

MOU 225-18-017

**MEMORANDUM OF UNDERSTANDING
Between the
FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
and the
NATIONAL INSTITUTES OF HEALTH
NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE**

I. PURPOSE

This Memorandum of Understanding (MOU) between the Food and Drug Administration/Center for Biologics Evaluation and Research (FDA/CBER) and the National Institutes of Health/National Institute of Neurological Disorders and Stroke (NIH/NINDS), each referred to as a "Party" and collectively referred to as "the Parties," provides a framework for coordination and collaborative efforts between these two entities, which are both components of the Department of Health and Human Services. This MOU also provides the principles and procedures by which information sharing between FDA/CBER and NIH/NINDS units shall take place.

II. BACKGROUND

FDA and NIH are sister agencies within the Department of Health and Human Services. Both FDA and NIH exist and work to protect the public health but have different statutory mandates and responsibilities.

FDA is a science-based regulatory agency authorized to enforce the Federal Food, Drug, and Cosmetic Act (the Act). 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. Within FDA, CBER's mission is to protect and enhance the public health through regulation of biological, device and combination products according to statutory authorities. The regulation of these products is founded on science and law to ensure their purity, potency, safety, and efficacy.

NIH is the Federal focal point for biomedical research in the United States. The NIH mission is to uncover new knowledge that will lead to better health for everyone. NIH works toward that mission by conducting research in its own laboratories; supporting the research of non-Federal scientists in universities, medical schools, hospitals and research institutions throughout the country and abroad; helping in the training of research investigators; and fostering communication of medical information. Within NIH, NINDS is the nation's leading supporter of biomedical research on disorders of the brain and nervous system. The mission of NINDS is to

reduce the burden of neurological disease. To achieve this mission, NINDS conducts, fosters, coordinates and guides research on the causes, prevention, diagnosis and treatment of neurological disorders and stroke, including basic research in related scientific areas. NIH's and FDA's respective missions to protect the public health are complementary and may overlap depending upon the subject matter. The agencies work collaboratively to protect and improve public health. Sometimes FDA/CBER or NIH/NINDS may have information that could be useful to the other unit in that unit's performance of its responsibilities. Timely sharing of information between NIH/NINDS and FDA/CBER is therefore critical to protect and improve the public health.

III. SUBSTANCE OF AGREEMENT AND RESPONSIBILITIES OF EACH AGENCY

A. Coordination and Collaboration Relative to Public Health Activities

It is mutually agreed that, on an as needed basis and as resources permit:

1. FDA/CBER and NIH/NINDS will coordinate and collaborate with each other to protect and improve the public health. To achieve this, each Party will capitalize on the expertise, resources, and relationships of the other in order to increase its own capability and readiness to respond to situations. In addition, each Party will designate central contact points¹ to coordinate communications from the other, dealing with matters covered by this agreement.
2. Each Party will participate in periodic meetings to promote better communication and understanding of regulations, policies, and statutory responsibilities, and to serve as a forum for questions and problems that may arise.
3. Each Party may notify the other when issues of mutual concern become evident to the extent such notification does not interfere with the public health, oversight, enforcement, or compliance responsibilities of the notifying agency.
4. Parties will present reciprocal in-house presentations to their corresponding staff on topics of common interest such as FDA's managed regulatory review process and NIH/NINDS's extramural, federally-funded translational research initiatives and programs, specifically those applicable to development of biologic therapies for treatment of neurologic diseases, conditions and disorders.
5. Where appropriate, FDA/CBER will provide relevant reference documents that describe the investigational product review process and marketing approval processes for use by NIH/NINDS staff involved in conferring with prospective translational research grantees to assist in the design and implementation of clinical studies that follow FDA/CBER guidance and regulations.

¹ See section V. of this MOU.

6. FDA/CBER and NIH/NINDS MOU Parties will seek opportunities to work collaboratively together to improve efficiency of the submission and review process for clinical investigator applications requesting funding from NIH/NINDS and that may require submission of an Investigational New Drug (IND) application to FDA/CBER.
7. Parties will promote communication and consultation on select policy issues and guidance documents of particular interest and relevance to researchers, consumers and/or health care professionals pertaining to novel cellular or gene transfer therapies. This cooperative interaction will target possible health risk posed to the public as well as address research and regulatory processes affecting the pace of bench top to bedside research translation. As an example, during drafting of policy documents such as FDA Guidance for Industry or NIH Points-to-Consider that apply to cellular/tissue-based or gene transfer therapies, each Party is encouraged to seek input from its counterpart in order that appropriate modifications to draft documents may be made prior to initiation of a formal clearance process.
8. NIH/NINDS will invite FDA/CBER input and recommendations during development of Funding Opportunity Announcements targeting relevant, essential research areas in order to foster and support development of biologic tissue, cellular, and gene transfer products for treating neurologic disease.
9. As appropriate, FDA/CBER will invite participation of NIH/NINDS experts in pre-decisional evaluation of selected INDs that seek FDA/CBER permission to initiate clinical studies involving novel cellular/tissue and gene transfer products whose scientific and clinical aspects may be complex and non-conventional.
10. NIH/NINDS will provide opportunity for FDA/CBER staff to participate in NIH/NINDS-sponsored conferences that pertain to development of cellular and gene transfer products. FDA/CBER contributions may include: (1) participation in workshops, (2) individual presentations, and (3) use of existing videotaped FDA conferences/workshops on selected regulatory policy and process issues.
11. This MOU does not preclude NIH/NINDS or FDA/CBER from entering into other agreements that may enable special programs to be handled more efficiently and expertly.

B. Principles and Procedures for the Sharing of Non-Public Information

FDA/CBER and NIH/NINDS agree that the following principles and procedures will govern the sharing of non-public information, as resources permit, between the two parties.

Although there is no legal requirement that FDA/CBER and NIH/NINDS exchange information in all areas, the parties agree that there should be a presumption in favor of full and free sharing of information between FDA/CBER and NIH/NINDS. As public health agencies within the Department of Health and Human Services, there are no legal prohibitions that preclude FDA or the NIH from sharing with each other most information in the possession of either agency. Both parties recognize and acknowledge, however, that it is essential that any non-public information that is shared between FDA/CBER and NIH/NINDS whether written or oral must be protected from any disclosure that is not authorized by law or regulation. See e.g., 21 U.S.C. § 331(j), 18 U.S.C. § 1905, 21 CFR Parts 20 and 21, 45 CFR Parts 5 and 5b, and 42 U.S.C. § 241(d). Safeguards are needed to protect non-public information shared, both written and oral, 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. The sharing of national security information is not contemplated by this MOU. Such safeguards also help ensure FDA/CBER's and NIH/NINDS's compliance with applicable laws and regulations.

To facilitate the sharing of non-public information, written or oral, FDA/CBER and NIH/NINDS will implement procedures to ensure that such sharing is appropriate and that the recipient party will guard the confidentiality of all information received.² 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 or agency policy and practice. The party receiving shared non-public information (requesting party), whether written or oral, will be responsible for protecting that information from any unauthorized disclosure. Provisions for sharing of non-public information, both written and oral, in accordance with applicable statutes or regulations are set out below:

1. The requesting party must specify, in writing³, the information requested (to facilitate identification of relevant information), provide a brief statement of why the information is needed, and include the following requesting party template language: “This request is made pursuant to the Memorandum of Understanding for Sharing of Non-Public Information between FDA/CBER and NIH/NINDS, dated [insert date agreement was signed]. [Requesting party] agrees not to disclose any non-public

² Each party has implemented or will implement the agency's data and information security statutory, regulatory, policy, or procedural requirements and has implemented or will implement, to the extent necessary and practicable, all data and information security recommendations suggested by the other agency.

³ The term “writing” used throughout this MOU includes writing by electronic means.

information shared between FDA/CBER and NIH/NINDS whether orally or in writing, in any manner.” This request shall state which internal unit offices and/or individuals are requesting the information.

2. The party receiving the request (sharing party) will determine, based upon the request described in section III.B.1 above, whether it is appropriate and practicable to share the requested non-public information.
3. 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 and/or have a need to know. The unit official who signs the request letter shall be responsible for ensuring information is not distributed to inappropriate recipients.
 - b. The requesting party will agree in writing not to disclose any shared non-public information in any manner not authorized by law or regulation, including disclosure in publications and public meetings, or in the context of other agency collaborations. If the requesting party wishes to disclose shared information that the sharing unit 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 the shared information, it shall: (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 releasability 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. According, the requesting will not indicate to the FOIA requester whether the sharing party has responsive records or releasable records.
 - c. 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.
 - d. 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.
4. The sharing party will include a response in writing along with any agency

information shared. The response will indicate the type of information (e.g., confidential commercial information, personal privacy, pre-decisional, etc.), and will include the following sharing party template language: "Pursuant to the Memorandum of Understanding for Sharing of Non-Public Information between the FDA/CBER and NIH/NINDS, dated [insert date agreement was signed], the non-public information provided in this communication may not be disclosed or shared in any manner." Any shared documents containing non-public information should be stamped "Do not disclose or further distribute."

IV. NAME AND ADDRESS OF PARTICIPATING PARTIES

Food and Drug Administration
Center for Biologics Evaluation and Research
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Telephone: 800-835-4709 or 240-402-8010

National Institutes of Health
National Institute of Neurological Disorders and Stroke
Building 31, Room 8A52
31 Center Drive MSC 2450
Bethesda, MD 20892-2540
Telephone: (301) 496-3167
Fax: (301) 496-0296

V. LIAISON OFFICERS

Liaison Officers will participate in the management, coordination and oversight of this agreement. The Liaison Officers will constitute a Steering Committee comprised of an equal number of member representatives from the FDA/CBER and the NIH/NINDS. Two Liaison Officers, one designate from each participating agency, will serve as co-chairs of the Committee.

Member appointments shall be authorized by the signatories to this agreement. The Liaison Officer Steering Committee shall meet at least once every six months for the first year of this agreement and then once annually thereafter to review the progress of this agreement, resolve any issues and disputes that may arise and oversee necessary modifications to the agreement.

A. For FDA/CBER

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B. For NIH/NINDS

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Director, Division of Translational Research
National Institute of Neurological Disorders and Stroke

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Linda McGavern, Ph.D.
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National Institute of Neurological Disorders and Stroke
National Institutes of Health
Neuroscience Center, 6001 Executive Blvd., Room 2118
Bethesda, MD 20892
Telephone: (301) 435-4909
Email: mcgavernlm@ninds.nih.gov

VI. PERIOD OF AGREEMENT

This agreement became effective on February 12, 2002, and shall continue in effect until February 11, 2023, as modified herein and pursuant to the attached summary of all modifications or terminated by either party upon a ninety (90) day advance written notice to the other party. Not later than 120 days prior to the expiration of this agreement, each Party will provide a recommendation regarding the extension of the agreement, including modifications if any.

SUMMARY OF RENEWAL EXTENSIONS

RENEWAL EXTENSION 1

An extension of twelve (12) months is added to the period of agreement; therefore, section VI. PERIOD OF AGREEMENT is modified to read as follows:

This agreement became effective on February 12, 2002, and shall continue in effect until February 11, 2008, unless modified by mutual written consent of both parties or terminated by either party upon a ninety (90) day advance written notice to the other party.

RENEWAL EXTENSION 2

An extension of five (5) years is added to the period of agreement which has been extended once previously for a period of twelve (12) months. Therefore, section VI. PERIOD OF AGREEMENT is modified to read as follows:

This agreement became effective on February 12, 2002, and as of this Modification 2, shall continue in effect until February 11, 2013, unless modified by mutual written consent of both parties or terminated by either party upon a ninety (90) day advance written notice to the other party.

RENEWAL EXTENSION 3

Present extension of five (5) years is added to the period of agreement, which has been extended twice previously, initially for a period of twelve (12) months and most recently for a period of five (5) years. Therefore, section VI. PERIOD OF AGREEMENT is modified to read as follows:

This agreement became effective on February 12, 2002, and shall continue in effect until February 11, 2018, as modified herein and pursuant to the attached summary of all modifications or terminated by either party upon a ninety (90) day advance written notice to the other party.

Previously, this agreement included an Implementation Work Plan as an appendix. Key elements of the Implementation Work Plan are now listed under section III.A. Coordination and Collaboration Relative to Public Health Activities. The agreement no longer includes an Implementation Work Plan appendix.

RENEWAL EXTENSION 4

Present extension of five (5) years is added to the period of agreement, which has been extended three times, previously, initially for a period of twelve (12) months and most recently for a period of five (5) years. Therefore, section VI. PERIOD OF AGREEMENT is modified to read

as follows:

This agreement became effective on February 12, 2002, and shall continue in effect until February 11, 2023, as modified herein and pursuant to the attached summary of all modifications or terminated by either party upon a ninety (90) day advance written notice to the other party.

This agreement has been updated, administratively, to reflect changes to Liaison Officers and their contact information (Section V) as well as a change in authorizing signatories for each party of the agreement, NIH/NINDS and FDA/CBER (page 11).

APPROVED AND ACCEPTED FOR
NATIONAL INSTITUTES OF HEALTH
National Institute of Neurological
Disorders and Stroke

By:  _____

Walter Koroshetz, M.D.
Director
National Institute of
Neurological Disorders and Stroke
National Institutes of Health

APPROVED AND ACCEPTED FOR THE
THE FOOD AND DRUG ADMINISTRATION
Center for Biologics Evaluation and Research

By: **Peter W.
Marks -S** _____
Digitally signed by Peter W. Marks -S
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People, cn=Peter W. Marks
-S,
0.9.2342.19200300.100.1.1-2009932716
Date: 2018.05.03 16:40:03 -0400

Peter Marks, M.D., Ph.D.
Director
Center for Biologics Evaluation and
Research
Food and Drug Administration

Date: **May 3, 2018**

Date: **May 3, 2018**

ATTACHMENTS:

- Model Request Letter for FDA/CBER
- Model Request Letter for NIH/NINDS
- Model Transmittal Letter: NIH/NINDS to FDA/CBER
- Model Transmittal Letter: FDA/CBER to NIH/NINDS

ATTACHMENTS

Model Language for Request from FDA/CBER

The Food and Drug Administration/Center for Biologics Evaluation and Research (FDA/CBER) requests the following information from the National Institutes of Health, National Institute of Neurological Disorders and Stroke (NIH/NINDS) for the following purposes: *[Identify information and purpose]*

FDA/CBER agrees that it will not disclose any information that NIH/NINDS shares with it and designates non-public without prior written permission from NIH/NINDS and that FDA/CBER will comply with the principles and procedures set forth in the Memorandum of Understanding on information sharing between FDA/CBER and NIH/NINDS dated *[Insert date MOU between FDA/CBER and NIH/NINDS initiated]*. FDA/CBER acknowledges that applicable laws and regulations may govern the disclosure of such information. See e.g., 21 U.S.C. § 331(j), 18 U.S.C. § 1905, 21 CFR Parts 20 and 21, 45 CFR Parts 5 and 5b, and 42 U.S.C. § 241(d).

FDA/CBER will limit dissemination of any shared information to the following FDA/CBER offices and/or employees, unless it identifies additional FDA/CBER employees who have a need to know the non-public information: [Identify office(s) and/or employee(s)]

Name

Date

[Signature and Date by FDA/CBER official with requisite responsibility and authority.]

Model Language for Request from NIH/NINDS

The National Institutes of Health/National Institute of Neurological Disorders and Stroke (NIH/NINDS) requests the following information from the Food and Drug Administration/Center for Biologics Research and Review (FDA/CBER) that for the following purposes: *[Identify information and purpose]*

NIH/NINDS agrees that it will not disclose any information that FDA/CBER shares with it and designates nonpublic without prior written permission from FDA/CBER and that NIH/NINDS will comply with the principles and procedures set forth in the Memorandum of Understanding on information sharing between NIH/NINDS and FDA/CBER dated _____.

NIH/NINDS acknowledges that applicable laws and regulations may govern the disclosure of such information. See e.g., 21 U.S.C. § 331(j), 18 U.S.C. § 1905, 21 CFR Parts 20 and 21, 45 CFR Parts 5 and 5b, and 42 U.S.C. § 241(d).

NIH/NINDS will limit dissemination of any shared information to the following NIH/NINDS offices and/or employees, unless it identifies additional NIH/NINDS employees who have a need to know the non-public information: *[Identify office(s) and/or employee(s)]*

Name

Date

[Signature and Date by NIH/NINDS official with requisite responsibility and authority.]

Model Transmittal letter from NIH/NINDS to FDA/CBER

This letter accompanies information that the National Institutes of Health/National Institute for Neurological Disorders and Stroke (NIH/NINDS) is sharing with the Food and Drug Administration/Center for Biologics Evaluation and Research (FDA/CBER) in response to FDA/CBER's request, dated _____. This information contains one or more of the following categories of non-public information, including information the disclosure of which may be prohibited by law:

[NIH/NINDS checks applicable numbers below]

- confidential research proposals, progress reports, and/or unpublished data;
- privileged or pre-decisional agency information;
- trade secrets;
- confidential commercial or financial information;
- information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;
- information contained in records subject to the Privacy Act;
- information contained in the inter-agency or intra-agency memoranda;
- records or information compiled for law enforcement purposes; or
- other (explain).

FDA/CBER shall notify the contact person or designee of NIH/NINDS if there are any attempts to obtain such shared non-public information by compulsory process, including, but not limited to, Freedom of Information Act requests, subpoenas, discovery requests, and litigation complaints or motions.

FDA/CBER shall notify NIH/NINDS before complying with any judicial order that compels the release of such shared non-public information so that FDA/CBER and/or NIH/NINDS may take appropriate measures, including filing a motion with the court or an appeal.

By a signed request letter dated _____, FDA/CBER has agreed not to disclose the above-described shared non-public information without prior written permission of NIH/NINDS. FDA/CBER has acknowledged that applicable laws and regulations may govern the disclosure of such information. See e.g., 21 U.S.C. § 331(j), 18 U.S.C. § 1905, 21 CFR Parts 20 and 21, 45 CFR Parts 5 and 5b, and 42 U.S.C. § 241(d).

FDA/CBER has also agreed to comply with the principles and procedures set forth in the Memorandum of Understanding on information sharing between FDA/CBER and NIH/NINDS, dated _____.

Model Transmittal letter from FDA/CBER to NIH/NINDS

This letter accompanies information that the Food and Drug Administration/Center for Biologics Evaluation and Research (FDA/CBER) is sharing with the National Institutes of Health/National Institute for Neurological Disorders and Stroke (NIH/NINDS) in response to NIH/NINDS's request, dated _____. This information contains one or more of the following categories of non-public information, including information the disclosure of which may be prohibited by law:

[FDA/CBER checks applicable numbers below]

- trade secrets;
- confidential commercial or financial information;
- information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy
- information contained in records subject to the Privacy Act;
- information contained in inter-agency or intra-agency memoranda;
- records or information compiled for law enforcement purposes; or

- other (explain).

NIH/NINDS shall notify the contact person or designee of FDA/CBER if there are any attempts to obtain such shared non-public information by compulsory process, including, but not limited to, Freedom of Information Act requests, subpoenas, discovery requests, and litigation complaints or motions.

NIH/NINDS shall notify FDA/CBER before complying with any judicial order that compels the release of such shared non-public information, so that FDA/CBER and/or NIH/NINDS may take appropriate measures, including filing a motion with the court or an appeal.

By a signed request letter dated _____, NIH/NINDS has agreed not to disclose the above-described shared non-public information without prior written permission of FDA/CBER. NIH/NINDS has acknowledged that applicable laws and regulations may govern the disclosure of such information. See e.g., 21 U.S.C. § 331(j), 18 U.S.C. § 1905, 21 CFR Parts 20 and 21, 45 CFR Parts 5 and 5b, and 42 U.S.C. § 241(d). NIH/NINDS has also agreed to comply with the principles and procedures set forth in the Memorandum of Understanding on information between FDA/CBER and NIH/NINDS, dated _____.