MOU 225-13-0028

MEMORANDUM OF UNDERSTANDING CONCERNING
INFORMATION-SHARING EXCHANGES INVOLVING FDA
AMONG AGENCIES PARTICIPATING IN THE
PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURE ENTERPRISE (PHEMCE)
OFFICES AND AGENCIES OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES:
OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE
CENTERS FOR DISEASE CONTROL AND PREVENTION
NATIONAL INSTITUTES OF HEALTH
FOOD AND DRUG ADMINISTRATION AND
THE DEPARTMENT OF DEFENSE
THE DEPARTMENT OF HOMELAND SECURITY
THE DEPARTMENT OF VETERANS AFFAIRS
THE DEPARTMENT OF AGRICULTURE

Preamble:

The Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) is a coordinated interagency effort which is responsible for, *inter alia*, focusing research, development, and procurement activities to provide medical countermeasures that will be safe and effective for use in the event of a public health or medical emergency. The PHEMCE is led by the Office of the Assistant Secretary for Preparedness and Response (ASPR) of the Department of Health and Human Services (HHS) and includes three primary HHS internal agencies: the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the National Institutes of Health (NIH). The Biomedical Advanced Research and Development Authority (BARDA) is also established within ASPR. The PHEMCE also includes other key federal partners: the Department of Homeland Security (DHS), the Department of Defense (DoD), including certain constituent components specified herein, the Department of Veterans Affairs (VA), and the Department of Agriculture. These offices, agencies, and Departments are thus considered and hereafter referred to in this document as PHEMCE Partners or Partners.

I. Purpose:

To promote efficiency and collaboration among and between FDA and PHEMCE Partners, by facilitating efforts to:

- Build a framework and processes that meet common needs for considering issues relating to the safety, efficacy, and utilization of drugs, biologics, and medical devices for use in emergencies, including response preparedness and planning.
- Further enhance efforts to share information and expertise through more efficient and robust inter-agency activities.
- Identify and develop enabling scientific tools and technologies that will support the ultimate development of useful medical products.
- Develop safe and effective medical countermeasures.

- Clarify FDA requirements applicable to medical countermeasure initiatives that are being sponsored by PHEMCE Partners.
- Exchange and share related information concerning medical and pharmaceutical countermeasures in real time or electronically in multiple media.
- Maintain appropriate, robust information and data security standards and practices.

II. Authority:

FDA has authority to enter into this agreement pursuant to sections 1003(b) and (c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. §§ 393(b) and (c)).

ASPR has authority to enter into this agreement pursuant to sections 319F-2, 319L(c), 2811(b)(3), 2811(b)(4)(A), 2811(b)(4)(D), and 2811(d) of the Public Health Service Act (PHS Act) (42 U.S.C. §§ 247d-6b, 247d-7e(c), 300hh-10(b)(3), 300hh-10(b)(4)(A), 300hh-10(b)(4)(D), and 300hh(d)).

CDC has the authority to enter into this agreement pursuant to sections 301 and 319F-2 of the Public Health Service Act (42 U.S.C. §§ 241 and 247d-6b).

NIH has authority to enter into this agreement pursuant to sections 301, 319F-1, 405, and 446 of the Public Health Service Act (42 U.S.C. §§ 241, 247d-6a, 285, and 285f).

The Department of Defense organizations have authority to enter into this agreement under authority of 50 U.S.C. § 1522, 10 U.S.C. § 2358, Department of Defense (DOD) Instruction 4000.19, Support Agreements (April 25, 2013), and Department of Defense Directive 5134.10, Defense Advanced Research Projects Agency, May 7, 2013.

The Department of Homeland Security has authority to enter into this agreement under authority of 6 U.S.C. §§ 112 and 321e.

The Department of Agriculture has authority to enter into this agreement under authority of 7 USC 2279g.

The Department of Veterans Affairs has authority to enter into this agreement under authority of 38 U.S.C. § 523(a), 38 U.S.C. § 8111 (VA/DoD Health Care Resources Sharing), 38 U.S.C. §8153 Sharing Health Care Resources, 38 C.F.R. §17.142 Authority to Approve Sharing Agreements, and 38 C.F.R. § 17.241 Sharing Medical Information Services.

III. Background:

Discussions among representatives of PHEMCE Partners may involve, in some circumstances, trade secret or other non-public information. Participation in such discussions also requires avoidance of the appearance of impropriety or conflicts of interests by participants. This Memorandum of Understanding (MOU) deals with these issues. The primary focus of this MOU is FDA interactions involving multiple PHEMCE Partners at the same time (e.g., inter-agency meetings). In the absence of other governing requirements, procedures, or MOU provisions, FDA may also rely on this agreement and implementing procedures as a framework for interactions between FDA and a single PHEMCE Partner that is a party to this MOU. However, FDA and other individual PHEMCE Partners may enter into separate MOU governing interactions of a more limited scope or for different purposes (e.g., an MOU between FDA and another HHS agency to address one-on-one interactions or subject matter beyond PHEMCE issues). This MOU does not affect or supersede any existing or future agreements or arrangements among the parties except to the extent provided in section V., below.

IV. Substance of Agreement: Each PHEMCE Partner to this MOU agrees to the following:

a. POCs: Each PHEMCE Partner will establish a principal point of contact (POC) to facilitate the actions carried out under this MOU.
b. Procedures: Each PHEMCE Partner agrees to attend an initial meeting to establish specific procedures and safeguards necessary to implement this MOU. The initial meeting will take place as soon as possible after signing and approval of this MOU. Periodic meetings will be scheduled thereafter on an as-needed basis.

c. Confidentiality:

1. All Partners recognize that information exchanged with FDA 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 FDCA (21 USC 301 *et seq*.), the Health Insurance Portability and Accountability Act (HIPAA), Pub. L. 104-191), Section 319L(e) of the PHS Act (42 U.S.C. § 247d-7e(e)), and disclosure restrictions subject to 41 U.S.C. 2101-2107 (Procurement Integrity Act) and 48 C.F.R 3.104 (Federal Acquisition Regulation). Additionally, all federal agencies and contractors supporting them are under the Federal Information Security Management Act (FISMA), E-Government Act of 2002 (Pub. L. 107-347 (http://www.law.cornell.edu/jureeka/index.php?doc=USPubLaws&cong=107&no=347) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)[1], 116 Stat. (http://en.wikipedia.org/wiki/United_States_Statutes_at_Large) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)[2] 2899, 44 U.S.C. § 3541 (http://www.law.cornell.edu/uscode/44/3541.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)[3] *et seq.* Pursuant to section 301(j) of the FDCA (21 USC 331(j)), FDA will not reveal to any participant who is not a representative of an agency within the Department of Health and Human Services any information entitled to protection as a trade secret unless there is in place a written authorization, from the owner of that information, that permits FDA to reveal such information to representatives of non-HHS PHEMCE Partners. Such authorization may be obtained in the form attached as Exhibit A to this MOU.

2. Each PHEMCE Partner will establish proper safeguards to ensure that information shared with or by FDA under this MOU shall be used and disclosed solely in accordance with applicable laws and regulations. Access to such information shared under this MOU shall be restricted to authorized employees, agents, and officials of PHEMCE Partners 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. Each such individual shall be required, prior to receiving any such information, to sign a confidentiality commitment in the form attached as Exhibit B to this MOU. Except as otherwise permitted under this MOU, each Partner agrees that information shared pursuant this MOU will not be further disclosed without the written permission of the originating agency or as required by law with advance notice to the originating agency.

3. Contractors, their subcontractors, and/or agents of parties participating in discussions covered by this MOU will be permitted to participate in discussions and to receive information under this MOU only if they have signed an agreement by which they will commit to keep the information confidential and have signed a Confidentiality Commitment. Individuals (e.g. contractors' employees or agents) shall be required, prior to receiving any such information, to sign a Confidentiality Commitment in the form attached as Exhibit B to this MOU.

4. Each PHEMCE Partner agrees to promptly notify the FDA of any actual or suspected unauthorized disclosure of information shared by FDA under this MOU. FDA agrees to promptly notify each PHEMC Partner of any actual or suspected unauthorized disclosure of information shared by that Partner with FDA under this MOU. Each partner is similarly under an affirmative obligation to report breaches of Personally Identifiable Information (PII), which might include Protected Health

Information (PHI), or Individually Identifiable Health Information (IIHI), under appropriate authorities and time frames, such as FISMA, HIPAA, and the Privacy and HITECH Acts.

5. If a PHEMCE Partner that has received information shared under this MOU receives a FOIA request for information shared by another PHEMCE Partner pursuant to this MOU, the receiving Partner will refer the request to the information-sharing Partner for that latter agency to respond directly to the requestor regarding whether or not the release of the information at issue is permissible. In such cases, the PHEMCE Partner making the referral will notify the requestor that a referral has been made and that a response will be issued directly from the other agency.

6. Each PHEMCE Partner agrees that a Partner may decide not to share information or expertise in response to a particular request made to or by FDA for information, or to limit the scope of information and expertise shared in response to a particular request. A decision not to share information in response to a specific request may be based on several factors, including, for example, the amount of resources necessary to fulfill the request, the reasonableness of the request, the responding PHEMCE Partner's priorities, or legal restrictions. There is, however, agreement to share information to the maximum extent possible in furtherance of the purposes of this MOU. The PHEMCE Partners further agree that a Partner may on its own initiative elect to share information pursuant to procedures established under section IV.b., above, to further the purposes of this MOU. In the event the relevant Partners cannot reach consensus on a decision to share or not share information, the issue will be referred to an official designated by those PHEMCE Partners, specified in procedures to implement this MOU described in section IV.b., above.

7. The PHEMCE Partners further agree that nothing in this MOU shall be construed to prevent a disclosure required by law or legal process. Notwithstanding this provision, should information shared pursuant to this MOU be subpoenaed or otherwise ordered through a legal process, the PHEMCE Partner to whom the subpoena or order is directed will notify an Authorized Official of the other Partner that shared the information immediately to provide an opportunity to seek to intervene and block the disclosure. This MOU does not prohibit disclosure of information that is available publicly or when authorized in writing by the information owner.

8. The PHEMCE Partners agree that termination of this MOU does not relieve them of their confidentiality obligations established under this MOU, including their obligations to safeguard and limit access to all information provided pursuant to this MOU.

9. This MOU does not address and has no effect on the application of, or compliance with any requirement or restriction on disclosure for national security purposes. Any national security clearance requirements or restrictions applicable to classified information (e.g., “Confidential,” “Secret,” “Top Secret”) that may be shared by or among any PHEMCE Partners must be satisfied independent of this MOU.

d. Conflict of Interest:

Executive Order 12674, Standards of Ethical Conduct for Employees of the Executive Branch, and individual agencies’ standards of conduct contain rules and regulations which govern the ethical obligations applicable to Government employees. Federal law generally prohibits a Federal employee from participating personally and substantially in any particular matter in which the employee has a financial interest. The restriction also applies to financial interests of an employee's spouse; minor child; partner; organization in which he or she is serving as officer, director, trustee, partner or employee; and any person or organization with whom the employee is negotiating or has any arrangement concerning prospective employment. Ethics requirements applicable to Federal personnel also broadly prohibit employees from engaging in a financial transaction using nonpublic information, and prohibit the improper use of nonpublic information to further his own private interest or that of another, whether through advice or recommendation, or by knowing unauthorized disclosure. In addition, HHS Supplemental Standards of Ethical Conduct impose additional conditions, such as unique prohibited-holdings regulations for certain FDA personnel.

Representatives to any PHEMCE discussion must not have a prohibited financial conflict of interest through personal or family investments in a sponsor, or a competitor to the sponsor, who will be affected by FDA decisions. If at any time prior to or during the performance of activities under this MOU, a person becomes aware that a potential or actual conflict exists, that person must notify the appropriate authorities within his or her own agency, and that PHEMCE Partner agency must contact the designated FDA official listed on the MOU so that any necessary actions can be undertaken.

e. Integrity of Regulatory Decision-Making Process:

FDA participation is predicated on a mutual understanding that PHEMCE Partner meetings under this MOU provide a forum for a mutual exchange of opinions and ideas, and that PHEMCE meetings must avoid any appearance that procurement or investment considerations may influence FDA regulatory decision-making concerning product approval or authorization. FDA employees generally will not participate in discussions or decision-making regarding the terms of procurement of or investment in a medical product. FDA representatives may participate in discussions under this MOU to provide FDA's current thinking on scientific or regulatory issues within FDA's areas of responsibility and expertise.

V. General Provisions:

This is an internal Government agreement among the parties to this MOU and does not confer any rights or benefits to any person or party. This MOU does not include any commitment, by any Partner, of resource contributions or exchanges.

This MOU does not supersede any existing agreements or arrangements among the parties; to the extent the provisions of this MOU conflict with any existing or future agreement between FDA and any other individual PHEMCE Partner, the provisions of this MOU shall govern FDA communications relating to medical countermeasures for emergency use that involve multiple PHEMCE Partners. This MOU and all associated agreements will be subject to the applicable policies, rules, regulations, and statutes under which the parties operate, and nothing in the MOU shall be construed as changing the current requirements under the statutes and regulations administered and enforced by any Partner. Further, nothing contained in this MOU constitutes a mandate or a requirement imposed on any Partner that is additional to the mandates or requirements imposed on them, individually or collectively, by Federal statutes and regulations.

VI. Liaison Officers:

a. For the Food and Drug Administration:
Luciana Borio, M.D.
Director, Office of Counterterrorism and Emerging Threats
Office of the Chief Scientist
Office of the Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Building 32, Fourth Floor
Silver Spring, MD 20993
301-796-8510

b. For the Assistant Secretary for Preparedness and Response (including the Biomedical Advance Research and Development Authority):
Debra Yeskey, Pharm.D.
Director, Regulatory and Quality Affairs Division
Office of Biomedical Advanced Research and Development Authority
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
200 Independence Avenue, S.W. (Room 638G)

Washington, D.C. 20201
202-205-3990

c. For the Centers for Disease Control and Prevention
Daniel Sosin, M.D., M.P.H., F.A.C.P.
Deputy Director and Chief Medical Officer
Office of Public Health Preparedness and Response
Centers for Disease Control and Prevention
1600 Clifton Road, Mailstop D-44
Atlanta, GA 30333
404-639-7855

d. For the National Institutes of Health
Robert Johnson, Ph.D.
Director, Office of Regulatory Affairs
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
National Institutes of Health
6610 Rockledge Drive
Bethesda, MD 20892
301-402-2126

e. For the Office of the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs
CDR Franca Jones
Office of the Assistant Secretary of Defense for Nuclear, Chemical and Biological
Defense/Chemical and Biological Defense Programs
3050 Defense Pentagon
Washington, DC 20301-3050
franca.r.jones.mil@mail.mil
571-256-0852

f. For the U.S. Army Medical Research and Material Command
COL Robert L. von Tersch, Ph.D.
Director, Strategic Partnerships Office
U.S. Army Medical Research and Materiel Command
810 Schreider Street
Fort Detrick, MD 21702-5012
301-619-2362

g. For the Defense Advance Research Projects Agency
Geoffrey Ling, M.D., Ph.D.
Deputy Director, Defense Sciences Office
Defense Advanced Research Projects Agency
675 North Randolph Street
Arlington, VA 22203
703-526-6630

h. For the Department of Homeland Security
Sally Phillips, R.N, Ph.D.
Deputy Assistant Secretary and Director

Health Threats Resilience Division
Office of Health Affairs
Department of Homeland Security
Washington, DC 20528
202-254-6489

i. For the Department of Veterans Affairs
Katherine Wallace. Pharm. D.
Director, Biosurveillance Preparedness
Office of the Deputy Under Secretary for Health Policy and Services
Veterans Health Administration
Department of Veterans Affairs
810 Vermont Avenue, NW
Washington DC 20420
202-461-5244

j. For the Department of Agriculture
CAPT David P. Goldman, M.D., M.P.H.
Assistant Administrator
Office of Public Health Science
Food Safety Inspection Service
Department of Agriculture
Room 341-E, Whitten Building
1400 Independence Avenue, SW
Washington, DC 20250
202-720-2644

VII. Term, Termination, and Modification:

This agreement will be effective as to a participating party when accepted by that party, that remain in effect unless terminated or superseded. This agreement may be modified or terminated by mutual written consent of all parties or may be terminated by any party, as to that party, upon a 60 day advance written notice to the other parties.

APPROVED AND ACCEPTED FOR FOOD AND DRUG ADMINISTRATION	APPROVED AND ACCEPTED FOR Assistant Secretary for Preparedness and Response
By: Stephen Ostroff, M.D.	By: Edward Gabriel, MPA, EMT-P, CEM, CBCP
Chief Scientist (Acting)	Principal Deputy Assistant Secretary for Preparedness and Response
Date: March 11, 2014	Date: July 13, 2013

APPROVED AND ACCEPTED FOR CENTERS FOR DISEASE CONTROL AND PREVENTION	APPROVED AND ACCEPTED FOR National Institutes of Health

By: U.S. Assistant Surgeon General Ali Khan (RET), M.D., M.P.H	By: Lawrence Tabak, D.D.S., Ph.D.
Director, Office of Public Health Preparedness and Response	Principal Deputy Director
Date: April 12, 2013	Date: April 10, 2013

APPROVED AND ACCEPTED FOR ASSISTANT SECRETARY OF DEFENSE for NUCLEAR, Chemical, and Biological Defense Programs	APPROVED AND ACCEPTED FOR UNITED STATES ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
By: Gerald W. Parker, Jr.	By: Joseph Caravalho, Jr.
Deputy Assistant Secretary of Defense for Chemical and Biological Defense	Major General, Medical Corps Commanding General
Date: May 30, 2013	/s/

APPROVED AND ACCEPTED FOR DEFENSE ADVANCED RESEARCH PROJECTS AGENCY	APPROVED AND ACCEPTED FOR DEPARTMENT OF HOMELAND SECU
By: Mari Maeda, Ph.D.	By: Kathryn Brinsfield, M.D., MPH
Director, Defense Sciences Office	Acting Assistant Secretary for Health Affairs and Chief Medical Offic
Date: June 11, 2013	Date: August 10, 2013

APPROVED AND ACCEPTED FOR DEPARTMENT OF AGRICULTURE	APPROVED AND ACCEPTED FOR DEPARTMENT OF VETERANS AFFAIRS
By: Elisabeth A. Hagen, M.D.	By: Kevin T. Hanretta
Under Secretary for Food Safety	Assistant Secretary for Operations, Security, and Preparedness
Date September 5, 2013	Date March 4, 2014

EXHIBIT A

MODEL AUTHORIZATION FOR FDA TO SHARE NON-PUBLIC INFORMATION WITH PHEMCE PARTNERS
[To be completed on sponsor/information- owner letterhead]

[FDA Center Official – e.g., Center or Office Director]
United States Food and Drug Administration
10903 New Hampshire Avenue
Building __, Room ____
Silver Spring, MD 20993

[Identify relevant FDA file number – e.g., NDA/ANDA/BLA, EUA/Pre-EUA, etc.)]
Re: FDA Sharing of Non-Public Information Concerning [*insert name of regulated product(s)*] with Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) Partners[1] (http://wcms.fda.gov/ucm/resources/wcm/sitestudio/elements/fckwysiwyg.htm#_ftn1)[4]

On behalf of [*insert name of information owner*], I authorize the United States Food and Drug Administration (FDA) to share with

PHEMCE Partners, and with contractors to those Partners, all information concerning the above described product(s) that [*insert name of information owner*] has provided or will provide to FDA or to any other PHEMCE Partner. I understand that those Partners have committed to use such information only for the purposes of the PHEMCE, and have committed or are otherwise legally required to maintain the confidentiality of such information (or both), and that contractors to PHEMCE are bound by their contracts to maintain the confidentiality of the information. I understand that the information may contain confidential commercial or financial information or trade secrets within the meaning of 18 U.S.C. § 1905, 21 U.S.C. § 331(j), and 5 U.S.C. § 552(b)(4), that is exempt from public disclosure. I agree to hold FDA harmless for any injury caused by FDA's disclosure of this information.

Authorization is given to FDA to share this information without deleting confidential commercial or financial or trade secret information. This authorization shall remain valid unless revoked in writing. As indicated by my signature, I am authorized to provide this consent on behalf of [*insert name of information owner*] and my full name, title, address, telephone number, and facsimile number are set out below for verification.
Sincerely,

(Signature)
(Printed name)
(Title)
(Telephone & Facsimile Numbers)

cc: Office of Counterterrorism and Emerging Threats (OCET), Office of the Chief Scientist, FDA

EXHIBIT B

PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURE ENTERPRISE Confidentiality Commitment

The Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) is a coordinated interagency effort which is responsible for, *inter alia*, focusing research, development, and procurement activities to provide medical countermeasures that will be safe and effective for use in the United States in the event of a public health or medical emergency. As part of meetings, discussions, or other communications with Food and Drug Administration officials involved with that effort, I understand that I may be exposed to information that is trade secret, confidential commercial or financial information, personal privacy information, or predecisional or deliberative information that has been provided to or belongs to an agency or department that is a member of the PHEMCE.

I, on this _____ day of _____, 20__, hereby agree that

I shall not release, publish, or disclose such information and I shall protect such information in accordance with all applicable law relating to my receipt of non-public information in connection with my participation in PHEMCE activities and that I may be subject to disciplinary action and, in some cases, criminal penalties as prescribed by law for unlawful disclosure of such information. I shall use such information only for the purposes of the PHEMCE in accordance with my official duties, and shall share such information only with individuals who either 1) are employed by or a contractor of the originating government agency that provided the information to me or to my agency and are authorized to have access to the information by virtue of their duties, or 2) are employed by or a contactor of a PHEMCE agency and have themselves signed a Confidentiality Commitment.

Signature: _____ Date: _____

Type or Print Name: _____

Agency: _____

Supervisor Signature (if applicable): _____ Date: _____

Type or Print Supervisor Name: _____

[1] PHEMCE Partners include, within the Department of Health and Human Services, the Office of the Assistant Secretary for Preparedness and Response (including the Biomedical Advanced Research and Development Authority), Centers for Disease Control and Prevention, National Institutes of Health, and FDA, as well as the Department of Defense, the Department of Homeland Security, the Department of Veterans Affairs, and the Department of Agriculture.

APPENDIX I to FDA-PHEMCE MOU

Implementing Procedures

This document outlines procedures for implementing the FDA-Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) Memorandum of Understanding Concerning Information-Sharing Exchanges Involving FDA (MOU) as provided in section IV.b. of the MOU.

I. PHSAT Participation

Food and Drug Administration (FDA) Public Health and Security Action Teams (PHSATs) are multidisciplinary teams within FDA, established to help advance select, high-priority PHEMCE medical countermeasures (MCMs) or technologies. Much of FDA's interaction with other PHEMCE Partners will be through FDA personnel who are PHSAT members. FDA intends to designate a PHSAT member (e.g., Project Manager) to record minutes of PHEMCE meetings; when applicable, minutes will be included in the relevant FDA product application files (e.g., IND, NDA, BLA, pre-EUA), with sufficient detail to identify and distinguish any information supplied by the sponsor/applicant.

II. Confidentiality

A. *PHEMCE Partners*: When sharing information with a PHEMCE Partner[1] (http://wcms.fda.gov/ucm/resources/wcm/sitestudio/elements/fckwysiwyg.htm#_ftn1)[5] under this MOU, Partner representatives (i.e., agency personnel designated to represent that agency for one or more purposes) will alert recipients/participants to the nature of information that is protected, and remind them of the need to take appropriate steps to ensure the information is not improperly disclosed.

1. Individual Disclosure & Consent: Each individual participating in PHEMCE communications that may involve information subject to protection as described in section IV.c. of the MOU shall be required, prior to receiving any such information, to sign a confidentiality commitment in the form attached as Exhibit B to the MOU. Each PHEMCE Partner shall have individual responsibility for obtaining, updating, and maintaining these agreements for each of its employees participating in PHEMCE communications.

2. Meetings/Telephone Conferences:

a. Personnel leading a meeting or telephone conference covered by the MOU should begin by confirming that each participant has signed a PHEMCE Confidentiality Commitment (MOU Exhibit B). Any person who has not signed such a commitment must identify themselves and either sign the agreement or stop participating in the meeting or telephone

conference. Although no particular form of statement is required, a general statement along these lines is recommended:

"This discussion may include trade secret or confidential commercial information protected from disclosure to the public under the Freedom of Information Act, the Trade Secrets Act, the Federal Food, Drug, and Cosmetic Act, or FDA regulations. Each participant must have signed an individual PHEMCEConfidentiality Commitment to participate today, and information provided may only be shared with employees or contractors who sign a PHEMCE Confidentiality Commitment. Please identify yourself if you have not yet signed this agreement and we will provide one to allow for your continued participation today. Participants should not further disclose or otherwise make public the information that is shared."

b. If for any reason the PHEMCE lead for a meeting omits this reminder, FDA personnel in attendance will provide it.

3. Other: Other requests for information subject to the MOU that involve FDA and other PHEMCE Partners, including meeting requests, will ordinarily be submitted in writing, which may include email or calendar invitation, describing the general subject for which the information is requested, and include the following statemen *"[Requesting Agency] understands that information that is shared in connection with or response to this request may include privileged, trade secret, or confidential commercial information protected from disclosure. This information will only be shared with employees or contractors who sign a PHEMCE Confidentiality Commitment and [Requesting Agency] agrees not to further disclose any shared information without your written permission or as required by law with advance notice to the originating agency."*

A response providing non-public information should also be in writing, which may include email, and should include the following statement

"This communication may contain privileged, trade secret, or confidential information exempt from public disclosure. Recipients of such information must have a signed PHEMCE Confidentiality Commitment on file with your agency, and it may not be further disclosed in any manner without our written permission or as required by law with advance notice to the originating agency. "

In an emergency, if submitting an email request or response is not feasible, this information may be conveyed orally and documented later.

4. Sharing Without a Request: In some cases one PHEMCE Partner may determine that it would further the purposes of this MOU to share information of which the other PHEMCE Partners may be unaware, but may need or want to know about. Therefore, the procedures above may also be used to share information that a PHEMCE Partner determines on its own initiative to share with the other Partners to further the purposes of this MOU.

5. Review of Decisions: In the event PHEMCE Partners are unable to agree, at the POC level, on a disclosure requested under the MOU, the request will be referred to the next higher level within each affected Partner for review and resolution. If needed, requests may be referred to successively higher levels until the matter is resolved.

B. *Trade Secrets & Information Owner Consent*: FDA will not disclose information that falls into the description of trade secret to PHEMCE Partners that are not part of HHS without the information owner's (e.g., sponsor) permission.

To best support interactions involving multiple PHEMCE Partners, some of which may not be part of HHS, PHEMCE Partners within HHS should also generally obtain information owner consent before trade secret information is requested from or disclosed by FDA under this MOU. The Partners recognize that numerous factors may affect the feasibility of requesting or obtaining consent, including the urgency of the request, the need for the information, and the potential impact of seeking consent (e.g., implications for law enforcement or other confidentiality limits). The PHEMCE Partners understand and agree that in the event trade secret information is shared with a PHEMCE Partner that is part of HHS without the information owner's consent, that information may not be further disclosed without FDA's written permission.

Ordinarily the PHEMCE Partner requesting disclosure of trade secret information should contact the information owner directly to seek their permission for FDA to disclose it.

1. Future contracts: The relevant PHEMCE Partner will, in the usual case, request all companies entering into contractual purchasing agreements with U.S. government partners (e.g., BARDA, DOD), as a part of the contract, to authorize PHEMCE partners, including FDA, to share non-public information (e.g., confidential commercial information (CCI), trade secrets, Agency investigations/deliberations, etc.), for purposes of PHEMCE activities. The authorization should include permission for FDA to make disclosures as described in the model authorization attached to the MOU as Exhibit A.

2. Pre-existing contracts or no contract: If no other separate agreement has otherwise been obtained by a PHEMCE Partner prior to FDA participation in a PHEMCE project meeting that is anticipated to discuss sponsor-specific information, FDA or the PHEMCE partner holding the contract will request the information owner (e.g., sponsor) to authorize the sharing of non-public information for purposes of PHEMCE activities using the model authorization attached to the MOU as Exhibit A.
3. PHEMCE Partners are responsible for confirming they have obtained required information-owner authorization on FDA request prior to sharing trade secret information.

C. *Contractors*: Each PHEMCE Partner is responsible for obtaining and maintaining its own contractors' commitments, required as provided in section IV.c. of the MOU, and for confirming that such contractors' receipt of non-public information is authorized.

D. *Federal Information Security management (FISMA)*: Every partner, member, signatory, agency official, manager, executive, staffer, and contractor are bound to protect Personally Identifiable Information (PII) as required by FISMA, E-Government Act of 2002 (Pub.L. 107-347,116 Stat. 2899, 44 U.S.C. § 3541 *et seq.* Each agency receiving PII under this MOU must have in place appropriate agency-wide programs to protect PII from unauthorized access, use, disclosure, and exposure through security controls and enhancements to their information systems that receive, maintain, and use such PII. This includes information systems maintained by or for the agency in question, whether Government-owned and operated or Contractor-owned and operated systems or other related sources.

E. *Health Insurance Portability & Accountability Act (HIPAA)*: If any partner or entity receiving information under this MOU that is a "covered entity" under HIPAA, Pub. L. 104-191, 110 Stat. 1936, or a covered "business associate" of such an entity, receives any individual's Protected Health Information (PHI) or individually identifiable health information (IIHI), that entity shall be responsible for maintaining appropriate security to safeguard that data from unauthorized access or disclosure. Similarly, any covered entity shall also be responsible for appropriate disclosures and reporting should any data breach involving that PHI or IIHI occur.

III. Financial Conflict of Interest

A. Under section IV.d. of the MOU, each PHEMCE Partner agrees to assure that its representatives to any covered PHEMCE discussion do not have a prohibited financial conflict of interest through personal or family investments in, or through personal service as an officer, director, trustee, general partner, or employee of a sponsor, or a competitor to the sponsor, who will be affected by FDA decisions.

B. If at any time prior to or during the performance of activities under this MOU a person becomes aware that a potential or actual conflict exists, the person must notify the appropriate authorities within its own agency (e.g., the Designated Agency Ethics Official). Each agency and individual will be responsible for analyzing and following appropriate ethics procedures, including, but not limited to post-employment conflict of interest standards.

C. In light of the unique prohibited holdings regulations applicable to FDA, a PHEMCE Partner that becomes aware of a prohibited conflict should also contact the designated FDA official listed on the MOU so that necessary action, if any, may be undertaken (e.g., screening the individual from receiving certain information).

IV. Appearances of Impropriety & Integrity of Regulatory Decision-Making Process.

A. The purpose of PHEMCE project meetings is to share participants' best scientific and technical expertise on issues or obstacles related to specified high-priority medical countermeasures. FDA will participate in PHEMCE project meetings to share in the free exchange of participants' current thinking on the specified topic.

B. As provided in section IV.e. of the MOU, each PHEMCE Partner affirms the obligation to avoid an appearance that procurement or investment considerations may influence FDA regulatory decision-making concerning product approval or authorization.

1. FDA employees generally will not participate in PHEMCE decision-making regarding the terms of procurement of or investment in a MCM product.

2. On request of a PHEMCE Partner, when FDA expertise may nonetheless appropriately have a bearing on a procurement issue, an FDA representative (such as a PHSAT lead or Project Manager), will identify FDA personnel generally knowledgeable about the scientific and technical regulatory considerations concerning the specified medical product to participate in such discussions to the extent necessary to provide FDA's current thinking on such considerations.

3. The fact that a MCM is under consideration for or has been procured by a U.S. government entity, including a PHEMCE Partner, may be disclosed to FDA personnel.

4. When a PHEMCE Partner meeting is expected to involve decision-making regarding the terms of procurement of or investment in MCM as well as other matters, the meeting lead should prepare an agenda sufficient to enable FDA personnel, including those directly responsible for review of or decisions about the safety and efficacy of specific medical countermeasure, to avoid participation in procurement decisions. Meeting minutes will reflect periods when FDA personnel do not participate.

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[1] (http://wcms.fda.gov/ucm/resources/wcm/sitestudio/elements/fckwysiwyg.htm#_ftnref1)[6] PHEMCE Partners include, within the Department of Health and Human Services, the Office of the Assistant Secretary for Preparedness and Response (which encompasses the Biomedical Advanced Research and Development Authority), Centers for Disease Control and Prevention, National Institutes of Health, and the Food and Drug Administration, as well as the Department of Defense, the Department of Homeland Security, the Department of Veterans Affairs, and the Department of Agriculture.