

DATA USE AGREEMENT

Between the U.S. Environmental Protection Agency and Health Canada

This AGREEMENT is made and entered into by and between **Health Canada** (“**Recipient**”), which has a principal place of business at 269 Laurier Avenue, Ottawa, Ontario, Canada and the **Center for Computational Toxicology and Exposure** on behalf of the **U.S. Environmental Protection Agency** (“**Provider**,” “**EPA**” or “**Agency**”) (together, the “**Parties**”). The Parties hereby agree as follows:

1. This Agreement establishes a formal data access and data use relationship between EPA and Health Canada. EPA agrees to provide the data described below (“**Data**”) to Recipient. Recipient must only use the Data for the project entitled **High Throughput Profiling for Chemical Risk Assessment** (“**Research Project**”), as further described below. The Parties shall abide by all applicable Federal and State laws, rules, and regulations including, without limitation, all patient confidentiality and medical record requirements and any applicable Institutional Review Board (“**IRB**”) requirements.

Description of Data Set:

EPA will provide the Recipient with data from high-throughput transcriptomics (HTTr) and high-throughput phenotypic profiling (HTPP) screening efforts. The data is derived from transcriptomic profiling by targeted RNA-seq and phenotypic profiling by high-content imaging of *in vitro* cell lines after exposure to test chemicals or environmental samples. The data is intended to be released publicly upon completion of related reports based on internal analysis work at EPA.

For HTTr, data will be in the form of sequence read files, tables of read counts for each probe in each sample, matrices of log₂-fold changes for each probe by each treatment. For HTPP, data will be in the form of tables of normalized phenotypic feature data summarized to the well level and results from concentration-response modeling of such data. Meta-data files will include the plate barcode and well identifier on each plate, cell line information, chemical treatment conditions, chemical names and identifiers, and study batch identifiers. Data and meta-data are linked by unique sample identifiers consisting of plate barcode and well location.

Description of the Research Project:

Recipient has a shared interest with EPA in the development of New Approach Methodologies (NAMs) including high-throughput transcriptomics (HTTr) and high-throughput phenotypic profiling (HTPP) for regulatory decision-making. Recipient will use the Data to develop and evaluate analysis methods for these types of studies in specific regulatory use contexts. Recipient will share results of subsequent analysis with EPA in the form of reports or presentations.

Transfer of data:

Data will be in the form of sequence read files, probe-level counts, log₂-fold change matrices, and chemical mapping files or other appropriate formats.

Data will be transferred between EPA and Recipient using secure protocols, such as SFTP, with password protected access.

2. Data being provided to the Recipient is currently unpublished, therefore, the data may not be

shared with other entities, or used for any commercial products or services, until it has been published and/or publicly released, or unless explicit permission is given by EPA. Recipient will only store the data on their own secure systems and will not share or provide access to the data to any other parties without EPA approval.

3. EPA agrees that Recipient may disclose the Data to its collaborators, provided that the collaborators are bound by confidentiality obligations no less restrictive than the terms of this Agreement. EPA reserves the right to distribute the Data to others and to use it for its own purposes.

4. This Agreement shall be effective upon full execution by both parties (“**Effective Date**”) and shall expire after 3 years, unless terminated earlier by either Party after thirty (30) days advance notice to the other Party. Upon completion of the Research Project, or upon expiration or earlier termination of this Agreement, whichever occurs first, Recipient will destroy or return the Data. However, no destruction or return is required if the Data is made publicly available by the EPA before completion of the Research Project, or upon expiration or earlier termination of this Agreement, whichever occurs first.

5. The Data 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 Data will not infringe any patent or proprietary rights of third parties.

6. The parties agree that any copyrightable subject matter, including but not limited to journal articles, training, educational or informational material or software, created jointly by the parties from the activities conducted under the Agreement may be copyrighted by Recipient. Further, if Recipient intends to disseminate the work(s) outside of the United States, Recipient may secure copyright to the extent authorized under the domestic laws of the relevant country. Recipient hereby grants to the U.S. federal government a royalty-free, worldwide, nonexclusive, irrevocable right to reproduce, distribute, publish, display or perform the work(s) publicly, to make derivative works and, in regard to all of the above-referenced uses, to authorize others to do the same on its behalf.

7. Provider will not be liable to Recipient for any claims or damages arising from Recipient’s use of the Research Material.

8. As an agency of the federal government, EPA’s responsibility for the payment of claims for the loss of property, personal injury or death, or otherwise arising out of any negligent act or omission of its employees in connection with the performance of work under this Agreement shall be governed by the Federal Torts Claims Act.

9. This Agreement shall be governed by and construed in accordance with the laws of the United States. All actions concerning this Agreement shall be brought in the federal district courts of the United States.

10. If either party desires a modification to this Agreement, the parties shall, upon reasonable notice of the proposed modification by the party desiring the change, confer in good faith to determine the desirability of such modification. Such modification shall not be effective until a written amendment is signed by all the parties hereto by their representatives duly authorized to execute such amendments.

11. All notices pertaining to or required by this Agreement shall be in writing and shall be signed by an authorized representative, addressed as follows:

(a) If to CENTER:

Authorized Representative (signator)
Russell Thomas
U.S. EPA Center for Computational Toxicology and Exposure (CCTE)
109 T.W. Alexander (MD-D-143-02)
Research Triangle Park, NC 27711
919.541.5776
thomas.russell@epa.gov

With a copy to:
Samantha Plishka
Extramural Management Analyst
U.S. EPA Center for Computational Toxicology and Exposure (CCTE)
109 T.W. Alexander (MD-B-205-01)
Research Triangle Park, NC 27711
919.541.2657
plishka.samantha@epa.gov

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

AND

Kathleen Graham
FTTA Program Coordinator
graham.kathleen@epa.gov
303.312.6137
FTTA@epa.gov

(b) If to RECIPIENT:

Authorized Representative (signator)
Tara Barton-Maclaren
Existing Substances Risk Assessment Bureau, Health Canada
269 Laurier Avenue West, 4th Floor
Ottawa, Ontario, Canada K1A 0P8
613.790.5459
tara.bartonmaclaren@hc-sc.gc.ca

With a copy to:
Craig Riedl
Existing Substances Risk Assessment Bureau, Health Canada
Laurier Avenue West, 4th Floor
Ottawa, Ontario, Canada K1A 0P8
613.462.7109
craig.riedl@hc-sc.gc.ca

Any party may change such address by notice given to the other party in the manner set forth above.

12. Paragraph 2 shall survive termination.

13. The illegality or invalidity of any provisions of this Agreement shall not impair, affect, or invalidate the other provisions of this Agreement.

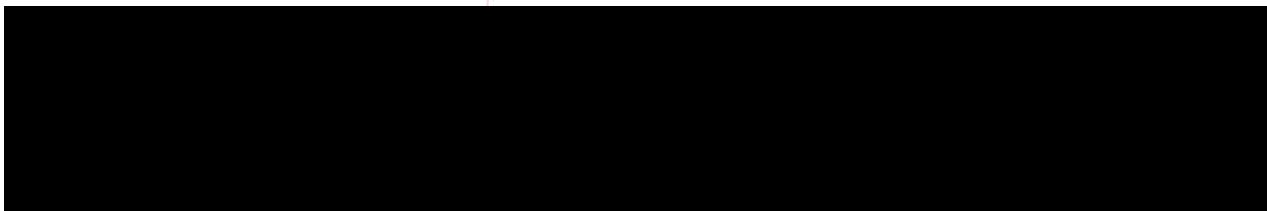
14. This Agreement constitutes the entire agreement between the parties concerning the subject matter hereof and supersedes any prior understanding or written or oral agreement relative to said matter.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives as follows:

RECIPIENT:



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY:



Read and Acknowledged by EPA Representative:

