from any personally identifiable information (PII) of the index individual or their parents or relatives.

Confidentiality. Assurance that PII is accessed by authorized individuals only and is not shared without express authorization of the parent or legal guardian of the index individual.
"Confidential public health record" includes a record, certificate, report, data, dataset, or information which is confidential under federal or state law. This includes personally identifiable medical information provided for the purpose of studies to reduce morbidity or mortality. Iowa Code §§ 135.40, 135.41.

Identified. Specimens or associated data which contain any information that directly or could reasonably be said to indirectly allow the linkage of a newborn screening (NBS) blood spot or data derived from the blood spot back to the index individual or the parents and relatives of the index individual from which the specimen was collected.

Privacy. Restriction or limitation of the accessibility of personally identifiable information.

Residual newborn screening specimen. The portion of the dried blood spot specimen that may be left over after all activities necessary for the INSP are completed. The INSP collection form consists of dried blood spots on filter paper and attached baby and birthing center information.

III. Rationale for Retention of Residual Newborn Screening Specimens

Residual newborn screening specimens are retained for several reasons:

1. INSP Quality Assurance and Improvement
    a. To confirm the existence of a specimen and its adequate collection
    b. To reconfirm newborn screening analytical results
    c. To retest a specimen when a newborn has been subsequently diagnosed with a screenable disorder
    d. To perform continuous quality assurance and improvement of testing methodologies

2. INSP Test Development, Evaluation, Research and Comparison
    a. To develop and validate new tests for congenital or inherited disorders
    b. To develop and validate new testing methodologies for INSP panel disorders
    c. To compare testing methodologies

3. Diagnostic/clinical purposes
    a. To provide a specimen for diagnostic purposes in the event of an unexplained neonatal, infant or SUID/SIDS death, or child death. Definitive diagnosis is beneficial for counseling families and providing risk assessment for future pregnancies.
    b. To provide a specimen to the healthcare provider when a parent requests additional testing.

4. Research external to the INSP and as allowed by Common Rule, 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.

5. Legal Accountability
    a. To confirm and allow the collection, testing, and appropriate follow-up of a newborn screening specimen during the newborn period in accordance with Iowa laws.

IV. Prohibited uses

A residual newborn screening specimen shall not be released to any person or entity for commercial purposes, law enforcement purposes, or to use as a resource for forensic identification without a legal request from the state medical examiner. A residual newborn screening specimen shall not be released for research unless the researcher has obtained express, documented consent from the parent or guardian for the release of the residual newborn screening specimen, and the research proposal has been approved by the research institution's IRB, the Congenital and Inherited Disorders Advisory Committee (CIDAC), and the IDPH Research and Ethics Review Committee (RERC).

V. Retention and Storage Conditions

- At least one residual dried blood spot from each newborn screening specimen shall be retained by the SHL at -75◦C to-80◦C for the first year of the newborn's life for uses relevant to that newborn.
- Due to the rarity of many newborn congenital and inherited conditions; the need for the INSP to conduct quality assurance and improvement activities; and INSP test development, evaluation, research and comparison for all conditions; residual newborn screening specimens may be retained for up to five years.
- After one year of storage, conditions under which residual newborn screening specimens are stored shall be defined by SHL policy and approved by the Congenital and Inherited Disorders Advisory Committee and the department.

VI. Guidelines for Disposal

Residual newborn screening specimens no longer retained will be permanently anonymized and destroyed. If specimens must be transported off site for disposal then special consideration will be made to ensure that safety precautions and privacy are maintained during transport to an offsite location. Records should indicate which specimens have been destroyed and notes regarding the disposal should be maintained. Specimens retained for eighteen years shall be destroyed between the seventeenth and eighteenth year of life.

VII. INSP Quality Assurance and Improvement

Quality improvement consists of multiple processes and measures, including quality control, to monitor a system and identify successes as well as potential problems before they adversely affect the final product. Continuous quality improvement (CQI) includes those activities designed to ensure test accuracy and to determine the feasibility of modified, additional, or enhanced newborn screening tests. Activities also include validation of the integrity of specimens for specified analytes at defined time periods. Continuous quality improvement activities may also include reconfirmation of screening results, comparisons to other benchmark testing, and emergency management protocol development. Authorized INSP personnel shall have unlimited access to specimens for the purposes of CQI. The Iowa

Newborn Screening Program laboratory must adhere to federal CLIA requirements for laboratory certification, including ongoing QA/QC and proficiency testing.

VIII. INSP Test Development, Evaluation, Research and Comparison

The INSP may use residual newborn screening specimens in feasibility studies approved by the Congenital and Inherited Disorders Advisory Committee for the purpose of incorporating new tests or evaluating new test methodologies. When there is any concern that the activity may have a research component, the project will be submitted to the UI Institutional Review Board, CIDAC, and the IDPH RERC for an opinion on how to proceed, including whether informed consent is required.

IX. Release of specimens

The INSP shall not release a residual newborn screening specimen except to the following persons and entities:

A. A health care provider acting on behalf of the patient.
B. A medical examiner authorized to conduct an autopsy on a child or an investigation into the death of a child.
C. A researcher for research purposes, under the terms and conditions provided in this policy in Section X.
D. Parent or guardian of the index newborn
   After the newborn screening testing and reporting is complete, parents or guardians may request that their child's newborn screening blood spots be returned to them at any time, as long as a directive to destroy the child's residual specimen has not already been received. Parents or legal guardians may contact the Executive Officer of the CCID to request that the newborn's residual newborn screening specimen be returned to them or destroyed. If the parent/guardian requests that a residual newborn screening specimen be returned, the procedure outlined in CCID Policy #001a shall be followed. If the parent/guardian requests destruction of the residual newborn screening specimen, CCID Policy #001b shall be followed. Confirmation of the destruction of the residual newborn screening specimen will be provided to the parent or legal guardian by the department.

X. Research to Benefit the Public Health

Residual newborn screening specimens may be made available to investigators for research external to the INSP and, pursuant to Section IV, as allowed by Common Rule 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.

XI. Confidentiality and Privacy

Reports, records, and other information collected by or provided to the INSP relating to an infant's newborn screening results and follow-up information are confidential records pursuant to Iowa Code section sections 22.7 and 136A.7. INSP shall maintain the confidentiality of all newborn screening records in accordance with state and federal laws and regulations. An appropriate manager will grant the necessary access if an employee needs such information to perform his or her duties. No other access is permitted. A person who knowingly violates the confidentiality statutes cited above may be subject to criminal prosecution for a simple misdemeanor and may be subject to disciplinary action under IDPH or the relevant county's personnel policies, up to and including discharge from employment.

INSP data may be retained indefinitely.

XII. Access to Residual Specimens

Only authorized SHL newborn screening laboratory personnel shall have access to residual specimens. Newborn screening records and/or residual newborn screening specimens shall only be released to researchers upon documentation of project approval by CIDAC and the RERC, list of residual specimens needed, and informed parental consents. Records and/or residual specimens shall only be released to the medical examiner's office or to a diagnostic laboratory upon documentation of the authority to make such request. The SHL shall only provide to researchers, the medical examiner's office, or diagnostic laboratory, a portion of the residual newborn screening specimen(s). The SHL shall assess a fee for retrieval of residual newborn screening specimens and the fee structure will be outlined in the SHL retention policy.