

MATERIALS TRANSFER AGREEMENT

Provider:

U.S. Environmental Protection Agency (EPA)
Office of Research and Development (ORD)
National Center for Computational Toxicology (NCCT)

Recipient:

ILSI North America

1. Provider (EPA) agrees to transfer to Recipient's Investigator named below the following Research Material:

Access to EPA ToxMiner data

2. This Research Material may not be used in human subjects. The Research Material will be used only for research purposes by Recipient's investigator in his/her laboratory, for the research project described below, under suitable containment conditions. This Research Material will not be used for screening, production or sale, for which a commercialization license may be required. Recipient agrees to comply with all Federal rules and regulations applicable to the Research Project and the handling of the Research Material.

3. Does the Research Material include specimens or data derived or collected from human subjects?

Yes – Go to item #3(a).

No – Skip to item #4.

- 3(a). Does the Research Material include specimens or data derived or collected from fetuses, children, pregnant women, or nursing women?

Yes

No

- 3(b). Was the Research Material obtained under a protocol that was reviewed and approved by an Institutional Review Board (IRB) that operated in accordance with the requirements of EPA Regulation 40 CFR 26, HHS Regulation 45 CFR 46, or any other

Federal Regulation for the protection of human research subjects?

Yes (Please indicate the applicable Regulation here _____ and provide copies of the protocol and IRB approval documents.)

No (Please provide explanation with documentary support as appropriate.)

3(c). Can the Provider of the Research Material identify the subjects directly or through identifiers (codes) linked to the subjects?

Yes – The Recipient's use of the Research Material may be human subject's research subject to 40 CFR 26. Go to item #3(d).

No – The Recipient's use of the Research Material is not human subjects research subject to 40 CFR 26. Skip to item #4.

3(d). Is the Provider of the Research Material prohibited by this agreement from releasing information to the Recipient that might allow the identification of any of the subjects, including but not limited to the key to any existing code?

Yes – The Recipient's use of the Research Material is not human subjects research subject to 40 CFR 26. Skip to item #4.

No – The Recipient's use of the Research Material may be human subjects research subject to 40 CFR 26. Go to item #3(e).

3(e). Is the Research Material publicly available?

Yes – The Recipient's use of the Research Material is human subjects research that is exempt from 40 CFR 26.

No – The Recipient's use of the Research Material is human subjects research that may be subject to 40 CFR 26 and must be further evaluated accordingly by the EPA Human Subjects Review Official.

4. This Research Material will be used by Recipient's investigator solely in connection with the following research project described with specificity as follows:

The Tox 21 and ToxCast high-throughput screening (HTS) programs screen thousands of chemicals for potential toxicity. The HTS approach aims to help prioritize chemicals that need more extensive toxicological evaluation, and to identify mechanisms of action for further investigation. To understand the potential impact of HTS on the food industry, data from the Tox21 and ToxCast programs will be evaluated. A chemical list based on interest to the food industry including anti-microbials, food additives and chemical contaminants will be mined from the Tox21 library to determine the activity of these compounds across assays. Furthermore, ToxCast datasets will also be evaluated for the chemicals of interest to further explore the profile of these compounds across hundreds of assays. Translation of *in vitro* concentrations to *in vivo* doses and complimentary literature reviews to identify pertinent *in vivo* studies will be included. Periodic updates and presentations to the Food and Chemical Safety Committee as well as a final written

document will be compiled to summarize the findings. Tox21 and ToxCast testing results will not be reported at the individual chemical level prior to publication of the results by the Tox21 and ToxCast research groups.

The designated Fellow for ILSI North America will be granted access to data contained in the EPA ToxMiner database. The Fellow will be permitted to share summary level data from the database with ILSI NA. Summary level data is defined as those data which do not identify a specific chemical substance with individual assay results. An example of permitted summary level data is the % active compounds and potency ranges from a food additive list in an assay for estrogenic transcriptional activity. At the time when the data from ToxCast become public through release, data at the individual chemical level may be shared with ILSI NA.

5. In all oral presentations or written publications concerning the Research Project, Recipient will acknowledge Provider's contribution of this Research Material unless requested otherwise. To the extent permitted by law, Recipient agrees to treat as confidential, any of Provider's written information about this Research Material that is stamped "CONFIDENTIAL" for a period of three (3) years from the date of its disclosure to recipient. The foregoing shall not apply to information that is or becomes publicly available or which is disclosed to Recipient without a confidentiality obligation. Any oral disclosures from Provider to Recipient which Provider wishes to be treated as confidential shall be identified as being Confidential at the time of the disclosure and by written notice delivered to Recipient within thirty (30) days after the date of the oral disclosure. Recipient may publish or otherwise publicly disclose the results of the Research Project, but if Provider has given Confidential information to Recipient, such public disclosure may be made only after Provider has had thirty (30) days to review the proposed disclosure to determine if it includes any Confidential information, to the extent such review period is permitted by law.

6. This Research Material represents a significant investment on the part of Provider and is considered proprietary to Provider. Recipient's investigator therefore agrees to retain control over this Research Material and further agrees not to transfer the Research Material to other people not under his/her direct supervision without advance written approval of Provider. Provider reserves the right to distribute the Research Material to others and to use it for its own purposes. When the Research Project is completed, the Research Material will be returned to the Provider or disposed, if directed by Provider.

7. This Research Material is provided as a service to the research community. It is being supplied to Recipient with no warranties, express or implied, including any warranty of merchantability or fitness for a particular purpose. Provider makes no representations that the use of the Research Material will not infringe any patent or proprietary rights of third parties.

8. Recipient shall retain title to any patent or other intellectual property rights in inventions made by its employees in the course of the Research Project. However, if said inventions contain any portion of the Research Material, are derived from the Research Material, or could not have been produced but for the use of the Research Material, Recipient agrees to contact the Provider to determine what ownership interests, if any, the Provider may have, and, where applicable, to negotiate in good faith the terms of a commercial license. Inventorship for a patent application or a commercialized product based on said inventions shall be determined according to United States patent law.

9. When Provider is the EPA: Recipient agrees not to claim, infer, or imply endorsement by the Government of the United States of America (hereinafter referred to as "Government") of the Research Project, the institution or personnel conducting the Research Project or any resulting product(s). Recipient agrees to hold the Government harmless and to indemnify the Government for all liabilities, demands, damages, expenses and losses arising out of Recipient's use for any purpose of the Research Material.

10. When Recipient is the EPA: Provider will not be liable to EPA for any claims or damages arising from EPA's use of the Research Material.

11. The Provider shall have the right to terminate this Agreement at any time if Recipient breaches any of the terms of this Agreement. Upon termination, Recipient shall return to the Provider all unused portions of the Research Materials.

12. Will EPA develop any products or services from information or materials provided by the Recipient?

Yes – go to item A

No – skip to #13 (next clause)

Item A: The EPA has a long history of applying principles of quality assurance/quality control to all technical work conducted by or for the Agency (CIO 2106: USEPA Quality Policy). Given EPA is receiving (*fill-in information/material*) and will use the (*fill-in information/material*) for Agency purposes, the Recipient is required to provide EPA with documentation such as a quality manual, describing their organization's quality system. Documentation showing third party accreditation to a relevant standard and scope is also acceptable for documenting an organization's quality system. EPA requirements for quality management plans can be found at this URL:
http://www.epa.gov/quality/qa_docs.html

13. All notices pertaining to or required by this Agreement shall be in writing and shall be signed by an authorized representative and shall be delivered by hand (including private courier

mail service) or sent by certified mail, return receipt requested, with postage prepaid, addressed as follows:

Provider's Administrative Contact Information:

John Southerland
National Center for Computational Toxicology (NCCT)
US EPA
109 TW Alexander (MD-B-205-01)
Research Triangle Park, NC 27711
For commercial courier address use:
4930 Old Page Rd.
Durham, NC 27703
919-541-3416
southerland.john@epa.gov

Recipient's Contact Information:

Alison Kretser
ILSI North America is:
1156 Fifteenth Street, NW
Suite 200
Washington, DC 20005
akretser@ilsil.org

- 14. Paragraphs 2, 7, 9 and 10 shall survive termination.
- 15. This Agreement shall be construed in accordance with law as applied by the Federal courts in the District of Columbia.
- 16. The undersigned Provider and Recipient expressly certify and affirm that the contents of any statements made herein are truthful and accurate.
- 17. This agreement shall enter into force as of the date of the last signature of the parties and shall remain in effect for one year from said date.
