

INTERAGENCY AGREEMENT
BETWEEN
U.S. DEPARTMENT OF WAR,
OFFICE OF THE ASSISTANT SECRETARY OF WAR FOR NUCLEAR DETERRENCE, CHEMICAL, AND
BIOLOGICAL DEFENSE POLICY AND PROGRAMS
AND THE
NATIONAL INSTITUTES OF HEALTH,
NATIONAL INSTITUTE FOR ALLERGIC AND INFECTIOUS DISEASES

This agreement is to establish an arrangement between the U.S. Department of War (DoW), Office of the Assistant Secretary of War for Nuclear Deterrence, Chemical, and Biological Defense Policy and Programs (OASW ND-CBD) and the National Institutes of Health NIH for research and development of therapeutics, diagnostics, and personal protective equipment against chemical, biological, radiological and nuclear (CBRN). When referred to collectively, OASW and NIH are referred to as “the Parties.”

I. BACKGROUND

For the Department of War (DoW), the Office of the Assistant Secretary of War for Nuclear Deterrence, Chemical, and Biological Defense Policy and Programs (OASW ND-CBD) leads efforts to ensure a safe, secure, and effective U.S. nuclear deterrent against weapons of mass destruction (WMD) threats. Furthermore, OASW ND-CBD is at the forefront of U.S. initiatives to provide chemical and biological defense and ensure compliance with international treaties and agreements. OASW ND-CBD is also responsible for interagency coordination and international engagement on WMD countermeasure policy and strategy, as well as operational and administrative efforts to accelerate the development and production of countermeasures against WMD threats.

The National Institutes of Health (NIH) engages in "the conduct and support of research, training, health information dissemination, and other programs with respect to allergic and immunologic diseases and disorders and infectious diseases, including tropical diseases" (42 U.S.C. § 285f). Additionally, NIH is authorized to "establish or continue a multidisciplinary research program to advance the discovery and preclinical development of medical products for priority virus families and other viral pathogens with a significant potential to cause a pandemic" (42 U.S.C. § 285f–5(a)). Furthermore, NIH "shall collaborate with the heads of other appropriate Federal departments, agencies, and offices with respect to the identification of additional priority virus families and other viral pathogens with a significant potential to cause a pandemic" (42 U.S.C. § 285f–5(e) (1)).

Through this agreement, NIH will leverage OASW ND-CBD’s procurement, grants, and funding network to allow for critical basic science, related research pathways, and basic research to support the translation and advanced development of medical countermeasures. This includes

therapeutics, diagnostics, and personal protective equipment (PPE) against pandemic influenza; chemical, biological, radiological, and nuclear (CBRN) threats; and emerging infectious diseases.

AUTHORITIES

This agreement is entered into pursuant to the Economy Act, 31 U.S.C. § 1535, 42 U.S.C. § 285f and 42 USC § 285f–5.

III. PURPOSE

This Interagency Agreement facilitates the transfer of funds from the National Institutes of Health (NIH) to the Office of the Assistant Secretary of War (OASW). The purpose is for OASW to provide acquisition services to support the advanced development of medical countermeasures against pandemic influenza, chemical, biological, radiological, and nuclear (CBRN) threats, and emerging infectious diseases. Supported by NIH's scientific data, product pipelines, and translational expertise, OASW will award contracts, grants, and other transactions to research and develop therapeutics, diagnostics, and personal protective equipment (PPE) to protect the United States.

RESPONSIBILITIES OF THE PARTIES

A. OASW ND-CBD will:

- i. Enter into contracts, grants, cooperative agreements or other transactions needed for research and development of medical countermeasures such as therapeutics, diagnostics and PPE to protect the United States from future pandemic strains, CBRN threats and other emerging infectious disease. Efforts may include antiviral, antibacterial, and antitoxin therapeutics for pathogens or toxins of concern, as determined by NIH and OASW ND-CBD.
- ii. Advise OASW ND-CBD and NIH on strategy and execution
- iii. Provide contractual technical and compliance oversight of the programs funded under this IAA NIH.
- iv. Provide NIH with access to all technical and business documents related to the development of the program.
- v. Provide rapid response analysis for emergent threats and development of white-paper capability action plans (to enable decision-making and mission adjustments by ASW/Sr Leaders)
- vi. Develop other medical countermeasures, either by modifying an existing contract or agreement, or by entering into a new contract or agreement.
- vii. Mature innovative technologies to enable detection, threat assessment, physical protection and MCM preparedness and response in operationally relevant timelines.

B. NIH will:

- i. Make data and novel products being developed for civilian healthcare at the NIH available for use or transfer by OASW ND-CBD in support of biodefense work conducted by DoW.
- ii. NIH shall coordinate with OASW ND-CBD to develop statements of work, establish estimated costs, and place orders using the FS form 7600B to transfer funding prior to contract award(s) as required for completion of specific acquisitions and terms associated with acquisitions (e.g., medical countermeasure development, therapeutics development, and PPE).
- iii. Ensure orders for research and development of medical countermeasures including therapeutics, diagnostics or PPE align with NIH's legal authorities.
- iv. Provide funding sufficient to support the research and development effort(s) ordered or requested by NIH, as well as funding to support OASW ND-CBD program management personnel and activities for the requested efforts, as needed.
- v. Comply with applicable regulatory terms and any reporting requirements included in any contract or agreement between OASW ND-CBD and the contracted developers of medical countermeasures, therapeutics, diagnostics and PPE.
- vi. Provide a technical team to support technical oversight of any programs funded under this IAA and related agreements (e.g., Economy Act orders), which will include participation in any project meetings and review of all technical deliverables.

C. Both parties will-

- i. Participate in regularly scheduled meetings to discuss progress. Meetings may include OASW ND-CBD and NIH discussions as well as meetings with awarded performers; At a minimum the OASW ND-CBD and NIH shall hold quarterly meetings to discuss progress on efforts covered under this IAA.
- ii. Both parties will appoint representatives from their institution or office to attend and participate in project coordination meetings.
- iii. Retain mutual concurrence on the final joint research agenda, provided that:
 - a. NIH holds final authority on requirements and product profiles aimed at civilian populations and public health preparedness; and
 - b. OASW ND-CBD holds final authority on requirements and product profiles tailored to warfighter protection, military operational environments, and tactical deployment

V. ORDERING

- A. NIH, the requesting agency, shall use Fiscal Service (FS) Form 7600A, General Terms and Conditions (GT&C) to establish an estimate of cost for all agreements enabled by this IAA.

- B. NIH, the requesting agency, shall use FS form 7600B, Order, to transfer funding prior to contract award(s) as required for completion of specific acquisitions and terms associated with acquisitions (e.g., medical countermeasure development, therapeutics development, and PPE).
- C. The Joint Project Manager, working at the direction of OASW ND-CBD, the servicing agency, will acquire for NIH the supplies and services identified by NIH as necessary only upon receipt of an FS Form 7600B (Order).
- D. The purchases by OASW ND-CBD for NIH may be distributed to the states, territories, local governments, tribal governments, and private organizations.
- E. Orders under these General Terms and Conditions are expected to be placed pursuant the Economy Act (31 U.S.C. 1535). NIH will ensure that each assisted acquisition order is consistent with Economy Act requirements and FAR 17.502-2.

VI. PERSONNEL

Each party is responsible for supervision and management of its personnel. However, funding may be provided from NIH to OASW ND-CBD to pay the expenses of any additional personnel necessary to fulfill orders placed pursuant to this agreement.

VII. GENERAL PROVISIONS

- A. REVIEW OF AGREEMENT: This agreement will be reviewed annually on or around the anniversary of its effective date for financial impacts, and in its entirety at least once every three (3) years (triennially) from the effective date to ensure currency, consistency with policy, and operational necessity.
- B. MODIFICATION OF AGREEMENT: This agreement may only be modified by the written agreement of the parties duly signed by their authorized representatives.
- C. DISPUTES: Disputes between an office of the Secretary of War or DoW component and another federal entity, in this instance, NIH, will be resolved in accordance with guidance provided in the U.S. Department of the Treasury Financial Manual Volume 1, Part 2, Chapter 4700, Appendix 5 at p.10.
- D. TERMINATION OF AGREEMENT: This agreement may be terminated by either party by giving at least 180 days written notice to the other party. The agreement may also be terminated at any time upon the mutual written consent of the parties.
- E. TRANSFERABILITY: This agreement is not transferable except with the written consent of the parties.

- F. NO EFFECT ON OTHER AGREEMENTS: Nothing in this agreement or 7600A or 7600B documents executed pursuant to this agreement are intended to modify, cancel, supplant or otherwise effect any other agreements in place between Department of War and the Department of Health and Human Services.
- G. EFFECTIVE DATE: This agreement takes effect beginning on date of last signature by the parties.
- H. EXPIRATION DATE: This agreement expires on 30 September 2036. The term may be extended by mutual consent of the parties.
- I. POINTS OF CONTACT: The party shall provide appropriate points of contact (POC) for each order at the time the order is placed on the form 7600B. Each party may change POC's upon reasonable notice to the other party. The NIH POCs will be as follows:

The NIH POCs will be as follows-

The OASW ND-CBD POCs will be as follows-

- J. PRESS RELEASES: Both parties agree to accurately and factually represent work conducted pursuant to this IAA, mentioning both parties in press releases. The issuer shall submit an advanced copy of any press release to the other party five business days prior to release for review and comment.
- K. THIRD PARTIES: This agreement is not intended, and should not be construed, to create any other benefit, substantive or procedural, enforceable by law or otherwise by any person or entity against either of the parties, any of their parent agencies, the United States or the other officers, employees, agents or other associated personnel.

VIII. FINANCIAL DETAILS

- A. AVAILABILITY OF FUNDS. This MOA does not document the obligation of funds between the Parties. The obligation of funds by the Parties, resulting from this MOA, is subject to the availability of funds. No provision of this agreement shall be interpreted to require obligation or payment of funds in violation of the Antideficiency Act, 31 U.S.C.

§ 1341. Any obligation of funds in support of orders placed under this agreement will be accomplished using the appropriate Treasury interagency forms.

- B. ECONOMY ACT. This agreement is being entered into pursuant to 31 U.S.C. § 1535, as amended (the Economy Act). Both parties agree that for each project it will ensure that any applicable requirements of the Economy Act will be met. The OASW ND-CBD has determined that it has sufficient capabilities to render the services described in this agreement without jeopardizing its assigned missions.

IX. SIGNATURE AND DATE

For OASW ND-CBD –

Robert Kadlec, SES
Assistant Secretary of War for Nuclear Deterrence,
Chemical, and Biological Defense Policy and Programs

For NIH –

Jayanta Bhattacharya, MD, PhD
Director
National Institutes of Health