A. PURPOSE

The purpose of this policy is to provide the Department of Community Health (DCH) guidelines for utilization of residual newborn screening dried blood spots (DBS) in health research.

B. REVISION HISTORY

Issued: November 19, 2010. Revised: June 13, 2014

C. 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: 1) policies that govern the ways in which blood spots will be acquired and used for research; 2) the governance structure of the BioTrust, including a meaningful role for the CVAB in ongoing BioTrust operations; and 3) 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 disorders, as 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 Disease Control, Prevention and Epidemiology or designee.

DCH IRB: DCH's Institutional Review Board established under DCH's Federal Wide Assurance to review all human subjects' research that is sponsored by, or involves DCH.

IRB approval: approval of research by DCH's IRB.

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

D. POLICY

It is the policy of the DCH to allow 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.

E. PROCEDURE

Responsibility	*Action*
Promoting the Public's Health	1. Research priorities may include but are not limited to: a. prenatal, childhood or adult-onset disorders, b. environmental exposures. 2. Utilization of residual DBS is not approved for research pertaining to: a. chemical, biological or nuclear warfare, b. cosmetics, or c. other non-health related ventures unless for purposes related to injury or medical conditions. 3. Research priorities and restrictions will be re-assessed by the Michigan BioTrust Community Values Advisory Board (CVAB) annually and upon request by DCH as technological and scientific advances occur.
Establishing Review and Approval Process	1. DBS specimens shall only be released to a researcher following review and approval by the BioTrust Scientific Advisory Board and the DCH IRB, completion of a material transfer agreement and completion of a Data Use Agreement (DCH-1294) (if applicable). 2. 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. 3. The DCH IRB, 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 IRB will rely on guidance from the Department's Scientific Advisory Board evaluation of the scientific merit and the CVAB advice on acceptable areas of research, to evaluate the potential benefit of the research in relation to any risk.

	4. Data housed by DCH will only be linked to DBS and released if the data is de-identified or accompanied by written informed consent. Approval must be obtained from the responsible DCH Program or Registry and a Data Use Agreement (DCH-1294) executed between DCH and the researcher.
Protecting Confidentiality	1. Specimens from the BioTrust and any related data may be used for research only if they cannot be manipulated by the researcher to identify an individual, unless specific informed consent is obtained. 2. DBS will not be released for research using whole genome or whole exome sequencing technology unless specific informed consent is obtained. 3. Following completion of newborn screening, DBS specimens shall be de-identified, coded with a unique number and retained in a secure storage facility. DCH 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, i.e. social security number, birth date, etc. 4. 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, i.e. name or address, shall only be released to researchers when specific informed consent is obtained.
Providing Information to the Public	1. Scientists shall provide DCH, while work is on-going, an abstract summarizing the aims of the research. Scientists shall provide DCH, 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 DCH for good cause. DCH will be given citation(s) for all published work utilizing the DBS.
Reserving a Dried Blood Spot in Trust for the Parent or Child	1. The DCH Bureau of Laboratories shall maintain a portion of every individual's DBS sample for uses that could directly benefit the child or the child's parent or legal representative; and not allow that portion of the sample to be utilized for any research purposes through the BioTrust. Requests for such use shall be submitted in writing by the child's parent or legal representative, by the child upon reaching the age of 18 years, or by the adult child's legal representative,

	by the child upon reaching the age of 18 years, or by the adult child's legal representative.
Destroying Dried Blood Spots Following Parental/Individual (≥18 years of age) Request	1. A parent or individual ≥18 years of age, may request that their child's or their own DBS sample be destroyed. The request must be made using the DCH 1183 (E) Authorization to Disclose Protected Health Information form. Upon receipt of the form in the DCH Bureau of Laboratories, the DBS sample will be destroyed by the Laboratory Manager in the presence of a witness. The requestor will receive a notification letter once the DBS sample has been destroyed.
Preserving Dried Blood Spots Associated with Newborn Screening Diagnoses	1. DCH and the Michigan Neonatal Biobank 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. If an emergency were to occur at the storage facility, the Michigan Neonatal Biobank, these samples will also be given priority.
Seeking Public Input	1. DCH 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.

F. REFERENCES

DCH Policy and Procedure 6.4 (Freedom of Information Act)
DCH Policy and Procedure 6.18 (Institutional Review Board)
DCH Policy and Procedure 11.1 (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

G. CONTACT

For additional information concerning this policy, contact the Genomics and Genetic Disorders Section at 517-335-8887.

RECOMMENDED BY: Susan Morgan DATE: 8-13-14
Deputy Director

APPROVED BY: Nick Lyon DATE: 8/18/14
Chief Deputy Director

APPROVED BY: DATE: 8/18/14
Director