MARYLAND DEPARTMENT OF HEALTH
LABORATORIES ADMINISTRATION

Newborn Screening Division

Dried Blood Spot Policies and Procedures

As part of its public health mission, the Laboratories Administration of the Maryland Department of Health (MDH) routinely receives tests and maintains dried blood spots (DBS) from all newborn babies. These DBS are screened by the Department's Newborn Screening Program to detect specific hereditary disorders and assure that appropriate treatment is instituted in the babies. As steward of the DBS, the MDH Laboratories Administration has established the following policies and procedures covering retention, disposal and requests for use by third parties.

Policy I: Possession, Storage and Disposal

1. All DBS submitted to the Laboratories Administration, once received, are stored and maintained by the MDH Laboratories Administration.

2. Consistent with the Code of Maryland Regulations (COMAR 10.10.13.15D(1)(b)), a DBS submitted to the Laboratories Administration after January 1, 2005, shall be stored for 25 years after newborn screening testing has been completed.

3. DBS stored by the Laboratories Administration shall be stored in a sealed, moisture-proof container at a temperature between -20° and 23°C.

4. Disposal of DBS at the end of their storage period shall be conducted by autoclaving in the presence of a witness, who shall sign a written record of disposal that includes the range of dates when the DBS were originally submitted for testing.

Policy II: Requests for Specimens by Third-Parties

1. Consideration. As part of its public health responsibility to support improving newborn screening and the public health, the Laboratories Administration will consider study requests to use DBS without patient identifiers, i.e., DBS that are either de-identified or anonymized.
    a. De-identified DBS are those that:
        (1) Are coded and separated from all identifiers;
        (2) Cannot be linked to any individual by an investigator and require a data access agreement under which an investigator agrees not to attempt to re-identify a DBS; and
        (3) Where, if critical to protect the health of an individual, MDH could use the code to re-link a DBS to the individual.

b. Anonymized DBS are those that are separated from all possible identifiers and cannot be re-linked to the individual.

2. Requests.
   a. A study request will be considered when it:
      (1) Is made by a qualified investigator whose work will:
         (i) Help improve a current, or develop a new, newborn screening test, i.e., investigations primary to newborn screening; or
         (ii) Provide a better understanding of diseases for the benefit of the general public, i.e., investigations not primary to newborn screening;
      (2) Preserves the confidentiality of test subjects;
      (3) Meets federal requirements related to human subjects research (HSR) as determined by the Institutional Review Board (IRB) process; and

   b. Prior to submitting a formal proposal for MDH IRB approval, an investigator must submit the following materials to the Director of the Laboratories Administration so the Director may better understand the request, determine whether the Laboratories Administration will have sufficient resources to meet the request, and respond to the request before the investigator initiates the IRB process:
      (1) A study proposal approved by the IRB at the investigator's institution;
      (2) Purpose of the study;
      (3) Anticipated public health or medical benefits;
      (4) Whether the proposed study is prospective or retrospective;
      (5) If parental or individual consent will be required;
      (6) Confidentiality requirements;
      (7) Any required demographic characteristics of the specimens;
      (8) Time period to be covered by the study;
      (9) Analyte(s) to be tested;
      (10) The quantity of DBS being requested;
      (11) Epidemiological/statistical evidence for the number of specimens requested; and
      (12) Support that would be provided to help retrieve and prepare the requested DBS.

3. Consent.
   a. Under federal regulation (45 CFR § 46.102(f)), a request to perform a study on anonymized DBS is not considered HSR and does not require parental or individual consent. However, prior to receiving authorization to use anonymized DBS from the MDH Laboratories Administration, the investigator must submit an application to the MDH IRB for review. If the IRB grants a waiver or exemption for use of the DBS, the third-party request can be submitted to the Director of Laboratories Administration for approval.

   b. Requests to perform a retrospective study using de-identified DBS requires IRB approval. Such a study, if found by an IRB to require parental or individual consent, will not be approved by the MDH Laboratories Administration.

c. A request to perform a prospective study using DBS found by an IRB to require parental or individual consent for the use of a DBS may be considered for approval by the MDH Laboratories Administration if:
   (1) Informed consent will be obtained prior to collecting the DBS;
   (2) Written proof, i.e., a copy of a consent form, for each newborn baby included in the study will be provided to the Laboratories Administration before the DBS are provided to the investigator;
   (3) Obtaining consent falls fully on the investigator; and
   (4) The investigator understands that refusal by a parent or individual to consent to the study means no DBS from the baby or individual involved will be provided by the Laboratories Administration for use in the study.

4. Responding to Requests. Affirmative responses by the Laboratories Administration to a study request using DBS also will depend on, but are not limited to:
   a. The availability of staff and staff time within the Laboratories Administration to identify DBS, retrieve DBS, remove patient identifiers, prepare appropriate documentation, and package and ship the DBS; and

   b. Review by MDH's IRB to determine that the study:
      (1) Complies with state and federal confidentiality and HSR protection requirements;
      (2) Has public health or medical benefit; and
      (3) Is appropriate for the purpose and intended outcome of the study.

Requests to use DBS in a study are to be submitted in writing to:

Director
Maryland Department of Health
Laboratories Administration
1770 Ashland Avenue
Baltimore, Maryland 21205

This policy is effective on the date signed:

Director, MDH Laboratories Administration

May 22, 2019