

MATERIALS TRANSFER AGREEMENT

Provider: University of Saint Thomas, Department of Biology

Provider Contact (not signator):

Name: Dr. Dalma Martinovic-Weigelt

Address: OWS 366, Mail OWS 390, 2115 Summit Ave, St. Paul, MN, USA

Phone: 651-962-5233

Email: mart6831@stthomas.edu

Recipient: US EPA Center for Computational Toxicology and Exposure (CCTE)

Recipient Contact (not signator):

Name: Dr. Daniel Villeneuve

Address: 6201 Congdon Blvd, Duluth, MN, 55804, USA

Phone: 218-529-5217 (office); 218-341-6707 (official duty mobile)

Email: villeneuve.dan@epa.gov

1. Provider agrees to transfer to Recipient the following Research Material:
Applied Biosystems Quantstudio 7 Flex Real-time QPCR instrument

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.

EPA ONLY: If the data or material that are being transferred constitute human subjects research, please visit the following intranet site to determine if your project needs review and approval by the HSRRO:

<https://intranet.ord.epa.gov/human-subject-research/hsr-projects-review>

There is no Human Subjects material being used in this Research Plan

Reviewed and approved by HSRRO: Name:

Date:

3. If the data or material that are being transferred involve life sciences research, or more specifically any of the select agents or toxins listed and/or the definitions provided in EPA Order 1000.19 *Policy and Procedures for Managing Dual Use Research of Concern*, then Principal Investigators should consult EPA's Institutional Contact for Dual Use Research of Concern (ICDUR) at DURC@epa.gov before completing the following section. If not, then check the first box below.

- This research does not meet any of the definitions of Dual Use Research of Concern (DURC) and no additional review or oversight are required. The PI must report to the ICDUR any results or changes in the research that meet any of the definitions of DURC.
- This research meets one or more definitions of DURC and requires additional oversight under the USG Policy for Institutional Oversight of DURC. The parties to this Agreement are required to comply with EPA Order 1000.19, *Policy and Procedures for Managing Dual Use Research of Concern*.

For information about DURC and EPA Order 1000.19, please visit:

<http://intranet.ord.epa.gov/homeland-security/dual-use-research-concern-durc-policies>

4. This Research Material will be used by Recipient's investigator solely in connection with the following research project ("Research Project") described with specificity as follows (*insert description here or use an attachment page if necessary*):

A. PURPOSE: The Research Material will be used by CCTE to conduct testing and evaluation of a novel analysis technology called the EcoToxChip in support of a cooperative research and development agreement between U.S. EPA, McGill University, and the University of Saskatchewan (#982-17) and CSS Research Outputs CSS 4.5 and CSS 4.7.
B. EcoToxChips (not the research material in the current MTA) are printed in a 384-well microplate format and a 384-well plate compatible real-time PCR instrument is needed to conduct the analyses. CCTE currently does not possess a 384-well plate compatible instrument. Given that the EcoToxChips are a novel technology whose utility for future CCTE research has not been established, it is premature for CCTE to invest in the purchase of a new instrument until additional needs and demands for such an instrument are identified. Consequently, a loaner instrument (the subject Research Material of this agreement) is an ideal way to support the current research objectives. University of St. Thomas has such an instrument but currently does not have critical need for its use and has agreed to temporarily transfer the instrument to CCTE for the duration needed to complete the EcoToxChip evaluation studies. CCTE has the appropriate infrastructure in terms of laboratory space and trained personnel to operate the instrument and conduct the research. In particular, CCTE recently purchased a Beckman Biomek liquid handling system that is ideally suited for loading reagents and samples onto the 384-well chip format. Consequently, all parties agreed the research objectives could be most efficiently and effectively accomplished through temporary transfer of the University of St. Thomas's Applied Biosystems Quantstudio 7 Flex Real-time QPCR instrument to CCTE in Duluth, MN, USA.
C. OBJECTIVES: The Research Material will be used to conduct research aimed at achieving the following objectives: (1) Testing and evaluating the novel EcoToxChip technology and providing feedback to the University of Saskatchewan, McGill University, and University of St. Thomas regarding the strengths, weaknesses, and overall utility of the technology; (2) generating novel data using the technology that supports scientific products under output areas 4.5 and 4.7 of the CSS national research program.
D. GOALS: The overall goals are to provide critical evaluation of new approach methodologies that are being developed for potential research and regulatory applications.
E. ROLES AND RESPONSIBILITIES
a. The Provider (University of St. Thomas) intends to loan its Applied Biosystems Quantstudio 7 Flex Real-time QPCR instrument to CCTE for the purpose of supporting EcoToxChip evaluation/validation research.
b. The Recipient (EPA) intends to: arrange for transport of the instrument from the University of St. Thomas, St. Paul, MN to the CCTE Duluth, MN laboratory using a government owned vehicle; set up and operate the instrument in a safe and secure location at the CCTE facility; calibrate the instrument with a commercial calibration plate; utilize the instrument for EcoToxChip evaluation/validation research; arrange for and cover costs of any service or maintenance that may be required to keep the instrument in good running condition for the duration of use at the CCTE Duluth facility, including but not limited to any repairs needed as a result of damage to the instrument during the period it is within the possession or control of EPA; and arrange for return transport of the instrument from the GLTED to the University of St. Thomas upon conclusion of the research, or at the request of the University of St. Thomas.

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. Recipient agrees to protect the information claimed as confidential business information from unauthorized disclosure to the extent permitted by law and consistent with EPA's regulations under 40 C.F.R. Part 2, Subpart B. In asserting a claim for protection, the Provider must stamp its Research Material as "CLAIMED AS CONFIDENTIAL BUSINESS INFORMATION." Documents that are stamped with "CLAIMED AS CONFIDENTIAL BUSINESS INFORMATION" represent that the Provider is asserting a confidentiality claim for a period of three (3) years. 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 assert as confidential business information, shall be identified as being confidential business information at the time of the disclosure and by written notice, stamped in the manner stated above, and 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 claimed confidential business 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 claimed confidential business 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 laboratory must coordinate on matters related to Quality Assurance with their QA Specialist.

If necessary, the Laboratory will develop/has developed a Quality Assurance Plan in coordination with the Quality Assurance Specialist.

No QA requirements are needed.

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 Contact Information (Signator):

Dr. Richard Plumb, Executive Vice President and Provost

Official's Name & Title

Aquinas Hall Room 116, 2115 Summit Ave., St. Paul, MN, 55104-1078

Mailing Address

651-962-6720

Phone Number

plum0019@stthomas.edu

Email address

Recipient's Contact Information (Signator):

Russell Thomas, Center Director

Official's Name & Title

109 T.W. Alexander Dr., Research Triangle Park, NC 27711

Mailing Address

919-541-5776

Phone Number

thomas.russell@epa.gov

Email address

With a copy to:

Kathleen Graham
FTTA Program Coordinator
Graham.Kathleen@epa.gov
(303) 312-6137
FTTA@epa.gov

14. Paragraphs 2, 5, 7, 8, 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.

Authorized Representative of Institution SIGNATURES

FOR THE RECIPIENT:

FOR THE PROVIDER:

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

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