THE MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
BUREAU OF LABORATORIES

MATERIAL TRANSFER AGREEMENT[1]

I. DEFINITIONS:

A. **PROVIDER**: MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

B. **PROVIDER SCIENTIST**:

C. **RECIPIENT**:

D. **RECIPIENT SCIENTIST**

E. **ORIGINAL MATERIAL**:

EE. **RESEARCH PURPOSE**:

F. **MATERIAL**: **ORIGINAL MATERIAL**, **PROGENY**, and **UNMODIFIED DERIVATIVES**. The **MATERIAL** shall not include: (a) **MODIFICATIONS**, or (b) other substances created by the **RECIPIENT** through the use of the **MATERIAL** which are not **MODIFICATIONS**, **PROGENY**, or **UNMODIFIED DERIVATIVES**.

G. **PROGENY**: Unmodified descendant from the **MATERIAL**, such as virus from virus, cell from cell, or organism from organism.

H. **UNMODIFIED DERIVATIVES**: Substances created by the **RECIPIENT** which constitute an unmodified functional sub-unit or product expressed by the **ORIGINAL MATERIAL**. Some examples include: subclones of unmodified cell lines, purified or fractionated subsets of the **ORIGINAL MATERIAL**, proteins expressed by DNA/RNA supplied by the **PROVIDER**, or monoclonal antibodies secreted by a hybridoma cell line.

I. **MODIFICATIONS**: Substances created by the **RECIPIENT** which contain/incorporate the **MATERIAL**.

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[1] Although not a signatory to the Association of University Technology Managers ("AUTM"), the MDCH has adopted the 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. MDCH has added additional terms and conditions, as set out in Part B below, that applies only to the transfer of newborn screening specimens for research.

J. **COMMERCIAL PURPOSES**: The sale, lease, license, or other transfer of the **MATERIAL** or **MODIFICATIONS** to a for-profit organization. **COMMERCIAL PURPOSES** shall also include uses of the **MATERIAL** or **MODIFICATIONS** by any organization, including **RECIPIENT**, to perform contract research, to screen compound libraries, to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, license, or transfer of the **MATERIAL** or **MODIFICATIONS** to a for-profit organization. However, industrially sponsored academic research shall not be considered a use of the **MATERIAL** or **MODIFICATIONS** for **COMMERCIAL PURPOSES** per se, unless any of the above conditions of this definition are met.

K. **NONPROFIT ORGANIZATION(S)**: A university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statute. As used herein, the term also includes government agencies.

PART A

II. TERMS AND CONDITIONS OF THIS AGREEMENT THAT APPLY TO ALL TRANSFERS OF MATERIAL

A. The **PROVIDER** retains ownership of the **MATERIAL**, including any **MATERIAL** contained or incorporated in **MODIFICATIONS**.

B. The **RECIPIENT** retains ownership of:

1. **MODIFICATIONS** (except that, the **PROVIDER** retains ownership rights to the **MATERIAL** included therein), and

2. those substances created through the use of the **MATERIAL** or **MODIFICATIONS**, but which are not **PROGENY**, **UNMODIFIED DERIVATIVES** or **MODIFICATIONS** (i.e., do not contain the **ORIGINAL MATERIAL**, **PROGENY**, **UNMODIFIED DERIVATIVES**).

If either B .1. or 2. above results from the collaborative efforts of the **PROVIDER** and the **RECIPIENT**, joint ownership may be negotiated.

C. The **RECIPIENT** and the **RECIPIENT SCIENTIST** agree that the **MATERIAL**:

1. is to be used solely for teaching and academic research purposes;

2. will not be used in human subjects, in clinical trials, or for diagnostic purposes involving human subjects without the written consent of the **PROVIDER**;

3. is to be used only at the **RECIPIENT** organization and only in the **RECIPIENT SCIENTIST's** laboratory under the direction of the **RECIPIENT SCIENTIST** or others working under his/her direct supervision; and

4. will not be transferred to anyone else within the **RECIPIENT** organization without the prior written consent of the **PROVIDER**.

D. The **RECIPIENT** and the **RECIPIENT SCIENTIST** agree to refer to the **PROVIDER** any request for the **MATERIAL** from anyone other than those persons working under the **RECIPIENT SCIENTIST's** direct supervision. To the extent supplies are available, the **PROVIDER** or the **PROVIDER SCIENTIST** agrees to make the **MATERIAL** available, under a separate agreement having terms consistent with the terms of this Agreement, to other scientists (at least those at **NONPROFIT ORGANIZATION(S)**) who wish to replicate the **RECIPIENT SCIENTIST's** research; provided that such other scientists reimburse the **PROVIDER** for any costs relating to the preparation and distribution of the **MATERIAL**.

1. The **RECIPIENT** and/or the **RECIPIENT SCIENTIST** shall have the right, without restriction, to distribute substances created by the **RECIPIENT** through the use of the **ORIGINAL MATERIAL** only if those substances are not **PROGENY**, **UNMODIFIED DERIVATIVES**, or **MODIFICATIONS**.

2. Under a separate agreement at least as protective of the **PROVIDER's** rights, the **RECIPIENT** may distribute **MODIFICATIONS** to **NONPROFIT ORGANIZATION(S)** for research and teaching purposes only.

3. Without written consent from the **PROVIDER**, the **RECIPIENT** and/or the **RECIPIENT SCIENTIST** may NOT provide **MODIFICATIONS** for **COMMERCIAL PURPOSES**. It is recognized by the **RECIPIENT** that such **COMMERCIAL PURPOSES** may require a commercial license from the **PROVIDER** and the **PROVIDER** has no obligation to grant a commercial license to its ownership interest in the **MATERIAL** incorporated in the **MODIFICATIONS**. Nothing in this paragraph, however, shall prevent the **RECIPIENT** from granting commercial licenses under the **RECIPIENT's** intellectual property rights claiming such **MODIFICATIONS**, or methods of their manufacture or their use.

E. The **RECIPIENT** acknowledges that the **MATERIAL** is or may be the subject of a patent application. Except as provided in this Agreement, no express or implied licenses or other rights are provided to the **RECIPIENT** under any patents, patent applications, trade secrets or other proprietary rights of the

PROVIDER, including any altered forms of the **MATERIAL** made by the **PROVIDER**. In particular, no express or implied licenses or other rights are provided to use the **MATERIAL**, **MODIFICATIONS**, or any related patents of the **PROVIDER** for **COMMERCIAL PURPOSES**.

F. If the **RECIPIENT** desires to use or license the **MATERIAL** or **MODIFICATIONS** for **COMMERCIAL PURPOSES**, the **RECIPIENT** agrees, in advance of such use, to negotiate in good faith with the **PROVIDER** to establish the terms of a commercial license. It is understood by the **RECIPIENT** that the **PROVIDER** shall have no obligation to grant such a license to the **RECIPIENT**, and may grant exclusive or non-exclusive commercial licenses to others, or sell or assign all or part of the rights in the **MATERIAL** to any third party(ies), subject to any pre-existing rights held by others and obligations to the Federal Government.

G. The **RECIPIENT** is free to file patent application(s) claiming inventions made by the **RECIPIENT** through the use of the **MATERIAL** but agrees to notify the **PROVIDER** upon filing a patent application claiming **MODIFICATIONS** or method(s) of manufacture or use(s) of the **MATERIAL**.

H. Any **MATERIAL** delivered pursuant to the Agreement is understood to be experimental in nature and may have hazardous properties. The **PROVIDER** MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE **MATERIAL** WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. The Recipient is responsible for maintaining a safe working environment in Recipient's laboratory through adequate training of personnel (including students), facility design, personal protective equipment availability and proper disposal of waste.

I. Except to the extent prohibited by law, the **RECIPIENT** assumes all liability for damages which may arise from its use, storage or disposal of the **MATERIAL**. The **PROVIDER** will not be liable to the **RECIPIENT** for any loss, claim or demand made by the **RECIPIENT**, or made against the **RECIPIENT** by any other party, due to or arising from the use of the **MATERIAL** by the **RECIPIENT**, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the **PROVIDER**.

II. MDCH represents and warrants that it has obtained review and approval from the MDCH Institutional Review Board for transfer of MATERIAL to _____ including but not limited to

review of the specific material, the proposed use, and the patient consents under which the materials were obtained."

J. This agreement shall not be interpreted to prevent or delay publication of research findings resulting from the use of the **MATERIAL** or the **MODIFICATIONS**. The **RECIPIENT SCIENTIST** agrees to provide appropriate acknowledgement of the source of the **MATERIAL** in all publication.

K. The **RECIPIENT** agrees to use the **MATERIAL** in compliance with all applicable statutes and regulations, including Public Health Service and National Institutes of Health regulations and guidelines such as, for example, those relating to research involving the use of animals or recombinant DNA.

L. This Agreement will terminate on the earliest of the following dates:

1. when the **MATERIAL** becomes generally available from third parties, for example, through reagent catalogs or public depositories, or

2. on completion of the **RECIPIENT's** current research with the **MATERIAL**, or

3. on thirty (30) days written notice by either party to the other,

provided that:

a. if termination should occur under L.1 the **RECIPIENT** shall be bound to the **PROVIDER** by the least restrictive terms applicable to the **MATERIAL** obtained from the then-available sources; and

b. if termination should occur under L.2., the **RECIPIENT** will discontinue its use of the **MATERIAL** and will, upon direction of the **PROVIDER**, return or destroy any remaining **MATERIAL**. The **RECIPIENT**, at its discretion, will also either destroy the **MODIFICATIONS** or remain bound by the terms of this agreement as they apply to **MODIFICATIONS**; and

c. in the event the **PROVIDER** terminates this Agreement under L.3. other than for breach of this Agreement or for cause such as an imminent health risk or patent infringement, the **PROVIDER** will defer the effective date of termination for a period of up to one year, upon request from the **RECIPIENT**, to permit completion of research in progress. Upon the effective date of termination, or if requested, the deferred effective date of termination, **RECIPIENT** will discontinue its use of the **MATERIAL** and will, upon direction of the **PROVIDER**, return or destroy any remaining **MATERIAL**. The **RECIPIENT**, at its discretion, will also either destroy the **MODIFICATIONS** or remain bound by the terms of this agreement as they apply to **MODIFICATIONS**.

M. Paragraphs F, I and J shall survive termination.

N. The **MATERIAL** is provided at no cost, or with an optional transmittal fee determined by the Michigan Neonatal Biobank solely to reimburse the **PROVIDER** for its preparation and distribution costs.

NN. Neither party shall use the name of the other or any contraction or derivative thereof or the name(s) of the other party's faculty members, employees, or students, as applicable, in any advertising, promotional, sales literature, or fundraising documents without prior written consent from the other party.

O. This Agreement may not be amended without the prior written consent of both parties.

P. This Agreement constitutes the entire agreement between the parties relating to the subject matter and supersedes any prior agreements, written or oral, regarding the subject matter hereof.

PART B

III. ADDITIONAL TERMS AND CONDITIONS OF THIS AGREEMENT THAT APPLY TO TRANSER OF NEWBORN SCREENING SPECIMENS FOR RESEARCH

A. RECIPIENT agrees to provide the following information to PROVIDER, which will be publicly posted and made available by PROVIDER to engage and inform the public about research that uses newborn screening specimens:

1. Summary or abstract describing the research project to be provided before newborn screening specimens are transferred to RECIPIENT.

2. Summary of the research project results to be provided within 1 year of research completion or no later than the acceptance for publication, whichever comes first. Upon request from RECIPIENT, 1-year deadline may be extended by PROVIDER for good cause. The PROVIDER will be given citation(s) for all published work utilizing the newborn screening specimens.

3. Within 6 months of research completion, RECIPIENT will complete and return Appendix A: Dried Blood Spot Final Inventory Log.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives effective as of the date last written below.

_____

University/Agency/Institution

_____

Street

_____

City, State ZIP

Name:_____ Title:_____

Signature:_____ Date:_____

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
BUREAU OF LABORATORIES
3350 N Martin Luther King, Jr. Blvd.
Lansing, Michigan 48909

Name:
Title: Laboratory Director
Signature: Date:

DCH – 1339 July 14, 2008

THE MICHIGAN DEPARTMENT OF COMMUNITY HEALTH BUREAU OF LABORATORIES

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Appendix A: DRIED BLOOD SPOT (DBS) FINAL INVENTORY LOG

(To be returned to MICHIGAN DEPARTMENT OF COMMUNITY HEALTH/BUREAU OF LABORATORIES when study is completed)

PRINCIPALINVESTIGATOR:

COLLABORATOR (IF INDICATED):

STUDY TITLE:

DBS RECIPIENT ADDRESS:

QUANTITY ACQUIRED: *Please indicate the number of samples received as well as the number and size of punches or number of spots per sample.*

Number of DBS Samples:
Size of DBS Samples:
Number and Size of Punches:
Number of Whole Dried Blood Spots:

DATE OF ACQUISTION:

FINAL INVENTORY OF USAGE: *Please confirm that all dried blood spots and related materials were used in their entirety or destroyed at the completion of the study.*

☐ **DBS and Related Material Used In Entirety** ☐ **DBS and Related Material Destroyed**

PRINCIPAL INVESTIGATOR:
DATE:

COLLABORATOR (IF INDICATED):
DATE:

COMMENTS:

Rev. 06/2013