the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute on Drug Abuse Special Emphasis Panel Economic Studies of Health Insurance Coverage on Drug Abuse Treatment.

*Date:* September 23, 2009.

*Time:* 1:30 p.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6101 Executive Boulevard, Rockville, MD 20852. (Telephone Conference Call)

*Contact Person:* Meenaxi Hiremath, PhD, Health Scientist Administrator, Office of Extramural Affairs, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6101 Executive Blvd., Suite 220, MSC 8401, Bethesda, MD 20892, 301–402–7964, *mh392g@nih.gov.*

*Name of Committee:* National Institute on Drug Abuse Initial Review Group, Health Services Research Subcommittee.

*Date:* October 6–7, 2009.

*Time:* 8:30 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The Madison Hotel, 1177 15th St., NW., Washington, DC 20005.

*Contact Person:* Meenaxi Hiremath, PhD, Health Scientist Administrator, Office of Extramural Affairs, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6101 Executive Blvd., Suite 220, MSC 8401, Bethesda, MD 20892, 301–402–7964, *mh392g@nih.gov.*

*Name of Committee:* National Institute on Drug Abuse Initial Review Group, Training and Career Development Subcommittee.

*Date:* November 3–5, 2009.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Ritz Carlton Hotel, 1150 22nd Street, NW., Washington, DC 20037.

*Contact Person:* Eliane Lazar-Wesley, PhD, Health Scientist Administrator, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, 6101 Executive Boulevard, Room 220, MSC 8401, Bethesda, MD 20892–8401, 301–451–4530, *el6r@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: August 20, 2009.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E9–20633 Filed 8–26–09; 8:45 am]

**BILLING CODE 4140–01–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2009–N–0667]**
**[FDA 09–209–RH–03MOU]**

### Memorandum of Understanding Between the Food and Drug Administration, National Center for Toxicological Research, and the Air Force Research Laboratory, 711 Human Performance Wing, Human Effectiveness Directorate, Biosciences and Protection Division, for Toxicity of Nanomaterials

**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 the Air Force Research Laboratory. This Memorandum of Understanding (MOU) between the Food and Drug Administration, National Center for Toxicological Research (NCTR), and the Air Force Research Laboratory, 711 Human Performance Wing, Human Effectiveness Directorate, Biosciences and Protection Division, Applied Biotechnology Branch (711 HPW/RHPB) (hereinafter referred to as ''the Parties''), sets forth the agreement of the Parties to facilitate information sharing in the area of toxicogenomic and computational toxicology research. Through the exchange of information, the Parties intend to coordinate research efforts so as to identify and expedite research and development of new tools and technologies that can be implemented that promote new understanding of the mechanisms of biological responses to environmental stressors, including toxic injury, and to identify biomarkers of exposure and disease that can be used to improve and protect human health.

**DATES:** The agreement became effective July 28, 2009.

**FOR FURTHER INFORMATION CONTACT:**

*Points of Contact: The following are Responsible Officers in NCTR and 711 HPW/RHP:*

(1) *For NCTR:* William Slikker, Jr., Director, National Center for Toxicological Research, Food and Drug Administration, 3900 NCTR Rd., Jefferson, AR 72079–9501, phone: 870–543–7950, fax: 870–543–7576, e-mail: *william.slikker@fda.hhs.gov.*

(2) *For 711 HPW/RHPB*: John J. Schlager, Chief, Applied Biotechnology Branch, 2729 R St., Wright-Patterson AFB, OH 45433–5707, phone: 937–904–9570, fax: 937–255–1474, e-mail: *john.schlager@wpafb.af.mil.*

*Points of Contact: The following are Principal Investigators in NCTR and 711 HPW/RHP:*

(1) *For NCTR*: Syed F. Ali, Senior Biomedical Research Scientist, National Center for Toxicological Research, Food and Drug Administration, 3900 NCTR Rd., Jefferson, AR 72079–9501, phone: 870–543–7123, fax: 870–543–7745, e-mail: *syed.ali@fda.hhs.gov.*

(2) *For 711 HPW/RHPB*: Saber M. Hussain, Scientist, Group Lead, Biological Interaction of Nanomaterials, 2729 R St., Wright-Patterson AFB, OH 45433–5707, phone: 937–904–9517, fax: 937–904–9610, e-mail: *saber.hussain@wpafb.af.mil.*

*Points of Contact: The following are points of contact for Agreement Administration in NCTR and 711 HPW:*

(1) *For NCTR:* Thomas J. Flammang, Deputy Director, Office of Research, National Center for Toxicological Research, Food and Drug Administration, 3900 NCTR Rd., Jefferson, AR 72079–9501, phone: 870–543–7291, fax: 870–543–7576, e-mail: *thomas.flammang@fda.hhs.gov.*

(2) *For 711 HPW/XPO*: James D. Kearns, Technology Transfer Manager, 2610 Seventh St., Wright-Patterson AFB, OH 45433–7901, phone: 937–255–3765, fax: 937–255–7215, e-mail: *jim.kearns@wpafb.af.mil.*

**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: August 18, 2009.

**David Horowitz,**

*Assistant Commissioner for Policy.*

**BILLING CODE 4160–01–S**

09-209-RH-03MOU

# MEMORANDUM OF UNDERSTANDING

**Between**

**U.S. FOOD AND DRUG ADMINISTRATION**
**NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH**

**And**

**AIR FORCE RESEARCH LABORATORY**
**711 HUMAN PERFORMANCE WING**
**HUMAN EFFECTIVENESS DIRECTORATE**
**BIOSCIENCES AND PROTECTION DIVISION**

**For**

**TOXICITY OF NANOMATERIALS**

## I. Purpose, Goals and Objectives

Purpose: This Memorandum of Understanding (MOU) between the U.S. Food and Drug Administration, National Center for Toxicological Research ("NCTR"), and the Air Force Research Laboratory, 711 Human Performance Wing, Human Effectiveness Directorate, Biosciences and Protection Division, Applied Biotechnology Branch ("711 HPW/RHPB"), (hereinafter referred to as "*the Parties*") sets forth the agreement of *the Parties* to facilitate information sharing in the area of toxicogenomic and computational toxicology research. Through the exchange of information, *the Parties* intend to coordinate research efforts so as to identify and expedite research and development of new tools and technologies that can be implemented that promote new understanding of the mechanisms of biological responses to environmental stressors, including toxic injury, and to identify biomarkers of exposure and disease that can be used to improve and protect human health.

Goal: Minimize duplication of research, identify research needs, and identify collaborative research opportunities with other organizations through separate agreements.

Objectives:

a. Exploit toxicity of nanomaterials and blood brain barrier.
b. Exploit global expression profiling by microarray and proteomics methods that provide the means to analyze many genes and proteins simultaneously.
c. Identify toxicogenomics methods as a means to compare and validate dose-dependent effects in animal and human cells or in expendable tissues.

d. Identify appropriate biosignatures of exposure to nanomaterials.
e. Identify computational methods of understanding biological sequences of exposure and responses to exposure.
f. Joint publications in peer reviewed scientific journals.

## II. Background, Program Scope, and Technical Approach

Background: The mission of NCTR is to conduct peer-reviewed scientific research that supports and anticipates the FDA's current and future regulatory needs. This involves fundamental and applied research specifically designed to define biological mechanisms of action underlying the toxicity of products regulated by the FDA. This research is aimed at understanding critical biological events in the expression of toxicity and at developing methods to improve assessment of human exposure, susceptibility and risk.

Research conducted at NCTR is targeted to fulfill the following research programs in support of FDA's public-health mission:

- **Personalized Nutrition and Medicine** (i.e. advance the scientific approaches and tools to promote personalized nutrition and medicine for the American public.)
- **Enhancing Product Safety** (i.e., integrate new technology and standards into the review and evaluation of regulated products through all stages of the product lifecycle.)
- **Food Safety** (i.e. conduct research to strengthen our understanding of food safety and food defense.)

In 2004 the 711 HPW/RHPB was created as part of the Air Force Research Laboratory to develop capabilities to detect, identify, mitigate and protect all airmen in all offensive and defensive environments from exposure to toxic and hazardous chemicals, materials, and biological threats such as chemical and physical insults, exotic weapon system components, fuels, etc. 711 HPW/RHPB specializes in –omics technologies and applications, predictive toxicology and Cellular Dynamics and Engineering. Co-located with 711 HPW/RHPB is a Navy Detachment that specializes in combustion and neurobehavioral toxicology.

Program Scope: The scope of this MOU is to set out the principles and guidelines which will govern the co-operation of *the Parties* hereto concerning the exchange of information surrounding toxicogenomic research.

## III. Responsibilities

General: Within the context of the Purpose and Scope above, *the Parties* agree to use reasonable efforts to fulfill the following:

a. Conduct semi-annual, or as otherwise mutually agreed upon, meetings and share knowledge necessary to highlight current advances and define opportunities and future directions for the field of toxicogenomics. Meeting participants from *the Parties* will include management staff,

principal investigators, and representatives from *the Parties'* other sectors and disciplines as needed.

b. Jointly develop and disseminate any public affairs messages on collaborative activities. *The Parties'* public affairs officials will be consulted in every case.
c. Establish an interagency working group to accelerate the development, evaluation, and utilization of toxicogenomics for the protection of public health and protection of all Air Force personnel.

All activities under or pursuant to this MOU are subject to the availability of appropriated funds, and no provision of this MOU shall be interpreted to require the obligation or payment of funds. As presently constituted this MOU does not constitute a financial obligation. If a subsequently identified activity or project is identified requiring a transfer of funds or other obligation between *the Parties*, a supplemental Memorandum of Understanding (MOU), Interagency Agreement (IAG), or other appropriate written agreement will be executed. Such activity or project must be independently authorized by appropriate statutory authority. This MOU does not provide such authority. Negotiation, execution, and administration of each such agreement must comply with all applicable statutes and regulations.

Each Party agrees to assume liability for its own risks associated with activities undertaken in this agreement.

**IV. Information Exchange**

Both parties recognize that information exchanged that contains any of the following types of information must be protected from unauthorized use and disclosure: (1) confidential commercial information, such as the information that would be protected from public disclosure pursuant to Exemption 4 of the Freedom of Information Act (FOIA); (2) personal privacy information, such as the information that would be protected from public disclosure pursuant to Exemption 6 or 7(C) of the FOIA; or (3) information that is otherwise protected from public disclosure by Federal statutes and their implementing regulations (e.g., Trade Secrets Act (18 USC 1905)), the Privacy Act (5 USC 552a), other Freedom of Information Act exemptions not mentioned above (5 USC 552(b)), the Federal Food, Drug, and Cosmetic Act (21 USC 301 et seq.), and the Health Insurance Portability and Accountability Act (HIPAA), Pub. L. 104-191). Pursuant to Federal Food, Drug, and Cosmetic Act section 301(j) (21 USC 331(j)), NCTR will not reveal to 711 HPW/RHPB any method or process which is entitled to protection as a trade secret.

The parties will establish proper safeguards to ensure that information shared under this MOU shall be used and disclosed solely in accordance with applicable laws and regulations. Access to the information shared under this MOU shall be restricted to authorized NCTR and 711 HPW/RHPB employees, agents, and officials who require access to perform their official duties in accordance with the uses of information as authorized by this MOU. Such personnel shall be advised of (1) the confidential nature of the information; (2) safeguards required to protect the information, and (3) the administrative, civil, and criminal penalties for noncompliance contained in applicable Federal laws. Contractors, their subcontractors, and agents requiring access to the information shared under this

agreement will be required to sign a business associate agreement by which they will commit to keep the information confidential.

NCTR and 711 HPW/RHPB agree to promptly notify the other agency of any actual or suspected unauthorized disclosure of information shared under this MOU. If an agency in receipt of information under this MOU receives a FOIA request for shared information, it will refer the request to the agency that shared the information for the latter agency to respond directly to the requestor regarding the releasability of the information at issue. In such cases, the agency making the referral will notify the requestor that a referral has been made and that a response will issue directly from the other agency.

**V. Memorandum of Understanding (MOU) Administration**

Information Releases: The Biosciences and Protection Division (711HEW/RHP) Chief and the National Center for Toxicological Research Director (or their designees) will jointly review and approve information regarding MOU activities (meetings, new developments, etc.) prior to public release.

Annual Management Meetings: *The Parties* will meet yearly (and more often if mutually agreed upon) to report, review, and coordinate science and technology activities under this MOU. Such meetings will be held at a mutually agreed upon location and on a date that is compatible with each organization. At this meeting, recommendations for adjustments to current activities, projects, and budget priorities will be proposed by the Responsible Officers Points of Contact for submission to the 711 HPW/RHP Chief and the NCTR Director.

Points of Contact: The following are Responsible Officers in NCTR and 711 HPW/RHP:

1) NCTR
William Slikker, Jr., Ph.D.
Director, National Center for Toxicological Research
U.S. Food and Drug Administration
3900 NCTR Road
Jefferson, AR 72079-9501
Phone: 870-543-7950
Fax: 870-543-7576
e-mail: william.slikker@fda.hhs.gov

2) 711 HPW/RHPB
John J. Schlager, Ph.D.
Chief, Applied Biotechnology Branch
2729 R Street
Wright-Patterson AFB, OH 45433-5707
Phone: 937-904-9570
Fax: 937-255-1474
e-mail: john.schlager@wpafb.af.mil

Points of Contact: The following are Principal Investigators in NCTR and 711 HPW/RHP:

1) NCTR
Syed F. Ali, Ph.D.
Senior Biomedical Research Scientist
National Center for Toxicological Research
U.S. Food and Drug Administration
3900 NCTR Road
Jefferson, AR 72079-9501
Phone: 870-543-7123
Fax: 870-543-7745
e-mail: syed.ali@fda.hhs.gov

2) 711 HPW/RHPB
Saber M. Hussain, Ph.D.
Scientist, Group Lead, Biological Interaction of Nanomaterials
2729 R Street
Wright-Patterson AFB, OH 45433-5707
Phone: 937-904-9517
Fax: 937-904-9610
e-mail: saber.hussain@wpafb.af.mil

Points of Contact: The following are POCs for Agreement Administration in NCTR and 711 HPW:

1) NCTR
Thomas J. Flammang, Ph.D.
Deputy Director, Office of Research
National Center for Toxicological Research
U.S. Food and Drug Administration
3900 NCTR Road
Jefferson, AR 72079-9501
Phone: 870-543-7291
Fax: 870-543-7576
e-mail: thomas.flammang@fda.hhs.gov

2) 711 HPW/XPO
James D. Kearns, Ph.D.
Technology Transfer Manager
2610 Seventh Street
Wright-Patterson AFB, OH 45433-7901
Phone: 937-255-3765
Fax: 937-255-7215
e-mail: jim.kearns@wpafb.af.mil

**VI. Terms of Agreement and Amendment**

This MOU shall be effective for **thirty-six (36) months** from the date of last signature unless terminated earlier by mutual agreement of *the Parties*. Either NCTR or 711 HPW/RHPB may unilaterally terminate this MOU by providing written notice to the other 90 days before the desired termination date. This MOU may be extended by mutual agreement.

Conflicts that may arise after this MOU is in effect will be resolved either by coming to informal agreement or by amending this MOU.

This MOU will be reviewed annually by the key personnel to determine if any changes or amendments should be incorporated.

VII. Signatures

IN WITNESS WHEREOF, each party has caused this Agreement to be executed by its duly authorized representative on the date indicated below.

**APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION**

*Signature*

WILLIAM SLIKKER, JR., Ph.D.
Director
National Center for Toxicological Research
U.S. Food and Drug Administration

July 6, 2009
*Date*

**APPROVED AND ACCEPTED FOR THE HUMAN EFFECTIVENESS DIRECTORATE**

*Signature*

JACK L. BLACKHURST
Director
Human Effectiveness Directorate
711th Human Performance Wing
Air Force Research Laboratory

28 Jul 09
*Date*



[FR Doc. E9–20634 Filed 8–26–09; 8:45 am]
BILLING CODE 4160–01–C