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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–03–6000]

Memorandum of Understanding Between the Food and Drug Administration and the University of Houston

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between the Food and Drug Administration and the University of Houston (UH). The purpose of the MOU is to implement an integrated system of shared interest in scientific progress through an exchange of scientific capital, in the diverse fields of science that directly, and indirectly affect human and animal health and medicine.

DATES: The agreement became effective March 29, 2003.

FOR FURTHER INFORMATION CONTACT: V. Michelle Chenault, Center for Devices and Radiological Health (HFZ–100), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–2889.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: June 27, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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225-03-6000

MEMORANDUM OF UNDERSTANDING

between

THE UNITED STATES FOOD AND DRUG ADMINISTRATION

and the

UNIVERSITY OF HOUSTON (UH)

The United States Food and Drug Administration (FDA) and the University of Houston (UH) have a shared interest in scientific progress through an exchange of scientific capital in the diverse fields of science that directly and indirectly affect human and animal health and medicine. Both institutions also endorse scientific training for academicians and students to foster a well-grounded foundation in interdisciplinary science on which scientific learning will grow.

This Memorandum of Understanding (MOU) establishes terms of collaboration between FDA and UH to support these shared interests that can proceed through a variety of programs such as sabbaticals, postdoctoral fellowships, and student internships.

I. FOOD AND DRUG ADMINISTRATION

For the programs listed below, FDA will provide UH the following:

- Laboratory and/or office space as needed.
- Openness and proactive efforts in establishing collaborative research efforts with UH faculty, students, and staff.

- Based on available resources, willingness to participate in graduate courses and seminars at UH.
- 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 this collaborative effort through web pages, informal conversations with colleagues, faculty and students.

In addition to above, FDA will provide UH personnel the following:

In the Sabbatical Program:

- Opportunities to apply for a sabbatical with the agency with terms of the sabbatical to be negotiated between the individual and the agency.
- Opportunities to apply for salary support, where appropriate, through a variety of funding mechanisms. Request for salary support must coincide with the current federal fiscal year.
- Opportunity to attend a variety of didactic courses.

In the FDA Service Fellowship Program:

- Opportunity to compete for appointments. For those who receive appointments, research training and mentoring of the Fellow will be the responsibility of the appointing office.

In the Graduate Student Internship Program:

- The University of Houston will select the graduate student and FDA will approve the student.
- With concurrence of both parties on a research project, FDA, as appropriate, will offer office support, laboratory support, and supplies.

- The student will have the opportunity to apply for salary support from the FDA through a variety of mechanisms including Internship Programs, the Student Career Experience Program, and other work-study programs by working with the FDA Outreach Coordinator, and the appropriate FDA Center Director.
- As appropriate with UH and FDA rules and regulations, and negotiated on a case-by-case basis, FDA mentors can, where appropriate, serve on thesis committees, attend examination and committee meetings, and participate in other aspects of the student's educational program at UH.
- As appropriate, openness and welcome to students wishing to rotate through FDA laboratories, as well as an opportunity to obtain short-term training in related areas.

General Appointments:

- Opportunity to submit resumes to apply for Special Government Employee (SGE) appointments.

II. UNIVERSITY OF HOUSTON

For the programs listed below, UH will provide FDA personnel the following:

- Laboratory and/or office space as needed.
- Openness and proactive efforts in establishing collaborative research 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 UH programs and laboratories.
- Promulgation and communication of this collaborative effort through web pages,

informal conversations with colleagues, faculty and students.

In addition to above, UH will provide FDA personnel the following:

In a Sabbatical Program at UH:

- Opportunities to apply for a sabbatical with the university. Terms of the sabbatical will be negotiated between the individual and the appropriate University unit.
- Opportunity to attend and/or participate in a variety of courses at the graduate level.

In the FDA Service Fellowship Program:

- Opportunities to apply for funding through internal and external mechanisms for additional research support for collaborative research efforts between UH and FDA laboratories.

For UH Graduate Students working at FDA Centers:

- The basic formal educational structure for students within any of its programs. It is understood that all students will meet all requirements for courses and degree programs as set up by the appropriate department or program at UH.
- Stipend support, health insurance coverage, and/or tuition support of said students in the forms of teaching assistantships, campus fellowships, or other mechanisms where appropriate.
- Opportunities for tuition support, when available, for students working at FDA, throughout each student's tenure at UH, including tuition support from the Graduate School for dissertation research credits for up to three students/year while they are supported by FDA funds.
- Long-term commitments from the graduate program to the graduate students for continued

education, typical of those provided routinely to all other graduates, as long as they remain in good standing in the program.

- Encouragement of graduate students to rotate through, and/or have short-term research opportunities in FDA laboratories.

- Adjunct faculty appointments in the relevant program or department, as appropriate and using standard UH policies, for those FDA staff members working with UH students, and/or assisting in teaching at UH.

III. COVERANCES

UH individuals participating in the MOU will be United States Citizens or Permanent Residents. Regarding the latter, all federal restrictions will be adhered to.

Individuals must establish authorship of an article in a peer-reviewed publication to the satisfaction of FDA prior to entering into the FDA program. Claims to patents and licenses by individuals entering the program must be documented by those entering the program and acknowledged by FDA prior to entry into the FDA program.

This MOU forms the basis for the initial relations between FDA and UH for sabbaticals, research, and scientific education. However, as this collaborative effort progresses, it is expected that new and wider areas of mutual interest will evolve and be included in expansions of this document.

IV. CONTACT

The individual to whom all inquiries to FDA should be addressed is:

V. Michelle Chenault, Ph.D., Associate Director for Science

Office of Science and Technology, Center for Devices and Radiological Health

Food and Drug Administration, 9200 Corporate Blvd. (HFZ-100), Rockville, MD 20850

Phone- (301) 827-4780, Fax- (301) 827-4787, Email- vmc@cdrh.fda.gov

The individual to whom all inquiries to UH should be addressed is:

For technical matters:

Sunny E. Ohia, Ph.D., Dean, University of Houston College of Pharmacy

4800 Calhoun Road, Houston, Texas 77204, phone 713-743-1300, Seohia.uh.edu

For administrative matters:

Thomas Lee Boozer, II, Director, Office of Contracts and Grants, University of Houston

316 E. Cullen Building, Houston, TX 77204-2015, phone: 713-743-9240, lboozer@uh.edu

AGREED TO:

UNIVERSITY OF HOUSTON

BY: _____ 3/11/03

Mr. Thomas L. Boozer II Date

Director, Office of Contracts and Grants

University of Houston

UNITED STATES FOOD AND DRUG ADMINISTRATION

BY: _____ 18 MAR 2003

Dr. David W. Feigal, Jr., MD, MPH Date

Director

Center for Devices and Radiological Health

Food and Drug Administration

BY: _____ March 21, 2003

Linda Arey Skladany, Esq. Date

Associate Commissioner

for External Relations

Food and Drug Administration

BY: _____ 29 Mar 03

Mark B. McClellan, M.D., Ph.D. Date

Commissioner of Food and Drugs

APPROVED AS TO FORM BY:

_____

OFFICE OF THE GENERAL COUNSEL
UNIVERSITY OF HOUSTON SYSTEM

[FR Doc. 05–13337 Filed 7–6–05; 8:45 am]
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DEPARTMENT OF HOMELAND SECURITY

[DHS–2005–0049]

United States Visitor and Immigrant Status Indicator Technology Program; Privacy Impact Assessment

AGENCY: Department of Homeland Security, United States Visitor and Immigrant Status Indicator Technology Program.

ACTION: Notice of availability of Privacy Impact Assessment.

SUMMARY: The Department of Homeland Security intends to modify the United States Visitor and Immigrant Status Indicator Technology Program to conduct a proof of concept in order to verify the utility of Radio Frequency Identification technology to automatically, passively, and remotely record the entry and exit of covered individuals. In conjunction with this change, US–VISIT is again revising its Privacy Impact Assessment to discuss the impact of this new technology on privacy. The revised Privacy Impact Assessment also covers the implementation of new technology and processes for recording the exit of covered individuals from air and sea ports. It is being published here and also is available on the Web site of the Privacy Office of the Department of Homeland Security, *http://www.dhs.gov/privacy,* and on the US–VISIT Web site, *http://www.dhs.gov/usvisit.*

The original US–VISIT PIA was published in the **Federal Register** on January 16, 2004 (69 FR 2608); a revised version reflecting subsequent changes was published on September 23, 2004 (69 FR 57036), and a notice about the availability of the most recent revision made to the PIA was published in the **Federal Register** on June 16, 2005 (70 FR 35110).

FOR FURTHER INFORMATION CONTACT: Steve Yonkers, Privacy Officer, US–VISIT, Department of Homeland Security, Washington, DC 20528, telephone (202) 298–5200, facsimile (202) 298–5201, e-mail: *usvisitprivacy@dhs.gov;* Nuala O'Connor Kelly, Chief Privacy Officer, Department of Homeland Security, Mail Stop 0550, 601 S. 12th Street, Arlington, VA 22202–4220; by telephone (571) 227–4127 or facsimile (571) 227–4171.

Dated: July 1, 2005.

Nuala O'Connor Kelly,

Chief Privacy Officer, Department of Homeland Security.

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