Attachment A
Statement of Work
(Incorporated as of Modification No. 01; changes to Section 5 are indicated in bold italics.)

For
Rapid (WF10) Advanced Research & Development to Large Scale Manufacturing of NVX-CoV-2373 as a Vaccine for SARS-CoV-2 Coronavirus

RPP #: 20-11
Project Identifier: MCDC2011-001
Consortium Member: Novavax, Inc.
Title of Proposal: Rapid (WF10) Advanced Research & Development to Large Scale Manufacturing of NVX-CoV-2373 as a Vaccine for SARS-CoV-2 Coronavirus
Requiring Activity: Joint Mission between the Department of Health and Human Services and Department of Defense to Combat COVID-19

1.0 INTRODUCTION, SCOPE, AND OBJECTIVES

1.1 Introduction

To meet the needs of the Coronavirus Disease 2019 (COVID-19) pandemic, the United States Government (USG) is identifying and will support development and at-scale manufacturing of selected vaccine candidates, to ensure timely availability to the US population when needed. This is the primary focus of the mission being executed by the Department of Health and Human Services (HHS) and Department of Defense (DoD), in support of Operation Warp Speed (OWS).

The USG is interested in pursuing prototype vaccines that are in an advanced stage of development, and will support companies that can, in parallel with nonclinical, clinical and regulatory development, rapidly establish the manufacturing capacity required to meet the USG's objective of supplying a safe and effective Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) vaccine to the entire US population. The USG is tasked with marshaling the efforts of the US biotechnology industry to achieve this goal.

1.2 Definition of the Prototype Project

Consistent with USG objectives, the "prototype project" under this agreement is defined as the manufacture and delivery of 100M doses of a SARS-CoV-2 vaccine, NVX-CoV2373, which is suitable for use in humans under a sufficiently informed deployment strategy, and the advanced positioning of a stockpile of critical long lead raw materials for the Matrix-M adjuvant. As such, the "prototype project" will effectively demonstrate Novavax's ability to rapidly stand up large scale manufacturing and seamlessly transition into ongoing production.

The NVX-CoV-2373 vaccine is comprised of the Matrix-M™ adjuvant, and antigen (SARS-CoV-2 spike protein). The vaccine is filled into a multi-dose vial (b) (4) and is stored at refrigerated temperature (2-8°C).

Successful development of the prototype will demonstrate Novavax's ability to rapidly stand up large scale manufacturing and seamlessly transition into ongoing production capability, in order to rapidly manufacture to meet surge requirements with little advance notification, and demonstrate capability to stockpile and distribute large quantities of the vaccine to respond when needed, including in order to supply use in clinical studies, under an Emergency Use Authorization (EUA), or pursuant to other clearance from the U.S. Food and Drug Administration (FDA).

Successful completion of the prototype will require three coordinated and integrated lines of effort:

a) Large scale manufacturing, compliant with 21 CFR Parts 210 and 211, and the Drug Supply Chain Security Act (DSCA), to the extent applicable at the time of manufacturing by statute and FDA interpretive guidance thereof.
b) Parallel nonclinical and clinical studies required to determine if the vaccine is safe and effective.
c) Compliance with all applicable U.S. regulatory requirements.

It is important to note that while results of nonclinical and clinical studies are critical to develop use case scenarios and, in turn, inform the USG's deployment strategy as it relates to product manufactured under this agreement, successful development of the prototype is dependent only on the validity of data from these studies. The degree to which the data are "positive" or "negative" is not a factor in demonstration of the prototype.

1.3 Follow-on Activity

This prototype project includes unpriced options for follow-on production/procurement. During the performance of the prototype, the USG and Novavax will negotiate the scope and price of production/procurement. If the prototype project is successful, the USG may then enter into follow-on production/procurement by executing these options through a separate stand-alone production/procurement agreement, to be negotiated in terms of scope and price as described in the following paragraph.

In accordance with 10.U.S.C. 2371b(f), and upon demonstration of the prototype, or at the accomplishment of particularly favorable or unexpected results that would justify transitioning to production/procurement, EUA, or Biologics License Application (BLA) approved by the FDA, the USG and Novavax may enter into a non-competitive production/procurement follow-on agreement or contract for additional production/procurement, to partially or completely meet the USG objective of supplying a safe and effective SARS-CoV-2 vaccine to vaccinate up to 300M people in the targeted population (≈560M additional doses).

1.4 Scope

Novavax has defined a scope of activities in order to successfully develop the prototype, as defined above. The scope is based on the following assumptions regarding manufacturing and clinical dose:

- Manufacturing Assumptions and Clinical Dose
  - The NVX-CoV-2373 vaccine is comprised of the Matrix-M™ adjuvant, and antigen (SARS-CoV-2 spike protein).
  - A dose range of 5-25 µg of antigen is under clinical study. The anticipated dose based on clinical data obtained to date is (b) µg of antigen with (b) µg of Matrix-M adjuvant.
  - For planning purposes, (b) [redacted] ((b) µg antigen/dose) has been used and the calculations in this scope of work have been based on this dose.
  - The antigen production is the rate-limiting step in vaccine production. The Matrix-M adjuvant will be available prior to antigen production. Dose production has been calculated based on the availability of antigen. Novavax is planning on a batch-by-batch rapid fill/finish once antigen is manufactured and available.
  - The estimated production schedule based on the (b) µg antigen/dose (base case) and (b) µg antigen /dose (anticipated case) is in the table below:

	Estimated Schedule of Cumulative Doses Manufactured by Month				
Dosage	**Oct 2020**	**Nov 2020**	**Dec 2020**	**Jan 2021**	**Feb 2021**
(b) µg/dose (base case)	(b) (4) [redacted]	[redacted]	[redacted]	[redacted]	[redacted]
(b) µg/dose (anticipated case)	(b) (4) [redacted]	[redacted]	100,000,000*		

*Actual cumulative projected production at (b) µg/dose is (b) (4) [redacted] in December 2020. Some doses may be in progress at the end of December 2020.

**Actual cumulative projected production at (b) µg/dose is (b) (4) [redacted] in February 2021.

The scope includes the following activities:

- Manufacturing
  - Manufacturing of 100M doses (at (b) µg/dose, (b) (4) [redacted]) of NVX-CoV-2373 vaccine in 2020 for distribution to the Government upon EUA under section 564 of the Food, Drug, and Cosmetic (FD&C) Act or a biologics licensure granted under Section 351(a) of the Public Health Service Act by the U.S. FDA.
  - Establishment of large-scale current Good Manufacturing Practice (cGMP) manufacturing capacity compliant with 21 CFR Parts 210 and 211, and the DSCA to the extent applicable at the time of manufacturing by statute and FDA interpretive guidance thereof.
  - Comparability among clinical vaccine lots and commercial lots using a comparability protocol linked to the product associated with the Phase 1 clinical study. For adjuvant components, the same raw material lot(s) will be used for the current and new Contract Manufacturing Organization (CMO) processes for the comparability protocol, and the same test lab will be used to ensure only process differences are being evaluated.
  - Validation of manufacturing processes will be performed to cGMP standards.

- Clinical
  - Phase 3 pivotal clinical trial harmonized with USG clinical strategies.
  - A Phase 3 clinical trial in pediatric populations (<18 years).
  - Phase 2 studies in at-risk subpopulations (co-morbidities, (b) (4) , immunocompromised), as well as studies to support manufacturing site comparability.
- Non-clinical
  - Studies to support EUA and regulatory approval (BLA).
- Regulatory
  - EUA submission when data supports it, while maintaining progress toward eventual BLA submission.
  - BLA submission when appropriate.
  - Regulatory support activities (Investigational New Drug (IND) submissions) for manufacturing, clinical, non-clinical studies.
  - Meetings as-needed with regulators.
- Project Management
  - Mandatory reporting requirements, as described in the Base Agreement.
  - Submission of Monthly Progress Reports. Format will be agreed on by the contractor and Agreements Officer's Representative (AOR), and will include both technical and financial status and expenditure forecast.
  - Facilitation of biweekly teleconferences with Novavax and USG Subject Matter Experts.
  - Final prototype project report and applicable patents report(s).
  - Work Breakdown Structure (WBS) and Integrated Master Schedule (IMS).
  - All Regulatory correspondence relevant to the scope of work proposed, including communications with the FDA, and all submissions.

1.4.1 Novavax Project Plan

This is Novavax's plan as of the date of the submission. Novavax desires to move quickly to large scale development as rapidly as possible, in order to meet the objectives of this proposal. As the COVID-19 pandemic is an evolving situation, Novavax may need to adapt its plan in response to FDA guidance, opportunities for manufacturing efficiencies, and clinical trial data.

1.5 Resolution of Conflicting Language

If there is a conflict between the Project Agreement (of which this Statement of Work is part) and the Base Agreement (Medical CBRN Consortium (MCDC) Base Agreement No.: 2020-530), the Project Agreement language will supersede and control the relationship of the parties.

2.0 APPLICABLE REFERENCES

N/A

3.0 REQUIREMENTS

3.1 Major Task: cGMP Manufacturing of NVX-CoV-2373 compliant with 21 CFR 210 and 211

3.1.1 Subtask: Raw Materials – Obtain Critical Starting Materials for Adjuvant Manufacturing

Sufficient Saponin to manufacture up to 100M vaccine doses will be purchased (Desert King, headquartered in San Diego, CA, facilities in Chile). Long-lead, critical, and limited-supply materials ((b) (4)) will be purchased for the additional 560M vaccine doses to meet the contact requirement, in order to ensure capability to rapidly manufacture to meet surge requirements with little advance notification and demonstrate capability to stockpile and distribute large quantities of the vaccine to respond when needed.

3.1.2 Subtask: Raw Materials – Obtain Critical Starting Materials for Antigen and Fill/Finish Manufacturing

Sufficient materials (vials, stoppers, other consumables) to manufacture up to 100M vaccine doses will be purchased (sources TBD).

3.1.3 Subtask: Raw Materials – (b) (4) Intermediates to Produce Matrix-M Adjuvant Matrix-M Adjuvant

(b) (4) to supply large-scale manufacturing of vaccine doses will be manufactured at (b) (4) and PolyPeptide (Torrance, CA & Malmö, Sweden). Technology transfer and start-up of the PolyPeptide facility in Torrance, CA will be completed. Long lead, critical, and limited supply materials will be purchased in order to achieve the goal of large-scale production.

3.1.4 Subtask: Matrix-M Adjuvant Manufacturing to Supply 100M Vaccine Doses

Matrix-M Adjuvant bulk components will be manufactured at ACG Biologics (Seattle, WA) to supply 100M vaccine doses. Technology transfer and start-up of the AGC Bio facility in Seattle will be completed. An analytical comparability manufacturing study and validation studies will be performed as part of the tech transfer to each manufacturing site.

3.1.5 Subtask: Antigen Manufacturing to Supply 100M Vaccine Doses

Antigen will be manufactured at Fuji (2 sites – College Station, TX and Research Triangle Park, NC) to supply 100M vaccine doses. Technology transfer and scale-up activities will be completed. An analytical comparability manufacturing study and validation studies will be performed as part of the tech transfer to each manufacturing site.

3.1.6 Subtask: Fill/Finish of 100M Vaccine Doses

100M doses of finished vaccine in (b) (4) vials will be manufactured at Baxter (Bloomington, IN, USA). This will include secondary packaging. Technology transfer and scale-up activities will be completed. An analytical comparability manufacturing study and validation studies will be performed as part of the tech transfer to each manufacturing site.

3.1.7 Subtask: Shipping and Storage

Novavax assumes that it will maintain a Vendor Managed Inventory (VMI) system for a period of 12 months, with shipments to 10 geographic zones in the USA. Novavax will perform activities to establish compliance with DSCA to the extent applicable at the time of manufacturing, by statute and FDA interpretive guidance thereof.

3.2 Major Task: Clinical Studies

Novavax will perform these clinical trials and deliver the results in an interim Clinical Study Report (CSR) at the completion of enrollment, and the final CSR when available. These trials will be conducted using a Clinical Research Organization (CRO) that is to be determined.

3.2.1 Subtask: Phase 3 Global Efficacy Study, Adults ≥ 18 and < 75 years

Study: Phase 3 – Global Efficacy Study (to be harmonized with other USG studies), 2019nCoV-301.

Population: Adults ≥ 18 years, inclusive of subjects with more severe co-morbid conditions.

Locations: North America, Europe; may include Africa, Asia, Oceania, South America.

Primary Objectives: Clinical efficacy, safety, immunogenicity.

Design: Randomized, observer-blinded, placebo-controlled.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + Matrix-M1 – dose determined by Phase 2 dose confirmation study, Placebo; ~0.5 mL dose Intramuscular (IM) injection, up to 2 doses at Day 0 and Day 21.

Enrollment: TOTAL N: ~30,000 (adjusted for expected endpoint incidence). (b) (4) (b) (4)

3.2.2 Subtask: Phase 2 Efficacy Expansion (US), Adults ≥ 18 and < 75 years

Study: Phase 2 - Part 3 efficacy expansion (US), 2019nCoV-204.

Population: Adults ≥ 18 and < 75 years.

Locations: USA.

Primary Objectives: Clinical efficacy, safety, immunogenicity.

Design: Randomized, observer-blinded, placebo-controlled.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + Matrix-M1 (b) (4) (b) (4) not greater than 25 µg antigen + 50 µg adjuvant, (b) (4) (b) (4) to allow for rapid initiation. Placebo. ~0.5 mL dose IM injection, up to 2 doses at Day 0 and Day 21.

Enrollment: TOTAL: (b) (4)
Adjusted for expected event occurrence. Event driven analysis. Initiation of study gated on completion of Phase 1 study, dose-selection and regulatory approval.

3.2.3 Subtask: Phase 2 Study in Immunocompromised Persons (HIV-positive adult subjects) (Africa)

Study: Phase 2 study in immunocompromised persons (HIV-positive adult subjects) (Africa).

Population: Adults ≥ 18 and < 65 years.

Locations: Republic of South Africa (RSA)

Primary Objectives: Safety, immunogenicity (serum and cellular).

Design: Randomized, observer-blinded, placebo-controlled.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + Matrix-M1; Placebo, 0.5 mL dose IM injection, up to 2 doses at Day 0 and Day 21.

Enrollment: Total N = 2,640 – 2,880 (with n=240 - 480 HIV+); 1:1 Vaccine to placebo. Initiation gated on completion of Phase 1 study, dose selection, and regulatory approval.

3.2.4 Subtask: (b) (4)

Study: (b) (4)

Population: (b) (4)

Locations: (b) (4)

Primary Objectives: (b) (4)

Design: Randomized, observer-blinded, placebo-controlled.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + Matrix-M1 (b) (4) .

Enrollment: (b) (4) . Initiation gated on benefit:risk assessment (derived from Task 2.3.1 and/or 2.3.2 and/or other Phase 2 studies) and regulatory approval to conduct studies in this vulnerable population.

3.2.5 Subtask: Phase 2 Manufacturing Site Lot Consistency/Comparability Study (US or other)

Study: Phase 2 manufacturing site lot consistency/comparability study (US or other), 2019nCoV-201.

Population: Adults ≥ 18 to < 50 years.

Locations: USA.

Primary Objectives: Safety, immunogenicity.

Design: Randomized, observer-blinded, placebo-controlled.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + Matrix-M1; (b) (4) .

Enrollment: ~600 per cohort, each cohort having (b) (4) Study size may be adjusted to allow non-inferiority testing.

3.2.6 Subtask: (b) (4)

Study: (b) (4)

Population: (b) (4).

Locations: (b) (4)

Primary Objectives: (b) (4).

Design: Randomized, observer-blinded, placebo-controlled.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + Matrix-M1; (b) (4).

Enrollment: Total = 800 mothers + baby. Initiation gated on benefit:risk assessment (derived from Task 2.3.1 and/or 2.3.2 and/or other Phase 2 studies) and regulatory approval to conduct studies in this vulnerable population.

3.2.7 Subtask: Pharmacovigilance; Establishment of Registration Safety Database

A registration safety database will be established to comply with FDA requirements for product safety and licensure.

3.2.8 Subtask: (b) (4)

Study: (b) (4)

(b) (4) (b) (4)

(b) (4) (b) (4)

(b) (4) (b) (4)

Design: Randomized, observer-blinded, placebo (or active vaccine) control.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + Matrix-M1 (b) (4).

Enrollment: TOTAL: N ~12,500 (based on agreed VE, power, and LBCI). (b) (4) Adjusted for expected event occurrence if robust demonstration of clinical efficacy is required by the FDA. Event driven analysis for study termination.

3.3 Major Task: Non-Clinical Studies

Novavax will perform these non-clinical studies and deliver the results in a study report at completion.

3.3.1 Mouse Study, Immunogenicity

Study 702-100. Immunogenicity (b) (4)) in mice for vaccine efficacy profile to comply with FDA guidelines.

3.3.2 Rhesus Study, Immunogenicity

Study 702-099. Immunogenicity/challenge (b) (4)) in rhesus monkeys for vaccine efficacy profile to comply with FDA guidelines.

3.3.3 Hamster Study, Immunogenicity

Study 702-102. Immunogenicity/challenge study in hamster ((b) (4) for vaccine efficacy profile to comply with FDA guidelines.

3.3.4 Mouse Study, T-Cell Immunogenicity

Study 702-103. T-cell immunogenicity/challenge study in mice (b) (4) for vaccine efficacy profile to comply with FDA guidelines.

3.3.5 Hamster Study, T-Cell Immunogenicity

Study 702-105. Immunogenicity/challenge study in hamster (b) (4) for vaccine efficacy profile to comply with FDA guidelines.

3.3.6 Mouse Study, T-Cell Immunogenicity

Study 702-104. Immunogenicity/challenge study in hamster ((b) (4)) for vaccine efficacy profile to comply with FDA guidelines.

3.3.7 Non-Clinical Studies: Collaboration with Univ. of Maryland School of Medicine

Three studies to study enhancement/inhibition and neutralization, and virus challenge of vaccinated mice:

1. Validation of Spike nanoparticles in cell inhibition studies: In vitro inhibition studies on cell line permissive to r2019-nCoV, readout TBD.
2. Neutralization studies with virus against bleeds from mice, In vitro microneutralization studies on cell line permissive to r2019-nCoV, TCID50 or fluorescence readout (TBD).
3. Virus challenge of vaccinated mice (mice vaccinated outside and shipped to UM for challenge), Challenge of vaccinated mice (shipped in for infection from Novavax), Lung pathology, Titer, viral Ribonucleic Acid (RNA) quantitation, pathology scoring and reports.

3.3.8 Structural Study of COVID-19 Spike Protein and its Complex with Host Receptor (cooperation with Baylor College of Medicine)

Study to determine the structures of recombinant COVID-19. Spike protein in nanoparticles used in Novavax's human vaccine and in complex with its host receptor ACE2. Will obtain a high-resolution cryoEM structure of full-length COVID-19 Spike protein and a high-resolution cryoEM structure of full-length COVID-19 Spike protein in complex with human receptor ACE2.

3.3.9 Neutralizing Assay Histopathology for On-going (b) (4)

Histopathology readings for current neutralization studies in (b) (4). This will support the safety profile of the vaccine for FDA approval.

3.3.10 Mouse Study, Immunogenicity (b) Studies

Individual immunogenicity studies (b) (4)) in mice for vaccine efficacy profile in different sub-populations to comply with FDA guidelines.

3.4 Major Task: Regulatory Affairs

Novavax will conduct the regulatory activities below, including BLA prep and submission, and provide the meeting minutes and applications to the USG.

3.4.1 Subtask: EUA Submission and Supporting Meetings and Regulatory Filings

An EUA will be submitted to the FDA upon obtaining sufficient clinical data. EUA, FDA meetings to support EUA, submission planning support for the Chemistry, Manufacturing, and Controls (CMC) team, EUA strategy and meeting support, and submission preparation support activities, will all be completed.

3.4.2 Subtask: IND Submission Updates and FDA Meetings

This task will include submissions to the IND and possible FDA meetings that will be required prior to the BLA submission.

3.4.3 Subtask: BLA Submission

A BLA will be submitted to the FDA upon obtaining sufficient clinical data, FDA meetings to support BLA, submission planning support for the CMC team, BLA strategy and meeting support, and submission preparation support activities, will all be completed.

3.5 Major Task: Project Management and Reporting

3.5.1 Subtask: Kick-Off Meeting and Initial Baseline Review of IMS

Novavax shall conduct a Kick-Off Meeting and an initial review with the USG of the IMS, upon initiation of the program.

3.5.2 Subtask: Biweekly Meetings with OWS

Novavax shall submit the agenda in advance. Any technical updates shall be provided in advance for the Government team to review. Minutes shall be submitted after the biweekly meeting to the USG.

3.5.3 Subtask: Written Quarterly Reports

Novavax shall submit quarterly reports to the USG.

3.5.4 Subtask: Written Annual Reports

Novavax shall submit the annual reports to the USG.

3.5.5 Subtask: Written Final Report

Novavax shall submit the final report to the USG.

3.6 Optional Task: Follow-On Production

Follow-on production of finished doses of vaccine up to 560M doses.

4.0 DELIVERABLES

Del. #	Deliverable Description	Due Date	Milestone Reference	SOW Reference	Government Role	Data Type/Data Rights
	Manufacturing					
4.1	(b) (4) [redacted]	[redacted]	5.1	3.1.1	Reviewer	(b) (4) [redacted]
4.2	(b) (4) [redacted]	[redacted]	5.2	3.1.2	Reviewer	(b) (4) [redacted]
4.3	(b) (4) [redacted]	[redacted]	5.3	3.1.3	Reviewer	(b) (4) [redacted]
4.4	(b) (4) [redacted]	[redacted]	5.4	3.1.4	Reviewer	(b) (4) [redacted]
4.5	(b) (4) [redacted]	[redacted]	5.5	3.1.5	Reviewer	(b) (4) [redacted]
4.6	(b) (4) [redacted]	[redacted]	5.6	3.1.6	Reviewer	(b) (4) [redacted]
4.7	(b) (4) [redacted]	[redacted]	5.7	3.1.7	Reviewer	(b) (4) [redacted]

Del. #	Deliverable Description	Due Date	Milestone Reference	SOW Reference	Government Role	Data Type/Data Rights
	Clinical					
4.8	(b) (4) [redacted]	[redacted]	5.8	3.2.1	Reviewer	(b) (4) [redacted]
4.9	(b) (4) [redacted]	[redacted]	5.9	3.2.2	Reviewer	(b) (4) [redacted]
4.10	(b) (4) [redacted]	[redacted]	5.10	3.2.3	Reviewer	(b) (4) [redacted]
4.11	(b) (4) [redacted]	[redacted]	5.11	3.2.4	Reviewer	(b) (4) [redacted]
4.12	(b) (4) [redacted]	[redacted]	5.12	3.2.5	Reviewer	(b) (4) [redacted]
4.13	(b) (4) [redacted]	[redacted]	5.13	3.2.6	Reviewer	(b) (4) [redacted]
4.14	(b) (4) [redacted]	[redacted]	5.14	3.2.7	Reviewer	(b) (4) [redacted]
4.15	(b) (4) [redacted]	[redacted]	5.15	3.2.8	Reviewer	(b) (4) [redacted]
	Non- Clinical					
4.16	(b) (4) [redacted]	[redacted]	5.16	3.3.1	Reviewer	(b) (4) [redacted]
4.17	(b) (4) [redacted]	[redacted]	5.17	3.3.2	Reviewer	(b) (4) [redacted]

[1] As used herein, "Government Purpose Rights" has the meaning set forth in Article XI, Section 11.01(9) of the Base Agreement, as modified by Section 8.2(b) below.

Del. #	Deliverable Description	Due Date	Milestone Reference	SOW Reference	Government Role	Data Type/Data Rights
4.18	(b) (4) [redacted]	[redacted]	5.18	3.3.3	Reviewer	(b) (4) [redacted]
4.19	(b) (4) [redacted]	[redacted]	5.19	3.3.4	Reviewer	(b) (4) [redacted]
4.20	(b) (4) [redacted]	[redacted]	5.20	3.3.5	Reviewer	(b) (4) [redacted]
4.21	(b) (4) [redacted]	[redacted]	5.21	3.3.6	Reviewer	(b) (4) [redacted]
4.22	(b) (4) [redacted]	[redacted]	5.22	3.3.7	Reviewer	(b) (4) [redacted]
4.23	(b) (4) [redacted]	[redacted]	5.23	3.3.8	Reviewer	(b) (4) [redacted]
4.24	(b) (4) [redacted]	[redacted]	5.24	3.3.9	Reviewer	(b) (4) [redacted]
4.25	(b) (4) [redacted]	[redacted]	5.25	3.3.10	Reviewer	(b) (4) [redacted]
	Regulatory Affairs					

Del. #	Deliverable Description	Due Date	Milestone Reference	SOW Reference	Government Role	Data Type/Data Rights
4.26	(b) (4)		5.26	3.4.1	Reviewer	(b) (4)
4.27	(b) (4)		5.27	3.4.2	Reviewer	(b) (4)
4.28	(b) (4)		5.28	3.4.3	Reviewer	(b) (4)
	Project Management					
4.29		(b) (4)	5.29	3.5.1	Reviewer	(b) (4)
4.30		(b) (4)	5.30	3.5.2	Reviewer	(b) (4)
4.31		(b) (4)	5.31	3.5.3	Reviewer	(b) (4)
4.32		(b) (4)	5.32	3.5.4	Reviewer	(b) (4)
4.33		(b) (4)	5.33	3.5.4	Reviewer	(b) (4)
4.34		(b) (4)	5.34	3.5.5	Reviewer	(b) (4)
TBD		(b)	Option 1	3.6	Reviewer	(b) (4)

5.0 MILESTONE PAYMENT SCHEDULE

Milestone #	Milestone Description (Deliverable Reference)	Due Date	Total Program Funds
	Manufacturing		
(b)	(b) (4)		
(b)	(b) (4)		
(b)	(b) (4)		
(b)	(b) (4)		
(b)	(b) (4)		
(b)	(b) (4)		
(b)	(b) (4)		
	(b) (4)		
(b)	(b) (4)		
(b)	(b) (4)		
(b)	(b) (4)		
(b)	(b) (4)		
(b)	(b) (4)		
(b)	(b) (4)		
(b)	(b) (4)		
(b)	(b) (4)		
	(b) (4)		
(b)	(b) (4)		
(b)	(b) (4)		
(b)	(b) (4)		
(b)	(b) (4)		
(b)	(b) (4)		

Milestone #	Milestone Description (Deliverable Reference)	Due Date	Total Program Funds
(b)	(b) (4)		
(b)	(b) (4)		
(b)	(b) (4)		
(b)	(b) (4)		
(b)	(b) (4)		
	(b) (4)		$10,362,788
(b)	(b) (4)		
(b)	(b) (4)		
(b)	(b) (4)		
	(b) (4)		$8,303,163
(b)	(b) (4)		
(b)	(b) (4)		
(b)	(b) (4)		
(b)	(b) (4)		
(b)	(b) (4)		
(b)	(b) (4)		
	(b) (4)		
(b)	(b) (4)		
(b)	(b) (4)		
(b)	(b) (4)		
	(b) (4)		

Milestone #	Milestone Description (Deliverable Reference)	Due Date	Total Program Funds
(b)	(b) (4)		
(b)	(b) (4)		
(b)	(b) (4)		
(b)	(b) (4)		
	(b) (4)		
(b)	(b) (4)		
		Total (Cost Plus Fixed Fee)	$1,600,434,522
		Period of Performance (July 6, 2020 – December 31, 2021)	18 Months (Base)
		Option 1: Follow-On Production	Cost: (b) (4)

Simplified Table: Estimated Cost by Project Areas

Area	Cost
Manufacturing (100M doses)	$418,151,118
Non-Clinical	$5,092,957
Clinical	$1,158,524,498
Regulatory	$10,362,788
Project Management	$8,303,163
Total Project Cost	**$1,600,434,523**

Simplified Table: Selected Estimated Costs for Key Deliverables*

Area	Milestone/Deliverable	Start	Finish	Cost
(b) (4)				

* For key deliverables only; does not encompass total project costs.

** Time to obtaining vaccine efficacy data.

6.0 SHIPPING PROVISIONS

The shipment of physical deliverables shall be coordinated with the AOR. Data deliverables shall be provided in accordance with the agreement, and in coordination with the AOR.

7.0 INTELLECTUAL PROPERTY, DATA RIGHTS, AND COPYRIGHTS

7.1 BACKGROUND IP

(a) Ownership. Prior to June 8, 2020, Novavax had funded the development of NVX-CoV2373, and other antecedent vaccine programs relevant to Novavax' proprietary position in the development of NVX-CoV2373, as well as its sf9/baculovirus manufacturing platform, (all "Background IP") through private funding or in collaboration with a funding partner other than the U.S. Government. Such private and non-governmental funding has continued since June 8, 2020 and is expected to continue during the performance of the Project Agreement. A list of all patents and patent applications included in the Background IP is provided below as Enclosure 4. Background IP also consists of (a) manufacturing know-how, including, without limitation, the NVAX-Cov2373 manufacturing process definitions, process development/characterization reports, laboratory scale process procedures, manufacturing records, analytical test methods, product quality target ranges/specifications, quality target product profile, critical quality attributes (collectively "Background Know-How"), (b) data from pre-clinical and clinical research studies, analytical and process development research, and data related to, or generated using, the Background Know-How (collectively, "Background Data"), and (c) proprietary manufacturing materials, including, without limitation, sf9 cell banks (master and working), baculovirus virus stock (master and working), product standards, reference standards, and critical reagents ("Background Materials"). On June 8, 2020, Novavax and the U.S. Department of Defense entered into a Letter Contract for specified U.S.-based clinical and manufacturing development of NVX-CoV2373 which acknowledged Background IP and made no explicit U.S. Government claims to Background IP or subsequent data arising therefrom. The U.S. Government hereby acknowledges such Background IP in full and further acknowledges that it has no ownership rights to Novavax Background IP under this Project Agreement.

(b) Background IP Limited License to Government. Subject to the terms of the Project Agreement, Novavax grants the U.S. Government a nonexclusive, worldwide, nontransferable, non-sublicenseable license to use the Background IP to the limited extent necessary for the U.S. Government to review and use the Deliverables tendered by Novavax under this Agreement identified in Section 4.0 above, and for no other purpose; provided that the U.S. Government agrees that it may not disclose the Background IP to third parties, or allow third parties to have access to, use, practice or have practiced the Background IP, without Novavax's prior written consent. To the extent that a Deliverable with Foreground IP incorporates or uses Background IP, the Deliverable shall be deemed and considered to comprise Background IP and shall be used by the U.S. Government in accordance with this Background IP Limited License.

(c) Background IP License to Novavax. Subject to the terms of the Project Agreement, the U.S. Government grants to Novavax a nonexclusive, worldwide, nontransferable, irrevocable,

paid-up license to any intellectual property (including patents and patent applications) to which the U.S. Government has rights thereto, provided that such license is limited to such intellectual property rights necessary to perform Novavax's obligations under the Project Agreement.

7.2 FOREGROUND IP

(a) Ownership. Notwithstanding anything in the Base Agreement to the contrary, Novavax owns all rights, title and interest in and to any development, modification, discovery, invention or improvement, whether or not patentable, conceived, made, reduced to practice, or created in connection with activities funded under the Project Agreement, including, without limitation, all data and inventions, and intellectual property rights in any of the foregoing ("Foreground IP").

(b) Foreground IP Special License. Subject to the terms of the Project Agreement, Novavax grants the U.S. Government a nonexclusive, worldwide, nontransferable, irrevocable, paid-up license to practice or have practiced the Foreground IP for or on behalf of the U.S. Government ("Foreground IP Special License").

8.0 DATA RIGHTS

Article XI, §11.03 of the Base Agreement is hereby amended, consistent with the "Specifically Negotiated License Rights" capability at Article XI, §§11.01(12) and 11.03(4), as follows:

8.1 Data Ownership.

Novavax owns all rights, title and interest to all Data (as defined in Article XI, Section 11.01(7) of the Base Agreement) generated as a result of the work performed under this Project Agreement, including Subject Data.

8.2 Rights to Data.

(a) Subject Data. Subject to the terms of the Project Agreement, Novavax grants to the U.S. Government a Government purpose rights license to Subject Data that will convert to an unlimited rights license (as the term is defined in Article XI, Section 11.01(14) of the Base Agreement)[2] after three (3) years from the date of delivery. As used herein, "Subject Data" shall mean Technical Data under Article XI, §11.01(13) of the Base Agreement Deliverables that are considered Subject Data are identified in the Deliverable Table set forth in Section 4.0 above.

(b) Transfer of Data. Each party, upon written request to the other party, shall have the right to review and to request delivery of Subject Data, and delivery of such Data shall be made to the requesting party within two weeks of the request, except to the extent that such Data are subject to a claim of confidentiality or privilege by a third party.

[2] As used herein, "Government Use" as used "Purpose Rights" has the meaning set forth in this Section 4.0 means Government purpose rights as defined in the Base Agreement, Article XI, Section 11.01(9).) of the Base Agreement, as modified by Section 8.2(b) below.

(c) Background IP Limited License. To the extent that Subject Data incorporates or uses Background IP, the data shall be deemed and considered to comprise Background IP and shall be used by the U.S. Government in accordance with the Background IP Limited License set forth in Section 7.3 above.

8.3 Background Technical Data Rights Assertions.

Novavax asserts background technical data rights as follows:

The Background Data, as defined in Section 7.1 above, was developed through private funding or in collaboration with a funding partner other than the U.S. Government. Such funding is expected to continue; accordingly, Novavax asserts Background Data as Category A Data pursuant to section 11.02(1) of the Base Agreement and the U.S. Government shall have no rights therein.

9.0 REGULATORY RIGHTS

This agreement includes research with an investigational drug, biologic or medical device that is regulated by the U.S. Food and Drug Administration (FDA) and requires FDA pre-market approval or clearance before commercial marketing may begin. It is expected that this agreement will result in the FDA authorization, clearance and commercialization of NVX-CoV-2373 as a Vaccine for SARS-CoV-2 Coronavirus (the "Technology"). Novavax is the Sponsor of the Regulatory Application (an investigational new drug application (IND), investigational device exemption (IDE), emergency use authorization (EUA), new drug application (NDA), biologics license application (BLA), premarket approval application (PMA), or 510(k) pre-market notification filing (510(k)) or another regulatory filing submitted to the FDA) that controls research under this contract. As the Sponsor of the Regulatory Application to the FDA (as the terms "sponsor" and "applicant" are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20), Novavax has certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application. This clause protects the return on research and development investment made by the U.S. Government in the event of certain regulatory product development failures related to the Technology.

Novavax agrees to the following:

a. Communications. Novavax will provide the U.S. Government with all communications and summaries thereof, both formal and informal, to or from FDA regarding the Technology and ensure that the U.S. Government representatives are invited to participate in any formal or informal Sponsor meetings with FDA;

b. Rights of Reference. The U.S. Government is hereby granted a right of reference as that term is defined in 21 C.F.R. § 314.3(b) (or any successor rule or analogous applicable law recognized outside of the U.S.) to any Regulatory Application submitted in support of the statement of work for the Project Agreement. When it desires to exercise this right, the U.S. Government agrees to notify Novavax in writing describing the request along with sufficient details for Novavax to generate a letter of cross-reference for the U.S. Government to file with the appropriate FDA

office. The U.S. Government agrees that such letters of cross-reference may contain reporting requirements to enable Novavax to comply with its own pharmacovigilance reporting obligations to the FDA and other regulatory agencies. Nothing in this paragraph reduces the U.S. Government's data rights as articulated in other provisions of the Project Agreement.

c. DoD Medical Product Priority. PL-115-92 allows the DoD to request, and FDA to provide, assistance to expedite development and the FDA's review of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel. Novavax recognizes that only the DoD can utilize PL 115-92. As such, Novavax will work proactively with the DoD to leverage this this law to its maximal potential under this Project Agreement. Novavax shall submit a mutually agreed upon Public Law 115-92 Sponsor Authorization Letter to the U.S. Government within 30 days of award.

10.0 ENSURING SUFFICIENT SUPPLY OF THE PRODUCT

a. In recognition of the Government's significant funding for the development and manufacturing of the product in this Project Agreement and the Government's need to provide sufficient quantities of a safe and effective COVID-19 vaccine to protect the United States population, the Government shall have the remedy described in this section to ensure sufficient supply of the product to meet the needs of the public health or national security. This remedy is not available to the Government unless and until both of the following conditions are met:

i. Novavax gives written notice, required to be submitted to the Government no later than 15 business days, of:
    a. any formal management decision to terminate manufacturing of the NVX-CoV-2373 vaccine prior to delivery of 100 million doses to USG;
    b. any formal management decision to discontinue sale of the NVX-CoV-2373 vaccine to the Government prior to delivery of 100 million doses to USG; or
    c. any filing that anticipates Federal bankruptcy protection; and
ii. Novavax has submitted an Emergency Use Authorization under §564 of the FD&C Act or a biologics license application provisions of §351(a) of the Public Health Service Act (PHSA).

b. If both conditions listed in section (a) occur, Novavax, upon the request of the Government, shall provide the following items necessary for the Government to pursue manufacturing of the NVX-CoV-2373 vaccine with a third party for exclusive sale to the U.S. Government:

i. a writing evidencing a non-exclusive, nontransferable, irrevocable (except for cause), royalty-free paid-up license to practice or have practiced for or on behalf of the U.S. Government any Background IP as defined in clause 7.1 necessary to manufacture or have manufactured the NVX-CoV2373 vaccine;

ii. necessary FDA regulatory filings or authorizations owned or controlled by Novavax related to NVX-Cov2373 and any confirmatory instrument pertaining thereto; and

iii. any outstanding Deliverables contemplated or materials purchased under this Project Agreement.

c. This Article shall be incorporated into any contract for follow-on activities for the Government to acquire and use additional doses of the product. Per section 1.3, the estimated quantity for follow-on production/procurement is approximately 560 million doses.

d. This Article will survive the acquisition or merger of the Contractor by or with a third party. This Article will survive the expiration of this agreement.

11. SECURITY

The security classification level for this effort is UNCLASSIFIED.

12.0 MISCELLANEOUS REQUIREMENTS (SAFETY, ENVIRONMENTAL, ETC.)

N/A

13.0 GOVERNMENT FURNISHED PROPERTY/MATERIAL/INFORMATION

14.0 AGREEMENTS OFFICER'S REPRESENTATIVE (AOR) AND ALTERNATE AOR CONTACT INFORMATION

AOR

NAME: (b) (6)
EMAIL: (b) (6)
PHONE: (b) (6)
AGENCY NAME/DIVISION/SECTION: Joint Program Executive Office, Joint Program Lead-Enabling Biotechnologies

Alternate AOR

NAME: TBD
MAILING ADDRESS:
EMAIL:
PHONE:
AGENCY NAME/DIVISION/SECTION: HHS/ASPR/BARDA

ENCLOSURE 3: PAYMENT REQUEST INFORMATION

Novavax, Inc. is requesting a payment upon incurring costs, for a total of (b) (4) to support the development of NVX-CoV2373 as a vaccine for SARS-CoV-2 Coronavirus. The costs, as outlined below, are incorporated into estimates from subcontractors under milestones associated with manufacture. Novavax will work with subcontractors to ensure the appropriate accounting for pre-award costs during subcontract finalization and subsequent billing.

Projected Expenditures

Cost Element	Task/Purpose	Amount
Materials		
Antigen	(b) (4)	
Adjuvant	(b) (4)	
Adjuvant	(b) (4)	
Reservations Fees		
AGC Bio Seattle	(b) (4)	
PolyPeptide	(b) (4)	
Fuji RTP	(b) (4)	
Fuji Texas	(b) (4)	
Acceleration Fee		
Fuji	(b) (4)	
Subtotal		(b) (4)
Indirect + Fee Burden		(b) (4)
Total Requested Amount		(b) (4)

I. Financial Institution Information
Novavax, Inc.
21 Firstfield Road
Gaithersburg, MD 20878

Name of Bank: (b) (4)
Address: (b) (4)
(b) (4)

ABA #: (b) (4) , (b) (4) (b) (4)
Swift: (b) (4)

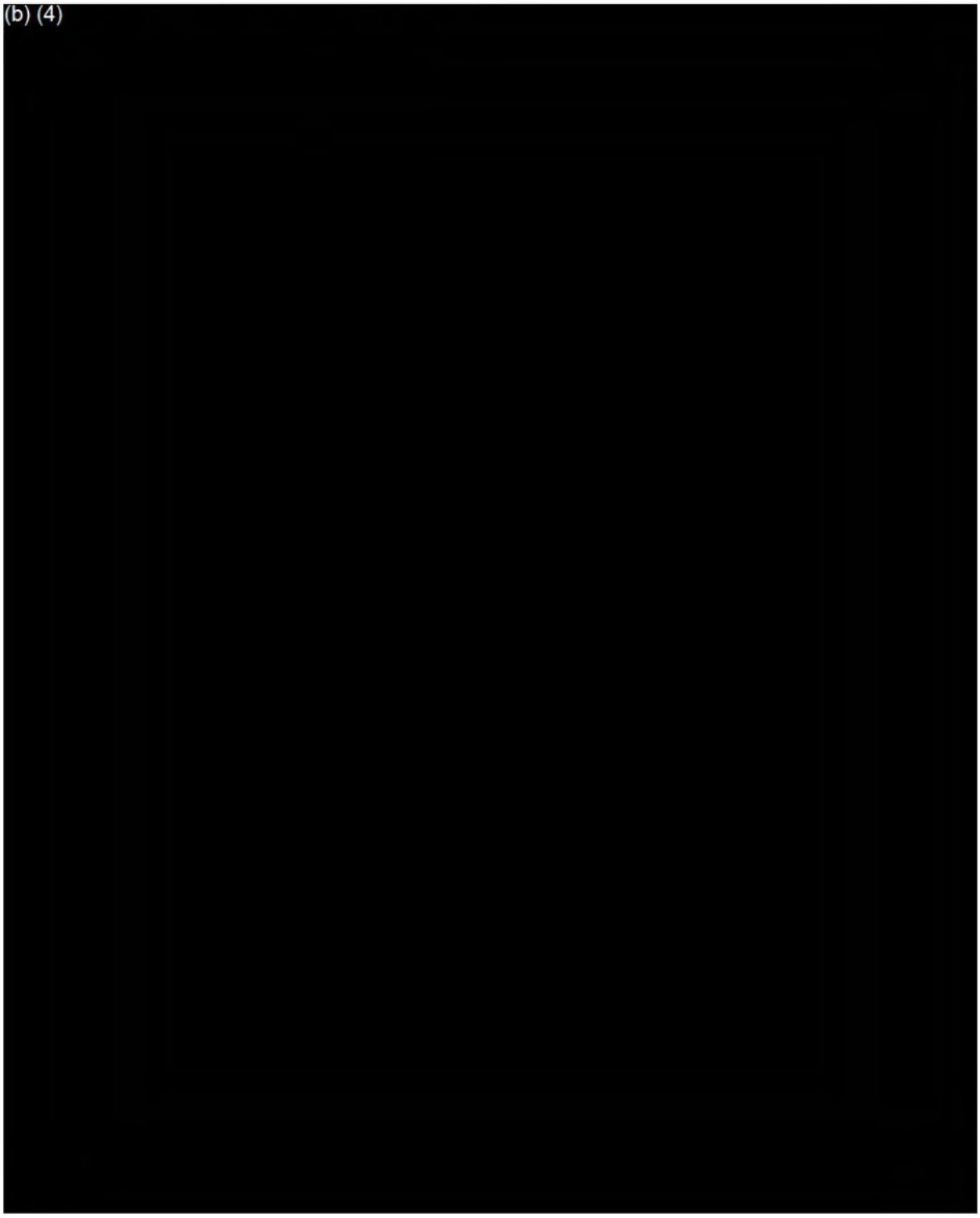
II. Justification for Requesting the Payment

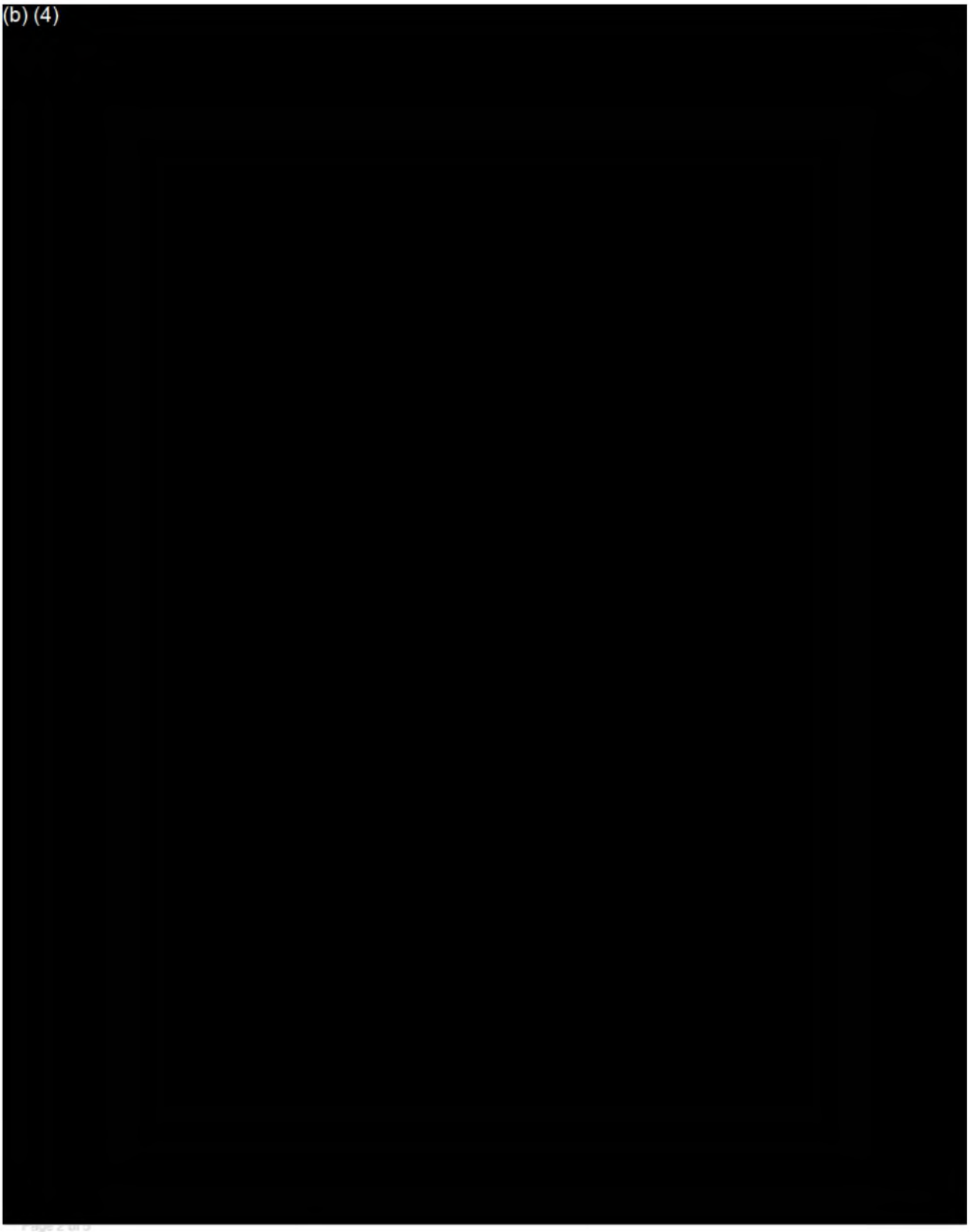
- **Materials Costs: -** (b) (4) **Direct Costs**
  Procurement and qualification of critical long lead raw materials needed to produce 100M doses of NVX-CoV-2373 in 2020 and to ensure availability of 100M additional doses of NVX-CoV-2373 in 2021. This also includes materials for the purchase of a stockpile of certain critical long lead raw materials for the Matrix-M Adjuvant, necessary to rapidly initiate large-scale manufacturing without a delay. This will ensure timely availability of the vaccine candidate to the US population when needed, a primary mission of HHS in support of OWS.

- **Reservation and Acceleration Fees: -** (b) (4) **Direct Costs**
  To quickly address the urgent need presented by the COVID-19 pandemic, Novavax will rely on the reservation of dedicated capacity from manufacturing service provides to be able to produce NVX-CoV-2373. This will ensure timely availability of the vaccine candidate to the US population when needed, a primary mission of HHS in support of OWS.

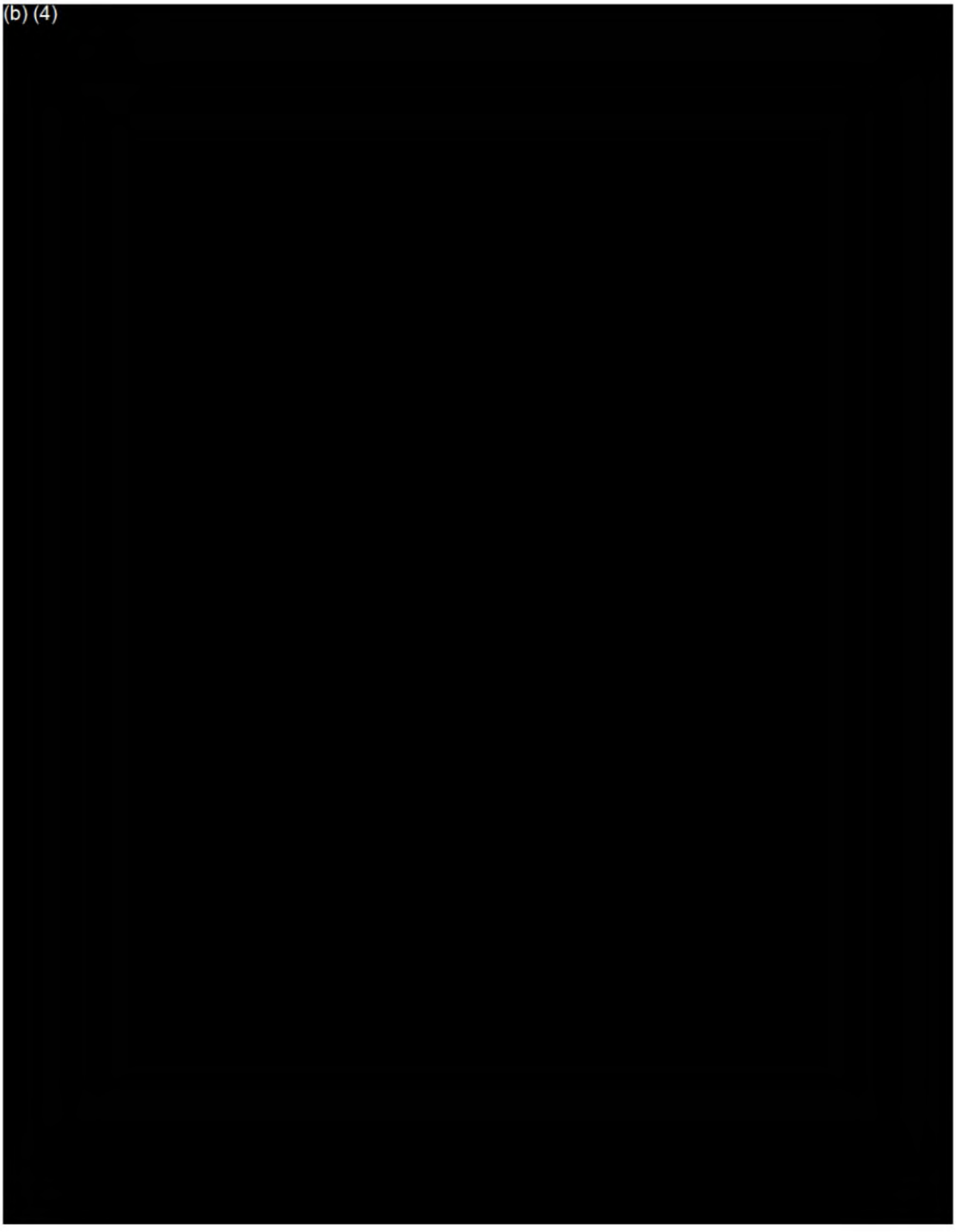
ENCLOSURE 4: PATENT LISTING

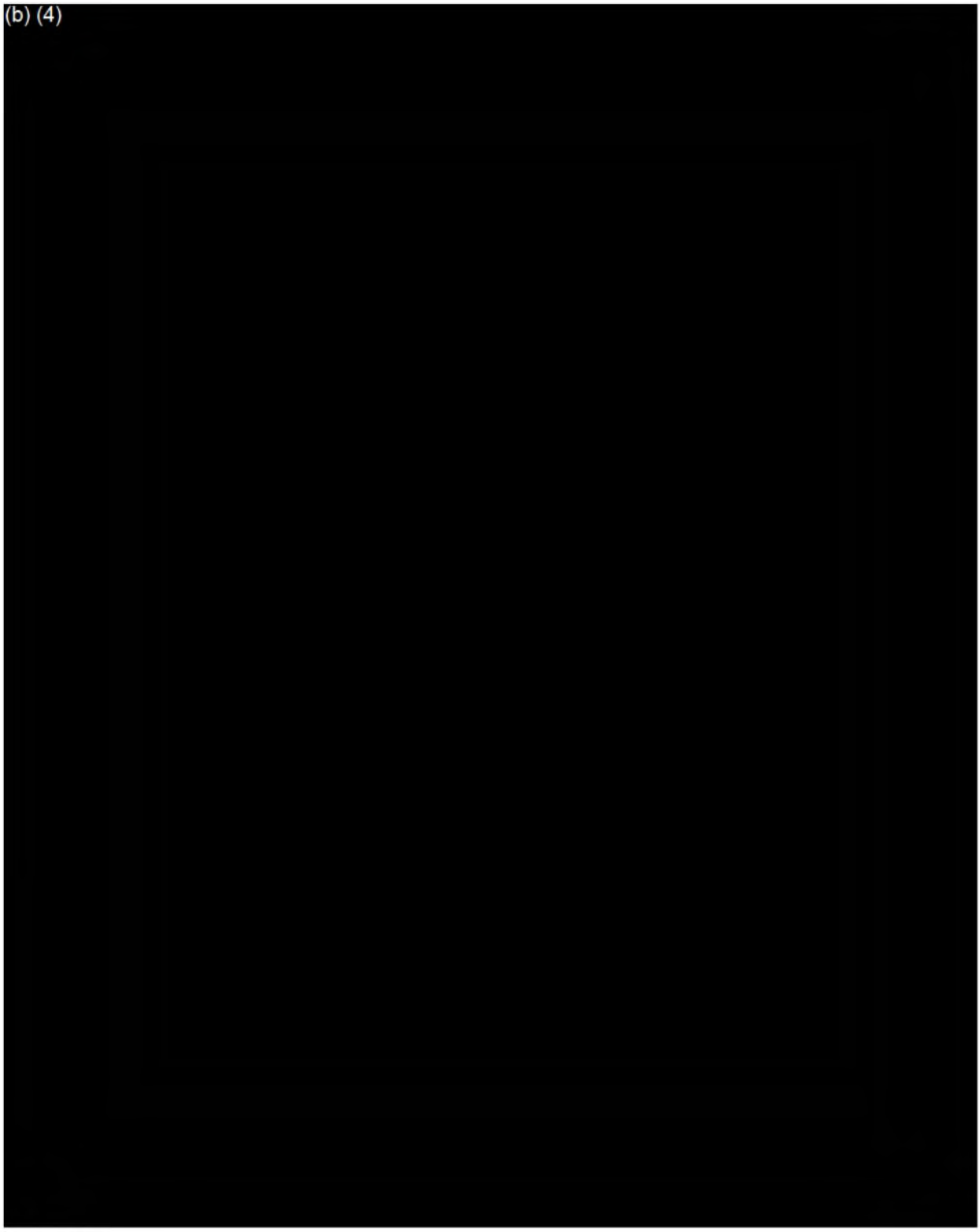
(b) (4)





(b) (4)




(b) (4)

(b) (4)

[redacted]

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Attachment C

52.204-25 Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.

As prescribed in 4.2105(b), insert the following clause:

PROHIBITION ON CONTRACTING FOR CERTAIN TELECOMMUNICATIONS AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT (AUG 2020)

(a) *Definitions.* As used in this clause—

Backhaul means intermediate links between the core network, or backbone network, and the small subnetworks at the edge of the network (e.g., connecting cell phones/towers to the core telephone network). Backhaul can be wireless (e.g., microwave) or wired (e.g., fiber optic, coaxial cable, Ethernet).

Covered foreign country means The People's Republic of China.

Covered telecommunications equipment or services means—

(1) Telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities);

(2) For the purpose of public safety, security of Government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities);

(3) Telecommunications or video surveillance services provided by such entities or using such equipment; or

(4) Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise connected to, the government of a covered foreign country.

Critical technology means—

(1) Defense articles or defense services included on the United States Munitions List set forth in the International Traffic in Arms Regulations under subchapter M of chapter I of title 22, Code of Federal Regulations;

(2) Items included on the Commerce Control List set forth in Supplement No. 1 to part 774 of the Export Administration Regulations under subchapter C of chapter VII of title 15, Code of Federal Regulations, and controlled—

(i) Pursuant to multilateral regimes, including for reasons relating to national security, chemical and biological weapons proliferation, nuclear nonproliferation, or missile technology; or

(ii) For reasons relating to regional stability or surreptitious listening;

(3) Specially designed and prepared nuclear equipment, parts and components, materials, software, and technology covered by part 810 of title 10, Code of Federal Regulations (relating to assistance to foreign atomic energy activities);

(4) Nuclear facilities, equipment, and material covered by part 110 of title 10, Code of Federal Regulations (relating to export and import of nuclear equipment and material);

(5) Select agents and toxins covered by part 331 of title 7, Code of Federal Regulations, part 121 of title 9 of such Code, or part 73 of title 42 of such Code; or

(6) Emerging and foundational technologies controlled pursuant to section 1758 of the Export Control Reform Act of 2018 (50 U.S.C. 4817).

Interconnection arrangements means arrangements governing the physical connection of two or more networks to allow the use of another's network to hand off traffic where it is ultimately delivered (e.g., connection of a customer of telephone provider A to a customer of telephone company B) or sharing data and other information resources.

Reasonable inquiry means an inquiry designed to uncover any information in the entity's possession about the identity of the producer or provider of covered telecommunications equipment or services used by the entity that excludes the need to include an internal or third-party audit.

Roaming means cellular communications services (e.g., voice, video, data) received from a visited network when unable to connect to the facilities of the home network either because signal coverage is too weak or because traffic is too high.

Substantial or essential component means any component necessary for the proper function or performance of a piece of equipment, system, or service.

(b) *Prohibition.*

(1) Section 889(a)(1)(A) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2019, from procuring or obtaining, or extending or renewing a contract to procure or obtain, any equipment, system, or service that uses covered telecommunications equipment or services

as a substantial or essential component of any system, or as critical technology as part of any system. The Contractor is prohibited from providing to the Government any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system, unless an exception at paragraph (c) of this clause applies or the covered telecommunication equipment or services are covered by a waiver described in FAR 4.2104.

(2) Section 889(a)(1)(B) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2020, from entering into a contract, or extending or renewing a contract, with an entity that uses any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system, unless an exception at paragraph (c) of this clause applies or the covered telecommunication equipment or services are covered by a waiver described in FAR 4.2104. This prohibition applies to the use of covered telecommunications equipment or services, regardless of whether that use is in performance of work under a Federal contract.

(c) *Exceptions.* This clause does not prohibit contractors from providing—

(1) A service that connects to the facilities of a third-party, such as backhaul, roaming, or interconnection arrangements; or

(2) Telecommunications equipment that cannot route or redirect user data traffic or permit visibility into any user data or packets that such equipment transmits or otherwise handles.

(d) *Reporting requirement.*

(1) In the event the Contractor identifies covered telecommunications equipment or services used as a substantial or essential component of any system, or as critical technology as part of any system, during contract performance, or the Contractor is notified of such by a subcontractor at any tier or by any other source, the Contractor shall report the information in paragraph (d)(2) of this clause to the Contracting Officer, unless elsewhere in this contract are established procedures for reporting the information; in the case of the Department of Defense, the Contractor shall report to the website at *https://dibnet.dod.mil.* For indefinite delivery contracts, the Contractor shall report to the Contracting Officer for the indefinite delivery contract and the Contracting Officer(s) for any affected order or, in the case of the Department of Defense, identify both the indefinite delivery contract and any affected orders in the report provided at *https://dibnet.dod.mil.*

(2) The Contractor shall report the following information pursuant to paragraph (d)(1) of this clause:

(i) Within one business day from the date of such identification or notification: The contract number; the order number(s), if applicable; supplier name; supplier unique entity identifier (if known); supplier Commercial and Government Entity (CAGE) code (if known);

brand; model number (original equipment manufacturer number, manufacturer part number, or wholesaler number); item description; and any readily available information about mitigation actions undertaken or recommended.

(ii) Within 10 business days of submitting the information in paragraph (d)(2)(i) of this clause: Any further available information about mitigation actions undertaken or recommended. In addition, the Contractor shall describe the efforts it undertook to prevent use or submission of covered telecommunications equipment or services, and any additional efforts that will be incorporated to prevent future use or submission of covered telecommunications equipment or services.

(e) *Subcontracts.* The Contractor shall insert the substance of this clause, including this paragraph (e) and excluding paragraph (b)(2), in all subcontracts and other contractual instruments, including subcontracts for the acquisition of commercial items.

(End of clause)

Attachment A
Statement of Work
(Incorporated as of Modification No. 03; changes to Sections 4, 5, and 11 are indicated in bold italics.)

For
Rapid (WF10) Advanced Research & Development to Large Scale Manufacturing of NVX-CoV-2373 as a Vaccine for SARS-CoV-2 Coronavirus

RPP #: 20-11
Project Identifier: MCDC2011-001
Consortium Member: Novavax, Inc.
Title of Proposal: Rapid (WF10) Advanced Research & Development to Large Scale Manufacturing of NVX-CoV-2373 as a Vaccine for SARS-CoV-2 Coronavirus
Requiring Activity: Joint Mission between the Department of Health and Human Services and Department of Defense to Combat COVID-19

1.0 INTRODUCTION, SCOPE, AND OBJECTIVES

1.1 Introduction

To meet the needs of the Coronavirus Disease 2019 (COVID-19) pandemic, the United States Government (USG) is identifying and will support development and at-scale manufacturing of selected vaccine candidates, to ensure timely availability to the US population when needed. This is the primary focus of the mission being executed by the Department of Health and Human Services (HHS) and Department of Defense (DoD), in support of Operation Warp Speed (OWS).

The USG is interested in pursuing prototype vaccines that are in an advanced stage of development, and will support companies that can, in parallel with nonclinical, clinical and regulatory development, rapidly establish the manufacturing capacity required to meet the USG's objective of supplying a safe and effective Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) vaccine to the entire US population. The USG is tasked with marshaling the efforts of the US biotechnology industry to achieve this goal.

1.2 Definition of the Prototype Project

Consistent with USG objectives, the "prototype project" under this agreement is defined as the manufacture and delivery of 100M doses of a SARS-CoV-2 vaccine, NVX-CoV2373, which is suitable for use in humans under a sufficiently informed deployment strategy, and the advanced positioning of a stockpile of critical long lead raw materials for the Matrix-M adjuvant. As such, the "prototype project" will effectively demonstrate Novavax's ability to rapidly stand up large scale manufacturing and seamlessly transition into ongoing production.

The NVX-CoV-2373 vaccine is comprised of the Matrix-M™ adjuvant, and antigen (SARS-CoV-2 spike protein). The vaccine is filled into a multi-dose vial ((b) (4)) and is stored at refrigerated temperature (2-8°C).

Successful development of the prototype will demonstrate Novavax's ability to rapidly stand up large scale manufacturing and seamlessly transition into ongoing production capability, in order to rapidly manufacture to meet surge requirements with little advance notification, and demonstrate capability to stockpile and distribute large quantities of the vaccine to respond when needed, including in order to supply use in clinical studies, under an Emergency Use Authorization (EUA), or pursuant to other clearance from the U.S. Food and Drug Administration (FDA).

Successful completion of the prototype will require three coordinated and integrated lines of effort:

a) Large scale manufacturing, compliant with 21 CFR Parts 210 and 211, and the Drug Supply Chain Security Act (DSCA), to the extent applicable at the time of manufacturing by statute and FDA interpretive guidance thereof.
b) Parallel nonclinical and clinical studies required to determine if the vaccine is safe and effective.
c) Compliance with all applicable U.S. regulatory requirements.

It is important to note that while results of nonclinical and clinical studies are critical to develop use case scenarios and, in turn, inform the USG's deployment strategy as it relates to product manufactured under this agreement, successful development of the prototype is dependent only on the validity of data from these studies. The degree to which the data are "positive" or "negative" is not a factor in demonstration of the prototype.

1.3 Follow-on Activity

This prototype project includes unpriced options for follow-on production/procurement. During the performance of the prototype, the USG and Novavax will negotiate the scope and price of production/procurement. If the prototype project is successful, the USG may then enter into follow-on production/procurement by executing these options through a separate stand-alone production/procurement agreement, to be negotiated in terms of scope and price as described in the following paragraph.

In accordance with 10.U.S.C. 2371b(f), and upon demonstration of the prototype, or at the accomplishment of particularly favorable or unexpected results that would justify transitioning to production/procurement, EUA, or Biologics License Application (BLA) approved by the FDA, the USG and Novavax may enter into a non-competitive production/procurement follow-on agreement or contract for additional production/procurement, to partially or completely meet the USG objective of supplying a safe and effective SARS-CoV-2 vaccine to vaccinate up to 300M people in the targeted population (≈560M additional doses).

1.4 Scope

Novavax has defined a scope of activities in order to successfully develop the prototype, as defined above. The scope is based on the following assumptions regarding manufacturing and clinical dose:

- Manufacturing Assumptions and Clinical Dose
  - The NVX-CoV-2373 vaccine is comprised of the Matrix-M™ adjuvant, and antigen (SARS-CoV-2 spike protein).
  - A dose range of 5-25 µg of antigen is under clinical study. The anticipated dose based on clinical data obtained to date is (µg of antigen with (b µg of Matrix-M adjuvant.
  - For planning purposes, (b) [redacted] (b) µg antigen/dose) has been used and the calculations in this scope of work have been based on this dose.
  - The antigen production is the rate-limiting step in vaccine production. The Matrix-M adjuvant will be available prior to antigen production. Dose production has been calculated based on the availability of antigen. Novavax is planning on a batch-by-batch rapid fill/finish once antigen is manufactured and available.
  - The estimated production schedule based on the (b µg antigen/dose (base case) and (µg antigen /dose (anticipated case) is in the table below:

	Estimated Schedule of Cumulative Doses Manufactured by Month				
Dosage	**Oct 2020**	**Nov 2020**	**Dec 2020**	**Jan 2021**	**Feb 2021**
(b µg/dose (base case)	(b) (4) [redacted]	[redacted]	[redacted]	[redacted]	[redacted]
(µg/dose (anticipated case)	(b) (4) [redacted]	[redacted]	100,000,000*		

*Actual cumulative projected production at (µg/dose is (b) (4) [redacted] in December 2020. Some doses may be in progress at the end of December 2020.

**Actual cumulative projected production at (b) µg/dose is (b) (4) [redacted] in February 2021.

The scope includes the following activities:

- Manufacturing
  - Manufacturing of 100M doses (at (b µg/dose, (b) (4) [redacted]) of NVX-CoV-2373 vaccine in 2020 for distribution to the Government upon EUA under section 564 of the Food, Drug, and Cosmetic (FD&C) Act or a biologics licensure granted under Section 351(a) of the Public Health Service Act by the U.S. FDA.
  - Establishment of large-scale current Good Manufacturing Practice (cGMP) manufacturing capacity compliant with 21 CFR Parts 210 and 211, and the DSCA to the extent applicable at the time of manufacturing by statute and FDA interpretive guidance thereof.
  - Comparability among clinical vaccine lots and commercial lots using a comparability protocol linked to the product associated with the Phase 1 clinical study. For adjuvant components, the same raw material lot(s) will be used for the current and new Contract

Manufacturing Organization (CMO) processes for the comparability protocol, and the same test lab will be used to ensure only process differences are being evaluated.

- Validation of manufacturing processes will be performed to cGMP standards.

- Clinical
  - Phase 3 pivotal clinical trial harmonized with USG clinical strategies.
  - A Phase 3 clinical trial in pediatric populations (<18 years).
  - Phase 2 studies in at-risk subpopulations (co-morbidities, (b) (4) , immunocompromised), as well as studies to support manufacturing site comparability.

- Non-clinical
  - Studies to support EUA and regulatory approval (BLA).

- Regulatory
  - EUA submission when data supports it, while maintaining progress toward eventual BLA submission.
  - BLA submission when appropriate.
  - Regulatory support activities (Investigational New Drug (IND) submissions) for manufacturing, clinical, non-clinical studies.
  - Meetings as-needed with regulators.

- Project Management
  - Mandatory reporting requirements, as described in the Base Agreement.
  - Submission of Monthly Progress Reports. Format will be agreed on by the contractor and Agreements Officer's Representative (AOR), and will include both technical and financial status and expenditure forecast.
  - Facilitation of biweekly teleconferences with Novavax and USG Subject Matter Experts.
  - Final prototype project report and applicable patents report(s).
  - Work Breakdown Structure (WBS) and Integrated Master Schedule (IMS).
  - All Regulatory correspondence relevant to the scope of work proposed, including communications with the FDA, and all submissions.

1.4.1 Novavax Project Plan

This is Novavax's plan as of the date of the submission. Novavax desires to move quickly to large scale development as rapidly as possible, in order to meet the objectives of this proposal. As the COVID-19 pandemic is an evolving situation, Novavax may need to adapt its plan in response to FDA guidance, opportunities for manufacturing efficiencies, and clinical trial data.

1.5 Resolution of Conflicting Language

If there is a conflict between the Project Agreement (of which this Statement of Work is part) and the Base Agreement (Medical CBRN Consortium (MCDC) Base Agreement No.: 2020-530), the Project Agreement language will supersede and control the relationship of the parties.

2.0 APPLICABLE REFERENCES

N/A

3.0 REQUIREMENTS

3.1 Major Task: cGMP Manufacturing of NVX-CoV-2373 compliant with 21 CFR 210 and 211

3.1.1 Subtask: Raw Materials – Obtain Critical Starting Materials for Adjuvant Manufacturing

Sufficient Saponin to manufacture up to 100M vaccine doses will be purchased (Desert King, headquartered in San Diego, CA, facilities in Chile). Long-lead, critical, and limited-supply materials (b) (4) will be purchased for the additional 560M vaccine doses to meet the contact requirement, in order to ensure capability to rapidly manufacture to meet surge requirements with little advance notification and demonstrate capability to stockpile and distribute large quantities of the vaccine to respond when needed.

3.1.2 Subtask: Raw Materials – Obtain Critical Starting Materials for Antigen and Fill/Finish Manufacturing

Sufficient materials (vials, stoppers, other consumables) to manufacture up to 100M vaccine doses will be purchased (sources TBD).

3.1.3 Subtask: Raw Materials – (b) (4) Intermediates to Produce Matrix-M Adjuvant Matrix-M Adjuvant

(b) (4) to supply large-scale manufacturing of vaccine doses will be manufactured at (b) (4) and PolyPeptide (Torrance, CA & Malmö, Sweden). Technology transfer and start-up of the PolyPeptide facility in Torrance, CA will be completed. Long lead, critical, and limited supply materials will be purchased in order to achieve the goal of large-scale production.

3.1.4 Subtask: Matrix-M Adjuvant Manufacturing to Supply 100M Vaccine Doses

Matrix-M Adjuvant bulk components will be manufactured at ACG Biologics (Seattle, WA) to supply 100M vaccine doses. Technology transfer and start-up of the AGC Bio facility in Seattle will be completed. An analytical comparability manufacturing study and validation studies will be performed as part of the tech transfer to each manufacturing site.

3.1.5 Subtask: Antigen Manufacturing to Supply 100M Vaccine Doses

Antigen will be manufactured at Fuji (2 sites – College Station, TX and Research Triangle Park, NC) to supply 100M vaccine doses. Technology transfer and scale-up activities will be completed. An analytical comparability manufacturing study and validation studies will be performed as part of the tech transfer to each manufacturing site.

3.1.6 Subtask: Fill/Finish of 100M Vaccine Doses

100M doses of finished vaccine in (b) (4) vials will be manufactured at Baxter (Bloomington, IN, USA). This will include secondary packaging. Technology transfer and scale-up activities will be completed. An analytical comparability manufacturing study and validation studies will be performed as part of the tech transfer to each manufacturing site.

3.1.7 Subtask: Shipping and Storage

Novavax assumes that it will maintain a Vendor Managed Inventory (VMI) system for a period of 12 months, with shipments to 10 geographic zones in the USA. Novavax will perform activities to establish compliance with DSCA to the extent applicable at the time of manufacturing, by statute and FDA interpretive guidance thereof.

3.2 Major Task: Clinical Studies

Novavax will perform these clinical trials and deliver the results in an interim Clinical Study Report (CSR) at the completion of enrollment, and the final CSR when available. These trials will be conducted using a Clinical Research Organization (CRO) that is to be determined.

3.2.1 Subtask: Phase 3 Global Efficacy Study, Adults ≥ 18 and < 75 years

Study: Phase 3 – Global Efficacy Study (to be harmonized with other USG studies), 2019nCoV-301.

Population: Adults ≥ 18 years, inclusive of subjects with more severe co-morbid conditions.

Locations: North America, Europe; may include Africa, Asia, Oceania, South America.

Primary Objectives: Clinical efficacy, safety, immunogenicity.

Design: Randomized, observer-blinded, placebo-controlled.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + Matrix-(b) – dose determined by Phase 2 dose confirmation study, Placebo; (b) (4)

Enrollment: TOTAL N: ~30,000 (adjusted for expected endpoint incidence). (b) (4)

3.2.2 Subtask: Phase 2 Efficacy Expansion (US), Adults ≥ 18 and < 75 years

Study: Phase 2 - Part 3 efficacy expansion (US), 2019nCoV-204.

Population: Adults ≥ 18 and < 75 years.

Locations: USA.

Primary Objectives: Clinical efficacy, safety, immunogenicity.

Design: Randomized, observer-blinded, placebo-controlled.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + (b) (4) not greater than (b) (4) to allow for rapid initiation. Placebo. ~0.5 mL dose IM injection, up to 2 doses at Day 0 and Day 21.

Enrollment: TOTAL: (b) (4). Adjusted for expected event occurrence. Event driven analysis. Initiation of study gated on completion of Phase 1 study, dose-selection and regulatory approval.

3.2.3 Subtask: Phase 2 Study in Immunocompromised Persons (HIV-positive adult subjects) (Africa)

Study: Phase 2 study in immunocompromised persons (HIV-positive adult subjects) (Africa).

Population: Adults ≥ 18 and < 65 years.

Locations: Republic of South Africa (RSA)

Primary Objectives: Safety, immunogenicity (serum and cellular).

Design: Randomized, observer-blinded, placebo-controlled.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + Matrix-M1; Placebo, 0.5 mL dose IM injection, up to 2 doses at Day 0 and Day 21.

Enrollment: Total N = 2,640 – 2,880 (with n=240 - 480 HIV+); 1:1 Vaccine to placebo. Initiation gated on completion of Phase 1 study, dose selection, and regulatory approval.

3.2.4 Subtask: (b) (4)

Study: (b) (4)

Population: (b) (4)

Locations: (b) (4)

Primary Objectives: (b) (4).

Design: Randomized, observer-blinded, placebo-controlled.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + Matrix-(b) (4)

Enrollment: (b) (4). Initiation gated on benefit:risk assessment (derived from Task 2.3.1 and/or 2.3.2 and/or other Phase 2 studies) and regulatory approval to conduct studies in this vulnerable population.

3.2.5 Subtask: Phase 2 Manufacturing Site Lot Consistency/Comparability Study (US or other)

Study: Phase 2 manufacturing site lot consistency/comparability study (US or other), 2019nCoV-201.

Population: Adults ≥ 18 to < 50 years.

Locations: USA.

Primary Objectives: Safety, immunogenicity.

Design: Randomized, observer-blinded, placebo-controlled.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + (b) (4)

Enrollment: ~600 per cohort, each cohort having 1:1 randomization with Emergent (antigen)/Novavax AB (adjuvant) manufacturing site and new manufacturing sites. Study size may be adjusted to allow non-inferiority testing.

3.2.6 Subtask: Phase 2, Maternal Immunization

Study: Phase 2, maternal immunization, (trial ID TBD).

Population: Adults ≥ 18 to < 40 years.

Locations: Global.

Primary Objectives: Safety, immunogenicity.

Design: Randomized, observer-blinded, placebo-controlled.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + Matrix-M1; Placebo, 0.5 mL dose IM injection, up to 2 doses at Day 0 and Day 22.

Enrollment: Total = 800 mothers + baby. Initiation gated on benefit:risk assessment (derived from Task 2.3.1 and/or 2.3.2 and/or other Phase 2 studies) and regulatory approval to conduct studies in this vulnerable population.

3.2.7 Subtask: Pharmacovigilance; Establishment of Registration Safety Database

A registration safety database will be established to comply with FDA requirements for product safety and licensure.

3.2.8 Subtask: (b) (4)

Study: (b) (4)

Population: (b) (4)

Location: (b) (4)

Primary Objective: (b) (4)

Design: Randomized, observer-blinded, placebo (or active vaccine) control.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + Matrix- (b) (4)

Enrollment: TOTAL: N ~12,500 (based on agreed VE, power, and LBCI). (b) (4) [redacted]. Adjusted for expected event occurrence if robust demonstration of clinical efficacy is required by the FDA. Event driven analysis for study termination.

3.3 Major Task: Non-Clinical Studies

Novavax will perform these non-clinical studies and deliver the results in a study report at completion.

3.3.1 Mouse Study, Immunogenicity

Study 702-100. Immunogenicity (b) (4)) in mice for vaccine efficacy profile to comply with FDA guidelines.

3.3.2 Rhesus Study, Immunogenicity

Study 702-099. Immunogenicity/challenge (b) (4) in rhesus monkeys for vaccine efficacy profile to comply with FDA guidelines.

3.3.3 Hamster Study, Immunogenicity

Study 702-102. Immunogenicity/challenge study in hamster ((b) (4) [redacted]) for vaccine efficacy profile to comply with FDA guidelines.

3.3.4 Mouse Study, T-Cell Immunogenicity

Study 702-103. T-cell immunogenicity/challenge study in mice ((b) (4) [redacted]) for vaccine efficacy profile to comply with FDA guidelines.

3.3.5 Hamster Study, T-Cell Immunogenicity

Study 702-105. Immunogenicity/challenge study in hamster ((b) (4) [redacted]) for vaccine efficacy profile to comply with FDA guidelines.

3.3.6 Mouse Study, T-Cell Immunogenicity

Study 702-104. Immunogenicity/challenge study in hamster ((b) (4) [redacted]) for vaccine efficacy profile to comply with FDA guidelines.

3.3.7 Non-Clinical Studies: Collaboration with Univ. of Maryland School of Medicine

Three studies to study enhancement/inhibition and neutralization, and virus challenge of vaccinated mice:

1. Validation of Spike nanoparticles in cell inhibition studies: In vitro inhibition studies on cell line permissive to r2019-nCoV, readout TBD.
2. Neutralization studies with virus against bleeds from mice, In vitro microneutralization studies on cell line permissive to r2019-nCoV, TCID50 or fluorescence readout (TBD).
3. Virus challenge of vaccinated mice (mice vaccinated outside and shipped to UM for challenge), Challenge of vaccinated mice (shipped in for infection from Novavax), Lung pathology, Titer, viral Ribonucleic Acid (RNA) quantitation, pathology scoring and reports.

3.3.8 Structural Study of COVID-19 Spike Protein and its Complex with Host Receptor (cooperation with Baylor College of Medicine)

Study to determine the structures of recombinant COVID-19. Spike protein in nanoparticles used in Novavax's human vaccine and in complex with its host receptor ACE2. Will obtain a high-resolution cryoEM structure of full-length COVID-19 Spike protein and a high-resolution cryoEM structure of full-length COVID-19 Spike protein in complex with human receptor ACE2.

3.3.9 Neutralizing Assay Histopathology for On-going (b) (4)

Histopathology readings for current neutralization studies in (b) (4). This will support the safety profile of the vaccine for FDA approval.

3.3.10 Mouse Study, Immunogenicity (b) Studies

Individual immunogenicity studies ((b) (4)) in mice for vaccine efficacy profile in different sub-populations to comply with FDA guidelines.

3.4 Major Task: Regulatory Affairs

Novavax will conduct the regulatory activities below, including BLA prep and submission, and provide the meeting minutes and applications to the USG.

3.4.1 Subtask: EUA Submission and Supporting Meetings and Regulatory Filings

An EUA will be submitted to the FDA upon obtaining sufficient clinical data. EUA, FDA meetings to support EUA, submission planning support for the Chemistry, Manufacturing, and Controls (CMC) team, EUA strategy and meeting support, and submission preparation support activities, will all be completed.

3.4.2 Subtask: IND Submission Updates and FDA Meetings

This task will include submissions to the IND and possible FDA meetings that will be required prior to the BLA submission.

3.4.3 Subtask: BLA Submission

A BLA will be submitted to the FDA upon obtaining sufficient clinical data, FDA meetings to support BLA, submission planning support for the CMC team, BLA strategy and meeting support, and submission preparation support activities, will all be completed.

3.5 Major Task: Project Management and Reporting

3.5.1 Subtask: Kick-Off Meeting and Initial Baseline Review of IMS

Novavax shall conduct a Kick-Off Meeting and an initial review with the USG of the IMS, upon initiation of the program.

3.5.2 Subtask: Biweekly Meetings with OWS

Novavax shall submit the agenda in advance. Any technical updates shall be provided in advance for the Government team to review. Minutes shall be submitted after the biweekly meeting to the USG.

3.5.3 Subtask: Written Quarterly Reports

Novavax shall submit quarterly reports to the USG.

3.5.4 Subtask: Written Annual Reports

Novavax shall submit the annual reports to the USG.

3.5.5 Subtask: Written Final Report

Novavax shall submit the final report to the USG.

3.6 Optional Task: Follow-On Production

Follow-on production of finished doses of vaccine up to 560M doses.

4.0 DELIVERABLES

Del. #	Deliverable Description	Due Date	Milestone Reference	SOW Reference	Government Role	Data Type/Data Rights
	Manufacturing					
4.1	(b) (4) [redacted]	[redacted]	5.1	3.1.1	Reviewer	(b) (4) [redacted]
4.2	(b) (4) [redacted]	[redacted]	5.2	3.1.2	Reviewer	(b) (4) [redacted]
4.3	(b) (4) [redacted]	[redacted]	5.3	3.1.3	Reviewer	(b) (4) [redacted]
4.4	(b) (4) [redacted]	[redacted]	5.4	3.1.4	Reviewer	(b) (4) [redacted]
4.5	(b) (4) [redacted]	[redacted]	5.5	3.1.5	Reviewer	(b) (4) [redacted]

Del. #	Deliverable Description	Due Date	Milestone Reference	SOW Reference	Government Role	Data Type/Data Rights
	(b) (4)					
4.6	(b) (4)		5.6	3.1.6	Reviewer	(b) (4)
4.7	(b) (4)		5.7	3.1.7	Reviewer	(b) (4)
	Clinical					
4.8	(b) (4)		5.8	3.2.1	Reviewer	(b) (4)
4.9	(b) (4)		5.9	3.2.2	Reviewer	(b) (4)
4.10	(b) (4)		5.10	3.2.3	Reviewer	(b) (4)
4.11	(b) (4)		5.11	3.2.4	Reviewer	(b) (4)
4.12	(b) (4)		5.12	3.2.5	Reviewer	(b) (4)
4.13	(b) (4)		5.13	3.2.6	Reviewer	(b) (4)
4.14	(b) (4)		5.14	3.2.7	Reviewer	(b) (4)
4.15	(b) (4)		5.15	3.2.8	Reviewer	(b) (4)

[1] As used herein, "Government Purpose Rights" has the meaning set forth in Article XI, Section 11.01(9) of the Base Agreement, as modified by Section 8.2(b) below.

Del. #	Deliverable Description	Due Date	Milestone Reference	SOW Reference	Government Role	Data Type/Data Rights
	Non- Clinical					
4.16	(b) (4) [redacted]	[redacted]	5.16	3.3.1	Reviewer	(b) (4) [redacted]
4.17	(b) (4) [redacted]	[redacted]	5.17	3.3.2	Reviewer	(b) (4) [redacted]
4.18	(b) (4) [redacted]	[redacted]	5.18	3.3.3	Reviewer	(b) (4) [redacted]
4.19	(b) (4) [redacted]	[redacted]	5.19	3.3.4	Reviewer	(b) (4) [redacted]
4.20	(b) (4) [redacted]	[redacted]	5.20	3.3.5	Reviewer	(b) (4) [redacted]
4.21	(b) (4) [redacted]	[redacted]	5.21	3.3.6	Reviewer	(b) (4) [redacted]
4.22	(b) (4) [redacted]	[redacted]	5.22	3.3.7	Reviewer	(b) (4) [redacted]
4.23	(b) (4) [redacted]	[redacted]	5.23	3.3.8	Reviewer	(b) (4) [redacted]
4.24	(b) (4) [redacted]	[redacted]	5.24	3.3.9	Reviewer	(b) (4) [redacted]

Del. #	Deliverable Description	Due Date	Milestone Reference	SOW Reference	Government Role	Data Type/Data Rights
	(b) (4) [redacted]					
4.25	(b) (4) [redacted]	[redacted]	5.25	3.3.10	Reviewer	(b) (4) [redacted]
	Regulatory Affairs					
4.26	(b) (4) [redacted]	[redacted]	5.26	3.4.1	Reviewer	(b) (4) [redacted]
4.27	(b) (4) [redacted]	[redacted]	5.27	3.4.2	Reviewer	(b) (4) [redacted]
4.28	(b) (4) [redacted]	[redacted]	5.28	3.4.3	Reviewer	(b) (4) [redacted]
	Project Management					
4.29	[redacted]	(b) (4) [redacted]	5.29	3.5.1	Reviewer	(b) (4) [redacted]
4.30	[redacted]	(b) (4) [redacted]	5.30	3.5.2	Reviewer	(b) (4) [redacted]
4.31	[redacted]	(b) (4) [redacted]	5.31	3.5.3	Reviewer	(b) (4) [redacted]
4.32	[redacted]	(b) (4) [redacted]	5.32	3.5.4	Reviewer	(b) (4) [redacted]
4.33	[redacted]	(b) (4) [redacted]	5.33	3.5.4	Reviewer	(b) (4) [redacted]
4.34	[redacted]	(b) (4) [redacted]	5.34	3.5.5	Reviewer	(b) (4) [redacted]

Del. #	Deliverable Description	Due Date	Milestone Reference	SOW Reference	Government Role	Data Type/Data Rights
4.35	(b) (4)		*5.35*	*N/A*	*Reviewer*	(b) (4)
TBD		(b)	Option 1	3.6	Reviewer	(b) (4)

Note: Attachment D of the Project Agreement shall be referenced for supplemental security requirements associated with deliverables under this project.

5.0 MILESTONE PAYMENT SCHEDULE

Milestone #	Milestone Description (Deliverable Reference)	Due Date	Total Program Funds
	Manufacturing		
5.1	(b) (4)		
5.2	(b) (4)		
5.3	(b) (4)		
5.4	(b) (4)		
5.5	(b) (4)		
5.6	(b) (4)		
5.7	(b) (4)		
	Clinical		
5.8	(b) (4)		
5.9	(b) (4)		
5.10	(b) (4)		
5.11	(b) (4)		
5.12	(b) (4)		
5.13	(b) (4)		
5.14	(b) (4)		

Milestone #	Milestone Description (Deliverable Reference)	Due Date	Total Program Funds
5.15	(b) (4)		
	Non- Clinical		
5.16	(b) (4)		
5.17	(b) (4)		
5.18	(b) (4)		
5.19	(b) (4)		
5.20	(b) (4)		
5.21	(b) (4)		
5.22	(b) (4)		
5.23	(b) (4)		
5.24	(b) (4)		
5.25	(b) (4)		
	Regulatory Affairs		$10,362,788
5.26	(b) (4)		
5.27	(b) (4)		
5.28	(b) (4)		
	Project Management		$8,303,163
5.29	(b) (4)		
5.30	(b) (4)		
5.31	(b) (4)		
5.32	(b) (4)		
5.33	(b) (4)		

Milestone #	Milestone Description (Deliverable Reference)	Due Date	Total Program Funds
5.34	(b) (4)		
5.35	(b) (4) *es / Regimen*		
	Advanced Material Purchases		
5.36	(b) (4)		
5.37	(b) (4)		
5.38	(b) (4)		
	Reservation Fees		
5.39	(b) (4)		
5.40	(b) (4)		
5.41	(b) (4)		
	Acceleration Fees		
5.43	(b) (4)		
		Total (Cost Plus Fixed Fee)	**$1,600,434,522**
		Period of Performance (July 6, 2020 – December 31, 2021)	**18 Months (Base)**
		Option 1: Follow-On Production	**Cost: (b) (4)**

Simplified Table: Estimated Cost by Project Areas

Area	Cost
Manufacturing (100M doses)	$418,151,118
Non-Clinical	$5,092,957
Clinical	$1,158,524,498
Regulatory	$10,362,788
Project Management	$8,303,163
Total Project Cost	**$1,600,434,523**

Simplified Table: Selected Estimated Costs for Key Deliverables*

Area	Milestone/Deliverable	Start	Finish	Cost

(b) (4)				

* For key deliverables only; does not encompass total project costs.

** Time to obtaining vaccine efficacy data.

6.0 SHIPPING PROVISIONS

The shipment of physical deliverables shall be coordinated with the AOR. Data deliverables shall be provided in accordance with the agreement, and in coordination with the AOR.

7.0 INTELLECTUAL PROPERTY, DATA RIGHTS, AND COPYRIGHTS

7.1 BACKGROUND IP

(a) Ownership. Prior to June 8, 2020, Novavax had funded the development of NVX-CoV2373, and other antecedent vaccine programs relevant to Novavax' proprietary position in the development of NVX-CoV2373, as well as its sf9/baculovirus manufacturing platform, (all "Background IP") through private funding or in collaboration with a funding partner other than the U.S. Government. Such private and non-governmental funding has continued since June 8, 2020 and is expected to continue during the performance of the Project Agreement. A list of all patents and patent applications included in the Background IP is provided below as Enclosure 4. Background IP also consists of (a) manufacturing know-how, including, without limitation, the NVAX-Cov2373 manufacturing process definitions, process development/characterization reports, laboratory scale process procedures, manufacturing records, analytical test methods, product quality target ranges/specifications, quality target product profile, critical quality attributes (collectively "Background Know-How"), (b) data from pre-clinical and clinical research studies, analytical and process development research, and data related to, or generated using, the Background Know-How (collectively, "Background Data"), and (c) proprietary manufacturing materials, including, without limitation, sf9 cell banks (master and working), baculovirus virus stock (master and working), product standards, reference standards, and critical reagents ("Background Materials"). On June 8, 2020, Novavax and the U.S. Department of Defense entered into a Letter Contract for specified U.S.-based clinical and manufacturing development of NVX-CoV2373 which acknowledged Background IP and made no explicit U.S. Government claims to

Background IP or subsequent data arising therefrom. The U.S. Government hereby acknowledges such Background IP in full and further acknowledges that it has no ownership rights to Novavax Background IP under this Project Agreement.

(b) Background IP Limited License to Government. Subject to the terms of the Project Agreement, Novavax grants the U.S. Government a nonexclusive, worldwide, nontransferable, non-sublicenseable license to use the Background IP to the limited extent necessary for the U.S. Government to review and use the Deliverables tendered by Novavax under this Agreement identified in Section 4.0 above, and for no other purpose; provided that the U.S. Government agrees that it may not disclose the Background IP to third parties, or allow third parties to have access to, use, practice or have practiced the Background IP, without Novavax's prior written consent. To the extent that a Deliverable with Foreground IP incorporates or uses Background IP, the Deliverable shall be deemed and considered to comprise Background IP and shall be used by the U.S. Government in accordance with this Background IP Limited License.

(c) Background IP License to Novavax. Subject to the terms of the Project Agreement, the U.S. Government grants to Novavax a nonexclusive, worldwide, nontransferable, irrevocable, paid-up license to any intellectual property (including patents and patent applications) to which the U.S. Government has rights thereto, provided that such license is limited to such intellectual property rights necessary to perform Novavax's obligations under the Project Agreement.

7.2 FOREGROUND IP

(a) Ownership. Notwithstanding anything in the Base Agreement to the contrary, Novavax owns all rights, title and interest in and to any development, modification, discovery, invention or improvement, whether or not patentable, conceived, made, reduced to practice, or created in connection with activities funded under the Project Agreement, including, without limitation, all data and inventions, and intellectual property rights in any of the foregoing ("Foreground IP").

(b) Foreground IP Special License. Subject to the terms of the Project Agreement, Novavax grants the U.S. Government a nonexclusive, worldwide, nontransferable, irrevocable, paid-up license to practice or have practiced the Foreground IP for or on behalf of the U.S. Government ("Foreground IP Special License").

8.0 DATA RIGHTS

Article XI, §11.03 of the Base Agreement is hereby amended, consistent with the "Specifically Negotiated License Rights" capability at Article XI, §§11.01(12) and 11.03(4), as follows:

8.1 Data Ownership.

Novavax owns all rights, title and interest to all Data (as defined in Article XI, Section 11.01(7) of the Base Agreement) generated as a result of the work performed under this Project Agreement, including Subject Data.

8.2 Rights to Data.

(a) Subject Data. Subject to the terms of the Project Agreement, Novavax grants to the U.S. Government a Government purpose rights license to Subject Data that will convert to an unlimited rights license (as the term is defined in Article XI, Section 11.01(14) of the Base Agreement)[2] after three (3) years from the date of delivery. As used herein, "Subject Data" shall mean Technical Data under Article XI, §11.01(13) of the Base Agreement Deliverables that are considered Subject Data are identified in the Deliverable Table set forth in Section 4.0 above.

(b) Transfer of Data. Each party, upon written request to the other party, shall have the right to review and to request delivery of Subject Data, and delivery of such Data shall be made to the requesting party within two weeks of the request, except to the extent that such Data are subject to a claim of confidentiality or privilege by a third party.

(c) Background IP Limited License. To the extent that Subject Data incorporates or uses Background IP, the data shall be deemed and considered to comprise Background IP and shall be used by the U.S. Government in accordance with the Background IP Limited License set forth in Section 7.3 above.

8.3 Background Technical Data Rights Assertions.

Novavax asserts background technical data rights as follows:

The Background Data, as defined in Section 7.1 above, was developed through private funding or in collaboration with a funding partner other than the U.S. Government. Such funding is expected to continue; accordingly, Novavax asserts Background Data as Category A Data pursuant to section 11.02(1) of the Base Agreement and the U.S. Government shall have no rights therein.

9.0 REGULATORY RIGHTS

This agreement includes research with an investigational drug, biologic or medical device that is regulated by the U.S. Food and Drug Administration (FDA) and requires FDA pre-market approval or clearance before commercial marketing may begin. It is expected that this agreement will result in the FDA authorization, clearance and commercialization of NVX-CoV-2373 as a Vaccine for SARS-CoV-2 Coronavirus (the "Technology"). Novavax is the Sponsor of the Regulatory Application (an investigational new drug application (IND), investigational device exemption (IDE), emergency use authorization (EUA), new drug application (NDA), biologics license application (BLA), premarket approval application (PMA), or 510(k) pre-market notification filing (510(k)) or another regulatory filing submitted to the FDA) that controls research under this contract. As the Sponsor of the Regulatory Application to the FDA (as the terms "sponsor" and "applicant" are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20), Novavax has certain standing before the FDA that entitles it to exclusive

[2] As used herein, "Government Use" as used "Purpose Rights" has the meaning set forth in this Section 4.0 means Government purpose rights as defined in the Base Agreement, Article XI, Section 11.01(9).) of the Base Agreement, as modified by Section 8.2(b) below.

communications related to the Regulatory Application. This clause protects the return on research and development investment made by the U.S. Government in the event of certain regulatory product development failures related to the Technology.

Novavax agrees to the following:

a. Communications. Novavax will provide the U.S. Government with all communications and summaries thereof, both formal and informal, to or from FDA regarding the Technology and ensure that the U.S. Government representatives are invited to participate in any formal or informal Sponsor meetings with FDA;

b. Rights of Reference. The U.S. Government is hereby granted a right of reference as that term is defined in 21 C.F.R. § 314.3(b) (or any successor rule or analogous applicable law recognized outside of the U.S.) to any Regulatory Application submitted in support of the statement of work for the Project Agreement. When it desires to exercise this right, the U.S. Government agrees to notify Novavax in writing describing the request along with sufficient details for Novavax to generate a letter of cross-reference for the U.S. Government to file with the appropriate FDA office. The U.S. Government agrees that such letters of cross-reference may contain reporting requirements to enable Novavax to comply with its own pharmacovigilance reporting obligations to the FDA and other regulatory agencies. Nothing in this paragraph reduces the U.S. Government's data rights as articulated in other provisions of the Project Agreement.

c. DoD Medical Product Priority. PL-115-92 allows the DoD to request, and FDA to provide, assistance to expedite development and the FDA's review of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel. Novavax recognizes that only the DoD can utilize PL 115-92. As such, Novavax will work proactively with the DoD to leverage this this law to its maximal potential under this Project Agreement. Novavax shall submit a mutually agreed upon Public Law 115-92 Sponsor Authorization Letter to the U.S. Government within 30 days of award.

10.0 ENSURING SUFFICIENT SUPPLY OF THE PRODUCT

a. In recognition of the Government's significant funding for the development and manufacturing of the product in this Project Agreement and the Government's need to provide sufficient quantities of a safe and effective COVID-19 vaccine to protect the United States population, the Government shall have the remedy described in this section to ensure sufficient supply of the product to meet the needs of the public health or national security. This remedy is not available to the Government unless and until both of the following conditions are met:

i. Novavax gives written notice, required to be submitted to the Government no later than 15 business days, of:

   a. any formal management decision to terminate manufacturing of the NVX-CoV-2373 vaccine prior to delivery of 100 million doses to USG;
   b. any formal management decision to discontinue sale of the NVX-CoV-2373 vaccine to the Government prior to delivery of 100 million doses to USG; or

c. any filing that anticipates Federal bankruptcy protection; and

ii. Novavax has submitted an Emergency Use Authorization under §564 of the FD&C Act or a biologics license application provisions of §351(a) of the Public Health Service Act (PHSA).

b. If both conditions listed in section (a) occur, Novavax, upon the request of the Government, shall provide the following items necessary for the Government to pursue manufacturing of the NVX-CoV-2373 vaccine with a third party for exclusive sale to the U.S. Government:

i. a writing evidencing a non-exclusive, nontransferable, irrevocable (except for cause), royalty-free paid-up license to practice or have practiced for or on behalf of the U.S. Government any Background IP as defined in clause 7.1 necessary to manufacture or have manufactured the NVX-CoV2373 vaccine;

ii. necessary FDA regulatory filings or authorizations owned or controlled by Novavax related to NVX-Cov2373 and any confirmatory instrument pertaining thereto; and

iii. any outstanding Deliverables contemplated or materials purchased under this Project Agreement.

c. This Article shall be incorporated into any contract for follow-on activities for the Government to acquire and use additional doses of the product. Per section 1.3, the estimated quantity for follow-on production/procurement is approximately 560 million doses.

d. This Article will survive the acquisition or merger of the Contractor by or with a third party. This Article will survive the expiration of this agreement.

11. SECURITY

The security classification level for this effort is UNCLASSIFIED. ***Attachment D of the Project Agreement shall be referenced for supplemental security requirements associated with the execution of this project.***

12.0 MISCELLANEOUS REQUIREMENTS (SAFETY, ENVIRONMENTAL, ETC.)

N/A

13.0 GOVERNMENT FURNISHED PROPERTY/MATERIAL/INFORMATION

14.0 AGREEMENTS OFFICER'S REPRESENTATIVE (AOR) AND ALTERNATE AOR CONTACT INFORMATION

AOR

NAME: (b) (6)

EMAIL: (b) (6)
PHONE: (b) (6)
AGENCY NAME/DIVISION/SECTION: Joint Program Executive Office, Joint Program Lead-Enabling Biotechnologies

Alternate AOR

NAME: TBD
MAILING ADDRESS:
EMAIL:
PHONE:
AGENCY NAME/DIVISION/SECTION: HHS/ASPR/BARDA

ENCLOSURE 3: PAYMENT REQUEST INFORMATION

Novavax, Inc. is requesting a payment upon incurring costs, for a total of (b) (4) to support the development of NVX-CoV2373 as a vaccine for SARS-CoV-2 Coronavirus. The costs, as outlined below, are incorporated into estimates from subcontractors under milestones associated with manufacture. Novavax will work with subcontractors to ensure the appropriate accounting for pre-award costs during subcontract finalization and subsequent billing.

Projected Expenditures

Cost Element	Task/Purpose	Amount
Materials		
Antigen	(b) (4)	
Adjuvant	(b) (4)	
Adjuvant	(b) (4)	
Reservations Fees		
AGC Bio Seattle	(b) (4)	
PolyPeptide	(b) (4)	
Fuji RTP	(b) (4)	
Fuji Texas	(b) (4)	
Acceleration Fee		
Fuji	(b) (4)	
Subtotal		(b) (4)
Indirect + Fee Burden		(b) (4)
Total Requested Amount		(b) (4)

I. Financial Institution Information
Novavax, Inc.
21 Firstfield Road
Gaithersburg, MD 20878

Name of Bank: (b) (4)
Address: (b) (4)
(b) (4)

ABA #: (b) (4), Checking Account #: (b) (4)
Swift: (b) (4)

II. Justification for Requesting the Payment

- **Materials Costs: - (b) (4) Direct Costs**
  Procurement and qualification of critical long lead raw materials needed to produce 100M doses of NVX-CoV-2373 in 2020 and to ensure availability of 100M additional doses of NVX-CoV-2373 in 2021. This also includes materials for the purchase of a stockpile of certain critical long lead raw materials for the Matrix-M Adjuvant, necessary to rapidly initiate large-scale manufacturing without a delay. This will ensure timely availability of the vaccine candidate to the US population when needed, a primary mission of HHS in support of OWS.

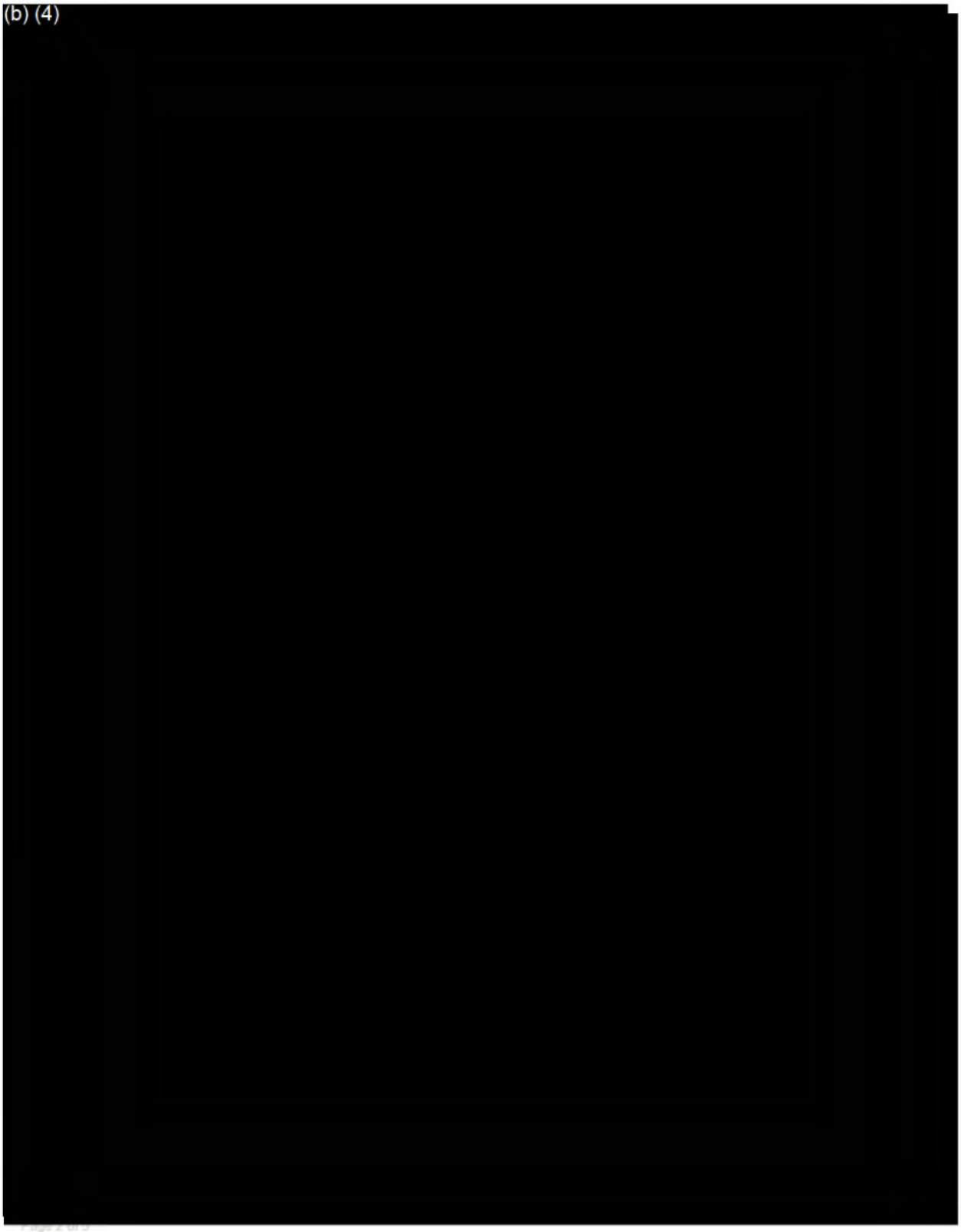
- **Reservation and Acceleration Fees: - (b) (4) Direct Costs**
  To quickly address the urgent need presented by the COVID-19 pandemic, Novavax will rely on the reservation of dedicated capacity from manufacturing service provides to be able to produce NVX-CoV-2373. This will ensure timely availability of the vaccine candidate to the US population when needed, a primary mission of HHS in support of OWS.

ENCLOSURE 4: PATENT LISTING

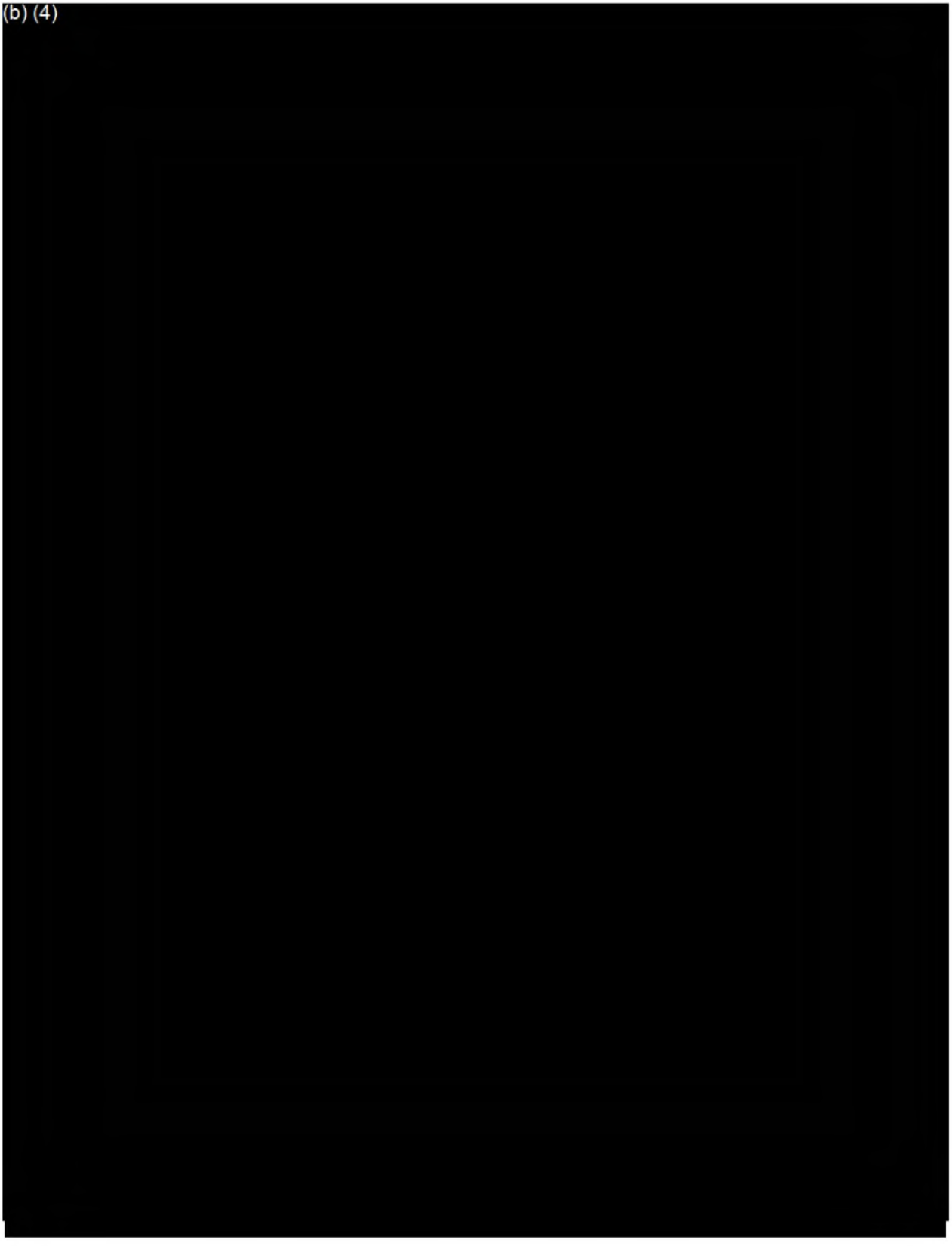
(b) (4)

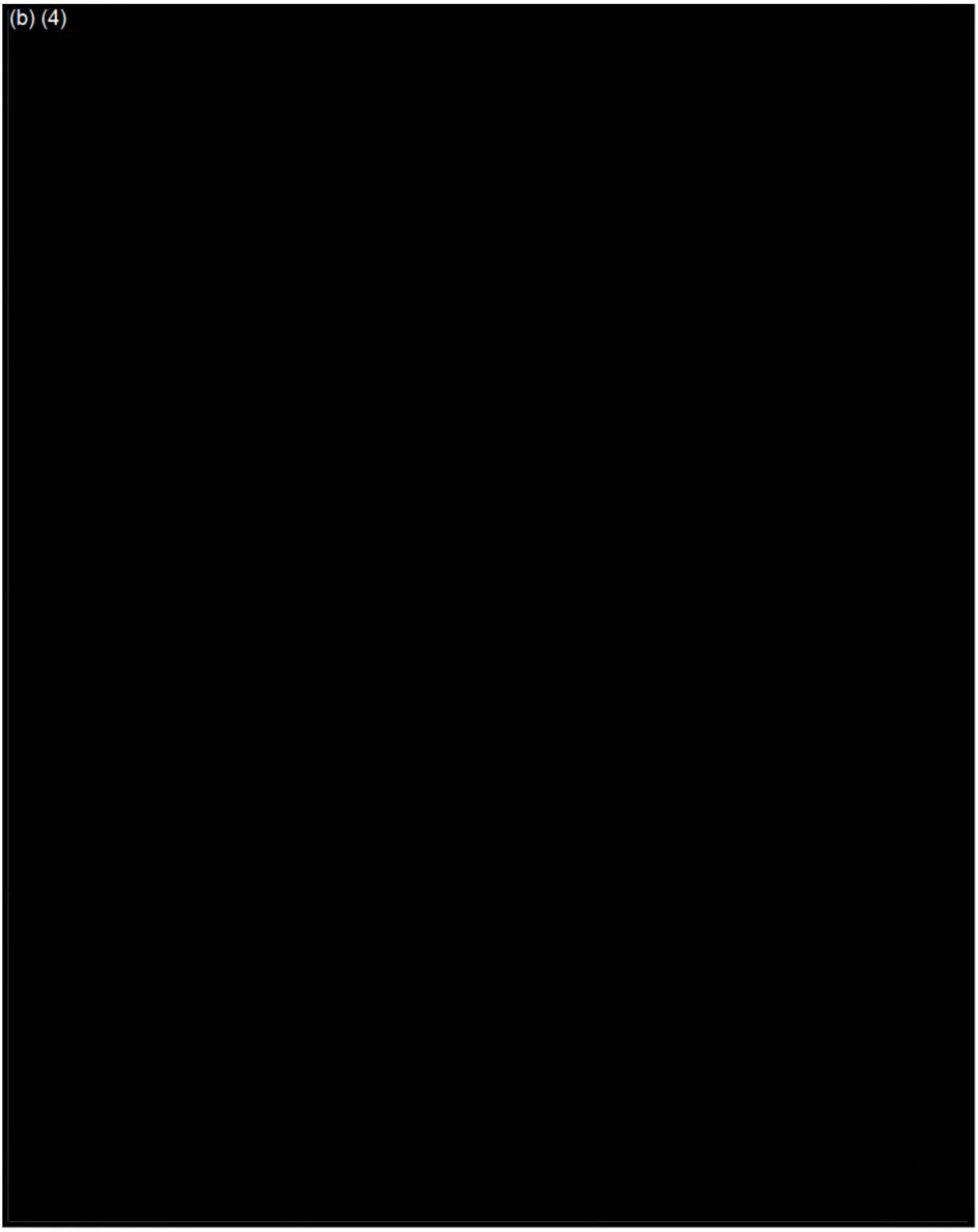
[redacted]

(b) (4)



(b) (4)





(b) (4)

[redacted]

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Attachment D
Clause for MCDC Consortium Other Transaction Authority Agreements
Standard Language OWS for Consortium OTA
(Incorporated as of Modification No. 03)

Required MCDC Base Agreement Modifications

The Medical CBRN Consortium (MCDC) Base Agreement, Article XVII, SECURITY & OPSEC shall apply to this Project Agreement. In addition, the below language shall replace Paragraph 6 of Article XVII of the MCDC Base Agreement, in regard to this Project Agreement.

(6) Access and General Protection/Security Policy and Procedures. This standard language text is applicable to ALL PAH employees working on critical program information or covered defense information related to Operation Warp Speed (OWS), and to those with an area of performance within an Army controlled installation, facility or area. PAH employees shall comply with applicable installation, facility and area commander installation/facility access and local security policies and procedures (provided by government representative). The PAH also shall provide all information required for background checks necessary to access critical program information or covered defense information related to OWS, and to meet installation access requirements to be accomplished by installation Provost Marshal Office, Director of Emergency Services or Security Office. The PAH workforce must comply with all personal identity verification requirements as directed by DOD, HQDA and/or local policy. In addition to the changes otherwise authorized by the changes clause of this agreement, should the Force Protection Condition (FPCON) at any individual facility or installation change, the Government may require changes in PAH security matters or processes.

Required SOW Language for Deliverables (in body of SOW or Deliverables Section)

Information Security
Classification guidance for Operation Warp Speed - The security level for this agreement is UNCLASSIFIED. "Controlled technical information," "covered contractor information system," "covered defense information," "cyber incident," "information system," and "technical information" are defined in DFARS Clause 252.204-7012, Safeguarding Covered Defense Information and Cyber Incident Reporting.

Personnel Security
In addition to the industry standards for employment background checks, Novavax must be willing to have key individuals, in exceptionally sensitive positions, identified for additional vetting by the United States Government.

Supply Chain Resiliency Plan
Novavax shall develop and submit within (b) (4) after execution of this Modification [#3], a comprehensive Supply Chain Resiliency Program that provides identification and reporting of critical components associated with the secure supply of drug substance, drug product, and work-in-process through to finished goods.

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

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

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

a) Communication for these requirements shall be updated as part of an annual review, or as necessary, as part of regular contractual communications.
b) For upstream and downstream processing, both single-use and re-usable in-place processing equipment, and manufacturing disposables also shall be addressed. For finished goods, the inspection, labeling, packaging, and associated machinery shall be addressed taking into account capacity capabilities.
c) The focus on the aspects of resiliency shall be on critical components and aspects of complying with the contractual delivery schedule. Delivery methods shall be addressed, inclusive of items that are foreign-sourced, both high and low volume, which would significantly affect throughput and adherence to the contractually agreed deliveries.

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

a) Production rates and lead times shall be understood and communicated to the Contracting/Agreement Officer or the Contracting/Agreement Officer's Representative as necessary.
b) Production throughput critical constraints should be well understood by activity and by design, and communicated to contractual personnel. As necessary, communication should focus on identification, exploitation, elevation, and secondary constraints of throughput, as appropriate.

Reports for critical items should include the following information:

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

The CO and COR reserve the right to request un-redacted copies of technical documents, during the period of performance, for distribution within the Government. Documents shall be provided within (b) (4) after CO issues the request in writing. Novavax may arrange for additional time if deemed necessary, and agreed to by the CO.

Manufacturing Data Requirements:

Novavax shall submit within (b) (4) after execution of this Modification [#3], detailed data regarding project materials, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing, processing, and fill/finish sites; and location and nature of non-clinical and clinical studies sites. The Government may provide a table in tabular format for Novavax, to be used to submit such data which would include but not be limited to the following:

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

Product Development Source Material and Manufacturing Reports and Projections:

Novavax 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.

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

- Novavax will submit Product Development Source Material Report
  - Within (b) (4) of execution of this Modification [#3]
  - Within (b) (4) of substantive changes are made to sources and/or materials
  - Or on the (b) (4) contract anniversary.
- Novavax will update the Dose Tracking Template (b) (4) during manufacturing campaigns and daily during response operations (where a Public Health Emergency has been declared) and COVID-19 response, with the first deliverable submission within (b) (4) of this Modification [#3]. Updates to be provided weekly in advance of commercial-scale manufacturing and daily once material for use in response operations begins manufacture
- The Government will provide written comments to the Product Development Source Material and Manufacturing Report within (b) (4) after the submission
- If corrective action is recommended, Novavax must address all concerns raised by the Government in writing

Novavax Locations:

Novavax shall submit detailed data regarding locations where work will be performed under this contract, including addresses, points of contact, and work performed per location, to include sub-contractors.
Contractor will submit Work Locations Report:

- Within (b) (4) of execution of this Modification [#3]
- Within (b) (4) after a substantive location or capabilities change
- Within (b) (4) 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

Required SOW Language for Security Section

This project requires an OPSEC Plan and a Security Plan.

Novavax shall develop a comprehensive security program that provides overall protection of personnel, information, data, and facilities associated with fulfilling the Government requirement. This plan shall establish security practices and procedures that demonstrate how Novavax will meet and adhere to the security requirements outlined below prior to the commencement of product manufacturing, and shall be delivered to the Government within (b) (4) of execution of this Modification[#3]. Novavax shall provide a Risk Assessment to evaluate which subcontractors, consultants, researchers, etc. performing work on behalf of this effort, are required to comply with all Operation Warp Speed and Project Agreement security requirements and prime contractor security plans.

a) The Government will review the plan and Risk Assessment in detail and submit comments within (b) (4) to the Contracting Officer (CO) to be forwarded to Novavax. Novavax shall review the Draft Security Plan comments, and, submit a Final Security Plan to the U.S. Government within (b) (4) after receipt of the comments.
b) The Security Plan shall include a timeline for compliance of all the required security measures outlined by the Government.
c) Upon completion of initiating all security measures, Novavax shall supply to the Contracting Officer a letter certifying compliance to the elements outlined in the Final Security Plan.
d) The OPSEC plan will include identifying the critical information related to this contract, why it needs to be protected, where it is located, who is responsible for it, and how to protect it.

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

Security Requirements:

1. **Facility Security Plan** Description: As part of the partner facility's overall security program, Novavax shall submit a written security plan with their proposal to the Agreement Officer for review and approval by Operation Warp Speed security subject matter experts. The performance of work under the Project Agreement will be in accordance with the approved security plan. The security plan will include the following processes and procedures at a minimum:	
Security Administration	• organization chart and responsibilities • written security risk assessment for site • threat levels with identification matrix (High, Medium, or Low) • enhanced security procedures during elevated threats • liaison procedures with law enforcement • annual employee security education and training program
Personnel Security	• policies and procedures • candidate recruitment process • background investigations process • employment suitability policy • employee access determination • rules of behavior/ conduct • termination procedures • non-disclosure agreements
Physical Security Policies and Procedures	• internal/external access control • protective services • identification/badging • employee and visitor access controls • parking areas and access control • perimeter fencing/barriers • product shipping, receiving and transport security procedures • facility security lighting • restricted areas • signage • intrusion detection systems • alarm monitoring/response • closed circuit television • product storage security • other control measures as identified
Information Security	• identification and marking of sensitive information • access control • storage of information • document control procedures • retention/ destruction requirements
Information Technology/Cyber Security Policies and Procedures	• intrusion detection and prevention systems • threat identification • employee training (initial and annual) • encryption systems • identification of sensitive information/media • password policy (max days 90) • lock screen time out policy (minimum time 20 minutes) • removable media policy • laptop policy • removal of IT assets for domestic/foreign travel • access control and determination • VPN procedures • WiFi and Bluetooth disabled when not in use

	• system document control • system backup • system disaster recovery • incident response • system audit procedures • property accountability
2. Site Security Master Plan Description: The partner facility shall provide a site schematic for security systems which includes: main access points; security cameras; electronic access points; IT Server Room; Product Storage Freezer/Room; and bio-containment laboratories.	
3. Site Threat / Vulnerability / Risk Assessment Description: The partner facility shall provide a written risk assessment for the facility addressing: criminal threat, including crime data; foreign/domestic terrorist threat; industrial espionage; insider threats; natural disasters; and potential loss of critical infrastructure (power/water/natural gas, etc.) This assessment shall include recent data obtained from local law enforcement agencies. The assessment should be updated annually.	
4. Physical Security Description:	
Closed Circuit Television (CCTV) Monitoring	a) Layered (internal/external) CCTV coverage with time-lapse video recording for buildings and areas where critical assets are processed or stored. b) CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract. c) Video recordings must be maintained for a minimum of 30 days. d) CCTV surveillance system must be on emergency power backup. e) CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract. f) Video recordings must be maintained for a minimum of 30 days. g) CCTV surveillance system must be on emergency power backup.
Facility Lighting	a) Lighting must cover facility perimeter, parking areas, critical infrastructure, and entrances and exits to buildings. b) Lighting must have emergency power backup. c) Lighting must be sufficient for the effective operation of the CCTV surveillance system during hours of darkness.
Shipping and Receiving	a) Must have CCTV coverage and an electronic access control system. b) Must have procedures in place to control access and movement of drivers picking up or delivering shipments. c) Must identify drivers picking up Government products by government issued photo identification.
Access Control	a) Must have an electronic intrusion detection system with centralized monitoring. b) Responses to alarms must be immediate and documented in writing. c) Employ an electronic system (i.e., card key) to control access to areas where assets critical to the contract are located (facilities, laboratories, clean rooms, production facilities, warehouses, server rooms, records storage, etc.). d) The electronic access control should signal an alarm notification of unauthorized attempts to access restricted areas. e) Must have a system that provides a historical log of all key access transactions and kept on record for a minimum of12 months.

	f) Must have procedures in place to track issuance of access cards to employees and the ability to deactivate cards when they are lost or an employee leaves the company. g) Response to electronic access control alarms must be immediate and documented in writing and kept on record for a minimum of 12 months. h) Should have written procedures to prevent employee piggybacking access i) to critical infrastructure (generators, air handlers, fuel storage, etc.) should be controlled and limited to those with a legitimate need for access. j) Must have a written manual key accountability and inventory process. k) Physical access controls should present a layered approach to critical assets within the facility.
Employee/Visitor Identification	a) Should issue company photo identification to all employees. b) Photo identification should be displayed above the waist anytime the employee is on company property. c) Visitors should be sponsored by an employee and must present government issued photo identification to enter the property. d) Visitors should be logged in and out of the facility and should be escorted by an employee while on the premises at all times.
Security Fencing	Requirements for security fencing will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment.
Protective Security Forces	Requirements for security officers will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment.
Protective Security Forces Operations	a) Must have in-service training program. b) Must have Use of Force Continuum. c) Must have communication systems available (i.e., landline on post, cell phones, handheld radio, and desktop computer). d) Must have Standing Post Orders. e) Must wear distinct uniform identifying them as security officers.
5. Security Operations Description:	
Information Sharing	a) Establish formal liaison with law enforcement. b) Meet in person at a minimum annually. Document meeting notes and keep them on file for a, minimum of 12 months. POC information for LE Officer that attended the meeting must be documented. c) Implement procedures for receiving and disseminating threat information.
Training	a) Conduct new employee security awareness training. b) Conduct and maintain records of annual security awareness training.
Security Management	a) Designate a knowledgeable security professional to manage the security of the facility. b) Ensure subcontractor compliance with all Government security requirements.
6. Personnel Security Description:	
Records Checks	Verification of social security number, date of birth, citizenship, education credentials, five-year previous employment history, five-year previous residence history, FDA disbarment, sex offender registry, credit check based upon position within the company; motor vehicle records check as appropriate; and local/national criminal history search.
Hiring and Retention Standards	a) Detailed policies and procedures concerning hiring and retention of employees, employee conduct, and off boarding procedures.

	b) Off Boarding procedures should be accomplished within 24 hour of employee leaving the company. This includes termination of all network access.
7. Information Security Description:	
Physical Document Control	a) Applicable documents shall be identified and marked as procurement sensitive, proprietary, or with appropriate government markings. b) Sensitive, proprietary, and government documents should be maintained in a lockable filing cabinet/desk or other storage device and not be left unattended. c) Access to sensitive information should be restricted to those with a need to know.
Document Destruction	Documents must be destroyed using approved destruction measures (i.e, shredders/approved third party vendors / pulverizing / incinerating).
8. Information Technology & Cybersecurity Description:	
Identity Management	a) Physical devices and systems within the organization are inventoried and accounted for annually. b) Organizational cybersecurity policy is established and communicated. c) Asset vulnerabilities are identified and documented. d) Cyber threat intelligence is received from information sharing forums and sources. e) Threats, vulnerabilities, likelihoods, and impacts are used to determine risk. f) Identities and credentials are issued, managed, verified, revoked, and audited for authorized devices, users and processes. g) Users, devices, and other assets are authenticated (e.g., single-factor, multifactor) commensurate with the risk of the transaction (e.g., individuals' security and privacy risks and other organizational risks)
Access Control	a) Limit information system access to authorized users. b) Identify information system users, processes acting on behalf of users, or devices and authenticate identities before allowing access. c) Limit physical access to information systems, equipment, and server rooms with electronic access controls. d) Limit access to/ verify access to use of external information systems.
Training	a) Ensure that personnel are trained and are made aware of the security risks associated with their activities and of the applicable laws, policies, standards, regulations, or procedures related to information technology systems.
Audit and Accountability	a) Create, protect, and retain information system audit records to the extent needed to enable the monitoring, analysis, investigation, and reporting of unlawful, unauthorized, or inappropriate system activity. Records must be kept for minimum must be kept for 12 months. b) Ensure the actions of individual information system users can be uniquely traced to those users. c) Update malicious code mechanisms when new releases are available. d) Perform periodic scans of the information system and real time scans of files from external sources as files are downloaded, opened, or executed.
Configuration Management	a) Establish and enforce security configuration settings. b) Implement sub networks for publically accessible system components that are physically or logically separated from internal networks.

Contingency Planning	a) Establish, implement, and maintain plans for emergency response, backup operations, and post-disaster recovery for information systems to ensure the availability of critical information resources at all times.
Incident Response	a) Establish an operational incident handling capability for information systems that includes adequate preparation, detection, analysis, containment, and recovery of cybersecurity incidents. Exercise this capability annually.
Media and Information Protection	a) Protect information system media, both paper and digital. b) Limit access to information on information systems media to authorized users. c) Sanitize and destroy media no longer in use. d) Control the use of removable media through technology or policy.
Physical and Environmental Protection	a) Limit access to information systems, equipment, and the respective operating environments to authorized individuals. b) Intrusion detection and prevention system employed on IT networks. c) Protect the physical and support infrastructure for all information systems. d) Protect information systems against environmental hazards. e) Escort visitors and monitor visitor activity.
Network Protection	Employ intrusion prevention and detection technology with immediate analysis capabilities.
9. **Transportation Security** Description: Adequate security controls must be implemented to protect materials while in transit from theft, destruction, manipulation, or damage.	
Drivers	a) Drivers must be vetted in accordance with the Government Personnel Security Requirements. b) Drivers must be trained on specific security and emergency procedures. c) Drivers must be equipped with backup communications. d) Driver identity must be 100 percent confirmed before the pick-up of any Government product. e) Drivers must never leave Government products unattended, and two drivers may be required for longer transport routes or critical products during times of emergency. f) Truck pickup and deliveries must be logged and kept on record for a minimum of 12 months.
Transport Routes	a) Transport routes should be pre-planned and never deviated from except when approved or in the event of an emergency. b) Transport routes should be continuously evaluated based upon new threats, significant planned events, weather, and other situations that may delay or disrupt transport.
Product Security	a) Government products must be secured with tamper resistant seals during transport, and the transport trailer must be locked and sealed. • Tamper resistant seals must be verified as "secure" after the product is placed in the transport vehicle. b) Government products should be continually monitored by GPS technology while in transport, and any deviations from planned routes should be investigated and documented. c) Contingency plans should be in place to keep the product secure during emergencies such as accidents and transport vehicle breakdowns.
10. Security Reporting Requirements Description: The partner facility shall notify the Agreement Officer within 24 hours of any activity or incident that is in violation of established security standards or indicates the loss or theft of government products. The facts and circumstances associated with these incidents will be documented in writing for government review.	
11. Security Audits	

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