

MEMORANDUM OF UNDERSTANDING  
 between  
 THE UNITED STATES FOOD AND DRUG ADMINISTRATION  
 and the  
 THE REGENTS OF THE UNIVERSITY OF CALIFORNIA

I. PURPOSE

The United States Food and Drug Administration (FDA) and The Regents of the University of California, on behalf of the University of California, Davis campus (UCD) (the Parties) have a shared interest in scientific progress in the diverse disciplines that directly and indirectly affect human and animal health. The Parties also endorse scientific training for faculty, students and staff to foster a well-grounded foundation in interdisciplinary fields in which academia and government share mutual interests.

This Memorandum of Understanding (MOU) establishes terms of collaboration between FDA and UCD to support these shared interests that can be pursued through a variety of programs including collaborative research, public outreach, extension activities, training, and exchange of scientists and staff, including sabbaticals, postdoctoral fellowships, and student internships.

II. BACKGROUND

FDA is authorized to implement the Federal Food, Drug, and Cosmetic Act (the Act) as amended (21 U.S.C. 301). In fulfilling its responsibilities under the Act, FDA among other things, directs its activities toward protecting and promoting the public health by ensuring the safety and security of foods and cosmetics and of animal feeds and veterinary products (Appendix A). To accomplish its mission, FDA must stay abreast of the latest developments in research and also communicate with stakeholders about complex scientific and public health issues. Increased development of research, education, and outreach partnerships with UCD will greatly contribute to FDA's mission.

UCD is one of the nation's top public research universities and is part of one of the world's pre-eminent public university systems. Through a distinctive tradition of core-discipline excellence, interdisciplinary collaborations and productive partnerships, UCD teaches students to think critically, objectively and creatively and to be lifelong learners, engaged leaders and productive citizens; pursues research to advance knowledge and to address state, national and global challenges; and serves the public through the generation, broad dissemination and application of knowledge. Beyond the traditional academic programs, UCD is home to extended partnerships such the Western Institute for Food Safety and Security and the Center for Produce Safety that conduct research, training, and outreach focused on issues such as produce safety and security. The scientific, public health and policy expertise within FDA provide opportunities for collaborations that support the UCD mission and strategic themes to provide access to

high-quality education, research discovery, and knowledge-based services responsive to both the promises and demands of the state and the nation in the new century.

### III. SUBSTANCE OF THE AGREEMENT

This MOU forms the basis for development of scientific collaborations, outreach, and educational initiatives and intellectual partnerships between FDA and UCD. The types of activities expected to develop from this MOU include:

- Exchanges between university faculty and staff and FDA scientists and staff;
- Educational opportunities for qualified students (graduate and undergraduate), staff members, and faculty members in the Parties' laboratories, classrooms and offices;
- Joint meetings for education and research;
- Research collaborations;
- Sharing of unique facilities and equipment for increased cost efficiencies for scientific endeavors.

Under this MOU, joint efforts will be undertaken to obtain grants and other extramural funds to support collaborative research and training as permitted under appropriate statutory authority. Before any specific collaboration is initiated or implemented, the parties shall identify priorities and topics of mutual interest, and develop separate, written agreements for collaboration and sharing of resources. The terms and conditions of any such agreements will be in accordance with the applicable federal law and regulations and shall be negotiated and executed by appropriate representatives of institutions within UCD and FDA. Where applicable, these agreements shall incorporate by reference this MOU.

#### A. FDA agrees to:

For programs agreed to in writing, and in advance by both parties, FDA may, as permitted by applicable statutes and regulations and subject to the availability of funds, and as it deems appropriate, offer UCD the following:

- Laboratory and/or office space in support of activities under this agreement.
- Access to facilities and equipment, including necessary training and guidance, in so far as such use does not interfere with the primary mission of either party.
- Active participation in establishing collaborative research, education, extension and outreach efforts with faculty, students, and staff within UCD institutions.
- Continuing and frequent communication with faculty and staff.
- Openness and welcome to faculty, staff, and students wishing to visit FDA laboratories.
- Promulgation and communication of identified collaborative efforts through appropriate means.

#### B. University of California, Davis agrees to:

For programs agreed to in advance by both parties, UCD may offer FDA the following:

- Laboratory and/or office space in support of activities under this agreement.
- Access to facilities and equipment, including necessary training and guidance, in so far as such use does not interfere with the primary mission of either party.
- Active participation in establishing collaborative research, education, extension and outreach efforts with FDA scientists and staff.
- Continuing and frequent communication with FDA scientists and staff.
- Openness and welcome to FDA scientists and staff wishing to visit relevant UCD programs and laboratories.
- Promulgation and communication of identified collaborative efforts through appropriate means.

C. Additionally it is agreed that:

1. Rights to any inventions resulting from collaborative research will be solely-owned by the party if invented solely, or jointly-owned if invented jointly by the parties.
2. Institutions within UCD and FDA may decide to enter into Cooperative Research and Development Agreements (CRADA) specific to particular collaborative projects. The terms of such CRADAs will address Intellectual Property rights.
3. Proprietary and/or nonpublic information may not be disclosed under this MOU, unless such disclosure is governed by appropriate confidentiality disclosure agreements, and unless such disclosure is permitted by law.
4. Each party shall 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, for any reason. UCD individuals participating in activities under this MOU on FDA property will comply with all applicable federal statutes and regulations.
5. It is recognized that from time to time FDA and entities within UCD 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.
6. To the extent that Federal employees are involved in the implementation of specific projects, federal employee participation will be governed by all applicable statutes, regulations and policies on interactions with outside organizations, and reviewed for permissibility by the appropriate authority within the employee's agency on a case-by-case basis.

7. This agreement may be amended any time upon mutual agreement between the parties in writing.

#### IV. FINANCES AND RESOURCES

The foregoing represents the broad outline of the Parties' present intent to enter into specific agreements for collaborative efforts in intellectual areas of mutual interest to FDA and the entities within UCD. It does not create binding, enforceable obligations against any Party. 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 Parties and does not affect the ability of the Parties to enter into other agreements or arrangements related to this MOU.

#### V. CONTACTS

The individuals to whom inquiries to FDA should be addressed are:

Mary I. Poos, Ph.D.  
Director of Academic and Intellectual Partnerships  
Office of the Commissioner  
Food and Drug Administration  
PKLN 13B-17, HF-10  
5600 Fishers Lane  
Rockville MD 20857  
301-827-2825  
[Mary.Poos@fda.hhs.gov](mailto:Mary.Poos@fda.hhs.gov)

Elizabeth Calvey, Ph.D.  
Team Leader, Liaison and Partnership Team  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway (HFS-006)  
College Park, MD 20740  
301-436-1981  
[Elizabeth.Calvey@fda.hhs.gov](mailto:Elizabeth.Calvey@fda.hhs.gov)

Marlene Wekell, Ph.D.  
Director, Office of Research  
Center for Veterinary Medicine  
Food and Drug Administration  
8401 Muirkirk Road (HFV-500)  
Laurel, MD 20708  
301-210-4136  
[Marlene.Wekell@fda.hhs.gov](mailto:Marlene.Wekell@fda.hhs.gov)

Mark Roh  
Deputy Regional Director  
Office of Regulatory Affairs  
Food and Drug Administration  
1301 Clay Street (HFR-PA1)  
Oakland, CA 94612  
510-637-3960  
Mark.Roh@fda.hhs.gov

The individual to whom all inquires to UCD should be addressed is:

Ahmad Hakim-Elahi, Ph.D., J.D.  
Director of Sponsored Programs  
Office of Research  
University of California, Davis  
1850 Research Park Drive, Suite 300  
Davis, CA 95618  
(530) 747-3825

VI. PERIOD OF AGREEMENT

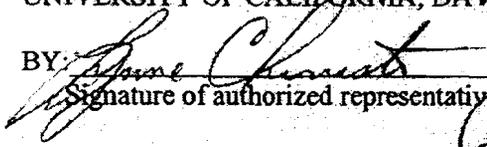
This MOU becomes effective upon signing by both parties and will continue in effect for five (5) years and may be renewed upon mutual agreement of the Parties.

VII. REGULATIONS

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

AGREED TO:

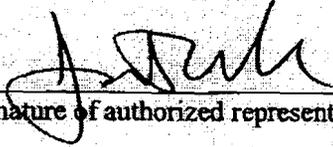
UNIVERSITY OF CALIFORNIA, DAVIS

BY:   
Signature of authorized representative

October 26, 2007  
Date

Lynne U. Chronister  
Associate Vice Chancellor for Research

UNITED STATES FOOD AND DRUG ADMINISTRATION

BY:   
Signature of authorized representative

10/27/07  
Date

Janet Woodcock, M.D.  
Deputy Commissioner and Chief Medical Officer

## APPENDIX A

## FDA Centers/Offices

The U.S. Food and Drug Administration (FDA) is comprised of product-oriented centers (Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research, Center for Devices and Radiological Health), a nationwide field force (Office of Regulatory Affairs), a cross-cutting research center (National Center for Toxicology Research), and the Office of the Commissioner. FDA is a scientific regulatory agency responsible for the safety of the nation's domestically produced and imported foods, cosmetics, animal feeds, veterinary products, drugs, biologics, medical devices, and radiological products. It is one of the oldest federal agencies whose primary function is consumer protection. The agency touches and directly influences the lives of everyone in the United States. FDA is recognized internationally as the leading food and drug regulatory agency in the world. Many foreign nations seek and receive FDA's help in improving and monitoring the safety of their products. FDA is part of the Executive Branch of the United States Government within the Department of Health and Human Services (DHHS) and the Public Health Service (PHS).

Any FDA center may participate in this MOU as appropriate. However, it is expected that initial interactions will primarily be with:

Center for Food Safety and Applied Nutrition (CFSAN)-

CFSAN, in conjunction with the Agency's field staff, is responsible for promoting and protecting the public's health by ensuring that the nation's food supply is safe, secure, sanitary, wholesome, and properly labeled, and that cosmetic products are safe, secure, and properly labeled.

Center for Veterinary Medicine (CVM)-

CVM is a consumer protection organization that fosters public and animal health by approving safe and effective products for animals and by enforcing applicable provisions of the Federal Food, Drug, and Cosmetic Act and other authorities.

Office of Regulatory Affairs (ORA)-

ORA is the lead office for all Field activities of the Food and Drug Administration including inspection of food, feed, and medical product manufacturing, transport and storage facilities for compliance with existing law; as well as enforcement activities. It includes the Office of Criminal Investigations

## APPENDIX B

## University of California, Davis

UCD is one of the nation's top public research universities. Through a distinctive tradition of core-discipline excellence, interdisciplinary collaborations and productive partnerships, UCD teaches students to think critically, creatively and to be lifelong learners, engaged leaders and productive citizens; pursues research to advance knowledge and to address state, national and global challenges; and serves the public through the generation, dissemination and application of knowledge. The primary core of UCD is comprised of the College of Agricultural and Environmental Sciences, College of Biological Sciences, College of Engineering, and College of Letters and Sciences, along with five professional schools, School of Veterinary Medicine, School of Medicine, School of Law, School of Education, and the Graduate School of Management. Complimenting this consortium of Colleges and Professional Schools is a long list of mission-specific Institutes and Centers that enhance the teaching, research, outreach, and service that is conducted by UCD. These Institutes and Centers, such as the Western Institute of Food Safety and Security, allow UCD to quickly and effectively address a wide range of societal concerns and issues, such as emerging threats to our nation's food safety and security. Lastly, as a Land Grant University, UCD helps comprise the Division of Agriculture and Natural Resources which is a statewide network of University of California researchers and educators dedicated to the creation, development and application of knowledge in agricultural, natural and human resources.

Any College, Professional School, Center, Institute, or other such organized research unit may participate in this MOU as appropriate. We anticipate that initial interaction will quickly occur with academic entities that are engaged in conducting research, education, outreach, and service in area of food safety and security anywhere along the farm-to-fork continuum for either plant- or animal-foods of origin. For example:

Western Institute of Food Safety and Security

Specific Departments within the School of Veterinary Medicine (Population Health and Reproduction; Medicine and Epidemiology)

Specific Departments within the College of Agricultural and Environmental Sciences (Nutrition; Plant Sciences; Land, Air, and Water Resources; Food Science and Technology)

Specific Departments within the College of Engineering (Biological and Agricultural Engineering)

Specialists of the Division of Agriculture and Natural Resources

A sampling of specific centers, institutes, organized research units, central facilities and resources at the University of California, Davis that may participate in this MOU follows:

College of Agricultural and Environmental Sciences Agricultural Experiment Station

Agricultural & Environmental Informatics Facility  
Agricultural Sustainability Institute  
California Crop Improvement Association  
California Institute of Food and Agricultural Research  
Center for Vector-Borne Disease Research  
Foundation Plant Services  
Foundation Seed Service  
Genomics Facility  
Greenhouses  
Long -Term Research on Agricultural Systems  
Robert Mondavi Institute for Wine and Food Science  
Seed Biotechnology Center

Research and Information Centers

Center for Agronomic Crops  
Center for Consumer Research  
Dairy Research and Information Center  
Fruit & Nut Research and Information Center  
Ornamental Horticulture Research and Information Center  
Postharvest Technology Research and Information Center  
Seed Biotechnology Center  
Weed Research and Information Center  
Vegetable Research and Information Center

School of Veterinary Medicine

California Animal Health & Food Safety Laboratory System  
Center for Food Animal Health  
Center for Laboratory Animal Science  
Center for Vector Borne Diseases  
Comparative Pathology Laboratory  
Dairy Food Safety Laboratory  
International Laboratory of Molecular Biology for Tropical Diseases  
Veterinary Genetics Laboratory  
Western Institute for Food Safety and Security

Central Facilities

Controlled Environment Facility  
Crocker Nuclear Laboratory  
McClellan Nuclear Radiation Center  
Molecular Structure Facility  
Nuclear Magnetic Resonance Facility

Interdisciplinary Research & Teaching Programs

Agricultural Health and Safety Center  
Agricultural Issues Center

Biotechnology Program  
California Institute of Food and Agricultural Research  
CalSpace: Center of Excellence Agriculture, Natural Resources, Environment  
Center for Animal Welfare  
Center for Ecological Health Research  
Center for Environmental Health Sciences  
Center for Health and the Environment  
Dairy Research and Information Center  
Genome Center  
Nanomaterials in the Environment, Agriculture and Technology  
Partnership for Plant Genomics Education  
Small Farm Center  
Statewide Integrated Pest Management Program  
Sustainable Agriculture Farming Systems Project  
Sustainable Agricultural Research and Education Program  
Toxic Substances Research and Teaching Program  
UC Groundwater Cooperative Extension Program  
UC Biotechnology Research and Education Program  
UC Statewide Integrated Pest Management Program  
UC Toxic Substances Research and Teaching Program  
Western Center for Agricultural Health and Safety