

**AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT**1. Contract ID Code  
Firm Fixed Price

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2. Amendment/Modification No.

P00002

3. Effective Date

2020SEP16

4. Requisition/Purchase Req No.

SEE SCHEDULE

5. Project No. (If applicable)

6. Issued By

ARMY CONTRACTING COMMAND - NJ

(b) (6)

PICATINNY ARSENAL, NJ 07806-5000

Code

W15QKN

7. Administered By (If other than Item 6)

Code

EMAIL: (b) (6)

8. Name And Address Of Contractor (No., Street, City, County, State and Zip Code)

GLAXOSMITHKLINE LLC

5 MOORE DR

RESEARCH TRIANGLE PARK, NC 27709-0143

9A. Amendment Of Solicitation No.

9B. Dated (See Item 11)

10A. Modification Of Contract/Order No.

W15QKN-20-C-0048

10B. Dated (See Item 13)

2020JUL30

Code (b) (4)

Facility Code

**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 amendments; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. **FAILURE OF YOUR ACKNOWLEDGMENT 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 telegram or letter, provided each telegram or letter 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)

NO CHANGE TO OBLIGATION DATA

**13. THIS ITEM ONLY APPLIES TO MODIFICATIONS OF CONTRACTS/ORDERS**

It Modifies The Contract/Order No. As Described In Item 14.

- A. This Change Order is Issued Pursuant To: \_\_\_\_\_ 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).
- C. This Supplemental Agreement Is Entered Into Pursuant To Authority Of: FAR 43.103 (a) (3)
- 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.)

SEE SECOND PAGE FOR DESCRIPTION

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

15A. Name And Title Of Signer (Type or print)

16A. Name And Title Of Contracting Officer (Type or print)

(b) (6)

15B. Contractor/Offeror

15C. Date Signed

16B. United States Of America

16C. Date Signed

(Signature of person authorized to sign)

By \_\_\_\_\_ /SIGNED/

2020SEP16

(Signature of Contracting Officer)

NSN 7540-01-152-8070

30-105-02

STANDARD FORM 30 (REV. 10-83)

PREVIOUS EDITIONS UNUSABLE

Prescribed by GSA FAR (48 CFR) 53.243

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**Name of Offeror or Contractor:** GLAXOSMITHKLINE LLC

SECTION A - SUPPLEMENTAL INFORMATION

Buyer Name: (b) (6)  
Buyer Office Symbol/Telephone Number: CCNJ-IC/(b) (6)  
Type of Contract 1: Firm Fixed Price  
Kind of Contract: Other  
Kind of Modification: G  
Type of Business: Large Business Performing in U.S.  
Surveillance Criticality Designator: A  
Contract Expiration Date: 2021FEB28

Paying Office: HQ0338  
DFAS-COLUMBUS CENTER  
SOUTH ENTITLEMENT OPERATIONS  
P O BOX 182317  
COLUMBUS OH 43218-2317

\*\*\* End of Narrative A0000 \*\*\*

The purpose of this modification is to:

1. Remove CDRL A001 "Quality Assessment Report" via Exhibit A "Contract Data Requirements List" and C.4 (a.) of the Statement of Work.
2. Update Key Personnel under the Mandatory Opsec Clause via the "Special Contract Requirements" Section of this contract.
3. Update Security Plan Requirements under the "Deliveries and Performance" Section of this contract.
4. Update CLIN 0001AA to show January and February breakout of quantities to be delivered.
5. Update FAR 52.212-5 to include the AUG 2020 version of FAR Clause 52.204-25.
6. All other terms and conditions of this contract remain in full force and effect.

\*\*\* END OF NARRATIVE A0003 \*\*\*

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ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
	SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS				
0001	COVID VACCINES NSN: 9999-99-999-9999				
0001AA	<p><u>ADJUVANT SYSTEM 03 (AS03)</u></p> <p>COMMODITY NAME: COVID VACCINES                      CLIN CONTRACT TYPE:                      Firm Fixed Price                      PRON: JP0EB73684 PRON AMD: 01 ACRN: AA                      PSC: 6505</p> <p><u>Packaging and Marking</u></p> <p><u>Inspection and Acceptance</u>                      INSPECTION: Origin ACCEPTANCE: Origin</p> <p><u>Deliveries or Performance</u>                      DOC SUPPL  <u>REL CD MILSTRIP ADDR SIG CD MARK FOR TP CD</u>                      001 W56HXN00207002 75A501 J 3  <u>DEL REL CD QUANTITY DEL DATE</u>                      001 (b) (4) [REDACTED]                      002 (b) (4) [REDACTED]</p> <p>FOB POINT: Origin</p> <p>SHIP TO:                      (75A501) OFFICE OF ACQ MGMT POLICY                      HUBERT HUMPHREY BLDG 200                      INDEPENDENCE AVENUE SW ROOM 336E                      WASHINGTON, DC, 20201</p>	(b) (4)	■	■	■

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## SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

## STATEMENT OF WORK

cGMP Adjuvant Commercial Scale Bulk Lot(s)

And

Fill-Finish of Adjuvant in (b) (4)

C.1 Scope. The Department of Defense and the Department of Health and Human Services (HHS) in support of the national emergency response to the Coronavirus Disease 2019 (COVID-19) requires the production of AS03 Adjuvant on a commercial item basis, to support (b) (4) doses of a vaccine to prevent the general population from developing COVID-19.

C.1.1 Background. The United States Department of Health and Human Services (HHS) continuously monitors emerging infectious disease risk and prepares to respond to the threat of novel emerging infectious disease outbreaks in the United States. HHS is responding to an outbreak of respiratory disease caused by a novel coronavirus that was first detected in China and which has now spread to worldwide, including in the United States. The virus has been named SARS-CoV-2 and the disease it causes has been named coronavirus disease 2019 (abbreviated COVID-19).

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the outbreak a "<https://www.who.int/news-room/detail/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-%282005%29-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-%282019-ncov%29>" (PHEIC). On January 31, Health and Human Services Secretary Alex M. Azar II declared a public health emergency (PHE) for the United States to aid the nations healthcare community in responding to COVID-19. On March 11, "<https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020>" characterized COVID-19 as a pandemic. On March 13, the President of the United States declared the COVID-19 outbreak a "<https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>". Vaccination is often the most effective measure for the control of infectious diseases. As part of HHS preparedness and response activities, HHS seeks to purchase AS03 adjuvant. AS03 adjuvant administration with vaccine antigen improves immunogenicity and achieves antigen dose-sparing.

C.2 Objectives: The Contractor shall manufacture and fill-finish a total of (b) (4) of AS03 adjuvant. This shall consist of (b) (4) for delivery no later than (b) (4) and (b) (4) for delivery no later than (b) (4). (b) (4)

## C.3. REQUIREMENTS

The contractor shall supply (b) (4) no later than (b) (4) and (b) (4) for delivery no later than (b) (4).

C.3.1 The contractor shall complete the following in support of cGMP Adjuvant: Commercial Scale Bulk Lot(s):

- Manufacture the bulk adjuvant (b) (4) equivalent(s) at commercial scale according to current Good Manufacturing Practices (cGMP) under 21 CFR parts 210, 211, and 600, as applicable, and store at appropriate conditions during lot release testing
- Make available batch records for review by HHS
- Execute lot release product testing of bulk adjuvant

C.3.2 The contractor shall complete Fill-finish of Adjuvant in (b) (4)

- Fill-finish adjuvant in final containers (b) (4)
- Fill-finish activities of adjuvant shall be carried out at facilities in compliance with FDA-cGMP guidelines.
- Full release testing of the fill-finished adjuvant (AS03) should be performed. (b) (4)

C.3.3 Storage and Stability: (b) (4)

C.3.4 Product Acceptance:

- The contractor will be paid for product (b) (4)

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b. Contractor will retain full responsibility for storing and maintaining product in (b) (4)

c. Contractor will label and release labeled product upon direction of the USG

d. Contractor will enter into an agreement with third party to support transfer of adjuvant to the third party. (b) (4)

C.3.5 AS03 Adjuvant Product Container Labeling: The contractor shall label and/or package final adjuvant product in alignment with the requirements of the regulatory authorities (FDA).

C.3.6 (b) (4)

C.4 Reporting Requirements:

a. RESERVED

b. Monthly Teleconferences and Communication: The contractor shall conduct monthly teleconferences with the Government throughout the performance of the Agreement to discuss tasks accomplished and direction for the upcoming tasks. The Government anticipates reducing the teleconferences once the manufacturing tasks begin. Awardee shall provide agendas and read-ahead material as required one day prior to the meetings and shall provide minutes of each meeting to the Government. Monthly progress reports will include baseline and updated project timelines, milestones and summaries of product manufacturing and testing. Awardee shall include key subcontractors as attendees at these teleconferences when applicable. The Awardee shall provide meeting minutes within three (3) business days after each formal scheduled meeting/teleconference conducted with the Government ((DI-ADMN-81250(Tailored))).

c. In addition to the monthly meetings, additional ad hoc meetings to address specific issues or to convey time-sensitive updates or scientific data related to the program will be held ((DI-ADMN-81250(Tailored))).

d. Incident Report. The contractor shall report any incident including any involving critical deviations, such as out of specification (OOS) results, or other product issues shall be reported to the USG within 3 calendar days. Notify the Technical Point of Contact (TPOC) within one day of incident. A written summary report shall be submitted within three (3) business days of an incident, to include what happened, what was the impact, if there are any available corrective actions and a time line for when the corrective actions would be in place ((DI-MGMT-82071(Tailored))).

e. Contract Summary Report shall be submitted 30 calendar days before the end of the PoP and the Final Technical Progress Report on or before the completion date of the PoP (DI-ADMN-80447A). The Reports shall contain manufacturing process description including:

- batch number
- date and location of manufacture (including building, room, line number)
- shelf life
- description of process/testing
- final production volume
- complete list of analytical tests performed and results to be agreed between contractor and the USG in advance of preparation of the report
- Certificate(s) of Analysis
- Certificate(s) of Current Good Manufacturing Practices (cGMP) Conformity
- Any critical deviations
- Final status, e.g., released, etc.
- Storage bag, vial, and container closure details
- Photos including USG Property labels

a. Product Development Source Material and Manufacturing Reports and Projections: The Contractor shall submit a detailed spreadsheet regarding critical project materials that are sourced from a location other than the United States, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing sites; and location and nature of non-clinical and clinical study sites. The contractor will submit a Product Development Source Material Report within one month of contract award. The contractor shall also, within 30 days of substantive changes are made to sources and/or materials, or on the 6th month contract anniversary. The contractor shall update the Dose Tracking Template weekly during manufacturing. The Contractor

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will provide manufacturing reports and manufacturing dose tracking projections/actuals utilizing the COVID-19 Dose Tracking Templates or similar, on any contract/agreement that is manufacturing product, including product for clinical trial use. manufacturing campaigns and daily during response operations (where a Public Health Emergency has been declared) and COVID-19 response, with the first deliverable submission within 15 days of award/modification. Updates to be provided weekly in advance of commercial-scale manufacturing and daily once material for use in response operations begins manufacture. The Government will provide written comments to the Product Development Source Material and Manufacturing Report within 15 business days after the submission. If corrective action is recommended, the contractor must address all concerns raised by BARDA in writing a Product Development and Source Material report to be submitted via spreadsheet; Dose Tracking can be completed via spreadsheet or other format (e.g. XML or JSON) as agreed to by USG and company (DI-SESS-81309).

b. Contractor Locations: The contractor shall submit detailed data regarding locations where work will be performed under this contract, including addresses, points of contact, and work performed per location, to include sub-contractors. Contractor will submit Work Locations Report within 5 business days of contract award, and within 30 business days after a substantive location or capabilities change. The contractor shall within 2 business days of a substantive change if the work performed supports medical countermeasure development that addresses a threat that has been declared a Public Health Emergency by the HHS Secretary or a PHEIC by the WHO (DI-ADMN-80447A).

C.5 Period of Performance: Deliveries are due no later than (b) (4) or (b) (4) as described above.

C.6 Inspection:

C.6.1 The TPOC is a duly authorized representative of the Government and is responsible for the inspection and/or acceptance of all items/activities to be delivered and/or completed under this agreement. The parties acknowledge that acceptance may depend on the compliance with FDA regulations at 21 CFR 600-680 regarding the BLA, cGMP regulations at 21 CFR 210, 211, and other FDA regulations. The COR reserves the right, prior to acceptance, to consult with FDA under its authority under Public Law 115-92 to determine compliance of the material to be delivered. To this end, contractor agrees to provide a letter to FDA authorizing the Government to engage in dialog with FDA about the ultimate compliance of this product prior to acceptance.

C.7 Packaging and Marking: The contractor shall package (b) (4).

C.8 Transportation: (b) (4)

C.9 Government Technical Point of Contact

(b) (6)  
BARDA  
(b) (6)  
(b) (6)

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## SECTION F - DELIVERIES OR PERFORMANCE

## Supply Chain Resiliency Plan

The contractor shall develop and submit within 30 calendar days of contract award, a comprehensive Supply Chain Resiliency Program that provides identification and reporting of critical components associated with the secure supply of drug substance, drug product, and work-in-process through to finished goods.

a) A critical component is defined as any material that is essential to the product or the manufacturing process associated with that product. Included in the definition are consumables and disposables associated with manufacturing. NOT included in the definition are facility and capital equipment.

Consideration of critical components includes the evaluation and potential impact of raw materials, excipients, active ingredients, substances, pieces, parts, software, firmware, labeling, assembly, testing, analytical and environmental componentry, reagents, or utility materials which are used in the manufacturing of a drug, cell banks, seed stocks, devices and key processing components and equipment. A clear example of a critical component is one where a sole supplier is utilized.

The contractor shall identify key equipment suppliers, their locations, local resources, and the associated control processes at the time of award. This document shall address planning and scheduling for active pharmaceutical ingredients, upstream, downstream, component assembly, finished drug product and delivery events as necessary for the delivery of product.

a) Communication for these requirements shall be updated as part of an annual review, or as necessary, as part of regular contractual communications.

b) For upstream and downstream processing, both single-use and re-usable in-place processing equipment, and manufacturing disposables also shall be addressed. For finished goods, the inspection, labeling, packaging, and associated machinery shall be addressed taking into account capacity capabilities.

c) The focus on the aspects of resiliency shall be on critical components and aspects of complying with the contractual delivery schedule. Delivery methods shall be addressed, inclusive of items that are foreign-sourced, both high and low volume, which would significantly affect throughput and adherence to the contractually agreed deliveries.

The contractor shall articulate in the plan, the methodology for inventory control, production planning, scheduling processes and ordering mechanisms, as part of those agreed deliveries.

a) Production rates and lead times shall be understood and communicated to the Contracting Officer or the Contracting Officer's Representative as necessary.

b) Production throughput critical constraints should be well understood by activity and by design, and communicated to contractual personnel. As necessary, communication should focus on identification, exploitation, elevation, and secondary constraints of throughput, as appropriate.

Reports for critical items should include the following information:

- a) Critical Material
- b) Vendor
- c) Supplier, Manufacturing / Distribution Location
- d) Supplier Lead Time
- e) Shelf Life
- f) Transportation / Shipping restrictions

The CO and COR reserve the right to request un-redacted copies of technical documents, during the period of performance, for distribution within the Government. Documents shall be provided within ten (10) days after CO issues the request. The Contractor may arrange for additional time if deemed necessary, and agreed to by the CO.

## Manufacturing Data Requirements

The Contractor shall submit within 30 calendar days of contract award detailed data regarding project materials, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing, processing, and fill/finish sites; and location and nature of non-clinical and clinical studies sites. The Government may provide a table in tabular format for Contractor to be used to submit such data which would include but not be limited to the following:

- Storage/inventory of ancillary materials (vials, needles, syringes, etc.)
- Shipment of ancillary materials (vials, needles, syringes, etc.)
- Disposal of ancillary materials (vials, needles, syringes, etc.)
- Seed development or other starting material manufacturing
- Bulk drug substance and/or adjuvant production
- Fill, finish, and release of product or adjuvant
- Storage/inventory of starting materials, bulk substance, or filled/final product or adjuvant
- Stability information of bulk substance and/or finished product
- Shipment of bulk substance of final product

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Disposal of bulk substance or final product

**Product Development Source Material and Manufacturing Reports and Projections**

The Contractor shall submit a detailed spreadsheet regarding critical project materials that are sourced from a location other than the United States, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing sites; and location and nature of non-clinical and clinical study sites.

The Contractor will provide manufacturing reports and manufacturing dose tracking projections/actuals utilizing the COVID-19 Dose Tracking Templates, on any contract/agreement that is manufacturing product

Contractor will submit Product Development Source Material Report

- o Within month of contract award
- o Within 30 days of substantive changes are made to sources and/or materials
- o Or on the 6th month contract anniversary.

Contractor will update the Dose Tracking Template weekly, during manufacturing campaigns and COVID response, with the first deliverable submission within 15 days of award/modification

The Government will provide written comments to the Product Development Source Material and Manufacturing Report within 15 business days after the submission

If corrective action is recommended, Contractor must address all concerns raised by the Government in writing

**Contractor Locations**

The contractor shall submit detailed data regarding locations where work will be performed under this contract, including addresses, points of contact, and work performed per location, to include sub-contractors.

Contractor will submit Work Locations Report:

- Within 5 business days of contract award
- Within 30 business days after a substantive location or capabilities change
- Within 2 business days of a substantive change if the work performed supports medical countermeasure development that addresses a threat that has been declared a Public Health Emergency by the HHS Secretary or a Public Health Emergency of International Concern (PHEIC) by the WHO

**Access and General Protection/Security Policy and Procedures**

This standard language text is applicable to ALL employees working on critical information related to Operation Warp Speed (OWS), and to those with an area of performance within a Government controlled installation, facility or area. Employees shall comply with applicable installation, facility and area commander installation/facility access and local security policies and procedures (provided by government representative). The performer also shall provide all information required for background checks necessary to access critical information related to OWS, and to meet Government installation access requirements to be accomplished by installation Director of Emergency Services or Security Office. The workforce must comply with all personnel identity verification requirements as directed by the Government and/or local policy. In addition to the changes otherwise authorized by the changes clause of this agreement, should the security status of OWS change the Government may require changes in performer security matters or processes. In addition to the industry standards for employment background checks, The Contractor must be willing to have key individuals, in exceptionally sensitive positions, identified for additional vetting by the United States Government.

**Operational Security (OPSEC)**

The performer shall develop an OPSEC Standard Operating Procedure (SOP)/Plan within ninety (90)-calendar-days of project award to be reviewed and approved by the responsible Government OPSEC officer. This plan will be submitted to the COR for coordination of approvals. This SOP/Plan will include identifying the critical information related to this contract, why it needs to be protected, where it is located, who is responsible for it, and how to protect it.

**Security Plan**

The contractor shall develop a comprehensive security program that provides overall protection of personnel, information, data, and facilities associated with fulfilling the Government requirement. This plan shall establish security practices and procedures that demonstrate how the contractor will meet and adhere to the security requirements outlined below prior to the commencement of product manufacturing, and shall be delivered to the Government within 30 calendar days of award. In the event that additional work location(s) are identified, a site security plan for the additional work location(s) should be delivered to the Government within 30 calendar days of identification. The contractor shall also ensure all subcontractors, consultants, researchers, etc. performing work on behalf of this effort, comply with all Government security requirements and prime contractor security plans.

a) The Government will review in detail and submit comments within ten (10) business days to the Contracting Officer (CO) to be forwarded to the Contractor. The Contractor shall review the Draft Security Plan comments, and, submit a Final Security Plan to the U.S. Government within thirty (10) calendar days after receipt of the comments.

b) The Security Plan shall include a timeline for compliance of all the required security measures outlined by the Government.

c) Upon completion of initiating all security measures, the Contractor shall supply to the Contracting Officer a letter certifying compliance to the elements outlined in the Final Security Plan.

At a minimum, the Final Security Plan shall address the following items:

Security Requirements:

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## 1. Facility Security Plan

Description: As part of the partner facilities overall security program, the contractor shall submit a written security plan with their proposal to the Government for review and approval by Government security subject matter experts. The performance of work under the contract will be in accordance with the approved security plan. The security plan will include the following processes and procedures at a minimum:

Security Administration	<ul style="list-style-type: none"> <li>organization chart and responsibilities</li> <li>written security risk assessment for site</li> <li>threat levels with identification matrix (High, Medium, or Low)</li> <li>enhanced security procedures during elevated threats</li> <li>liaison procedures with law enforcement</li> <li>annual employee security education and training program</li> </ul>
Personnel Security	<ul style="list-style-type: none"> <li>policies and procedures</li> <li>candidate recruitment process</li> <li>background investigations process</li> <li>employment suitability policy</li> <li>employee access determination</li> <li>rules of behavior/ conduct</li> <li>termination procedures</li> <li>non-disclosure agreements</li> </ul>
Physical Security Policies and Procedures	<ul style="list-style-type: none"> <li>internal/external access control</li> <li>protective services</li> <li>identification/badging</li> <li>employee and visitor access controls</li> <li>parking areas and access control</li> <li>perimeter fencing/barriers</li> <li>product shipping, receiving and transport security procedures</li> <li>facility security lighting</li> <li>restricted areas</li> <li>signage</li> <li>intrusion detection systems</li> <li>alarm monitoring/response</li> <li>closed circuit television</li> <li>product storage security</li> <li>other control measures as identified</li> </ul>
Information Security	<ul style="list-style-type: none"> <li>identification and marking of sensitive information</li> <li>access control</li> <li>storage of information</li> <li>document control procedures</li> <li>retention/ destruction requirements</li> </ul>
Information Technology/Cyber Security Policies and Procedures	<ul style="list-style-type: none"> <li>intrusion detection and prevention systems</li> <li>threat identification</li> <li>employee training (initial and annual)</li> <li>encryption systems</li> <li>identification of sensitive information/media</li> <li>password policy (max days 90)</li> <li>lock screen time out policy (minimum time 20 minutes)</li> <li>removable media policy</li> <li>laptop policy</li> <li>removal of IT assets for domestic/foreign travel</li> <li>access control and determination</li> <li>VPN procedures</li> <li>WiFi and Bluetooth disabled when not in use</li> <li>system document control</li> <li>system backup</li> <li>system disaster recovery</li> <li>incident response</li> <li>system audit procedures</li> <li>property accountability</li> </ul>

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## 2. Site Security Master Plan

Description: The partner facility shall provide a site schematic for security systems which includes: main access points; security cameras; electronic access points; IT Server Room; Product Storage Freezer/Room; and bio-containment laboratories.

## 3. Site Threat / Vulnerability / Risk Assessment

Description: The partner facility shall provide a written risk assessment for the facility addressing: criminal threat, including crime data; foreign/domestic terrorist threat; industrial espionage; insider threats; natural disasters; and potential loss of critical infrastructure (power/water/natural gas, etc.) This assessment shall include recent data obtained from local law enforcement agencies. The assessment should be updated annually.

## 4. Physical Security

Description:

### Closed Circuit Television (CCTV) Monitoring

- a) Layered (internal/external) CCTV coverage with time-lapse video recording for buildings and areas where critical assets are processed or stored.
- b) CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract.
- c) Video recordings must be maintained for a minimum of 30 days.
- d) CCTV surveillance system must be on emergency power backup.
- e) CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract.
- f) Video recordings must be maintained for a minimum of 30 days.
- g) CCTV surveillance system must be on emergency power backup.

### Facility Lighting

- a) Lighting must cover facility perimeter, parking areas, critical infrastructure, and entrances and exits to buildings.
- b) Lighting must have emergency power backup.
- c) Lighting must be sufficient for the effective operation of the CCTV surveillance system during hours of darkness.

### Shipping and Receiving

- a) Must have CCTV coverage and an electronic access control system.
- b) Must have procedures in place to control access and movement of drivers picking up or delivering shipments.
- c) Must identify drivers picking up Government products by government issued photo identification.

### Access Control

- a) Must have an electronic intrusion detection system with centralized monitoring.
- b) Responses to alarms must be immediate and documented in writing.
- c) Employ an electronic system (i.e., card key) to control access to areas where assets critical to the contract are located (facilities, laboratories, clean rooms, production facilities, warehouses, server rooms, records storage, etc.).
- d) The electronic access control should signal an alarm notification of unauthorized attempts to access restricted areas.
- e) Must have a system that provides a historical log of all key access transactions and kept on record for a minimum of 12 months.
- f) Must have procedures in place to track issuance of access cards to employees and the ability to deactivate cards when they are lost or an employee leaves the company.
- g) Response to electronic access control alarms must be immediate and documented in writing and kept on record for a minimum of 12 months.
- h) Should have written procedures to prevent employee piggybacking access
- i) to critical infrastructure (generators, air handlers, fuel storage, etc.) should be controlled and limited to those with a legitimate need for access.
- j) Must have a written manual key accountability and inventory process.
- k) Physical access controls should present a layered approach to critical assets within the facility.

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Employee/Visitor Information	<ul style="list-style-type: none"> <li>a) Should issue company photo identification to all employees.</li> <li>b) Photo identification should be displayed above the waist anytime the employee is on company property.</li> <li>c) Visitors should be sponsored by an employee and must present government issued photo identification to enter the property.</li> <li>d) Visitors should be logged in and out of the facility and should be escorted by an employee while on the premises at all times.</li> </ul>
Security Fencing	Requirements for security fencing will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment.
Protective Security Forces	Requirements for security officers will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment.
Protective Security Forces Operations	<ul style="list-style-type: none"> <li>a) Must have in-service training program.</li> <li>b) Must have Use of Force Continuum.</li> <li>c) Must have communication systems available (i.e., landline on post, cell phones, handheld radio, and desktop computer).</li> <li>d) Must have Standing Post Orders.</li> <li>e) Must wear distinct uniform identifying them as security officers.</li> </ul>
5. Security Operations Description:	
Information Sharing	<ul style="list-style-type: none"> <li>a) Establish formal liaison with law enforcement.</li> <li>b) Meet in person at a minimum annually. Document meeting notes and keep them on file for a, minimum of 12 months. POC information for LE Officer that attended the meeting must be documented.</li> <li>c) Implement procedures for receiving and disseminating threat information.</li> </ul>
Training	<ul style="list-style-type: none"> <li>a) Conduct new employee security awareness training.</li> <li>b) Conduct and maintain records of annual security awareness training.</li> </ul>
Security Management	<ul style="list-style-type: none"> <li>a) Designate a knowledgeable security professional to manage the security of the facility.</li> <li>b) Ensure subcontractor compliance with all Government security requirements.</li> </ul>
6. Personnel Security Description:	
Records Checks	Verification of social security number, date of birth, citizenship, education credentials, five-year previous employment history, five-year previous residence history, FDA disbarment, sex offender registry, credit check based upon position within the company; motor vehicle records check as appropriate; and local/national criminal history search.
Hiring and Retention Standards	<ul style="list-style-type: none"> <li>a) Detailed policies and procedures concerning hiring and retention of employees, employee conduct, and off boarding procedures.</li> <li>b) Off Boarding procedures should be accomplished within 24 hour of employee leaving the company. This includes termination of all network access.</li> </ul>
7. Information Security Description:	
Physical Document Control	<ul style="list-style-type: none"> <li>a) Applicable documents shall be identified and marked as procurement sensitive, proprietary, or with appropriate government markings.</li> <li>b) Sensitive, proprietary, and government documents should be maintained in a lockable filing cabinet/desk or other storage device and not be left unattended.</li> <li>c) Access to sensitive information should be restricted to those with a</li> </ul>

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need to know.

Document Destruction Documents must be destroyed using approved destruction measures (i.e, shredders/approved third party vendors / pulverizing / incinerating).

8. Information Technology & Cybersecurity  
Description:

Identity Management	<ul style="list-style-type: none"> <li>a) Physical devices and systems within the organization are inventoried and accounted for annually.</li> <li>b) Organizational cybersecurity policy is established and communicated.</li> <li>c) Asset vulnerabilities are identified and documented.</li> <li>d) Cyber threat intelligence is received from information sharing forums and sources.</li> <li>e) Threats, vulnerabilities, likelihoods, and impacts are used to determine risk.</li> <li>f) Identities and credentials are issued, managed, verified, revoked, and audited for authorized devices, users and processes.</li> <li>g) Users, devices, and other assets are authenticated (e.g., single-factor, multifactor) commensurate with the risk of the transaction (e.g., individuals security and privacy risks and other organizational risks)</li> </ul>
Access Control	<ul style="list-style-type: none"> <li>a) Limit information system access to authorized users.</li> <li>b) Identify information system users, processes acting on behalf of users, or devices and authenticate identities before allowing access.</li> <li>c) Limit physical access to information systems, equipment, and server rooms with electronic access controls.</li> <li>d) Limit access to/ verify access to use of external information systems.</li> </ul>
Training	<ul style="list-style-type: none"> <li>a) Ensure that personnel are trained and are made aware of the security risks associated with their activities and of the applicable laws, policies, standards, regulations, or procedures related to information technology systems.</li> </ul>
Audit and Accountability	<ul style="list-style-type: none"> <li>a) Create, protect, and retain information system audit records to the extent needed to enable the monitoring, analysis, investigation, and reporting of unlawful, unauthorized, or inappropriate system activity. Records must be kept for minimum must be kept for 12 months.</li> <li>b) Ensure the actions of individual information system users can be uniquely traced to those users.</li> <li>c) Update malicious code mechanisms when new releases are available.</li> <li>d) Perform periodic scans of the information system and real time scans of files from external sources as files are downloaded, opened, or executed.</li> </ul>
Configuration Management	<ul style="list-style-type: none"> <li>a) Establish and enforce security configuration settings.</li> <li>b) Implement sub networks for publically accessible system components that are physically or logically separated from internal networks.</li> </ul>
Contingency Planning	<ul style="list-style-type: none"> <li>a) Establish, implement, and maintain plans for emergency response, backup operations, and post-disaster recovery for information systems to ensure the availability of critical information resources at all times.</li> </ul>
Incident Response	<ul style="list-style-type: none"> <li>a) Establish an operational incident handling capability for information systems that includes adequate preparation, detection, analysis, containment, and recovery of cybersecurity incidents. Exercise this capability annually.</li> </ul>
Media and Information Protection	<ul style="list-style-type: none"> <li>a) Protect information system media, both paper and digital.</li> <li>b) Limit access to information on information systems media to authorized users.</li> <li>c) Sanitize and destroy media no longer in use.</li> <li>d) Control the use of removable media through technology or policy.</li> </ul>
Physical and Environmental Protection	<ul style="list-style-type: none"> <li>a) Limit access to information systems, equipment, and the respective operating environments to authorized individuals.</li> <li>b) Intrusion detection and prevention system employed on IT networks.</li> <li>c) Protect the physical and support infrastructure for all information systems.</li> </ul>

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- d) Protect information systems against environmental hazards.
- e) Escort visitors and monitor visitor activity.

## Network Protection

Employ intrusion prevention and detection technology with immediate analysis capabilities.

## 9. Transportation Security

Description: Adequate security controls must be implemented to protect materials while in transit from theft, destruction, manipulation, or damage.

## Drivers

- a) Drivers must be vetted in accordance with Government Personnel Security Requirements.
- b) Drivers must be trained on specific security and emergency procedures.
- c) Drivers must be equipped with backup communications.
- d) Driver identity must be 100 percent confirmed before the pick-up of any Government product.
- e) Drivers must never leave Government products unattended, and two drivers may be required for longer transport routes or critical products during times of emergency.
- f) Truck pickup and deliveries must be logged and kept on record for a minimum of 12 months.

## Transport Routes

- a) Transport routes should be pre-planned and never deviated from except when approved or in the event of an emergency.
- b) Transport routes should be continuously evaluated based upon new threats, significant planned events, weather, and other situations that may delay or disrupt transport.

## Product Security

- a) Government products must be secured with tamper resistant seals during transport, and the transport trailer must be locked and sealed.  
Tamper resistant seals must be verified as secure after the product is placed in the transport vehicle.
- b) Government products should be continually monitored by GPS technology while in transport, and any deviations from planned routes should be investigated and documented.
- c) Contingency plans should be in place to keep the product secure during emergencies such as accidents and transport vehicle breakdowns.

## 10. Security Reporting Requirements

Description: The partner facility shall notify the Government Security Team within 24 hours of any activity or incident that is in violation of established security standards or indicates the loss or theft of government products. The facts and circumstances associated with these incidents will be documented in writing for government review.

## 11. Security Audits

Description: The partner facility agrees to formal security audits conducted at the discretion of the government. Security audits may include both prime and subcontractor.

\*\*\* END OF NARRATIVE F0001 \*\*\*

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SECTION H - SPECIAL CONTRACT REQUIREMENTS  
Associated Contractor Agreement (ACA)

In the following clause "Contractor" shall mean "subcontractor/supplier" and

a) It is recognized that success of the Adjuvanted Recombinant COVID-19 Vaccine Development research effort depends in part upon the open exchange of information between the various Associate Contractors involved in the effort. This clause is intended to insure that there will be appropriate coordination and integration of work by the Associate Contractors to achieve complete compatibility and to prevent unnecessary duplication of effort.

By executing this contract, the Contractor assumes the responsibilities of an Associate Contractor. For the purpose of this clause, the term Contractor includes subsidiaries, affiliates, and organizations under the control of the contractor (e.g. subcontractors).

(b) Work under this contract may involve access to proprietary or confidential data from an Associate Contractor. To the extent that such data is received by the Contractor from any Associate Contractor for the performance of this contract, the Contractor hereby agrees that any proprietary information received shall remain the property of the Associate Contractor and shall be used solely for the purpose of the Adjuvanted Recombinant COVID-19 Vaccine Development research effort. Only that information which is received from another contractor in writing and which is clearly identified as proprietary or confidential shall be protected in accordance with this provision. The obligation to retain such information in confidence will be satisfied if the Contractor receiving such information utilizes the same controls as it employs to avoid disclosure, publication, or dissemination of its own proprietary information. The receiving Contractor agrees to hold such information in confidence as provided herein so long as such information is of a proprietary/confidential or limited rights nature.

(c) The Contractor hereby agrees to closely cooperate as an Associate Contractor with the other Associate Contractors on this research effort. This involves as a minimum:

- (1) Maintenance of a close liaison and working relationship;
  - (2) Maintenance of a free and open information network with all Government-identified Associate Contractors;
  - (3) Delineation of detailed interface responsibilities;
  - (4) Entering into a written agreement with the other Associate Contractors setting forth the substance and procedures relating to the foregoing, and promptly providing the Agreements Officer/Procuring Contracting Officer with a copy of same; and,
  - (5) Receipt of proprietary information from the Associate Contractor and transmittal of Contractor proprietary information to the Associate Contractors subject to any applicable proprietary information exchange agreements between associate contractors when, in either case, those actions are necessary for the performance of either.
- (d) In the event that the Contractor and the Associate Contractor are unable to agree upon any such interface matter of substance, or if the technical data identified is not provided as scheduled, GlaxoSmithKline shall promptly notify the JPEO OR BARDA Program Manager. The Government will determine the appropriate corrective action and will issue guidance to the affected Contractor.
- (e) The Contractor agrees to insert in all subcontracts hereunder which require access to proprietary information belonging to the Associate Contractor, a provision which shall conform substantially to the language of this clause, including this paragraph (e).

11.2 (a) The Contractor should enter into Associate Contractor Agreements (ACA) for any portion of the contract requiring joint participation in the accomplishment of the Governments requirement. The agreements should include the basis for sharing information, data, technical knowledge, expertise, and/or resources essential to the integration of the (insert name of the program or project), to ensure the greatest degree of cooperation for the development of the program to meet the terms of the contract. Associate contractors are listed in (g) below.

(b) ACAs should include the following general information:

- (1) Identify the associate contractors and their relationships.
- (2) Identify the program involved and the relevant Government contracts of the associate contractors.
- (3) Describe the associate contractor interfaces by general subject matter.
- (4) Specify the categories of information to be exchanged or support to be provided.
- (5) Include the expiration date (or event) of the ACA.

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(6) Identify potential conflicts between relevant Government contracts and the ACA; include agreements on protection of proprietary data and restrictions on employees.

(c) Provide a copy of such agreement to the Contracting Officer for review before execution of the document by the cooperating contractors.

(d) The Contractor is not relieved of any contract requirements or entitled to any adjustments to the contract terms because of a failure to resolve a disagreement with an associate contractor.

(e) Liability for the improper disclosure of any proprietary data contained in or referenced by any agreement rests with the parties to the agreement, and not the Government.

(f) All costs associated with the agreements are included in the negotiated cost of this contract. Agreements may be amended as required by the Government during the performance of this contract.

(g) The following contractors are associate contractors with whom agreements are required:

Contractor	Address	Program/Contract
(b) (4)	(b) (4)	OWS Project Entitled: Adjuvanted Recombinant COVID-19 Vaccine Development
GlaxoSmithKline	(b) (4), (b) (4) (b) (4)	cGMP Adjuvant Commercial Scale Bulk Lot(s) And Fill-Finish of Adjuvant in (b) (4)

MANDATORY OPSEC CLAUSE

Key Personnel

Any key personnel specified in this contract are considered to be essential to work performance. At least thirty (30) calendar days prior to the Contractor voluntarily diverting any of the specified individuals to other programs or contracts the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the Contractor is terminated for cause or separates from the Contractor voluntarily with less than thirty (30) calendar-day notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties. The following individuals are determined to be key personnel:

(b) (6)

Substitution of Key Personnel

The Contractor agrees to assign to the contract those persons whose resumes/CVs were submitted with the proposal who are necessary to fill the requirements of the contract. No substitutions shall be made except in accordance with this clause.

All requests for substitution must provide a detailed explanation of the circumstance necessitating the proposed substitution, a complete resume for the proposed substitute and any other information requested by the contracting officer to approve or disapprove the proposed substitution. All proposed substitutes must have qualifications that are equal to or higher than the qualifications of the person to be replaced. The contracting officer or authorized representative will evaluate such requests and promptly notify the contractor of his approval or disapproval thereof.

The contractor further agrees to include the substance of this clause in any subcontract, which may be awarded under this contract.

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#### Disclosure of Information

Performance under this contract may require the Contractor to access non-public data and information proprietary to a Government agency, another Government Contractor or of such nature that its dissemination or use other than as specified in the work statement would be adverse to the interests of the Government or others. Neither the Contractor, nor Contractor personnel, shall divulge nor release data nor information developed or obtained under performance of this contract, except authorized by Government personnel or upon written approval of the CO in accordance with OWS or other Government policies and/or guidance. The Contractor shall not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as specified in this contract, or any information at all regarding this agency.

The Contractor shall comply with all Government requirements for protection of non-public information. Unauthorized disclosure of nonpublic information is prohibited by the Governments rules. Unauthorized disclosure may result in termination of the contract, replacement of a Contractor employee, or other appropriate redress. Neither the Contractor nor the Contractors employees shall disclose or cause to be disseminated, any information concerning the operations of the activity, which could result in, or increase the likelihood of, the possibility of a breach of the activitys security or interrupt the continuity of its operations.

No information related to data obtained under this contract shall be released or publicized without the prior written consent of the COR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity for submission to any securities exchange on which the Contractors (or its parent corporations) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

#### Publications and Publicity

The contractor shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this contract without written notice in advance to the Government.

(a) Unless otherwise specified in this contract, the contractor may publish the results of its work under this contract. The contractor shall promptly send a copy of each submission to the COR for security review prior to submission. The contractor shall also inform the COR when the abstract article or other publication is published, and furnish a copy of it as finally published.

(b) Unless authorized in writing by the CO, the contractor shall not display Government logos including Operating Division or Staff Division logos on any publications.

(c) The contractor shall not reference the products(s) or services(s) awarded under this contract in commercial advertising, as defined in FAR 31.205-1, in any manner which states or implies Government approval or endorsement of the product(s) or service(s) provided.

(d) The contractor shall include this clause, including this section (d) in all subcontracts where the subcontractor may propose publishing the results of its work under the subcontract. The contractor shall acknowledge the support of the Government whenever publicizing the work under this contract in any media by including an acknowledgement substantially as follows:

"This project has been funded in whole or in part by the U.S. Government under Contract No. XXXX. The US Government is authorized to reproduce and distribute reprints for Governmental purposes notwithstanding any copyright notation thereon.

#### Confidentiality of Information

a. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor shall obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

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f. Contracting Officer Determinations will reflect the result of internal coordination with appropriate program and legal officials.

g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

All above requirements MUST be passed to all Sub-contractors.

Organizational Conflicts of Interest

Performance under this contract may create an actual or potential organizational conflict of interest such as are contemplated by FAR Part 9.505-General Rules. The Contractor shall not engage in any other contractual or other activities which could create an organizational conflict of interest (OCI). This provision shall apply to the prime Contractor and all sub-Contractors. This provision shall have effect throughout the period of performance of this contract, any extensions thereto by change order or supplemental agreement, and for two (2) years thereafter. The Government may pursue such remedies as may be permitted by law or this contract, upon determination that an OCI has occurred.

The work performed under this contract may create a significant potential for certain conflicts of interest, as set forth in FAR Parts 9.505-1, 9.505-2, 9.505-3, and 9.505-4. It is the intention of the parties hereto to prevent both the potential for bias in connection with the Contractors performance of this contract, as well as the creation of any unfair competitive advantage as a result of knowledge gained through access to any non-public data or third party proprietary information.

The Contractor shall notify the Contracting Officer immediately whenever it becomes aware that such access or participation may result in any actual or potential OCI. Furthermore, the Contractor shall promptly submit a plan to the Contracting Officer to either avoid or mitigate any such OCI. The Contracting Officer will have sole discretion in accepting the Contractors mitigation plan. In the event the Contracting Officer unilaterally determines that any such OCI cannot be satisfactorily avoided or mitigated, other remedies may be taken to prohibit the Contractor from participating in contract requirements related to OCI.

Whenever performance of this contract provides access to another Contractors proprietary information, the Contractor shall enter into a written agreement with the other entities involved, as appropriate, in order to protect such proprietary information from unauthorized use or disclosure for as long as it remains proprietary; and refrain from using such proprietary information other than as agreed to, for example to provide assistance during technical evaluation of other Contractors offers or products under this contract. An executed copy of all proprietary information agreements by individual personnel or on a corporate basis shall be furnished to the CO within fifteen (15) calendar days of execution.

Institutional Responsibility Regarding Investigator Conflicts of Interest

The Institution (includes any Contractor, public or private, excluding a Federal agency) shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Investigators (defined as the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded under Government contracts, or proposed for such funding, which may include, for example, collaborators or consultants) will not be biased by any Investigator financial conflicts of interest. 45 CFR Part 94 is available at the following Web site: <http://www.ecfr.gov/cgi-bin/textidx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=>

As required by 45 CFR Part 94, the Institution shall, at a minimum:

a. Maintain an up-to-date, written, enforceable policy on financial conflicts of interest that complies with 45 CFR Part 94, inform each Investigator of the policy, the Investigator's reporting responsibilities regarding disclosure of significant financial interests, and the applicable regulation, and make such policy available via a publicly accessible Web site, or if none currently exist, available to any requestor within five business days of a request. A significant financial interest means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. Included are payments and equity interests;

2. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest; or

3. Intellectual property rights and interests, upon receipt of income related to such rights and interest.

Significant financial interests do not include the following:

1. Income from seminars, lectures, or teaching, and service on advisory or review panels for Government agencies, Institutions of higher education, academic teaching hospitals, medical centers, or research institutes with an Institution of higher learning; and

2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

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- b. Require each Investigator to complete training regarding the Institution's financial conflicts of interest policy prior to engaging in research related to any Government funded contract and at least every four years. The Institution must take reasonable steps [see Part 94.4(c)] to ensure that investigators working as collaborators, consultants or subcontractors comply with the regulations.
- c. Designate an official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the Government funded research.
- d. Require that each Investigator who is planning to participate in the Government funded research disclose to the Institution's designated official(s) the Investigator's significant financial interest (and those of the Investigator's spouse and dependent children) no later than the date of submission of the Institution's proposal for Government funded research. Require that each Investigator who is participating in the Government funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Institution during the period of the award as well as within thirty days of discovering or acquiring a new significant financial interest.
- e. Provide guidelines consistent with the regulations for the designated official(s) to determine whether an Investigator's significant financial interest is related to Government funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to Government funded research when the Institution, through its designated official(s), reasonably determines that the significant financial interest: Could be affected by the Government funded research; or is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists when the Institution, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the Government funded research.
- f. Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subcontractor Investigator. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report pursuant to Part 94.5(a).
- g. Provide initial and ongoing FCOI reports to the Contracting Officer pursuant to Part 94.5(b).
- h. Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures, and all actions under the Institution's policy or retrospective review, if applicable, for at least 3 years from the date of final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.
- i. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.
- j. Complete the certification in Section K - Representations, Certifications, and Other Statements of Contractors titled "Certification of Institutional Policy on Financial Conflicts of Interest".

If the failure of an Institution to comply with an Institution's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the Government funded research, the Institution must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will consider the situation and, as necessary, take appropriate action or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the Government funded research project.

The Contracting Officer and/or Government may inquire at any time before, during, or after award into any Investigator disclosure of financial interests, and the Institution's review of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of a financial conflict of interests. The Contracting Officer may require submission of the records or review them on site. On the basis of this review of records or other information that may be available, the Contracting Officer may decide that a particular financial conflict of interest will bias the objectivity of the Government funded research to such an extent that further corrective action is needed or that the Institution has not managed the financial conflict of interest in accordance with Part 94.6(b). The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that Government funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution, the Institution shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

**CONTINUATION SHEET****Reference No. of Document Being Continued**

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PIIN/SIIN

W15QKN-20-C-0048

MOD/AMD P00002

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## SECTION I - CONTRACT CLAUSES

<u>Status</u>	<u>Regulatory Cite</u>	<u>Title</u>	<u>Date</u>
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I-1 CHANGED	52.212-5	CONTRACT TERMS AND CONDITIONS REQUIRED TO IMPLEMENT STATUTES OR EXECUTIVE ORDERS--COMMERCIAL ITEMS	JUN/2020
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(a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

(1) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (JAN 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(2) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).

(3) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (AUG 2020) (Section 889(a)(1)(A) of Pub. L. 115-232).

(4) 52.209-10, Prohibition on Contracting with Inverted Domestic Corporations (Nov 2015)

(5) 52.233-3, Protest After Award (AUG 1996) (31 U.S.C. 3553).

(6) 52.233-4, Applicable Law for Breach of Contract Claim (OCT 2004) (Public Laws 108-77 and 108-78 (19 U.S.C. 3805 note)).

(b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the contracting officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

(1) 52.203-6, Restrictions on Subcontractor Sales to the Government (Jun 2020), with Alternate I (Oct 1995) (41 U.S.C. 4704 and 10 U.S.C. 2402).

(2) 52.203-13, Contractor Code of Business Ethics and Conduct (Jun 2020) (41 U.S.C. 3509).

(3) 52.203-15, Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (Jun 2010) (Section 1553 of Pub. L. 111-5). (Applies to contracts funded by the American Recovery and Reinvestment Act of 2009.)

(4) 52.204-10, Reporting Executive Compensation and First-Tier Subcontract Awards (Jun 2020) (Pub. L. 109-282) (31 U.S.C. 6101 note).

(5) [Reserved].

(6) 52.204-14, Service Contract Reporting Requirements (Oct 2016) (Pub. L. 111-117, section 743 of Div. C).

(7) 52.204-15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts (Oct 2016) (Pub. L. 111-117, section 743 of Div. C).

(8) 52.209-6, Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment (Jun 2020) (31 U.S.C. 6101 note).

(9) 52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters (Oct 2018) (41 U.S.C. 2313).

(10) [Reserved]

(11) (i) 52.219-3, Notice of HUBZone Set-Aside or Sole-Source Award (MAR 2020) (15 U.S.C. 657a).

(ii) Alternate I (MAR 2020) of 52.219-3.

(12) (i) 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (MAR 2020) (if the offeror elects to waive the preference, it shall so indicate in its offer) (15 U.S.C. 657a).

(ii) Alternate I (MAR 2020) of 52.219-4.

(13) [Reserved]

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- (14) (i) 52.219-6, Notice of Total Small Business Set-Aside (MAR 2020) (15 U.S.C. 644).
- (ii) Alternate I (MAR 2020) of 52.219-6.
- (iii) Alternate II (Nov 2011) of 52.219-6.
- (15) (i) 52.219-7, Notice of Partial Small Business Set-Aside (MAR 2020) (15 U.S.C. 644).
- (ii) Alternate I (MAR 2020) of 52.219-7.
- (iii) Alternate II (Mar 2004) of 52.219-7.
- (16) 52.219-8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C. 637(d)(2) and (3)).
- (17) (i) 52.219-9, Small Business Subcontracting Plan (Jun 2020) (15 U.S.C. 637(d)(4)).
- (ii) Alternate I (Nov 2016) of 52.219-9.
- (iii) Alternate II (Nov 2016) of 52.219-9.
- (iv) Alternate III (Jun 2020) of 52.219-9.
- (v) Alternate IV (Jun 2020) of 52.219-9.
- (18) 52.219-13, Notice of Set-Aside of Orders (MAR 2020) (15 U.S.C. 644(r)).
- (19) 52.219-14, Limitations on Subcontracting (MAR 2020) (15 U.S.C. 637(a)(14)).
- (20) 52.219-16, Liquidated Damages--Subcontracting Plan (JAN 1999) (15 U.S.C. 637(d)(4)(F)(i)).
- (21) 52.219-27, Notice of Total Service-Disabled Veteran-Owned Small Business Set-Aside (MAR 2020) (15 U.S.C. 657 f)
- (22) 52.219-28, Post Award Small Business Program Rerepresentation (MAR 2020) (15 U.S.C. 632(a)(2)).
- (i) Alternate I (MAR 2020) of 52.219-28.
- (23) 52.219-29 Notice of Total Set-Aside for Economically Disadvantaged Women-Owned Small Business (EDWOSB) Concerns (MAR 2020) (15 U.S.C. 637(m)).
- (24) 52.219-30 Notice of Total Set-Aside for Women-Owned Small Business (WOSB) Concerns Eligible Under the WOSB Program (MAR 2020) (15 U.S.C. 637(m)).
- (25) 52.219-32, Orders Issued Directly Under Small Business Reserves (MAR 2020) (15 U.S.C. 644(r)).
- (26) 52.219-33, Nonmanufacturer Rule (MAR 2020) (15 U.S.C. 637(a)(17)).
- (27) 52.222-3, Convict Labor (June 2003) (E.O. 11755).
- (28) 52.222-19, Child Labor Cooperation with Authorities and Remedies (Jan 2020) (E.O. 13126).
- (29) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).
- (30) (i) 52.222-26, Equal Opportunity (Sep 2016) (E.O. 11246).
- (ii) Alternate I (Feb 1999) of 52.222-26.
- (31) (i) 52.222-35, Equal Opportunity for Veterans (Jun 2020) (38 U.S.C. 4212).
- (ii) Alternate I (July 2014) of 52.222-35.
- (32) (i) 52.222-36, Equal Opportunity for Workers with Disabilities (Jun 2020) (29 U.S.C. 793).
- (ii) Alternate I (July 2014) of 52.222-36.
- (33) 52.222-37, Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (Jun

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2020) (38 U.S.C. 4212).

- (34) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496).
- (35) (i) 52.222-50, Combating Trafficking in Persons (Jan 2019) (22 U.S.C. chapter 78 and E.O. 13627).
- (ii) Alternate I (Mar 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).
- (36) 52.222-54, Employment Eligibility Verification (Oct 2015). (Executive Order 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in 22.1803.)
- (37) (i) 52.223-9, Estimate of Percentage of Recovered Material Content for EPA-Designated Items (May 2008) (42 U.S.C. 6962(c)(3)(A)(ii)). (Not applicable to the acquisition of commercially available off-the-shelf items.)
- (ii) Alternate I (May 2008) of 52.223-9 (42 U.S.C. 6962(i)(2)(C)). (Not applicable to the acquisition of commercially available off-the-shelf items.)
- (38) 52.223-11, Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (June, 2016) (E.O. 13693).
- (39) 52.223-12, Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (June, 2016) (E.O. 13693).
- (40) (i) 52.223-13, Acquisition of EPEAT[supreg]-Registered Imaging Equipment (Jun 2014) (E.O.s 13423 and 13514).
- (ii) Alternate I (Oct 2015) of 52.223-13.
- (41) (i) 52.223-14, Acquisition of EPEAT[supreg]-Registered Televisions (Jun 2014) (E.O.s 13423 and 13514).
- (ii) Alternate I (Jun 2014) of 52.223-14.
- (42) 52.223-15, Energy Efficiency in Energy-Consuming Products (Dec 2007) (42 U.S.C. 8259b).
- (43) (i) 52.223-16, Acquisition of EPEAT[supreg]-Registered Personal Computer Products (Oct 2015) (E.O.s 13423 and 13514).
- (ii) Alternate I (Jun 2014) of 52.223-16.
- (44) 52.223-18, Encouraging Contractor Policies to Ban Text Messaging While Driving (Jun 2020) (E.O. 13513).
- (45) 52.223-20, Aerosols (June, 2016) (E.O. 13693).
- (46) 52.223-21, Foams (June, 2016) (E.O. 13693).
- (47) (i) 52.224-3, Privacy Training (JAN 2017) (5 U.S.C. 552a).
- (ii) Alternate I (JAN 2017) of 52.224-3.
- (48) 52.225-1, Buy American--Supplies (MAY 2014) (41 U.S.C. chapter 83).
- (49) (i) 52.225-3, Buy American--Free Trade Agreements--Israeli Trade Act (MAY 2014) (41 U.S.C. chapter 83, 19 U.S.C. 3301 note, 19 U.S.C. 2112 note, 19 U.S.C. 3805 note, 19 U.S.C. 4001 note, Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43).
- (ii) Alternate I (MAY 2014) of 52.225-3.
- (iii) Alternate II (MAY 2014) of 52.225-3.
- (iv) Alternate III (MAY 2014) of 52.225-3.
- (50) 52.225-5, Trade Agreements (Oct 2019) (19 U.S.C. 2501, et seq., 19 U.S.C. 3301 note).
- (51) 52.225-13, Restrictions on Certain Foreign Purchases (Jun 2008) (E.o.s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).
- (52) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Jul 2013) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).
- (53) 52.226-4, Notice of Disaster or Emergency Area Set-Aside (Nov 2007) (42 U.S.C. 5150).
- (54) 52.226-5, Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov 2007) (42 U.S.C. 5150).

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\_\_\_ (55) 52.229-12, Tax on Certain Foreign Procurements (JUN 2020).

\_\_\_ (56) 52.232-29, Terms for Financing of Purchases of Commercial Items (Feb 2002) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).

\_\_\_ (57) 52.232-30, Installment Payments for Commercial Items (Jan 2017) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).

\_\_\_ (58) 52.232-33, Payment by Electronic Funds Transfer -- System for Award Management (Oct 2018) (31 U.S.C. 3332).

\_\_\_ (59) 52.232-34, Payment by Electronic Funds Transfer -- Other Than System for Award Management (Jul 2013) (31 U.S.C. 3332).

\_\_\_ (60) 52.232-36, Payment by Third Party (MAY 2014) (31 U.S.C. 3332).

\_\_\_ (61) 52.239-1, Privacy or Security Safeguards (Aug 1996) (5 U.S.C. 552a).

\_\_\_ (62) 52.242-5, Payments to Small Business Subcontractors (Jan 2017) (15 U.S.C. 637(d) (13)).

\_\_\_ (63) (i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx 1241(b) and 10 U.S.C. 2631).

\_\_\_ (ii) Alternate I (Apr 2003) of 52.247-64.

\_\_\_ (iii) Alternate II (Feb 2006) of 52.247-64.

(c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or executive orders applicable to acquisitions of commercial items:

\_\_\_ (1) 52.222-41, Service Contract Labor Standards (Aug 2018) (41 U.S.C. chapter 67).

\_\_\_ (2) 52.222-42, Statement of Equivalent Rates for Federal Hires (MAY 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

\_\_\_ (3) 52.222-43, Fair Labor Standards Act and Service Contract Labor Standards--Price Adjustment (Multiple Year and Option Contracts) (MAY 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

\_\_\_ (4) 52.222-44, Fair Labor Standards Act and Service Contract Labor Standards--Price Adjustment (MAY 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

\_\_\_ (5) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment--Requirements (MAY 2014) (41 U.S.C. chapter 67).

\_\_\_ (6) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services--Requirements (MAY 2014) (41 U.S.C. chapter 67).

\_\_\_ (7) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015) (Executive Order 13658).

\_\_\_ (8) 52.222-62, Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).

\_\_\_ (9) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (Jun 2020) (42 U.S.C. 1792).

(d) Comptroller General Examination of Record. The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, as defined in FAR 2.101, on the date of award of this contract, and does not contain the clause at 52.215-2, Audit and Records -- Negotiation.

(1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractors directly pertinent records involving transactions related to this contract.

(2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR Subpart 4.7, Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.

(3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in

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the ordinary course of business or pursuant to a provision of law.

(e) (1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c) and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e) (1) in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause--

(i) 52.203-13, Contractor Code of Business Ethics and Conduct (Jun 2020) (41 U.S.C. 3509).

(ii) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (JAN 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(iii) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).

(iv) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (AUG 2020) (Section 889(a) (1) (A) of Pub. L. 115-232).

(v) 52.219-8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C. 637(d) (2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds the applicable threshold specified in FAR 19.702(a) on the date of subcontract award, the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.

(vi) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).

(vii) 52.222-26, Equal Opportunity (Sep 2016) (E.O. 11246).

(viii) 52.222-35, Equal Opportunity for Veterans (Jun 2020) (38 U.S.C. 4212).

(ix) 52.222-36, Equal Opportunity for Workers with Disabilities (Jun 2020) (29 U.S.C. 793).

(x) 52.222-37, Employment Reports on Veterans (Jun 2020) (38 U.S.C. 4212).

(xi) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (DEC 2010) (E.O. 13496).

(xii) 52.222-41, Service Contract Labor Standards (Aug 2018) (41 U.S.C. chapter 67).

(xiii) (A) 52.222-50, Combating Trafficking in Persons (Jan 2019) (22 U.S.C. 7104(g)).

(B) Alternate I (Mar 2015) of 52.222-50 (22 U.S.C. 7104(g)).

(xiv) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment--Requirements (MAY 2014) (41 U.S.C. chapter 67).

(xv) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services--Requirements (MAY 2014) (41 U.S.C. chapter 67).

(xvi) 52.222-54, Employment Eligibility Verification (Oct 2015).

(xvii) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015) (Executive Order 13658).

(xviii) 52.222-62 Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).

(xix) (A) 52.224-3, Privacy Training (JAN 2017) (5 U.S.C. 552a).

(B) Alternate I (JAN 2017) of 52.224-3.

(xx) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Jul 2013) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).

(xxi) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (Jun 2020) (42 U.S.C. 1792). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.

(xxii) 52.247-64, Preference for Privately-Owned U.S. Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx 1241(b) and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.

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(2) While not required, the Contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(End of Clause)