**SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS**
*OFFEROR TO COMPLETE BLOCKS 12, 17, 23, 24, & 30*

| 1. REQUISITION NUMBER | PAGE | OF |
|---|---|---|
| OS263349 | 1 | 68 |

| 2. CONTRACT NO. | 3. AWARD/ EFFECTIVE DATE | 4. ORDER NUMBER | 5. SOLICITATION NUMBER | 6. SOLICITATION ISSUE DATE |
|---|---|---|---|---|
| | | 75A50120P00103 | | |

| 7. FOR SOLICITATION INFORMATION CALL | a. NAME | b. TELEPHONE NUMBER (No collect calls) | 8. OFFER DUE DATE/LOCAL TIME |
|---|---|---|---|
| | DE IONNE JONES | | |

9. ISSUED BY — CODE ASPR-BARDA

ASPR-BARDA
200 Independence Ave., S.W.
Room 640-G
Washington DC 20201

10. THIS ACQUISITION IS ☒ UNRESTRICTED OR ☐ SET ASIDE: % FOR:

☐ SMALL BUSINESS
☐ HUBZONE SMALL BUSINESS
☐ SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS
☐ WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOMEN-OWNED SMALL BUSINESS PROGRAM
☐ EDWOSB
☐ 8(A)

NAICS: 541715
SIZE STANDARD: 1,000

| 11. DELIVERY FOR FOB DESTINATION UNLESS BLOCK IS MARKED | 12. DISCOUNT TERMS | 13a. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700) | 13b. RATING / 14. METHOD OF SOLICITATION |
|---|---|---|---|
| ☒ SEE SCHEDULE | | ☐ | ☐ RFQ ☐ IFB ☐ RFP |

15. DELIVER TO — CODE HHS/OS/ASPR

HHS/OS/ASPR
200 C St SW
WASHINGTON DC 20201

16. ADMINISTERED BY — CODE ASPR-BARDA

ASPR-BARDA
US DEPT OF HEALTH & HUMAN SERVICES
BIOMEDICAL ADVANCED RESEACH & DEVELOPMENT AUT
200 INDEPENDENCE AVE, S.W.
Washington DC 20201

17a. CONTRACTOR/ OFFEROR — CODE 375787 — FACILITY CODE

ORTHO CLINICAL DIAGNOSTICS 375787
Attn: [redacted]
ORTHO-CLINICAL DIAGNOSTICS, INC.
1001 RTE 202 US HWY
RARITAN NJ 088691424

TELEPHONE NO. [redacted]

☐ 17b. CHECK IF REMITTANCE IS DIFFERENT AND PUT SUCH ADDRESS IN OFFER

18a. PAYMENT WILL BE MADE BY — CODE ASPR-BARDA

ASPR-BARDA
US DEPT OF HEALTH & HUMAN SERVICES
BIOMEDICAL ADVANCED RESEACH & DEVEL
200 INDEPENDENCE AVE, S.W; ROOM 640
Washington DC 20201

18b. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 18a UNLESS BLOCK BELOW IS CHECKED ☐ SEE ADDENDUM

| 19. ITEM NO. | 20. SCHEDULE OF SUPPLIES/SERVICES | 21. QUANTITY | 22. UNIT | 23. UNIT PRICE | 24. AMOUNT |
|---|---|---|---|---|---|
| | Tax ID Number: 22-3329332<br>DUNS Number: 068715424<br>ASPR-20-03105 -- COVID-19 Base period funds to Ortho Clinical Diagnostics Inc<br><br>This is a fully funded, firm-fixed price contract. Payments to be made in accordance with Milestones Chart in Attachment 1.<br><br>The following clauses are incorporated by reference:<br>1. FAR 52.204-7, System for Award Management (Oct 2018)<br>2. FAR 52.204-16, Commercial and Government Entity Code Reporting (Aug 2020)<br>3. FAR 52.204-24, Representation Regarding Certain Telecommunications and Video<br>*(Use Reverse and/or Attach Additional Sheets as Necessary)* | | | | |

25. ACCOUNTING AND APPROPRIATION DATA
2020.199C023.25106

26. TOTAL AWARD AMOUNT *(For Govt. Use Only)*
$12,850,000.00

☐ 27a. SOLICITATION INCORPORATES BY REFERENCE FAR 52 212-1, 52.212-4. FAR 52.212-3 AND 52.212-5 ARE ATTACHED. ADDENDA ☐ ARE ☐ ARE NOT ATTACHED.
☒ 27b. CONTRACT/PURCHASE ORDER INCORPORATES BY REFERENCE FAR 52.212-4. FAR 52 212-5 IS ATTACHED. ADDENDA ☒ ARE ☐ ARE NOT ATTACHED.

☒ 28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 1 COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED.

☐ 29. AWARD OF CONTRACT: _____ OFFER DATED _____. YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN, IS ACCEPTED AS TO ITEMS:

| 30a. SIGNATURE OF OFFEROR/CONTRACTOR | 31a. UNITED STATES OF AMERICA *(SIGNATURE OF CONTRACTING OFFICER)* |
|---|---|
| [redacted] | [redacted] |

| 30b. NAME AND TITLE OF SIGNER *(Type or print)* | 30c. DATE SIGNED | 31b. NAME OF CONTRACTING OFFICER *(Type or print)* | 31c. DATE SIGNED |
|---|---|---|---|
| [redacted] | 09/18/2020 | [redacted] | 09/18/2020 |

| 19. ITEM NO. | 20. SCHEDULE OF SUPPLIES/SERVICES | 21. QUANTITY | 22. UNIT | 23. UNIT PRICE | 24. AMOUNT |
|---|---|---|---|---|---|
| | Surveillance Services or Equipment (Aug 2020)<br><br>The following attachments are applicable to this order:<br>1. Statement of Work<br>2. Contract Administration Requirements<br>3. Reporting and Meeting Requirements<br>4. Special Contracting Requirements<br>5. Addendum to the clause at FAR 52.212-4, Contract Terms and Conditions - Commercial Items (Oct 2018)<br>6. The clause at FAR 52.212-5, Contract Terms and Conditions Required to Implement Statutes or Executive Orders - Commercial Items (Aug 2020)<br>Delivery: 09/08/2021<br>Appr. Yr.: 2020 CAN: 199C023 Object Class: 25106<br>Period of Performance: 09/18/2020 to 09/17/2021 | | | | |
| 1 | ASPR-20-03105 -- COVID-19 Base period funds to Ortho Clinical Diagnostics Inc | | | | 12,850,000.00 |
| | The total amount of award: $12,850,000.00. The obligation for this award is shown in box 26. | | | | |

32a. QUANTITY IN COLUMN 21 HAS BEEN

☐ RECEIVED ☐ INSPECTED ☐ ACCEPTED, AND CONFORMS TO THE CONTRACT, EXCEPT AS NOTED: _____

| 32b. SIGNATURE OF AUTHORIZED GOVERNMENT REPRESENTATIVE | 32c. DATE | 32d. PRINTED NAME AND TITLE OF AUTHORIZED GOVERNMENT REPRESENTATIVE |
|---|---|---|
| | | |

| 32e. MA LING ADDRESS OF AUTHORIZED GOVERNMENT REPRESENTATIVE | 32f. TELEPHONE NUMBER OF AUTHORIZED GOVERNMENT REPRESENTATIVE<br>32g. E-MA L OF AUTHORIZED GOVERNMENT REPRESENTATIVE |
|---|---|
| | |

| 33. SHIP NUMBER<br>☐ PARTIAL ☐ FINAL | 34. VOUCHER NUMBER | 35. AMOUNT VERIFIED CORRECT FOR | 36. PAYMENT<br>☐ COMPLETE ☐ PARTIAL ☐ FINAL | 37. CHECK NUMBER |
|---|---|---|---|---|
| | | | | |

| 38. S/R ACCOUNT NUMBER | 39. S/R VOUCHER NUMBER | 40. PAID BY |
|---|---|---|
| | | |

| 41a. I CERTIFY THIS ACCOUNT IS CORRECT AND PROPER FOR PAYMENT | | 42a. RECEIVED BY *(Print)* | |
|---|---|---|---|
| 41b. SIGNATURE AND TITLE OF CERTIFY NG OFFICER | 41c. DATE | 42b. RECEIVED AT *(Location)* | |
| | | 42c. DATE REC'D *(YY/MM/DD)* | 42d. TOTAL CONTAINERS |

**Biomedical Advanced Research and Development Authority (BARDA)**

# Advancement of Ortho Clinical Diagnostics VITROS Immunodiagnostic Products Assays for the Detection of Antigen and Antibodies to SARS-CoV-2

**Statement of Work (SOW)**

## PREAMBLE

Independently, and not as an agent of the government, the contractor shall furnish all necessary services; qualified professional, technical, and administrative personnel; and material, equipment, and facilities not otherwise provided by the government under the terms of this contract, as needed to perform the tasks set forth below.

The government reserves the right to modify the budget, progress, schedule, or milestones to add or delete processes, schedules, or deliverables if the need arises. Because of the nature of this research and development (R&D) contract and the complexities inherent in this and prior programs, at designated milestones the government will evaluate whether work should be redirected or removed, or whether schedule or budget adjustments should be made. The government reserves the right to change the product, process, schedule, or events to add or delete part or all of these elements as the need arises.

## Overall Objectives and Scope

The first objective of this contract is to develop a highly accurate VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Test Kit and submit an Emergency Use Authorization (EUA) filing to the United States Food and Drug Administration (FDA). The second objective of this contract is to meet all requirements for submissions of de novo or 510k applications to the FDA for the highly accurate VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Test Kit and the VITROS Immunodiagnostic Products anti-SARS-CoV-2 Total Test Kit.

The R&D effort for the Development of the VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Test Kit will progress in work segments with key Deliverables being due during the Base Period of performance of the contract (the Base Period will be labeled Contract Line Item Number (CLIN) 0001). Each Deliverable will require a concrete work segment with a well-defined objective, scope of work, and success metric for accomplishing the Deliverable. The work segments for each Deliverable may occur sequentially or simultaneously based on the pathway and needs of the project.

In addition to the requirements outlined under "Section F.2 Deliverables" of the contract, the following deliverables are defined for this project:

1. **Deliverable 1 –** Project Plan
2. **Deliverable 2** – EUA Submission of a VITROS Immunodiagnostic Products SARS-CoV – 2 Antigen Test Kit
3. **Deliverable 3 –** De novo or 510k Submission for the VITROS Immunodiagnostic Products anti-SARS-CoV-2 IgG Test Kit
4. **Deliverable 4 –** De novo or 510k Submission for the VITROS Immunodiagnostic Products anti-SARS-CoV-2 Total Test Kit

**Deliverable 1: Project Plan**

**Objective:**
Provide a detailed project plan outlining the goals, deliverables, and intended pathway for the project.

**Scope of Work:**
- Create a Gantt Chart that identifies all goals and deliverables for the project
- Create a resource tracking document
- Provide a description of the tools/techniques used to track and monitor the cost and schedule
- Provide a Risk Management Plan for the entire project

**Success Metric for Completion of Deliverable 1:**
Provide Project Plan, Gantt Chart, and Risk Mitigation Plan that is received and approved by the Contracting Officer (CO) and Contracting Officer's Representative (COR), within 10 days of contract award.

**Deliverable 2: EUA Submission of a VITROS Immunodiagnostic Products SARS-CoV – 2 Antigen Test Kit**

**Deliverable 2a: Creation of a prototype SARS-CoV-2 Antigen Assay**

**Deliverable 2a.1: Product Requirement Document**

**Objective:**
Establish the verifiable qualitative and quantitative requirements of the assay

**Scope of Work:**
- Define sensitivity and specificity requirements relative to the chosen predicate
- Define sample collection devices and sample matrices
- Identify key cross reactants
- Define calibrator and control characteristics

**Success Metric for the Completion of Deliverable 2:**
See Appendix 1 – Milestone 2 Deliverables and Success Criteria

**Deliverable 2a.2: Secure Key Materials**

**Objective:**
Identify critical rare reagents for assay performance and gain intellectual property rights for their commercial use. Purchase additional components to initiate assay development.

**Scope of Work:**
- Obtain all candidate materials from multiple sources.
- Measure reactivity and affinities
- Synthesize bioconjugates
- Coat solid phase, formulate liquid reagents, calibrators and controls
- Obtain does response curve with recombinant antigen
- Select optimal materials
- Secure all materials supply through licensing and approved supplier list

**Success Metric for Completion of Deliverable 2a.2:**
See Appendix 1 – Milestone 2 Deliverables and Success Criteria

**Deliverable 2a.3: Successful Patient Sample Testing**

**Objective:**
Demonstrate initial patient testing sensitivity with native antigen from swabs and transport media and negative sample from the same matrix spiked with key cross reactants

**Scope of Work**

- Define sample prep formulation and protocol
- Develop and optimize assay formulation and protocol
- Develop and optimize calibrators and controls
- Run greater than five NAT positive samples
- Run key cross reactants and greater than five NAT negative samples

**Success Metric for Completion of Deliverable 2a.3:**
See Appendix 1 – Milestone 2 Deliverables and Success Criteria

**Deliverable 2a.4: Prototype Assay Complete**

**Objective:**
Assay formulations and protocols are compatible with and have been successfully demonstrated on the VITROS automated analyzers.

**Scope of Work:**

- Assay liquid formulations defined
- Assay solid phase coating defined
- Calibrator and control formulations defined
- Assay sample prep defined
- Assay protocol defined
- Dose / response obtained
- Preliminary precision assessed
- Preliminary accuracy assessed with patient samples and key cross reactants

**Success Metric for Completion of Deliverable 2a.4:**
See Appendix 1 – Milestone 2 Deliverables and Success Criteria

**Deliverable 2a.5: Feasibility Design Review**

**Objective:**
Assay design reviewed against product requirements by a cross functional team including an independent reviewer.

**Scope of Work:**

- Prepare review material
- Schedule review and assure all voting members are present
- Record action items and gain formal approval
- Document review in quality system and gain sign off

**Success Metric for Completion of Deliverable 2a.5:**
See Appendix 1 – Milestone 2 Deliverables and Success Criteria

**Deliverable 2b. Technology Transfer of Prototype Assay to Pilot Manufacturing**

**Deliverable 2b.1: Follow Up Actions form the Feasibility Design Review**

**Objective:**
Develop a plan to follow up on action items from the Feasibility Design Review

**Scope of Work:**

- To be determined from the Feasibility Design Review action items

**Success Metric for Completion of Deliverable 2b.1:**
See Appendix 1 – Milestone 2 Deliverables and Success Criteria

**Deliverable 2b.2: Create Preliminary Device Master Record**

**Objective:** Create the initial draft of the Device Master Record

**Scope of Work:**

- Draft a bill of materials
- Draft raw material specifications
- Draft all work instructions
- Draft batch records
- Draft quality assurance testing with acceptance criteria (QAT)

**Success Metric for Deliverable 2b.2**
Device Master Record approved in Ortho's quality system

**Deliverable 2b.3: Complete Readiness to Manufacture Verification Lot**

**Objective:**
Assure that all materials, equipment, and procedures are in place to successfully complete manufacture of the verification and validation lot.

**Scope of Work:**

- Prepare review material
- Schedule review and assure all voting members are present
- Record action items and gain formal approval
- Document review in quality system and gain sign off

**Success Metric for Deliverable 2b.3**
See Appendix 1 – Milestone 2 Deliverables and Success Criteria

**Deliverable 2b.4: Build Verification Lot**

**Objective:** Manufacture the first lot of the assay in pilot production facility in Rochester, NY.

**Scope of Work:**

- Secure all components and materials
- Train operators
- Synthesize conjugates
- Coat wells
- Formulate and bottle liquid reagents, calibrators and controls
- Assemble and package components
- Test QAT
- Release for V&V purposes

**Success Metric for Deliverable 2b.4:**
See Appendix 1 – Milestone 2 Deliverables and Success Criteria

**Deliverable 2c: Emergency Use Authorization Submission**

**Deliverable 2c.1: Draft Design Verification Protocols**

**Objective:** Draft specific test designs, analysis plans and acceptance criteria for quantitative requirements.

**Scope of Work:**

- Identify key testable parameters
- Derive acceptance criteria for parameters from product requirements
- Create test plans including statistical analysis

**Success Metric for Deliverable 2c.1:**
See Appendix 1 – Milestone 2 Deliverables and Success Criteria

**Deliverable 2c.2, 2c3, 2c4, 2c5: Complete Sample Collection for All Required Matrices**

**Objective:** Obtain 500 positive and 1,000 negative samples for all 10 claimed combination of matrices, swabs, and saliva for the EUA submission

**Scope of Work:**

- Prepare document describing sample criteria and pay for samples only meeting sample criteria in the contract.
- Contact potential vendors
- Negotiate contract
- Execute prospective collection.

**Success Metric for Completion of Deliverable 2c.2, 2c3, 2c4, 2c5:**
See Appendix 1 – Milestone 2 Deliverables and Success Criteria

**Deliverable 2c.6: Execute Verification Testing**

**Objective:** Successfully execute all verification testing.

**Scope of Work:**

- Precision
- Cal Traceability
- Clinical Specificity
- Specificity – Cross Reactivity
- Specificity - Interferents
- Stability – Reagent Pack
- Stability – Calibrator
- Stability – Controls

**Success Criteria for Deliverable 2c.6**
See Appendix 1 – Milestone 2 Deliverables and Success Criteria

**Deliverable 2c.7: Design Verification Reports**

**Objective:** All verification reports are complete, approved by the Ortho cross functional team, and filed in the Ortho quality system.

**Scope of Work:**

- Analyze data by accepted CLSI methods
- Document assay meets requirements by comparing results to predetermined acceptance criteria.
- Note any non-conformances

**Success Metric for Deliverable 2c.7:**
See Appendix 1 – Milestone 2 Deliverables and Success Criteria

**Deliverable 2c.8: Generate Labeling for Product**

**Objective:** Draft Instructions for Use (IFU) and all appropriate claims and product labelling from the output of Verification.

**Scope of Work:**

- Draft and approve IFU
- Draft and approve labelling artwork

**Success Metric for Deliverable 2c.8:**
See Appendix 1 – Milestone 2 Deliverables and Success Criteria

**Deliverable 2c.9: Emergency Use Authorization (EUA) Submission**

**Objective:** EUA submission package received by FDA

**Scope of Work:**

- Regulatory filing drafted and approved by Ortho's Quality System
- Regulatory filing reviewed and agreed upon by BARDA
- Regulatory filing submitted to FDA

**Success Metric for Deliverable 2c.9:**
See Appendix 1 – Milestone 2 Deliverables and Success Criteria

**Deliverable 3 –** De novo or 510k Submission for the VITROS Immunodiagnostic Products anti-SARS-CoV-2 IgG Test Kit

**Deliverables 3a.1: Identify Clinical Collection Sites and Testing Sites**

**Objective:**
Identify candidate collection and testing sites to complete the project on time.

**Scope of Work:**

- Prepare a clinical collection scope document
- Identify sites meeting various collection criteria (ED, Urgent Care, Physician's Office, etc)
- Contact potential sites to gauge interest

**Success Metric for Completion of Deliverables 3a.1**
See Appendix 2 – Milestone 3 Deliverables and Success Criteria

**Deliverables 3a.2: FDA Pre-Sub Submission**

**Objective:**
Communicate with FDA to gain clear expectations of requirements for a successful de novo or 510k submission.

**Scope of Work:**

- Propose all analytical testing to be completed under the verification plan.
- Propose clinical design including numbers of positive and negative samples
- Propose cross reactants to be tested.
- Propose any specific sub-populations to be tested.

- Draft and submit pre-sub
- Communicate with FDA as needed to close any gaps in the proposed verification and validation proposal.

**Success Metric for Completion of Deliverables: 3a.2**
See Appendix 2 – Milestone 3 Deliverables and Success Criteria

**Deliverables 3a.3: Finalize Sample Collection Criteria**

**Objective:**
Document and gain approval of a Clinical Trial Plan based on feedback from FDA on the agreed upon pre-Sub.

**Scope of Work:**
- Define required patient populations
- Define clinical data required with each sample
- Define number of samples in each category.
- Define number of clinical collection sites.
- Define internal testing site

**Success Metric for Completion of Deliverables 3a.3:**
See Appendix 2 – Milestone 3 Deliverables and Success Criteria

**Deliverables 3a.4: Finalize Contracts with Collection and Testing Sites**

**Objective:**
Have a sufficient number of collection and testing sites under contract to complete the project on time.

**Scope of Work:**
- Negotiate terms
- Regulatory review of contract
- Legal review of contract
- Set up billing and payment

**Success Metric for Completion of Deliverables 3a.4:**
See Appendix 2 – Milestone 3 Deliverables and Success Criteria

**Deliverables 3a.5: Sample Collection Site Readiness**

**Objective:**
Readiness complete to collect, document and ship patient samples

**Scope of Work:**
- IRB approval
- Create all forms
- Supply collection devices
- Supply shipping materials
- Set up site monitoring plan
- Train personnel

**Success Metric for Completion of Deliverables 3a.5:**
See Appendix 2 – Milestone 3 Deliverables and Success Criteria

**Deliverables 3a.6: Create Sample Collection Infrastructure**

**Objective:**
Readiness complete to receive, document and secure patient samples

**Scope of Work:**

- Secure assigned storage space in biobank
- Audit freezer performance harts and maintenance records
- Create database to document patient sample records
- Train personnel

**Success Metric for Completion of Deliverables 3a.6**

**Deliverables 3a.7, 3a.8, 3a.9, 3a.10: Complete Set of Samples Secured in Biobank**

**Objective:**
All samples (500 positive, 500 negative) acquired and secured to meet the requirement of the Clinical Trial Plan.

**Scope of Work:**

- Sample received and checked into biobank: 500 positive, 500 negative samples and pay for samples only meeting sample criteria in the contract.
- Samples aliquoted to specific volumes
- Patient data received and recorded in data base
- Sample collection site monitored for adherence to protocols

**Success Metric for Completion of Deliverables 3a.7, 3a.8, 3a.9, 3a.10:**
See Appendix 2 – Milestone 3 Deliverables and Success Criteria

**Deliverables 3b.1: Update Product Requirement Document**

**Objective:**
Establish the verifiable qualitative and quantitative requirements of the assay

**Scope of Work:**

- Obtain VOC from KOLs
- Assess field performance of the EUA assay
- Review complaint files
- Analyze e-connectivity data
- Review raw material supply issues
- Assess process capability

**Success Metric for the Completion of Deliverables 3b.1:**
See Appendix 2 – Milestone 3 Deliverables and Success Criteria

**Deliverables 3b.2: Demonstrate Feasibility of the Assay to Meet Updated PRD Requirements**

**Objective:**
All testing is completed to demonstrate that the assay design meets the product requirements as documented in Deliverable 3b.1.

**Scope of Work:**

- Lot received in R&D
- Analyzers and personnel secured for testing
- Test designs in place
- Test fluids prepared and delivered to team
- Testing completed and data analyzed

- Formal review completed

**Success Metric for Deliverables 3b.2:**
See Appendix 2 – Milestone 3 Deliverables and Success Criteria

**Deliverables 3b.3: Complete Guard Band Studies**

**Objective:**
Complete all guard band studies meeting product requirements as documented in Deliverables 3b.1

**Scope of Work:**
- Determine CTQs for each critical process
- Design factorial experiments to challenge operating limits
- Create guard band lots
- Test guard band lots
- Analyze data
- Draft and approve reports

**Success Metric for Deliverables 3b.3:**
See Appendix 2 – Milestone 3 Deliverables and Success Criteria

**Deliverable 3b.4: Update Device Master Record**

**Objective:** Update the Device Master Record as required

**Scope of Work:**
- Update bill of materials
- Update raw material specifications
- Update all work instructions
- Update batch records
- Update quality assurance testing with acceptance criteria (QAT)

**Success Metric for Deliverable 3b.4**
See Appendix 2 – Milestone 3 Deliverables and Success Criteria

**Deliverables 3b.5: Build Verification and Validation Lots**

**Objective:** Manufacture three verification and validation lots of the updated assay in full scale production

**Scope of Work:**
- Secure all components and materials
- Train operators
- Synthesize conjugates
- Coat wells
- Formulate and bottle liquid reagents, calibrators and controls
- Assemble and package components
- Test QAT
- Release for V&V purposes

**Success Metric for Deliverable 3b.5:**
See Appendix 2 – Milestone 3 Deliverables and Success Criteria

**Deliverables 3b.6: Update Labeling for Product**

**Objective:** Update Instructions for Use (IFU) and all appropriate claims and product labelling from the output of the Verification and Clinical Studies.

**Scope of Work:**

- Update and approve IFU
- Update and approve labelling artwork

**Success Metric for Deliverables 3b.6:**
See Appendix 2 – Milestone 3 Deliverables and Success Criteria

**Deliverable 3c.1 Design Verification Plan / Protocols**

**Objective:**
All design plans/protocols are documented and approved in the Ortho quality system.

**Scope of Work:**

- Identify key testable parameters
- Derive acceptance criteria for parameters from product requirements
- Create test plans including statistical analysis
- Draft and approve plans and /or protocols

**Success Metric for Deliverable 3c.1:**
See Appendix 2 – Milestone 3 Deliverables and Success Criteria

**Deliverable 3c.2 Design Validation Plan and /or Protocols**

**Objective:**
All clinical design plans/protocols are documented and approved in the Ortho quality system.

**Scope of Work:**

- All testing sites identified
- All analyzer placements approved
- All test protocols approved
- Statistical analysis plan in place

**Success Metric for Deliverable 3c.2:**
See Appendix 2 – Milestone 3 Deliverables and Success Criteria

**Deliverable 3c.3 Execute Verification Testing**

**Objective:** Successfully execute all verification testing.

**Scope of Work:**

- Precision
- Cal Traceability
- Hook Effect
- Method Comparison
- Specificity - Interferents
- Specificity – Cross Reactivity
- Stability – Reagent Pack
- Stability – Calibration Interval
- Stability – Calibrator
- Stability – Controls

**Success Criteria for Deliverable 3c.3**
See Appendix 2 – Milestone 3 Deliverables and Success Criteria

**Deliverable 3c.4 Design Verification Reports**

**Objective:** All verification reports are complete, approved by the Ortho cross functional team, and filed in the Ortho quality system.

**Scope of Work:**

- Analyze data by accepted CLSI methods
- Document assay meets requirements by comparing results to predetermined acceptance criteria.
- Note any non-conformances

**Success Metric for Deliverable 3c.4:**
See Appendix 2 – Milestone 3 Deliverables and Success Criteria

**Deliverable 3c.5 Execute Validation Testing**

**Objective:** Successfully execute all validation testing as per approved clinical plan.

**Scope of Work:**

- Reproducibility
- Clinical Samples run on multiple analyzers at multiple sites
- Clinical Sensitivity
- Clinical Specificity

**Success Criteria for Deliverable 3c.5**
See Appendix 2 – Milestone 3 Deliverables and Success Criteria

**Deliverable 3c.6 Clinical Summary**

**Objective:** All validation reports are complete, approved by the Ortho cross functional team, and filed in the Ortho quality system.

**Scope of Work:**

- Lock clinical data base
- Analyze data
- Draft claims

**Success Metric for Deliverable 3c.6:**
See Appendix 2 – Milestone 3 Deliverables and Success Criteria

**Deliverable 3c.7 De novo or 510k Submission**

**Objective:** De novo or 510k submission package received by

FDA **Scope of Work:**

- Regulatory filing drafted and approved by Ortho's Quality System
- Submission reviewed and agreed upon by BARDA
- Regulatory filing submitted to FDA

**Success Metric for Deliverable 3c.7:**
See Appendix 2 – Milestone 3 Deliverables and Success Criteria

**Deliverable 4 –** De novo or 510k Submission for the VITROS Immunodiagnostic Products anti-SARS-CoV-2 Total Test Kit

**Deliverables 4a.1: Identify Clinical Collection Sites and Testing Sites**

**Objective:**
Identify candidate collection and testing sites to complete the project on time.

**Scope of Work:**
- Prepare a clinical collection scope document
- Identify sites meeting various collection criteria (ED, Urgent Care, Physician's Office, etc)
- Contact potential sites to gauge interest

**Success Metric for Completion of Deliverables 4a.1**
See Appendix 3 – Milestone 4 Deliverables and Success Criteria

**Deliverables 4a.2: FDA Pre-Sub Submission**

**Objective:**
Communicate with FDA to gain clear expectations of requirements for a successful de novo or 510k submission.

**Scope of Work:**
- Propose all analytical testing to be completed under the verification plan.
- Propose clinical design including numbers of positive and negative samples
- Propose cross reactants to be tested.
- Propose any specific sub-populations to be tested.
- Draft and submit pre-sub
- Communicate with FDA as needed to close any gaps in the proposed verification and validation proposal.

**Success Metric for Completion of Deliverables: 4a.2a**
See Appendix 3 – Milestone 4 Deliverables and Success Criteria

**Deliverables 4a.3: Finalize Sample Collection Criteria**

**Objective:**
Document and gain approval of a Clinical Trial Plan based on feedback from FDA on the agreed upon pre-Sub.

**Scope of Work:**
- Define required patient populations
- Define clinical data required with each sample
- Define number of samples in each category.
- Define number of clinical collection sites.
- Define internal testing site

**Success Metric for Completion of Deliverables 4a.3:**
See Appendix 3 – Milestone 4 Deliverables and Success Criteria

**Deliverables 4a.4: Finalize Contracts with Collection and Testing Sites**

**Objective:**
Have a sufficient number of collection and testing sites under contract to complete the project on time.

**Scope of Work:**
- Negotiate terms
- Regulatory review of contract

- Legal review of contract
- Set up billing and payment

**Success Metric for Completion of Deliverables 4a.4:**
See Appendix 3 – Milestone 4 Deliverables and Success Criteria

**Deliverables 4a.5: Sample Collection Site Readiness**

**Objective:**
Readiness complete to collect, document and ship patient samples

**Scope of Work:**
- IRB approval
- Create all forms
- Supply collection devices
- Supply shipping materials
- Set up site monitoring plan
- Train personnel

**Success Metric for Completion of Deliverables 4a.5:**
See Appendix 3 – Milestone 4 Deliverables and Success Criteria

**Deliverables4a.6: Create Sample Collection Infrastructure**

**Objective:**
Readiness complete to receive, document and secure patient samples

**Scope of Work:**
- Secure assigned storage space in biobank
- Audit freezer performance harts and maintenance records
- Create database to document patient sample records
- Train personnel

**Success Metric for Completion of Deliverables 3a.6, 4a.6**
See Appendix 3 – Milestone 4 Deliverables and Success Criteria

**Deliverables 4a.7, 4a.8, 4a.9, 4a.10: Complete Set of Samples Secured in Biobank**

**Objective:**
All samples (500 positive, 500 negative) acquired and secured to meet the requirement of the Clinical Trial Plan.

**Scope of Work:**
- Sample received and checked into biobank: 500 positive, 500 negative samples and pay for samples only meeting sample criteria in the contract.
- Samples aliquoted to specific volumes
- Patient data received and recorded in data base
- Sample collection site monitored for adherence to protocols

**Success Metric for Completion of Deliverables 4a.7, 4a.8, 4a.9, 4a.10:**
See Appendix 3 – Milestone 4 Deliverables and Success Criteria

**Deliverables 4b.1: Update Product Requirement Document**

**Objective:**

Establish the verifiable qualitative and quantitative requirements of the assay

**Scope of Work:**

- Obtain VOC from KOLs
- Assess field performance of the EUA assay
- Review complaint files
- Analyze e-connectivity data
- Review raw material supply issues
- Assess process capability

**Success Metric for the Completion of Deliverables 4b.1:**
See Appendix 3 – Milestone 4 Deliverables and Success Criteria

**Deliverables4b.2: Demonstrate Feasibility of the Assay to Meet Updated PRD Requirements**

**Objective:**
All testing is completed to demonstrate that the assay design meets the product requirements as documented in Deliverables 4b.1.

**Scope of Work:**

- Lot received in R&D
- Analyzers and personnel secured for testing
- Test designs in place
- Test fluids prepared and delivered to team
- Testing completed and data analyzed
- Formal review completed

**Success Metric for Deliverables 4b.2:**
See Appendix 3 – Milestone 4 Deliverables and Success Criteria

**Deliverables 4b.3: Complete Guard Band Studies**

**Objective:**
Complete all guard band studies meeting product requirements as documented in Deliverables 4b.1

**Scope of Work:**

- Determine CTQs for each critical process
- Design factorial experiments to challenge operating limits
- Create guard band lots
- Test guard band lots
- Analyze data
- Draft and approve reports

**Success Metric for Deliverables 4b.3:**
See Appendix 3 – Milestone 4 Deliverables and Success Criteria

**Deliverable 4b.4: Update Device Master Record**

**Objective:** Update the Device Master Record as required

**Scope of Work:**

- Update bill of materials
- Update raw material specifications
- Update all work instructions
- Update batch records

- Update quality assurance testing with acceptance criteria (QAT)

**Success Metric for Deliverable 4b.4**
See Appendix 3 – Milestone 4 Deliverables and Success Criteria

**Deliverables 4b.5: Build Verification and Validation Lots**

**Objective:** Manufacture three verification and validation lots of the updated assay in full scale production

**Scope of Work:**

- Secure all components and materials
- Train operators
- Synthesize conjugates
- Coat wells
- Formulate and bottle liquid reagents, calibrators and controls
- Assemble and package components
- Test QAT
- Release for V&V purposes

**Success Metric for Deliverable 4b.5:**
See Appendix 3 – Milestone 4 Deliverables and Success Criteria

**Deliverables 4b.6: Update Labeling for Product**

**Objective:** Update Instructions for Use (IFU) and all appropriate claims and product labelling from the output of the Verification and Clinical Studies.

**Scope of Work:**

- Update and approve IFU
- Update and approve labelling artwork

**Success Metric for Deliverables 4b.6:**
See Appendix 3 – Milestone 4 Deliverables and Success Criteria

**Deliverable 4c.1 Design Verification Plan / Protocols**

**Objective:**
All design plans/protocols are documented and approved in the Ortho quality system.

**Scope of Work:**

- Identify key testable parameters
- Derive acceptance criteria for parameters from product requirements
- Create test plans including statistical analysis
- Draft and approve plans and /or protocols

**Success Metric for Deliverable 4c.1:**
See Appendix 3 – Milestone 4 Deliverables and Success Criteria

**Deliverable 4c.2 Design Validation Plan and /or Protocols**

**Objective:**
All clinical design plans/protocols are documented and approved in the Ortho quality system.

**Scope of Work:**

- All testing sites identified
- All analyzer placements approved

- All test protocols approved
- Statistical analysis plan in place

**Success Metric for Deliverable4c.2:**
See Appendix 3 – Milestone 4 Deliverables and Success Criteria

**Deliverable 4c.3 Execute Verification Testing**

**Objective:** Successfully execute all verification testing.

**Scope of Work:**
- Precision
- Cal Traceability
- Hook Effect
- Method Comparison
- Specificity - Interferents
- Specificity – Cross Reactivity
- Stability – Reagent Pack
- Stability – Calibration Interval
- Stability – Calibrator
- Stability – Controls

**Success Criteria for Deliverable 4c.3**
See Appendix 3 – Milestone 4 Deliverables and Success Criteria

**Deliverable 4c.4 Design Verification Reports**

**Objective:** All verification reports are complete, approved by the Ortho cross functional team, and filed in the Ortho quality system.

**Scope of Work:**
- Analyze data by accepted CLSI methods
- Document assay meets requirements by comparing results to predetermined acceptance criteria.
- Note any non-conformances

**Success Metric for Deliverable 4c.4:**
See Appendix 3 – Milestone 4 Deliverables and Success Criteria

**Deliverable 4c.5 Execute Validation Testing**

**Objective:** Successfully execute all validation testing as per approved clinical plan.

**Scope of Work:**
- Reproducibility
- Clinical Samples run on multiple analyzers at multiple sites
- Clinical Sensitivity
- Clinical Specificity

**Success Criteria for Deliverable 4c.3**
See Appendix 3 – Milestone 4 Deliverables and Success Criteria

**Deliverable 4c.6 Clinical Summary**

**Objective:** All validation reports are complete, approved by the Ortho cross functional team, and filed

in the Ortho quality system.

**Scope of Work:**

- Lock clinical data base
- Analyze data
- Draft claims

**Success Metric for Deliverable 4c.6:**
See Appendix 3 – Milestone 4 Deliverables and Success Criteria

**Deliverable 4c.7 De novo or 510k Submission**

**Objective:** De novo or 510k submission package received by

FDA **Scope of Work:**

- Regulatory filing drafted and approved by Ortho's Quality System
- Submission reviewed and agreed upon by BARDA
- Regulatory filing submitted to FDA

**Success Metric for Deliverable 4c.7:**
See Appendix 3 – Milestone 4 Deliverables and Success Criteria

**PROGRAM MANAGEMENT**

The contractor shall provide the following as outlined below:

a) The overall management, integration, and coordination of all contract activities, including a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, and direction of all contract activities;

b) A Principal Investigator (PI) or Project Manager (PM) responsible for project management, communication, tracking, monitoring, and reporting on status, progress, and modifications to the project requirements, deliverables and timelines, including projects undertaken by subcontractors;

c) A PM with responsibility for monitoring and tracking day-to-day progress and timelines of deliverables, coordinating communication and project activities, costs incurred, and program management.

d) A BARDA liaison (maybe be the PM) with responsibility for effective communication with the Contracting Officer (CO), Contract Specialist (CS), and Contracting Officer's Representative (COR);

e) Administrative and legal staff capable of developing compliant subcontracts, consulting, and other legal agreements, while also ensuring timely acquisition of all proprietary rights, including intellectual property (IP) rights and reporting all inventions made in the performance of the contract;

f) Administrative staff capable of financial management and reporting on all activities conducted by the contractor and any subcontractors;

g) Contract Review Meetings

The contractor shall participate in weekly meetings to coordinate and oversee the contract effort conjointly with the CO, CS, and COR. Such meetings may include, but are not limited to, the following:

- Meeting with the contractors and subcontractors to discuss clinical manufacturing progress, product development, product assay development, scale-up manufacturing development, clinical

sample assays development, preclinical/clinical study designs and regulatory issues.

- Meeting with individual contractors and other government officials to discuss the technical, regulatory, and ethical aspects of the program.

- Meeting with technical consultants to discuss technical data provided by the contractor.

h) The contractor shall participate in teleconferences every month with the CO, CS and COR to discuss the performance of the contract, unless otherwise directed. Teleconferences or additional face-to-face meetings may be more frequent at the request of the CO.

i) Gantt Chart

Within 30 calendar days of the effective date of the contract, the contractor shall submit a first draft of an updated Gantt Chart to the CO, CS and COR for review. The Gantt Chart shall be incorporated into the contract and will be used to monitor performance. The contractor shall include the key milestones, deliverables, and Go/No-Go decision gates.

j) Project Management Plan

In the management of this contract, the contractor is encouraged to utilize Project Management tools/techniques to track and monitor the cost and schedule of the project. The contractor and the government agree that at a minimum, the contractor shall utilize the cost and schedule tools/techniques in the contract deliverable for project management purposes.

k) Risk Management Plan

The contractor shall develop a risk management plan within 90 days of contract award highlighting potential problems or issues that may arise during the life of the contract, including the impact on cost, schedule, and performance. Appropriate remediation plans. should reference relevant work segments where appropriate. Updates to this plan shall be included, at a minimum, on a quarterly basis (every three months) in the monthly Project Status Report.

l) Monthly and Annual Reports

The contractor shall deliver Project Status Reports on a monthly basis. The reports shall address the items below cross referenced to the SOW or other Project Management Plan tool(s):

- Executive summary highlighting the progress, issues, and relevant manufacturing, non-clinical, clinical, and regulatory activities.

- Progress in meeting contract deliverables, detailing the planned progress and actual progress during the reporting period, explaining any differences between the two and corrective steps.

- Updated Risk Management Plan (when appropriate).

- Three-month rolling forecast of planned activities.

- Progress of regulatory submissions.

m) Data Management

The contractor shall:

- Develop and implement data management and quality control systems/procedures, including transmission, storage, confidentiality, and retrieval of all contract data.

- Provide for the statistical design and analysis of data resulting from the research.

- Provide raw data or specific analyses of data generated with contract funding to the CO, CS, and COR, upon request.

**REGULATORY**

The contractor shall perform the following as outlined below:

a) Engage the Food and Drug Administration (FDA) on a path to support the use of the product for the specific indication.

b) Prepare materials for and requesting, scheduling, and participating in all meetings with the FDA, including meetings to review all data packages.

c) Provide BARDA with (1) initial draft minutes and final draft minutes of any formal meeting with the FDA, and (2) final draft minutes of any informal meeting with the FDA.

**FACILITIES, EQUIPMENT, & OTHER RESOURCES**

The contractor shall provide equipment, facilities, and other resources required for implementation of the SOW to comply with all Federal and HHS regulations in:

a) The humane care and use of vertebrate animals.

b) The acquisition, handling, storage, and shipment of potentially dangerous biological and chemical agents, including select agents under biosafety levels required for working with the biological agents under study

**Appendix 1**

**Milestone 2 Deliverables and Success Criteria**
Acceptance of all listed reports by BARDA will be considered to be closure of the Milestone 2

| Milestone Number | Milestone | Deliverable/Success Criteria | Estimated Timing |
|---|---|---|---|
| **2. EUA submission of the VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Test Kit** | | | |
| 2a. Creation of a prototype SARS-CoV-2 Antigen Assay | | | |
| 2a.1 | Complete Product Requirements Document | Provide BARDA with a copy of the Product Requirements Document that specifies all testable qualitative and quantitative product parameters. BARDA acceptance of the plan closes this milestone. | (b) (4) |
| 2a.2 | Secure Key Rare Reagents | Provide BARDA with a summary of materials screened and key data for selecting prototype candidates | (b) (4) |
| 2a.3 | Successful Patient Sample Testing | Provide BARDA with a summary demonstrating that a limited number of positive and negative samples and key cross reactants have yielded appropriate results on the prototype assay. | |
| 2a.4 | Prototype Assay Design Complete | Provide Summary to BARDA demonstrating that the prototype assay meets all essential requirements. | (b) (4) |
| 2a.5 | Feasibility Design Review | Formal Design Review approved and documented in Ortho's quality system. Provide BARDA with documentation for review. | (b) (4) |
| 2b. Technology Transfer of the Prototype Assay to Pilot Manufacturing | | | |
| 2b.1 | Follow Up Actions from Feasibility Design Review | Provide Summary to BARDA documenting open action items, planned mitigations and completion dates. | (b) (4) |
| 2b.2 | Create Preliminary Device Master Record (DMR) | Device Master Record approved and documented in Ortho's quality system. Provide BARDA with documentation for review. | (b) (4) |
| 2b.3 | Complete Readiness to Manufacture of Verification Lot | Design Transfer Review approved and documented in Ortho's quality system. Provide BARDA with documentation for review. | (b) (4) |
| 2b.4 | Build Verification Lot | Provide Summary to BARDA documenting the manufacture and release of the verification and validation lot. | (b) (4) |
| 2c. Emergency Use Authorization Submission | | | |
| 2c.1 | Draft specific test designs, analysis plans and acceptance criteria for quantitative requirements. | Verification Protocols approved and documented in Ortho's quality system. Provide BARDA with documentation for review. | (b) (4) |
| 2c.2 | Complete sample collection for all required matrices. Receive and secure samples | Provide summary to BARDA documenting receipt of 125 positive and 250 negative of required samples (125 positive total, 250 | (b) (4) |

| | | | |
|---|---|---|---|
| | | negative total) | |
| 2c.3 | Receive and secure samples | Provide summary to BARDA documenting receipt of 125 positive and 250 negative of required samples (250 positive total, 500 negative total) | (b) (4) |
| 2c.4 | Receive and secure samples | Provide summary to BARDA documenting receipt of 125 positive and 250 negative of required samples (375 positive total, 750 negative total) | (b) (4) |
| 2c.5 | Receive and secure samples | Provide summary to BARDA documenting receipt of 125 positive and 250 negative of required samples (500 positive total, 1000 negative total) | (b) (4) |
| 2c.6 | Execute all verification testing as per approved protocols | Provide summary to BARDA documenting the successful completion of all prescribed testing. | (b) (4) |
| 2c.7 | Completion and approval of verification reports | Provide BARDA with Verification reports summarizing the completion of verification activities to support IVD submission. | (b) (4) |
| 2c.8 | Complete all product labeling | Provide summary (IFU) to BARDA of all claims and labeling based on the outcome of verification testing. | (b) (4) |
| 2c.9 | Submit SARS-CoV-2 antigen assay to the FDA | Provide BARDA with the completed submission files sent to the FDA for a SARS-CoV-2 antigen assay. | (b) (4) |
| 2d.1 | Prepare a document summarizing project success and lessons learned | Provide BARDA with a project summary report | (b) (4) |

## Appendix 2

**Milestone 3 Deliverables and Success Criteria**
Acceptance of all listed reports by BARDA will be considered to be closure of the Milestone 3.

| Milestone Number | Milestone | Deliverable/Success Criteria | Estimated Timing |
|---|---|---|---|
| **3. De novo or 510k Submission of the VITROS Immunodiagnostic Products anti-SARS-CoV-2 IgG Test Kit** | | | |
| 3a. Creation of a sample bank to be used for a clinical trial supporting the de novo or 510k submission of the anti-SARS-CoV-2 IgG Test Kit | | | |
| 3a.1 | Identify clinical collection sites and testing sites | Provide a summary to BARDA documenting the specific sites for sample collection and testing sites | (b) (4) |
| 3a.2 | Pre-sub sent to FDA for the de novo or 510k submission of the anti-SARS-CoV-2 IgG Test Kit | Provide BARDA with a copy of the pre-sub submission sent to FDA. | (b) (4) |
| 3a.3 | Finalize sample collection criteria | Document sample populations and collection criteria as part of Ortho's Clinical Plan. Provide BARDA with documentation for review. | (b) (4) |
| 3a.4 | Finalize contracts with clinical collection and testing sites | Provide a summary to BARDA documenting executed contracts with all collection sites | (b) (4) |
| 3a.5 | Sample collection site readiness | Provide a summary to BARDA documenting external readiness to begin sample collection. | (b) (4) |
| 3a.6 | Create sample collection infrastructure | Provide a summary to BARDA documenting internal readiness to receive samples. | (b) (4) |
| 3a.7 | Receive and secure samples | Provide summary to BARDA documenting receipt of 125 positive and 125 negative of required samples (125 positive total, 125 negative total) | (b) (4) |
| 3a.8 | Receive and secure samples | Provide summary to BARDA documenting receipt of additional 125 positive and 125 negative of required samples (250 positive total, 250 negative total) | (b) (4) |
| 3a.9 | Receive and secure samples | Provide summary to BARDA documenting receipt of additional 125 positive and 125 negative of required samples (375 positives total, 375 negatives total) | (b) (4) |
| 3a.10 | Receive and secure samples | Provide summary to BARDA documenting receipt of additional 125 positive and 125 negative of required samples (500 positives total, 500 negatives total) | (b) (4) |
| 3b. Assay Improvements and Technology Transfer | | | |
| 3b.1 | Update Product Requirement Document | Provide BARDA with a copy of the updated PRD | (b) (4) |
| 3b.2 | Demonstrate feasibility of the assay to meet updated PRD | Provide summary to BARDA documenting the formal Design Review | (b) (4) |
| 3b.3 | Complete guard band studies | Provide summary to BARDA documenting outcomes of guard band studies. | (b) (4) |
| 3b.4 | Update Device Master Record | Provide a summary to BARDA documenting changes made to the DMR | (b) (4) |
| 3b.5 | Build three verification and | Provide summary to BARDA documenting the | (b) (4) |

| | | | |
|---|---|---|---|
| | validation lots | availability of three manufactured lots for V&V testing | |
| 3b.6 | Update Product Labelling | Provide a summary to BARDA documenting the updates made to product labelling | (b) (4) |
| 3c. De novo or 510k Submission | | | |
| 3c.1 | Draft specific test designs, analysis plans and acceptance criteria for quantitative requirements. | Verification Protocols approved and documented in Ortho's quality system. Provide BARDA with documentation for review. | (b) (4) |
| 3c.2 | Draft specific test designs and analysis plans for testing of the clinical samples in the biobank | Clinical (Validation) Protocols approved and documented in Ortho's quality system. Provide BARDA with documentation for review. | (b) (4) |
| 3c.3 | Execute all verification testing as per approved protocols | Provide summary to BARDA documenting the successful completion of all prescribed testing. | (b) (4) |
| 3c.4 | Completion and approval of verification reports | Provide BARDA with Verification reports summarizing the completion of verification activities to support IVD submission. | (b) (4) |
| 3c.5 | Execute all validation testing as per approved clinical plan | Provide summary to BARDA documenting the successful completion of all prescribed testing. | (b) (4) |
| 3c.6 | Completion and approval of validation reports | Provide BARDA with Validation reports summarizing the completion of clinical trial activities to support IVD submission. | (b) (4) |
| 3c.7 | Submit anti-SARS-CoV-2 IgG assay to the FDA | Provide BARDA with the completed submission files sent to the FDA for the anti-SARS-CoV-2 IgG assay. | (b) (4) |

**Appendix 3**

**Milestone 4 Deliverables and Success Criteria**
Acceptance of all listed reports by BARDA will be considered to be closure of the Milestone 4.

| Milestone Number | Milestone | Deliverable/Success Criteria | Estimated Timing |
|---|---|---|---|
| **4. De novo or 510k Submission of the VITROS Immunodiagnostic Products anti-SARS-CoV-2 Total Test Kit** | | | |
| 4a. Creation of a sample bank to be used for a clinical trial supporting the de novo or 510k submission of the anti-SARS-CoV-2 Total Test Kit | | | |
| 4a.1 | Identify clinical collection sites and testing sites | Provide a summary to BARDA documenting the specific sites for sample collection and testing sites | (b) (4) |
| 4a.2 | Pre-sub sent to FDA for the de novo or 510k submission of the anti-SARS-CoV-2 IgG Test Kit | Provide BARDA with a copy of the pre-sub submission sent to FDA. | (b) (4) |
| 4a.3 | Finalize sample collection criteria | Document sample populations and collection criteria as part of Ortho's Clinical Plan. Provide BARDA with documentation for review. | (b) (4) |
| 4a.4 | Finalize contracts with clinical collection and testing sites | Provide a summary to BARDA documenting executed contracts with all collection sites | (b) (4) |
| 4a.5 | Sample collection site readiness | Provide a summary to BARDA documenting external readiness to begin sample collection. | (b) (4) |
| 4a.6 | Create sample collection infrastructure | Provide a summary to BARDA documenting internal readiness to receive samples. | (b) (4) |
| 4a.7 | Receive and secure samples | Provide summary to BARDA documenting receipt of 125 positive and 125 negative of required samples (125 positive total, 125 negative total) | (b) (4) |
| 4a.8 | Receive and secure samples | Provide summary to BARDA documenting receipt of additional 125 positive and 125 negative of required samples (250 positive total, 250 negative total) | (b) (4) |
| 4a.9 | Receive and secure samples | Provide summary to BARDA documenting receipt of additional 125 positive and 125 negative of required samples (375 positives total, 375 negatives total) | (b) (4) |
| 4a.10 | Receive and secure samples | Provide summary to BARDA documenting receipt of additional 125 positive and 125 negative of required samples (500 positives total, 500 negatives total) | (b) (4) |
| 4b. Assay Improvements and Technology Transfer | | | |
| 4b.1 | Update Product Requirement Document | Provide BARDA with a copy of the updated PRD | (b) (4) |
| 4b.2 | Demonstrate feasibility of the assay to meet updated PRD | Provide summary to BARDA documenting the formal Design Review | (b) (4) |
| 4b.3 | Complete guard band studies | Provide summary to BARDA documenting outcomes of guard band studies. | (b) (4) |
| 4b.4 | Update Device Master Record | Provide a summary to BARDA documenting changes made to the DMR | (b) (4) |
| 4b.5 | Build three verification and | Provide summary to BARDA documenting the | (b) (4) |

| | | | |
|---|---|---|---|
| | validation lots | availability of three manufactured lots for V&V testing | |
| 4b.6 | Update Product Labelling | Provide a summary to BARDA documenting the updates made to product labelling | (b) (4) |
| 4c. De novo or 510k Submission | | | |
| 4c.1 | Draft specific test designs, analysis plans and acceptance criteria for quantitative requirements. | Verification Protocols approved and documented in Ortho's quality system. Provide BARDA with documentation for review. | (b) (4) |
| 4c.2 | Draft specific test designs and analysis plans for testing of the clinical samples in the biobank | Clinical (Validation) Protocols approved and documented in Ortho's quality system. Provide BARDA with documentation for review. | (b) (4) |
| 4c.3 | Execute all verification testing as per approved protocols | Provide summary to BARDA documenting the successful completion of all prescribed testing. | (b) (4) |
| 4c.4 | Completion and approval of verification reports | Provide BARDA with Verification reports summarizing the completion of verification activities to support IVD submission. | (b) (4) |
| 4c.5 | Execute all validation testing as per approved clinical plan | Provide summary to BARDA documenting the successful completion of all prescribed testing. | (b) (4) |
| 4c.6 | Completion and approval of validation reports | Provide BARDA with Validation reports summarizing the completion of clinical trial activities to support IVD submission. | (b) (4) |
| 4c.7 | Submit anti-SARS-CoV-2 IgG assay to the FDA | Provide BARDA with the completed submission files sent to the FDA for the anti-SARS-CoV-2 IgG assay. | (b) (4) |

## ATTACHMENT 5 – SCHEDULE OF PAYMENTS

Pursuant to FAR 52.232-2, payments will be made upon receipt and acceptance of a deliverable and acceptable invoice for partial delivery of work, as outlined in the table below:

| Payment No | Milestone | Deliverable/Success Criteria | Payment Amount |
|---|---|---|---|
| 1 | Project Plan | Provide all documentation to BARDA within 30 days of initiating the project. | (b |
| 2a.1 | Complete Product Requirements Document | Provide BARDA with a copy of the Product Requirements Document that specifies all testable qualitative and quantitative product parameters. BARDA acceptance of the plan closes this milestone. | (b) (4) |
| 2a.2 | Secure Key Rare Reagents | Provide BARDA with a summary of materials screened and key data for selecting prototype candidates | (b) (4) |
| 2a.3 | Successful Patient Sample Testing | Provide BARDA with a summary document demonstrating the initial patient performance of the assay. | (b) (4) |
| 2a.4 | Prototype Assay Design Complete | Provide Summary to BARDA demonstrating that the prototype assay meets all essential requirements. | (b) (4) |
| 2a.5 | Feasibility Design Review | Formal Design Review approved and documented in Ortho's quality system | (b) (4) |
| 2b.1 | Follow Up Actions from Feasibility Design Review | Provide Summary to BARDA documenting open action items, planned mitigations and completion dates. | (b) (4) |
| 2b.2 | Create Preliminary Device Master Record (DMR) | Device Master Record approved and documented in Ortho's quality system. Provide BARDA with documentation for review. | (b) (4) |
| 2b.3 | Complete Readiness to Manufacture of Verification Lot | Design Transfer Review approved and documented in Ortho's quality system. Provide BARDA with documentation for review. | (b) (4) |
| 2b.4 | Build Verification Lot | Provide Summary to BARDA documenting the manufacture and release of the verification and validation lot. | (b) (4) |
| 2c.1 | Draft specific test designs, analysis plans and acceptance criteria for quantitative requirements. | Verification Protocols approved and documented in Ortho's quality system. Provide BARDA with documentation for review. | (b) (4) |
| **2c.2** | Receive and secure samples | Provide summary to BARDA documenting receipt of 125 positive and 250 negative of required samples (125 positive total, 250 negative total) | (b) (4) |

| | | | |
|---|---|---|---|
| **2c.3** | Receive and secure samples | Provide summary to BARDA documenting receipt of 125 positive and 250 negative of required samples (250 positive total, 500 negative total) | (b) (4) |
| **2c.4** | Receive and secure samples | Provide summary to BARDA documenting receipt of 125 positive and 250 negative of required samples (375 positive total, 750 negative total) | (b) (4) |
| **2c.5** | Receive and secure samples | Provide summary to BARDA documenting receipt of 125 positive and 250 negative of required samples (500 positive total, 1000 negative total) | (b) (4) |
| 2c.6 | Execute all verification testing as per approved protocols | Provide summary to BARDA documenting the successful completion of all prescribed testing. | (b) (4) |
| 2c.7 | Complete and approve verification reports | Provide BARDA with Verification reports summarizing the completion of verification activities to support IVD submission. | (b) (4) |
| 2c.8 | Complete all product labeling | Provide summary (IFU) to BARDA of all claims and labeling based on the outcome of verification testing. | (b) (4) |
| 2c.9 | Submit SARS-CoV-2 antigen assay to the FDA | Provide BARDA with the completed submission files sent to the FDA for a SARS-CoV-2 antigen assay. | (b) (4) |
| 2d.1 | Prepare a document summarizing project success and lessons learned | Provide BARDA with a project summary report | (b) (4) |
| 3a.1 | Identify clinical collection sites and testing sites | Provide a summary to BARDA documenting the specific sites for sample collection and testing sites | (b) (4) |
| 3a.2 | Pre-sub sent to FDA for the de novo or 510k submission of the anti-SARS-CoV-2 IgG Test Kit | Provide BARDA with a copy of the pre-sub submission sent to FDA | (b) (4) |
| 3a.3 | Finalize sample collection criteria | Document sample populations and collection criteria as part of Ortho's Clinical Plan. Provide BARDA with documentation for review. | (b) (4) |
| 3a.4 | Finalize contracts with clinical collection and testing sites | Provide a summary to BARDA documenting executed contracts with all collection sites | (b) (4) |
| 3a.5 | Sample collection site readiness | Provide a summary to BARDA documenting external readiness to begin sample collection. | (b) (4) |
| 3a.6 | Create sample collection infrastructure | Provide a summary to BARDA documenting internal readiness to receive samples. | (b) (4) |

| | | | |
|---|---|---|---|
| 3a.7 | Receive and secure samples | Provide summary to BARDA documenting receipt of 125 positive and 125 negative of required samples (125 positive total, 125 negative total) | (b) (4) |
| 3a.8 | Receive and secure samples | Provide summary to BARDA documenting receipt of additional 125 positive and 125 negative of required samples (250 positive total, 250 negative total) | (b) (4) |
| 3a.9 | Receive and secure samples | Provide summary to BARDA documenting receipt of additional 125 positive and 125 negative of required samples (375 positives total, 375 negatives total) | (b) (4) |
| 3a.10 | Receive and secure samples | Provide summary to BARDA documenting receipt of additional 125 positive and 125 negative of required samples (500 positives total, 500 negatives total) | (b) (4) |
| 3b.1 | Update Product Requirement Document | Provide BARDA with a copy of the updated PRD | (b) (4) |
| 3b.2 | Demonstrate feasibility of the assay to meet updated PRD | Provide summary to BARDA documenting the formal Design Review | (b) (4) |
| 3b.3 | Complete guard band studies | Provide summary to BARDA documenting outcomes of guard band studies. | (b) (4) |
| 3b.4 | Update Device Master Record | Provide a summary to BARDA documenting changes made to the DMR | (b) (4) |
| 3b.5 | Build three verification and validation lots | Provide summary to BARDA documenting the availability of three manufactured lots for V&V testing | (b) (4) |
| 3b.6 | Update Product Labelling | Provide a summary to BARDA documenting the updates made to product labelling | (b) (4) |
| 3c.1 | Draft specific test designs, analysis plans and acceptance criteria for quantitative requirements. | Verification Protocols approved and documented in Ortho's quality system. Provide BARDA with documentation for review. | (b) (4) |
| 3c.2 | Draft specific test designs and analysis plans for testing of the clinical samples in the biobank | Clinical (Validation) Protocols approved and documented in Ortho's quality system. Provide BARDA with documentation for review. | (b) (4) |
| 3c.3 | Execute all verification testing as per approved protocols | Provide summary to BARDA documenting the successful completion of all prescribed testing. | (b) (4) |
| 3c.4 | Completion and approval of verification reports | Provide BARDA with Verification reports summarizing the completion of verification activities to support IVD submission. | (b) (4) |

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| 3c.5 | Execute all validation testing as per approved clinical plan | Provide summary to BARDA documenting the successful completion of all prescribed testing. | (b) (4) |
| 3c.6 | Completion and approval of validation reports | Provide BARDA with Validation reports summarizing the completion of clinical trial activities to support IVD submission. | (b) (4) |
| 3c.7 | Submit anti-SARS-CoV-2 IgG assay to the FDA | Provide BARDA with the completed submission files sent to the FDA for the anti-SARS-CoV-2 IgG assay. | |
| 4a.1 | Identify clinical collection sites and testing sites | Provide a summary to BARDA documenting the specific sites for sample collection and testing sites | |
| 4a.2 | Pre-sub sent to FDA for the de novo or 510k submission of the anti-SARS-CoV-2 IgG Test Kit | Provide BARDA with a copy of the pre-sub submission sent to FDA | |
| 4a.3 | Finalize sample collection criteria | Document sample populations and collection criteria as part of Ortho's Clinical Plan. Provide BARDA with documentation for review. | |
| 4a.4 | Finalize contracts with clinical collection and testing sites | Provide a summary to BARDA documenting executed contracts with all collection sites | |
| 4a.5 | Sample collection site readiness | Provide a summary to BARDA documenting external readiness to begin sample collection. | |
| 4a.6 | Create sample collection infrastructure | Provide a summary to BARDA documenting internal readiness to receive samples. | |
| 4a.7 | Receive and secure samples | Provide summary to BARDA documenting receipt of 125 positive and 125 negative of required samples (125 positive total, 125 negative total) | |
| 4a.8 | Receive and secure samples | Provide summary to BARDA documenting receipt of additional 125 positive and 125 negative of required samples (250 positive total, 250 negative total) | |
| 4a.9 | Receive and secure samples | Provide summary to BARDA documenting receipt of additional 125 positive and 125 negative of required samples (375 positives total, 375 negatives total) | |
| 4a.10 | Receive and secure samples | Provide summary to BARDA documenting receipt of additional 125 positive and 125 negative of required samples (500 positives total, 500 negatives total) | |
| 4b.1 | Update Product Requirement Document | Provide BARDA with a copy of the updated PRD | |

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| 4b.2 | Demonstrate feasibility of the assay to meet updated PRD | Provide summary to BARDA documenting the formal Design Review | [redacted] |
| 4b.3 | Complete guard band studies | Provide summary to BARDA documenting outcomes of guard band studies. | [redacted] |
| 4b.4 | Update Device Master Record | Provide a summary to BARDA documenting changes made to the DMR | [redacted] |
| 4b.5 | Build three verification and validation lots | Provide summary to BARDA documenting the availability of three manufactured lots for V&V testing | [redacted] |
| 4b.6 | Update Product Labelling | Provide a summary to BARDA documenting the updates made to product labelling | [redacted] |
| 4c.1 | Draft specific test designs, analysis plans and acceptance criteria for quantitative requirements. | Verification Protocols approved and documented in Ortho's quality system. Provide BARDA with documentation for review. | [redacted] |
| 4c.2 | Draft specific test designs and analysis plans for testing of the clinical samples in the biobank | Clinical (Validation) Protocols approved and documented in Ortho's quality system. Provide BARDA with documentation for review. | [redacted] |
| 4c.3 | Execute all verification testing as per approved protocols | Provide summary to BARDA documenting the successful completion of all prescribed testing. | [redacted] |
| 4c.4 | Completion and approval of verification reports | Provide BARDA with Verification reports summarizing the completion of verification activities to support IVD submission. | [redacted] |
| 4c.5 | Execute all validation testing as per approved clinical plan | Provide summary to BARDA documenting the successful completion of all prescribed testing. | [redacted] |
| 4c.6 | Completion and approval of validation reports | Provide BARDA with Validation reports summarizing the completion of clinical trial activities to support IVD submission. | [redacted] |
| 4c.7 | Submit anti-SARS-CoV-2 IgG assay to the FDA | Provide BARDA with the completed submission files sent to the FDA for the anti-SARS-CoV-2 IgG assay. | [redacted] |

# ATTACHMENT 2 – CONTRACT ADMINISTRATION

## A. CONTRACTING OFFICER

The following CO will represent the Government for the purpose of this Contract:

(b) (6)

The CO is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the CO can make any changes to the terms, conditions, general provisions, or other stipulations of this Contract.

The CO is the only person with the authority to act as agent of the Government under this contract. Only the CO has authority to (1) direct or negotiate any changes in the Statement of Work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor of any costs incurred during the performance of this Contract; and (5) otherwise change any terms and conditions of this Contract.

No information other than that which may be contained in an authorized modification to this Contract, duly issued by the CO, which may be received from any person employed by the Government, otherwise, shall be considered grounds for deviation from any stipulation of this Contract.

The Government may unilaterally change its CO designation, after which it will notify the Contractor in writing of such change.

## B. CONTRACTING OFFICER'S REPRESENTATIVE

The following Contracting Officer's Representative (COR) will represent the Government for the purpose of this contract:

(b) (6)

The COR is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; (5) otherwise change any terms and conditions of this contract; or (6) sign written licensing agreements. Any signed agreement shall be incorporated by reference in Section K of the contract

The Government may unilaterally change its COR designation.

## C. INVOICING

1. Invoices will be submitted for each deliverable in accordance with the agreed upon payment schedule. In the event that a deliverable is not submitted or not deemed acceptable for approval by the COR and CO, the CO reserves the right to not process the invoice and payment until an acceptable deliverable has been submitted and approved by the COR and CO.

2. Invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the Government.

3. The Contractor shall submit an electronic copy of the payment request to the approving official instead of a paper copy. The payment request shall be transmitted as an attachment via e-mail to: PSC_Invoices@psc.hhs.gov, the Contracting Officer, and the Contracting Officer's Representative.

## D. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

1. Contractor Performance Evaluations

   A final evaluation of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15 at the time of completion of work.

   The final evaluation will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted fourteen days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

   A copy of the evaluation, Contractor response, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

2. Electronic Access to Contractor Performance Evaluations

   Contractors may access evaluations through a secure Web site for review and comment at the following address: http://www.cpars.gov.

## ATTACHMENT 3 – REPORTING AND MEETINGS REQUIREMENTS

| Item | Report/Meeting | Description | Due |
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| 1 | Kickoff Meeting | The Contractor shall complete a Kickoff meeting after contract award, either as a videoconference or an in-person meeting, to outline activities for the next 30 days. The Contractor shall provide an itinerary and agenda at least 2 business days in advance of meeting. | Within 10 days following contract award. |
| 2 | Gantt Chart | The Contract shall deliver a Gantt Chart that includes key milestones, deliverables, and Go/No-Go decision gates. | Draft within 30 days following contract award. |
| 3 | Weekly Teleconference | The Contractor shall participate in teleconferences every week with BARDA to discuss the performance of the contract. The Contractor shall provide slides 24 hours in advance of scheduled meetings. | Held weekly. Minutes provided by Contractor within 3 business days of the meeting. |
| 4 | Monthly Reports | Submit monthly reports summarizing data and progress to date on each aim in the SOW. | Due the 15th of the month following the preceding reporting month. The COR and CO will review the monthly reports with the Contractor and provide feedback. |
| 5 | Product Development Source Material and Manufacturing Report | 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. | Within 30 days of award date, and within 30 days after substantive changes are made to sources or materials. The Government will provide written comments to the Product Development Source Material and Manufacturing Report within 15 business days after submission. |

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| | | | If corrective action is recommended, Contractor must address and document all concerns raised by BARDA. |
| 6 | Work Location Tracking | The Contractor shall submit a detailed spreadsheet regarding locations where work will be performed under this contract, including addresses, points of contact, and work performed per location, to include any subcontractors, if necessary. | Within 5 business days of award date, and within 30 days after substantive changes are made to locations or capabilities.<br><br>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. |
| 7 | Pandemic Management Plan | A pandemic facility and/or operational management plan including change procedures from normal to pandemic operations Contractor will prepare an operational plan to continue operations in the event of a declared pandemic emergency. | Draft within 15 days of award. Final within 30 days of award. |
| 8 | Product/Technology Transition Strategy | Contractor shall provide a 1-2 page summary document containing a Transition Strategy. The Transition Strategy should provide a strategic business and technical plan for further development and | Contractor shall provide the Transition Strategy 30 days prior to the |

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| | | transitioning the product and/or technology. | end of each year of the Base Period. |
| 9 | Final Data Submission Package | Contractor must submit a data package consisting of all raw data produced under this contract. Data may be used by BARDA for analysis, evaluation, shared with other agencies, or shared outside of the government consistent with FAR 52.227-14. This submission package must be delivered in a non-proprietary format.<br><br>If clinical trial data is included, that data must be provided consistent with applicable privacy laws to protect personally identifiable information (PII). | Contractor will submit at least 15 days prior to contract end date. Partial data-sets may also be requested for delivery prior to submission of the Final Data Submission Package. |
| 10 | Draft Final Report & Final Report | These reports are to include a summation of the work performed and results obtained for the entire contract period of performance. | Draft Final Report to the COR and CO 30 calendar days prior to contract end date; Final Report shall be delivered on or before the completion date of the contract. |
| 11 | Supplemental Technical Documents, Raw Data, or Data Analysis | The Contractor shall provide all raw data, data analysis, or a data report to BARDA in accordance with FAR 52.227-14. | Contractor shall provide the Technical Documents, Raw Data, or Data Analysis upon request from the CO or COR. |
| 12 | Deliverables Arising from FDA Correspondence | See descriptions below for FDA Meetings, FDA Submissions & Correspondence, FDA Audits, and Other FDA Correspondence. | See descriptions below for FDA Meetings, FDA Submissions & Correspondence, FDA Audits, and Other FDA Correspondence. |
| 13 | Invention Reporting Requirements | All reports and documentation required by FAR Clause 52.227-11 Patent Rights- | On or before contract closeout. |

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| | | Ownership by the Contractor, including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification, and a copy of the final invention statement, shall be submitted to the CO. A final invention statement (see FAR 27.303 (b)(2)(ii)) shall be submitted to the CO prior to the closeout of the Contract. | |

**ATTACHMENT 4 – SPECIAL CONTRACT REQURIEMENTS**

## A. ENGAGEMENT WITH THE U.S. FOOD AND DRUG ADMINISTRATION (FDA)

### 1. FDA Meetings

The Contractor shall forward the dates and times of any meeting with the FDA to BARDA and make arrangements for appropriate BARDA staff to attend the FDA meetings if requested by BARDA. BARDA may include up to a maximum of four people (COR, CO and up to 2 subject matter experts).

Contractor shall notify BARDA of upcoming FDA meetings within 24 hours of scheduling.

The Contractor shall forward initial Contractor and FDA-issued draft minutes and final minutes of any meeting with the FDA to the CO and COR within 5 business days of receipt. All documents shall be duly marked as either "Draft" or "Final."

### 2. FDA Submissions & Correspondence

The Contractor shall provide BARDA the opportunity to review and comment upon all documents submitted to the FDA. In addition, an electronic copy of the final FDA submissions will also need to be submitted. All documents shall be duly marked as either "Draft" or "Final."

If draft documents are submitted to the COR for review, the COR will provide feedback to Contractor within 10 business days of receipt, or sooner as necessary to address FDA deadlines or requests.

If BARDA reviews draft documents, the Contractor shall revise, as appropriate, their documents to address BARDA's concerns and/or recommendations prior to FDA submission.

Final FDA submissions and all email correspondence with the FDA related to submissions shall be submitted to the CO and COR no later than 5 calendar days of their submission to, or email correspondence with, the FDA.

### 3. FDA Audits

In the event of an FDA inspection which occurs as a result of this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the CO and COR with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR) within five (5) business days after the Contractors receipt of those documents. The Contractor shall provide the COR and CO with copies of the plan for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution and a copy of all final responses to the FDA. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. To the extent feasible, the Contractor shall make arrangements for BARDA representative(s) to be present during the final debrief by the regulatory inspector.

If draft documents are submitted to the COR for review, the COR will provide feedback to Contractor within 10 business days of receipt, or sooner as necessary to address FDA deadlines or requests.

If BARDA reviews draft documents, the Contractor shall revise as appropriate their documents to address BARDA's written concerns and/or recommendations prior to FDA submission.

Contractor shall notify CO and COR within 10 business days of a scheduled FDA audit or within 24 hours of an ad hoc site visit/audit if the FDA does not provide 10 business days' advance notice.

Contractor shall provide copies of any FDA audit report received from subcontractors that occur as a result of this contract or for this product within 5 business days of receiving correspondence from the FDA, Subcontractor, or third party.

Within 15 business days of audit report, Contractor shall provide CO with a plan for addressing areas of nonconformance, if any are identified.

Final FDA submissions shall be submitted to the CO and COR.

**4. Other FDA Correspondence**

The Contractor shall document any material correspondence between Contractor and FDA as related to activities funded under this contract and submit to BARDA. All such documents shall be duly marked as either "Draft" or "Final." Contractor shall provide such written summary of any FDA correspondence or engagement within 5 business days and submit to the CO and COR. The written summary shall include:

A tracking log of progress on regulatory submissions with the FDA, description of the submission, date of the submission, status of submission and next steps.

**B. REPORTING MATTERS OF FRAUD, WASTE, AND ABUSE**

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in BARDA funded programs should report such matters to the DHHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is 1-800-HHS-TIPS (1-800-447-8477). All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov and the mailing address is:

Office of Inspector General
Department of Health and Human Services TIPS HOTLINE
P.O. Box 23489 Washington, D.C. 20026

**C. PROHBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES**

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the

Contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this Contract.

**D. IDENTIFICATION AND DISPOSTION OF DATA**

The Contractor will be required to provide certain data generated under this Contract to DHHS. DHHS reserves the right to review any other data related to performance of this Contract.

The Contractor shall keep copies of all data required by the FDA relevant to this Contract for the time specified by the FDA.

**E. EXPORT CONTROL NOTIFICATION**

Contractors are responsible for ensuring compliance with all export control laws and regulations that may be applicable to the export of and foreign access to their proposed technologies. Contractors may consult with the Department of State with any questions regarding the International Traffic in Arms Regulation (ITAR) (22 C.F.R. Parts 120-130) and /or the Department of Commerce regarding the Export Administration Regulations (15 C.F.R. Parts 730-774).

**F. CONFLICT OF INTEREST**

The Contractor represents and warrants that, to the best of the Contractor's knowledge and belief, there are no relevant facts or circumstances which could give rise to an organizational conflict of interest, as defined in FAR 2.101 and Subpart 9.5, or that the Contractor has disclosed all such relevant information. Prior to commencement of any work, the Contractor agrees to notify the CO promptly that, to the best of its knowledge and belief, no actual or potential conflict of interest exists or to identify to the CO any actual or potential conflict of interest the firm may have. In emergency situations, however, work may begin but notification shall be made within five (5) working days. The Contractor agrees that if an actual or potential organizational conflict of interest is identified during performance, the Contractor shall promptly make a full disclosure in writing to the CO. This disclosure shall include a description of actions which the Contractor has taken or proposes to take, after consultation with the CO, to avoid, mitigate, or neutralize the actual or potential conflict of interest. The Contractor shall continue performance until notified by the CO of any contrary action to be taken. Remedies include termination of this Contract for convenience, in whole or in part, if the CO deems such termination necessary to avoid an organizational conflict of interest. If the Contractor was aware of a potential organizational conflict of interest prior to award or discovered an actual or potential conflict after award and did not disclose it or misrepresented relevant information to the CO, the Government may terminate the Contract for default, debar the Contractor from Government contracting, or pursue such other remedies as may be permitted by law or this Contract.

**G. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION**

The Contractor shall not use contract funds to disseminate information that is deliberately false or misleading.

**H. NEEDLE DISTRIBUTION**

The Contractor shall not use contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

**I. CONFIDENTIAILTIY OF INFORMATION**

1. 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.

2. The CO 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 and providing further that the Government is not entitled to unlimited rights to that information pursuant to FAR 52.227-14. Similarly, the CO 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.

3. 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.

4. 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.

5. 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 should obtain a written determination from the CO prior to any release, disclosure, dissemination, or publication.

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

**J. ACCESS TO DOCUMENTATION / DATA**

The Government shall have physical and electronic access to all documentation and data generated under this Contract, including: all data documenting Contractor performance; all data generated; all communications and correspondence with regulatory agencies and bodies to include all audit observations, inspection reports, milestone completion documents, and all Offeror commitments and responses. Contractor shall provide the Government with an electronic copy of all correspondence and submissions to the FDA within 5 business days of receipt. The Government shall acquire unlimited rights to all data funded under this contract in accordance with FAR Subpart 27.4 and FAR Clause 52.227-14.

**K. ACKNOWLEDGEMENT OF FEDERAL FUDNING**

Section 507 of P.L. 104-208 mandates that Contractors funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. This requirement is in addition to the continuing requirement to provide an acknowledgment of support and disclaimer on any publication reporting the results of a contract funded activity.

Publication and Publicity

No information related to data obtained under this Contract shall be released or publicized without providing BARDA with at least thirty (30) days advanced notice and an opportunity to review the proposed release or publication.

In addition to the requirements set forth in this Contract, Section 507 of P.L. 104-208 mandates that Contractors funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. Contractors are required to state:

1. The percentage and dollar amounts of the total program or project costs financed with Federal money and;

2. The percentage and dollar amount of the total costs financed by non-governmental sources. For purposes of this Contract "publication" is defined as an issue of printed material offered for distribution or any communication or oral presentation of information, including any manuscript or scientific meeting abstract. Any publication containing data generated under this Contract must be submitted for BARDA review no less than thirty (30) calendar days for manuscripts and fifteen (15) calendar days for abstracts before submission for public presentation or publication. Contract support shall be acknowledged in all such publications substantially as follows:

> "This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. _____."

Press Releases

Misrepresenting contract results or releasing information that is injurious to the integrity of BARDA may be construed as improper conduct. Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. With the exception of ad-hoc press releases required by applicable law or regulations, the Contractor shall ensure that the COR has received an advance copy of any press release related to the contract not less than two (2) business days prior to the issuance of the press release.

The Contractor shall acknowledge the support of the Department of Health and Human Service, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, Division of Research Innovation and Ventures under Contract No. _____."

BARDA Use of Contractor Logo

Contractor hereby grants BARDA the right to use Contractor's corporate logo (and other artwork as agreed to by the parties), for presentations, internal and external websites, and other reasonable promotional and reporting uses relating to the project during the period of performance of the Contract (or for a longer period, if agreed between the parties).

**L. PRIVACY ACT APPLICABILITY**

Notification is hereby given that the Contractor and its employees are subject to criminal penalties for violation of the Privacy Act to the same extent as employees of the Government. The Contractor shall assure that each of its employees knows the prescribed rules of conduct and that each is aware that he or she can be subjected to criminal penalty for violation of the Act. A copy of 45 C.F.R. Part 5b, Privacy Act Regulations, may be obtained at https://www.gpo.gov/fdsys/granule/CFR-2007- title45-vol1/CFR-2007-title45-vol1-part5b.

The Contractor is responsible for monitoring contractor compliance with the Privacy Act.

The Contractor shall follow the Privacy Act guidance as contained in the Privacy Act System of Records number 09-25-0200.

**M. LABORATORY LICENSE REQUIREMENTS**

The Contractor shall comply with all applicable requirements of Section 353 of the Public Health Service Act (Clinical Laboratory Improvement Act as amended) (42 U.S.C. 263a) and 42 CFR Part 493. This requirement shall also be included in any subcontract for services under the Contract.

**N. QUALITY ASSURANCE (QA) AUDIT REPORTS**

BARDA reserves the right to participate in QA audits as related to activities funded under this Contract. Upon completion of the audit/site visit the Contractor shall provide a report capturing the findings, results and next steps in proceeding with the subcontractor. If action is requested of the subcontractor, detailed concerns for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to BARDA. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action execution.

1. Contractor shall notify CO and COR of upcoming, ongoing, or recent audits/site visits of subcontractors as part of weekly communications.
2. Contractor shall notify the COR and CO within five (5) business days of report completion.

**O. BARDA AUDITS**

Contractor shall accommodate periodic or reasonable ad hoc site visits during normal business hours by the Government with forty-eight (48) hours advance notice. If the Government, the Contractor, or other parties identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to the Government.

1. If issues are identified during the audit, Contractor shall submit a report to the CO and COR detailing the finding and corrective action(s) within 10 business days of the audit.
2. COR and CO will review the report and provide a response to the Contractor with ten (10) business days.
3. Once corrective action is completed, the Contractor will provide a final report to the CO and COR.

**P. RESTRICTION ON EMPLOYMENT OF UNAUTHORIZED ALIEN WORKERS**

The Contractor shall not use Contract funds to employ workers described in Section 274A (h)(3) of the Immigration and National Act, which reads as follows:

"(3) Definition of unauthorized alien – As used in this Section, the term 'unauthorized alien' with respect to the employment of an alien at a particular time, that the alien is not at that time either an alien lawfully admitted for permanent residence, or (B) authorized to be so employed by this Act or by the Attorney General."

**Q. NOTIFICATION OF CRITICAL PROGRAMMATIC CONCERNS, RISK, OR POTENTIAL RISKS**

If any action occurs that creates a cause for critical programmatic concern, risk, or potential risk to BARDA or the Contractor an Incident Report shall be delivered to BARDA.

1. Within 48 hours of activity or incident or within 24 hours for a security related activity or incident, Contractor must notify BARDA.
2. Additional updates due to COR and CO within 48 hours of additional developments.
3. Contractor shall submit within 5 business days a Corrective Action Plan (if deemed necessary by either party) to address any potential issues.

If corrective action is deemed necessary, Contractor must address in writing its consideration of concerns raised by BARDA within 5 business days of receiving comments by BARDA.

**R. DISSEMINATION OF INFORMATION**

Other than scientific and technical data for which the Contractor can assert a copyright under FAR Clause 52.227-14 (c), no information related to data obtained under this Contract shall be released or publicized without the prior written consent of the CO. In the event that the Contractor seeks to publicize scientific and technical data, the contractor shall provide BARDA, through the COR, with a minimum of thirty (30) business days to review the particular scientific and technical data prior to publication.

**S. REGISTRATION WITH THE SELECT AGENT PROGRAM FOR WORK INVOLVING THE POSSESSION, USE, AND / OR TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS**

Work involving select biological agents or toxins shall not be conducted under this Contract until the Contractor and any affected subcontractor(s) are granted a certificate of registration or are authorized to work with the applicable select agents.

For prime or subcontract awards to domestic institutions who possess, use, and/or transfer Select Agents under this contract, the institution must complete registration with the Centers for Disease Control and Prevention (CDC), DHHS or the Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA), as applicable, before performing work involving Select Agents, in accordance with 42 C.F.R. Part 73. No Government funds can be used for work involving Select Agents, as defined in 42 C.F.R. Part 73, if the final registration certificate is denied.

For prime or subcontract awards to foreign institutions who possess, use, and/or transfer Select Agents under this Contract, the institution must provide information satisfactory to the Government that a process equivalent to that described in 42 C.F.R. Part 73 (http://www.cdc.gov/od/sap/docs/42cfr73.pdf ) for U.S. institutions is in place and will be administered on behalf of all Select Agent work sponsored by these funds before using these funds for any work directly involving the Select Agents. The Contractor must provide information addressing the following key elements appropriate for the foreign institution: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the Select Agents, and any applicable laws, regulations and policies equivalent to 42 C.F.R. Part 73. The Government will assess the policies and procedures for comparability to the U.S. requirements described in 42 C.F.R. Part 73. When requested by the CO, the Contractor shall provide key information delineating any laws, regulations, policies, and procedures applicable to the foreign institution for the safe and secure possession, use, and transfer of Select Agents. This includes summaries of safety, security, and training plans, and applicable laws, regulations, and policies. For the purpose of security risk assessments, the Contractor must provide the names of all individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals have access to Select Agents under the Contract.

Listings of HHS select agents and toxins, biologic agents and toxins, and overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program Web site at https://www.selectagents.gov/

**T. MANUFACTURING STANDARDS**

The Good Manufacturing Practice Regulations (GMP) (21 C.F.R. Part 820) will be the standard to be applied for manufacturing, processing, packaging, storage and delivery of this product.

If at any time during the life of the Contract, the Contractor fails to comply with GMP in the manufacturing, processing, packaging, storage, stability and other testing of the manufactured drug substance or product and delivery of this product and such failure results in a material adverse effect on the safety, purity or potency of the product (a material failure) as identified by

the FDA, the Contractor shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure. If, within the thirty (30) calendar day period, the Contractor fails to take such an action to the satisfaction of the Government Project Officer/COR, or fails to provide a remediation plan that is acceptable to the COR, then the Contract may be terminated.

**U. SHARING RESEARCH DATA**

The Contractor's data sharing plan, due date to be determined at contract award, is hereby incorporated by reference. The Contractor agrees to adhere to its plan and shall request prior approval of the CO for any changes in its plan.

BARDA endorses the sharing of final research data to serve health. This contract is expected to generate research data that must be shared with the public and other researchers.

BARDA recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule (see HHS-published documentation on the Health Information Privacy at http://www.hhs.gov/ocr/privacy/index.html). The rights and privacy of people who participate in BARDA-funded research must be protected at all times; thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

**V. PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM ASPER FUNDED RESEARCH**

All ASPR-funded investigators shall submit to the National Institutes of Health (NIH) National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, of any peer-reviewed scientific publications resulting from research supported in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response. ASPR defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and ASPR. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov.

**W. INSITUTIONAL RESPONSBILITY REGARDING CONFLICTING INTERESTS OF INVESTIGATORS**

The Contractor shall comply with the requirements of 45 C.F.R. Part 94, Responsible Prospective

Contractors, which promotes objectivity in research by establishing standards to ensure that investigators (defined as the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded under BARDA contracts) will not be biased by any conflicting financial interest.

As required by 45 C.F.R. Part 94, the Contractor shall, at a minimum:

1. Maintain a written, enforceable policy on conflict of interest that complies with 45 C.F.R. Part 94 and inform each investigator of the policy, the investigator's reporting responsibilities, and the applicable regulations. The Contractor must take reasonable steps to ensure that investigators working as collaborators or subcontractors comply with the regulations.

2. Designate an official(s) to solicit and review financial disclosure statements from each investigator participating in BARDA-funded research. Based on established guidelines consistent with the regulations, the designated official(s) must determine whether a conflict of interest exists, and if so, determine what actions should be taken to manage, reduce, or eliminate such conflict. A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the BARDA-funded research. The Contractor may require the management of other conflicting financial interests in addition to those described in this paragraph, as it deems appropriate. Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests are included in 45 C.F.R. Part 94, under Management of Conflicting Interests.

3. Require all financial disclosures to be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

4. Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the Contractor with respect to each conflicting interest 3 years after final payment or, where applicable, for the other time periods specified in 48 C.F.R. Part 4, subpart 4.7, Contract Records Retention.

5. Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

If a conflict of interest is identified, the Contractor shall report to the CO, the existence of the conflicting interest found. This report shall be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis, within sixty (60) days of that identification.

If the failure of an investigator to comply with the conflict of interest policy has biased the design, conduct, or reporting of the BARDA-funded research, the Contractor must promptly notify the CO of the corrective action taken or to be taken. The CO will take appropriate action or refer the matter to the Contractor for further action, which may include directions to the Contractor on how to maintain appropriate objectivity in the funded research.

The CO may at any time inquire into the Contractor's procedures and actions regarding conflicts of interests in BARDA-funded research, including a review of all records pertinent to compliance with 45 C.F.R. Part 94. The CO may require submission of the records or review them on site. On the basis of this review, the CO may decide that a particular conflict of interest will bias the objectivity of the BARDA-funded research to such an extent that further corrective action is

needed or that the Contractor has not managed, reduced, or eliminated the conflict of interest. The issuance of a Stop Work Order by the CO may be necessary until the matter is resolved.

If the CO determines that BARDA-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 conflict of interest that was not disclosed or managed, the Contractor must require disclosure of the conflict of interest in each public presentation of the results of the research.

## X. CLINICAL TERMS OF AWARD

In addition to those terms and conditions outlined under applicable HHSAR clauses incorporated by reference by Section I of this Contract, the following clinical terms of award detail an agreement between the BARDA and the Contractor; they apply to all contracts involving clinical research.

Draft protocols for each clinical study will be submitted to BARDA for evaluation and comment. BARDA comments will be addressed and/or incorporated into the draft protocol prior to submission to the FDA for comment, if required and as appropriate.

BARDA shall have unlimited rights to all protocols, data generated from the execution of these protocols, and final reports, funded by BARDA under this Contract, as defined in Rights in Data Clause in FAR 52.227-14. BARDA reserves the right to request that the Contractor provide any contract deliverable in a non-proprietary form without any restrictive legends to ensure BARDA has the ability to review and distribute the deliverables, as BARDA deems necessary.

Important information regarding performing human subject research is available here and should be addressed by the contractor. https://www.hhs.gov/ohrp/

Any updates to clinical studies (enrollment, technical results, etc) are to be addressed in the Monthly and Annual Progress Reports, as well as technical monthly calls. The Contractor shall advise the COR or designee in writing and via electronic communication in a timely manner of any issues potentially affecting contract performance.

### 1. Safety and Monitoring Issues

#### i. Institutional Review Board or Independent Ethics Committee Approval

Before award and then with the annual progress report, the Contractor must submit to BARDA a copy of the current IRB-or IEC-approved informed consent document, documentation of continuing review and approval and the OHRP federal wide assurance number for the institution or site.

If other institutions are involved in the research (e.g., a multicenter clinical trial or study), each institution's IRB or IEC must review and approve the protocol. They must also provide BARDA initial and annual documentation of continuing review and approval, including the current approved informed consent document and federal wide number.

The Contractor must ensure that the application as well as all protocols are reviewed by their IRB or IEC.

To help ensure the safety of participants enrolled in BARDA-funded studies, the Contractor must provide BARDA copies of documents related to all major changes in the status of ongoing protocols, including the following:

a. All amendments or changes to the protocol, identified by protocol version number, date, or both and dates it is valid.

b. All changes in informed consent documents, identified by version number, dates, or both and dates it is valid.

c. Termination or temporary suspension of patient accrual.

d. Termination or temporary suspension of the protocol.

e. Any change in IRB approval.

f. Any other problems or issues that could affect the participants in the studies.

The Contractor must notify BARDA through the COR or CO of any of the above changes within five (5) working days by email or fax, followed by a letter signed by the institutional business official, detailing notification of the change of status to the local IRB and a copy of any responses from the IRB or IEC.

If a clinical protocol has been reviewed by an institutional biosafety committee (IBC) or the NIH Recombinant DNA Advisory Committee (RAC), the Contractor must provide information about the initial and ongoing review and approval, if any. See the NIH Guidelines for Research Involving Recombinant DNA Molecules.

**ii. Data and Safety Monitoring Requirements**

BARDA strongly recommends independent safety monitoring for clinical trials of investigational drugs, devices, or biologics; clinical trial of licensed products; and clinical research of any type involving more than minimal risk to volunteers. Independent monitoring can take a variety of forms. Phase III clinical trials must be reviewed by an independent data and safety monitoring board (DSMB); other trials may require DSMB oversight as well. The Contractor shall inform BARDA of any upcoming site visits and/or audits of CRO facilities funded under this effort. BARDA reserves the right to accompany the Contractor on site visits and/or audits of CROs as BARDA deems necessary. The Contractor shall inform BARDA 30 days in advance of a DSMB board meetings for studies funded under this effort. BARDA reserves the right to participate in the DSMB board meetings on an impromptu basis as a non-voting member, if feasible per the structure of the study. If not, the communications from the DSMB to the Contractor should be made available to BARDA upon receipt.

A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For examples, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of a routine physical examination (45 C.F.R. § 46.102(j)).

Final decisions regarding the type of monitoring to be used must be made by the Contractor, based on FDA and BARDA guidance, before enrollment starts. Discussions with the responsible BARDA PO/COR regarding appropriate safety monitoring must take place, and the Contractor must submit a written response to all concerns raised by BARDA, before patient enrollment begins and may include discussions about the appointment of one of the following:

**Independent Safety Monitor –** a physician or other appropriate expert who is independent of the study and available in real time to review and recommend appropriate action regarding adverse events and other safety issues.

**Independent Monitoring Committee (IMC) or Safety Monitoring Committee (SMC) –** a small group of independent investigators and biostatisticians who review data from a particular study.

**Data and Safety Monitoring Board –** an independent committee charged with reviewing safety and trial progress and providing advice with respect to study continuation, modification, and termination. The Contractor may use an established BARDA DSMB or to organize an independent DSMB. All phase III clinical trials must be reviewed by a DSMB; other trials may require DSMB oversight as well. Please refer to: NIAID Principles for Use of a Data and Safety Monitoring Board (DSMB) For Oversight of Clinical Trials Policy. BARDA should be provided documentation from DSMB and should be provided with any decisions by Contractor regarding the DMSB as it relates to work under this contract.

When a monitor or monitoring board is organized, a description of it, its charter or operating procedures (including a proposed meeting schedule and plan for review of adverse events), and roster and curriculum vitae from all members must be submitted to BARDA before enrollment starts. If concerns are raised, Contractor must address all concerns to BARDA, in writing, before enrollment begins. The Contractor will also ensure that the monitors and board members report any conflicts of interest and the Contractor will maintain a record of this. The Contractor will share conflict of interest reports with BARDA.

Additionally, the Contractor must submit written summaries of all reviews conducted by the monitoring group to the BARDA within thirty (30) days of reviews or meetings.

**2. BARDA Protocol Review Process Before Patient Enrollment Begins**

BARDA has a responsibility to ensure that mechanisms and procedures are in place to protect the safety of participants in BARDA-supported clinical trials. Therefore, before patient accrual or participant enrollment, the Contractor must ensure the following (as applicable) are in place at each participating institution, prior to patient accrual or enrollment:

i. IRB- or IEC-approved clinical research protocol identified by version number, date, or both, including details of study design, proposed interventions, patient eligibility, and exclusion criteria.

ii. Documentation of IRB or IEC approval, including OHRP federal wide number, IRB or IEC registration number, and IRB and IEC name.

iii. IRB- or IEC- approved informed consent form/document, identified by version number, date, or both and dates it is valid.

iv. Plans for the management of side effects.

v. Procedures for assessing and reporting adverse events.

vi. Plans for data and safety monitoring (see above) and monitoring of the clinical study site, pharmacy, and laboratory.

vii. Documentation that the Contractor and all study staff responsible for the design or conduct of the research have received training in the protection of human subjects.

Documentation to demonstrate that each of the above items are in place shall be submitted to BARDA) for evaluation and comment in conjunction with the protocol. Execution of clinical studies requires written authorization from BARDA in accordance with this section of this contract.

**3. Investigational New Drug or Investigational Device Exemption Requirements**

Consistent with federal regulations, applicable clinical research projects involving the use of investigational therapeutics, vaccines, or other medical interventions (including licensed products and devices for a purpose other than that for which they were licensed) in humans under a research protocol must be performed under a FDA investigational new drug (IND) or investigational device exemption (IDE).

Where an IND and IDE is otherwise required, exceptions must be granted in writing by FDA. If the proposed clinical trial will be performed under an IND or IDE, the Contractor must provide BARDA with the name and institution of the IND or IDE sponsor, the date the IND or IDE was filed with FDA, the FDA IND or IDE number, any written comments from FDA, and the written responses to those comments.

In instances in which an IND or IDE is required, unless FDA notifies Contractor otherwise, the Contractor must wait thirty (30) calendar days from FDA receipt of an initial IND or IDE application before initiating a clinical trial.

The Contractor must notify BARDA if the FDA places the study on clinical hold and provide BARDA any written comments from FDA, written responses to the comments, and documentation in writing that the hold has been lifted.

The Contractor must not use grant or contract funds during a clinical hold to fund clinical studies that are on hold other than costs that are associated with activities related to patients coming off study, monitoring, or ending the study. The Contractor must not enter into any new financial obligations related to clinical activities for the clinical trial on clinical hold.

**4. Required Time-Sensitive Notification**

i. Under an IND or IDE, the sponsor must provide FDA safety reports of serious adverse events. Under these Clinical Terms of Award, the Contractor must submit copies to the responsible BARDA representative or the COR as follows:

a. Expedited safety report of unexpected or life-threatening experience or death. A copy of any report of unexpected or life-threatening experience or death associated with the use of an IND drug, which must be reported to FDA by telephone or fax as soon as possible but no later than seven (7) days after the IND sponsor's receipt of the information, must be submitted to BARDA representative or COR within 24 hours of FDA notification.

b. Expedited safety reports of serious and unexpected adverse experiences. A copy of any report of unexpected and serious adverse experience associated with use of an IND drug or any finding from tests in laboratory animals that suggests a significant risk for human subjects, which must be reported in writing to FDA as soon as possible but no later than 15 days after the IND sponsor's receipt of the information, must be submitted to the BARDA representative or COR within 24 hours of FDA notification.

c. IDE reports of unanticipated adverse device effect. A copy of any reports of unanticipated adverse device effect submitted to FDA must be submitted to BARDA representative or COR within 24 hours of FDA notification.

d. Expedited safety reports. Sent to BARDA representative or the COR concurrently with the report to FDA.

e. Other adverse events documented during the course of the trial should be included in the annual IND or IDE report and reported to BARDA annually.

ii. Safety reporting for research not performed under an IND or IDE:

Final decisions regarding ongoing safety reporting requirements for research not performed under an IND or IDE must be made jointly by the BARDA PO or the COR and the Contractor.

In case of problems or issues the COR will contact the Contractor within ten (10) working days by email or fax, followed within thirty (30) calendar days by an official letter to the Contractor's Project Manager, with a copy to the institutions' office of sponsored programs, listing issues and appropriate actions to be discussed.

**5. Human Material (Assurance of OHRP Compliance).**

The acquisition and supply of all human specimen material (including fetal material) used under this Contract shall be obtained by Contractor in full compliance with applicable Federal, State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this Contract, by collaborating sites, or by subcontractors identified under this Contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 C.F.R. 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by Contractor.

Provision by the Contractor to the CO of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self-designated form provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

**Y. FOREIGN TRANSFER OF ASSETS OR TECHNOLOGY**

This clause shall remain in effect during the term of the Contract and for five (5) years thereafter.

**1. Definitions**

AFFILIATES: Associated business concerns, non-profit organizations, or individuals if, directly or indirectly, (1) either one controls or can control the other; or (2) a third party controls or can control both.

ASSET(S): Tangible or intangible manifestations of technologies having economic value and capable of being conveyed between economic or Governmental entities that is the focus/scope of development by the U.S. Government ("USG") and Contactor in this Contract.

ASSET(S): Tangible or intangible manifestations of technologies having economic value and capable of being conveyed between economic or Governmental entities that is the focus/scope of development by the U.S. Government (the "USG") and Contactor in this Contract.

FOREIGN FIRM OR INSTITUTION: A firm or institution organized or existing under the laws of a country other than the United States of America (U.S.), its territories, or possessions. The term includes, for purposes of this Contract, any agency or instrumentality of a foreign government; and firms, institutions or business organizations which are owned or substantially controlled by foreign governments, firms, institutions, or individuals.

TECHNOLOGY: Technical Data, Computer Software, manufactured materials and Subject Inventions funded by the USG under this Contract. Technology also includes contractor know how and personnel expertise, as well as other Assets necessary to assure successful completion of this Contract.

U.S. FIRM OR INSTITUTION: A firm or institution organized or existing under the laws of the United States, its territories, or possessions. The term includes, for purposes of this Contract, any agency or instrumentality of the USG; and firms, institutions or business organizations which are owned or substantially controlled by U.S. citizens, firms, institutions, governmental agencies or individuals.

**2. General**

The parties agree that research findings and technological developments made under this Contract constitute an investment by the USG on behalf of its citizens in the interest of their economic and national health security. These investments are made for the primary benefit of the citizenry of the United States with those same benefits potentially accruing to the people of all nations. Therefore, the USG has a fiduciary responsibility to protect the full invested value of the Assets and Technology developed under this Contract. The USG is also cognizant of the duty the Contractor has to its shareholders and other stakeholders with a vested interested in the economic success of the Contractor. At times both parties are aware their respective interests may diverge. Therefore, in the course of conducting business though the Contract, access to technology developments under this Contract by Foreign Firms or Institutions must be carefully considered.

**3. Export Controls**

Contractor agrees to comply with all applicable laws regarding export controls and not to export any Asset or Technology to any U.S. embargoed countries.

**4. Post-award Transfer of Ownership of Assets or Technology**

The Contractor shall provide notice to the CO and COR within three (3) business days of any discussions of a proposed transfer of ownership or establishment of a licensing agreement of any Asset or Technology funded under this Contract from the Contractor to a Foreign Firm or Institution. Notice will also be given within three (3) business days of any discussions of a proposed transfer of operational, corporate, or economic control of Assets and Technology funded under this Contract to Foreign Firms or Institutions. This Article shall not apply to transfers by the Contractor to Affiliated entities of the Contractor, as well as technology transfers for the purposes of manufacturing in accordance with the Statement of Work.

Prior to transferring any Asset funded by the USG under this Contract, the Contractor should carefully review the USG rights under FAR Subpart 42.12 pertaining to Novation, specifically FAR section 42.1204. That provision provides that the USG may recognize a third party assignment only if the transfer of Assets and Technology is determined to be in the USG's interests. The Contractor should be aware that the USG is under no obligation to recognize a successor in interest. If the CO determines that a transfer of Assets and Technology may have adverse consequences to the economic well-being or national health security interests of the U.S., the Contractor, and the CO shall jointly endeavor to find alternatives to the proposed transfer which obviate or mitigate potential adverse consequences of the transfer but which may provide substantially equivalent benefits to the Contractor.

In addition to the USG licensing rights to subject inventions and technical data funded under this Contract, see FAR clause 52.227-11 (Patent Rights-Ownership by the Contractor) and FAR Clause 52.227-14 (Rights in Data - General), the USG shall have a first right of refusal for the purchase of the Asset and/or Technology funded under the Contract. The USG may waive this first right of refusal in writing submitted to the Contractor within ninety (90) calendar days of the initial notification to the USG of the Contractor's intent to conduct any form of Asset or corporate transfer.

Except for transfers to affiliates of the Contractor, including those entities necessary to complete the Statement of Work, the Contractor shall provide written notice to the CO and COR of the scheduled transfer to a Foreign Firm or Institution at least ninety (90) calendar days prior to the scheduled date of transfer. Such notice shall cite this Article and shall specifically identify the Asset or Technology proposed for the transfer and the general terms of the transfer. No transfer shall take place without written concurrence from the CO.

**5. Transfer to a Prohibited Source**

In the event of a transfer of an Asset and/or Technology by the Contractor to a Foreign Firm or Institution which is identified as a Prohibited Source pursuant to FAR Subpart 25.7: (a) the USG may terminate this Contract for cause and (b) the license rights to the technical data and subject invention under the relevant FAR IP Clauses (FAR Clause

52.227-11 and FAR Clause 52-227-14) shall survive the termination. Upon request of the USG, the Contractor shall provide written confirmation of such licenses.

**6. Lower Tier Agreements**

The Contractor shall include this Article, suitably modified, to identify the Parties, in all subcontracts or lower tier agreements, regardless of tier.

Addendum to FAR 52.212-4 Terms and Conditions – Commercial Items

(s) *Order of precedence*. Any inconsistencies in this solicitation or contract shall be resolved by giving precedence in the following order:

(1) The schedule of supplies/services
(2) The Assignments, Disputes, Payments, Invoice, Other Compliances, Compliance with Laws Unique to Government Contracts, Unauthorized Obligations, and Commercial Supplier Agreements – Unenforceable Clauses paragraphs of this clause.
(3) The clause at 52.212-5.
(4) Addenda to this solicitation or contract, including any commercial supplier agreements as amended by the Commercial Supplier Agreements – Unenforceable Clauses provision.
(5) Solicitation provisions if this is a solicitation.
(6) Other paragraphs of this clause.
(7) The Standard Form 1449.
(8) Other documents, exhibits, and attachments.
(9) The specification.

(w) *Commercial supplier agreements–unenforceable clauses*.

(1) Definition. For the purpose of this contract, "Commercial supplier agreements" (referred to at FAR 12.216 as "Supplier License Agreements") means terms and conditions customarily offered to the public by vendors of supplies or services that meet the definition of "commercial item" set forth in FAR 2.101 and intended to create a binding legal obligation on the end user. Commercial supplier agreements are particularly common in information technology acquisitions, including acquisitions of commercial computer software and commercial technical data, but they may apply to any supply or service. The term applies–

(a) Regardless of the format or style of the document. For example, a commercial supplier agreement may be styled as standard terms of sale or lease, Terms of Service (TOS), End User License Agreement (EULA), or another similar legal instrument or agreement, and may be presented as part of a proposal or quotation responding to a solicitation for a contract or order;

(b) Regardless of the media or delivery mechanism used. For example, a commercial supplier agreement may be presented as one or more paper documents or may appear on a computer or other electronic device screen during a purchase, software installation, other product delivery, registration for a service, or another transaction.

(2) When any supply or service acquired under this contract is subject to a commercial supplier agreement, and notwithstanding any other provision of this agreement, when the end user is an agency or instrumentality of the U.S. Government, the following language shall be deemed incorporated into the commercial supplier agreement. As used herein, "this agreement" means the commercial supplier agreement.

(i) *Applicability*. This agreement is a part of a contract between the commercial supplier and the U.S. Government for the acquisition of the supply or service that necessitates a license or other similar legal instrument (including all contracts, task orders, and delivery orders under FAR Part 12).

(ii) *End user*. This agreement shall bind the ordering activity as end user but shall not operate to bind a Government employee or person acting on behalf of the Government in his or her personal capacity.

(iii) *Law and disputes*. This agreement is governed by Federal law.

(A) Any language purporting to subject the U.S. Government to the laws of a U.S. state, U.S. territory, district, or municipality, or a foreign nation, except where Federal law expressly provides for the application of such laws, is hereby deleted.

(B) Any language requiring dispute resolution in a specific forum or venue that is different from that prescribed by applicable Federal law is hereby deleted.

(C) Any language prescribing a different time period for bringing an action than that prescribed by applicable Federal law in relation to a dispute is hereby deleted.

(iv) *Continued performance.* The supplier or licensor shall not unilaterally revoke, terminate or suspend any rights granted to the Government except as allowed by this contract. If the supplier or licensor believes the ordering activity to be in breach of the agreement, it shall pursue its rights under the Contract Disputes Act or other applicable Federal statute while continuing performance as set forth in subparagraph 52.212-4(d) (Disputes).

(v) *Arbitration; equitable or injunctive relief*. In the event of a claim or dispute arising under or relating to this agreement, a binding arbitration shall not be used unless specifically authorized by agency guidance, and equitable or injunctive relief, including the award of attorney fees, costs or interest, may be awarded against the U.S. Government only when explicitly provided by statute (e.g., Prompt Payment Act or Equal Access to Justice Act).

(vi) Updating terms.

(A) After award, the contractor may unilaterally revise commercial supplier agreement terms if they are not material. A material change is defined as:

(1) Terms that change Government rights or obligations;

(2) Terms that increase Government prices;

(3) Terms that decrease overall level of service; or

(4) Terms that limit any other Government right addressed elsewhere in this contract.

(B) For revisions that will materially change the terms of the contract, the revised commercial supplier agreement must be incorporated into the contract using a bilateral modification.

(C) Any agreement terms or conditions unilaterally revised subsequent to award that are inconsistent with any material term or provision of this contract shall not be enforceable against the Government, and the Government shall not be deemed to have consented to them.

(vii) *No automatic renewals.* If any license or service tied to periodic payment is provided under this agreement (e.g., annual software maintenance or annual lease term), such license or service shall not renew automatically upon expiration of its current term without prior express consent by an authorized Government representative.

(viii) *Indemnification*. Any clause of this agreement requiring the commercial supplier or licensor to defend or indemnify the end user is hereby amended to provide that the U.S. Department of Justice has the sole right to represent the United States in any such action, in accordance with 28 U.S.C. 516.

(ix) *Audits*. Any clause of this agreement permitting the commercial supplier or licensor to audit the end user's compliance with this agreement is hereby amended as follows:

(A) Discrepancies found in an audit may result in a charge by the commercial supplier or licensor to the ordering activity. Any resulting invoice must comply with the proper invoicing requirements specified in the underlying Government contract or order.

(B) This charge, if disputed by the ordering activity, will be resolved in accordance with subparagraph (d) (Disputes); no payment obligation shall arise on the part of the ordering activity until the conclusion of the dispute process.

(C) Any audit requested by the contractor will be performed at the contractor's expense, without reimbursement by the Government.

(x) *Taxes or surcharges*. Any taxes or surcharges which the commercial supplier or licensor seeks to pass along to the Government as end user will be governed by the terms of the underlying Government contract or order and, in any event, must be submitted to the Contracting Officer for a determination of applicability prior to invoicing unless specifically agreed to otherwise in the Government contract.

(xi) *Non-assignment*. This agreement may not be assigned, nor may any rights or obligations thereunder be delegated, without the Government's prior approval, except as expressly permitted under subparagraph (b) of this clause.

(xii) *Confidential information.* If this agreement includes a confidentiality clause, such clause is hereby amended to state that neither the agreement nor the contract price list, as applicable, shall be deemed “confidential information.” Issues regarding release of “unit pricing” will be resolved consistent with the Freedom of Information Act. Notwithstanding anything in this agreement to the contrary, the Government may retain any confidential information as required by law, regulation or its internal document retention procedures for legal, regulatory or compliance purposes; provided, however, that all such retained confidential information will continue to be subject to the confidentiality obligations of this agreement.

(3) If any language, provision, or clause of this agreement conflicts or is inconsistent with the preceding paragraph (1), the language, provisions, or clause of paragraph (1) shall prevail to the extent of such inconsistency.

(End of clause)

**52.212-5 CONTRACT TERMS AND CONDITIONS REQUIRED TO IMPLEMENT STATUTES OR EXECUTIVE ORDERS—COMMERCIAL ITEMS (Aug 2020)**

(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 2019) (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:

[Contracting officer check as appropriate.]

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| ☑ | (1) | 52.203-6 | Restrictions on Subcontractor Sales to the Government (Sept 2006), 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 (Oct 2015) (41 U.S.C. 3509)). |
| ☐ | (3) | 52.203-15 | Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (June 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 (Oct 2018) (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. (Oct 2015) (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) | 52.219-3 | Notice of HUBZone Set-Aside or Sole-Source Award (Nov 2011) (15 U.S.C.657a). |
| ☐ | | | (ii) Alternate I (Nov 2011) of 52.219-3. |

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| ☐ | (12) | 52.219-4 | (i), Notice of Price Evaluation Preference for HUBZone Small Business Concerns (OCT 2014) (if the offeror elects to waive the preference, it shall so indicate in its offer) (15 U.S.C. 657a). |
| ☐ | | | (ii) Alternate I (JAN 2011) of 52.219-4. |
| | (13) | | [Reserved]. |
| ☐ | (14) | 52.219-6 | (i) Notice of Total Small Business Set-Aside (Nov 2011) (15 U.S.C. 644). |
| ☐ | | | (ii) Alternate I (Nov 2011). |
| ☐ | | | (iii) Alternate II (Nov 2011). |
| ☐ | (15) | 52.219-7 | (i) 52.219-7, Notice of Partial Small Business Set-Aside (June 2003) (15 U.S.C. 644). |
| ☐ | | | (ii) Alternate I (Oct 1995) of 52.219-7. |
| ☐ | | | (iii) Alternate II (Mar 2004) of 52.219-7. |
| ☑ | (16) | 52.219-13 | Utilization of Small Business Concerns (Oct 2018) (15 U.S.C. 637(d)(2) and (3)). |
| ☑ | (17) | 52.219-9 | (i), Small Business Subcontracting Plan (Aug 2018) (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 (Nov 2016) of 52.219-9. |
| ☐ | | | (v) Alternate IV (Aug 2018) of 52.219-9. |
| ☐ | (18) | 52.219-13 | Notice of Set-Aside of Orders (Nov 2011) (15 U.S.C. 644(r)). |
| ☐ | (19) | 52.219-14 | Limitations on Subcontracting (Jan 2017) (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 Service-Disabled Veteran-Owned Small Business Set-Aside (Nov 2011) (15 U.S.C. 657 f). |
| ☑ | (22) | 52.219-28 | Post Award Small Business Program Rerepresentation (Jul 2013) (15 U.S.C. 632(a)(2)). May require contractor completion. |
| ☐ | (23) | 52.219-29 | Notice of Set-Aside for, or Sole Source Award to, Economically Disadvantaged Women-Owned Small Business Concerns (Dec 2015) (15 U.S.C. 637(m)). |
| ☐ | (24) | 52.219-30 | Notice of Set-Aside for, or Sole Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (Dec 2015) (15 U.S.C. 637(m)). |
| ☑ | (25) | 52.222-3 | Convict Labor (June 2003) (E.O. 11755). |
| ☑ | (26) | 52.222-19 | Child Labor—Cooperation with Authorities and Remedies (Jan 2018) (E.O. 13126). |
| ☑ | (27) | 52.222-21 | Prohibition of Segregated Facilities (Apr 2015). |

☑ (28) 52.222-26 (i) Equal Opportunity (Sept 2016) (E.O. 11246).

(ii) Alternate I (Feb 1999) of 52.222-26. Alt I requires CO completion.

If FAR 52.222-26 is included, then HHSAR 353.222-70,Contractor Cooperation in Equal Employment Opportunity Investigations is incorporated by reference.

☑ (29) 52.222-35 (i) Equal Opportunity for Veterans (Oct 2015)(38 U.S.C. 4212).

(ii) Alternate I (July 2014) of 52.222-35. Alt I requires CO completion.

☑ (30) 52.222-36 (i) Equal Opportunity for Workers with Disabilities (Jul 2014) (29 U.S.C. 793).

☐ (ii) Alternate I (July 2014) of 52.222-36. Alt I requires CO completion.

☑ (31) 52.222-37 Employment Reports on Veterans (FEB 2016) (38 U.S.C. 4212).

☑ (32) 52.222-40 Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496).

☑ (33) 52.222-50 (i) 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). Alt I requires CO completion.

☑ (34) 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.)

☐ (35) 52.223-9 (i) 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.) Requires CO completion.

☐ (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.) Alt I requires contractor certification.

☐ (36) 52.223-11 Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (JUN 2016) (E.O. 13693). Requires contractor completion.

☐ (37) 52.223-12 Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (JUN 2016) (E.O. 13693).

☐ (38) 52.223-13 (i), Acquisition of EPEAT®-Registered Imaging Equipment (JUN 2014) (E.O.s 13423 and 13514).

☐ (ii) Alternate I (Oct 2015) of 52.223-13.

☐ (39) 52.223-14 (i) Acquisition of EPEAT®-Registered Televisions (JUN 2014) (E.O.s 13423 and 13514).

☐ (ii) Alternate I (Jun 2014) of 52.223-14.

☐ (40) 52.223-15 Energy Efficiency in Energy-Consuming Products (DEC 2007) (42 U.S.C. 8259b).

☐ (41) 52.223-16 (i), Acquisition of EPEAT®-Registered Personal Computer Products (OCT 2015) (E.O.s 13423 and 13514).

☐ (ii) Alternate I (Jun 2014) of 52.223-16.

☑ (42) 52.223-18 Encouraging Contractor Policies to Ban Text Messaging While Driving (AUG 2011) (E.O. 13513).

☐ (43) 52.223-20 Aerosols (JUN 2016) (E.O. 13693).

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| ☐ | (44) | 52.223-21 | Foams (JUN 2016) (E.O. 13693). |
| ☑ | (45) | 52.224-3 | (i), Privacy Training (JAN 2017) (5 U.S.C. 552a). |
| ☐ | | | (ii) Alternate I (JAN 2017) of 52.224-3. |
| ☐ | (46) | 52.225-1 | Buy American—Supplies (May 2014) (41 U.S.C. chapter 83). |
| ☐ | (47) | 52.225-3 | (i), 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. |
| ☐ | (48) | 52.225-5 | Trade Agreements (AUG 2018) (19 U.S.C. 2501, et seq., 19 U.S.C. 3301 note). |
| ☑ | (49) | 52.225-13 | Restrictions on Certain Foreign Purchases (June 2008) (E.O.'s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury). |
| ☐ | (50) | 52.225-26 | Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note). |
| ☐ | (51) | 52.226-4 | Notice of Disaster or Emergency Area Set-Aside (Nov 2007) (42 U.S.C. 5150). Requires CO completion. |
| ☐ | (52) | 52.226-5 | Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov 2007) (42 U.S.C. 5150). |
| ☐ | (53) | 52.232-29 | Terms for Financing of Purchases of Commercial Items (Feb 2002) (41 U.S.C. 4505, 10 U.S.C. 2307(f)). |
| ☐ | (54) | 52.232-30 | Installment Payments for Commercial Items (Jan 2017) (41 U.S.C. 4505, 10 U.S.C. 2307(f)). |
| ☑ | (55) | 52.232-33 | Payment by Electronic Funds Transfer—System for Award Management (Oct 2018) (31 U.S.C. 3332). |
| ☐ | (56) | 52.232-34 | Payment by Electronic Funds Transfer—Other than System for Award Management (Jul 2013) (31 U.S.C. 3332). Requires CO completition. |
| ☐ | (57) | 52.232-36 | Payment by Third Party (May 2014) (31 U.S.C. 3332). |
| ☐ | (58) | 52.239-1 | Privacy or Security Safeguards (Aug 1996) (5 U.S.C. 552a). |
| ☑ | (59) | 52.242-5 | Payments to Small Business Subcontractors (JAN 2017)(15 U.S.C. 637(d)(13)). |
| ☐ | (60) | 52.247-64 | (i), 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:

[Contracting Officer check as appropriate.]

| | | | |
|---|---|---|---|
| ☐ | (1) | 52.222-17 | Nondisplacement of Qualified Workers (May 2014)(E.O. 13495). |
| ☑ | (2) | 52.222-41 | Service Contract Labor Standards (Aug 2018) (41 U.S.C. chapter 67). |
| ☑ | (3) | 52.222-42 | Statement of Equivalent Rates for Federal Hires (May 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67). Requires CO completion. |
| ☐ | (4) | 52.222-43 | Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (Multiple Year and Option Contracts) (Aug 2018) (29 U.S.C. 206 and 41 U.S.C. chapter 67). |
| ☑ | (5) | 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). |
| ☐ | (6) | 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). |
| ☐ | (7) | 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). |
| ☑ | (8) | 52.222-55 | Minimum Wages Under Executive Order 13658 (Dec 2015). |
| ☐ | (9) | 52.222-62 | Paid Sick Leave Under Executive Order 13706 (JAN 2017) (E.O. 13706). |
| ☐ | (10) | 52.226-6 | Promoting Excess Food Donation to Nonprofit Organizations (May 2014) (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, 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 Contractor's 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 the ordinary course of business or pursuant to a provision of law.

(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 (Oct 2015) (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 2019) (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 $700,000 ($1.5 million for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.
(vi) 52.222-17, Nondisplacement of Qualified Workers (May 2014) (E.O. 13495). Flow down required in accordance with paragraph (l) of FAR clause 52.222-17.
(vii) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).
(viii) 52.222-26, Equal Opportunity (Sept 2015) (E.O.11246).
(ix) 52.222-35, Equal Opportunity for Veterans (Oct 2015) (38 U.S.C.4212).
(x) 52.222-36, Equal Opportunity for Workers with Disabilities (Jul 2014) (29 U.S.C.793).
(xi) 52.222-37, Employment Reports on Veterans (Feb 2016) (38 U.S.C.4212)
(xii) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause 52.222-40.
(xiii) 52.222-41, Service Contract Labor Standards (Aug 2018) (41 U.S.C. chapter 67).
(xiv) (A) 52.222-50, Combating Trafficking in Persons (Jan 2019) (22 U.S.C. chapter 78 and E.O 13627).
(B) Alternate I (Mar 2015) of 52.222-50(22 U.S.C. chapter 78 and E.O 13627).
(xv) 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).
(xvi) 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).
(xvii) 52.222-54, Employment Eligibility Verification (Oct 2015) (E.O. 12989).
(xviii) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015).
(xix) 52.222-62, Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).
(xx) (A) 52.224-3, Privacy Training (Jan 2017) (5 U.S.C. 552a).
(B) Alternate I (Jan 2017) of 52.224-3.
(xxi) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).
(xxii) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (May 2014) (42 U.S.C. 1792). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.
(xxiii) 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.

(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)

Alternate I (Feb 2000). As prescribed in 12.301(b)(4)(i), delete paragraph (d) from the basic clause, redesignate paragraph (e) as paragraph (d), and revise the reference to “paragraphs (a), (b), (c), or (d) of this clause” in the redesignated paragraph (d) to read “paragraphs (a), (b), and (c) of this clause.”

Alternate II (Aug 2019). As prescribed in 12.301(b)(4)(ii), substitute the following paragraphs (d)(1) and (e)(1) for paragraphs (d)(1) and (e)(1) of the basic clause as follows:

(d)(1) The Comptroller General of the United States, an appropriate Inspector General appointed under section 3 or 8 G of the Inspector General Act of 1978 (5 U.S.C. App.), or an authorized representative of either of the foregoing officials shall have access to and right to—

(i) Examine any of the Contractor's or any subcontractors' records that pertain to, and involve transactions relating to, this contract; and

(ii) Interview any officer or employee regarding such transactions.

(e)(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), and (c), of this clause, the Contractor is not required to flow down any FAR clause in a subcontract for commercial items, other than-

(i) Paragraph (d) of this clause. This paragraph flows down to all subcontracts, except the authority of the Inspector General under paragraph (d)(1)(ii) does not flow down; and

(ii) Those clauses listed in this paragraph (e)(1). Unless otherwise indicated below, the extent of the flow down shall be as required by the clause-

(A) 52.203-13, Contractor Code of Business Ethics and Conduct (Oct 2015) (41 U.S.C. 3509).

(B) 52.203-15, Whistleblower Protections Under the American Recovery and Reinvestment Act of 2009 (Jun 2010) (Section 1553 of Pub. L. 111-5).

(C) 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).

(D) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (Aug 2019) (Section 889(a)(1)(A) of Pub. L. 115-232).

(E) 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 $700,000 ($1.5 million for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.

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

(G) 52.222-26, Equal Opportunity (Sept 2016) (E.O. 11246).

(H) 52.222-35, Equal Opportunity for Veterans (Oct 2015) (38 U.S.C. 4212).

(I) 52.222-36, Equal Opportunity for Workers with Disabilities (Jul2014) (29 U.S.C. 793).

(J) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause 52.222-40.

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

(L) ___(1) 52.222-50, Combating Trafficking in Persons (Jan 2019) (22 U.S.C. chapter 78 and E.O 13627).

___(2) Alternate I (Mar2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O 13627).

(M) 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).

(N) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (May2014) (41 U.S.C. chapter 67).

(O) 52.222-54, Employment Eligibility Verification (Oct 2015) (Executive Order 12989).

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

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

(R)(1) 52.224-3, Privacy Training (Jan 2017) (5 U.S.C. 552a).

(2) Alternate I (Jan 2017) of 52.224-3.

(S) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).

(T) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations. (May 2014) (42 U.S.C. 1792). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.

(U) 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.