

## MATERIALS TRANSFER AGREEMENT

**Provider:**

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

**Recipient:**

Waters Technologies Corporation  
Research Material should be sent to:  
Waters Corporation,  
34 Maple Street, Milford,  
MA-01757  
Attn: Gareth Cleland (508-482-3506)

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

Chemicals and Materials

- ☒ A list identifying selected chemicals from the ToxCast chemical library to be tested by Recipient ("Recipient Investigator") using the Recipient's Technology. This list will be provided in electronic format and contain chemical structures and chemical identifiers (e.g. DSSTOX ID, chemical names and synonyms)
- ☒ A copy of the current ToxCast chemical library, or subset, consisting of chemical samples prepared as solution in dimethyl sulfoxide at a concentration of 20 millimolar. Additional chemicals may be provided in the future concurrent with expansion of the ToxCast chemical library.
- ☐ Samples of nanomaterials and characterization data on said materials

Data and Summary Information

- ☐ In vitro assay data derived from the ToxCast Program. This data is derived from chemicals analyzed using a variety of high throughput assay techniques. Below this is referred to as the "ToxCast Data".
- ☐ In vivo whole animal toxicology data summary data derived from the EPA Toxicology Reference Database (ToxRefDB). Below this is referred to as the "ToxRefDB Data".
- ☐ Summary descriptions of the individual data sets.

- ☐ Individual subsets of this data will be delivered to XXX after they have been prepared for use at EPA and cleared for release to XXXX.

1b. The Recipient agrees to transfer to the EPA Investigator named below the following results generated from the Research Project (as defined below) results:

- ☒ All data or data summaries resulting from chemical screening performed on the ToxCast chemical library in both binary data file formats and, where necessary, in open file formats.
- ☐ Results of any data analyses that include use of provided ToxCast or ToxRef data.
- ☐ Relevant data on these chemicals from non-public sources.
- ☐ Unique chemicals for the ToxCast chemical library and subsequent testing by EPA.

1c. The Recipient and Provider agree that “Technology” means without limitation, any (1) Waters mass spectrometry or chromatography system or component thereof or any equipment that contains or uses any Waters mass spectrometry or chromatography system or component thereof; (2) any software that contains or controls any Waters mass spectrometry or chromatography system or component thereof; (3) any literature or instructions, including safety warnings regarding any such component, equipment or software; (4) any reagents, columns, consumables, data interpretation techniques, training materials, systems and programs, operational techniques; and (5) sample preparation techniques, sample analysis techniques, or data interpretation techniques; and methodology, ideas, concepts, documents, inventions, improvements, processes, algorithms, know-how, or proprietary data relating to items (1), (2), (3) or (4) that Recipient may use and/or develop in the performance of the Research Project.

2. This Research Material may not be used in human subjects. The Research Material will be used only for research purposes by Recipient 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, except as described herein. 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).

\_\_\_x\_\_\_ 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 Investigator solely in connection with the following research project ("Research Project") described with specificity as follows:

- The materials will be used for the generation of mass spectrometry data to perform compound identification and analysis.



- A copy of the experimental data will be made available to NCCT in Waters binary file format for the purpose of internal hosting and analysis.
- Recipient shall be free to include the Results in a chemical compound structure library to be used for both non-commercial and commercial purposes.

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 or which is independently developed by Recipient without reference to the Research Material. 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; provided however, Recipient may disclose Provider's Research Material to its and its affiliates' employees, representatives, directors, and officers. 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. Provider represents that it has the right to provide the Research Materials to Recipient hereunder. RECIPIENT MAKES NO OTHER AND DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, AND DISCLAIMS ALL LIABILITY ARISING FROM OR IN

RELATION TO ANY TESTING, ANALYSIS OR REPORTS PROVIDED UNDER THIS AGREEMENT.

8. Recipient shall retain title to any patent or other intellectual property rights in inventions relating to the Technology or made by its employees in the course of the Research Project. . Recipient shall retain a worldwide, royalty-free, nonexclusive license to use the Results for both internal and commercial purposes.
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). EPA will not be liable to Recipient for any claims or damages arising from Recipient's use 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 analytical screening data and will use the data for Agency purposes, the Recipient is required to provide EPA with documentation such as a quality manual, describing their organization's quality system. In lieu of such documentation, Standard Operating Protocols for compound handling and the assays performed are acceptable or 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](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:**

Russell Thomas,  
National Center for Computational Toxicology (NCCT)  
US EPA  
109 TW Alexander (MD-B205-01)  
Research Triangle Park, NC 27711  
Tel: 919-541-5776  
Thomas.russell@epa.gov

With a copy to:  
Sandra Roberts  
National Center for Computational Toxicology (NCCT)  
US EPA  
109 TW Alexander (MD-B205-01)  
Research Triangle Park, NC 27711  
919-541-3850  
Roberts.sandra@epa.gov

For commercial courier address use:  
4930 Old Page Rd.  
Durham, NC 27703



**Recipient's Contact Information:**

Gareth Cleland, Ph.D., Principal Scientist  
Waters Corporation  
34 Maple Street  
Milford, MA 01757  
Mailing Address  
Tel: 508-482-3506 Fax: 508-244-9657  
gareth\_cleland@waters.com  
Email address

**With a copy to:**

Legal Department  
Waters Corporation  
34 Maple Street  
Milford, MA 01757  
Fax: 508-482-2320  
legal@waters.com

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.

Any false or misleading statements made, presented, or submitted to the Government, including any material omissions, under this Agreement and during the course of negotiation of this Agreement are subject to all applicable civil and criminal statutes including 31 U.S.C. ' ' 3801-3812 (civil liability), 18 U.S.C. ' 1001 (criminal liability), and 31 U.S.C. ' ' 3729-33 (False Claims Act).