US EPA Office of Research and Development

EXHIBIT 1

ORD MOU CONFLICT OF INTEREST (COI) ASSESSMENT FORM

1. Are funds or other resources being provided to parties, who are not signatories, in support of this MOU? [No] Yes

2. Are any of the parties, either direct partners of ORD or partners in the MOU through an intermediary, being given any special treatment or access due to their status as a partner? Examples of special treatment could include, early access to data, images or materials; or, involvement in ORD decision-making, such as positions on steering committees and involvement in review procedures. [No] Yes

3. Do any of the parties, given their organizations missions, pose an organizational COI, either real or perceived, with that of ORD? For example, organizational COI could occur or be perceived or give the appearance as possible with organizations that are part of a regulated industry. [No] Yes See below for additional information.
If yes, attach a full description of the facts and, if applicable, a programmatic rationale and/or steps taken to avoid, mitigate or neutralize any potential conflicts.

The Hamner's effort in this proposed MOU is funded by the American Chemistry Council (ACC), a trade organization for EPA regulated industry. Funding is through ACC's Long-Range Research Initiative, and The Hamner's research data and conclusions are not under ACC control. Data resulting from this MOU, and all analyses and reports will be made publicly accessible through peer-reviewed journal articles, public presentations, EPA internet sites, and other means, once properly cleared for release through EPA/ORD/NCCT. The fact that all analyses and reports will be reviewed and cleared by EPA/ORD/NCCT prior to release mitigates and neutralizes any potential conflict of interest.

4. A copy of the proposed MOU is attached for review and approval.

MEMORANDUM OF UNDERSTANDING

ON
Research Activities Related to the ToxCast™ Program

BETWEEN THE

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Research and Development
National Center for Computational Toxicology

AND
The Hamner Institutes for Health Sciences

I. PURPOSE/OBJECTIVES/GOALS

The purpose of this MOU is to establish a framework for research collaboration activities between The Hamner Institutes for Health Sciences and the Office of Research and Development's National Center for Computational Toxicology (NCCT) in furthering the science involved in the ToxCast™ research program. In general, the participants intend to focus on *in vitro* chemical toxicology.

II. BACKGROUND

The NCCT of the Office and Research and Development of the U.S. Environmental Protection Agency (EPA) is undertaking a research program called ToxCast™ which aims to develop an approach for prioritizing a large number of chemicals quickly and efficiently based on their potential for producing adverse health effects. The program intends to use a large number of high-throughput screening (HTS) assays to interrogate a broad base of biological pathways and mechanisms. The data from the HTS assays is going to be used to build statistical models to predict the potential toxicity of the chemicals. The ultimate goal is to use these predictions for hazard identification and prioritizing chemicals for additional toxicological evaluation.

The Hamner Institute for Health Sciences (The Hamner) is a nonprofit organization that unites academia, the private sector, and government to conduct translational research to improve public

health and enable the development of new and safe medicines. The Hamner plans to form partnerships with businesses, government agencies and academia in the development of life sciences research. The Hamner has been conducting a research program on the use of short-term gene expression biomarkers for predicting the results of a rodent cancer bioassay. The long-term goal of the project is to provide a means for cheaply and efficiently assessing the carcinogenic potential of chemicals and use the results for hazard identification. It is the use of these short-term cellular, biochemical, and molecular measurements to predict the long-term toxicity and subsequent human health risks that would benefit from closer coordination and collaborative efforts.

The research programs and missions of The Hamner and NCCT are very complementary, providing an excellent mix of expertise and interests for collaboration in this type of activity. For example, The Hamner brings a broad range of expertise in genomics, bioinformatics, computational biology, and the development of physiologically based pharmacokinetic models for characterizing of target tissue dosimetry. NCCT brings a wide breadth of scientific expertise in the areas of high-throughput screening, data analysis, human exposure and dose assessment, exposure and pharmacokinetic modeling, and toxicant-induced effects in various target organs. Both organizations have long-standing experience in research to improve hazard identification and dose response assessment within risk assessment process. A close collaboration on research activities within the structure of the existing ToxCast ^{TM} program will provide the opportunity to leverage expertise and effort from both institutions and would be extremely beneficial to both participants.

III. AUTHORITIES

EPA enters into this MOU pursuant to Section 103 of the Clean Air Act [42 U.S.C. §7403 (a) and (b)]; Section 104 of the Clean Water Act; [33 U.S.C. § 1254 (a) and (b)]; Section 300 j-1 of the Safe Drinking Water Act (42 U.S.C. §1442); Section 10 of the Toxic Substances Control Act [15 U.S.C. § 2609 (a)]; and Section 20 of the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. § 136r (a)].

IV. ROLES AND RESPONSIBILITIES

Each participant intends to implement the following provisions of this MOU, under the responsibility of the President, The Hamner Institutes for Health Sciences, and the Director, NCCT.

The Hamner and NCCT agree to confer and consult prior to any release or publication of data generated through jointly conducted research. The NCCT and The Hamner agree to strive toward co-authorship of publications. Prior to submitting any manuscript or document co-authored by staff from the two organizations for outside review or journal submission, each participant shall be offered 14 days to review such proposed publication. A 7-day review period shall apply to submission of any co-authored abstracts.

EPA intends, depending upon NCCT priorities and guidance from the Director of NCCT, to allow:

(1) The Hamner personnel to develop a complementary and collaborative research effort within the structure of the NCCT ToxCast™ program;
(2) NCCT personnel to exchange ToxCast™ chemicals with The Hamner personnel;
(3) NCCT personnel to exchange all data related to this research effort with The Hamner personnel;
(4) NCCT personnel to coordinate and schedule research activities with The Hamner personnel that are related to this research effort;
(5) NCCT personnel to participate in discussions, studies and seminars conducted by The Hamner that are related to this research effort;
(6) The Hamner personnel to participate in discussions, studies and seminars conducted by NCCT that are related to this research effort;
(7) The NCCT personnel to place all data and models resulting from this research effort in the public domain, after suitable scientific and administrative review.

The Hamner Institutes for Health Sciences intends, depending upon The Hamner priorities and guidance from the President of The Hamner, to allow:

(1) The Hamner personnel to develop a complementary and collaborative research effort within the structure of the NCCT ToxCast™ program;
(2) The Hamner personnel to exchange ToxCast™ chemicals with NCCT personnel;
(3) The Hamner personnel to exchange all data related to this research effort with NCCT personnel;
(4) The Hamner personnel to coordinate and schedule research activities with NCCT personnel that are related to this research effort;
(5) The Hamner personnel to participate in discussions, studies and seminars conducted by NCCT that are related to this research effort;
(6) NCCT personnel to participate in discussions, studies and seminars conducted by The Hamner that are related to this research effort;
(7) The Hamner personnel to place all data and models resulting from this research effort in the public domain, after suitable scientific and administrative review.

V. LIMITATIONS

A. All commitments made in this MOU are subject to the availability of appropriated funds and each participant's budget priorities. Nothing in this MOU, in and of itself, obligates The Hamner Institutes for Health Sciences or EPA to expend appropriations or to enter into any contract, assistance agreement, interagency agreement, or other financial obligation. **The MOU does not exempt The Hamner from EPA policies on competition for financial assistance or contracts. The Hamner Institutes for Health Sciences agrees not to submit a claim for compensation for services rendered to EPA or any other federal agency for activities it undertakes in carrying out this MOU.**

B. This MOU is neither a fiscal nor a funds obligation document. Any endeavor involving

reimbursement or contribution of funds between the participants to this MOU will be handled in accordance with applicable laws, regulations, and procedures, and will be subject to separate subsidiary agreements that will be effected in writing by representatives of both participants.

C. Except as provided in Section V. paragraphs (A) and (B) and Section VII. INTELLECTUAL PROPERTY, this MOU is not legally binding and does not create any right or benefit, substantive or procedural, enforceable by law or equity against The Hamner Institutes for Health Sciences or EPA, their officers or employees, or any other person. This MOU does not direct or apply to any person outside The Hamner Institutes for Health Sciences and EPA.

D. The Hamner Institutes for Health Sciences may make factual statements to the public which describe its cooperation with EPA. However, nothing in this MOU allows EPA to endorse the purchase or sale of The Hamner Institutes for Health Sciences products or services. The Hamner Institutes for Health Sciences agrees not to make statements to the public in news releases, product brochures, on web sites or in any media that imply EPA endorsement of The Hamner Institutes for Health Sciences products or services.

VI. PROPRIETARY INFORMATION

To carry out the joint work resulting from this MOU, The Hamner Institutes for Health Sciences may need to disclose proprietary information to EPA. For the purpose of this MOU, proprietary information is defined as information that an affected business claims to be confidential and is not otherwise available to the public. The Hamner Institutes for Health Sciences agrees to clearly identify as such confidential information disclosed to EPA in writing; and to clearly memorialize in writing, within a reasonable time, any confidential information initially disclosed orally. EPA agrees not to disclose, copy, reproduce or otherwise make available in any form whatsoever to any other person, firm, corporation, partnership, association or other entity information designated as proprietary or confidential information without consent of The Hamner Institutes for Health Sciences except as such information may be subject to disclosure under the Freedom of Information Act (5 U.S.C. § 552), and EPA's regulations at 40 C.F.R. Part 2, or as otherwise authorized by law.

VII. INTELLECTUAL PROPERTY

The participants agree that any copyrightable subject matter, including but not limited to journal articles, training, educational or informational material or software, created jointly by the participants from the activities conducted under the MOU may be copyrighted by The Hamner Institutes for Health Sciences. The Hamner Institutes for Health Sciences hereby grants to the government a royalty-free, nonexclusive, irrevocable right to reproduce, distribute, make derivative works, and publish or perform the work(s) publicly, or to authorize others to do the same on its behalf.

The participants agree that any patented invention created by The Hamner Institutes for Health Sciences pursuant to the terms of this MOU will be jointly owned by the participants regardless of inventorship, unless an alternative agreement indicates otherwise.

VIII. POINTS OF CONTACT

The following individuals are designated points of contact for the MOU:

U.S. Environmental Protection Agency:

David Dix
National Center for Computational Toxicology
Office of Research and Development
U.S. Environmental Protection Agency
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Email: dix.david@epa.gov
Phone 919 541 2701 Fax 919 541 3513

The Hamner Institutes for Health Sciences:

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6 Davis Drive
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Phone 919 558 1311 Fax 919 558 1300

IX. MODIFICATION/DURATION/TERMINATION

This MOU is to take effect upon signature of both participants and remain in effect for a period of five (5) years, at the close of which, the participants may elect, per mutual written decision, to renew this MOU. In the interim, the participants are to review this MOU every 12 months to determine whether it should be revised or terminated. This MOU may be amended at any time by the mutual written decision of the participants. Additionally, this MOU may be terminated by either participant at anytime by one participant providing the other participant with notice of termination at least ninety (90) days in advance of the desired termination date.