



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

**Biomanufacturing Research Institute and Technology Enterprise Center for Excellence
of North Carolina Central University**

I. PURPOSE/OBJECTIVES/GOALS

The purpose of this MOU is to establish a framework for research collaboration activities between Biomanufacturing Research Institute and Technology Enterprise Center for Excellence of North Carolina Central University (The BRITE Institute) 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* chemical genetics.

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 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 BRITE Institute is a newly established Institute with a goal to provide research and training for undergraduates and graduate students in areas critical to biotechnology and biomanufacturing. The BRITE Institute is located at North Carolina Central University (NCCU), Durham, North Carolina. The Institute has expertise in HTS, liquid handling, automation and assay development. The BRITE Institute has been testing large libraries of chemicals in assays designed to measure a wide variety of biological activities. One of the goals of this approach is to identify pharmacological probes that can be used as chemical tools to better understand physiological and pathological processes. For example, a specific chemical structure found to affect the activity of a specific molecular target can be used to understand the role of that target in more complex biological systems including cells, tissues and whole organisms. The characterization of the biological activity of chemical libraries provides a platform of mutual interest to The BRITE Institute and NCCT.

The research programs and missions of The BRITE Institute and NCCT are complementary, providing an excellent mix of expertise and interests for collaboration in this type of activity. For example, The BRITE Institute brings a broad range of expertise in developing assays and conducting high-throughput screening of chemical libraries. The NCCT provides expertise in data analysis and model development that will utilize the screening data provided by The BRITE Institute. The broad profiling of the ToxCast™ chemical library by NCCT contractors will also provide valuable information to The BRITE Institute as to the utility of chemical probes discovered in the ToxCast™ library.

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 party intends to implement the following provisions of this MOU, under the responsibility of the Director, The BRITE Institute, and the Director, NCCT.

The BRITE Institute and NCCT agree to confer and consult prior to any release or publication of data generated through jointly conducted research. The NCCT and The BRITE Institute 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 14 days to review such proposed publication. A 7-day review period shall apply to submission of any co-authored abstracts.

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

- (1) Allow the BRITE Institute personnel to access certain non-confidential profiling data generated by other NCCT partners for the ToxCast™ library;
- (2) Allow the BRITE Institute personnel to access certain non-confidential toxicity data collated by the NCCT for the ToxCast™ library;
- (3) Provide The BRITE Institute 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.

The BRITE Institute intends, depending upon The BRITE Institute priorities and guidance from the Director of The BRITE Institute, to:

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

V. 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 BRITE Institute 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 BRITE Institute from EPA policies on competition for financial assistance or contracts. The BRITE Institute 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 V. paragraphs (A) and (B) and Section VII. INTELLECTUAL PROPERTY, this MOU does not create any right or benefit, substantive or procedural, enforceable by law or equity against The BRITE Institute or EPA, their officers or employees, or any other person. This MOU does not direct or apply to any person outside The BRITE Institute and EPA.

D. The BRITE Institute 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 BRITE Institute products or services. The BRITE Institute 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 BRITE Institute.

VI. PROPRIETARY INFORMATION

To carry out the joint work resulting from this MOU, The BRITE Institute 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 BRITE Institute 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 BRITE Institute 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 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. Privately published journal articles created separately by The BRITE Institute or jointly by the parties from the activities conducted under the MOU, may be copyrighted by The BRITE Institute. The BRITE Institute hereby grants to the U.S. government a royalty-free, nonexclusive, irrevocable right to reproduce, distribute, make derivative works, and publish or perform such work(s) publicly, or to authorize others to do the same on its behalf.

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.

The parties agree that any patented invention created by The BRITE Institute pursuant to the terms of this MOU will be jointly owned by the parties 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:

Keith Houck
National Center for Computational Toxicology
Office of Research and Development
U.S. Environmental Protection Agency
Research Triangle Park, NC 27711

Email: houck.keith@epa.gov
Phone: 919-541-5519 Fax: 919-541-3513

The BRITE Institute:

Li-An Yeh
The BRITE Institute Center of Excellence
Mary M. Towne Science Complex
North Carolina Central University
1801 Fayetteville Street
Durham, NC 27707
Email: lyeh@ncu.edu
Phone: 919-530-7013 Fax: 919-530-7001

IX. MODIFICATION/DURATION/TERMINATION

This MOU will be effective when signed by all parties. This MOU may be amended at any time by the mutual written consent of the parties. The parties will review this MOU every 12 months to determine whether it should be revised, renewed, or cancelled. This MOU may be terminated by either party at anytime by one party notifying the other party in writing 90 days in advance of the termination date.