



**MEMORANDUM OF UNDERSTANDING
BETWEEN
THE U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Research and Development
National Center for Computational Toxicology
AND
THE U.S. ARMY CENTER FOR ENVIRONMENTAL HEALTH RESEARCH**

SUBJECT: Research Activities Related to the ToxCast™ Program

1. Purpose: The purpose of this MOU is to establish a framework for research collaboration activities between the U.S. Army Center for Environmental Health Research (USACEHR) 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 parties intend to focus on *in vitro* toxicity assays.

2. 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 will 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 will 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 characterization of the biological activity of chemical libraries provides a platform of mutual interest to USACEHR and NCCT. The research programs and missions of USACEHR and NCCT are complementary, providing an excellent mix of expertise and interests for collaboration in this type of activity. For example, the USACEHR brings a broad range of expertise in cell-based toxicity assays. The NCCT provides expertise in developing assays and conducting high-throughput screening of chemical libraries, and in data analysis and model development that can be utilized by the research programs at the USACEHR. The broad profiling of the ToxCast™ chemical library by NCCT contractors will also provide valuable information to USACEHR as to the utility of toxicity-linked bioactivity profiles discovered in the ToxCast™ library.

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3. Authorities. The 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-l 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)].

4. Roles and Responsibilities.

a. Each party intends to implement the following provisions of this MOU, under the responsibility of Commander, USACEHR, and the Director, NCCT.

b. The USACEHR and NCCT agree to confer and consult prior to any release or publication of data generated through jointly conducted research. The NCCT and the USACEHR 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 party shall be offered 45 days to review such proposed publication. A 38-day review period shall apply to submission of any co-authored abstracts.

c. The EPA intends, according to NCCT priorities and guidance from the Director of NCCT, to:

(1) Allow USACEHR personnel to access certain non-confidential profiling data generated by other NCCT partners for the ToxCast™ library.

(2) Allow the USACEHR personnel to access certain non-confidential toxicity data collated by the NCCT for the ToxCast™ library.

(3) Provide the USACEHR personnel assistance with interpretation of the data provided by NCCT with regard to items (1) and (2) above.

(4) Place all data and models resulting from the research efforts conducted under this MOU in the public domain.

d. The USACEHR intends, depending upon USACEHR priorities and guidance from the Commander of USACEHR, to:

(1) Share the data obtained with chemicals from the ToxCast™ library with the NCCT.

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(2) Provide NCCT personnel with assistance with interpretation of the data provided.

(3) Allow NCCT to place any of the data and models resulting from the research efforts conducted under this MOU in the public domain.

5. Limitations:

a. All commitments made in this MOU are subject to the availability of appropriated funds and each party's budget priorities. Nothing in this MOU, in and of itself, obligates the USACEHR 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 USACEHR from EPA policies on competition for financial assistance or contracts. The USACEHR 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 parties 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 parties.

c. Except as provided in Section 5. paragraphs a. and b. and Section 6. Intellectual Property, this MOU does not create any right or benefit, substantive or procedural, enforceable by law or equity against the USACEHR or EPA, their officers or employees, or any other person. This MOU does not direct or apply to any person outside the USACEHR and EPA.

d. The USACEHR 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 USACEHR products or services. The USACEHR 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 USACEHR products or services.

6. Proprietary Information.

To carry out the joint work resulting from this MOU, the USACEHR 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

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and is not otherwise available to the public. The USACEHR 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. The 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 USACEHR 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.

7. Intellectual Property.

a. The parties agree that any copyrightable subject matter, including but not limited to training, educational or informational material or software, except privately published journal articles, created either jointly or separately by the parties from the activities conducted under this MOU, will be placed in the public domain.

b. The parties agree that all journal articles, presentations and other communications created jointly by the parties from the activities conducted under the MOU need to be reviewed and approved in accordance with the policies of both parties prior to publication or presentation.

c. The parties agree that any patented invention created by the USACEHR pursuant to the terms of this MOU will be jointly owned by the parties regardless of inventorship, unless an alternative agreement indicates otherwise.

8. Points of Contact.

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

U.S. Environmental Protection Agency:

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