[FR Doc. 03–30027 Filed 12–2–03; 8:45 am]
BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–02–8000]

Memorandum of Understanding Between the Food and Drug Administration and Johns Hopkins University

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 FDA and Johns Hopkins University. The purpose of the MOU is to develop collaboration in the areas of education, research, and outreach.

DATES: The agreement became effective April 30, 2002.

FOR FURTHER INFORMATION CONTACT: Peter Pitts, Office of External Relations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3330.

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: November 24, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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225-02-8000

MEMORANDUM OF UNDERSTANDING
Between the

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND

And

JOHNS HOPKINS UNIVERSITY
BALTIMORE, MARYLAND

This Memorandum of Understanding between the **U.S. Food and Drug Administration** and **Johns Hopkins University** is established to develop collaboration between the two parties in the areas of education, research, and outreach.

I. PURPOSE

The purpose of this **Memorandum of Understanding (MOU)** is to establish the framework for a collaborative partnership on mutually agreed activities in the scientific research and education.

II. OBJECTIVE

The objectives of this collaborative partnership resulting from this **MOU** include:

1. development of a collaborative working relationship between **U.S. Food and Drug Administration** and **Johns Hopkins University**,
2. provision of exchange of graduate and undergraduate students, faculty, and personnel, for the purposes of advanced training and outreach,
3. stimulation of cooperative activities, research, and information exchange in areas such as bioethics,
4. development of training programs for **U.S. Food and Drug Administration** and potentially other Government agencies and Industry in the broad areas of biotechnology and bioethics.

III. PROGRAM FOCUS

The **Memorandum of Understanding** is intended as a broad vehicle to promote programmatic interaction in the form of joint collaboration between **U.S. Food and Drug Administration** and **Johns Hopkins University** researchers, students, and personnel as well as joint development of relevant projects.

The collaboration may include the following:

Joint exchange programs. These exchanges would include internships, research opportunities, and shadowing opportunities for **Johns Hopkins University** undergraduate, post-baccalaureate and graduate students at the **U.S. Food and Drug Administration.** Faculty and senior staff from **U.S. Food and Drug Administration** and **Johns Hopkins University** and other partners will be encouraged to participate in the work of the sister institutions for mutual research and training interactions to possibly include short or long-term exchanges of staff (e.g. sabbaticals).

Joint research programs. Joint research programs will be formed by scientists from the respective institutions with mutual complementary interests in certain areas such as bioethics.

Joint training activities. Training activities arising from complementary interests will be developed by **Johns Hopkins University** and offered to **U.S. Food and Drug Administration,** industry, and others as identified needs arise.

Joint dissemination of information and outreach. The partners will disseminate information and enhance the visibility of the work of the collaboration through mutually agreed vehicles including training activities, meetings, and symposia.

IV. PARTICIPANTS

A wide range of faculty including representatives from the Schools of Arts and Sciences, Engineering, Medicine, Nursing, and Hygiene and Public Health and their respective departments would be potential participants from **Johns Hopkins University**. Senior Scientists from the Commissioners Office, Centers and Offices of **U.S. Food and Drug Administration** would be participants from the **U.S. Food and Drug Administration**. Other participants could include representatives from industry, field laboratories and others identified for joint training and outreach activities.

V. ORGANIZATION TO IMPLEMENT MOU

An organization will be formed to implement this **MOU** that will include representation from the **U.S. Food and Drug Administration's** Office of the Commissioner, **Johns Hopkins University** Provost's Office and other interested parties. The organization will operate under terms agreed to by the Parties.

VI. RESOURCE OBLIGATIONS

This **MOU** describes in general terms the basis upon which the Parties intend to cooperate in these activities. 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 appropriated funds.

VII. OTHER AGREEMENTS OR ARRANGEMENTS

This **MOU** does not affect or supercede 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**.

VIII. NAMES AND ADDRESSES OF PARTICIPANT PARTIES

A. U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

B. Johns Hopkins University
3400 North Charles Street
Baltimore, Maryland 21218

IX. LIASON OFFICERS

A. Liaison Office for FDA
The Office of the Commissioner

B. Liaison Office for Johns Hopkins
Office of the Vice Provost for Research

X. DURATION OF MOU

This **MOU** shall become effective upon the signature or all the Parties and will continue in effect for five (5) years. It may be extended by mutual written agreement of the Parties in writing. It may be modified by mutual consent or terminated by either Party upon a 30-day advance notice to the other Party.

XI. REGULATIONS

This **MOU** and all associated agreements will be subject to the applicable federal and state laws and regulations.

JOHNS HOPKINS UNIVERSITY

BY Wm R Brody

WILLIAM R. BRODY Ph.D.
PRESIDENT OF THE JOHNS HOPKINS UNIVERSITY

DATE

FOOD AND DRUG ADMINISTRATION

BY Lester M Crawford

LESTER M. CRAWFORD DVM, Ph.D.
DEPUTY COMMISSIONER FOOD AND DRUG ADMINISTRATION

DATE April 30, 2002

[FR Doc. 03–30026 Filed 12–2–03; 8:45 am]
BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, as amended, 44 U.S.C. Chapter 35), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Data System for Organ Procurement and Transplantation Network (42 CFR Part 121, OMB No. 0915–0184): Extension

The operation of the Organ Procurement and Transplantation Network (OPTN) necessitates certain record keeping and reporting requirements in order to perform the functions related to organ transplantation under contract to HHS. This is a request for an extension of the current record keeping and reporting requirements associated with the OPTN. These data will be used by HRSA in monitoring the contracts for the OPTN and the Scientific Registry of Transplant Recipients (SRTR) and in carrying out other statutory responsibilities. Information is needed to match donor organs with recipients, to monitor compliance of member organizations with OPTN rules and requirements, and to ensure that all qualified entities are accepted for membership in the OPTN.