

MOU# 225-07-8006

**MEMORANDUM OF UNDERSTANDING
BY AND AMONG THE**

UNITED STATES FOOD AND DRUG ADMINISTRATION

BAYLOR COLLEGE OF MEDICINE

THE UNIVERSITY OF TEXAS M.D. ANDERSON CANCER CENTER

RICE UNIVERSITY

UNIVERSITY OF HOUSTON

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON

TEXAS A&M HEALTH SCIENCE CENTER

THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

THE METHODIST HOSPITAL RESEARCH INSTITUTE

FOR THE

FDA-ANH NANOTECHNOLOGY INITIATIVE

FDA. 2009-N. 0667

MOU

This Memorandum of Understanding (MOU) is executed by and among the United States Food and Drug Administration (FDA), Baylor College of Medicine (BCM), William Marsh Rice University (Rice), University of Houston (UH), The University of Texas M. D. Anderson Cancer Center (UTMDACC), The University of Texas Medical Branch at Galveston (UTMB), The University of Texas Health Science Center at Houston (UTHSCH), Texas A & M Health Science Center (Texas A&M) and The Methodist Hospital Research Institute (TMHRI), hereafter referred to individually as a "Party" and collectively as the "Parties." This MOU is deemed effective on the date of the last Party to sign (Effective Date).

WHEREAS, each Party has unique expertise in certain areas of nanotechnology, regulatory science, and other areas of translational, health related and clinical sciences; and

WHEREAS, the Parties wish to leverage their expertise and resources for the purposes of stimulating innovation in the field of nanotechnology and working collaboratively to bridge scientific gaps and to develop evaluative and predictive tools to facilitate the development of nanoengineered medical products in the interest of public health; and

WHEREAS, the Parties recognize the existence of a collaboration among the eight (8) academic institutions represented in this MOU called the Alliance for NanoHealth (ANH) which functions under the terms and conditions of the Alliance for NanoHealth Operating Agreement. The ANH will serve to facilitate and coordinate the activities contemplated hereunder,

NOW, THEREFORE, in consideration of the mutual agreement of the Parties hereto, and of the covenants and conditions hereinafter expressed, the Parties hereby agree as follows:

I. PURPOSE

The Parties will work with multiple organizations, facilitated and coordinated through the ANH, to identify scientific and translational gaps in moving nanoengineered medical products from the preclinical stages of development through clinical stages and then to commercialization, all with immediate benefit to public health. The activities described herein are aligned with the mutual interests and respective missions of the Parties, including the FDA's Critical Path Initiative which seeks to modernize the product development and regulatory sciences needed to reduce uncertainties about product performance throughout the product life cycle. Thus, a key goal for the Parties is to improve the safety and efficacy of nanoengineered products and speed their delivery to the patients who need them and the consumers who use them.

II. BACKGROUND

The FDA's mission is to protect the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is interested in understanding the risks and benefits of nano-engineered medical product development to the extent that this information can facilitate the regulatory review and evaluation of new medical products that incorporate nanotechnology.

The ANH was created out of a unique multi-disciplinary, multi-institutional collaborative research endeavor linking eight (8) academic and clinical institutions in the Greater Houston region with an aim of leveraging their resources and technical expertise in nanotechnology to bridge the gaps between medicine, biology, materials science, computer technology, and public policy.

The Parties have expressed a willingness to leverage their combined strengths among the scientific disciplines, with goals in applied research, educational, and training activities. The Parties are committed to developing and applying nanotechnology tools in the battle against multiple diseases and in the development of cross-cutting technologies.

III. PARTICIPATION OF PARTIES

The Parties agree to the following, to be developed and pursued through separate written agreements as needed:

1. To form a subcommittee of the ANH made up of representatives of the Parties and other key stakeholders to: (a) recommend program and funding priorities, implement programs, and oversee the activities to fulfill the purpose of this MOU as set forth in Paragraph I above; and (b) to form task/program/project-specific working groups, as needed, to develop strategic program plans, establish project selection criteria, develop feasible funding and implementation plans for programs/projects, including leveraging resources and expertise from multiple sources including the private sector, academia, professional organizations and others.
2. To share information and data, to the extent permitted by protocol and by State and Federal law, and provide access to best practices and know-how produced from activities under this MOU, in a timely manner and as appropriate. Such shared information may, if deemed permissible under applicable State and Federal statutes, include assessment tools for use during the FDA's regulatory evaluation and during guidance development to facilitate medical product development, characterization approaches, and best practices to: (a) support understanding and resolution of potential implications of nanotechnology-based products for clinical application; (b) facilitate the development of measurement methods and standard protocols appropriate to innovative technologies; and (c) facilitate transfer of science and engineering discovery and development to the clinic through careful linkage with the measurement science and standard programs and regulatory science and policy development.
3. To develop and implement separate programs and agreements, within the framework of this MOU and to the extent time, resources, and applicable State and Federal statutory and regulatory requirements permit, to allow:
 - a. Development and refinement of the preclinical and early clinical pathway(s) for nanotechnology-based drugs, biologics, devices and combination products to guide technology development leading to medical products;

- b. Development and validation of standards, risk/benefit analyses and other evaluative tools to identify risks and assess safety and efficacy in newly emerging nanoengineered products;
 - c. Generation of data and best practices that will be publicly available e.g. protocols, assay cascades, and other pre-competitive tools developed collaboratively by the Parties, and that may guide further advancement in the field of nanotechnology;
 - d. Development, validation, and assessment of assays and other appropriate test methods, with close review and input from all Parties prior to standardization and validation of said assays;
 - e. Development of joint translational research programs that also support academic scientists, trainees and scientific fellows identified under joint training programs, and under the FDA's Critical Path Initiative, to perform research at the respective facilities of the Parties and in collaboration with respective scientists and staff comprising the Parties, as well as potential research collaborations with other organizations; and
 - f. Representation for each Party at jointly held meetings and other scientific conferences, as applicable and appropriate.
4. To serve as an infrastructure for fostering additional concepts or ideas involving joint projects or integrated approaches to science or technology development specifically aimed at developing nanoengineered products. To achieve this goal, and as permissible by State and Federal law, designated representatives from the Parties will meet at least quarterly to review progress and address new opportunities for collaboration and associated sources of funding. Such opportunities will be formally presented to the ANH for approval and implementation. As needed and as permitted by State and Federal law, technical and programmatic advisory working groups made up of employees from the respective Parties may be assembled to make formal recommendations for collaboration. Any individual project(s), group(s), or committees established pursuant to this MOU shall be defined in separate written agreements which will also outline procedures and processes for such project(s), group(s) or committees. Any such separate agreements must be approved in writing by authorized representatives of each of the parties involved. Any separate written agreement must be in compliance with all applicable State and Federal law, and FDA shall ensure its participation in any such separate agreements is permissible under applicable statutory and regulatory requirements. Such agreements shall set forth at a minimum, the scope of work; tasks, deliverables (if any) and delivery dates; anticipated products and outcomes; periods of performance; and any other appropriate and necessary aspects of project(s).
5. In addition to the activities set forth herein, the Parties may, as resources and State and Federal law permit, collectively develop and validate standards, nomenclature, assessment tools, and toxicology approaches to facilitate and accelerate the development of, and the evidence base for, new diagnostics and medical products that incorporate nanotechnology. The Parties may also develop educational programs and tools, and publications to make information and data generated widely available to patients, clinicians, and researchers. Any such activities, if deemed permissible under applicable

State and Federal statutes and regulations, shall be developed under, and governed by, separate written agreements signed by the Parties.

IV. RESOURCES

Sources of support for projects under this MOU will be governed by State and Federal law and applicable policies and procedures. The terms for such support will be set forth in the specific written agreements for each project.

V. GENERAL PROVISIONS

1. Nothing in this MOU alters the statutory authorities or obligations of FDA. This MOU is intended to facilitate cooperative efforts among the Parties in the area of nanotechnology.
2. U.S. Federal law and to the extent applicable the laws of the State of Texas govern this MOU for all purposes, including, but not limited to, determining the validity of the MOU, the meaning of its provisions, and the rights, obligations, and remedies of the Parties.
3. Proprietary and/or nonpublic information will not be disclosed under this MOU, unless such disclosure is governed by appropriate, separate, written Confidentiality Disclosure Agreements (CDAs), and to the extent such disclosure is permitted by State and Federal law.
4. It is understood that, although the Parties have mutual interests, there may be opportunities for independent collaborations and activities outside the scope of this MOU, but which are within the scope of the Parties' respective missions. As such, the Parties may, as appropriate, enter into independent negotiations and agreements with prospective partner/s without any effect on this MOU.
5. Materials and data being analyzed/studied under the terms and conditions of this MOU may be shared among the Parties only if permitted by applicable State and Federal law and any such sharing of materials and data will be governed by separate written Material and Data Transfer Agreements (MDTA). Parties will ensure that their participation in any MDTA is appropriate and permissible under applicable State and Federal law.
6. Rights to inventions or intellectual property developed will be addressed in separate written development and implementation agreements among the Parties. To the extent there is FDA participation in any projects related to development of any product, invention or property developed, such activities will be governed by applicable Federal law. This MOU does not license or convey any intellectual property or inventions owned or managed by any of the Parties to any other Party or to the ANH.
7. Any notice or other communication required or permitted under this MOU shall be in writing and will be deemed effective on the date it is received by the receiving Party.
8. FDA participation in this MOU is governed by Federal statutes and regulations.

VI. TERM, TERMINATION AND MODIFICATIONS

1. This MOU constitutes the entire agreement among the Parties and to the matters herein. There are no representations, warranties, agreements, or understandings, expressed or implied, written or oral, among the Parties relating to the subject matter of this MOU that are not fully expressed herein.
2. This MOU may be modified only upon the mutual written consent of all Parties. Modifications must be signed by the original signatories to this MOU, or by their designees or successors. No oral statement by any person shall be interpreted as modifying or otherwise affecting the terms of this MOU.
3. This MOU, when accepted by the Parties, will remain in effect for three (3) calendar years from the Effective Date, unless modified or terminated.
4. Any Party to this MOU may terminate its participation by written notice by at any time, with or without cause, and without incurring any liability or obligation. Such written notice shall be given by the terminating Party to the other Parties at least 60 days prior to the date of actual termination.

VIII. CONTACTS

Notices or formal communications pursuant to this MOU shall be sent in writing by personal delivery, overnight delivery, facsimile telecommunication with confirmatory receipt, or certified or registered mail, return receipt requested, to the following contact for each Party:

For FDA: Wendy R. Sanhai, Ph.D.
Senior Scientific Advisor
Office of the Commissioner, FDA
5600 Fishers Lane, Suite 14 B-45, HZ-1
Rockville, MD. 20857
Phone: (301) 827-7867, Fax: (301) 827-5891
Email: wendy.sanhai@fda.hhs.gov

With a copy to: Chekesha S. Clingman, Ph.D.
LCDR, USPHS
Senior Scientific Program Manager
Office of the Commissioner, FDA
5600 Fishers Lane, Suite 6A-08
Rockville, MD 20857
Phone: (301) 827-4044, Fax: (301) 827-5891
Email: chekesha.clingman@fda.hhs.gov

MOU# 225-07-8006

For ANH: Mauro Ferrari, Ph.D.
President, Alliance for NanoHealth
1825 Pressler, Suite 537D
Houston, TX 77031
Phone: (713) 500-2444, Fax: (713) 500-2462
Email: mauro.ferrari@uth.tmc.edu

For BCM: William T. Butler, M.D.
Interim President, Baylor College of Medicine
One Baylor Plaza
Houston, Texas 77030
Fax Number: (713) 798-8811

With a copy to: Office of General Counsel
Baylor College of Medicine
One Baylor Plaza, Room 106A
Houston, Texas 77030
Fax Number: (713) 798-6368

For Rice: David W. Leebron
President, Rice University
6100 Main Street, MS-1
Houston, Texas 77005
Fax Number (713) 348-5271

With a copy to: Office of General Counsel
Rice University
6100MainStreet, MS-94
Houston, Texas 77005
Fax Number (713) 348-5464

For Texas A&M: Nancy W. Dickey, M.D.
President, Texas A & M Health Science Center
John B. Connally Building, 7th Floor
301 Tarrow
College Station, Texas 77840-7896
Fax No. (979) 458-7202

With a copy to: Chief Legal Officer
Texas A & M Health Science Center
John B. Connally Building, 7th Floor
301 Tarrow
College Station, Texas 77840-7896
Fax No. (979) 458-7202

MOU# 225-07-8006

For UH: Dr. Renu Khator
Chancellor, UH System
President, University of Houston
212 E. Cullen Building
Houston, Texas 77204-2018
713-743-8820
713-743-8837 (fax)

With a copy to: Vice Chancellor for Legal Affairs, UH System
Vice President for Legal Affairs, UH
General Counsel, UH System/UH
311 E. Cullen Building
Houston, Texas 77204-2028
Phone: (713) 743-0949
Fax: (713) 743-0948

For UTMDACC: John Mendelsohn, M.D.
President, University of Texas
M. D. Anderson Cancer Center
1515 Holcombe Blvd., Box 91
Houston, Texas 77030
Fax Number: (713) 799-2210

With a copy to: Senior Vice President for
Administrative Services and Chief Legal Officer
The University of Texas
M. D. Anderson Cancer Center
1515 Holcombe Boulevard, Box 537
Houston, Texas 77030
Fax Number: (713) 799-8801

For UTMB: David L. Callender, M.D.
President, University of Texas
Medical Branch at Galveston
301 University Blvd.
Galveston, Texas 77555-0129
Fax Number: (409) 772-5064

With a copy to: Department of Legal Affairs
301 University Blvd.
Galveston, Texas 77555-0124
Fax Number (409) 772-6049

MOU# 225-07-8006

For UTHSCH: Larry R. Kaiser, M.D.
President, The University of Texas Health Science
Center at Houston
7000 Fannin, Suite 1700
Houston, Texas 77030
Fax Number (713) 500-3026

With a copy to: Office of Legal Affairs
The University of Texas Health Science
Center at Houston
7000 Fannin Street, Suite 1460
Houston, Texas 77030
Fax Number: (713) 500-3275

For TMHRI: Michael W. Lieberman, M.D., Ph.D.
President & CEO
The Methodist Hospital Research Institute
6565 Fannin Street, B490
Houston, Texas 77030
Fax Number: (713) 441-3886

With a copy to: Vice President, Legal Services
The Methodist Hospital System
6565 Fannin Street, D200
Houston, Texas 77030
Fax Number: (713) 793-7092

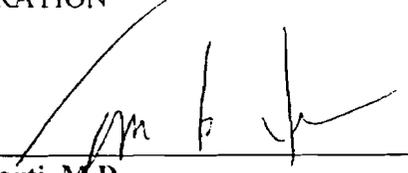
The Parties shall notify each other of any change of address or change of named contact by written notice. All notices shall be effective upon date of receipt.

Signatures begin on next page

SIGNATURES OF RESPONSIBLE PARTIES:

We, the undersigned, agree to abide by the terms and conditions of this MOU.

APPROVED AND ACCEPTED FOR THE UNITED STATES FOOD AND DRUG ADMINISTRATION



Date 2/16/09

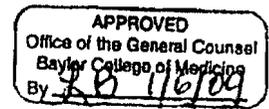
Frank M. Torti, M.D.
Principal Deputy Commissioner and Chief Scientist *Acting Commissioner*
Food and Drug Administration

APPROVED AND ACCEPTED FOR THE BAYLOR COLLEGE OF MEDICINE



Date 1/9/09

William T. Butler, M.D.
Interim President, Baylor College of Medicine



APPROVED AND ACCEPTED FOR THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON

Date _____

Larry R. Kaiser, M.D.
President, The University of Texas Health Science Center at Houston

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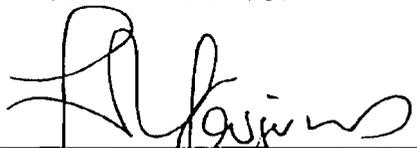
APPROVED AND ACCEPTED FOR THE UNITED STATES FOOD AND DRUG
ADMINISTRATION

_____ Date _____
Frank M. Torti, M.D.
~~Principal Deputy Commissioner and Chief Scientist~~ *Acting Commissioner*
Food and Drug Administration

APPROVED AND ACCEPTED FOR THE BAYLOR COLLEGE OF MEDICINE

_____ Date _____
William T. Butler, M.D.
Interim President, Baylor College of Medicine

APPROVED AND ACCEPTED FOR THE UNIVERSITY OF TEXAS HEALTH SCIENCE
CENTER AT HOUSTON


_____ Date 12/12/08
Larry R. Kaiser, M.D.
President, The University of Texas Health Science
Center at Houston

APPROVED AND ACCEPTED FOR WILLIAM MARSH RICE UNIVERSITY

David W. Leebron

David W. Leebron
President, Rice University

Date Jan. 16, 2009

APPROVED AND ACCEPTED FOR THE UNIVERSITY OF TEXAS M.D. ANDERSON
CANCER CENTER

John Mendelsohn, M.D.
President, The University of Texas
M.D. Anderson Cancer Center

Date _____

APPROVED AND ACCEPTED FOR UNIVERSITY OF HOUSTON

Renu Khator, Ph.D.
President, University of Houston

Date _____

APPROVED AND ACCEPTED FOR THE UNIVERSITY OF TEXAS MEDICAL BRANCH
AT GALVESTON

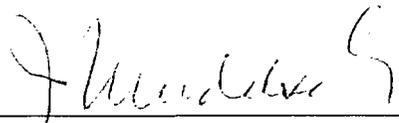
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President, The University of Texas Medical
Branch at Galveston

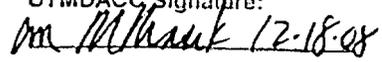
Date _____

APPROVED AND ACCEPTED FOR WILLIAM MARSH RICE UNIVERSITY

Date _____
David W. Leebron
President, Rice University

APPROVED AND ACCEPTED FOR THE UNIVERSITY OF TEXAS M.D. ANDERSON
CANCER CENTER



Date 1/5/07
John Mendelsohn, M.D.
President, The University of Texas
M.D. Anderson Cancer Center
Reviewed and Approved by
UTMDACC Legal Services for
UTMDACC Signature:
 12-18-08

APPROVED AND ACCEPTED FOR UNIVERSITY OF HOUSTON

Date _____
Renu Khator, Ph.D.
President, University of Houston

APPROVED AND ACCEPTED FOR THE UNIVERSITY OF TEXAS MEDICAL BRANCH
AT GALVESTON

Date _____
David L. Callender, M.D.
President, The University of Texas Medical
Branch at Galveston

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Date _____
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President, Rice University

APPROVED AND ACCEPTED FOR THE UNIVERSITY OF TEXAS M.D. ANDERSON
CANCER CENTER

Date _____
John Mendelsohn, M.D.
President, The University of Texas
M.D. Anderson Cancer Center

APPROVED AND ACCEPTED FOR UNIVERSITY OF HOUSTON

dhc *Renu Khator* _____ Date _____
Renu Khator, Ph.D.
President, University of Houston

APPROVED AND ACCEPTED FOR THE UNIVERSITY OF TEXAS MEDICAL BRANCH
AT GALVESTON

Date _____
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President, The University of Texas Medical
Branch at Galveston

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President, Rice University

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Date _____
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President, University of Houston

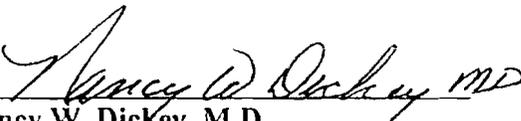
APPROVED AND ACCEPTED FOR THE UNIVERSITY OF TEXAS MEDICAL BRANCH
AT GALVESTON



Date **DEC 19 2008**
David L. Callender, M.D.
President, The University of Texas Medical
Branch at Galveston

Content reviewed


APPROVED AND ACCEPTED FOR TEXAS A&M HEALTH SCIENCE CENTER


Nancy W. Dickey, M.D.
President, Texas A&M Health Science Center

Date 1/20/09

APPROVED AND ACCEPTED FOR THE METHODIST HOSPITAL RESEARCH INSTITUTE

Michael W. Lieberman, M.D., Ph.D.
President & CEO, The Methodist Hospital
Research Institute

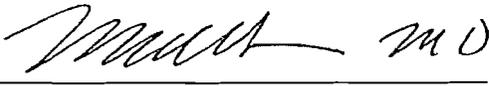
Date _____

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Nancy W. Dickey, M.D.
President, Texas A&M Health Science Center

Date _____

APPROVED AND ACCEPTED FOR THE METHODIST HOSPITAL RESEARCH INSTITUTE



Michael W. Lieberman, M.D., Ph.D.
President & CEO, The Methodist Hospital
Research Institute

Date 12/19/08

APPROVED AS TO FORM
By 
TMH Legal Services