



MATERIAL TRANSFER AGREEMENT
FOR THE TRANSFER OF HUMAN MATERIALS
FOR NON-PROFIT RESEARCH PURPOSES

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 National Center for Computational Toxicology (NCCT) ("RECIPIENT"), part of the United States Environmental Protection Agency located at 109 T.W. Alexander Rd., Research Triangle Park, NC 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.

PROVIDER Investigator: Stavros Garantziotis

RECIPIENT Investigator: John Wambaugh

RECIPIENT and PROVIDER agree as follows:

1. PROVIDER will transfer to RECIPIENT the following: de-identified serum samples with the following data samples will be divided by demographic information (gender, race, age group), but no other data will accompany the samples (collectively "Human Material").
2. Descriptive title of RECIPIENT's research with Human Material is: Screening for Xenobiotic Chemicals in Pooled Blood Samples ("Research Project").
3. RECIPIENT agrees to use Human Material for teaching and non-profit research purposes only and will not use 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 Human Material: (check appropriate box)

Yes

No

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

- a. The Privacy Act of 1974, as amended, at 5 U.S.C. §552a ("Privacy Act") requirements;
- 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 by 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);

(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 only use Human Material for the Research Project.
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 Investigator and RECIPIENT 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 other than RECIPIENT Investigator's research team requires the advanced written approval of 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 providing Party and maintained in confidence by the receiving Party for a period of three (3) years from the receiving Party's receipt of the Confidential Information. Any Confidential Information that is orally disclosed must be reduced to writing and marked "CONFIDENTIAL" by the providing Party and such notice must be provided to the receiving Party 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 receiving Party; were in the possession of or were readily available to the receiving Party without being subject to a confidentiality obligation from another source prior to the disclosure;
 - b. have become publicly known, by publication or otherwise, not due to any unauthorized act of the receiving Party;
 - c. the receiving Party can demonstrate it developed independently, or acquired without reference to, or reliance upon, such Confidential Information; or
 - d. is required to be disclosed by law, regulation, or court order.
10. RECIPIENT will not contact or make any effort to identify individuals who are or may be the sources of Human Material, without specific written approval from PROVIDER.



11. 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 MTA with sixty (60) days written notice to the other Party.
13. When the Research Project is completed or this MTA is terminated, whichever comes first, any unused Human Material will either be destroyed in compliance with all applicable statutes and regulations or will be returned to the PROVIDER as requested by the PROVIDER.
14. In all oral presentations or written publications concerning the use of Human Materials, RECIPIENT will acknowledge PROVIDER's contribution of Human Material unless requested otherwise by PROVIDER.
15. Any Human Material delivered pursuant to this MTA is understood to be experimental in nature and may have hazardous properties. 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 HUMAN MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.
16. 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 Government, may be liable only to the extent as provided under the Federal Tort Claims Act (28 U.S.C. Chapter 171
17. 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 FOLLOW ON NEXT PAGE