MATERIAL TRANSFER AGREEMENT
FOR THE TRANSFER OF HUMAN MATERIALS
from the Environmental Polymorphisms Registry (EPR)

This Human Material Transfer Agreement ("MTA") is between the National Institute of Environmental Health Sciences (NIEHS) ("PROVIDER"), part of the National Institutes of Health, a component of the United States Department of Health and Human Services and _____("RECIPIENT"), located at _____, for the transfer of human material, with or without accompanying data, for research purposes as further defined below. PROVIDER and RECIPIENT may each be referred to as Party or collectively as Parties. This MTA will become effective on the date of the last signature below.

The RECIPIENT and the PROVIDER agree as follows:

1. The PROVIDER will transfer to the RECIPIENT the following:

   _____

   with the following data _____

   (collectively "Human Material").

2. Descriptive title of RECIPIENT's research with Human Material is:

   _____

   ("Research Project" described in Appendix A).

3. RECIPIENT agrees to use the Human Material for teaching and non-profit research purposes only and will not use the Human Material for any commercial purposes, including selling, commercial screening, or transferring Human Material to a third party for commercial purposes.

4. PROVIDER will provide RECIPIENT with personally identifiable information or the code to personally identifiable information with the Human Material:

   ☐ Yes

   ☐ No

   If Box "Yes" is checked above, then RECIPIENT's use of the Human Material is subject to:

   a. The Privacy Act of 1974, as amended, at 5 U.S.C. §552a ("Privacy Act") requirements; and
   b. Applicable human subjects regulations and guidance, which may include 45 C.F.R. Part 46, 21 C.F.R. Parts 50 and 56, and FDA Good Clinical Practice Guidelines (ICH E6 Good Clinical Practice: Consolidated Guidance, 62 FR 25692 (1997)); and
   c. RECIPIENT's agreement to:

      (i) maintain any transferred personally identifiable information in a secure manner that restricts

access to any individual not involved in the Research Project (e.g., for paper records – locked file cabinets or continual physical presence in a room that locks, or for electronic records – encryption and password protection); and

(ii) remove or destroy the information that identifies the individual who is the subject at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the Research Project; and

(iii) make no further use or disclosure of the information unless approved by the PROVIDER, except as required by law.

5. RECIPIENT will use the Human Material only for the Research Project described in the attached EPR – Sample Request/ Genotyping Overview Form (Appendix A), which has been approved by the EPR Steering Committee.

6. RECIPIENT represents that it has obtained Institutional Review Board approval, as appropriate, to use Human Material.

7. THE RECIPIENT AGREES THAT THIS HUMAN MATERIAL MAY NOT BE USED IN HUMANS OR FOR ANY DIAGNOSTIC, PROGNOSTIC, OR TREATMENT PURPOSES.

8. RECIPIENT will allow the use of Human Materials only by RECIPIENT's Investigator and RECIPIENT's Investigator's research team that are under the direct supervision of RECIPIENT Investigator and only after they have been informed of and agreed to the provisions and restrictions stated herein. Any transfer of Human Material to anyone other than RECIPIENT's Investigator's research team requires the advanced written approval of the PROVIDER.

9. All Confidential Information that is transferred between PROVIDER and RECIPIENT is subject to the following:

   All information to be deemed confidential under this MTA shall be clearly marked "CONFIDENTIAL" by the PROVIDER and maintained in confidence by the RECIPIENT for a period of three (3) years from the RECIPIENT's receipt of the Confidential Information. Any Confidential Information that is orally disclosed must be reduced to writing and marked "CONFIDENTIAL" by the PROVIDER and such notice must be provided to the RECIPIENT within thirty (30) days of the oral disclosure.

   For the purposes of this MTA, Confidential Information includes any scientific or business data relating to the Human Material that a Party asserts are confidential and proprietary, except for data that:

   a. have been published or otherwise publicly available at the time of disclosure to the RECIPIENT; or

   b. were in the possession of or were readily available to the RECIPIENT without being subject to a confidentiality obligation from another source prior to the disclosure; or

   c. have become publicly known, by publication or otherwise, not due to any unauthorized act of the RECIPIENT; or

d. the RECIPIENT can demonstrate it developed independently, or acquired without reference to, or reliance upon, such Confidential Information; or

e. are required to be disclosed by law, regulation, or court order.

10. The RECIPIENT will not contact or make any effort to identify individuals who are or may be the sources of the Human Material, without specific written approval from the PROVIDER.

11. The RECIPIENT will comply with all laws, rules and regulations applicable to the handling and use of the Human Material.

12. Either Party may terminate this Agreement with sixty (60) days written notice to the other Party.

13. When the Research Project is completed or this Agreement is terminated, whichever comes first, any unused Human Material will be returned to the PROVIDER or RECIPIENT shall send PROVIDER documentation that the unused Human Material has been destroyed in compliance with all applicable statutes and regulations.

14. RECIPIENT agrees to provide a copy of the results of each analysis within 30 days of completion, if requested by PROVIDER. RECIPIENT further agrees to provide to the PROVIDER with a copy of any abstract ten (10) days in advance of submission for publication and any manuscript or other disclosure document thirty (30) days in advance of submission for publication, in order to permit review and comment, and ensure compliance with the confidentiality requirements of this Agreement.

15. In all oral presentations or written publications concerning the use of Human Materials, the RECIPIENT will acknowledge the PROVIDER's contribution of the Human Material unless requested otherwise by PROVIDER.

16. Any Human Material delivered pursuant to this 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 HUMAN MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

17. No indemnification for any loss, claim, damage, or liability is intended or provided by either Party under this MTA. Each Party shall be liable for any loss, claim, damage, or liability that said Party incurs as a result of said Party's activities under this MTA, except that the PROVIDER, as an agency of the United States, may be liable only to the extent as provided under the Federal Tort Claims Act (28 U.S.C. Chapter 171). No indemnification for third party claims is intended or implied by either Party.

18. This MTA shall be construed in accordance with United States Federal law as applied by the Federal courts in the District of Columbia. The Parties have executed this MTA by their respective duly authorized officers on the day and year hereinafter written. Any communication or notice to be given shall be forwarded in writing to the respective addresses listed below.

SIGNATURES

FOR THE PROVIDER:

PROVIDER's INVESTIGATOR:
I have read and understood the terms and conditions of this MTA and I agree to abide by them.

(Signature) Date
Shepherd H. Schurman, M.D., Principal Investigator, EPR

(Signature of Authorized Official) Date
William T. Schrader, Ph.D., Deputy Scientific Director

(Signature of Authorized Official) Date
Elizabeth M. Denholm, Ph.D., Director, Office of Technology Transfer
Email Address for Documents: denholme@niehs.nih.gov

FOR THE RECIPIENT:

(Signature of Authorized Official) Date
(Printed Name and Title)

Email Address for Documents:

RECIPIENT's INVESTIGATOR:
I have read and understood the terms and conditions of this MTA and I agree to abide by them in the receipt and use of the Human Material.

(Signature) Date
(Printed Name and Title)