PURPOSE

The purpose is to establish the process for the Michigan Department of Health and Human Services (MDHHS) to review research that proposes to use newborn screening dried blood spot specimens.

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.

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

BioTrust Coordinator: an individual designated by the deputy director of the population health administration to coordinate BioTrust community outreach, manage BioTrust parental consent processes, and provide logistical support for scientific merit and Michigan Department of Health and Human Services Institutional Review Board review of research that proposes to use DBS.

IRB Approval: means approval of research by Michigan Department of Health and Human Services Institutional Review Board.

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. 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. The department has added additional terms and conditions that apply only to the transfer of newborn screening specimens for research.

Director: Director of the Michigan Department of Health and Human Services, 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 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.

DBS Program Representative: State Registrar, Director of Bureau of Laboratories, and Director of the Bureau of Epidemiology and Population Health 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, 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 provides guidelines and monitors 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.

PROCEDURE

Director or designee

Appoints members to the BioTrust Scientific Advisory Board (upon recommendations from department 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 three 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

1. Serves as a primary point of contact to ensure completion of scientific review of research proposing use of DBS.

2. Must have approved institutional review board training.

3. Tracks status of reviews and outcomes.

4. Provides support services as directed by the DBS Program Representatives:

    - Suggests Scientific Advisory Board Members for review panels.

    - Enters information into tracking system to monitor status and outcome of reviews covered by this policy.

    - Assures that relevant Michigan Department of Health and Human Services 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.

    - Summarizes concerns and questions of panel members and communicates with researcher, distributes researchers' responses and any protocol adjustments to the panel until the needs and concerns of the panel are appropriately addressed.

    - Coordinates and consults with the Administrator of the Michigan Department of Health and Human Services Institutional Review Board as indicated.

    - Following a recommendation to approve the proposal by the BioTrust Scientific Review Panel and Michigan Department of Health and Human Services Institutional Review Board, forwards the research proposal with a summary of panel recommendations to the DBS program representatives.

5. Facilitates execution of Material Transfer Agreement and Data Use Agreement, if applicable.

6. Notifies Institutional Review Board 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

8. 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.

9. Provide oversight of the review process:

    - 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.

    - 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

10. Panel members review research proposals. Review criteria include assessing applicant qualifications/capabilities and scientific merit of the proposal.

11. Panel members can:

    - Request research applicants provide additional information or clarification.

    - State specific concerns on the study proposal or methodology.

    - Comment on strengths, weaknesses or special concerns relative to the proposal.

12. 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

greater than or equal to 4.5 or by the simple majority if more than three members are appointed to a specific panel.

REFERENCES

APL 618, Institutional Review Board Policy and Procedure.

Administrative Policy Manual Facilities and Hospital (APF) 111, 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.

CONTACT

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