PURPOSE

The purpose of this policy is to provide the Michigan Department of Health and Human Services (MDHHS) guidelines for utilization of residual newborn screening dried blood spots (DBS) in health research.

DEFINITIONS

Community Values Advisory Board (CVAB)

A board of representatives from the community at large as well as community based and state advocacy organizations established and appointed by the director or designee to advise the department on:

- Policies that govern the ways in which blood spots will be acquired and used for research.
- The governance structure of the BioTrust, including a meaningful role for the CVAB in ongoing BioTrust operations.
- Strategies and methods to assure ongoing community awareness and engagement for informing development, review and revision of BioTrust policies.

Dried Blood Spot (DBS): the blood specimen collected from the heel of a newborn for screening for hereditary and other treatable but otherwise disabling conditions as designated by the Department and required by the Michigan Public Health Code, Act 368 of 1978, MCL 333.5431.

DBS Program Representative: State Registrar, Director of Bureau of Laboratories, and Director of the Bureau of Epidemiology and Population Health or designee.

Michigan Department of Health and Human Services (MDHHS) IRB: MDHHS's Institutional Review Board established under MDHHS's Federal Wide Assurance to review all human subjects research that is sponsored by, or involves MDHHS.

Institutional Review Board (IRB) approval: approval of research by MDHHS's IRB.

Material Transfer Agreement: a contract governing the transfer of tangible research materials between two organizations and the recipient's intentions are for use in research purposes. The

department has adopted definitions, terms, and conditions of the Uniform Biological Material Transfer Agreement (UBMTA) published in the Federal Register, vol. 60, March 8, 1995, page 12771 et seq. with the following exception. MDHHS has added additional terms and conditions that apply only to the transfer of newborn screening specimens for research.

Michigan BioTrust for Health: the initiative by the department to make residual DBS from newborn screening more useful for medical and public health research by storing these DBS in optimal conditions and promoting their availability to researchers.

BioTrust Scientific Advisory Board: a board of scientists established consistent with the requirements of Administrative Rule 325.9055 and appointed by the director, or designee, for participation on scientific advisory panels that review proposed research covered by this policy for scientific merit.

BioTrust Scientific Review Panel: a panel of at least three members selected from the BioTrust scientific advisory board to review a specific research proposal.

POLICY

MDHHS allows use of DBS in health research after a research proposal is evaluated for scientific rigor; innovation and significance to medical and public health research; human subjects protections; and ethical standards as outlined in the procedures below, based on guiding principles set forth below with input from the Community Values Advisory Board.

PROCEDURE

Promoting the Public's Health

Research priorities may include but are not limited to:

- Prenatal, childhood or adult-onset disorders.
- Environmental exposures.

Utilization of residual DBS is not approved for research pertaining to:

- Chemical, biological or nuclear warfare.

- Cosmetics.
- Other non-health related ventures unless for purposes related to injury or medical conditions.

Research priorities and restrictions will be re-assessed by the Michigan BioTrust Community Values Advisory Board (CVAB) annually and upon request by the department as technological and scientific advances occur.

Establishing Review and Approval Process

DBS specimens will only be released to a researcher:

- Following review and approval by the BioTrust Scientific Advisory Board and the Michigan Department of Health and Human Services Institutional Review Board.
- Completion of a material transfer agreement.
- Completion of a DCH-1294, Data Use Agreement, (if applicable).

Members of a Review Panel, from the BioTrust Scientific Advisory Board, shall independently review each research protocol requesting utilization of DBS. Panel members are responsible for evaluating the study for scientific rigor, innovation and significance to medical and public health research, feasibility and consistency with the priorities and restrictions set forth above.

The Michigan Department of Health and Human Services Institutional Review Board, comprised of representatives from its various programs and members from the community, shall evaluate proposals to use DBS for research to assure compliance with US regulations that govern human subject’s research (45 CFR 46) and adherence to the ethical principles of the Belmont Report.

In addition, the Michigan Department of Health and Human Service's Institutional Review Board will rely on guidance from the department’s Scientific Advisory Board's evaluation of the scientific merit and the CVAB's advice on acceptable areas of research, to evaluate the potential benefit of the research in relation to any risk.

Data housed by the department will only be linked to DBS and released if the data is de-identified or if the data is identified, but written informed consent has been obtained specifically permitting the release of identifiable information. Approval must be obtained

from the responsible Michigan Department of Health and Human Services program or registry and a DCH-1294, Data Use Agreement, executed between MDHHS and the researcher.

PROTECTING CONFIDENTIALITY

Specimens from the BioTrust and any related data cannot be released in an identifiable manner and may not be manipulated by the researcher to identify an individual, unless written informed consent is obtained specifically permitting that release or manipulation.

DBS will not be released for research using whole genome or whole exome sequencing technology unless written informed consent is obtained specifically permitting such use.

Following completion of newborn screening, DBS specimens shall be de-identified, coded with a unique number and retained in a secure storage facility. MDHHS serves as the honest broker and maintains the sole link that would enable re-coding to identify a sample. The storage code does not contain nor is it derived from directly identifiable information, such as social security number, birth date, etc.

DBS specimens released to researchers shall be coded with a different unique number that does not contain any directly identifiable information. Any accompanying data shall only be released to a researcher after de-identification. Directly identifiable information, such as name or address, shall only be released to researchers when written informed consent is obtained specifically permitting that release.

PROVIDING INFORMATION TO THE PUBLIC

Scientists shall provide the department, while work is on-going, an abstract summarizing the aims of the research. Scientists shall provide the department, within one year of research completion (cessation of data analysis) or no later than the acceptance for publication, whichever comes first, a summary of the research results in aggregate form so that they can be made available to the public on a website and as required through procedures established under the Freedom of Information Act (FOIA). Upon request from the scientist, 1-year deadline may be extended by the

department for good cause. MDHHS will be given citation(s) for all published work utilizing the DBS.

PRESERVING DRIED BLOOD SPOTS ASSOCIATED WITH NEWBORN SCREENING DIAGNOSES

MDHHS will take steps to preserve DBS associated with newborn screening diagnoses due to the rarity of their conditions and vast potential in future research. These DBS will not be used for random population-based research and researchers will be told of this caveat.

SEEKING PUBLIC INPUT

The department shall establish mechanisms to seek input from the public and key stakeholders within the community on the research direction of the BioTrust that may modify the priorities set forth in this policy.

REFERENCES

Administrative Policy Manual Legal (APL) 410, Freedom of Information Act.

APL 618, Institutional Review Board Policy and Procedure.

Laboratories Manual (HPL) 111, Newborn Screening Specimens.

DCH-1183(E) Authorization to Disclose Protected Health Information

DCH-1294 Data Use and Non-Disclosure Agreement

Human Subjects Research, 45 CFR 46

Michigan Administrative Code R 325.167, R 325.9055, R 325.9075

Michigan Public Health Code, Act 369 of 1978, MCL 333.2611, 333.2619, 333.5431, 333.5717, 333.5721, 333.9207, 333.9227

Uniform Biological Material Transfer Agreement (UBMTA), 60 CFR 12771

CONTACT

For additional information concerning this policy, contact the Public Health Genomics Section at 517-335-6497 or at BioTrust@Michigan.gov.