AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 8

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
P00005	04/14/2020	OS257435	

6. ISSUED BY	CODE	7. ADMINISTERED BY *(If other than Item 6)*	CODE
ASPR-BARDA	ASPR-BARDA		

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

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*

MERCK SHARP & DOHME CORP 1374565
MERCK SHARP & DOHME CORP. ONE
ONE MERCK DRIVE
WHITEHOUSE STATION NJ 088893400

CODE	FACILITY CODE
1374565	

(x) 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED *(SEE ITEM 11)*

X 10A. MODIFICATION OF CONTRACT/ORDER NO. HHSO100201600031C

10B. DATED *(SEE ITEM 13)* 09/29/2016

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

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

12. ACCOUNTING AND APPROPRIATION DATA *(If required)* Net Increase: $38,033,570.00
(b)(4)

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

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation data, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X	FAR 52.243-2 Changes - Cost-Reimbursement. Alt I (Apr 1984) and 52.217-9
	D. OTHER *(Specify type of modification and authority)*

E. IMPORTANT: Contractor ☐ is not X is required to sign this document and return 1 copies to the issuing office.

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

Tax ID Number: 22-1261880
DUNS Number: 001317601
The purpose of this modification is (1) extend the period of performance for the base period from May 31,2020 through September 30, 2024, without additional costs to the Government; (2) exercise Options one (1) and two (2); (3) modify Key Personnel; and (3) revise the Statement of Work.
Accordingly, Articles B.2, B.3, B.5, F.2, G.3. and Section J are hereby modified.

Delivery: (b)(4)
Delivery Location Code: HHS
Continued ...

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

15A. NAME AND TITLE OF SIGNER *(Type or print)*	16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*
Roger M. Perlmutter, President, Merck Research Laboratories	JILL M. JOHNSON

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
Roger Perlmutter	Apr 14, 2020		
(Signature of person authorized to sign)		*(Signature of Contracting Officer)*	

Previous edition unusable

STANDARD FORM 30 (REV. 11/2016)
Prescribed by GSA FAR (48 CFR) 53.243

NAME OF OFFEROR OR CONTRACTOR
MERCK SHARP & DOHME CORP 1374565

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	HHS 200 Independence Avenue, SW Washington DC 20201 US Appr. Yr.: 2020 CAN: 199COV1 Object Class: 25103 Period of Performance: 04/27/2017 to 09/30/2024 Change Item 2 to read as follows(amount shown is the obligated amount):				
2	Option 1 - Manufacturing Development, Testing of Lots, IND Preparation and IND Activities				(b)(4)
	Change Item 3 to read as follows(amount shown is the obligated amount):				
3	Option 2 - Natural History Clinical Trial				(b)(4)
	The contract current value is increased by (b)(4) from (b)(4) to (b)(4) The contract obligated amount is increased by (b)(4) from (b)(4) to (b)(4) The contract overall value remains as (b)(4) UNCHANGED. The period of performance is extended through (b)(4)				

SUPPLEMENTAL AGREEMENT

Beginning with the effective date of this modification, the Government and the Contractor mutually agree as follows:

PLEASE NOTE: RED FONT DENOTES MODIFIED LANGUAGE

Under **SECTION B – SUPPLIES OR SERVICES AND PRICES/COSTS, ARTICLE B.2 ESTIMATED COST** is hereby modified as follows:

1. The total estimated cost of this contract is (b)(4)
2. CLIN 0001, is the base performance segments, and CLINs 0002 through 0004 are the option periods, with all being cost-reimbursement CLINs.
3. The Government shall provide monies for the base performance segment (CLIN 0001) in an amount not to exceed (b)(4) The total amount obligated by the Government for the base segment of the contract shall not exceed the Total Estimated Cost of (b)(4) and the Government will not be responsible for any Contractor incurred costs that exceed this amount unless a modification to the contract is signed by the Contracting officer which expressly increases this amount.
4. The Contractor shall maintain records of all contract costs and such records shall be subject to the Audit and Records-Negotiation and Final Decisions on Audit Findings clauses of the General Clauses.
5. Costs contributed by the Contractor shall not be charged to the Government under any other contract, grant, or cooperative agreement (including allocation to other grants, contracts, or cooperative agreements as part of an independent research and development program).
6. Consistent with FAR 52.216-8, Fixed-Fee (Jun 2011), any fixed fees payable in the base or option periods may be invoiced, and will be paid, in an amount proportionate to the percentage of total estimated costs for each applicable option period that the Contractor is estimated to have incurred at the time at which an invoice is submitted. Amounts paid under this provision will not exceed the total fixed fee identified in Article B.2. and B.3 for each option period, and the Contracting Officer may withhold a portion of the total fixed fee for each option period in an amount not to exceed 15 percent of the fixed fee or $100,000, whichever is less, consistent with FAR 52.216-8, Fixed Fee (Jun 2011).
7. It is estimated that the amount currently allotted will cover performance of the contract through (b)(4) for the base period.

ARTICLE B.2. ESTIMATED COST the TABLE is hereby modified as follows:

BASE PERIOD

CLIN	Estimated Period of Performance	Supplies/Services	Estimated USG Cost	Fee/Profit	Total Estimated Cost
0001	(b)(4)	Facility, Site, Process Performance Qualification (PPQ) Readiness Activities	(b)(4)		

ARTICLE B.3. OPTION PRICES the **TABLE** is hereby modified as follows:

OPTIONS
Option 1 (CLIN 0002) thru Option 3 (CLIN 0004)

CLIN	Period of Performance	Supplies/Services	Estimated USG Cost	Fee/Profit	Total Estimated Cost
0002	(b)(4)	Manufacturing Development, Testing of Lots, IND Preparation and IND Activities	(b)(4)		
0003		Natural History Clinical Trial-see Article B.5 (k)			
0004		Additional Process Simulations and Manufacturing of PPQ Lots			

ARTICLE B.5 ADVANCED UNDERSTANDINGS is hereby modified as noted below:

c. **Subcontracts**

Prior written consent from the Contracting Officer in the form of Contracting Officer Authorization (COA) is required for any subcontract that:

- Is of the cost-reimbursement type; or
- Is Fixed-Price and exceeds (b)(4) of the total estimated cost of the Contract, whichever value is greater.

The Contracting Officer shall request appropriate supporting documentation in order to review and determine authorization, pursuant with FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, the Contractor shall provide a copy of the signed, executed subcontract and consulting agreement to the Contracting Officer.

Note: Consulting services are treated as subcontracts and subject to the 'consent to subcontract' provisions set forth in this Article.

Consent is hereby provided for the following subcontracts:

Subcontractor	Address/Location	Business Classification **	Not to Exceed
(b)(4)			

(b)(4)

j. Equipment

(b)(4)

Item	Cost (Not to Exceed)	Manufacturer
(b)(4)		

(b)(4)

k. **Natural History Study**

The Contractor is authorized to proceed with the clinical study in CLIN 0003 once the Protocol, Informed Consent Form, and evidence of IRB approval have been submitted to BARDA. BARDA and contractor will continue to discuss in good faith adjustments to the study protocol as the study progresses.

l. **Government-Sponsored Animal Studies**

The Government may request the Contractor provide vaccine material for use in Government-sponsored animal studies. Material for such studies will only be provided after the Contractor has performed its own animal studies to confirm the appropriate dosage regimen. In addition, the Contractor shall have the right to review the Government-sponsored animal study protocol, and shall have access to the Government-sponsored animal study results associated with the Contractor's material and any positive or negative controls.

Under **SECTION F – DELIVERABLES OR PERFORMANCE, ARTICLE F.2. DELIVERABLES** is hereby modified to include the following:

(b)(4)

ARTICLE G.3. KEY PERSONNEL is revised to include only the following Key Personnel:

(b)(6)

SECTION J - LIST OF ATTACHMENTS – Attachment 1, SOW, is hereby replaced as follows:

1. Statement of Work, dated April 13, 2020, 16 pages.

(b)(4)

All other terms and conditions of this contract remain unchanged.
End of Modification #005

BARDA Broad Agency Announcement (BAA)

(Solicitation # CBRN-BAA-13-100-SOL-00013)

Advanced Research and Development of Chemical, Biological, Radiological and Nuclear Medical Countermeasures

Topic Area of Interest No. (#1), Vaccines

MANUFACTURING AND LICENSURE OF BPSC1001/V920 (rVSVΔG-ZEBOV-GP)

Statement of Work 4/13/20

PREAMBLE

Independently and not as an agency of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work submitted in response to the BARDA Broad Agency Announcement (BAA) BARDA CBRN BAA-13-100-SOL-00013.

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

(b)(4)

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Withheld pursuant to exemption

(b)(4)

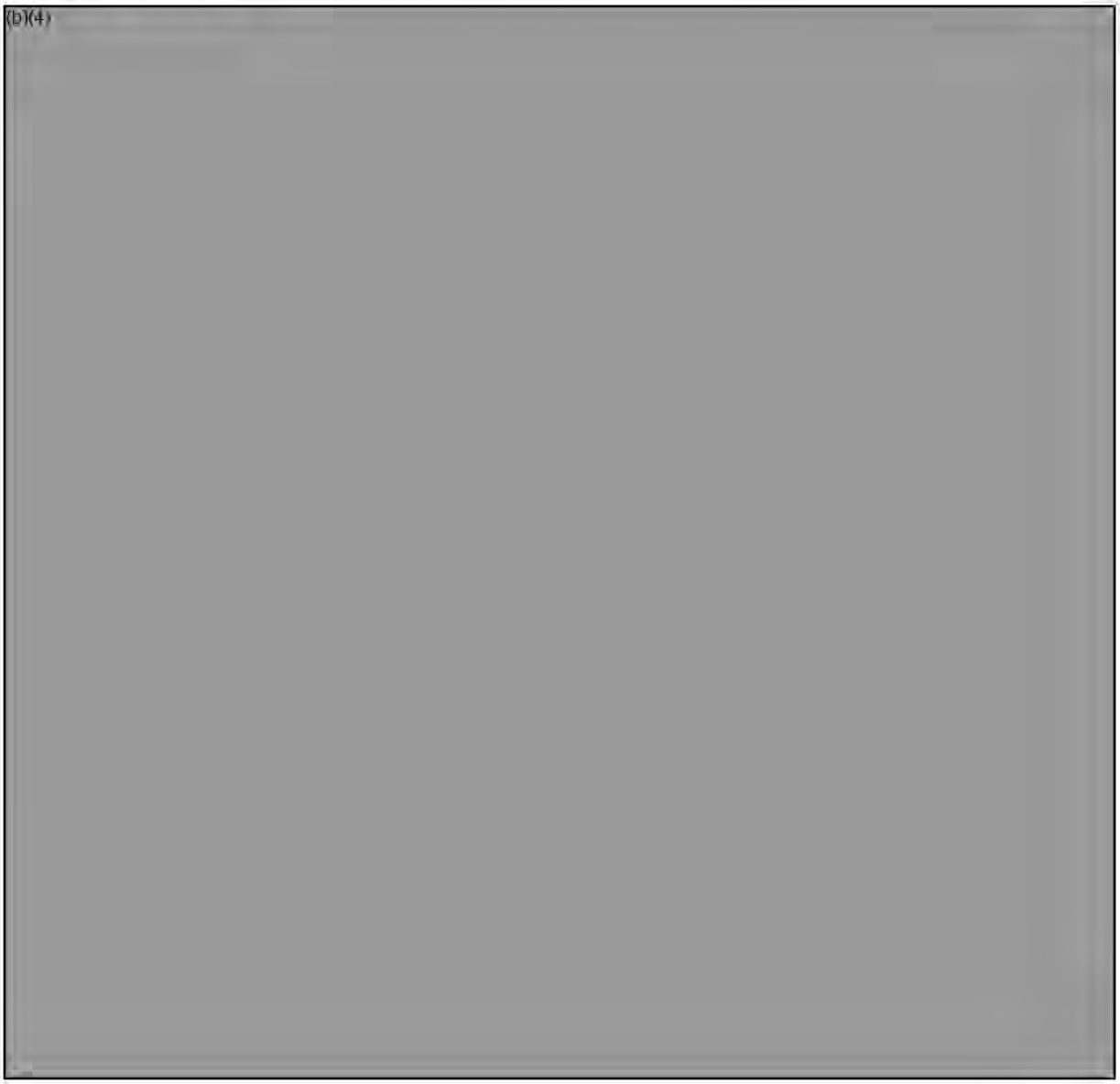
of the Freedom of Information Act

1. **Base: Facility, Site, Process Performance Qualification (PPQ) Readiness Activities, Manufacturing and Testing of Process Simulations**

The BASE contract will support the necessary activities at the final commercial manufacturing facility at the expected commercial process scale (400RB process).

The SOW thus includes:

(b)(4)



1.1.1 Program Management

The Contractor, Merck Sharpe and Dohme Corp. shall provide for the following as outlined below and in the contract deliverables list (Article F.2):

1.1.1.1. The overall management, integration and coordination of all contract activities, including a technical and administrative

infrastructure to ensure the efficient planning, initiation, implementation, and direction of all contract activities;

- Principal Investigator (PI) responsible for project management, communication, tracking, monitoring and reporting on status and progress, and modification to the project requirements and timelines, including projects undertaken by subcontractors; The contract deliverables list (reference), identifies all contract deliverables and reporting requirements for this contract.
- Project Manager(s) with responsibility for monitoring and tracking day-to-day progress and timelines, coordinating communication and project activities; costs incurred; and program management; The contract deliverables list (reference), identifies all contract deliverables and reporting requirements for this contract. BARDA Liaison with responsibility for effective communication with the Project Officer and Contracting Officer. May be the PI or Project Manager. Administrative and legal staff to provide development of compliant subcontracts, consulting, and other legal agreements, and to ensure timely acquisition of all proprietary rights, including IP rights, and reporting all inventions made in the performance of the project. Administrative staff with responsibility for financial management and reporting on all activities conducted by the Contractor and any subcontractors.

1.1.1.2. Program Management Deliverables

- **Contract Review Meetings**
- The Contractor shall participate in regular meetings to coordinate and oversee the contract effort as directed by the Contracting and Project Officers. Such meetings may include, but are not limited to, meeting of the Contractors and subcontractors to discuss manufacturing progress, product development, product assay development, scale up manufacturing development, clinical sample assays development, preclinical/clinical study designs and regulatory issues; meetings with individual contractors and other HHS officials to discuss the technical, regulatory, and ethical aspects of the program; and meeting with technical consultants to discuss technical data provided by the Contractor.
- The Contractor shall participate in teleconferences every two weeks between the Contractor and subcontractors (as required) and BARDA to review technical progress. Teleconferences or additional face-to-face meetings shall be more frequent at the request of BARDA.
- **Integrated Master Schedule**

Within 180 days of the effective date of the approved COA by the CO for the subcontractor performing the work, the Contractor shall submit a first draft of an updated Integrated Master Schedule in a format agreed upon by BARDA to the Project Officer and the Contracting Officer for review and comment. The Integrated Master Schedule shall be incorporated into the contract, and will be used to monitor performance of the contract. Contractor shall include the key milestones and Go/No Go decision gates. The IMS for the period of performance will be accepted by BARDA at the PMBR.

- **Program Management Plan**

Within 90 days of the effective date of the approved COA by the CO for the subcontractor performing the work, the Contractor will develop, and submit to BARDA for approval, a revised version of the Program Management Plan (PMP) that was initially submitted to HHS under contract No. HSSO100201500002C. The revised plan will detail the tools and techniques that BPS intends to employ in its management of the proposed work.

This plan is intended to be a living document and changes to any of the individual sub-plans as well as the addition or subtraction of sub-plans will be documented and must be approved by the Program Manager and Principal Investigator.

The Program Management Plan will update the following individual sub-plans:

- Scope/Schedule Management Plan
- Costs Management Plan
- Communications Management Plan
- Stakeholder Management Plan
- Change Management Plan
- Quality Management Plan
- Human Resources/Staffing Plan

- **Product Development Plan**

Within 90 days of the effective date of the approved COA by the CO for the subcontractor performing the work , the Contractor will submit a revised version of the Integrated Product Development Plan (IPDP) that

was initially submitted to HHS under contract No. HSSO100201500002C. Ultimately, this plan will require approval by BARDA's Contracting Officer's Representative and the Contracting Officer prior to initiation of any activities related to their implementation. This plan will be updated, as required.

- **Subcontractor Management**

The Contractor will manage all subcontractors to oversee effective and timely execution of deliverables in the scope of work and to meet reporting requirements under this contract.

(b)(4)

- **Financial Management, Accounting and Reporting**

Within 90 days of the effective date of the approved COA by the CO for the subcontractor performing the work. The Contractor will engage a subcontractor to provide specific services in Contracts and Subcontracts Management to help ensure compliance with contracts clauses and requirements, Federal Acquisition Regulations; and purchasing. Specific services will include:

- Subcontract Requests for Proposal
- Contracts reporting and monitoring
- Contracting Office Consent to Subcontract
- Price Reasonableness analysis
- Internal Controls

The Contractor and/or its subcontractor will provide Project Accounting and Finance Management to help ensure compliance with contracts clauses and requirements, Federal Acquisition Regulations; and cost accounting and billing. Specific services will include:

- Monthly Job Cost reporting and billing
- Time Reporting
- Indirect Rate calculations
- Internal Controls and training
- QA/QC Plans and Ongoing activity

Decision Gate Reporting

On completion of a stage of the product development, as defined in the agreed upon Integrated Master Schedule and Integrated Master Plan, the Contractor shall prepare and submit to the Project Officer and the Contracting Officer a Decision Gate Report that contains (i) sufficient detail, documentation and analysis to support successful completion of the stage according to the predetermined qualitative and quantitative criteria that were established for Go/No Go decision making; and (ii) a description of the next stage of product development to be initiated and a request for approval to proceed to the next stage of product development.

- **Risk Management Plan**

Within 90 days of the effective date of the approved COA by the CO for the subcontractor performing the work, the Contractor shall develop a risk management plan award highlighting potential problems and/or issues that may arise during the life of the contract, their impact on cost, schedule and performance, and appropriate remediation plans. This plan should reference relevant WBS elements where appropriate. Updates to this plan shall be included every three months (quarterly) in the monthly Project Status Report.

- **Quality Management Plan**

Within 90 days of the effective date of the approved COA by the CO for the subcontractor performing the work, the Contractor will update, and submit to BARDA for approval, a revised quality plan for the program to ensure compliance with specified requirements, guidance documents and GCP/GMP/GLP regulations; and to ensure continual improvement. The quality plan will:

- Describe the quality planning process;
- Establish quality objectives;
- Identify quality system changes in alignment with compliance requirements, contractual requirements and operational requirements; and
- Ensure comprehensive quality oversight of the subcontractors through documentation reviews and quality system compliance audits.

This quality plan will be maintained by the BPS quality lead who will be responsible for assuring that all quality objectives are appropriately documented and accomplished. This quality plan may be supplemented with additional, separate implementation plans and schedules.

The Contractor will manage the program's quality activities according to the approved quality plan.

- **Deviation Request:**

During the course of contract performance, in response to a need to change IMS activities as baselined at the PMBR, the Contractor shall submit a Deviation Report. This report shall request a change in the agreed-upon IMS and timelines. This report shall include: (i) discussion of the justification/rationale for the proposed change; (ii) options for addressing the needed changes from the agreed upon timelines, including a cost-benefit analysis of each option; and (iii) recommendations for the preferred option that includes a full analysis and discussion of the effect of the change on the entire product development program, timelines, and budget.

- **Monthly and Annual Reports**

The Contractor shall deliver Project Status Reports on a monthly basis. The reports shall address the items below cross referenced to the WBS, SOW, IMS, and EVM:

- Executive summary highlighting the progress, issues, and relevant activities in manufacturing, non-clinical, clinical, and regulatory;
- Progress in meeting contract milestones, detailing the planned progress and actual progress during the reporting period, explaining any differences between the two and corrective steps;
- Updated IMS;
- Updated EVM;
- Updated Risk Management Plan (Every 3 months);
- Three month rolling forecast of planned activities;
- Progress of regulatory submissions;
- Estimated and actual expenses;

- **Data Management**

The Contractor shall develop and implement appropriate data management and quality control systems/procedures, including transmission, storage, confidentiality, and retrieval of all contract data;

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

1.1.1.13 Long-term Storage and Stability Testing, 90 Roller Bottle Drug Product Lots Produced Under Contract HHS0100201500002C

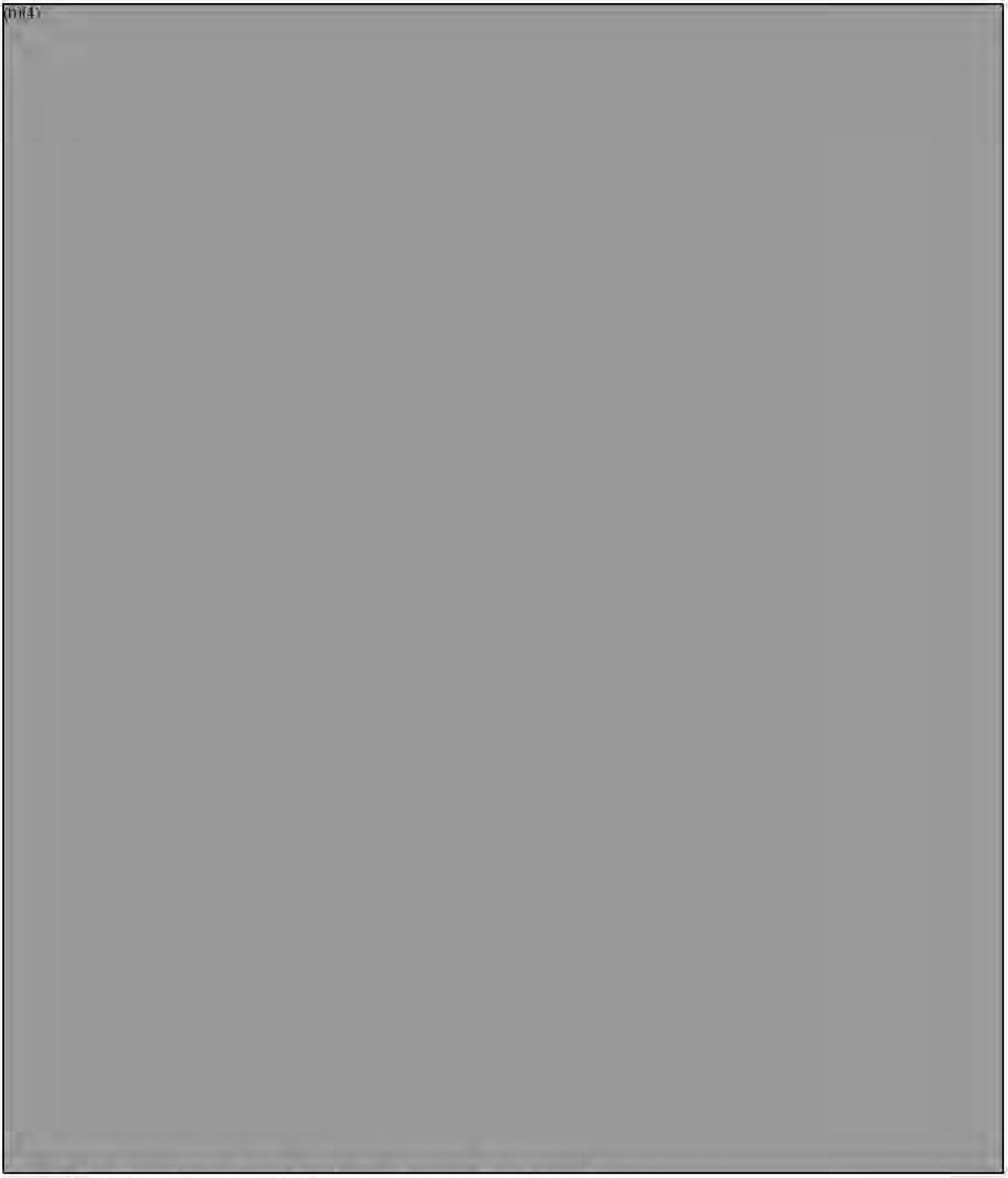
(b)(4)

1.1.2 Process Performance Qualification (PPQ) and Site Readiness Activities

The contractor and/or its subcontractor(s) shall complete the necessary facility upgrades and implementation of quality systems to support cGMP production of Ebola Zaire Vaccine BPSC1001/V920 (rVSVΔG-ZEBOV-GP.)

(b)(4)

(b)(4)

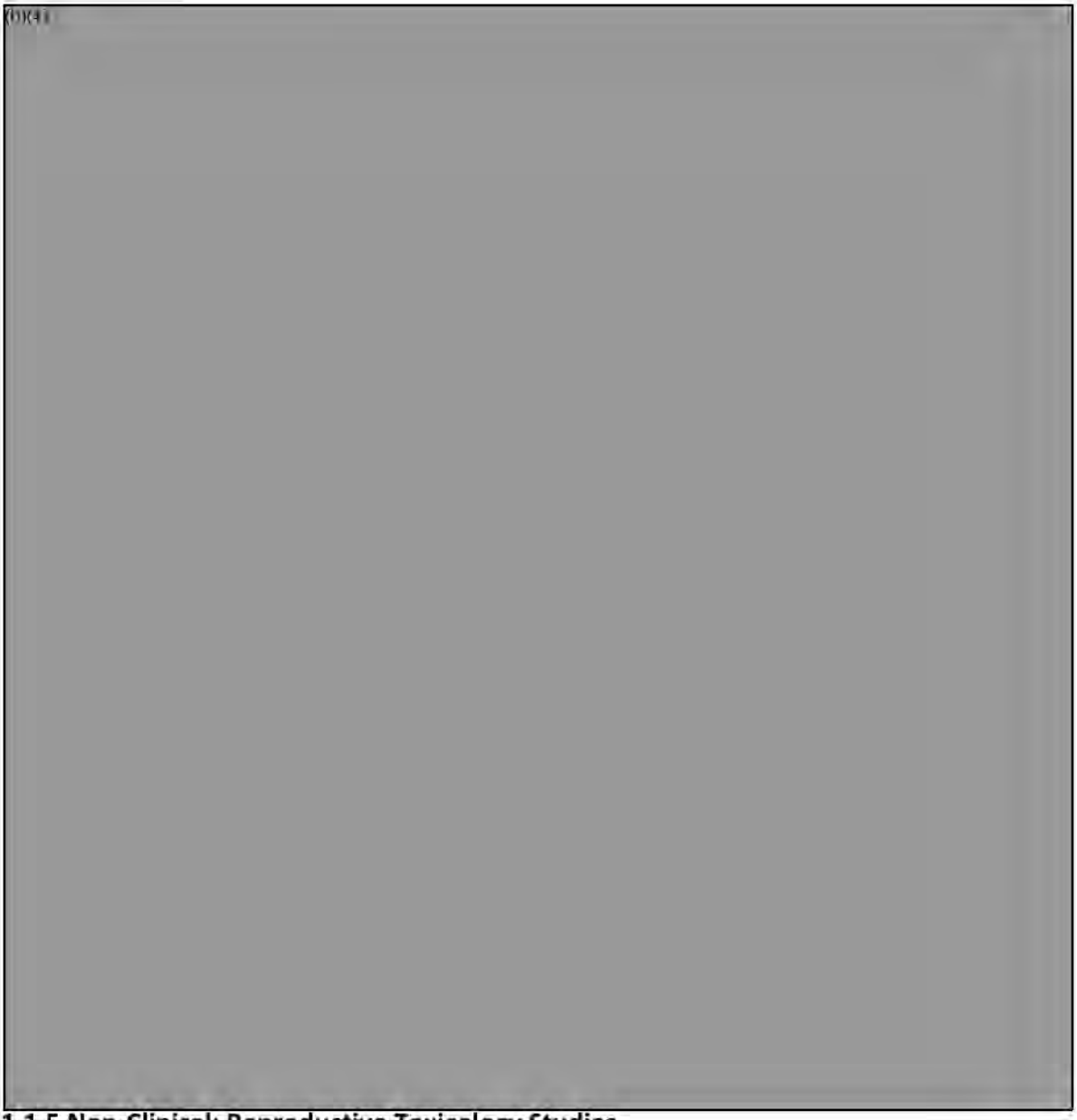


1.1.3 Manufacture and Testing of Process Simulations

Complete the necessary three consecutive end-to-end Process Simulations for DS and DP product with the expected commercial process.

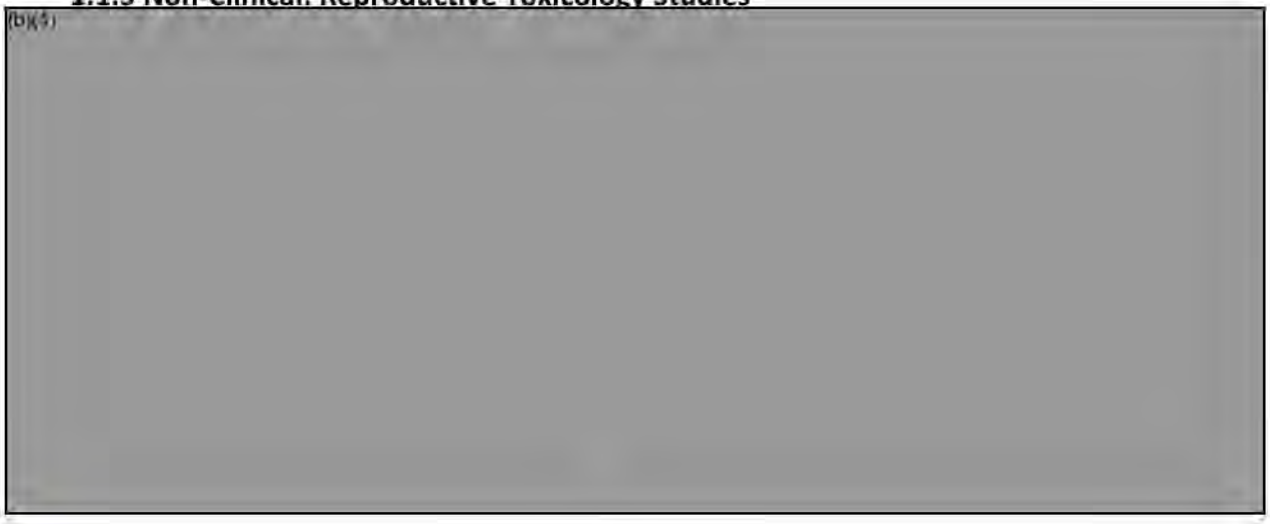
Activities include:

(b)(4)



1.1.5 Non-Clinical: Reproductive Toxicology Studies

(b)(4)



(b)(4)

1.1.6 Clinical Studies: Immunogenicity for PREVAIL and PREPARE Studies

(b)(4)

2. Option 1: Manufacturing Development, Testing of Lots, IND Preparation and IND Activities

The Contractor and/or its subcontractor(s) shall carry out the following tasks and subtasks.

2.1 Program Management (consistent with section 1.1.1)

Program management scope in BASE year is consistent with program management scope in each option year.

(b)(4)

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(b)(4)

of the Freedom of Information Act

(b)(4)

3. **Option 2: Natural History Clinical Trial**

The contractor and/or its subcontractor(s) shall carry out the following tasks and subtasks.

The contractor and/or its subcontractor(s) shall conduct a natural history and immune response study of an emerging infectious disease associated with the vaccine pursued under Option 1 in order to develop correlates of protection, disease phenotyping, and disease detection, to inform vaccine clinical design and development strategy. The Results from the study will be made publicly available.

3.1 Program Management (Consistent with section 1.1.1)

Program management scope in BASE year is consistent with program management scope in each option year.

3.2 Design and Implementation for Natural History and Immunophenotyping Clinical Trial

(b)(4)

(b)(4)

4. **Option 3: Additional Process Simulations and Manufacturing of PPQ Lots**

Go/No Go Decision Criteria: Option 3 will be considered if additional process simulation and/or Process Performance Qualification Lots are needed. This decision will be considered after completion of all milestones under WBS 1.4, and again after all milestones under WBS 2.2 (if Option 2 should be exercised).

The contractor and/or its subcontractor(s) shall carry out the following tasks and subtasks and in accordance with an agreed upon Integrated Master Schedule and Integrated Master Plan (defined in 4.1.1.2 and 4.1.1.3) which shall further detail the conduct of the specific tasks and subtasks.

4.1 Program Management (Consistent with section 1.1.1) (WBS 6.1)

Program management scope in BASE year is consistent with program management scope in each option year.

(b)(4)

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Withheld pursuant to exemption

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of the Freedom of Information Act