

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT		1. CONTRACT ID CODE	PAGE OF PAGES 1 4
2. AMENDMENT/MODIFICATION NO. P00001	3. EFFECTIVE DATE See Block 16C	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
6. ISSUED BY HHS/OS/ASPR/BARDA 330 Independence Ave., S.W. Room 640-G Washington DC 20201	CODE HHS/OS/ASPR/BARDA	7. ADMINISTERED BY (If other than Item 6) ASPR-BARDA 330 Independence Ave, SW, Rm G640 Washington DC 20201	CODE ASPR-BARDA02
8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) THE TEXAS A&M UNIVERSITY SYSTEM 1380740 TEXAS A&M UNIVERSITY SYSTEM, THE 301 TARROW ST # 6 COLLEGE STATION TX 778407896		9A. AMENDMENT OF SOLICITATION NO. (x)	
CODE 1380740		9B. DATED (SEE ITEM 11)	
FACILITY CODE		10A. MODIFICATION OF CONTRACT/ORDER NO. HHSO1002012000021 75A50120F33002	
		10B. DATED (SEE ITEM 13) 07/23/2020	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers is extended. is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

See Schedule

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation data, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
X	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR 43.103(a)(3) - Bilateral Mutual Agreement of the Parties
	D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor is not is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Tax ID Number: 74-2648747
DUNS Number: 042915991
TAMUS CIADM Manufacturing Capacity Reservation and Expansion

See attached pages
Discount Terms: NET 30P
Period of Performance: 07/23/2020 to 12/31/2021

Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect.

(b) (6)	15A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) (b) (4)
15B. CONTRACTOR/OFFEROR (b) (4)	15C. DATE SIGNED 8/27/20
15D. UNITED STATES OF AMERICA (b) (6)	15E. DATE SIGNED 08/27/2020

Previous edition unusable

- A. This is Modification No. P0001 to 75A50120F33002.

The purpose of this no cost bilateral modification P0001 is to accomplish four (4) actions:

1. Add Advance Understanding H.1.9 to provide notice, terms, and conditions that this is a priority DO-H5 rated task order #75A50120F33002 under Contract #HHSO100201200002I with a Period of Performance 07/23/2020 to 12/31/2021 certified for national defense use.
2. Update FAR 52.236-1 Performance of Work by the Contractor (Apr 1984), at I.3.1 to include the portion of work to be performed by TAMUS.
3. Add Advance Understanding H.1.10 to establish the minimum amount of notice the Government must provide to exercise FAR Clause 52.217-8 Option to Extend Services (NOV 1999) to be no less than six (6) months.
4. Correct a typographical error in Attachment 2 to Task Order, to reflect the reservation period through December 31, 2021.

- B. Accordingly, the following changes are made to the contract:

1. Advance Understanding H.1.9 is added as follows:

H.1.9 Defense Priorities and Allocations Systems Rating

- a. This is a priority **DO-H5** rated task order (#75A50120F33002 under Contract #HHSO100201200002I) with a Period of Performance 07/23/2020 to 12/31/2021 certified for national defense use.
- b. The Parties agree that this change from an unrated Task Order to a DO-H5 priority Rated Task Order is a no-cost change.
- c. The Parties agree that this modification to rate this Task Order does not significantly alter the production or delivery schedule required by the Task Order already in existence.
- d. The Contractor agrees that the Government's right to exercise priorities and allocations authority with respect to this Task Order to include the use of directives constitutes a no-cost change to this contract. The written signature on a manually placed order, or the digital signature or name on an electronically placed order, of an individual authorized to sign rated orders for the person placing the order is provided. The signature, manual or digital, certifies that the rated order is authorized under this regulation and that the requirements of this regulation are being followed. This language shall be added to the contract or task order and subcontracts by modification, if previously awarded.
- e. The Contractor and its subcontractors at all tiers are required to follow all of the provisions of the *Defense Priorities and Allocations System regulation (15 C.F.R. part 700)* as this task order is certified for national defense and emergency preparedness

use. The authority for this rating is attached (Task Order Attachment 3). The priority rating issued pursuant to the authorization is subject to the restrictions in the authorization.

- f. The required Delivery Date from the Contractor is January 1, 2021.
 - g. The Contractor and its subcontractors must give the appropriate preferential treatment to the Task Order. The Contractor shall accept, perform, and prioritize this Task Order issued under the contract.
 - h. This Task Order shall take precedence over any and all other orders or contracts that do not have a priority rating and shall take precedence over orders or contracts that have the same level of priority rating but were received later in time.
 - i. This priority rating allows the Contractor to priority rate orders to its subcontractors and suppliers for purpose of fulfilling the priority-rated order expediently.
 - j. This priority rating automatically expires at the end of the Task Order period of performance. The parties agree that the U.S. Government (USG) may withdraw or extend this authorization at any time prior to the expiration of any Task Order period of performance at no cost to the USG.
 - k. If the Contractor and/or its subcontractors are unable to comply fully with the terms of this rated order Clause, the Contractor must immediately notify the Assistant Secretary for Preparedness and Response in writing and explain the extent to which compliance is possible and provide reasons why full compliance is not possible.
2. Section I.3 Additional FAR Contract Clauses Included in Full Text is modified to read as follows:
- I.3.1 FAR Clause 52.236-1 Performance of Work by the Contractor (Apr 1984)**
The Contractor shall perform on the site, and with its own organization, work equivalent to at least four (4) percent of the total amount of work to be performed under the contract. This percentage may be reduced by a supplemental agreement to this contract if, during performing the work, the Contractor requests a reduction and the Contract Officer determines that the reduction would be to the advantage of the Government.
3. Advance Understanding H.1.10 is added as follows:
- H.1.10 Option to Extend Services**
Notwithstanding FAR Clause 52.217-8 Option to Extend Services (NOV 1999) included in Section I.1.2.1. Clauses Applicable to the Entire Contract of IDIQ Contract HHSO100201200002I, the parties agree the Government will provide no less than six months written notice of its intent to exercise the Government's right to extend the services being provided under this Task Order 75A50120F33002 pursuant FAR Clause 52.217-8.
4. Attachment 2 to the Task Order is changed as follows:

Contract No. HHSO1002012000021

Task Order No. 75A50120F33002

Modification No. P0001

Page 4 of 4

Table 1, First Item Description changed to read:

Provisional Construction Schedule for Task 2, Updated Equipment Procurement Dashboard, Official letter to BARDA reserving FBF areas HTP-1, HTP-2, and CC-3 through December 31, 2021.

- C. No additional funding is incorporated into the task order under this modification.
- D. All other terms and conditions remain the same.

Attachment 3: The following documents are attached and incorporated in to this task order:

Attachment Number	Title	Date
3	Request Authorization to priority rate TAMUS contract for industrial resources	August 17, 2020
	Authorization to issue Defense Priorities and Allocations System Rating for Operation Warp Speed Contract – Texas A&M University Systems (TAMUS)	August 19, 2020

Attachment 3 (three additional pages)



DATE:

TO: Alex M. Azar II, Secretary

THROUGH: Ann C. Agnew, Executive Secretary

FROM: Robert P. Kadlec, MD, MTM&H, MS
Assistant Secretary for Preparedness and Response

SUBJECT: Request authorization to priority rate TAMUS contract for industrial resources – **DECISION**

ACTION REQUESTED

This memorandum requests Secretarial approval to priority rate the Operation Warp Speed Texas A&M University System (TAMUS) contract for vaccine preproduction activities under the Defense Priorities and Allocations System (DPAS).

SUMMARY

As part of a broader strategy to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics, Operation Warp Speed (OWS) aims to be prepared to deliver 300 million doses of a vaccine for COVID-19 by January 2021, to ensure rapid scale-up, production, and delivery as soon as a safe and effective vaccine is developed. Through the direction of OWS leadership, manufacturing of vaccine components and finished vaccine products will occur in parallel with vaccine clinical development and testing. OWS implemented these concurrent work streams to speed the delivery of a safe and effective vaccine for responding to the COVID-19 pandemic since large scale bio manufacturing has traditionally had long lead times which are actively being mitigated through early activation of manufacturing.

Candidate vaccines under development as part of the OWS portfolio will be manufactured domestically within a mix of company-owned facilities, contract development and manufacturing organizations (CDMOs), and two HHS Centers for Innovation in Advanced Development and Manufacturing (CIADMs); one of which is the Texas A&M University System (TAMUS) CIADM facility managed by subcontractor FUJIFILM Diosynth Biotechnologies (FDBT).

Domestic manufacturing capacity for any of the candidate vaccines remains limited, given the number of doses required and accelerated timeframe established by OWS, as well as use of the facilities by other organizations outside the OWS portfolio that are developing COVID-19 and other vaccines.

In order to prepare manufacturing facilities for commercial-scale production of a COVID-19 vaccine (in the case that FDA authorization or approval is received), accelerated facility expansion and facility reservation for domestic vaccine manufacturing is required in order to compress the timeline to make the production facility space ready for manufacturing the new vaccine. DPAS priority rating is requested for vaccine pre-production activities and accelerated facilities expansion to ensure the readiness of the TAMUS/FDBT facility within the OWS-established timeframe by prioritizing orders for the production of BARDA- or OWS-supported vaccines or therapeutics and aiding the Contractor and its subcontractors in securing needed raw materials or equipment.

ANTICIPATED REACTION

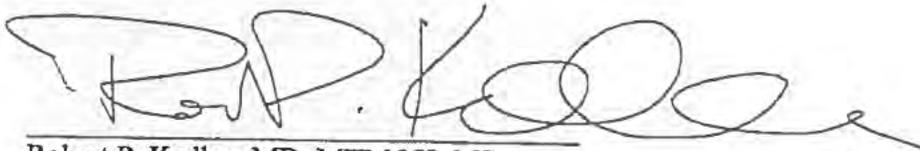
No impacts are expected for other US healthcare needs (e.g., hospitals, seasonal flu response). Current customer production requirements are being moved to other TAMUS and FDBT facilities.

ROLLOUT

If approved, this request will be briefed to the Operation Warp Speed Board for review.

RECOMMENDATION

I recommend that you approve the request to priority rate the Operation Warp Speed Texas A&M University System (TAMUS) contract for vaccine preproduction activities under the Defense Priorities and Allocations System (DPAS).



Robert P. Kadlec, MD, MTM&H, MS
Assistant Secretary for Preparedness and Response

DECISION

Approved Disapproved Need More Information


Alex M. Azar II
Secretary

AUG 17 2020
Date

**Authorization to issue Defense Priorities and Allocations
System Rating for Operation Warp Speed Contract – Texas
A&M University Systems (TAMUS)**

On August 19, 2020, the Department of Health and Human Services' (HHS) Biomedical Advanced Research and Development Authority (BARDA) was granted, from the U.S. Department of Commerce, rating authority under the Defense Priorities and Allocations System (DPAS) regulation (15 C.F.R. part 700) for contracts and orders for "industrial resources" supporting Operation Warp Speed (OWS) projects. The U.S. Department of Commerce's Bureau of Industry and Security (DOC/BIS) authorized HHS to use the "DO-HIS" priority rating on OWS contracts or orders to support private domestic production through August 31, 2022. HHS will monitor all acquisitions that carry a priority rating to ensure that each is in compliance with the DPAS regulation, and will inform DOC/BIS of any alleged violations of the DPAS of which it may become aware. HHS will also report quarterly to DOC/BIS on the contracts assigned priority ratings and their dollar value.

OWS was formed by HHS and the Department of Defense (DOD) to ramp up and expand domestic production capacity of critical health and medical resources in response to the coronavirus (COVID-19), and are funded through the Defense Production Act of 1950 (DPA) Title III authority, Coronavirus Aid, Relief, and Economic Security (CARES) Act, and/or other HHS funding sources.

Pursuant to this authority, I authorize the Contracting Officer to issue a DPAS priority rating on the Texas A&M University System (TAMUS) Center for Innovation in Advanced Development and Manufacturing (CIADM) facility (through the existing partnership (subcontract) with FUJIFILM Diosynth Biotechnologies) ("the Company") contract for industrial resources supporting the OWS Task Order. The order or contract issued pursuant to this authorization is subject to the following restrictions:

1. The Company shall accept, perform, and prioritize this order or contract for vaccine produced under task order #75A50120F33002 under Contract #HHSO100201200002I in order to ensure the delivery within the OWS-established timeframe.
2. This order or contract shall take precedence over any and all orders for the Products that do not have a priority rating, and shall take precedence over orders or contracts that have the same level of priority rating but were received later in time.
3. This order or contract shall allow the Company to priority rate orders to its suppliers for purposes of fulfilling the priority-rated contracts or orders expediently.

This authorization automatically expires at the end of the contract period of performance.

(S) (6)

Digitally signed by [REDACTED]
DN: c=US, o=U.S. Government,
ou=HHS, ou=OS, ou=People,
0.9.2342.19200300.100.1.1=200001242
5, cn=[REDACTED]
Date: 2020.08.19 12:45:25 -0400

[REDACTED] Acting Director

HHS/Biomedical Advanced Research and Development Authority

Date: