

	STATE OF MICHIGAN DEPARTMENT OF COMMUNITY HEALTH POLICY AND PROCEDURE MANUAL <i>POLICY AND PROCEDURE</i>	CHAPTER
		Public Health
		NUMBER
		11.3
		EFFECTIVE DATE
		November 19, 2010
SUBJECT		
Guidelines for Review and Approval of Research Using Dried Blood Spots		Page 1 of 4

A. PURPOSE

The purpose is to establish the process for the Department of Community Health (DCH) to review research that proposes to use newborn screening dried blood spot specimens.

B. REVISION HISTORY

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

C. DEFINITIONS

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.

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.

BioTrust Coordinator: an individual designated by the Deputy Director of the Public Health Administration to coordinate BioTrust community outreach, manage BioTrust parental consent processes, and provide logistical support for scientific merit and IRB review of research that proposes to use DBS.

IRB Approval: means 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 use 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.

Director: the Director of the Department of Community Health, or designee.

Identifying Information: information about an individual that is identifiable or potentially identifiable to an individual.

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.

DBS Program Representative: State Registrar, Director of Bureau of Laboratories, and Director of the Bureau of Disease Control, Prevention and Epidemiology or designee.

BioTrust Scientific Advisory Board (SAB): 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.



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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 provide guidelines and monitor the implementation of the BioTrust Scientific Advisory Board review process for research that proposes to use DBS made available for potential research, whether identified or not.

E. PROCEDURE

<i>Responsibility</i>	<i>Action</i>
Director or designee	<ol style="list-style-type: none"> 1. Appoints members to the DCH BioTrust Scientific Advisory Board (upon recommendations from DCH staff, research institutions and other organizations) who have the expertise and availability for review of research proposing use of DBS. The term for each member shall be two years and may be renewable by the Director or designee. To ensure availability of individuals with appropriate expertise, the Director or designee may make short term appointments or appointments for specific research proposals.
BioTrust Coordinator	<ol style="list-style-type: none"> 1. Serves as a primary point of contact to ensure completion of scientific review of research proposing use of DBS. 2. Must have approved IRB training. 3. Tracks status of reviews and outcomes. 4. Provides support services as directed by the DBS Program Representatives. <ol style="list-style-type: none"> a. Suggests Scientific Advisory Board Members for review panels. b. Enters information into tracking system to monitor status and outcome of reviews covered by this policy. c. Assures that relevant DCH programs are notified when the research proposes to make use of other data that are governed by administrative regulations that require review by other scientific review boards. d. Summarizes concerns and questions of panel members and communicates with researcher, distributing researcher's responses and any adjustments to the protocol to the panel until the needs and concerns of the panel are appropriately addressed. e. Coordinates and consults with the Administrator of the IRB as indicated. f. Following a recommendation to approve the proposal by the BioTrust Scientific Review Panel and DCH IRB,

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	<p>forwards the research proposal with a summary of panel recommendations to the DBS Program Representatives.</p> <ol style="list-style-type: none"> 5. Facilitates execution of Material Transfer Agreement and Data Use Agreement, if applicable. 6. Notifies IRB Administrator, BioTrust Scientific Review Panel and research applicant of the review outcome. 7. Posts abstract, provided by research applicant, on BioTrust website.
DBS Program Representative	<ol style="list-style-type: none"> 1. On an annual basis, or as needed, reviews appointments to the BioTrust Scientific Advisory Board specifically for appropriateness of members who can provide expert review of research proposing use of DBS. Make recommendations to the Director on adding or discontinuing appointments. 2. Provide oversight of the review process. <ol style="list-style-type: none"> a. Approves selection of at least three members of the BioTrust Scientific Advisory Board to serve on a BioTrust Scientific Review Panel to review a specific research proposal. Communicates with panel member relative to the review. b. If a research proposal includes a request for additional data or specific DBS based on stated criteria, the DBS Program Representatives will confirm with BioTrust Coordinator that the appropriate program responsible for the data has been notified and that their own respective advisory board has reviewed and approved the proposal if needed.
BioTrust SAB Scientific Review Panel	<ol style="list-style-type: none"> 1. Panel members review research proposals. Review criteria include assessing applicant qualifications/capabilities and scientific merit of the proposal. 2. Panel members can: <ol style="list-style-type: none"> a. request research applicants provide additional information or clarification, b. state specific concerns on the study proposal or methodology, and, c. comment on strengths, weaknesses or special concerns relative to the proposal. 3. Scientific Review Panel members make approval or disapproval recommendations. A recommendation for approval is required from a minimum of two panel members and composite score of ≥ 4.5 or by the simple majority if more than three members are appointed to a specific panel.



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F. REFERENCES

DCH Policy and Procedure 6.18 (Institutional Review Board)
DCH Policy and Procedure 11.1 (Newborn Screening Specimens)
DCH-1294 Data Use and Non-Disclosure Agreement
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:  DATE: 8-13-14
Deputy Director

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

APPROVED BY:  DATE: 8/18/14
Director