MEMORANDUM OF UNDERSTANDING
BETWEEN
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
THE FOOD AND DRUG ADMINISTRATION
ILSI HEALTH AND ENVIRONMENTAL SCIENCES INSTITUTE

MOU NUMBER

I. Purpose

The United States Food and Drug Administration (FDA) and ILSI Health and Environmental Sciences Institute (HESI) share interests in promoting scientific progress through the exchange of scientific capital to address and reach consensus on scientific questions impacting the development of FDA regulated products and the evaluation of human safety. Both institutions foresee benefits from the mutual exchange of training and research expertise in pharmacology, toxicology and translational science. This Memorandum of Understanding (MOU) establishes the terms for collaboration to promote these shared interests, which can be pursued through a variety of programs including collaborative education and applied research. The FDA and HESI (Partners) desire to collaborate on multiple activities, including: developing new methods to evaluate the toxicity of substances regulated by the FDA; improving the pathway for the review and approval of regulated substances; facilitating the FDA’s engagement with scientists from academia, government and industry on regulatory science questions that impact drug development and safety prediction; sharing information that is in the public domain and considered non-confidential; and publicly disseminating scientific knowledge to help bring safe and effective products to market. To this end, the Partners hereby agree upon a framework pursuant to which the Partners may pursue such collaborations through applied research, outreach and education.

II. Background

FDA is authorized to enforce the Federal Food, Drug, and Cosmetic Act (the FD&C Act) as amended (21 U.S.C. 301, et seq.). In fulfilling its responsibilities under the FD&C Act, FDA, among other things, directs its activities toward promoting and protecting the public health by assuring the safety, efficacy, and security of drugs, veterinary products, and medical devices and the safety and security of foods, dietary supplements, cosmetics, and radiological products. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. To accomplish its mission, FDA must stay abreast of the latest developments in research and communicate with stakeholders about complex scientific and public health issues. Increased development of research, education, and outreach partnerships within the ILSI will greatly contribute to FDA’s mission.
HESI was established in 1989 as a global branch of the International Life Sciences Institute to provide an international forum to advance the understanding of scientific issues related to human health, toxicology, risk assessment, and the environment. In 2002, the U.S. Internal Revenue Service granted HESI tax-exempt status as a publicly supported, independently chartered, charitable scientific organization pursuant to Section 501(c)(3) of the Internal Revenue Code. HESI's scientific programs bring together scientists from around the world from academia, industry, governmental institutions, and research institutes and foundations to address and reach consensus on human and environmental health issues that have the potential to be resolved through creative application of intellectual and financial resources.

III. Substance of Agreement:

The United States Food and Drug Administration (“FDA”) and HESI agree that collaborative activities between them will be conducted according to the terms expressed below.

This MOU forms the basis for development of scientific collaborations, outreach and educational initiatives and intellectual partnerships between the Partners. Under this MOU, the Partners will seek opportunities to participate together in collaborative research and training as permitted under appropriate statutory authority. Before any specific collaboration is initiated or implemented, the Parties shall identify priorities, topics of mutual interest, and develop separate, written agreements for collaboration and sharing of resources. Where applicable, these agreements shall incorporate by reference this MOU. FDA may enter into supplemental agreements with HESI to the extent authorized by law and available appropriations. The terms and conditions of any awards will be in accordance with applicable federal law and regulations, and shall be negotiated and executed by appropriate representatives of the Partners. The Partners anticipate that most of their collaborations will be informal in nature.

To help educate and build consensus across government, academic and industry stakeholders, the Partners may elect to share with each other information that is in the public domain and considered non-confidential. Among other things, this may include data obtained from internal laboratory research or harvested from publicly available documents (e.g. FDA Approval Packages, peer-reviewed literature). As the custodian of information, including toxicological information that is owned by entities that FDA regulates, the FDA will not, as part of the activities covered by this MOU, share with other parties to the HESI any information that is confidential or constitutes a trade secret.

The collaborative activities of the Partners may at times result in scientific communications. In the course of preparing jointly-authored articles, each party agrees to notify each other if it learns that a non-government employee will be included as a co-author. In such cases, the participants should ensure that all necessary rights under copyright are acquired to the satisfaction of all parties. The Partners may co-sponsor scientific events, including but not limited to conferences, workshops, and think tanks (individually an “Event,” collectively “Events”). When the Partners agree to co-sponsor an Event, they will abide by the legal memorandum of August 8, 2002, entitled “Co-Sponsorship Guidance,” issued by the HHS Designated Agency Ethics Official.
IV. General Provisions:

A. Rights to any inventions resulting from collaborative research will be determined by the separate written research agreements governing the effort, based on current U.S. Government patent regulations and any other applicable statutes and regulations.

B. The Partners may decide to enter into Cooperative Research and Development Agreements (CRADA) or other supplemental agreements specific to particular collaborative projects. The terms of such CRADAs and other supplemental agreements will address Intellectual Property rights.

C. Proprietary and/or nonpublic information will not be disclosed under this MOU, unless such disclosure is governed by appropriate confidentiality disclosure agreements and to the extent applicable laws and regulations permits such disclosure.

D. Each Party will comply with the other Party's security procedures and policies regarding access to and use of facilities. Either Party may restrict or limit access to its property and facilities at any time and for any reason. HESI individuals participating in activities under this MOU on FDA property will comply with all applicable federal statutes and regulations.

E. It is recognized that from time to time FDA and HESI will be sharing in expenses and may require compensation of either Party by the other. As research projects are developed, details of how costs are to be shared will be agreed to in advance under other contractual mechanisms as appropriate and in compliance with all applicable federal requirements.

V. Resource Obligations:

This MOU represents the broad outline of the Partners’ intent to enter into specific agreements for collaborative efforts in intellectual areas of mutual interest to FDA and HESI. All activities undertaken pursuant to the MOU are subject to the availability of personnel, resources, and funds. This MOU does not affect or supersede any existing or future agreements or arrangements among the Partners. This MOU does not create binding, enforceable obligations against any Partner. This MOU and all associated agreements will be subject to the applicable policies, rules, regulations, and statutes under which the Partners operate.

VI. Liaison Officers:

A. For the ILSI Health and Environmental Sciences Institute:
   Individual's name: Ms. Syril Pettit
   Organization: HESI
   Title: Executive Director
   Address: 1156 Fifteenth Street, NW, Suite 200, Washington, DC 20005
   Telephone Number: 202-659-3306
B. For the Food and Drug Administration:
   Individual's name: (optional)
   Organization:
   Title:
   Address:
   Telephone Number:

Each Partner may designate new liaisons by notifying the other Partner's liaison in writing. If an individual designated as a liaison under this MOU becomes unavailable to fulfill those functions, the Partner affected will name a new liaison within two (2) weeks and notify the other Partner through the designated liaison.

VII. Term, Termination, and Modification:

This agreement will be effective when accepted by all participating Partners. This agreement may be modified or terminated by mutual written consent by the Partners or may be terminated by either Partner upon a 90 day advance written notice to the other.

VIII. Statutes, Regulations, Rules, and Policies

This MOU and all associated agreements will be subject to the applicable statutes, regulations, rules, and policies under which FDA and HESI operate.

APPROVED AND ACCEPTED FOR
THE ILSI HEALTH AND
ENVIRONMENTAL SCIENCES INSTITUTE

By    Syril D. Pettit, MEM

Title   HESI Executive Director
Date    12 September 2013

APPROVED AND ACCEPTED BY THE U.S.
FOOD AND DRUG ADMINISTRATION

By    [Signature]

Title   [Title]
Date    9/19/13

HESI-FOODANDDRUGADMINISTRATION-20130912