# ORDER FOR SUPPLIES OR SERVICES

PAGE 1 OF PAGES 12

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

1. DATE OF ORDER: 02/14/2020

2. CONTRACT NO. (If any): HHSO100201600005I

3. ORDER NO.: (b)(4)

4. REQUISITION/REFERENCE NO.:

5. ISSUING OFFICE (Address correspondence to):
ASPR-BARDA
200 Independence Ave., S.W.
Room 640-G
Washington DC 20201

6. SHIP TO:

a. NAME OF CONSIGNEE: HHS/OS/ASPR

b. STREET ADDRESS: 200 C St SW
WASHINGTON DC 20201

c. CITY: WASHINGTON

d. STATE: DC

e. ZIP CODE: 20201

7. TO: (b)(6)

a. NAME OF CONTRACTOR: PROTEIN SCIENCES CORPORATION 373074

b. COMPANY NAME:

c. STREET ADDRESS: PROTEIN SCIENCES CORPORATION 1
1000 RESEARCH PKWY

d. CITY: MERIDEN

e. STATE: CT

f. ZIP CODE: 064507149

f. SHIP VIA:

8. TYPE OF ORDER

☐ a. PURCHASE
REFERENCE YOUR:

Please furnish the following on the terms and conditions specified on both sides of this order and on the attached sheet, if any, including delivery as indicated.

☒ b. DELIVERY

Except for billing instructions on the reverse, this delivery order is subject to instructions contained on this side only of this form and is issued subject to the terms and conditions of the above-numbered contract.

9. ACCOUNTING AND APPROPRIATION DATA: (b)(4)

10. REQUISITIONING OFFICE: BARDA

11. BUSINESS CLASSIFICATION (Check appropriate box(es))

☒ a. SMALL ☐ b. OTHER THAN SMALL ☐ c. DISADVANTAGED ☐ d. WOMEN-OWNED ☐ e. HUBZone

☐ f. SERVICE-DISABLED VETERAN-OWNED ☐ g. WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOSB PROGRAM ☐ h. EDWOSB

12. F.O.B. POINT:

13. PLACE OF

a. INSPECTION: Destination

b. ACCEPTANCE: Destination

14. GOVERNMENT B/L NO.:

15. DELIVER TO F.O.B. POINT ON OR BEFORE (Date): 06/14/2021

16. DISCOUNT TERMS:

17. SCHEDULE (See reverse for Rejections)

| ITEM NO. (a) | SUPPLIES OR SERVICES (b) | QUANTITY ORDERED (c) | UNIT (d) | UNIT PRICE (e) | AMOUNT (f) | QUANTITY ACCEPTED (g) |
|---|---|---|---|---|---|---|
| | Tax ID Number: (b)(4)<br>DUNS Number:<br>ASPR-20-00906 -- Protein Sciences Corporation manufacture of master working seed lot research lots and laboratory testing assays for 2019 nCoV under contract<br>HHSO100201600005I<br>Appr. Yr.: 2020 CAN: (b)(4) Object Class: (b)(4)<br>Continued ... | | | | | |

18. SHIPPING POINT:

19. GROSS SHIPPING WEIGHT:

20. INVOICE NO.:

17(h) TOTAL (Cont. pages)

21. MAIL INVOICE TO:

a. NAME: PSC/FMS

SEE BILLING INSTRUCTIONS ON REVERSE

b. STREET ADDRESS (or P.O. Box): PSC_invoices@psc.hhs.gov

c. CITY:

d. STATE:

e. ZIP CODE:

(b)(4)

17(i) GRAND TOTAL

22. UNITED STATES OF AMERICA BY (Signature):

23. NAME (Typed): WENDELL CONYERS

TITLE: CONTRACTING/ORDERING OFFICER

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

| DATE OF ORDER | CONTRACT NO. | ORDER NO. |
|---|---|---|
| 02/14/2020 | HHSO100201600005I | (b)(4) |

| ITEM NO. (a) | SUPPLIES/SERVICES (b) | QUANTITY ORDERED (c) | UNIT (d) | UNIT PRICE (e) | AMOUNT (f) | QUANTITY ACCEPTED (g) |
|---|---|---|---|---|---|---|
| | Period of Performance: (b)(4) | | | | (b)(4) | |
| 1 | ASPR-20-00906 -- CLIN 1801B Vaccine Research Lots (qty 2) - 2019 nCoV 1 - rapid research grade process and material 1- cGMP ready process | | | | | |
| 2 | ASPR-20-00906 -- CLIN 1801C Laboratory Testing Assay - 2019 nCoV | | | | | |
| 3 | ASPR-20-00906 --Protein Sciences Corporation (PSC), has agreed to cost share with the USG. PSC will Manufacture Master/Working virus seeds lot(s) for nCoV vaccine Amount: (b)(4) (Option Line Item) (Not Separately Priced) | 1 | EA | (b)(4) | | |
| | The total amount of award: (b)(4). The obligation for this award is shown in box 17(i). | | | | | |

| TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H)) | | | | | (b)(4) | |
|---|---|---|---|---|---|---|

SECTION B – SUPPLIES OR SERVICES AND PRICES/COSTSIDIQ

**B.2. Contract Line Item Numbers (CLINs) and Pricing:**

The Contractor shall be reimbursed by the Government in an amount not less than a total of (b)(4) (minimum) and no more than a total of (b)(4) (maximum) if all optional CLINs are exercised.

The prices set forth in this ARTICLE B.2. will cover the Base Period August 22, 2016 through August 21, 2019, Option Period I – August 22, 2019 through August 21, 2020 and Option Period II August 22, 2020 through August 21, 2021. Upon delivery and acceptance of the item(s) described in SECTION C of this contract and identified in the schedule of charges below, the Government shall pay to the Contractor the unit prices (s) set forth below. Contractors shall provide the following items for the manufacturing, testing, packaging, delivery, storage and disposal of influenza MCM products. **Add additional pricing to cover requirements in response to a HHS designated Public Health Emergency.**

**The following CLINs are added effective February 12, 2020 through August 21, 2020**

**OPTION 1:** (b)(4)

| CLIN | SUPPLIES/ SERVICES | UNIT | QUANTITY | UNIT PRICE | TOTAL EXTENDED PRICE |
|---|---|---|---|---|---|
| 1801A | cGMP Vaccine Master and Working Seed Lot | Lot | TBD | $ (b)(4) | $ |
| 1801B | Vaccine Research Lot(s) | Lot | TBD | $ | $ |
| 1801C | cGMP Vaccine Investigational Lot(s) | Lot | TBD | $ (b)(4) | $ |
| 1801D | cGMP Vaccine Commercial Scale Bulk Lot(s) | Lot | TBD | $ (b)(4) | $ |

***Pricing is based on current Option 1 PSC pricing for flu and are subject to changes at time of award of Coronavirus activities task order (s).**

**OPTION 2** (b)(4)

| CLIN | SUPPLIES/ SERVICES | UNIT | QUANTITY | UNIT PRICE | TOTAL EXTENDED PRICE |
|---|---|---|---|---|---|
| 3401A | cGMP Vaccine Master and Working Seed Lot | Lot | TBD | $ (b)(4) | $ |
| 3401B | Vaccine Research Lot(s) | Lot | TBD | $ | $ |
| 3401C | cGMP Vaccine Investigational Lot(s) | Lot | TBD | $ (b)(4) | $ |
| 3401D | cGMP Vaccine Commercial Scale Bulk Lot(s) | Lot | TBD | $ (b)(4) | $ |

***Pricing is based on current Option 2 PSC pricing for flu and are subject to changes at time of award of Coronavirus activities task order (s).**

**A.1 Background**

An outbreak of respiratory illness caused by a novel (new) coronavirus (named "COVID-19") that was first detected in Wuhan City, Hubei Province, China continues to expand. Chinese health officials have reported thousands of infections with COVID-19 in China, with the virus reportedly spreading from person-to-person in many parts of that country. Infections with COVID-19, most of them associated with travel from Wuhan, also are

being reported in a growing number of international locations, including the United States. The United States reported the first confirmed instance of person-to-person spread with this virus on January 30, 2020.

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization declared the outbreak a "public health emergency of international concern" (PHEIC). On January 31, 2020, Health and Human Services Secretary Alex M. Azar II declared a public health emergency (PHE) for the United States to aid the nation's healthcare community in responding to COVID-19.

As part of HHS preparedness and response activities, HHS has requested PSC to submit a Proposal to produce a Working Virus Bank derived from 2019-CoV and a Vaccine Research Lot in preparation for possible CoV vaccine production.

(b)(4)

### A.1.1 Scope of Work

**BARDA Requirement**
HHS requires:

- Working Virus Bank (WVB) for 2019 Novel Coronavirus (COVID-19), under CLIN 1801A, cGMP Vaccine Master and Working Seed Lot
- Vaccine Research Lot(s) under CLIN 1801B produced from the WVB produced in CLIN 1801A
- Analytical laboratory testing and assays under CLIN 1101 on the Research Lot(s) produced under CLIN

(b)(4)

Independently and not as an agent of the U.S. Government (USG), PSC, a Sanofi company, will furnish the necessary services, qualified personnel, materials, supplies, equipment and facilities not otherwise provided by the USG as needed to in support of this RTOR.

### A.1.2 Scope of Work for CLIN 1801A – cGMP Vaccine Master and Working Seed Lot

As a service to the USG (HHS/BARDA), free of charge and exclusive to any forthcoming Task Order associated with this RTOR, PSC will produce a cGMP Working Virus Bank (WVB). This WVB is solely to be used for the production of recombinant nCoV vaccine using the sequence agreed to with BARDA.

(b)(4)

(b)(4)

Antibody Reagents: Antibodies will be required to verify protein identity and track expression during CLIN1801A. PSC will source commercially available anti-CoV antibodies and well as those available within the Sanofi network and screen antibodies to determine suitability for use in Western blotting. We will develop antibodies using purified recombinant protein if necessary. Reagents used for release of the GMP WVB will be qualified for that use.

For CLIN 1801A, PSC will:

- Manufacture Master/Working virus seeds lot(s) for nCoV vaccine
  - Using the same facilities, systems, equipment, processes and testing as those described and referenced in (b)(4) ccording to current Good Manufacturing Practices (cGMP) as applicable and store at appropriate conditions during lot release testing.
  - Using the gene sequence as specified by CDC/BARDA.
  - Provide a Certificates of Analysis and Compliance
- Store the WVB according to FDA cGMP guidelines, add manufactured WVB lot to ongoing inventory reports and controlled storage.
- Provide reports including, at minimum, the information identified in Section F of contract HHSO100201600005I.

***Deviation from base contract technical proposal:*** None

**A.1.3 CLIN 1801B – Vaccine Research Lot(s)**

The P3 WVB(s) produced in CLIN 1801A will be used for downstream process development and the production of small-scale (up to 40L of culture) research lot(s). In order to provide purified protein for study as soon as possible and to mitigate the risks associated with undetermined methods for purifying nCoV (b)(4) we propose a 2-tiered development approach:

- **Tier 1 – Rapid Research-Grade Process and Material**

- Will (b)(4) rocess
- May use processes and materials not carried forward to GMP-ready process
- Will begin assay and reagent work
- Develop preliminary stability data
- Provide purified protein for characterization studies, animal studies and reagent/analytical development as quickly as possible

- **Tier 2 – cGMP-Ready Process**
  - Continue to develop an Industrial Process and analytics for GMP manufacturing
  - Characterize protein
  - Conduct stability study
  - Provide purified protein for non-clinical use

**Tier 1 – Rapid Research-Grade Process and Material**

We will conduct small-scale scouting experiments to begin understanding the behavior of the nCoV (b)(4) General purification includes centrifugation of the cell culture, extraction of cell-associated proteins, clarification, purification of the target protein, concentration, buffer exchange and 0.2 µM filtration, see ***Table A.1.3-a***.

***Table A.1.3-a: General DSP Steps***

| Process Step | Purpose |
|---|---|
| Centrifugation | Separation of cells and medium. (b)(4) (b)(4) |
| Extraction | **Expected to be required only for** (b)(4) Extraction and solubilization of the protein from the cell membranes |
| Clarification | Clarification of the cell extract or medium by removal of particulates and cell debris |
| (b)(4) Chromatography | Initial chromatographic steps to remove impurities |
| (b)(4) Chromatography | Final orthogonal chromatography steps to improve purity |
| Ultrafiltration | Concentration of target protein and buffer exchange |
| Bulk Filtration | Final filtration through a 0.2-micron filter to ensure a low bioburden bulk |

If a (b)(4) rotein is expressed, we expect spike protein to reside in the *expres*SF+ cell membrane; therefore, these experiments will include extraction from the cell membrane. If a (b)(4) is selected; then extraction development is unlikely. We expect development efforts to focus on:

- Extraction (if required)
- (b)(4) hromatography and
- Ultrafiltration

Process performance parameters will be monitored during development, initially with assays available and later with specialized assays. SDS-PAGE, Western blotting and BCA will be used in Tier 1 to assess yield, purity and protein size/integrity.

In Tier 1 development, we may use materials (e.g. chromatography resins, buffers, surfactants, ultra-filters) that are not in the Flublok® licensed process, including affinity resins. These materials may not be in the final GMP-

ready process. Once basic steps are defined, we will conduct process experiments at the (b)(4) bioreactor scales. A brief stability characterization study (b)(4) will be conducted in Tier 1 using the available appropriate tests.

The goal of Tier 1 work will be to provide purified nCoV recombinant protein suitable for characterization studies, animal studies and reagent/analytical development as quickly as possible.

*Analytical Development*

Antibodies will be required to verify protein identity and track purification during CLIN 1801B. Based on our experience with SARS-CoV (b)(4) we anticipate the development of an ELISA potency assay, which will require CoV antibodies. PSC will source commercially available anti-CoV antibodies and well as those available within the Sanofi network and screen antibodies to determine suitability for use in Western blotting and ELISA. We will develop antibodies using purified recombinant protein if necessary. Reagents and assays used for GMP will be qualified for that use under a separate task order.

During Tier 1, we will begin to examine the analytical tools intended for protein characterization and those which may be used for drug substance release; see ***Table A.1.3-b***. Assay work is expected to continue into Tier 2. This work will be done in our Manufacturing Technology development laboratories.

***Table A.1.3-b: Assays for Initial Examination.*** Specifications are TBD.

| Test | Method | Comments |
|---|---|---|
| **Potential release tests** | | |
| Total Protein Content | (b)(4) | No development anticipated |
| Purity | SDS-PAGE / Densitometry | Will require suitable antibody |
| Identity | Western blot or ELISA signal | Will require suitable antibody ELISA will require assay development |
| Host Cell Protein | (b)(4) | Will require assessment, may require suitable antibody |
| Potency | ELISA (b)(4) will be used as a starting point) | Will require suitable antibody and assay development. |
| Total DNA | Picogreen | No development anticipated |
| Size Analysis | U/HPLC-SEC and/or DLS | HPLC-SEC: TBD<br>DLS: No development anticipated |
| Appearance | Visual inspection | No development anticipated |
| Microbial Enumeration | | No development anticipated |
| Endotoxin | LAL Gel Clot | No development anticipated |
| pH | Potentiometry | No development anticipated |
| Infectious Baculovirus | Titer | No development anticipated |

| Test | Method | Comments |
|---|---|---|
| **Characterization only test** | | |
| Deglycosylation | Enzyme treatment and SDS-PAGE | Characterization test<br>No development anticipated<br>Detects presence of glycosylation |

**Tier 2 – cGMP-Ready Process**

The process will be refined and scaled-up in our Manufacturing Technology laboratory to the (b)(4) bioreactor scales. We will verify that the process consistently produces protein of acceptable quantity and quality. These larger scales are sufficiently predictive of process performance to allow technology transfer to cGMP manufacturing.

Reagent and assay development initiated in Tier 1 is expected to continue into Tier 2. During Tier 2 we expect to develop sufficient data to support the creation of release specifications and the required assay documentation. In-process yields will be assessed by total protein (BCA), SDS-PAGE/Western blot and ELISA when available.

*Characterization Testing*

The proposed product characterization for the Tier 2 research lot (***Table A.1.3-c***), will allow an assessment of product quality, readiness for cGMP production and suitability of use in non-clinical studies. These studies will be performed in by our Manufacturing Technology group.

***Table A.1.3-c: Proposed Product Characterization Testing for rCoV Research Lot(s).*** Acceptance Criteria are TBD.

| Parameters/Assays Performed | Method |
|---|---|
| Purity | SDS-PAGE / Densitometry |
| Total Protein Content | BCA |
| Potency | ELISA |
| Size Analysis | UPLC-SEC and/or DLS |
| Deglycosylation | Enzyme treatment and SDS-PAGE |
| Total DNA Content | Picogreen |
| Host Cell Protein | (b)(4) |
| Endotoxin | LAL Assay |
| Infectious Baculovirus | Titer |
| Microbial Enumeration | |

Process transfer for manufacturing, GMP documentation, generation of release specifications, and GMP qualification of reagents and assays will be done under a separate task order.

***Deliverables:*** For CLIN 1801B, we will:

- Prepare research lot(s) as directed by HHS as specified in the task order.
- Provide data derived from the manufacturing process.

- Provide reports including, at minimum, the information identified in Section F of contract HHSO100201600005I.
- We will issue a Final Report after completion of activities relating to Master and Working Virus Seed Lot (CLIN 1801A) and Research Lot (CLIN 1801B) and will include activities up to release of the WVB and completion of development lot testing (CLIN 1801B).

***Deviations from base contract technical proposal:*** The base contract technical proposal was developed to utilize the licensed Flublok design space; which is not appropriate for nCoV (b)(4) To the greatest extent possible we will adhere to licensed materials, procedures and processes.

**A.1.4 CLIN 1101 – Analytical Laboratory Testing/Assays**

*Stability*

We propose the following stability program for the research lot. We will discuss the details of the stability program with HHS. Research lots will be placed on real-time and accelerated stability. Stability storage temperatures and containers are to be determined. The study will be conducted by our Manufacturing Technology group. The proposed schedule is shown in ***Table A.1.4***.

***Table A.1.4: Proposed Stability Schedule.*** X indicates time point is performed; acceptance criteria are to be determined.

(b)(4)

At each time point, we will assess:

- Potency by ELISA,
- Size by HPLC-SEC and/or DLS,
- Protein integrity and conformation by SDS-PAGE/Western Blot (reducing and non-reducing conditions).

***Deliverables:*** For CLIN 1101, we will:

- Conduct laboratory testing/assay as required by HHS and specified in the task order
- Provide reports including, at minimum, the information identified in Section F of contract HHSO100201600005I.

***Deviation from base contract technical proposal:*** The CLIN 1101 activities in the base contract technical proposal were based on the studies performed for the Flublok® influenza vaccine; some of which are not appropriate for nCoV spike protein. To the greatest extent possible we will adhere to the tests and study protocols used for Flublok®.

**A. DELIVERY SCHEDULE**

**A.1 Schedule for cGMP Vaccine Master and Working Seed Lot**

CLIN 1801A GMP freeze-down and WVB release may be delayed to accommodate commercial influenza vaccine production; however, such delay will not impact development work under CLIN 1801B. If there are no delays, we

expect freeze-down 11 weeks after agreement on target sequence and release by (b)(4)

### A.2 Delivery schedule for Vaccine Research Lot(s)

Work under CLIN 1801B is early-stage development; therefore, this schedule may shift. We will adhere to this schedule to the greatest extent possible and will inform BARDA of our progress and anticipated delays. We expect to have Tier 1 material available (b)(4) after agreement on target sequence and Tier 2 material after (b)(4)

### A.3 Gantt chart including at a minimum the major tasks, critical subtasks, and deliverables

(b)(4)

### A.4 Business Proposal

Below is our Business Proposal for activities as we understand them today quoted as a firm fixed price, with the exception of CLIN 1801A which will be performed as service to the USG (HHS/BARDA), free of charge and exclusive to any forthcoming Task Order associated with this RTOR. Should any of the project requirements/deliverables deviate from the items noted above in our Technical Proposal, we would then initiate a request for task order modification. For a list of Key Assumptions and Clarifications regarding this Proposal, please see Appendix B.1 -Key Assumptions and Clarifications.

PSC will furnish the necessary services, qualified personnel, materials, supplies, equipment and facilities not otherwise provided by the USG as needed to manufacture 1 cGMP Vaccine Master and Working Seed Lot, 1 Vaccine Research Lot, and conduct all specified Laboratory Testing on each lot. The WVB produced under CLIN 1801A will be at Sanofi's own cost See ***Table B.4-a*** for proposed pricing of CLIN 1801A; ***Table B.4-b*** for propose pricing of CLINs, 1801B, 1101, and 1601; and ***Table B.4-c*** for proposed pricing on Optional CLINs.

***Table B.4-a Proposed Pricing of CLIN 1801A***

| CLIN | SUPPLIES/ SERVICES | UNIT | QTY | TOTAL COST | COST SHARE PSC 100% | COST SHARE BARDA 0% |
|---|---|---|---|---|---|---|
| 1801A | cGMP Vaccine Master and Working Seed Lot | LOT | 1 | (b)(4) | | |

***Table B.4-b Proposed Pricing of CLINs 1801B, 1101, and 1601***

| CLIN | SUPPLIES/ SERVICES | UNIT | QTY | UNIT PRICE | TOTAL EXPECTED PRICE |
|---|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| 1801B | Vaccine Research Lot* | LOT | 1 | (b)(4) |
| 1801C | Laboratory Testing/Assay** | Each | 1 Study | |
| 1601 | Additional Reporting | Report | N/A | |

* As described in our technical proposal section A.1.3 CLIN1801B includes the manufacture of ***Tier 1 – Rapid Research-Grade Process and Material and Tier 2 – cGMP-Ready Process***

**1101 for Stability Testing only

***Table B.4-c Proposed Pricing for Optional CLINs***

| CLIN | SUPPLIES/ SERVICES | UNIT | QTY | UNIT PRICE | TOTAL EXPECTED PRICE |
|---|---|---|---|---|---|
| 1801C | cGMP Investigational Lot(s) | LOT | TBD | TBD | TBD |
| 0601A | Formulation and Filling: Antigen Single Dose Vials | EACH | TBD | TBD | TBD |

## APPENDIX B.1 - KEY ASSUMPTIONS AND CLARIFICATIONS

### KEY ASSUMPTIONS AND CLARIFICATIONS

Regarding our proposal to this Revised Request for Task Order Response# 2020-002, PSC makes the following Key Assumptions and Clarifications:

- This Proposal is in direct response to Revised RTOR-2020-002 and the deliverables set forth under CLIN 1801A - cGMP Vaccine Master/Working Seed Lot(s), CLIN 1801B - Vaccine Research Lot(s), CLIN 1101 Analytical Laboratory Testing/ Assay(s) Contract HHSO100201600005I.
- Task Order is issued by HHS no later than 21 February 2020 in order to meet projected timelines. This is to allow internal resource and facility allocation and commitment to assure we can meet the specified delivery dates in the project plan.
- Acceptance of material created under this contract will be made by duly authorized USG representatives (the CO or the duly authorized representative who for purposes of this contract will be the TOCO) and they will notify PSC of acceptance or rejection within 5 business days. Absent formal notification, acceptance will be presumed.
- HHS will not seek to transfer the materials to another manufacturer without considering the regulatory and legal issues surrounding the sharing of manufactured drug product materials produced under this RTOR.
- Invoice payment is expected per CLIN upon completion of deliverables specified in separate or combined task orders.
- Timing of distribution of genetic sequence(s) will be coordinated by BARDA with CDC and will reflect the start of CLIN 1801A.
- PSC understands that the USG shall grant an irrevocable worldwide non-exclusive sublicensable royalty-free license to use for any purpose any and all improvements and intellectual property that result from the USG or USG's collaborator's use of the material provided hereunder by PSC

and affiliates to the USG.

- No products manufactured and stored under this contract will be moved from the manufacturer's facilities unless and until a Material Transfer Authorization is mutually agreed to and implemented.

# ORDER FOR SUPPLIES OR SERVICES

PAGE 1 OF PAGES 7

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

1. DATE OF ORDER: 04/07/2020

2. CONTRACT NO. *(If any)*: HHSO100201600005I

3. ORDER NO.: (b)(4)

4. REQUISITION/REFERENCE NO.: (b)(4)

5. ISSUING OFFICE *(Address correspondence to)*:
US DEPT OF HEALTH & HUMAN SERVICES
ASST SEC OF PREPAREDNESS & RESPONSE
ACQ MANAGEMENT, CONTRACTS, & GRANTS
O'NEILL HOUSE OFFICE BUILDING
Washington DC 20515

7. TO: (b)(4)

a. NAME OF CONTRACTOR: PROTEIN SCIENCES CORPORATION 373074

b. COMPANY NAME:

c. STREET ADDRESS: PROTEIN SCIENCES CORPORATION 1
1000 RESEARCH PKWY

d. CITY: MERIDEN | e. STATE: CT | f. ZIP CODE: 064507149

6. SHIP TO:

a. NAME OF CONSIGNEE: HHS/OS/ASPR

b. STREET ADDRESS: 200 C St SW
WASHINGTON DC 20201

c. CITY: WASHINGTON | d. STATE: DC | e. ZIP CODE: 20201

f. SHIP VIA:

8. TYPE OF ORDER

☐ a. PURCHASE
REFERENCE YOUR:

Please furnish the following on the terms and conditions specified on both sides of this order and on the attached sheet, if any, including delivery as indicated.

☒ b. DELIVERY

Except for billing instructions on the reverse, this delivery order is subject to instructions contained on this side only of this form and is issued subject to the terms and conditions of the above-numbered contract.

9. ACCOUNTING AND APPROPRIATION DATA: See Schedule

10. REQUISITIONING OFFICE: BARDA

11. BUSINESS CLASSIFICATION *(Check appropriate box(es))*
☒ a. SMALL ☐ b. OTHER THAN SMALL ☐ c. DISADVANTAGED ☐ d. WOMEN-OWNED ☐ e. HUBZone
☐ f. SERVICE-DISABLED VETERAN-OWNED ☐ g. WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOSB PROGRAM ☐ h. EDWOSB

12. F.O.B. POINT:

13. PLACE OF
a. INSPECTION: Destination
b. ACCEPTANCE: Destination

14. GOVERNMENT B/L NO.:

15. DELIVER TO F.O.B. POINT ON OR BEFORE *(Date)*: 10/07/2022

16. DISCOUNT TERMS:

**17. SCHEDULE** ***(See reverse for Rejections)***

| ITEM NO. (a) | SUPPLIES OR SERVICES (b) | QUANTITY ORDERED (c) | UNIT (d) | UNIT PRICE (e) | AMOUNT (f) | QUANTITY ACCEPTED (g) |
|---|---|---|---|---|---|---|
| | Tax ID Number: 06-1098847<br>DUNS Number: 109124933<br><br>ASPR-20-01742 -- Protein Sciences Corporation is to conduct the non-clinical and Phase I clinical studies for a (b)(4)<br>Continued ... | | | | | |

18. SHIPPING POINT:

19. GROSS SHIPPING WEIGHT:

20. INVOICE NO.:

17(h) TOTAL *(Cont. pages)*: (b)(4)

21. MAIL INVOICE TO:

a. NAME: PSC/FMS

*SEE BILLING INSTRUCTIONS ON REVERSE*

b. STREET ADDRESS (or P.O. Box): PSC_invoices@psc.hhs.gov

17(i) GRAND TOTAL: (b)(4)

c. CITY | d. STATE | e. ZIP CODE

22. UNITED STATES OF AMERICA BY *(Signature)*:

23. NAME *(Typed)*: WENDELL CONYERS
TITLE: CONTRACTING/ORDERING OFFICER

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

| DATE OF ORDER | CONTRACT NO. | ORDER NO. |
|---|---|---|
| 04/07/2020 | HHSO100201600005I | (b)(4) |

| ITEM NO. (a) | SUPPLIES/SERVICES (b) | QUANTITY ORDERED (c) | UNIT (d) | UNIT PRICE (e) | AMOUNT (f) | QUANTITY ACCEPTED (g) |
|---|---|---|---|---|---|---|
| | COVID-19 vaccine candidate (the Candidate Vaccine) reconstituted with two adjuvants, (b)(4) for 2019 nCoV under contract HHSO100201600005I.<br>Period of Performance: 04/07/2020 to 10/07/2022 | | | | (b)(4) | |
| 1 | CLIN 1101 - Laboratory Testing / Assay (IAW Section E)<br>Firm Fixed Price (FFP)<br><br>Accounting Info:<br>(b)(4) Appr. Yr.: 2020 CAN: 199COV1 Object Class: 251<br>Funded: (b)(4) | | | | | |
| 2 | CLIN 1201 - Animal Studies & Tox (IAW Section F)<br>Firm Fixed Price (FFP)<br><br>Accounting Info:<br>(b)(4) Appr. Yr.: 2020 CAN: 199COV1 Object Class: 251<br>Funded: (b)(4) | | | | | |
| 3 | CLIN 1301 - Clinical Studies (IAW Section G)<br>Firm Fixed Price (FFP)<br><br>Accounting Info:<br>(b)(4) Appr. Yr.: 2020 CAN: 199COV1 Object Class: 25106<br>Funded: (b)(4) | | | | | |
| 4 | CLIN 1601 - Additional Reporting (IAW Section H)<br>Firm Fixed Price (FFP) | | | | 0.00 | |
| 5 | CLIN 1801 cGMP Vaccine Investigational Lot(s)(IAW Section C)<br>Cost-Sharing (CS)<br><br>Protein Sciences Corporation(PSC)has agreed to provide 100% funding toward this CLIN in the amount of (b)(4) to the existing Cost-Sharing Task Order.<br><br>(b)(4) | | | | 0.00 | |
| 6 | CLIN 0601 Formulation and Filling Antigen-Single dose vials (IAW Section D)<br>Continued ... | | | | 0.00 | |

TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H)) (b)(4)

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

| DATE OF ORDER | CONTRACT NO. | ORDER NO |
|---|---|---|
| 04/07/2020 | HHSO100201600005I | (b)(4) |

| ITEM NO. (a) | SUPPLIES/SERVICES (b) | QUANTITY ORDERED (c) | UNIT (d) | UNIT PRICE (e) | AMOUNT (f) | QUANTITY ACCEPTED (g) |
|---|---|---|---|---|---|---|
| | Cost-Sharing (CS)<br><br>Protein Sciences Corporation(PSC)has agreed to provide 100% funding toward this CLIN in the amount of (b)(4) to the existing Cost-Sharing Task Order.<br>(b)(4) | | | | | |
| 7 | Adjuvant Drug Product AF03 (Sanofi)<br>Cost-Sharing (CS)<br><br>Protein Sciences Corporation(PSC)has agreed to provide 100% funding toward this CLIN in the amount of (b)(4) o the existing Cost-Sharing Task Order.<br>(b)(4)<br><br>Attachment:<br>Attachment 1 - Statement of Work<br><br>The total amount of award: (b)(4) . The obligation for this award is shown in box 17(i). | | | | 0.00 | |

**In addition to all terms and conditions of the Base Contract, the following Articles are also applicable to this task order.**

## ARTICLE B.2. PRICES

a. The total fixed price of this task order (with the exception of CLINs 1801C, 0601 and Sanofi Adjuvant (b)(4)

b. Upon delivery and acceptance of the services described in SECTION K of the Business Proposal (in response to Request for Task Order (RTOR) # 2020-003 COVID-19 Candidate Vaccine Activities) and identified in the schedule of charges below, the Government shall pay to the Contractor the unit price(s) set forth below:

| CLIN | SUPPLIES/SERVICES | UNIT | QUANTITY | UNIT PRICE | TOTAL EXTENDED PRICE |
|---|---|---|---|---|---|
| 1101 | Laboratory Testing / Assay | each | 1 | (b)(4) | |
| 1201 | Animal Studies & Tox | each | 1 | | |
| 1301 | Clinical Studies | each | 1 | | |
| 1601 | Additional Reporting | | N/A | NSP | $0 |
| (b)(4) | Total Amount | | (b)(4) | | (b)(4) |

c. Upon delivery and acceptance of the services described in SECTION K of the Business Proposal (in response to RTOR # 2020-003 COVID-19 Candidate Vaccine Activities) and identified in the schedule of charges below, the Protein Sciences Corporation (PSC) is responsible and shall furnish the necessary services, qualified personnel, materials, supplies, equipment and facilities to unit price(s) set forth below:

| | | | | | | COST SHARE | |
|---|---|---|---|---|---|---|---|
| CLIN | SUPPLIES/SERVICES | UNIT | QUANTITY | UNIT PRICE | TOTOAL EXTENDED PRICE | PSC 100% | BARDA 0% |
| 1801C | cGMP vaccine investigational lot(s) | lot(s) | (b)(4) | | | | $0 |
| 0601 | Formulation and Filling Antigen-Single dose vials | vials | Up to (TBD | (b)(4) | | | $0 |
| N/A | Adjuvant Drug Product Sanofi) | vials | (b)(4) | | | | $0 |
| (b)(4) | Total Amount | | (b)(4) | | (b)(4) | | $0 |

## ARTICLE C.1. STATEMENT OF WORK

Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated **March 2020**, attached hereto and made a part of this Task Order (See SECTION J- List of Attachments).

## ARTICLE C.2. REPORTING REQUIREMENTS

In addition to the requirements of the clause, REPORTING REQUIREMENTS AND DELIVERABLES, incorporated in SECTION F-3 of this contract, all reports required herein shall be submitted in electronic format via email as attachments to the followings:

1. Contracting Officer's Representative (COR) (b)(6)
2. Contracting Officer (CO) (b)(4)
3. Contract Specialist (CS) at (b)(4)

**NOTE:** Hard copies of reports are not required. Each email submission shall contain only one deliverable. If the attached file for the deliverable exceeds 50 MB, the Contractor shall divide the deliverable into files of 50 MB each. All deliverables should be limited to five file attachments or less. In cases where it is necessary, more than five attachments will be accepted.

The subject of the email shall read as follows:

Deliverable_Contract Number_Task Order Number_Vendor's Name_Deliverable Description_Due Date

## ARTICLE F.1. PERIOD OF PERFORMANCE

The period of performance of this Task Order shall be fron (b)(4)

## ARTICLE F.2. DELIVERIES

Satisfactory performance of the task order shall be deemed to occur upon performance of the work described in the Statement of Work Article in SECTION C of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule.

a. The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract will be required to be delivered F.O.B. destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL1984), and in accordance with and by the date(s) specified below and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of this contract.

   Adhere to Deliverables the Statement of Work, dated **March 2020**, attached hereto and made a part of this Task Order (See SECTION J- List of Attachments).

b. The above items shall be addressed and delivered to:

| Addressee | Deliverable Items | Submit to: |
|---|---|---|
| Contracting Officer's Representative | All | (b)(6) |
| Contracting Officer | All | |
| Contract Specialist | All | |

## ARTICLE G.1. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

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

(b)(4)

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 G of the contract.

The Government may unilaterally change its COR designation.

## ARTICLE G.4. INVOICE SUBMISSION

In addition to the requirements specified in the base contract and FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all task order payment requests:
Contract Title: Acquisition of MCMs for Pandemic Influenza Preparedness and Response
Task Order Title: 2020-003 COVID-19 Candidate Vaccine Activities

## ARTICLE G.6. GOVERNMENT PROPERTY

In addition to the requirements of the clause, GOVERNMENT PROPERTY, incorporated in SECTION G-7 of this contract, the contractor shall Reference Section C.2.3. Additional Requirements. Products manufactured and stored under this contract are 'Government Property'. These materials should be maintained in the contractor's quality and inventory systems, ready for use in the continued manufacture of bulk material or final container doses intended for clinical use or use under the license.

## SECTION J – LIST OF ATTACHMENT

1. Statement of Work dated March 2020, 5 pages

END OF TASK ORDER 75A50120F33010

**Statement of Work**

**March 2020**

# Phase 1 Clinical Development of a COVID-19 Candidate Vaccine

## Background

The United States Department of Health and Human Services (HHS) continuously monitors emerging infectious disease risk and prepares to respond to the threat of novel emerging infectious disease outbreaks in the United States.

HHS is responding to an outbreak of respiratory disease caused by a novel coronavirus that was first detected in China and which has now spread to 156 countries or territories, including in the United States. The virus has been named "SARS-CoV-2" and the disease it causes has been named "coronavirus disease 2019" (abbreviated "COVID-19").

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the outbreak a "public health emergency of international concern" (PHEIC). On January 31, Health and Human Services Secretary Alex M. Azar II declared a public health emergency (PHE) for the United States to aid the nation's healthcare community in responding to COVID-19. On March 11, WHO publicly characterized COVID-19 as a pandemic. On March 13, the President of the United States declared the COVID-19 outbreak a national emergency.

Coronaviruses are a large family of viruses that are common in many different species of animals, including camels, cattle, cats, and bats. Rarely, animal coronaviruses can infect people and then spread between people such as with MERS, SARS, and now with SARS-CoV-2.

Vaccination is often the most effective measure for the control of infectious diseases. The best strategy for rapid development, production, and administration of a COVID-19 vaccine entails leveraging existing vaccine platform technologies. Development efficiency is accelerated by drawing on approaches used for related coronaviruses. Therefore, as part of HHS preparedness and response activities, HHS seeks to accelerate COVID-19 vaccine development by supporting Phase 1 clinical development of Protein Sciences Corporation's recombinant DNA platform technology.

## Project Scope

Objectives:

1. cGMP vaccine investigational lot(s)

    a. manufacture the clinical vaccine lot in manufacturing facilities according to cGMP under 21 CFR parts 210, 211, and 600
    b. Perform lot release product testing of cGMP SARS-CoV-2 recombinant (b)(4) vaccine.
    c. Make batch records available for review by HHS.
    d. Set aside samples for stability testing up to 60 months.

2. Formulation and filling antigen in single-dose vials

    cGMP SARS-CoV-2 recombinant (b)(4) ccine manufactured under aseptic conditions will be formulated into single-dose vials.
    a. Aseptic process development may be proposed.
    b. Multiple formulations filled into single dose vials per formulation are required.

c. Full release testing, including potency, of the final drug product should be proposed.

3. Animal Studies

   Evaluation of vaccine safety and efficacy in animal studies should be proposed to support Phase 1 clinical development.
   a. Multiple animal models may be proposed.
   b. Testing for the potential of vaccine-enhanced disease is required.
   c. Testing of adjuvants for enhancement of effectiveness and antigen-sparing, as well for effect on vaccine-enhanced disease is required: it is likely that multiple adjuvants will be assessed – these may be suggested and/or supplied by BARDA.

4. Clinical Study

   Conduct a Phase 1 clinical study to test the safety, dose, schedule, and immunogenicity of the vaccine candidate to support entering Phase 2/3 clinical studies.
   a. Qualified and/or validated immunogenicity assays are required.
   b. A plan to assess the duration of immunogenicity is required.
   c. The need for adjuvant is likely.
   d. Additional serum samples should be collected and stored for future use. These samples and associated data will be transferred to a BARDA-managed repository at a future date to be determined.
   e. Plan to publish study findings in a peer-reviewed journal

**Conditions:**

1. Animal studies may include a toxicology study.
2. Stability testing on the final drug substance and drug product will be performed. The number of samples to be set aside for stability study testing should be sufficient for at least (b)(4) months of testing.
3. Regulatory documents to support an Investigational New Drug (IND) application (e.g., Investigator's Brochure (IB), letters of authorization (LOA) to cross reference Biologics Master File (BMF), stability, Module 3 CMC documents, etc.) will be provided to BARDA.
4. Provide stability testing results to BARDA on a frequency and a duration requested by BARDA, with immediate notification to BARDA of any out of specification results during stability testing.

**Anticipated Period of Performance**
The period of performance is approximately (b)(4) months

**Deliverables**
1. Final Report for Aseptic Process Development if required
2. Certificates of Analysis
3. Certificates of Compliance
4. Draft and Final Reports for formulation and filling of drug product
5. Animal Studies:
   a. Draft and Final Protocols
   b. Quality Assurance Plan(s)
   c. Draft and Final Study Reports

| | |
|---|---|
| Draft Statistical Analysis Plan | (b)(4) days post award |
| Final Statistical Analysis Plan | Prior to database lock |
| Interim reports for primary immunogenicity endpoint* | Within (b)(4) f primary immunogenicity endpoint |
| SAEs related to the product during the entire duration of the study | Within 24 hours of SAE notification to Sponsor |
| Enrollment updates | Bi-weekly while enrollment is ongoing, monthly after enrollment complete |
| Safety information** | Monthly |
| Investigator Brochure | Due: With the final protocol |
| Clinical Site information | Due: With the final protocol |
| Final Clinical Study Report | Within (b)(4) months of study completion |
| Final data package submitted to FDA | Within months of study completion |
| *Interim report should include a summary of safety and immunogenicity data.<br>**Monthly safety report is a listing of all SAEs regardless of relationship to the product. | |

**Additional Requirements**

| CDRL# | Deliverable | Deliverable Description | Reporting Procedures and Due Dates |
|---|---|---|---|
| **01** | **Meetings** | | |
| 01.6 | Daily check in with project staff for **COVID-19 Contract** | Upon request of the Government, the Contractor shall participate in a daily check-in update with the project staff (via teleconference or email).<br><br>The updates will address key cost, schedule and technical updates. Daily updates may be shared with senior Government leaders during the COVID- 19 response and should be provided on a non-confidential basis, unless the update includes confidential information in which case Contractor shall provide the update in both confidential and non-confidential formats.<br><br>Daily check-ins may occur on weekdays, excluding federal holidays. Upon request of the Government, check-ins may also occur on weekends and on | • No agenda will be required for the meeting<br>• No meeting minutes are required<br>• Contractor will provide bulleted email updates following any call or in lieu of a call by 2PM for that day |

| CDRL# | Deliverable | Deliverable Description | Reporting Procedures and Due Dates |
|---|---|---|---|
| | | Federal holidays, provided at least 24 hours' notice. | |
| **02** | **Technical Reporting** | | |
| 02.8 | 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. | • Contractor will submit Product Development Source Material Report<br>○ Within month of contract award<br>○ Within (b)(4) of substantive changes are made to sources and/or materials<br>○ Or on the 6th month contract anniversary.<br>• The Government will provide written comments to the Product Development Source Material and Manufacturing Report within (b)(4) (b)(4) after the submission<br>• If corrective action is recommended, Contractor must address all concerns raised by BARDA in writing |
| 02.9 | Contractor Locations | The contractor shall submit detailed data regarding locations where work will be performed under this contract, including addresses, points of contact, and work performed per location, to include sub-contractors. | Contractor will submit Work Locations Report:<br>• Within (b)(4) business days of contract award<br>• Within (b)(4) business days after a substantive location or capabilities change<br>• Within (b)(4) 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 |

**Place of performance**

Contractor facilities or Subcontractor facilities

**Government Property**

Reference Section C.2.3. Additional Requirements. Products manufactured and stored under this contract are 'Government Property'. These materials should be maintained in the contractor's quality and inventory systems, ready for use in the continued manufacture of bulk material or final container doses intended for clinical use or use under the license.