SMG 2820.1

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

AGREEMENTS WITH OTHER AGENCIES, INSTITUTIONS OF HIGHER EDUCATION, AND NONPROFIT ORGANIZATIONS

MEMORANDUMS OF UNDERSTANDING

Effective Date: 03/29/2012

1. PURPOSE

This Staff Manual Guide (SMG) is revised to reflect changes in oversight, policy, advanced coordination, and responsibility for managing, developing and executing Memoranda of Understanding (MOU) between the United States Food and Drug Administration (FDA or Agency) and other government agencies, States, institutions of higher education, nonprofit organizations, and/or other entities (Partner(s)).

The FDA frequently wishes to record in writing the terms of an understanding or arrangement between the Agency and its Partner(s). To do this, the FDA may choose to use a collaborative instrument, such as an MOU. This SMG establishes policy and areas of responsibility for managing, developing, and executing MOUs to which FDA becomes an involved Partner(s).

2. POLICY

It is FDA’s policy to enter into MOUs with other entities in situations in which there are a need to define lines of authority or responsibility, or to clarify cooperative procedures. The intent of the MOU should be to improve consumer protection through more effective use of collective resources and to eliminate duplication of activities.

All MOUs covered by this Guide, to which FDA becomes a Partner(s), are to be cleared **prior to final negotiation and signature** through the Office of the Assistant Commissioner for External Relations (OER) and the Office of the Chief Counsel (OCC), regardless of the initiating entity. The format of all MOUs initiated by FDA shall be in general conformance with that outlined in Attachments A through F.

3. SCOPE

MOUs are non-binding collaborative instruments that can be used to show intent of both the Agency and the Partner(s). The types of collaborations MOUs can be used to memorialize include, but are not necessarily limited to, the following:

1. Collaborations between FDA and Partner(s), most commonly another government agency, that focuses almost exclusively on information sharing and/or information technology systems, such as shared electronic infrastructures.

2. Collaborations with academic or other nonprofit scientific organizations that serve as umbrellas for research, training, and outreach activities with academic or other nonprofit scientific organizations. These collaborations may raise issues concerning computer information systems.

3. Collaborations where FDA and Partner(s) intend to work together in an area of common interest and therefore need to define respective roles and jurisdiction.

4. Collaborations with nonprofit organizations designed to help FDA spread its public health message.

5. Collaborations with academic or other agencies that establish or address fellowship programs.

MOUs should not be used in place of the following agreements:

1. Grants or Cooperative Agreements – Grants or Cooperative Agreements are assistance mechanisms for awarding federal funds or property to accomplish a public purpose (Staff Manual Guide 2150).

2. Contracts – Contracts are used for purchases and to transfer funds when the government is receiving goods or services (Staff Manual Guide 2610.1).

3. Interagency Agreements – Interagency Agreements are used to commit to the transfer personnel, to transfer funds, or to transfer real or personal property to or from another federal agency (Staff Manual Guide 2810.1).

4. International Partnership Agreements – See Compliance Policy Guide Sec. 100.900 (International Memoranda of Understanding), Compliance Policy Guide Sec. 100.950 (International partnership Agreements for Compliance Activities), and Staff Manual Guide 2830.1, which establishes areas of responsibility and clearance procedures for developing, approval and monitoring of Memoranda of Understanding (MOUs) and other agreements between FDA and foreign government agencies or international organizations.

5. Work-Share Agreements – Office of Regulatory Affairs' Regional Directors are authorized to negotiate and sign Work-Share Agreements with state agencies. Work-Share Agreements are not considered to be Domestic MOUs. (See Regulatory Procedures Manual, Chapter 3.) The Division of Federal-State Relations in the Office of Regulatory Affairs publishes a list of active Work-Share Agreements every two years (see 21 CFR 20.108(c)).

6. Cooperative Research and Development Agreements (CRADA) – A CRADA is an agreement between FDA and nonfederal partners under which the collaborating partner(s) may provide or exchange personnel, scientific expertise, facilities, equipment, or other resources toward the conduct of specific research or scientific development efforts.

7. Material Transfer Agreement (MTA) – An MTA is used when proprietary, typically commercial, material is exchanged. An MTA may be appropriate when the receiving Partner(s) intends to use such material for research purposes.

8. Binding International Agreements – Binding International Agreements require clearance by the Department of State and are coordinated by FDA's Office of International Programs. See HHS Staff Manual Guide 2830.1.

4. DEFINITIONS

A. Memorandum of Understanding (MOU). The term MOU, as used herein, means a formal statement describing an understanding between the FDA and other government agencies, States, institutions of higher education, nonprofit organizations, or, in some cases, other nongovernmental institutions. An MOU recites understandings between the signing parties.

It is not, however, an agreement and it does not impose enforceable obligations on any party.

B. Sponsor. Center or Office having the predominant interest in the proposed agreement.

C. Partner(s). Other government agencies, States, institutions of higher education, nonprofit organizations, and/or other entities collaborating with the FDA.

5. ADVANCED COORDINATION

For those MOUs that require advanced intra-Center/Office coordination, the documents initiating such action shall indicate that this coordination has been accomplished.

1. Any proposed MOU for research, studies, tests, etc., of a scientific nature shall be prepared in consultation with the Office of the Chief Scientist.

2. Any proposed MOU for research, studies, tests, etc., of a medical nature shall be prepared in consultation with the Office of the Chief Scientist.

3. Any proposed MOU with States, or which requires Regional Office participation, shall be prepared in consultation with the Office of Regulatory Affairs.

4. Any proposed informal MOU with foreign governments or other foreign institutions or organizations shall be prepared in consultation with FDA's International Affairs Programs, Office of the Associate Commissioner for International Programs.

6. AREAS OF RESPONSIBILITY

A. Sponsor

1. Informs the Assistant Commissioner for External Relations. Any Center or Office wishing to enter into an MOU on behalf of FDA, shall:

   - Submit a proposed MOU to Office of External Relations for approval or comments prior to commencing final negotiations.

   - Accomplish all required intra-Center or Office coordination.

- Work with the Office of Regulatory Affairs when the MOU impacts regional operations.

- Work with the Office of the Chief Scientist and Deputy Commissioner for Science and Public Health when a proposed MOU involves intellectual property.

2. After final signatures of both partners have been obtained, sends the document to the Assistant Commissioner for External Relations for publication.

3. Periodically evaluates each MOU that originated in that Office or Center and initiates appropriate action for the cancellation, continuation, modification or termination of those MOUs. Such continuation, modification or termination of MOUs shall be initiated by the use of a formal memorandum addressed to the Assistant Commissioner for External Relations.

B. Office of External Relations

1. Reviews each proposed MOU submitted for appropriateness and completeness and to assure that all coordination and final negotiations have been accomplished by intra-Center or Office coordination and the collaborating Partner(s).

2. Upon approval, forwards the MOU to the Office of Office of Acquisitions and Grants Services (OAGS) for review and assignment of an MOU control number.

3. Upon return of proposed MOU from OAGS, sends the same to the Office of Chief Counsel (OCC) for legal review.

4. Upon return of MOU cleared by OCC, sends the same to the Sponsor for signatures of sponsoring Center or Office and the collaborating Partner(s).

5. Oversees posting the MOU on the FDA website and facilitates publication in the Federal Register upon receipt of an executed MOU (pdf, word copy, and the Federal Register Clearance Record.

6. Serves as the central FDA repository for all executed MOUs.

C. Office of Acquisitions, Contracts and Grants Management (OAGS)

1. Reviews all proposed MOUs.

2. Assigns a control number and returns the MOU to OER.

D. Office of the Chief Counsel

The Office of the Chief Counsel reviews the draft MOU for legal sufficiency, consulting with Office of General Counsel's (OGC) General Legal Division (GLD) and Ethics Division as needed, and returns the draft MOU with concurrence or comments to OER. Changes made to an MOU after clearance by OCC must also be cleared by OCC.

E. Signing of MOUs

1. Center or Office specific MOUs should be signed by the sponsoring Center or Office Director or designee.

2. MOUs involving two or more Offices and Centers shall be signed by the Commissioner of Food and Drugs or an official designated by the Commissioner.

NOTE: Templates should be used to structure draft MOUs. Because templates may be updated, please contact the Office of External Relations for the most recent version of each template. The following attachments are current (as of October, 2011) versions of six types of templates.

7. EFFECTIVE DATE

The effective date of this guide is March 29, 2012.

8. Document History -- SMG 2820.1, Memorandums of Understanding

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	03/29/2012	N/a	OC/OER	Lawrence L. Bachorik, Assistant Commissioner OER

Attachment A (Information Sharing) – Use for MOUs that focus exclusively on information sharing with government agencies and institutions of higher education.

MOU Number _____

MEMORANDUM OF UNDERSTANDING

BETWEEN THE

(Partner(s))

AND THE

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

I. Preamble: (Optional: Describe the respective missions and mutual objectives of the Partner(s)

II. Purpose: Describe the specific purpose of the MOU.

III. Authority: Describe the agency's legal authority to take the actions described in the MOU.

IV. Background: FDA is authorized to enforce the Federal Food, Drug, and Cosmetic Act (the Act) as amended (21 U.S.C. 301, et seq.). In fulfilling its responsibilities under the Act, FDA, among other things, directs its activities toward promoting and protecting the public health by assuring the safety, efficacy, and security of drugs, veterinary products, medical devices and radiological products and the safety and security of foods, dietary supplements, and cosmetics. FDA also has responsibility for regulating the manufacturing, marketing and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. To accomplish its mission, FDA must stay abreast of the latest developments in research and communicate with stakeholders about complex scientific and public health issues. Increased development of research, education and outreach partnerships within the [insert name of participate in party] will greatly contribute to FDA's mission.

[Insert description of participating party as relevant to this MOU.]

V. Substance of Agreement: Provide a comprehensive description of programs to be implemented and areas to be addressed. Include the following, as applicable:

1. Description of research, training, educational activities

2. Roles and responsibilities of the Partners.

VI. General Provisions: Include the following applicable statements in the MOU:

- Data Sharing Guidelines:

If HHS sister agency:

> "As public health agencies within DHHS, there are no legal prohibitions that preclude FDA or [Insert Name of Participating Party] from sharing with each other most information in the possession of either agency. Both parties recognize and acknowledge, however, that all non-public information shared between FDA and [Insert Name of Participating Party], whether in writing or orally, must be protected from any disclosure not authorized by law or regulation. See e.g., 18 U.S.C. § 1905; 5 U.S.C. § 552a; 21 U.S.C. § 331(j); 21 CFR Parts 20 and 21; 42 U.S.C. § 241(d); 42 CFR Parts 5 and 5b. Safeguards are needed to protect shared non-public information, such as trade secrets and confidential commercial information; identities of study participants and other personal privacy information; privileged and/or pre-decisional agency information; research proposals, progress reports, and/or unpublished data; or national security information. Such safeguards also help ensure compliance by FDA and [Insert Name of Participating Party] with other applicable laws and regulations.
>
> To facilitate the sharing of non-public information, FDA and [Insert Name of Participating Party] will implement procedures to ensure that such sharing is appropriate and that the recipient party will guard the confidentiality of all information received. Both parties are committed to responding to requests for information in a complete and timely manner, consistent with budgetary and resource constraints, and to the extent permitted by law, regulation, and agency policy and practice. The party receiving shared non-public information (requesting party) will be responsible for protecting that information from any unauthorized disclosure.

Provisions for sharing of non-public information in accordance with applicable statutes or regulations are set out below:

The requesting party will comply with the following conditions:

a. The requesting party will limit the dissemination of shared non-public information it receives to internal unit offices and/or employees that have been identified in its written request. If the requesting party determines that employees other than those identified in the original

request have a need to know the requested information, then an update to the request letter will be supplied to the sharing party before the requesting party distributes the information to those employees. The unit official who signs the request letter will be responsible for ensuring that there are no inappropriate recipients of the information.

b. The requesting party will agree in writing, by using the model request letter (or a reasonable, mutually agreed upon variation), not to disclose any shared non-public information in any manner not authorized by law or regulation, including disclosure in publications and public meetings. If the requesting party wishes to disclose shared information that the sharing party has designated as non-public, the requesting party will ask the sharing party whether the information's non-public status has changed, and if so, will first obtain written confirmation and permission from the sharing party before disclosing that information. If the requesting party receives a Freedom of Information Act (FOIA) request for shared information, the requesting party will: (a) refer the FOIA request to the information-sharing contact person or designee for the sharing party to respond directly to the FOIA requester regarding the releaseability of the information, and (b) notify the FOIA requester of the referral and that a response will issue directly from the sharing party. The requesting party will leave all final disclosure decisions up to the sharing party, including decisions on whether the records are responsive and whether they must be disclosed. Accordingly, the requesting party will not indicate to the FOIA requester whether the sharing party has responsive records or releasable records.

c. The sharing party will include a transmittal letter along with any agency information shared. The transmittal letter will indicate the type of information (e.g., confidential commercial information, personal privacy, pre-decisional, etc.). A model transmittal letter is attached. The shared documents containing non-public information should be stamped "Do not disclose without permission of FDA/ [or] [Insert Name of Participating Party]" whichever is applicable.

d. The requesting party will promptly notify the contact person or designee of the sharing party of any attempt by a third party to obtain shared non-public information by compulsory process, including, but not limited to, a FOIA request, subpoena, discovery request, or litigation complaint or motion.

e. The requesting party will notify the sharing party before complying with any judicial order that compels the release of shared non-public information, so that the parties may determine the appropriate measures to take, including, where appropriate, legal action."

If Non-HHS Federal Agency:

"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)), FDA will not reveal to **[other party]** 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 FDA and **[other party]** 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.

Provisions for sharing of non-public information in accordance with applicable statutes or regulations are set out below:

The requesting party will comply with the following conditions:

a. The requesting party will limit the dissemination of shared non-public information it receives to internal unit offices and/or employees that have been identified in its written request. If the requesting party determines that employees other than those identified in the original request have a need to know the requested information, then an update to the request letter will be supplied to the sharing party before

the requesting party distributes the information to those employees. The unit official who signs the request letter will be responsible for ensuring that there are no inappropriate recipients of the information.

b. The requesting party will agree in writing, by using the model request letter (or a reasonable, mutually agreed upon variation), not to disclose any shared non-public information in any manner not authorized by law or regulation, including disclosure in publications and public meetings. If the requesting party wishes to disclose shared information that the sharing party has designated as non-public, the requesting party will ask the sharing party whether the information's non-public status has changed, and if so, will first obtain written confirmation and permission from the sharing party before disclosing that information. If the requesting party receives a Freedom of Information Act (FOIA) request for shared information, the requesting party will: (a) refer the FOIA request to the information-sharing contact person or designee for the sharing party to respond directly to the FOIA requester regarding the releaseability of the information, and (b) notify the FOIA requester of the referral and that a response will issue directly from the sharing party. The requesting party will leave all final disclosure decisions up to the sharing party, including decisions on whether the records are responsive and whether they must be disclosed. Accordingly, the requesting party will not indicate to the FOIA requester whether the sharing party has responsive records or releasable records.

c. The sharing party will include a transmittal letter along with any agency information shared. The transmittal letter will indicate the type of information (e.g., confidential commercial information, personal privacy, pre-decisional, etc.). A model transmittal letter is attached. The shared documents containing non-public information should be stamped "Do not disclose without permission of FDA/ [or] [Insert Name of Participating Party]" whichever is applicable.

d. The requesting party will promptly notify the contact person or designee of the sharing party of any attempt by a third party to obtain shared non-public information by compulsory process, including, but not limited to, a FOIA request, subpoena, discovery request, or litigation complaint or motion.

e. The requesting party will notify the sharing party before complying with any judicial order that compels the release of shared non-public information, so that the parties may determine the appropriate measures to take, including, where appropriate, legal action."

Attachment A (Information Sharing) – Use for MOUs that focus exclusively on information sharing with government agencies and institutions of higher education.

If a Non-Federal Government Partner:

"Access to non- public information shall be govered by separate Confidentiality Disclosure Agreements in which the Partners will agree and certify in writing that they shall not further release, publish or disclose such information and that they shall protect such information in accordance with the provisions of 21 U.S.C. 331(j), 21 U.S.C. 360j(c), 18 U.S.C. 1905, and other pertinent laws and regulations governing the confidentiality of such information. No proprietary data, tradesecrets or patient confidential information shall be disclosed among the Partners unless permitted by applicable law."

- Intellectual Property Guidelines [for MOUs with non-Federal government partners]: ""Invention" refers to any subject matter and discovery patentable or otherwise protected under Title 35 of the United States Code and will refer to Inventions conceived or first reduced to practice under the activities of the MOU. "Intellectual Property" refers to patents, patent applications, know-how, trade secrets, copyrights and computer programs either use or developed under the activities of the MOU. Rights to Inventions or Intellectual Property developed under the MOU will be addressed in separate project-specific development and implementation agreements among the Partners. Inventorship will be governed by U.S. law. In the case of sole inventorship, ownership will be governed by the policies of the employer of the Invention. In the case of joint Inventorship, ownership of Inventions will be governed by the policies of the employer of each inventor. Licenses for Inventions made under a Federal grant or contract, will be subject to the Bayh-Dole Act. Accordingly, all employees [of non-government partner] who work on any project under this MOU shall be required to sign an agreement that effects a present assignment of their future inventions to non government partner. No Partner(s), by virtue of their participation in activities under the MOU, will be required to disclose or license intellectual property to the other Partner(s)."

- Conflict of Interest [for MOUs with non-Federal government partners]: "Individuals must be free of conflict prior to entering into activities under this MOU. As required, the Partners may need to sign a Conflict of Interest Clearance agreement, pursuant to the Ethics in Government Act of 1978, and the Partners may also be asked to file a financial disclosure report. The Partners will be advised of any potential conflict so that conflicting assignments can be avoided consistent with the HHS/FDA requirements. If at any time prior to or during the performance of the activities under the MOU, the Partners believe that a potential or actual conflict exists, the Partners must notifiy the

appropriate authorities within their respectives institutions and contact the designated FDA official listed on the MOU so that the necessary action/s can be undertaken. A determination will be made by FDA as to whether a conflict of interest exists and, if so, as to how to resolve or mitigate it. Partners to the MOU will make every effort to avoid activities or relationships that would cause a reasonable person to question the impartiality of their actions."

VII. Resource Obligations: This MOU represents the broad outline of the Partner(s') intent to enter into specific agreements for collaborative efforts in intellectual areas of mutual interest to FDA and Partner(s). All activities undertaken pursuant to the MOU are subject to the availability of personnel, resources, and funds. This MOU does not affect or supersede any existing or future agreements or arrangements among the Partners. This MOU does not create binding, enforceable obligations against any Party. This MOU and all associated agreements will be subject to the applicable policies, rules, regulations, and statutes under which FDA and Partner(s)] operate.

VIII. Liaison Officers:

A. For the (Partner(s)):

Individual's name: (optional)

Organization:

Title:

Address:

Telephone Number:

B. For the Food and Drug Administration:

Individual's name: (optional)

Organization:

Title:

Address:

Telephone Number:

Each Party may designate new liaisons at any time by notifying the other Party's administrative liaison in writing. If, at any time, an individual designated as a liaison under this agreement becomes unavailable to fulfill those functions, the Parties will name a new liaison within 2 weeks and notify the other Party through the designated administrative liaison.

IX. Term, Termination, and Modification: "This agreement, when accepted by all partners, will have an effective period of performance from the date of the latest signature until _____ and may be modified or terminated by mutual written consent the partners or may be terminated by either Partner(s) upon a _____ day advance written notice to the other."

If there is no expiration date for the MOU, state, "This agreement will be effective when accepted by all participating partners. This agreement may be modified or terminated by mutual written consent by the partners or may be terminated by either Partner(s) upon a _____ day advance written notice to the other."

APPROVED AND ACCEPTED FOR (Partner(s)) By _____ Title _____ _____ Date _____	APPROVED AND ACCEPTED FOR FOOD AND DRUG ADMINISTRATION By _____ Title _____ _____ Date _____

Attachment A1 -- Model Language for Information Sharing Request from Participating Partner(s) to FDA

MOU Control No. (Insert number)

Process for Information Sharing

Pursuant to Section __of the Memorandum of Understand (MOU) entered by the Food and Drug Administration (FDA) and the _____any Federal partner "may decide not to share information or expertise in response to a particular request for information, or to limit the scope of information and expertise sharing in response to a particular request." Nothing in the process described below changes Section __.

When, under the current MOU, staff at the FDA or _____request for the other agency information that may contain confidential material, the request should be in writing, which includes an informal email, or need only identify the subject for which information is requested. Although a more specific description of the information asked for may be helpful, it would not be required for purposes of making a request. However, the following language should be included in the request:

> "Information that is shared under this agreement will be under the FDA _____Memorandum of Understanding. We agree not to disclose any shared information in any manner without your written permission or as required by law with advance notice to the originating agency." With the inclusion of this statement, requestors would not have to use a particular format or include other pre-specified text.

A response to a request should also be in writing and can be an informal email that acknowledges transmission of information in response to the request. Although identifying each piece of information/document provided may be helpful, it would not be required for purposes of responding to a request. However, the following language should be included in the response:

> "Pursuant to the FDA _____Memorandum of Understanding, this communication may contain privileged and/or confidential information exempt from public disclosure. It may not be disclosed or shared in any manner without the express written consent or as required by law with advance notice to the originating agency." With the inclusion of this statement, responders would not have to use a particular format or include other pre-specified text.

Appendix A2 -- Model Language for Information Sharing Request from Participating Partner(s) to FDA

MOU Control No. (Insert number)

This letter accompanies agency records the (Participating Partner(s)) is sharing with the Food and Drug Administration (FDA) in response to FDA's request, dated _____. These agency records contain one or more of the following categories of nonpublic information, including information the public disclosure of which may be prohibited b law.

(Participating Partner(s)) checks applicable items below]

____ Trade secrets

____ Confidential commercial or financial information

____ Information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy

____ Information subject to the Privacy Act

____ Intra-agency records

____ Records or information compiled for law enforcement purposes

____ Information protected for national security reasons; or

____ Other

FDA shall notify the appropriate office of the information-sharing agency if there are any attempts to obtain shared information by compulsory process, including but not limited to, Freedom of Information Act requests, subpoenas, discovery requests, and litigation complaints or motions.

FDA shall notify the information-sharing agency before complying with any judicial order that compels the release of such information that FDA and Partner(s) may take appropriate measures, including filing a motion with the court or an appeal.

Appendix A2 -- Model Language for Information Sharing Request from Participating Partner(s) to FDA

FDA has agreed, by this letter or e-mail and by a signed request letter dated _____, not to disclose the above-described information without prior written permission of the (Partner(s). FDA acknowledges that applicable laws and regulations may prohibit the disclosure of such information. See, e.g., 21 U.S.C. section 331(j); 18 U.S.C. section 1095, 21 C.F.R. Parts 20 and 21, 45 CF.R. Parts 5 and 5b and 42 U.S.C. Section 241(d).

_____ _____

Name Date

Attachment B - (Umbrella MOU with academic institutions for Research, Training and Outreach activities) – Use for MOUs that serve as umbrellas for research, training and outreach activities with academic institutions.

MEMORANDUM OF UNDERSTANDING

BETWEEN

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVI CES

THE FOOD AND DRUG ADMINISTRATION

[insert, if appropriate, Center or Office of FDA entering into MOU]

AND

[Insert Name of Participating Party]

I. Purpose

The United States Food and Drug Administration (FDA) and [Insert Name of Participating Party] (the Parties) share interests in promoting scientific progress through exchange of scientific capital in [insert appropriate description of shared interest]. Both institutions foresee benefits from the mutual exchange of training and research expertise in clinical pharmacology and translational science. This Memorandum of Understanding (MOU) establishes the terms for collaboration to promote these shared interests, which can be pursued through a variety of programs including collaborative education and research.

II. Background

FDA is authorized to enforce the Federal Food, Drug, and Cosmetic Act (the Act) as amended (21 U.S.C. 301, et seq.). In fulfilling its responsibilities under the Act, FDA, among other things, directs its activities toward promoting and protecting the public health by assuring the safety, efficacy, and security of drugs, veterinary products, medical devices and radiological products and the safety and security of foods, dietary supplements, and cosmetics. FDA also has responsibility for regulating the manufacturing, marketing and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. To accomplish its mission, FDA must stay abreast of the latest developments in research and communicate with stakeholders about complex scientific and public health issues. Increased development of research, education and outreach partnerships within the [insert name of participate in party] will greatly contribute to FDA's mission.

[Insert description of participating party as relevant to this MOU.]

III. Substance of Agreement:

This MOU forms the basis for development of scientific collaborations, outreach and educational initiatives and intellectual partnerships between FDA and [PARTICIPATING PARTY]. The types of initiatives expected to develop from this MOU include:

1. Advancing student education and matriculation into the health and biomedical science professions.

2. Opportunities for FDA staff to serve as adjunct faculty or on advisory boards;

3. Opportunities to convene joint meetings for education and research;

4. Research collaborations;

5. Cooperative international initiatives; and

6. Access to unique facilities and equipment for scientific endeavors.

Under this MOU, FDA and [PARTICIPATING PARTY] will seek opportunities to participate together in collaborative research and training as permitted under appropriate statutory authority. Before any specific collaboration is initiated or implemented, the Parties shall identify priorities, topics of mutual interest, and develop separate, written agreements for collaboration and sharing of resources. Where applicable, these agreements shall incorporate by reference this MOU. FDA may enter into a contract, grant or cooperative agreement with [PARTICIPATING PARTY] to the extent authorized by law and available appropriations. The terms and conditions of any such awards will be in accordance with applicable federal law and regulations, and shall be negotiated and executed by appropriate representatives of institutions within [PARTICIPATING PARTY] and FDA.

IV. General Provisions:

1. Rights to any inventions resulting from collaborative research will be determined by the separate written research agreements governing the effort, based on current U.S. Government patent regulations and any other applicable statutes and regulations.

2. Institutions within [PARTICIPATING PARTY] and FDA may decide to enter into Cooperative Research and Development Agreements

(CRADA) specific to particular collaborative projects. The terms of such CRADAs will address Intellectual Property rights.

3. Proprietary and/or nonpublic information will not be disclosed under this MOU, unless such disclosure is governed by appropriate confidentiality disclosure agreements or to the extent such disclosure is permitted by law.

4. Each Party will comply with the other Party's security procedures and policies regarding access to and use of facilities. Either Party may restrict or limit access to its property and facilities at any time and for any reason. [PARTICIPATING PARTY] individuals participating in activities under this MOU on FDA property will comply with all applicable federal statutes and regulations.

5. It is recognized that from time to time FDA and institutions within [PARTICIPATING PARTY] will be sharing in expenses and may require compensation of either Party by the other. As research projects are developed, details of how costs are to be shared will be agreed to in advance under other contractual mechanisms as appropriate and in compliance with all applicable federal requirements.

V. Resource Obligations:

This MOU represents the broad outline of the FDA and [PARTICIPATING PARTY]'s intent to collaborate in areas of mutual interest. All activities that may be undertaken by this MOU are subject to the availability of personnel, resources, and funds. This MOU does not create binding, enforceable obligations against any Party. This MOU does not affect or supersede any existing or future agreements or arrangements among the Parties and does not affect the ability of the Parties to enter other agreements or arrangements related to this MOU.

VI. Liaison Officers:

A. For the (Partner(s)):

Individual's name: (optional)

Organization:

Title:

Address:

Telephone Number:

B. For the Food and Drug Administration:

Individual's name: (optional)

Organization:

Title:

Address:

Telephone Number:

Each Party may designate new liaisons at any time by notifying the other Party's administrative liaison in writing. If, at any time, an individual designated as a liaison under this agreement becomes unavailable to fulfill those functions, the Parties will name a new liaison within 2 weeks and notify the other Party through the designated administrative liaison.

VII. Term, Termination, and Modification: "This agreement, when accepted by all partners, will have an effective period of performance from the date of the latest signature until _____ and may be modified or terminated by mutual written consent the partners or may be terminated by either Partner(s) upon a _____ day advance written notice to the other."

If there is no expiration date for the MOU, state, "This agreement will be effective when accepted by all participating partners. This agreement may be modified or terminated by mutual written consent by the partners or may be terminated by either Partner(s) upon a _____ day advance written notice to the other."

Attachment B - (Umbrella MOU with academic institutions for Research, Training and Outreach activities) – Use for MOUs that serve as umbrellas for research, training and outreach activities with academic institutions.

VIII. Statutes, Regulations, Rules, and Policies

This MOU and all associated agreements will be subject to the applicable statutes, regulations, rules, and policies under which FDA, [PARTICIPATING PARTY], and the institutions within [PARTICIPATING PARTY] operate.

APPROVED AND ACCEPTED FOR (Partner(s))	APPROVED AND ACCEPTED FOR FOOD AND DRUG ADMINISTRATION
By _____	By _____
Title _____	Title _____
_____	_____
Date _____	Date _____

Attachment C (Defining Responsibilities of Partner(s) – Use for MOU that defines roles and jurisdictions of FDA and participating Partner(s) (other Federal agencies and other organizations) and explains how FDA and the other Partner(s) works together for common interests.

MOU Control No. [Insert number]

MEMORANDUM OF UNDERSTANDING BETWEEN THE

(Insert Name of Domestic Participating Partner(s))

AND

THE FOOD AND DRUG ADMINISTRATION

I. Preamble: (Optional: Describe the respective missions and mutual objectives of Partner(s)

II. Purpose: Describe the specific purpose of the MOU.

III. Authority: Describe the agency's legal authority to take the actions described in the MOU.

IV. Background:

FDA is authorized to enforce the Federal Food, Drug, and Cosmetic Act (the Act) as amended (21 U.S.C. 301, et seq.). In fulfilling its responsibilities under the Act, FDA, among other things, directs its activities toward promoting and protecting the public health by assuring the safety, efficacy, and security of drugs, veterinary products, medical devices and radiological products and the safety and security of foods, dietary supplements, and cosmetics. FDA also has responsibility for regulating the manufacturing, marketing and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. To accomplish its mission, FDA must stay abreast of the latest developments in research and communicate with stakeholders about complex scientific and public health issues. Increased development of research, education and outreach partnerships within the [insert name of participate in party] will greatly contribute to FDA's mission.

[Insert description of participating party as relevant to this MOU.]

V. Substance of Agreement: Provide a comprehensive description of programs to be implemented and areas to be addressed.

VI. Roles and responsibilities of the Partner(s).

VII. General Provisions: Include the applicable statements in the MOU:

Attachment C (Defining Responsibilities of Partner(s) – Use for MOU that defines roles and jurisdictions of FDA and participating Partner(s) (other Federal agencies and other organizations) and explains how FDA and the other Partner(s) works together for common interests.

"This is an internal government agreement between FDA and [Insert Name of Participating Partner(s)] and does not confer any rights or benefits to any person or Partner(s)."

VII. Resource Obligations: This MOU represents the broad outline of the Partner(s)' present intent to enter specific agreements for collaborative efforts in areas of mutual interest to FDA and the participating Partner(s) [INSERT NAME]. All activities undertaken through the MOU are subject to the availability of personnel, resources, and funds. This MOU does not affect or supersede any existing or future agreements or arrangements among the Partner(s). This MOU does not create binding, enforceable obligations against any Party. This MOU and all associated agreements will be subject to the applicable policies, rules, regulations, and statutes under which FDA and the participating Partner(s) [INSERT NAME] operate.

IX. Liaison Officers:

A. For the [Insert Name of Participating Partner(s)]:

Individual's name: (optional)

Organization:

Title:

Address:

Telephone Number:

Email Address:

B. For the Food and Drug Administration:

Individual's name: (optional)

Organization:

Title:

Address:

Telephone Number:

Email Address:

Each Party may designate new liaisons at any time by notifying the other Party's administrative liaison in writing. If, at any time, an individual designated as a liaison under this agreement becomes unavailable to fulfill those functions, the Parties will name a new liaison within 2 weeks and notify the other Party through the designated administrative liaison.

X. Term, Termination, and Modification: "This agreement, when accepted by all participating Partner(s), will have an effective period of performance from the date of the latest signature until _____ and may be modified or terminated by mutual written consent by both Partner(s) or may be terminated by either Partner(s) upon a _____ day advance written notice to the other.

[If there is no expiration date for the MOU, state] "This agreement will be effective when accepted by all participating Partner(s). This agreement may be modified or terminated by mutual written consent by both Partner(s) or may be terminated by either Partner(s) upon a _____ day advance written notice to the other."

APPROVED AND ACCEPTED FOR (Partner(s)) By _____ Title _____ _____ Date _____	APPROVED AND ACCEPTED FOR FOOD AND DRUG ADMINISTRATION By _____ Title _____ _____ Date _____

Attachment D (Cooperation in Disseminating Health Information) – Use for MOUs with outside organizations to spread FDA's public health messages (print and web partnerships).

MOU Control No. [Insert number]

MEMORANDUM OF UNDERSTANDING BETWEEN THE

(Insert Name of Domestic Participating Partner(s))

AND

THE FOOD AND DRUG ADMINISTRATION

I. Preamble: (Optional: Describe the respective missions and mutual objectives of Partner(s)

II. Purpose: Describe the specific purpose of the MOU.

III. Authority: Describe the agency's legal authority to take actions described in the MOU.

Background: FDA is authorized to enforce the Federal Food, Drug, and Cosmetic Act (the Act) as amended (21 U.S.C. 301, et seq.). In fulfilling its responsibilities under the Act, FDA, among other things, directs its activities toward promoting and protecting the public health by assuring the safety, efficacy, and security of drugs, veterinary products, medical devices and radiological products and the safety and security of foods, dietary supplements, and cosmetics. FDA also has responsibility for regulating the manufacturing, marketing and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. To accomplish its mission, FDA must stay abreast of the latest developments in research and communicate with stakeholders about complex scientific and public health issues. Increased development of research, education and outreach partnerships within the [insert name of participate in party] will greatly contribute to FDA's mission.

[Insert description of participating party as relevant to this MOU.]

IV. Substance of Agreement: Provide a comprehensive description of programs to be implemented and areas to be addressed in the MOU.

V. General Provisions: Include the applicable statements in the MOU:

Printed and online Web pages containing FDA Consumer Health Information must be free of advertisements to avoid implying FDA's endorsement or support for a particular product, service or Web site.

Attachment D (Cooperation in Disseminating Health Information) – Use for MOUs with outside organizations to spread FDA's public health messages (print and web partnerships).

All activities within the scope of this Agreement must comply with Section 508 of the Rehabilitation Act (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 (P.L. 105-220), August 7, 1998 (see HHS policy on Section 508 compliance at http://www.hhs.gov/od/508policy/index.html); and Office of Management and Budget (OMB) policies for protecting private information (see www.usa.gov/webcontent/reqs_bestpractices/laws_regs/privacys.html).

FDA and [Insert Name of Participating Partner(s)] will cooperate in maintenance of each Partner(s)'s trademarks and logos. The FDA will not permit use of its logo for marketing purposes other than to promote the Program. The use of FDA names or logos shall not imply any exclusive arrangement. Any use of FDA logos must be approved, in advance, by FDA's Consumer Health Information Staff and adhere to published FDA logo policies (see http://www.fda.gov/graphics/FDAlogos1999/).

Subject to the terms and conditions of this Section and FDA's compliance with its obligations under this MOU, [insert name of partner] grants FDA a revocable, non-exclusive license to use the [insert name of partner]'s name, its service marks, trademarks, or logos (collectively, "Marks") solely for the purposes set forth in this MOU. All rights licensed to FDA under this subsection shall be revoked upon terminating this MOU.

Both Partner(s) agree that information FDA provides to [insert name of partner] shall be public domain material. FDA shall have full rights to reuse the content for all FDA purposes and the right to share with other collaborators or requestors.

[For agreements with Web partners:] [Web Partner] agrees to maintain links to current FDA Information within the Program activities and components. Links to FDA information must be removed in the following circumstances: (1) within a reasonable time three (3) years following the date of its first publication of the linked item of content; (2) upon termination of this MOU, if the MOU terminates less than three (3) years after the material is posted; (3) within a reasonable time upon FDA's request in circumstances in which the linked information becomes revised or outdated; or (4) as soon as commercially practicable but no longer than 72 hours after receipt of a written request from FDA to remove links to material, regardless of reason. [Web Partner] failure to display current links FDA Information may result in terminating this MOU.

This MOU does not and is not intended to transfer to either Partner(s) any rights in any technology or intellectual property.

Attachment D (Cooperation in Disseminating Health Information) – Use for MOUs with outside organizations to spread FDA's public health messages (print and web partnerships).

VI. Representations and Warranties

The Partner(s) have all licenses, right, title and interest necessary to enter and perform their respective obligations under this MOU.

Neither the goods, nor the services nor any other material or thing provided to one Partner(s) by or for the other by this MOU will infringe or violate any intellectual property, proprietary or other right of any third-Partner(s).

VII. Links

FDA and [Web Partner] will provide inbound and outbound links to and from the Program and the FDA's Web page.'

FDA will not provide [Web Partner] access to any document or information that by providing such access would place the FDA in breach of the Trade Secrets Act, codified at 18 U.S.C. sec. 1905; the Privacy Act, codified at 5 U.S.C. sec. 552a; the Federal Food, Drug, and Cosmetic Act, codified at 21 U.S.C. sec. 301, et seq (particularly 21 U.S.C. sec. 331(j)); FDA regulations (21 Code of Federal Regulations (CFR)); or any other Federal law or regulation.

VIII. Liaison Officers

A. For the (Partner(s)):

Individual's name: (optional)

Organization:

Title:

Address:

Telephone Number:

B. For the Food and Drug Administration:

Individual's name: (optional)

Organization:

Title:

Address:

Telephone Number:

Each Party may designate new liaisons at any time by notifying the other Party's administrative liaison in writing. If, at any time, an individual designated as a liaison under this agreement becomes unavailable to fulfill those functions, the Parties will name a new liaison within 2 weeks and notify the other Party through the designated administrative liaison.

IX. Length of the Agreements

Term, Termination, and Modification: This MOU, when accepted by all participating Partner(s), will have an effective period of performance from the date of the latest signature until three (3) years from the date of signature by the later Partner(s) to sign it. This MOU may be modified or terminated by mutual written consent by both Partner(s) or may be terminated by either Partner(s) upon a 60- day advance written notice to the other.

X. Resource Obligations

This MOU represents the broad outline of the Partner(s)' present intent to enter specific agreements for collaborative efforts in intellectual areas of mutual interest to FDA and the participating (Partner(s)). All activities undertaken through the MOU are subject to available of personnel, resources, and funds. This MOU does not create binding, enforceable obligations against any Party. This MOU and all associated agreements will be subject to the applicable policies, rules, regulations, and statutes under which FDA and the participating (Partner(s)) operate.

XI. Limitations on Liability

In no event will either partner(s) be liable to the other under any theory of liability, however, arising, or for any costs of cover or for indirect, special, incidental, or consequential damages arising out of this MOU. The provisions of this Section XI shall survive termination, cancellation or expiration of this MOU or any reason whatsoever.

Attachment D (Cooperation in Disseminating Health Information) – Use for MOUs with outside organizations to spread FDA's public health messages (print and web partnerships).

XII. Signatures of Responsible Partner(s)

By signing this MOU, the responsible Partner(s) agree to the terms and conditions of this MOU, and they further agree to adhere to FDA's policy statement on co-branding.

APPROVED AND ACCEPTED FOR (Partner(s)) By _____ Title _____ _____ Date _____	APPROVED AND ACCEPTED FOR FOOD AND DRUG ADMINISTRATION By _____ Title _____ _____ Date _____

Attachment E (Information Technology) – Use for MOUs with nonprofit organizations or sister agencies, such as the National Cancer Institute or the National Institutes of Health, involving information technology systems, e.g., shared electronic infrastructure.

MOU Control No. (Insert Number)

MEMORANDUM OF UNDERSTANDING BETWEEN THE

(Insert Name of Domestic Participating Partner(s))

AND

THE FOOD AND DRUG ADMINISTRATION

I. Preamble: (Optional: Describe respective missions and mutual objectives of Partner(s))

II. Purpose: (Describe specific purpose of the MOU)

III. Authority: Describe the agency's legal authority to take the actions described in the MOU

IV. Substance of Agreement: (Provide a comprehensive description of programs to be implemented and areas to be addressed. Include applicable information:

1. Description of research, training, educational activities

2. Roles and responsibilities of the Partner(s)

VI. General Provisions: (Include the applicable information in the MOU):

Conflict of Interest:

Participants in activities under this MOU who are not U.S. Government employees will be expected to abide by conflict of interest rules and policies as specified by FDA. This may require participants to disclose their financial holdings and those of their spouse and minor children, and may limit their ability to accept gifts and have employment with entities that are substantially regulated by FDA. The Partner(s) will be advised of any potential conflict so conflicting assignments can be avoided consistent with the HHS/FDA requirements. If before or during the performance of the activities under the MOU, the Partner(s) believe that a potential or actual conflict exists; the Partner(s) must notify the appropriate authorities within their respective institutions and contact the designated FDA official listed on the MOU so that the necessary action/s can be undertaken. A determination will be made by FDA on whether a conflict of interest exists and, if so, as to how to resolve or mitigate it. Partner(s) to the MOU shall avoid activities or relationships that would cause a reasonable person to question the impartiality of their actions.

Funds (when participating Partner(s) is a Federal agency): None of the activities outlined in this memorandum currently requires the exchange of funds between (Partner(s)) and FDA. If transfer of funds is deemed to be required in the future, the Partner(s) may enter an interagency agreement by Section 601 of the Economy Act of 1932, as amended (31 U.S.C. 1535).

Information sharing (when participating Partner(s) is a Federal agency): FDA shall determine, by applicable law, whether to disclose information that will be available in the (information technology system covered by the MOU). If (Partner(s)) receives a request, order, or demand for FDA records, including a request under the Freedom of Information Act, 5 U.S.C. 552, (Partner(s)) will refer that request to FDA for response." Attachments A1 and A2 apply.

VII. Resource Obligations: This MOU represents the broad outline of the Partner(s)' present intent to enter specific agreements for collaborative efforts in intellectual areas of mutual interest to FDA and the participating Partner(s). All activities undertaken by this MOU are subject to available personnel, resources, and funds. This MOU does not affect or supersede any existing or future agreements or arrangements among the Partner(s). This MOU does not create binding, enforceable obligations against any Party. This MOU and all associated agreements will be subject to the applicable policies, rules, regulations, and statutes under which FDA and the participating Partner(s) operate.

VIII. Liaison Officers: (Provide names, titles, addresses, and phone numbers)

A. For the (Partner(s) :

Individual's name: (optional)

Organization:

Title:

Address:

Telephone Number:

Email Address:

B. For the Food and Drug Administration:

Individual's name: (optional)

Attachment E (Information Technology) – Use for MOUs with nonprofit organizations or sister agencies, such as the National Cancer Institute or the National Institutes of Health, involving information technology systems, e.g., shared electronic infrastructure.

Organization:

Title:

Address:

Telephone Number:

Email Address:

Each Party may designate new liaisons at any time by notifying the other Party's administrative liaison in writing. If, at any time, an individual designated as a liaison under this agreement becomes unavailable to fulfill those functions, the Parties will name a new liaison within 2 weeks and notify the other Party through the designated administrative liaison.

V. Terms, Termination and Modification: “This agreement, when accepted by all partners, will have an effective period of performance from the date of the latest signature until _____ and may be modified or terminated by mutual written consent the partners or may be terminated by either Partner(s) upon a _____ day advance written notice to the other.”

"If there is no expiration date for the MOU, state, “This agreement will be effective when accepted by all participating partners. This agreement may be modified or terminated by mutual written consent by the partners or may be terminated by either Partner(s) upon a _____ day advance written notice to the other.”

APPROVED AND ACCEPTED FOR (Partner(s))	APPROVED AND ACCEPTED FOR FOOD AND DRUG ADMINISTRATION
By _____	By _____
Title _____	Title _____
_____	_____
Date _____	Date _____

Attachment F (Fellowship Programs) – Use for MOUs with academic or Federal agencies that establish or address fellowship programs.

MOU Control No. (INSERT)

MEMORANDUM OF UNDERSTANDING BETWEEN THE

(Insert Name of Domestic Participating Partner(s))

AND

THE FOOD AND DRUG ADMINISTRATION

I. Preamble: (Optional: Describe respective missions and mutual objectives of Partner(s))

II. Purpose: (Describe specific purpose of the MOU)

III. Background: (FDA is authorized to enforce the Federal Food, Drug, and Cosmetic Act (the Act) as amended (21 U.S.C. 301, et seq.). In fulfilling its responsibilities under the Act, FDA, among other things, directs its activities toward promoting and protecting the public health by assuring the safety, efficacy, and security of drugs, veterinary products, medical devices and radiological products and the safety and security of foods, dietary supplements, and cosmetics. FDA also has responsibility for regulating the manufacturing, marketing and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. To accomplish its mission, FDA must stay abreast of the latest developments in research and communicate with stakeholders about complex scientific and public health issues. Increased development of research, education and outreach partnerships within the [insert name of participate in party] will greatly contribute to FDA's mission.

[Insert description of participating party as relevant to this MOU.]

IV. Substance of Agreement: (Provide a comprehensive description of programs to be implemented and areas to be addressed. Include applicable information:

1. Description of research, training, and educational activities

2. Roles and responsibilities of the Partner(s)

V. General Provisions: (Include the applicable information in the MOU):

- Conflict of Interest: Participants in activities under this MOU who are not U.S. Government employees will be expected to abide by conflict of interest rules and policies as specified by FDA. This ay require participants to disclose their financial holdings and t hose of their spouse and minor children, and may limit their ability to accept gifts and have

employment with entities that are substantially regulated by FDA. The Partner(s) will be advised of any potential conflict so conflicting assignments can be avoided consistent with the HHS/FDA requirements. If before or during the performance of the activities under the MOU, the Partner(s) believe that a potential or actual conflict exists, the Partner(s) must notify the appropriate authorities within their respective institutions and contact the designated FDA officials listed on the MOU so the necessary action/s can be undertaken. A determination will be made by FDA on whether a conflict of interest exists and, if so, as to how to resolve or mitigate it. Partner(s) to the MOU will make shall avoid activities or relationships that would cause a reasonable person to question the impartiality of their actions.

- Funds (when participating Partner(s) is a Federal agency): " None of the activities outlined in this memorandum currently requires the exchange of funds between [Partner(s)] and FDA. In the event the transfer of funds is deemed to be required in the future, the parties may enter an interagency agreement by Section 601 of the Economy Act of 1932, as amended (31 U.S.C. 1535)."

- Liability: While assigned to the program and while performing duties pursuant to this memorandum, FDA employees perform duties within the course and scope of the Federal employment. Consequently, the provisions of the Federal Tort Claims Act (28 U.S.C. 1346(b), 2671-2680), including its defenses and immunities, will apply to allegations of negligence or wrongful acts or omissions by FDA employees while they are acting within the scope of their duties by this memorandum.

- Disqualification: Participants in this program will not be permitted to serve on FDA advisory panels reviewing a product for which they provided consultative or review services. Participants will agree that they will be disqualified from any FDA decisions regarding approval of products that result directly from activities conducted under this MOU. The statutory provisions about former and post federal employment restrictions will apply to the participants in this program.

- Citizenship and security clearance: (Insert Name of Participating Partner(s)) individuals participating in the MOU will be United States citizens or permanent residents. Regarding the latter, all federal restrictions will be adhered to. Information may be obtained from participants by the agency for security clearance or access to FDA facilities and offices. Information obtained may be shared with other Federal agencies for the above purposes and in fulfillment of official responsibilities as disclosure is permitted by law.

Attachment F (Fellowship Programs) – Use for MOUs with academic or Federal agencies that establish or address fellowship programs.

- Protection of nonpublic information: "Residents, fellows, faculty and students appointed to a position at FDA will be required to sign a Commitment to Protect Nonpublic Information agreement. When access to privileged information in the files of the Food and Drug Administration is required in performing official duties, the Partner(s) will agree and certify in writing that they shall not further release, publish, or disclose such information and that they shall protect such information by the provisions of 21 U.S.C. 331(j), 21 U.S.C. 360j(c), 18 U.S.C. 1905, and other pertinent laws and regulations governing the confidentiality of privileged information.

- Intellectual Property Guidelines: “Invention” refers to any subject matter or discovery patentable under Title 35 of the United States Code and conceived or first reduced to practice under the activities of the MOU. “Intellectual Property” refers to patents, patent applications, know-how, trade secrets, copyrights and computer programs either use or developed under the activities of the MOU. Rights to Inventions or Intellectual Property developed under the MOU will be addressed in separate project-specific development and implementation agreements among the Parties. Inventorship will be governed by U.S. law. In the case of sole inventorship, ownership will be governed by the policies of the employer of the Invention. In the case of joint Inventorship, ownership of Inventions will be jointly owned. Inventions made under a Federal grant or contract will be subject to the Bayh-Dole Act. Accordingly, all GULC employees who work on any project under this MOU shall be required to sign an agreement that effects a present assignment of their future inventions to GULC. No Party, by virtue of their participation in activities under the MOU, will be required to disclose or license intellectual property to the other Party.”

VI. Resource Obligations: This MOU represents the broad outline of the Partner(s)’ present intent to enter specific agreements for collaborative efforts in intellectual areas of mutual interest to FDA and the participating Partner(s). All activities undertaken pursuant to the MOU are subject to available personnel, resources, and funds. This MOU does not affect or supersede any existing or future agreements or arrangements among the Partner(s). This MOU does not create binding, enforceable obligations against any Party. This MOU and all associated agreements will be subject to the applicable policies, rules, regulations, and statutes under which FDA and the participating Partner(s) [INSERT NAME] operate.

VII. Liaison Officers: (Provide names, titles, addresses, and phone numbers)

A. For the (Partner(s)):

Individual's name: (optional)

Organization:

Title:

Address:

Telephone Number:

B. For the Food and Drug Administration:

Individual's name: (optional)

Organization:

Title:

Address:

Telephone Number:

Each Party may designate new liaisons at any time by notifying the other Party's administrative liaison in writing. If, at any time, an individual designated as a liaison under this agreement becomes unavailable to fulfill those functions, the Parties will name a new liaison within 2 weeks and notify the other Party through the designated administrative liaison.

VIII. Terms, Termination and Modification: "This agreement, when accepted by all partners, will have an effective period of performance from the date of the latest signature until _____ and may be modified or terminated by mutual written consent the partners or may be terminated by either Partner(s) upon a _____ day advance written notice to the other."

Attachment F (Fellowship Programs) – Use for MOUs with academic or Federal agencies that establish or address fellowship programs.

If there is no expiration date for the MOU, state, “This agreement will be effective when accepted by all participating partners. This agreement may be modified or terminated by mutual written consent by the partners or may be terminated by either Partner(s) upon a _____ day advance written notice to the other.”

APPROVED AND ACCEPTED FOR (Partner(s)) By _____ Title _____ _____ Date _____	APPROVED AND ACCEPTED FOR FOOD AND DRUG ADMINISTRATION By _____ Title _____ _____ Date _____