

COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT
WITH THE
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

This Material Cooperative Research and Development Agreement ("MCRADA" or "Agreement") is entered into by and between the Minnesota Department of Health which has its principal place of business in St. Paul, MN ("the Cooperator"), and the EPA, National Center for Computational Toxicology ("NCCT"), of the U.S. Environmental Protection Agency ("EPA") under the authority of Title 15, United States Code Sections 3710a-3710d, commonly known as the Federal Technology Transfer Act of 1986 ("FTTA").

WITNESSETH:

- A. WHEREAS**, the Congress, in enacting the FTFTA, has found that Federal laboratories' developments should be made accessible to private industry and state and local governments, and has declared that one of the purposes of the Act is to improve the economic, environmental and social well-being of the United States by stimulating the utilization of Federally-funded technology developments by such parties;
- B. WHEREAS**, the FTFTA provides each Federal agency with the authority to permit the Directors of Government-operated laboratories to enter into cooperative research and development agreements with Federal or non-Federal entities, including state governments, for the purpose of providing to, or obtaining from, collaborating parties, personnel, services, property, facilities, equipment, intellectual property or other resources toward the conduct of specified research and development efforts, which may include the licensing of patent or other intellectual property rights in the inventions resulting from such collaboration;
- C. WHEREAS**, NCCT has performed and has sponsored substantial research and development with respect to innovative approaches, data, and tools to evaluate thousands of chemicals for potential health effects.
- D. WHEREAS**, NCCT possesses certain advanced scientific skills, facilities, special equipment, information, computer software, and know-how pertaining to new approaches to evaluating chemicals for potential health effects such as gathering, generating, and analyzing information including chemistry, toxicity, and exposure that can be used to produce new data and online tools.
- E. WHEREAS**, the Cooperator possesses certain knowledge of Minnesota's approaches to evaluating emerging chemicals of concern. The Cooperator has expertise in their

organization's chemical regulatory authority, and is able to work with NCCT to determine how newly developed chemical tools and data can be used to better prioritize chemicals for further evaluation and risk assessment.

F. WHEREAS, NCCT and the Cooperator are interested in using new chemical data generated from scientific approaches such as read-across, Quantitative Structure Activity Relationship (QSAR), high-throughput toxicology screening, and computational modeling of exposure and toxic kinetics to prioritize chemicals for further evaluation and risk assessments.

G. WHEREAS, the both NCCT and the Cooperator desires to provide the other with expertise about the approach each uses to assess the health risks of emerging chemicals of concern ; and

H. WHEREAS, the NCCT views its collaboration with the Cooperator to provide expertise to use new chemical data generated from scientific approaches to help prioritize and inform the Cooperator's risk assessment of emerging chemicals of concern as a furtherance of the public interest.

NOW, THEREFORE, the parties hereto agree as follows:

Article 1. Definitions

As used in this Agreement, the following terms shall have the assigned meanings, and such meanings should be equally applicable to both the singular and plural forms of the terms defined:

1.1 "MCRADA" or "Agreement" means this Cooperative Research and Development Agreement entered into by the NCCT pursuant to 15 U.S.C. Section 3710a.

1.2 "Computer Software" means computer software, computer programs, computer data bases, and documentation thereof developed, in whole or in part, under this Agreement.

1.3 "Government" means the Government of the United States of America.

1.4 "Invention" means any invention or discovery that is or may be patentable or otherwise protectable under the intellectual property laws of this or any foreign country.

1.5 "Made" in relation to any Invention means the conception or first actual reduction to practice of such Invention.

1.6 **"Proprietary Information"** means information which embodies trade secrets developed at private expense, or which is confidential scientific, business or financial information, provided that such information:

- (a) Is not generally known or available from other sources without obligation concerning its confidentiality;
- (b) Has not been made available by the owners to others without obligation concerning its confidentiality; and
- (c) Is not already available to the Government without obligation concerning its confidentiality.

1.7 **"Subject Data"** means all recorded information first produced in the performance of this Agreement. This term includes Computer Software.

1.8 **"Subject Invention"** means any Invention conceived or first actually reduced to practice in the performance of work under this Agreement.

1.9 **"Technology"** means the new chemical data generated from scientific approaches such as read-across, QSAR, high-throughput toxicology screening, and computational modeling of exposure and toxic kinetics.

1.10 **"Works"** means any Computer Software or subject matter information first produced in the performance of this Agreement that is copyrightable.

Article 2. Cooperative Research

2.1 **Statement of Work.** Cooperative research and development work performed under this Agreement shall be performed in accordance with the Statement of Work ("SOW") which is attached hereto and incorporated into this Agreement as Attachment A. NCCT and the Cooperator agree to perform the cooperative research and development work as set forth in the SOW, and in doing so to utilize such personnel, resources, facilities, equipment, skills, knowledge, and information as is reasonably necessary

2.2 **Review of Work.** Periodic conferences shall be held between NCCT and Cooperator personnel to review the progress of the work to be accomplished under this Agreement. NCCT shall have exclusive control and supervision over the conduct of all cooperative research and development work conducted at the NCCT facilities. The Cooperator shall have exclusive control and supervision over the conduct of all cooperative research and development work conducted at Cooperator's facilities. It is understood that the nature of this cooperative research and development work is such that completion within the period of performance specified in the SOW or within the limits of each party's allocated financial support cannot necessarily be

guaranteed. Accordingly, it is agreed that all cooperative research is to be performed on a best efforts basis.

2.3 Assigned Personnel. Each party to this Agreement shall perform its respective obligations under this Agreement under the direction of a "Project Manager" and a "Principal Investigator." Project Managers shall be responsible for the overall direction of the work and providing such approvals and consents as are required hereunder. Principal Investigators shall be responsible for the scientific and technical conduct of the work, including the exchange of Subject Data and other information. The parties designate the following individuals as their respective representatives:

	NCCT	Cooperator
Project Manager	Monica Linnenbrink	Sarah Johnson
Principal Investigator	Reeder Sams	Helen Goeden

2.4 Scope Change. If at any time the Project Managers determine that the research data justify a substantial change in the direction of the work, the parties shall make a good faith effort to agree on any necessary changes to the SOW. Any material change to the SOW shall require an amendment of the SOW and this Agreement.

Article 3. Reports/Publications

3.1 Final Report/Document. NCCT and the Cooperator shall write a report and a publication summarizing how the new chemical data could be used to inform and prioritize the Cooperator's risk assessments. The report/publication will be completed within one year of either the completion of the SOW or the termination or expiration of this Agreement, whichever occurs first.

Article 4. Financial Obligations.

No financial obligations will be exchanged. Both NCCT and the Cooperator are each responsible for their own costs and expenses necessary for their respective compliance with the terms of this Agreement and the SOW. This Agreement is neither a fiscal nor a funds obligation document. Nothing in this Agreement, in and of itself, obligates the NCCT or the Cooperator to expend appropriations or to enter into any contract, assistance agreement, interagency agreement, or other financial obligation.

4.1 Assignment of Personnel. The Cooperator shall provide qualified staff to comply with its obligations under the SOW. The staff will be employees of the Cooperator stationed at the Cooperator's principal place of business. NCCT shall provide qualified research staff whom to comply with its obligations under the SOW who will be stationed at the EPA's Office of Research and Development.

Article 5. Invention, Computer Software, and Patent Rights

5.1 NCCT and the Cooperator will be using open-sourced software under this CRADA. NCCT and the Cooperator believe that no Subject Inventions or Computer Software will be created during the work specified in this Agreement. Should it appear that any activity of this Agreement might involve the creation of a Subject Invention or Computer Software that will not be publicly available, NCCT and the Cooperator will negotiate in good faith an amendment to this Agreement. The amendment will assign responsibilities for obtaining patents or other intellectual property rights pertaining to the Subject Inventions or Computer Software and will provide for appropriate allocation of any patent or intellectual property rights resulting from those Subject Inventions or Computer Software.

Article 6. Data and Publication

6.1 Release Restrictions. The NCCT, pursuant to the terms of this Agreement, shall have the right to use all Subject Data for any Governmental purpose; provided, however, that the NCCT shall not release such Subject Data publicly or provide such Subject Data to any Government regulatory body or agency other than the EPA except:

- (a) the NCCT in reporting the results of cooperative research may publish Subject Data, subject to the provisions of paragraph 6.2 below, and provided the Cooperator is given 45 days to review the manuscript and provide suggestions before publication; and
- (b) the NCCT may release such Subject Data where such release is required pursuant to a request under the Freedom of Information Act (5 U.S.C. Section 552) and the EPA regulations at 40 C.F.R. Part 2 or as required to be disclosed by other statutes.
- (c) The Cooperator agrees to not release any Subject Data without obtaining prior written consent from the NCCT unless such release is required or authorized by applicable law.
- (d) Pursuant to 35 U.S.C. Section 205, neither the NCCT nor the Cooperator shall release to the public any Subject Data or other data that discloses or enables an invention if a patent application is to be filed, until the party having the right to file a patent application or provisional patent application has had a reasonable time to file.

6.2 Publication. The NCCT and the Cooperator agree to confer and consult prior to the publication of Subject Data to ensure patent rights are not jeopardized. Prior to submitting a manuscript for outside review which contains the results of the research under this Agreement, or prior to publication if no such review is made, each party shall be offered at least 45 calendar days to review such proposed publication and to file patent applications in a timely manner, if it is so entitled or required under this Agreement.

Article 7. Representations and Warranties

7.1 Representation and Warranties of the NCCT. The NCCT hereby represents and warrants to the Cooperator as follows:

7.1.1 Organization. The NCCT is a Federal Laboratory of the EPA and is wholly owned by the Government. The NCCT's substantial purpose is the performance of research or development.

7.1.2 Mission. The performance of the activities specified by this Agreement is consistent with the mission of the NCCT.

7.1.3 Authority. All prior reviews and approvals required by Federal regulations and laws have been obtained by the NCCT prior to the execution of this Agreement. The NCCT official executing this Agreement has the requisite authority to do so.

7.2 Representations and Warranties of the Cooperator. The Cooperator hereby represents and warrants to the NCCT as follows:

7.2.1 Corporate Organization. The Cooperator, as of the date hereof, is a state governmental agency in the United States of America validly existing and in good standing under the laws of the State of Minnesota.

7.2.2 Power and Authority. The Cooperator has the requisite power and authority to enter into this Agreement and to perform according to the terms thereof.

7.2.3 Due Authorization. The Cooperator have taken all actions, if any, required to be taken by law or otherwise to authorize the execution and delivery of this Agreement.

7.2.4 No Violation. The execution and delivery of this Agreement do not contravene any material provision of, or constitute a material default under, any material agreement binding on the Cooperator or any valid order of any court, or any regulatory agency or other body having authority to which the Cooperator is subject, nor, to the best of its knowledge, is the Cooperator the subject of any adversarial proceeding by any regulatory governmental agency.

Article 8. Termination

8.1 Termination by Mutual Consent. The NCCT and the Cooperator may elect to terminate this Agreement, or portions thereof, at any time by mutual consent. In such event, the parties shall specify the disposition of all property, patents, and the results arising from the work completed or in progress under this Agreement. Upon termination by mutual consent, the NCCT, as of the termination date, shall make no new commitments, and as soon after the termination date as feasible, shall cancel all outstanding commitments that relate to those portions of this Agreement that have been mutually terminated.

8.2 Termination by Unilateral Action. Either party may unilaterally terminate this entire Agreement at any time by giving the other party written notice not less than 30 calendar days prior to the desired termination date. The NCCT shall make no new commitments after receipt of a written termination notice from the Cooperator and shall to the extent possible, by the termination date, cancel all outstanding commitments and contracts that were entered into as a consequence of the requirements of the SOW. However, the NCCT may, at its own expense, continue said commitments beyond said termination date without liability on the part of the Cooperator.

8.3 Termination Costs. Each party shall pay its own termination costs out of its own funds. In no event shall either party be liable for the direct and indirect termination costs of the other party or said other party's expenses caused by or related to the termination.

8.4 Survival. To the extent rights and obligations hereunder have accrued as of the date of expiration or termination, the following Articles of this Agreement shall survive any expiration or termination hereof: 5, 6, and 10, and any expiration or termination hereof shall not affect any license granted hereunder.

Article 9. Disputes

9.1 Settlement. Any dispute arising under this Agreement that cannot be readily resolved shall be submitted jointly to the signatories of this Agreement. A joint decision of the signatories or their designees shall be the disposition of such dispute.

9.2 Continuation of Work. Pending the resolution of any dispute or claim pursuant to this Article, the parties agree that performance of all obligations shall be pursued diligently in accordance with the terms of this Agreement.

Article 10. Liability

10.1 EPA. EPA's responsibility for the payment of claims to the Cooperator or its employees for loss of property, personal injury or death caused by the negligence or the wrongful act or omission of employees of EPA, while acting within the scope of their employment, is in accordance with the provisions of the Federal Tort Claims Act, 28 U.S.C. Section 2671-80 and 40 C.F.R. Part 10.

10.2 Cooperator. Cooperator's responsibility for the payment of claims to the EPA, NCCT, or any other party for loss of property, personal injury or death caused by the negligence or the wrongful act or omission of the Cooperator's employees, while acting within the scope of their employment, is in accordance with the provisions of the Minnesota Tort Claims Act, Minnesota Statutes Section 3.736, and other applicable laws.

10.3 No Warranty. Except as specifically stated in Article 7, neither party makes any express or implied warranty as to any matter whatsoever, including the conditions of the research

or as to any Invention made or product developed, or the ownership, merchantability, or fitness for a particular purpose, of the research or any such Invention or product.

10.4 Force Majeure. Neither party shall be liable for any event or circumstance beyond its reasonable control not caused by the fault or negligence of such party, which causes such party to be unable to perform its obligations under this Agreement (and which it has been unable to overcome by the exercise of due diligence), including but not limited to flood, drought, earthquake, storm, fire, pestilence, lightning and other natural catastrophes, epidemic, war, riot, civil disturbance or disobedience, strikes, labor dispute, sabotage of the NCCT facilities, or any order or injunction made by a court or public agency. In the event of the occurrence of such a force majeure event, the party unable to perform shall promptly notify the other party. It shall further use its best efforts to resume performance as quickly as possible and shall suspend performance only for such period as is necessary because of the force majeure event.

10.5 Cooperator. The Cooperator agrees that during the term of this Agreement it will carry commercial general liability insurance in the amount set forth on the attached certificate of insurance to cover any liability to the Government or to Government employees and private individuals that may arise as a result of negligent acts or omissions of any of the Cooperator's employees or agents while they are performing work under this Agreement.

Article 11. Miscellaneous

11.1 No Benefits. No member of, or delegate to the United States Congress, or resident commissioner, shall be admitted to any share or part of this Agreement, nor to any benefit that may arise therefrom. This provision shall not be construed to extend to this Agreement if the Agreement is made with the Cooperator for the Cooperator's general benefit.

11.2 Governing Law. The construction, interpretation, validity, performance and effect of this Agreement for all purposes shall be governed by the laws applicable to the federal government. Notwithstanding the foregoing, nothing in this Agreement shall be construed to deprive the Cooperator of its sovereign immunity, nor to any defenses or limitations of liability available to the Cooperator under Minnesota law.

11.3 Headings. Titles and headings of the Sections and Subsections of this Agreement are for the convenience of references only and do not form a part of this Agreement and shall in no way affect the interpretation thereof.

11.4 Waivers. None of the provisions of this Agreement shall be considered waived by any party hereto unless such waiver is given in writing to all other parties. The failure of any party to insist upon strict performance of any of the terms and conditions hereof, or failure or delay to exercise any rights provided herein or by law, shall not be deemed a waiver of any rights of any party hereto.

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

11.6 Amendments. 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.

11.7 Assignment. Except as otherwise permitted herein, neither this Agreement nor any rights or obligations of any party hereunder shall be assigned or otherwise transferred by either party without the prior written consent of the other party. However, the Cooperator may assign this Agreement to the successors or assignees of a substantial portion of the Cooperator's business interests to which this Agreement directly pertains.

11.8 Notices. 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 or sent by certified mail, return receipt requested, with postage prepaid, addressed as follows:

(a) If to NCCT:

Authorized Representative (signatory)

Name: Russell Thomas

Title: Director

Address: 109 TW Alexander Drive, Durham NC 27709

Phone: 919-541-5776

Email: thomas.russell@epa.gov

AND

FTTA Program Coordinator:

Kathleen Graham

Graham.kathleen@epa.gov

(303) 312-6137

ftta@epa.gov

(b) If to COOPERATOR:

Authorized Representative (signatory)

Name: Tom Hogan

Title: Environmental Health Division Director

Address: 625 Robert Street N

P.O. Box 64975

St. Paul, MN 55164-0975

Phone: 651-201-4675

Email: tom.hogan@state.mn.us

With a copy to (PM and PI or other):

Name: Sarah Johnson
Title: Health Risk Assessment Unit Supervisor
Address: 625 Robert Street N
P.O. Box 64975
St. Paul, MN 55164-0975
Phone: 651-201-4080
Email: sarah.fossen.johnson@state.mn.us

Name: Helen Goeden
Title: Senior Toxicologist/Risk Assessor
Address: 625 Robert Street N
P.O. Box 64975
St. Paul, MN 55164-0975
Phone: 651-201-4904
Email: helen.goeden@state.mn.us

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

11.9 Independent Parties. The relationship of the NCCT and the Cooperator is that of independent parties and not as agents of each other or as joint venturers or partners. The NCCT shall maintain sole and exclusive control over its personnel and operations. The Cooperator shall maintain sole and exclusive control over its personnel and operations.

11.10 Use of Name or Endorsements.

11.10(a) The Cooperator shall not use the name of the NCCT or EPA, on any product or service that is directly or indirectly related to either this Agreement or any patent license or assignment agreement that implements this Agreement, without the prior approval of the NCCT. By entering into this Agreement the NCCT does not directly or indirectly endorse any product or service provided, or to be provided, by the Cooperator, its successors, assignees, or licensees. The Cooperator shall not in any way imply that this Agreement is an endorsement of any such product or service. This section in no way prohibits the publication of any EPA indication or statement regarding the efficacy of any Subject Invention and/or any other results of this Agreement.

11.10(b) Neither the NCCT, the EPA, nor any other Federal Government Agency shall use the Cooperator's name, nor the name State of Minnesota, on any product or service that is directly or indirectly related to either this Agreement or any patent license or assignment agreement which implements this Agreement, without the prior approval of the Cooperator. By entering into this Agreement neither the State of Minnesota nor the Cooperator directly or indirectly endorse any product or service provided, or to be provided, by the NCCT or the EPA

or its successors, assignees, or licensees. NCCT and EPA shall not in any way imply that this Agreement is an endorsement of any such product or service. This section in no way prohibits the publication of any of Cooperator's indication or statement regarding the efficacy of any Subject Invention and/or any other results of this Agreement.

11.11 No Approval. Nothing in this Agreement shall be deemed to constitute regulatory or scientific approval of the use of any particular product or technology. The Cooperator agrees that (a) nothing in this Agreement relieves it of any obligation to comply with applicable federal, state, or local laws, regulations, or requirements, and (b) possession or acquisition by the NCCT of Subject Data, or other information generated or otherwise acquired pursuant to performance of work under this Agreement, does not constitute knowledge of or possession or receipt of such data or information by or on behalf of the Administrator of the EPA for purposes of statutory or regulatory reporting requirements such as, but not limited to, Section 8 of the Toxic Substances Control Act.

11.12 Entire Agreement. 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.

Article 12. Duration of Agreement and Effective Date

12.1 Effective Date. This Agreement shall enter into force as of September 1, 2018, or the date of the last signature of the parties is obtained, whichever occurs last.

12.2 Duration. This Agreement shall expire on August 31, 2020, or when all obligations have been fulfilled, whichever occurs first.