

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES****Food and Drug Administration****[FDA No. 225-07-3002]****Memorandum of Understanding
Between the Walter Reed Army
Institute for Research, the Food and
Drug Administration, and the F.
Edward Herbert School of Medicine of
the Uniformed Services University of
the Health Sciences****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 Walter Reed Army Institute of Research, FDA, and the F. Edward Herbert School of Medicine of the Uniformed Services University of the Health Sciences. This MOU identifies the terms of collaboration between the three Federal entities in the coordination of the established Clinical Pharmacology Fellowship Training Program. Specifically, this collaboration provides for active duty Army, Air Force, Navy, and Public Health Service Medical Corps officers in the fellowship program to arrange a 2 to 4 month internship within FDA's Center for Drug Evaluation and Research (CDER) through CDER's Office of Clinical Pharmacology.

DATES: The agreement became effective January 8, 2008.**FOR FURTHER INFORMATION CONTACT:**

Shiew Mei Huang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Silver Spring, MD 20993, 301-796-1541.

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: February 8, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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FDA RECORD No. 225-07-3002



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food & Drug Administration

MEMORANDUM OF UNDERSTANDING
BETWEEN
THE WALTER REED ARMY INSTITUTE OF RESEARCH
AND
THE FOOD AND DRUG ADMINISTRATION
AND
THE F. EDWARD HERBERT SCHOOL OF MEDICINE
OF THE
THE UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES

SUBJECT: MOU with FDA and USUHS continuing a fellowship training program.

1. Purpose. This Memorandum of Understanding (MOU) documents the affiliation among the Institute, the School, and the FDA in the established Clinical Pharmacology Fellowship Training Program. This affiliation permits the coordination of resources to develop a unified program, maximize efficient utilization of government facilities, and strengthen the joint education and research efforts among the parties.

2. Problem. Military and civilian elements within the Federal Government are separately empowered and funded by Congressional Acts. In working together, they must accommodate legal and monetary restrictions, and assure that each party receives mission benefit from any Agreements arranged.

3. Scope. The Clinical Pharmacology Fellowship Training Program (the Program) consists of two years of training. Fellows may be selected and trained at each year level. Fellows shall be Medical Corps officers on active duty in the U.S. Army, the U.S. Navy, the U.S. Air Force, or the U.S. Public Health Service. Additionally, civilian fellows may also be trained when there is an available source of funding. The Program has been in effect under an MOU between the same parties. The parties to this MOU are:

a. The Walter Reed Army Institute of Research (the Institute) is an element of the United States Army. The Institute conducts research on a range of military relevant issues, including naturally occurring infectious diseases, combat casualty care, operational health hazards, and medical defense against biological and chemical weapons.

b. The Food and Drug Administration (the FDA) is an agency of the Department of Health and Human Services. The FDA promotes and protects the public health by helping safe and

effective products reach the market in a timely way, and by monitoring products for continued safety after they are in use.

c. The F. Edward Hébert School of Medicine (the School) is a major component of the Uniformed Services University of Health Sciences, an element within the Department of Defense. A fully-accredited educational institution, the School offers professional and academic degrees in medicine, health administration, biomedical sciences, and related fields.

4. Understandings.

This MOU involves the combined and coordinated efforts of the parties to the MOU, and is only amenable to separation of responsibilities as noted below:

a. The School and the Institute will coordinate the technical and support personnel involved in the Program. The FDA's contribution to the Program will be to offer a two-month to four-month internship to second year fellows and potentially clinical pharmacology staff who have not had this component as part of their training. Each party will provide qualified civilian or uniformed personnel who are assigned to serve as mentors.

b. The Program's Fellows will be directly responsible to and under the direction of the Co-Directors of the Program at the School and at the Institute.

c. The Co-Directors of the Clinical Pharmacology Fellowship Training Program will be responsible for the direction of all Fellows. Fellows will be evaluated semiannually by the Co-Directors for the first year fellows and progress monitored as needed during the second year.

d. The FDA's Office of Clinical Pharmacology within the Center for the Drug Evaluation and Research will arrange a two-month to four-month internship in the therapeutic area of interest for second-year Fellows. The Office of Clinical Pharmacology will contact the appropriate review division within the FDA. During this rotation, a member of the Office of Clinical Pharmacology or the appropriate office or review division hosting the internship will be assigned as a mentor (team leader or reviewer) to the Fellow during the period of training. The Fellows will attend Office of Clinical Pharmacology and related review division briefings and other scientific activities. Reviews by the Fellow of protocols and study reports and other submissions will be conducted under appropriate supervision to the extent permitted under applicable statutes and regulations. The rotation should be arranged to allow the Fellow to participate in educational activities sponsored by the FDA such as the Topics in Clinical Trials course, the bimonthly scientific seminar, the annual Academics to the Center for Drug Evaluation and Research course and, if possible, the NDA review course.

e. The parties agree that they will abide by all requirements of the American Board of Clinical Pharmacology, including, but not limited to, those involving the supervision of Fellows, Fellows' work hours, and Fellows' work environment.

5. Resources.

a. The Institute will bear all special costs for training of Army Fellows outside of normal day to day operations. This will include travel costs and, as a minimum, provision of funds sufficient for one trip each year for each fellow to attend a scientific meeting approved by the Fellowship Training Program Co-Directors. Payment for the tuition of courses and books necessary for training in the discipline of clinical pharmacology also will be from the Institute's training fund.

b. There is no reimbursement contemplated between the parties in the fulfillment of this Agreement. In the event the transfer of funds is required in the future, the parties may enter into an interagency agreement pursuant to the Economy Act of 1932, as amended, 31 U.S.C. 1535.

6. Fellows' Eligibility Requirements

The minimum academic and professional qualifications to enter the program are an M.D. or D.O. degree from an accredited institution and training and board eligibility in a medical specialty.

7. Liability

For liability purposes, it is recognized that the three parties to this Agreement all are entities of the United States Government whose employees are covered by the provisions of the Federal Tort Claims Act. In the event a potentially compensable event occurs, the institution that first learns of the event will notify as soon as practicable the point of contact of the other two institutions listed in the agreement.

While assigned to the Program and while performing duties pursuant to this agreement, Fellows, Directors, mentors, and support staff remain employees of the United States performing duties within the course and scope of their Federal employment. Consequently, the provisions of the Federal Tort Claims Act (Title 28, U.S.C. § 1346(b), 2671 – 2680), including its defense and immunities, will apply to allegations of negligence or wrongful acts or omissions by Fellows, directors, mentors, and support staff while they are acting within the scope their duties pursuant to this agreement.

The foregoing represents the broad outline of the agreements of the parties to engage in collaborative training efforts. All activities undertaken pursuant to the MOU are subject to the availability of personnel, resources, and funds and are further subject to applicable statutes and regulations. This MOU does not affect or supersede any existing or future arrangements among the parties and does not affect the ability of the parties to enter into other agreements or arrangements related to this MOU.

8. Implementation Instructions:

- a. **Effective Date.** This MOU will become effective when signed by all parties and will remain in effect until 30 September 2011.
- b. **Review and Modification.** This MOU may be modified at any time by the written consent of the three parties. This MOU will be reviewed annually to assure its continued necessity and accuracy.
- c. **Termination.** This MOU may be terminated at any time by the written consent of the three parties. One party may terminate this agreement by giving at least 60 days written notice of termination to the other two parties. Such notice will include provision for Fellows who are in the Program at the time the notice is given.
- d. **Dispute Resolution.** In the event of any disagreement on the administration management of the program or focus of research of the Fellows, guidance will be sought initially from the liaison officers of the parties listed below. If a resolution among these officers is not possible, then the dispute will be referred for settlement to the signatories of this Agreement.

9. Technical points of contact (POCs) for this MOU:

COL Colin K. Ohrt
Program Director, Division of Experimental
Therapeutics, Clinical Pharmacology
Fellowship Program
Consultant for Clinical Pharmacology
to Surgeon General
Walter Reed Army Institute of Research

503 Robert Grant Avenue
Silver Spring, Maryland 20910-7500
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Louis R. Cantilena, M.D., Ph.D
Director, Division of Clinical Pharmacology
Department of Medicine
F. Edward Hébert
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of the Health Services
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Shiew Mei Huang, Ph.D.
Deputy Director
Office of Clinical Pharmacology
Food and Drug Administration
White Oak CDER Office Building 21
10903 New Hampshire Avenue
Silver Spring, Maryland 20993
Phone: 301.796.9738

11. Approvals:

FOR the F. Edward Hébert
School of Medicine

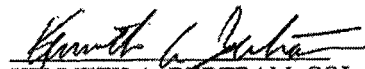


LARRY W. LAUGHLIN, M.D., PH.D.
DEAN

JAN 7 2008

DATE

FOR the WRAIR

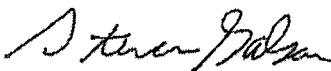


KENNETH A. BERTRAM, COL, MC
WRAIR, Commander

8 Jan 2008

DATE

FOR the FDA



STEVEN GALSON, MD, MPH.
Director
Center for Drug Evaluation and Research

9/26/07

DATE