OTHER TRANSACTION AGREEMENT (OTA)

OTHER TRANSACTION FOR ADVANCED RESEARCH (OTAR)

BETWEEN

Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591-6717

AND

THE UNITED STATES OF AMERICA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE
200 C Street, S.W.
WASHINGTON, DC 20515

CONCERNING

(b)(4)

Date: January 31, 2020

PR No. (b)(4)

Total Amount of the Agreement (b)(4)

Total Estimated Government Funding of the Agreement (b)(4)
Total Estimated Recipient Funding of the Agreement (b)(4)
Funds Obligated: (b)(4)
Period of Performance: September 30, 2017 through June 30, 2022 (Changed)

Authority: Section 319L(c) (4) (B) and/or 319L(c) (4) (D) of the Pandemic and All-Hazards Preparedness Act, P.L. 109-417

(b)(4)

Line of Accounting and Appropriation
(b)(4)

Line of Accounting and Appropriation
(b)(4)

Line of Accounting and Appropriation
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Line of Accounting and Appropriation
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Line of Accounting and Appropriation
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Line of Accounting and Appropriation: (b)(4) (b)(4)

Line of Accounting and Appropriation: (b)(4) (b)(4)

Line of Accounting and Appropriation: (b)(4) (b)(4)

Line of Accounting and Appropriation: (b)(4) (b)(4)

PURPOSE: The purpose of this modification is to (1) (b)(4) nd (2) Replace Attachment 1: SOW revision dated January 31, 2020.

Beginning with the effective date of this modification, the Government and Other Transaction Agreement holder mutually agree as follows:

1. Agreement No.: HHSO100201700020C Line Items and corresponding values:

   Funding for this OTA is revised as follows:

Line Item	Recipient Cost-Share	Government Cost-Share	Total Estimated Cost	Total Government Funds Obligated to Date
(b)(4)				

Note:

(i) (b)(4)

(ii) External (Subrecipient or Affiliates) Expenses. External expenses will be billed based on actual third-party charges submitted to Regeneron.

(iii) (b)(4)

(b)(4)

(Iv

2. Attached are the following documents which support the modified (b)(4)

1) Delete and replace Attachment 1 – Revised Statement of Work (SOW) dated January 31, 2020 18 pages)

All other terms and conditions remain the same.

FOR THE UNITED STATES OF AMERICA
OFFICE OF ACQUISITION MANAGEMENT,
CONTRACTS & GRANTS SECRETARY
FOR PREPAREDNESS AND RESPONSE

(b)(6)

FOR Regeneron Pharmaceuticals, Inc.

(b)(6)

END OF MODIFICATION (b)(4) TO HHSO100201700020C

(b)(4)

(b)(4)

Total Amount of the Agreement: (b)(4)

Total Estimated Government Funding of the Agreement: (b)(4)
Total Estimated Recipient Funding of the Agreement: (b)(4)
Funds Obligated: (b)(4)
Period of Performance: September 30, 2017 through March 31, 2026 (Changed)

Authority: Section 319L(c) (4) (B) and/or 319L(c) (4) (D) of the Pandemic and All-Hazards Preparedness Act, P.L. 109-417

(b)(4)

(b)(4)

(b)(4)

Beginning with the effective date of this modification, the Government and Other Transaction Agreement holder mutually agree as follows:

1. Agreement No.:
   HHSO100201700020C Line Items and corresponding values:

   Funding for this OTA is revised as follows:

Line Item	Recipient Cost Share	Government Cost Share	Total Estimated Cost	Total Government Funds Obligated to Date

(b)(4)

Note:

(i) (b)(4)

(ii) External (Subrecipient or Affiliates) Expenses. External expenses will be billed based on actual third-party charges submitted to Regeneron.

(iii) (b)(4)

(iv)

2. Under Article II PERIOD OF PERFORMANCE, delete and replace as follows:

Line Item	Description of Services	Period of Performance
(b)(4)		

3. Under **ATTACHMENT 2, REPORTING REQUIREMENTS**, add three deliverables as follows:

Unless otherwise stated, each deliverable in the table below shall be provided as one (1) electronic copy to the COR, CS, and CO.

In addition to or in replacement of electronic copies, the CO may direct the Contractor to submit the below deliverables via BARDA Digital Resources Portal in machine readable format.

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
01.6	(b)(4)	Upon request of the Government relating to COVID-19, the Contractor shall participate in regular updates with the project staff (via teleconference or email). Contractor will respond in a timely fashion (if reasonable and practicable under the circumstances, within the same day as the request).	No agenda will be required for the meeting No meeting minutes are required

		(b)(4) The updates will address the content reasonably requested by BARDA and in the possession of, and reasonably accessible to, Regeneron, including key cost, schedule and technical (b)(4) provide the update in both confidential and non-confidential formats. Updates may occur on weekdays, excluding federal holidays. Upon request of the Government, check-ins may also occur on weekends and on federal holidays, provided at least 24 hours' notice.	Contractor will provide updates verbally, in bulleted emails or other mutually agreed formats
02.8	Product Development Source Material and Manufacturing Report for COVID-19 Programs	(b)(4) he Contractor shall submit a spreadsheet regarding critical project materials. The form and content of the spreadsheet will be similar to past updates (b)(4)	• Contractor will submit Product Development Source Material Report Within 30 business days of contract award Within 30 business days of substantive changes are made to sources and/or materials The Government will provide written comments to the Product Development Source Material and Manufacturing Report within 15 business days after the submission If corrective action is recommended, Contractor will respond to such concerns in writing

4. Attached are the following revised documents:

   1) Delete and replace Attachment 1 – Revised Statement of Work (SOW) dated March 20, 2020 18 pages).
   2) Delete and replace Attachment 6 - Requisition Table

All other terms and conditions remain the same.

FOR THE UNITED STATES OF AMERICA
OFFICE OF ACQUISITION MANAGEMENT,
CONTRACTS & GRANTS SECRETARY

(b)(6)

FOR Regeneron Pharmaceuticals, Inc.

(b)(6)

END OF MODIFICATION No. 0006 TO HHSO100201700020C

AWARD/CONTRACT

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)

RATING

PAGE OF PAGES 1 | 63

2. CONTRACT (Proc. Inst. Ident.) NO.
HHSO100201700020C

3. EFFECTIVE DATE
See Block 20C

4. REQUISITION/PURCHASE REQUEST/PROJECT NO.
(b)(4)

5. ISSUED BY CODE ASPR-BARDA

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

6. ADMINISTERED BY (If other than Item 5) CODE ASPR-BARDA02

US DEPT OF HEALTH & HUMAN SERVICES
ASST SEC OF PREPAREDNESS & RESPONSE
ACQ MANAGEMENT, CONTRACTS, & GRANTS
O'NEILL HOUSE OFFICE BUILDING
Washington DC 20515

7. NAME AND ADDRESS OF CONTRACTOR (No., Street, City, Country, State and ZIP Code)

REGENERON PHARMACEUTICALS, INC. 1466256
777 OLD SAW MILL RIVER RD
TARRYTOWN NY 105916717

CODE 1466256 FACILITY CODE

8. DELIVERY
☐ FOB ORIGIN ☒ OTHER (See below)

9. DISCOUNT FOR PROMPT PAYMENT

10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN

ITEM

11. SHIP TO/MARK FOR CODE

Multiple Destinations

12. PAYMENT WILL BE MADE BY CODE FMS

FMS
7700 Wisconsin Ave
Bethesda MD 20814

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION:
☐ 10 U.S.C. 2304 (c) ( ) ☐ 41 U.S.C. 253 (c) ( )

14. ACCOUNTING AND APPROPRIATION DATA
See Schedule

15A. ITEM NO	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	Continued				

15G. TOTAL AMOUNT OF CONTRACT (b)(4)

16. TABLE OF CONTENTS

(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
		PART I - THE SCHEDULE				PART II - CONTRACT CLAUSES	
	A	SOLICITATION/CONTRACT FORM			I	CONTRACT CLAUSES	
	B	SUPPLIES OR SERVICES AND PRICES/COSTS				PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.	
	C	DESCRIPTION/SPECS./WORK STATEMENT			J	LIST OF ATTACHMENTS	
	D	PACKAGING AND MARKING				PART IV - REPRESENTATIONS AND INSTRUCTIONS	
	E	INSPECTION AND ACCEPTANCE			K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	
	F	DELIVERIES OR PERFORMANCE					
	G	CONTRACT ADMINISTRATION DATA			L	INSTRS., CONDS., AND NOTICES TO OFFERORS	
	H	SPECIAL CONTRACT REQUIREMENTS			M	EVALUATION FACTORS FOR AWARD	

CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE

17. ☒ CONTRACTOR'S NEGOTIATED AGREEMENT (*Contractor is required to sign this document and return* 1 *copies to issuing office.*) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by

(b)(6)

18. ☐ SEALED-BID AWARD (*Contractor is not required to sign this document.*) Your bid on Solicitation Number
including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract.)

20A. NAME OF CONTRACTING OFFICER
SALIM K. ROBERTS

20B. UNITED STATES OF AMERICA
BY
(Signature of the Contracting Officer)

20C. DATE SIGNED
9/21/2017

STANDARD FORM 26 (Rev. 5/2011)
Prescribed by GSA - FAR (48 CFR) 53.214(a)

NAME OF OFFEROR OR CONTRACTOR

REGENERON PHARMACEUTICALS, INC. 1466256

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Tax ID Number: 13-3444607 DUNS Number: 194873139 IGF::OT::IGF - Regeneron Other Transaction Authority (OTA) Award				
	(b)(4)				
1					
	(b)(4)				
	Continued				

CONTINUATION SHEET	REFERENCE NO. OF DOCUMENT BEING CONTINUED HHSO100201700020C	PAGE 3 OF 63

NAME OF OFFEROR OR CONTRACTOR

REGENERON PHARMACEUTICALS, INC. I466256

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
(b)(4)					
(b)(4)					
(b)(4)					

Note: On the preceeding three pages of this award (i.e. Standard Form 26), the term "Contractor" is included to refer to Regeneron. It is agreed that this is an award made under Other Transaction Authority and the term "Contractor" is only included above as it is system generated. The term "Recipient" is used hereafter.

OTHER TRANSACTION AGREEMENT (OTA)

OTHER TRANSACTION FOR ADVANCED RESEARCH (OTAR)

BETWEEN

REGENERON PHARMACEUTICALS, INC.
777 OLD SAW MILL RIVER ROAD
TARRYTOWN, NY 10591

AND

THE UNITED STATES OF AMERICA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE
200 C STREET, SW
WASHINGTON, DC 20515

CONCERNING

Novel Antibodies against Influenza Virus, Emerging, re-Emerging, and pre-Emerging pathogens

Agreement No.: HHSO100201700020C
Line Items and corresponding values:

Line Item	Recipient Cost-Share	Government Cost-Share	Total Estimated Cost	Total Government Funds Obligated to Date
(b)(4)			(b)(4) (b)(4) (b)(4)	(b)(4) (b)(4)

Authority: Section 319L(c) (4) (B) and/or 319L(c) (4) (D) of the Pandemic and All-Hazards Preparedness Act, P.L. 109-417.

This Agreement is entered into between the United States of America, hereinafter called "Government," represented by the Department of Health and Human Services (Government); Office of the Assistant Secretary for Preparedness & Response (ASPR); Office of Biomedical Advanced Research and Development Authority (BARDA) (represented by Office of Acquisition Management, Contracts and Grants (AMCG)) and Regeneron Pharmaceuticals Inc., hereinafter called "Recipient," pursuant to and under U.S. Federal law. Recipient and the Government are each referred to as a Party and collectively referred to as the Parties. The individual signing on behalf of the Government has the authority to bind the Government and the Agreement includes adequate consideration contributed by Parties.

FOR REGENERON PHARMACEUTICALS, INC.

(b)(6)

(Signature)

(b)(6)

(Name, Title)

(b)(4)

FOR THE UNITED STATES OF AMERICA OFFICE OF ACQUISITION MANAGEMENT, CONTRACTS & GRANTS, OFFICE OF ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

(see signature on cover page)

(Signature)

Kyle Roberts
Other Transaction Agreement Officer
(Name, Title)

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ARTICLE I: OVERVIEW OF THE AGREEMENT

A. Introduction

(b)(4)

Definitions

Affiliate: Affiliates are entities in the consortium identified in Attachment 3. It is conceived that this consortium will be vertically structured, thereby Affiliates will perform duties related to the Statement of Work ("SOW"), in conjunction with Recipient. The term 'Affiliate' is limited to the scope of this Agreement and does not include other corporate entities commonly referred to as "affiliates" in the normal course of conducting commercial business.

Agreement: The body of this Agreement and Attachments, which are expressly incorporated in and made a part of this Agreement.

Computer Software:

1. To perform and further this Agreement:

   (i) Computer programs that comprise a series of instructions, rules, routines, or statements, regardless of the media in which recorded, that allow or cause a computer to perform a specific operation or series of operations; and

   (ii) Recorded information comprising source code listings, design details, algorithms, processes, flow charts, formulas, and related material that would enable the computer program to be produced, created, or compiled.

2. Does not include computer databases or computer software documentation.

Consortium: Consists of Recipient and Affiliates. Note that Sub-Recipients are not a member of the Consortium.

Control: The term "Control" as used in this Agreement shall mean the ability of a Party to grant rights to Technology or supply materials to another Party without violating the terms of any agreement that such Party might have with any other party.

Corporate Affiliate: means, with respect to a Party, any entity that, directly or indirectly (through one (1) or more intermediaries), controls, is controlled by or is under common control with such Party. For purposes of this definition, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" means (a) the possession, directly or indirectly, of the power to direct the management or policies of an entity, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance, or otherwise; or (b) the ownership, directly or indirectly, of fifty percent (50%) or more of the voting securities or other ownership interest of an entity(or, with respect to a limited partnership or other similar entity, of its general partner or other controlling entity).

Data: Means recorded information, regardless of form or the media on which it may be recorded. The term includes technical data and Computer Software. The term does not include information incidental to contract administration, such as financial, administrative, cost or pricing, or management information.

(b)(4)

Foreign Firm or Institution: A firm or institution organized or existing under the laws of a country other than the United States, its territories, or possessions. The term includes, for purposes of this Agreement, any agency or instrumentality of a foreign government; and firms, institutions or business organizations that are owned or substantially controlled by foreign governments, firms, institutions, or individuals. Specifically excluded from the definition of Foreign Firm or Institution are entities listed on Attachment 3 along with Regeneron's Corporate Affiliates (see Attachment 4).

Financial Status Report: A report prepared by Recipient to address quarterly costs.

Government: The United States of America, as represented by the Department of Health & Human Services ("Government"), Office of the Assistant Secretary for Preparedness & Response ("ASPR"), Office of Biomedical Advanced Research and Development ("BARDA") (represented by Office of Acquisition Management, Contracts and Grants (AMCG)).

Government Purpose.: Any activity in which the United States Government is a party, including cooperative agreements with international or multi-national defense organizations, or sales or transfers by the United States Government to foreign governments or international organizations. Government purposes include competitive procurement, but do not include the rights to use, modify, reproduce, release, perform, display, or disclose technical data for commercial purposes or authorize others to do so.

Government Purpose Rights: The rights by Government to—

1. Use, modify, reproduce, release, perform, display, or disclose technical data within the Government without restriction; and

2. Release or disclose technical data outside the Government and authorize persons to whom release or disclosure has been made to use, modify, reproduce, release, perform, display, or disclose that data for United States Government Purpose.

Invention: Any invention or discovery that is or may be patentable or otherwise protectable under Title 35 of the United States Code.

Know-How: Information, practical knowledge, techniques, and skill development by Recipient in the performance of work under this Agreement necessary for the Practical Application of a Subject Invention (as defined below) within the Field. Know-How does not include patents and patent applications.

Limited Rights: The rights to use, modify, reproduce, perform, display, or disclose Data, in whole or in part, within the Government solely for research purposes for the Field. Government will ensure that disclosed information is safeguarded in accordance with the restrictions of this Agreement. The Government may not, without the prior written permission of Recipient, release or disclose the Data outside the Government, use the Data for competitive procurement or manufacture, release or disclose the data for commercial purposes, or authorize the Data to be used by another party. The Parties shall maintain the confidentiality of all Data subject to or designated as falling within Limited Rights.

Limited Rights Data: Data, other than Computer Software, that embody trade secrets or are commercial or financial and confidential or privileged, to the extent that such Data pertain to items, components, or processes developed at private expense, including minor modifications.

Made: The conception or first actual reduction to practice of the invention as defined in this Agreement.

Option: An option, entered into by bilateral agreement pursuant to a Statement of Work and budget, by which, for a specified time, the Government may elect to purchase additional supplies or services called for by the Agreement.

Other Transaction for Advanced Research ("OTAR"): A legally binding, non-acquisition instrument (generally called an "agreement") used in instances where the principal purpose is the stimulation and/or support of advanced research and development, where a non-traditional Government awardee participates to significant extent in the work.

Other Transaction Agreement Officer ("OTAO"): Is the responsible Government official authorized to bind the Government by signing this Agreement and bilateral modifications.

Other Transaction Agreement Specialist ("OTAS"): Is a supporting official that assists and represents the OTAO. The OTAO is the only official who can bind the Government.

Other Transaction Agreement Technical Representative ("OTTR"): Is the primary Government official for all technical matters on the Agreement.

(b)(4)

Practical Application: With respect to a Subject Invention, to manufacture, in the case of a composition or product; to practice, in the case of a process or method; or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the Subject Invention is capable of being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public for a regulatory approved product.

Program: Research and development being conducted by Parties pursuant to this Agreement.

Prohibited Sources: A person or entity covered by the restrictions described at 48 CFR section 25.701

Property: Any tangible personal property other than property actually consumed during the execution of work under this Agreement.

Recipient: Regeneron Pharmaceuticals, Inc.

Subject Matter Expert (SME): Members of the BARDA technical team who provide technical insights into development activities being undertaken by the Recipient to satisfy the terms of this Agreement as set forth in the SOW. BARDA generally enters into an agreement with an outside entity to gain the services of SMEs on a contractual basis. As non-federal employees, SMEs are subject to non-disclosure agreements as determined by each contract or agreement that they support.

Subject Invention: Any Invention Made in the performance of work under this Agreement within the Field for which Recipient pursues a patent; provided that, all (b)(4) are Inventions Made under this Agreement within the Field (b)(4) Agreement will be deemed to be Subject Inventions.

Sub-Recipient: Akin to a subcontractor. Any supplier, distributor, vendor, or firm that furnishes supplies or services to or for the Recipient, an Affiliate, or a Sub-Recipient. A Sub-Recipient differs from an Affiliate in that Sub-Recipients are not listed as an Affiliate in Attachment 3 and may be used to execute tasks under the SOW by Recipient or Affiliate.

Sub-Recipient Agreement: any contract entered into by a Sub-Recipient to furnish supplies or services for performance of this Agreement. This term describes an agreement with a 1st-Tier Sub-Recipient, except as expressly noted in this Agreement.

Technology: Discoveries, innovations, Know-How and Subject Inventions, conceived in the performance of work under this Agreement and Controlled by Recipient, including Computer Software, recognized under U.S. law as intellectual creations to which rights of ownership accrue, including, but not limited to, patents, trade secrets, and copyrights developed under this Agreement.

B. Scope & General Operation of the Agreement

(b)(4)

The Government will have involvement with the Recipient as set forth in the SOW. The Government will also obtain access to research results and certain rights in Data pursuant to Article VIII of the Agreement. Parties are bound to each other by a duty of good faith and commercially reasonable research effort in achieving the goals of the Program.

This Agreement is formally executed as a "other transaction" pursuant to Sections 319L(c)(4)(B) and 319L(c)(4)(D) of the Pandemic and All-Hazards Preparedness Act, P.L. 109-417. The Federal Acquisition Regulation (FAR) does not apply to this Agreement, except where noted otherwise within this Agreement. The Parties agree that the principal purpose of this Agreement is to support commercially reasonable efforts in advanced research & development and not for the acquisition of Property or services for the direct benefit or use of the Government.

(b)(4)

The Agreement may be modified by mutual agreement of the Parties consistent with Article III.

(b)(4)

and reduce overall risk, and to capitalize on emergent opportunities in order to maximize the probability of success and the preparedness posture of the Government.

(b)(4)

ARTICLE II: PERIOD OF PERFORMANCE

Line Item	Description of Services	Period of Performance
(b)(4)		

A. Base & Option Periods

The term of this Agreement commences upon the date it is duly executed by both Parties. The period of performance for this Agreement for each target commences with a base period ("Base Period"). Additionally, independent Options for discrete periods of work have been established, as detailed in the SOW. The aggregate of these periods for all targets will constitute the period of performance of this Agreement, which may also be revised via mutual agreement of the Parties.

Option periods may be exercised by mutual written agreement of the Parties which would take the form of a modification to the Agreement (b)(4) (b)(4) (b)(4) The Parties acknowledge that the exercise of Option CLINS will be subject to the availability of funds.

The length of Option and Base Periods can be lengthened or shortened by mutual agreement of Parties. (b)(4) (b)(4)

B. Termination Provisions

Either Party may terminate this Agreement for convenience by providing at least ninety calendar (90) days prior written notice to the other Party, provided that such written notice is preceded by consultation between the Parties. In the event of a termination of the Agreement, it is agreed that disposition of Data developed under Agreement shall be in accordance with the provisions set

forth in Article VIII, Data Rights. In the event of termination by either Party, the Recipient's termination costs shall be reimbursable pursuant to the terms of this Paragraph B and Article VI. Upon termination of this Agreement, the Government will reimburse Recipient for its allowable costs and expenses, including, without limitation, non-cancellable allowable (i.e., expenses that cannot be cancelled during the ninety day calendar notice period, regardless of when such expenses are actually incurred – assuming the expenses are deemed allowable under Article VII.C.) expenses and other costs and expenses incurred prior to or during the ninety (90) calendar day notice period.

For purposes of this Agreement, termination costs shall be those costs identified in Federal Acquisition Regulation 31.205-42. The Government and the Recipient will negotiate in good faith a reasonable and timely adjustment of all outstanding issues between the Parties as a result of termination, including disposition of animals acquired for research use. Failure of the Parties to agree to a reasonable adjustment will be resolved pursuant to Article VIII, Disputes. In the event of termination under this clause by the Government, all of the terms and conditions of this Agreement will expire and neither Party shall have any continuing obligations to perform under this Agreement, except as provided in this Article with respect to the reimbursement of allowable and/or non-cancellable costs and expenses. All of the terms and conditions of this Agreement will expire in the event of a termination of this Agreement by either Party, except as for the following provisions, which shall survive termination: this Paragraph B of Article II, Article VI, Article VII, and Paragraphs A, B, C, E, I, and J of Article VIII.

C. Extending the Term of the Agreement

The Parties may, consistent with all fiscal and appropriations laws governing the Government, extend the term of the Agreement by mutual written agreement if funding is available and research opportunities reasonably warrant. Any extension shall be formalized through modification of the Agreement by the OTAO and the Recipient. If the Recipient desires an extension to the term of this Agreement, the Recipient shall submit a request in writing to the OTAO. Any request for an extension should include a revised milestone/project schedule (if applicable).

ARTICLE III: MODIFICATIONS

As a result of quarterly meetings, annual reviews, or at any time during the term of the Agreement, research progress or results may indicate that a change in the SOW would be beneficial to program objectives. Any modification to the Agreement shall be by mutual written agreement of the Parties. Recommendations for modifications, including justifications to support any changes to the SOW, will be documented in a letter and submitted by the Recipient to the OTTR with a copy to the Government OTAO and OTAS. This letter will detail the technical, chronological, and financial impact (if any) of the proposed modification to the Program.

The OTAO shall be responsible for authorizing any modifications to this Agreement on behalf of the Government.

(b)(4)

(b)(4)

ARTICLE IV: MANAGEMENT OF THE PROJECT

A. Recipient/Government Joint Oversight Committee

(b)(4)

(b)(4) The Parties may change the number of JOC participants upon mutual agreement. Additional representatives from either Party or external advisors may also be included in this body on an ad hoc basis, as dictated by the circumstances. Either Party may substitute alternate senior level representatives, on either a temporary or an ongoing basis, by providing advance written notice.

JOC Members:

(b)(6)

The responsibility of the Recipient/Government Joint Oversight Committee is to mutually evaluate risks and progress of assets covered under this Agreement, endorse potential new assets and agree on modifications to the allocation of funding of activities covered under this Agreement. This committee will also jointly evaluate progress towards achievement of Portfolio

Performance Metrics (see Attachment 1, Section 1.1.1.1.). Decisions of the JOC will be made by consensus, with each Party having one (1) vote.

The Recipient/Government Joint Oversight Committee will meet approximately every six (6) months by phone, ad-hoc, via video conference, or in-person to review progress. The JOC will recommend the strategy to be covered under this Agreement during the subsequent funding period, as well as how Government and Recipient funding will be allocated across these activities. The recommendations would be submitted, as appropriate, to the relevant Recipient governance board(s) for endorsement and decision. If endorsed by the Recipient and by the Government, the recommendations will be incorporated into the SOW and this Agreement through modifications as described in Article III. The Recipient will be solely responsible for the conduct of, and will have final decision making authority for activities within the SOW.

B. Project Meetings

Project Teleconferences. A conference call between the OTTR and the Recipient's project leader shall occur bi-weekly (every other week), or as mutually agreed by the Parties. During this call, the project leader will discuss the activities undertaken during the reporting period, any problems that have arisen and the activities planned for the ensuing reporting period. The project leader may choose to include other key personnel on the conference call to give detailed updates on specific projects as may be requested by the OTTR. The OTTR or project leader may assign this responsibility to a delegate. The Recipient may choose to include other key personnel on the conference call to give detailed updates on specific projects or this may be requested by the OTTR.

Other Meetings. In addition to Project Teleconferences, Recipient and the Government shall participate in additional Project Meetings to coordinate the performance of the Agreement. These meetings may include face-to-face meetings with BARDA/AMCG in Washington, D.C. and at work sites of the Recipient, Affiliates, or any Sub-Recipients. Such meetings may include, but are not limited to, meetings of the Recipient (and Sub-Recipients invited by the Recipient) to discuss study designs, site visits to the Recipient's and Sub-Recipient's facilities, and meetings with the Recipient and Government officials to discuss the technical, financial, regulatory and ethical aspects of the Program. In order to facilitate review of Agreement activities, it is expected that the Recipient will provide data, reports, and presentations to Government personnel as requested by the OTTR. Recipient shall provide itinerary/agenda at least five (5) business days in advance of any face to face meeting. The Recipient shall notify the OTTR of formal and informal correspondence with the Food and Drug Administration (FDA) or other regulatory agencies directly related to (b)(4) specified in Attachment 2. Recipient shall not be required to notify OTTR of any correspondence that does not materially impact a Program.

In Process Review Meeting (IPR). As the Government's deems necessary, but no more frequently than annually, the Government may invite the Recipient to give a presentation at an In Process Review Meeting attended by BARDA, AMCG, and select, invited interagency representatives and other interested Government parties, as needed. The Recipient will present Data generated under this Agreement. Progress against Portfolio Performance Metrics will be assessed. Successes and challenges of the Program will be discussed and plans for the coming year will be presented.

Subject Matter Experts. The Parties understand that SMEs are likely contractor employees to the Government who provide the Government services not otherwise available in-house. SMEs

may represent at Government meetings as it relates to this Agreement, but will not provide direction to Recipient and have no authority to bind the Government to any additional obligation. That authority lies solely with the OTAO. All SMEs are subject to nondisclosure agreements and will comply with the terms and conditions of this Agreement.

C. Document Review

The Recipient shall provide the Government sufficient opportunity to review study protocols, reports, and regulatory correspondence as set forth in Attachment 2. The Government's review and comments on these documents are non-binding and advisory in nature. Specific timelines for document review and responses are outline in Attachment 2, Reporting Requirements.

ARTICLE V: AGREEMENT ADMINISTRATION

Administrative and contractual matters under this Agreement will be referred to the following representatives of the Parties:

Government Points of Contact:

(b)(6)

Recipient Points of Contact

(b)(6)

Technical matters under this Agreement will be referred to the following representatives:

Government Points of Contact

(b)(6)

Alternate OTTR:

(b)(6)

Recipient Points of Contact

(b)(6)

(b)(6)

ARTICLE VI: COST SHARING

A. (b)(4)

(b)(4) The Parties acknowledge that the exercise of Options will be subject to the availability of Government funding.

B. (b)(4)

C. Recipient's entitlement to reimbursement for approved costs under this Agreement is limited by the Government funding obligated to the award, as defined on Page 1 of the Award, or as otherwise obligated by modification to this Agreement, and the Recipient may cease performance under this Agreement in the event that it reasonably believes that remaining funds obligated to this Agreement will not continue to cover the actual cost of performance. The Parties' agree that sole remedy to address the total cost exceeding or falling below the estimated total cost to perform the Statement to Work is to agree to a mutual modification of the Agreement in advance of costs being incurred in excess of the Government obligated funds, which also may entail changes to the SOW.

D. Recipient will provide bi-annual (twice annually) Financial Status Reports to the Government identifying the total actual costs of performing this Agreement (outlined in Attachment 2 of this Agreement). This report is for informational purposes only. Recipient's accounting for Government-reimbursed and Recipient costs shall be in accordance with Recipient's accounting practices but must comply with Generally Accepted Accounting Principles (GAAP). Recipient's accounting methods to determine total actual costs are not required to comply with the Cost Accounting Standards or the cost principles at Federal Acquisition Regulation Subpart 31.2; however, Recipient must comply with reasonable cost and accounting standards which may be reviewed by the Government.

(b)(4)

ARTICLE VII: OBLIGATION OF FUNDING & FINANCIAL TERMS

A. Obligation

The Government's liability to make payments to the Recipient is limited to only those funds obligated of this Agreement, which will be denoted on Page 1 of this Agreement (and will be

updated after modifications affecting obligation amount) Recipient may cease performance under this Agreement in the event that it reasonably believes that remaining funds obligated to this Agreement will not continue to cover the actual cost of performance. (b)(4) (b)(4) (b)(4) All Option periods set forth in Article II are subject to the availability of funds. The Parties agree that the Options do not represent an obligation by the Government or Recipient until exercised, following a negotiation on scope and cost.

B. Payments

The Recipient has and agrees to maintain an established accounting system that complies with GAAP standards and the requirements of this Agreement, and shall ensure that appropriate arrangements have been made for receiving, distributing and accounting for Government funds. Recipient will not be required to maintain Government funds in a separate, interest-bearing account. Further, Recipient may request and receive payment for invoices received from an Affiliate or Sub-Recipients before Recipient actually makes payment on such invoices. Government auditors may confirm adequacy of accounting system. Recipient's properly prepared invoice(s) will be submitted for payment quarterly in Adobe Acrobat (.pdf) format, along with the submission of hard copy to the OTAS; provided that the first three invoices shall be submitted for payment on a bi-monthly (every other month) basis for the bi-monthly periods ending on November 30, 2017, January 31, 2018 and March 31, 2018. If directed by the OTAO, the invoice shall be accompanied by appropriate documentation to support the payment request to support a reasonableness determination. However, Recipient will be required to prepare and maintain records, with supporting documentation that is consistent with commercial practices. Each invoice must contain the following information in order to be deemed properly prepared:

1. Name and address of Recipient
2. Invoice Date and Invoice Number
3. Agreement Number
4. Description, quantity, unit of measure, unit price, and extended price (if applicable)
5. Recipient cost share
6. Name and address of OTAR official to whom voucher is to be sent
7. Name, title, phone number, and mailing address of person to notify in the event of a defective invoice
8. Taxpayer Identification Number (TIN)
9. Electronic funds transfer (EFT) banking information
10. The Recipient will convert foreign currency costs to US dollars based on the daily rates interfaced to the Oracle system from the Reval Treasury system on the invoice transaction date.
11. Invoices must include cumulative total costs submitted for reimbursement to date, adjusted (as applicable) to show any amounts suspended by the Government

Payments will be made for costs incurred and do not constitute financing payments. Payment will be made for the performance of services under this assistance agreement, whether or not the services achieve the intended result of the deliverable, except in the case a result or deliverable is not achieved as a result of Regeneron's gross negligence or willful misconduct. Deliverables under Attachment 2 of this Agreement must still be delivered, regardless of failure to achieve initially intended result with performance of any additional required work to be compensated on the same basis for services performed.

Documents should be delivered electronically to the OTAO, OTAS, OTTR, PSC, and e-room electronically. Unless otherwise specified by the OTAO, all deliverables and reports furnished to the Government under this Agreement (including invoices) shall be addressed as follows:

NAME	E-mail invoices to:	Address**:
Matthew A. McCord (OTAS)	matthew.mccord@hhs.gov	ASPR – AMCG 11J24 - O'Neil House Office Bldg. 200 C Street, SW Washington, D.C. 20515
Karl Erlandson (OTTR)	karl.erlandson@hhs.gov	ASPR – BARDA O'Neil House Office Bldg. Washington, D.C. 20515
Kyle Roberts (OTAO)	kyle.roberts@hhs.gov	ASPR – AMCG 11J24 - O'Neil House Office Bldg. 200 C Street, SW Washington, D.C. 20515
PSC	PSC_Invoices@psc.hhs.gov	
E-Room:	(as provided by Government)	

Note: The address in the table is correct for parcels shipped via U.S. Postal Service, United Parcel Service (UPS), and Federal Express (FedEx). If shipping is through another private carrier please contact a Government representative for special instruction.

The Recipient agrees to promptly notify the OTAO in writing if there is an anticipated overrun or unexpended balance (greater than 10 percent) of the estimated costs for the Base Period or any Option and the reasons for the variance.

The Government will pay in US dollars all proper invoices within 30 days of receipt or pay interest on any amounts due in accordance with the Prompt Payment Act.

C. Limitation of Payments

It is herein understood and agreed that Government funds are to be used solely to reimburse Recipient, its Affiliates and Sub-Recipients for activities performed in connection with this Agreement and must be reasonable in nature and amount. The following cost principles shall be used for determining the allowability of costs for which reimbursement is sought by Recipient. These cost principles are not applicable to Recipient's contribution and the Financial Status Report.

1. Allocability shall be determined in accordance with the standards set forth in FAR 31.201-4. Note, the Cost Accounting Standards do not apply to the Recipient, Affiliate, or any Sub-Recipient. Costs shall be accounted for in accordance with the Recipient's, Affiliate's, or Sub-Recipient's GAAP compliant (or foreign equivalent) commercial accounting practices.

2. To be reasonable, a cost must: be generally recognized as an ordinary or necessary part of the business; follow sound business practices; follow what a prudent business person would accept; comply with federal, state, and local laws; and be consistent with the Recipient's, Affiliate's, or the Sub-Recipient's established practices.

   Travel Costs: In order for travel costs to be deemed reasonable, they must be in compliance with the Federal Travel Regulations (FTR), unless otherwise approved by Government.

3. In addition, Recipient's costs that are passed onto the Government for reimbursement are subject to the restrictions on allowable costs described in FAR 31.2.

   a. The cost principles set forth in FAR 31.2 shall only apply to the reimbursement of direct costs under cost-type Affiliate and Sub-Recipient Agreements. These cost principles will be applicable to the pricing of fixed priced Affiliate agreements or Sub-Recipient Agreements only to the extent required by FAR 31.102.

   b. A cost-type Sub-Recipient or Affiliate may propose indirect rates as a component of its proposal to Recipient or an Affiliate, if necessary and Recipient or an Affiliate may accept such rates. For Sub-Recipients, the Government will review these indirect rates as part of the Sub-Recipient approval process set forth in Article VIII. The Government's approval to issue the Sub-Recipient Agreement constitutes the Government's agreement that the proposed indirect rate(s) may be used during the performance of the Sub-Recipient Agreement to determine the Sub-Recipient's reimbursable indirect costs. The approved indirect rate(s) will not be subject to audit or adjustment based upon the Sub-Recipient's or Affiliate's actual cost experience during the performance of the Sub-Recipient Agreement, unless requested by the Sub-Recipient or Affiliate.

D. Financial Records & Reports

As directed by the OTAO, the Recipient shall maintain records in accordance with commercially acceptable business practices to account for all funding under this Agreement and shall maintain records in accordance with commercially acceptable business practices to account for Recipient funding provided under this Agreement in support of the Financial Status Report required under Article VI. Upon completion or termination of this Agreement, whichever occurs earlier, the Recipient shall furnish to the OTAO a copy of the Final Technical Report required by Attachment 2,: Deliverables. The Recipient's relevant financial records are subject to examination or audit on behalf of Government and/or the Comptroller General for a period not to exceed three (3) years after final payment of the Agreement. The OTAO or designee shall have direct access to complete records and information of the Recipient, to the extent necessary to audit to ensure full accountability for all amounts reimbursed by the Government under this Agreement. Such audit, examination, or access shall be performed during business hours on business days upon at least six weeks prior written notice and shall be subject to the security requirements of the audited Party. These records will be deemed Confidential Information of Recipient under Article VIII.B

E. General Access to Records

(b)(4)

(b)(4)

(b)(4) This Paragraph only applies to any record that is created or maintained in the ordinary course of business or pursuant to a provision of law. Recipient shall ensure that its Sub-Recipient Agreements are consistent with this Paragraph.

ARTICLE VIII: OTHER TERMS & CONDITIONS

A. DISPUTES

a. General

The Parties shall communicate with one another in good faith and in a timely and cooperative manner when raising issues under this Article.

b. Dispute Resolution Procedures

i. Any claim or dispute between Government and Recipient concerning questions of fact or law arising from or in connection with this Agreement, and, whether or not involving an alleged breach of this Agreement, shall only be raised as permitted under this Paragraph A.

ii. In the event that any disagreement, claim or dispute between the Parties as described under Article VIII A. b. i. above, or a Modification under Article III in this Agreement results in an increase or decrease in the estimated costs of or time required to perform work under this Agreement, the Party asserting the need for a change in the costs, performance time agrees to notify the other Party within 6 months of the time when the asserting Party knew or should have known the facts establishing the need for the change(s).

iii. Whenever disputes, disagreements, or misunderstandings arise, the Parties shall attempt to resolve the issue(s) involved by discussion and mutual agreement as soon as practicable. Any waiver on behalf of the Government shall be made in writing by the Head of Contracting Activity for AMCG.

iv. Failing resolution by mutual agreement, the aggrieved Party shall document the dispute, disagreement, or misunderstanding by notifying the other Party (through the OTAO or Consortium's Administrator, as the case may be) in writing of the relevant facts, identifying unresolved issues, and specifying the clarification or remedy sought. Within five (5) working days after providing notice to the other Party, the aggrieved Party may, in writing, request a joint decision by the Assistant Secretary for Preparedness and Response ("ASPR") Head of

Contracting Activity, and senior executive appointed by Consortium. The other Party shall submit a written response on the matter(s) in dispute within thirty (30) calendar days after being notified that a decision has been requested. The ASPR Head of Contracting Activity ("HCA") and the Recipient senior executive shall conduct a review of the matter(s) in dispute and render a decision in writing within thirty (30) calendar days of receipt of such written position. Any such joint decision is final and binding.

v. In the absence of a joint decision, upon written request to the Senior Procurement Executive ("SPE") made within thirty (30) calendar days of the expiration of the time for a decision under sub-section b.iv above, the dispute shall be further reviewed. The SPE may elect to conduct this review personally or through a designee or jointly with a senior executive appointed by Consortium. Following the review, the Chief Acquisition Officer or designee will issue a proposed resolution of the dispute within thirty (30) calendar days of referral of the dispute to the SPE or designee. The Parties may accept the Chief Acquisition Officer or designee's decision by mutual agreement. However, if Recipient is unwilling to accept this decision, Recipient may pursue a contract dispute as described in Subparagraph b.vi below.

vi. The Parties agree that the Agreement satisfies the elements of a "contract" for jurisdiction under the Tucker Act. After appropriate exhaustion of the administrative and other remedies identified in this Agreement, Recipient shall have the right to appeal or pursue any contract dispute arising under this Agreement at the Court of Federal Claims or, if applicable, the Court of Appeals for the Federal Circuit or the Supreme Court. Notwithstanding the foregoing or any other provision in this Article VIII.a.b, Recipient is not required to comply with the procedures described in this Article VIII.a.b when seeking injunctive or declaratory relief or when Recipient would otherwise be barred from filing a claim in a particular forum based on a limitations period.

vii. The pendency of a dispute shall not interfere with each Party's right to terminate the Agreement pursuant to Article II and recover any resulting terminations costs.

viii. Escalation Procedure for Technical Matters. In the event of a technical disagreement the procedures for resolution are depicted in Attachment 5, Technical Escalation Procedure

c. Limitation of Damages

Except for claims of non-payment of amounts due under Article VI, any claims for damages of any nature whatsoever pursued under this Agreement shall be limited to direct damages only up to the aggregate amount of Government funding disbursed as of the time the dispute arises. In no event shall the Parties be liable for claims for consequential, punitive, special and incidental damages, claims for lost profits, re-procurement costs, or other indirect damages. Each of the foregoing limitations on damages shall not apply to an action against the Government brought under 28 USC § 1498. Either Party may recover interest on any amounts submitted for payment and denied during the disputes process. Interest on an amount found due on a disagreement,

claim or dispute shall be paid for the period beginning with the date the Government Senior Procurement Executive receives a request for a joint decision as described herein until the date of payment of the claim. Simple interest shall accrue and be paid at the same rate as that which the Secretary of the Treasury shall specify as applicable for each successive 6-month period under the Prompt Payment Act.

B. DATA RIGHTS

a. Allocation of Principal Rights

i. For Data produced under this Agreement including Computer Software, to the extent developed with Government funds, the Recipient grants to the Government a paid-up, nonexclusive, nontransferable, irrevocable, worldwide license in such Data to exercise Government Purpose Rights except as expressly provided elsewhere in this Agreement. For Data produced under this Agreement, excluding Computer Software, to the extent developed with private funds, the Recipient grants to the Government a paid-up, nonexclusive, nontransferable, irrevocable, worldwide license in such Data to exercise Limited Rights. The Government will not obtain any rights in Computer Software produced under this Agreement to the extent developed with private funds.

ii. Recipient agrees to retain and maintain in good condition all Data produced under this Agreement and necessary to achieve Practical Application of any Subject Invention in accordance with the Recipient's established record retention practices. In the event of an exercise of the Government's compulsory licensing rights as set forth under this Article VIII.C.h, Recipient agrees, upon written request from the Government, to deliver at no additional cost to the Government, all existing Data produced under this Agreement necessary to achieve Practical Application of the relevant Subject Invention within sixty (60) calendar days from the date of the written request.

iii. Recipient's right to use Data is not restricted and includes the right under Recipient's established business policies to make public research Data (especially human research Data) by publication in the scientific literature, by making trial protocols, trial results summaries, and clinical studies reports publicly available, and by making trial patient-level data available for third-party analysis.

b. Marking of Data

The Recipient will mark any Limited Rights Data delivered under this Agreement with appropriate Limited Rights markings.

c. Lower Tier Agreements

The Recipient shall ensure that its Affiliate agreements and Sub-Recipient Agreements regardless of tier, for experimental, developmental, or research work entered into after the Effective Date and submitted for reimbursement under this Agreement, are consistent with this Paragraph B.

The Recipient shall execute modifications to the existing third party to ensure compliance to terms and conditions outlined herein within 90 calendar days of the execution of this Agreement.

d. Identification and Disposition of Data

The Recipient shall keep copies of all Data relevant to this Agreement as required by the Food and Drug Administration (FDA) for the time specified by the FDA. In addition, the Recipient shall provide regulatory data to the OTTR and OTAS in accordance with Attachment 2, Reporting Requirements. The Government reserves the right to review any other data determined by the Government to be relevant to this Agreement. The Government further acknowledges that Recipient holds the commercialization rights for all products developed under this Agreement in the U.S. and will be responsible for their registration with the FDA. This provision is subject to any applicable limitations on the Government's rights under Article VIII.B.a-b.

e. Publication and Publicity

No Data or other information obtained under this Agreement shall be released or publicized without concurrence from the Recipient. For purposes of this Agreement, "publication" is defined as an issue of printed material offered for distribution or any communication or oral presentation of information, including any manuscript or scientific meeting abstract. Any publication containing Data generated under this Agreement must be submitted to the Recipient and the OTTR for review and comment no less than thirty (30) calendar days for manuscripts and fifteen (15) calendar days for abstracts before submission for public presentation or publication. The Government's support shall be acknowledged in all such publications substantially as follows:

> "This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under OT number: HHSO100201700020C ."

f. Review of Press Releases

All Parties agree to accurately and factually represent the work conducted under this Agreement in all press releases. Misrepresenting results or releasing information that is injurious to the integrity of a Party may be construed as improper conduct. Press releases shall be defined as the public release of information via any medium, excluding peer-reviewed scientific publications. Each Party agrees to provide the other Party with an advance copy of any press release related to this Agreement not less than ten (10) business days prior to the issuance of the press release. The review time may be expedited for press releases issued to address safety concerns or issues of significant internal importance to Recipient. BARDA support shall be acknowledged in all such press releases substantially as follows:

> "This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under OT number: HHSO100201700020C ."

g. Confidential Information

Unless other terms and conditions outlined within this Agreement apply, each Party may receive Information from the other Party during the term of this Agreement. Solely with respect to this

Subparagraph g, "Information" shall mean any and all information, data or know-how, whether technical or non-technical, oral or written, that is disclosed by one Party ("Disclosing Party") to the other Party ("Receiving Party") and is identified by the Disclosing Party as confidential or may reasonably be considered confidential based on the nature of the item disclosed.. For a period of ten (10) years from the date of disclosure of a given item of Information, the Receiving Party agrees:

1. To use the Information only in connection with its performance of this Agreement;

2. To treat the Information as it would its own proprietary and confidential information;

3. To disclose the Information only to employees or agents of Receiving Party, or Affiliates or Sub-Recipients who are providing services hereunder and who agree to be bound by these confidentiality obligations; and

4. To take all reasonable precautions to prevent the disclosure of Information to any third-party not performing work under this Agreement other than a Corporate Affiliate without the prior written consent of the Disclosing Party.

Each Party shall be relieved of its obligations under this subparagraph if the Information:

1. Was known to the Receiving Party, Affiliate, or Corporate Affiliate prior to receipt hereunder and without a duty of confidentiality as set forth in written records; or

2. Information is generated by the Receiving Party or its Corporate Affiliate by persons who have not had access to or knowledge of the Information disclosed hereunder; or

3. At the time of disclosure by the Disclosing Party to the Receiving Party, was generally available to the public, or which after disclosure hereunder becomes generally available to the public through no fault attributable to the Receiving Party; or

4. Is hereafter made available to the Receiving Party or its Corporate Affiliate for use or disclosure by the Receiving Party from a third party having a right to do so; or

5. Is required by law, regulation, subpoena, or judicial or governmental order to be disclosed, provided that the Receiving Party gives the Disclosing Party sufficient notice to permit Disclosing Party to seek a protective order or other similar order with respect to such Information.

C. PATENT RIGHTS.

a. Allocation of Principal Rights

This Agreement does not grant any express or implied rights in either Party's background intellectual property.

Unless Recipient shall have notified the Government (in accordance with Subparagraph (b) below) that Recipient does not intend to retain title, in which case title shall vest with the Government, Recipient shall retain the entire right, title, and interest throughout the world to each Subject Invention developed under this Agreement, consistent with the provisions of this Article. With respect to any Subject Invention developed under this Agreement, in which Recipient retains title, the Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the Subject Invention throughout the world. For clarity, this license does not include the right to use or allow others to use the Subject Invention for commercial purposes.

b. Invention Disclosure, Election of Title, and Filing of Patent Application

i. Recipient shall disclose in writing each Subject Invention to the OTTR within 12 months after the inventor discloses it in writing to Recipient personnel responsible for patent matters. The disclosure shall identify the inventor(s) and this Agreement under which the Subject Invention was made. It shall be sufficiently complete in technical detail to convey a clear understanding of the Subject Invention. The disclosure shall also identify any publication, on sale (i.e., sale or offer for sale), or public use of the Subject Invention, or whether a manuscript describing the Subject Invention has been submitted for publication and, if so, whether it has been accepted for publication. In addition, after disclosure to the agency, the Recipient shall promptly notify the OTTR of the acceptance of any manuscript describing the Subject Invention for publication and any on sale or public use.

(b)(4)

iii. Recipient shall file either a provisional or a non-provisional patent application for an elected Subject Invention within 1 year after election. However, in any case where a publication, on sale, or public use has initiated the 1-year statutory period during which valid patent protection can be obtained in the United States, the Recipient shall file the application prior to the end of that statutory period. If the Recipient files a provisional application, it shall file a non-provisional application within 12 months of the filing of the provisional application.

iv. Recipient may request extensions of time for disclosure, election, or filing under subparagraphs (b)((i), (b)(ii) and (b)(iii) of this clause.

v. If Recipient determines that it does not intend to retain title to any such Subject Invention, Recipient shall notify the Government, in writing, within two (2) years of disclosure to the Government. However, in any case where publication, sale, or public use has initiated the one (1)-year statutory period wherein valid patent protection can still be obtained in the United States, the period for such notice may be shortened by the Government to a date that is no more than sixty (60) calendar days prior to the end of the statutory period.

c. Conditions When the Government May Obtain Title

Upon the Government's written request, Recipient shall convey title to any Subject Invention to the Government if Recipient fails to disclose or elects not to retain title to the Subject Invention within the times specified in Subparagraph b of Paragraph C of this Article; provided, that the Government may only request title within sixty (60) calendar days after learning of the failure of Recipient to disclose or elect within the specified times.

d. Rights to Recipient and Protection of Recipient's Right to File

Recipient shall retain a fully paid up, sub-licensable, nonexclusive, royalty-free license throughout the world in each Subject Invention to which the Government obtains title. The Recipient license extends to the Recipient's subsidiaries and other affiliates (outside this Agreement), if any, within the corporate structure of which Recipient is a party and includes the right to grant licenses of the same scope to the extent that Recipient was legally obligated or permitted to do so at the time the Agreement was executed. The license is otherwise transferable only with the approval of the Government, except when transferred to an Affiliate or successor of that part of Recipient's business to which the Subject Invention pertains. The Government approval for license transfer shall be provided on a timely basis (and in no event later than 90 calendar days following Recipient's request) and shall not be unreasonably withheld.

i. The Recipient license may be revoked or modified by the Government to the extent necessary to achieve expeditious Practical Application of the Subject Invention pursuant to an application for an exclusive or nonexclusive license submitted consistent with appropriate provisions at 37 CFR Part 404. Recipient's license shall not be revoked in that field of use or the geographical areas in which Recipient has achieved Practical Application of the Subject Invention and continues to make the benefits of the Subject Invention accessible to the public.

ii. Before revocation or modification of Recipient's license, the Government shall furnish Recipient with a written notice of its intention to revoke or modify the license, which notice shall include a detailed explanation of the reasons for such revocation or modification, and Recipient shall be allowed thirty (30) calendar days (or such other time as may be authorized for good cause shown) after the notice to show cause why the license should not be revoked or modified.

e. Action to Protect the Government's Interest

Recipient agrees to execute or to have executed and promptly deliver to the Government all instruments necessary to (i) establish or confirm the rights the Government has throughout the world in those Subject Inventions to which Recipient elects to retain title, and (ii) convey title to the Government when requested under Subparagraph c of Paragraph C of this Article and to enable the Government to obtain patent protection throughout the world in that Subject Invention.

i. Recipient agrees to require, by written agreement, its employees, other than clerical and non-technical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by Recipient, each Subject Invention made under this Agreement so Recipient can comply with the disclosure provisions of Paragraph C of this Article. Recipient shall use reasonable efforts to instruct employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

ii. Recipient shall notify the Government of any decisions not to continue the prosecution of a patent application for a Subject Invention, pay maintenance fees, or defend in a reexamination or opposition proceedings on a patent of a Subject Invention, in any country, not less than thirty (30) calendar days before the expiration of the response period required by the relevant patent office.

Recipient shall include, within the specification of any United States patent application and any patent issuing thereon covering a Subject Invention, the following statement: "This invention was made with Government support under Agreement **HHSO100201700020C**, awarded by the U.S. Department of Health and Human Services. The Government has certain rights in the invention."

f. Lower Tier Agreements

The Recipient shall ensure that its Affiliate agreements and Sub-Recipient Agreements regardless of tier, for experimental, developmental, or research work entered into after the Effective Date and submitted for reimbursement under this Agreement, contain invention reporting and assignment requirements sufficient to permit Recipient to comply with this Article.

The Recipient shall execute modifications to the existing third party agreements to ensure compliance to terms and conditions outlined herein within 90 days of the execution of this Agreement.

g. Reporting on Utilization of Subject Inventions

i. Recipient agrees to submit, during the term of the Agreement, an annual report on the utilization of a Subject Invention or on efforts at obtaining such utilization that is being made by Recipient or its licensees or assignees. Such reports shall include information regarding the status of development, date of first commercial sale or use, and such other data and information as the agency may reasonably specify. Recipient also agrees to provide additional reports as may be requested by the Government in connection with any march-in proceedings undertaken by the Government in accordance with Subparagraph h of Paragraph C of this Article. Consistent with 35 U.S.C. § 202(c)(5), the Government agrees it shall not disclose such information to persons outside the Government without permission of Recipient.

ii. All required reports shall be submitted to the e-room, OTAS, OTAO, and OTTR.

h. Compulsory Licensing Rights

The Recipient agrees that, with respect to any Subject Invention in which it has retained title, the Government has the right to require Recipient, an assignee, or exclusive licensee of a Subject Invention to grant a non-exclusive license to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if Recipient, assignee, or exclusive licensee refuses such a request, the Government has the right to grant such a license within the Field itself *only* if the Government determines that:

i. (b)(4)

D. FOREIGN ACCESS TO TECHNOLOGY

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

a. General

The Parties agree that research findings and technology developments arising under this Agreement may constitute a significant enhancement to the national security and to the economic vitality of the United States. Accordingly, access to important technology developments under this Agreement by Foreign Firms or Institutions must be carefully controlled. The Recipient agrees to comply with all applicable laws regarding export controls and not to export any Technology to any US embargoed countries.

The Recipient shall provide timely notice to the Government of any proposed transfers from the Recipient of Technology developed under this Agreement to Foreign Firms or Institutions; provided that, this Article shall not apply to transfers by Recipient of Technology to subsidiaries of Recipient or as part of the sale, merger, or acquisition of Recipient, or as part of the sale or transfer of that part of Recipient's business to which the Technology developed under this Agreement pertains or (ii) commercialization (itself or through domestic or foreign licensees) of products developed under this Agreement to non-U.S. embargoed countries in a manner compliant with all applicable laws regarding export controls. If the Government determines that a transfer may have adverse consequences to the national security interests of the United States, the Recipient, its vendors, and the Government shall jointly endeavor to find alternatives to the proposed

transfer which obviate or mitigate potential adverse consequences of the transfer but which provide substantially equivalent benefits to the Recipient.

In any event, the Recipient shall provide written notice to the OTTR and OTAO of any proposed transfer to a Foreign Firm or Institution at least thirty (30) calendar days prior to the proposed date of transfer. Such notice shall cite this Article and shall state specifically what is to be transferred and the general terms of the transfer. Within fifteen (15) calendar days of receipt of the Recipient's written notification, the OTAO shall advise the Recipient whether it consents to the proposed transfer. In cases where the OTAO does not concur or fifteen (15) calendar days after receipt and the Government provides no decision, the Recipient may utilize the procedures under Article VIII.A, Disputes. However, no transfer shall take place until a decision is rendered.

In the event of a transfer of Technology by Recipient to a Foreign Firm or Institution which is identified as a Prohibited Source pursuant to Federal Acquisition Regulation Subpart 25.7: (a) the Government may terminate this Agreement for cause and (b) the Government shall have a non-exclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the Technology throughout the world for Government and any and all other purposes, particularly to effectuate the intent of this Agreement. Upon request of the Government, the Recipient shall provide written confirmation of such licenses.

b. Lower Tier Agreements

The Recipient shall ensure that its Affiliate agreements and Sub-Recipient Agreements regardless of tier, for experimental, developmental, or research work entered into after the Effective Date and submitted for reimbursement under this Agreement, are consistent with this Article.

The Recipient shall execute modifications to the existing third party agreements to ensure compliance to terms and conditions outlined herein within 90 calendar days of the execution of this Agreement.

E. TITLE TO AND DISPOSITION OF PROPERTY

a. Title to Property Acquired under this Agreement

Title to each item of Property acquired under this Agreement with an acquisition value of $50,000 or less shall vest in Recipient upon acquisition with no further obligation of the Parties unless otherwise determined by the OTAO. Should any item of Property with an acquisition value greater than $50,000 be required, Recipient shall obtain prior written approval of the OTAO before acquiring such property. Title to this Property shall also vest in Recipient and Government upon acquisition with proportion to the respective value of Recipient and Government funds used to acquire the Property. Recipient shall be responsible for the maintenance, repair, protection, and preservation of all Property at its own expense.

b. Disposition of Property Acquired under this Agreement

(b)(4)

i. (b)(4)

c. (b)(4)

F. SUB-RECIPIENTS

The Recipient shall award any Sub-Recipient Agreement (akin to a traditional subcontract) via competitive bids to the maximum extent practicable and commercially reasonable under the circumstances. It is first and foremost the responsibility of the Recipient to ensure the Sub-Recipient selection is a best value decision for the project.

For any firm-fixed price, time and materials, cost-reimbursement, or labor hour Sub-Recipient Agreement with a value in excess of $500,000, the Recipient will provide the OTAO the opportunity to review all Sub-Recipient Agreements and related justification for cost or price reasonableness ten (10) calendar days before execution. This shall include the nature of the work that the Sub-Recipient is going to perform, an estimated period of performance and the proposed costs for the work. The OTAO will submit a written response within ten (10) calendar days stating approval or disapproval of the Sub-Recipient Agreement. In the event that the OTAO disapproves of the Sub-Recipient Agreement, the OTAO must provide written justification to support his/her decision. Recipient will provide the OTAO with an electronic copy of the final Sub-Recipient Agreement.

Master service agreements already existing at the time of award will likely be exempt from re-competition, assuming evidence of adequate competition is produced. These will be approved by Government on an ad-hoc basis upon the Recipient's request.

Notwithstanding the foregoing, this Paragraph F will not apply to any transactions between Recipient and its Corporate Affiliates.

G. CIVIL RIGHTS ACT

Performance of this Agreement in the U.S. is subject to the compliance requirements of Title VI of the Civil Rights Act of 1964 as amended (42 U.S.C. 2000-d) relating to nondiscrimination in Federally assisted programs. The Recipient has signed an Assurance of Compliance with the nondiscriminatory provisions of the Act.

H. EXECUTION

This Agreement may be revised only by written consent of the Recipient and the Government OTAO. This Agreement, or modifications thereto, may be executed in counterparts each of which shall be deemed as original, but all of which taken together shall constitute one and the same instrument.

I. LIABILITY

No Warranty.

The Parties make no express or implied warranty as to any matter whatsoever, including the conditions of the research or any invention or other intellectual property ("IP"), or product, whether tangible or intangible, made or developed under this Agreement, or the merchantability, or fitness for a particular purpose of the research or any invention or other IP, or product. The Parties further make no warranty that the use of any invention or other IP or product contributed, made or developed under this Agreement will not infringe on any other U.S. or foreign patent or other IP right. In no event will any Party be liable to any other Party for punitive, exemplary, or consequential damages. Limitations on the Parties' liability under this Agreement are included in Article VIII.A.c above.

Other Liability.

The Government shall not be liable to any Party to this Agreement, whether directly or by way of contribution or indemnity, for any claim made by any person or other entity for personal injury or death or for property damage or loss, arising in any way from this Agreement, including, but not limited to, the later use, sale or other disposition of research and technical developments, whether by resulting products or others, whether made or developed under this Agreement or contributed by either Party pursuant to this Agreement, except as provided under the Federal Tort Claims Act (28 USC 2671 *et seq*) or other federal law whether sovereign immunity has been waived.

J. SEVERABILITY

The illegality or invalidity of any provision of this Agreement shall not impair, affect, or invalidate the other provisions of this Agreement. In the event that any provision of this Agreement is determined to be illegal or invalid, the Parties shall modify the remaining provisions in this Agreement as necessary to achieve their original intent as closely as possible.

K. SPECIAL CLAUSES

a. Protection of Human Subjects

i. The Recipient agrees that the rights and welfare of human subjects involved in research under this Agreement shall be protected in accordance with 45 CFR Part 46 and with the Recipient's current Assurance of Compliance on file with the Office for Human Research Protections (OHRP), Office of Public Health and Science (OPHS). The Recipient further agrees to provide certification that the Institutional Review Board ("IRB") has reviewed and approved the procedures, which involve human subjects, in accordance with 45 CFR Part 46 and the Assurance of Compliance.

ii. The Recipient shall bear full responsibility for the performance of all work and services involving the use of human subjects under this Agreement and shall ensure that work is conducted in a proper manner and as safely as is feasible. The Parties hereto agree that Recipient retains the right to control and direct the performance of all work under this Agreement. Nothing in this Agreement shall be deemed to constitute Recipient or any subconsortium, agent or employee of Recipient, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. Recipient agrees that it has entered into this Agreement and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent consortium without imputing liability on the part of the Government for the acts of the Recipient or its employees.

iii. If at any time during the performance of this Agreement, the Government OTAO determines, in consultation with the OHRP, OPHS, Assistant Secretary for Health ("ASH"), that the Recipient is not in compliance with any of the requirements and/or standards stated in Paragraphs (i) and (ii) above, the Government OTAO may immediately suspend, in whole or in part, work and further payments under this Agreement until the Recipient corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Recipient fails to complete corrective action within the period of time designated in the OTAO's written notice of suspension, the Government OTAO may, in consultation with OHRP, OPHS, ASH, terminate this Agreement in a whole or in part, and the Recipient's name may be removed from the list of those performers with approved Health and Human Services Human Subject Assurances.

b. Human Materials (Assurance of OHRP Compliance)

i. The acquisition and supply of all human specimen material (including fetal material) used under this Agreement shall be obtained by Recipient in full compliance with applicable federal, state and local laws and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

ii. The Recipient shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this Agreement, by collaborating sites, or by Sub-Recipients identified under this Agreement, were obtained with prior approval by the OHRP of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects.

This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by the Recipient.

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

c. Research Involving Human Fetal Tissue

All research involving human fetal tissue shall be conducted in accordance with the Public Health Service Act, 42 U.S.C. 289g-1 and 289g-2. Implementing regulations and guidance for conducting research on human fetal tissue may be found at 45 CFR 46, Subpart B. The Recipient shall make available, for audit by the Secretary, Government, the physician statements and informed consents required by 42 USC 289g-1(b) and (c), or ensure Government access to those records, if maintained by an entity other than the Recipient.

d. Needle Exchange

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

e. Care of Live Vertebrate Animals

i. Before undertaking performance of any Agreement involving animal-related activities where the species is regulated by the United Sates Department of Agriculture (USDA), the Recipient shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR sections 2.25 through 2.27. The Recipient shall furnish evidence of the registration to the OTAO.

ii. The Recipient shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR sections 2.1-2.11, or from a source that is exempt from licensing under those sections.

iii. The Recipient agrees that the care, use, and intended use of any live vertebrate animals in the performance of this Agreement shall conform with the Public Health Service (PHS) Policy on Humane Care of Use of Laboratory Animals (PHS Policy), the current Animal Welfare Assurance , the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC) and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 CFR subchapter A, Parts 1-4). In case of conflict between standards, the more stringent standard shall govern.

iv. If at any time during performance of this Agreement, the OTAO determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Recipient or their Sub-Recipients are not in compliance with any of the requirements and standards stated in subparagraphs (i) through (iii) above, the OTAO may immediately suspend, in whole or in part, work and further payments under this Agreement until the Recipient or Sub-Recipient corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Recipient or Sub-Recipient fails to complete corrective action within the period of time designated in the OTAO written notice of suspension, the OTAO may, in consultation with OLAW, NIH, terminate this Agreement in whole or in part, and the Recipient's or Sub-Recipient's name may be removed from the list of those contractors with Animal Welfare Assurances.

Note: The Recipient may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service ("APHIS"), USDA, for the region in which its research facility is located. Information concerning this program may be obtained by contacting your regional office or the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737.

f. Animal Welfare

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals. This policy may be accessed at: http://grants1.nih.gov/grants/olaw/references/phspol.htm . Primate studies will not begin until a contract research organization's Institutional Animal Care and Use Committee and the Recipient's Animal Welfare Department provide final approval of the study protocol.

g. Protection of Personnel Who Work with Nonhuman Primates

All Recipient personnel who work with nonhuman primates or enter rooms or areas containing nonhuman primates shall comply with the procedures set forth in NIH Policy Manual 3044-2, entitled, "Protection of NIH Personnel Who Work with Nonhuman Primates," located at the following URL: https://policymanual.nih.gov/3044-2

Information on Compliance with Animal Care Requirements

Registration with the USDA is required to use regulated species of animals for biomedical purposes. USDA is responsible for the enforcement of the Animal Welfare Act (7 U.S.C. 2131 et. seq.), https://awic.nal.usda.gov/.

The PHS Policy is administered by the OLAW: http://grants2.nih.gov/grants/olaw/olaw.htm . An essential requirement of the PHS Policy http://grants2.nih.gov/grants/olaw/references/phspol.htm is that every institution using live vertebrate animals must obtain an approved assurance from OLAW before they can receive funding from any component of the U.S. Public Health Service. If the Recipient does not have an assurance and will be utilizing a Sub-Recipient to perform the animal work then the Recipient and Sub-Recipient must have an Inter-Institutional Assurance in place to allow the Recipient to utilize the assurance of the Sub-Recipient to meet the Government's requirements for assurance. The request for this negotiation of this assurance must be submitted to OLAW by the Government on behalf of the Recipient.

The PHS Policy requires that Assured institutions base their programs of animal care and use on the Guide for the Care and Use of Laboratory Animals https://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf and that they comply with the regulations (9 CFR, Subchapter A) http://awic.nal.usda.gov/final-rules-animal-welfare-9-cfr-parts-1-2-and-3 issued by the USDA under the Animal Welfare Act. The Guide may differ from USDA regulations in some respects. Compliance with the USDA regulations is an absolute requirement of this Policy.

The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) http://www.aaalac.org is a professional organization that inspects and evaluates programs of animal care for institutions at their request. Those that meet the high standards are given the accredited status. As of the 2002 revision of the PHS Policy, the only accrediting body recognized by PHS is the AAALAC. While AAALAC accreditation is not required to conduct biomedical research, it is highly desirable. AAALAC uses the Guide as their primary evaluation tool. They also use the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching. It is published by the Federated of Animal Science Societies http://www.fass.org.

h. Approval of Required Assurance by Law

Under governing regulations, federal funds that are administered by the Department of Health and Human Services, BARDA shall not be expended by the Recipient for research involving live vertebrate animals, nor shall live vertebrate animals be involved in research activities by the Recipient under this award unless a satisfactory assurance of compliance with 7 U.S.C. 2136 and 9 CFR Sections 2.25-2.27 is submitted by Recipient 30 calendar days prior to commencing research involving live vertebrate animals and approved by the OLAW. Each performance site (if any) must also assure compliance with 7 U.S.C. 2136 and 9 CFR Sections 2.25-2.27 with the following restriction: Only activities that do not directly involve live vertebrate animals (i.e. are clearly severable and independent from those activities that do involve live vertebrate animals) may be conducted by individual performance sites pending OLAW approval of their respective assurance of compliance with 7 U.S.C. 2136 and 9 CFR Sections 2.25-2.27. Additional information regarding OLAW may be obtained via the Internet at http://grants.nih.gov/grants/olaw/olaw.htm.

Registration with the Select Agent Program for Work Involving the Possession, Use, and/or Transfer of Select Biological Agents or Toxins:

Work involving select biological agents or toxins shall not be conducted under this Agreement until the Recipient and any affected Sub-Recipients are granted a certificate of registration or are authorized to work with the applicable select agents.

For Recipient or Sub-Recipient awards to domestic institutions who possess, use, and/or transfer Select Agents under this Agreement, the institution must complete registration with the Centers for Disease Control and Prevention (CDC), HHS or APHIS, USDA, as applicable, before performing work involving Select Agents, in accordance with 42 CFR Part 73. No Government funds can be used for work involving Select Agents, as defined in 42 CFR Part 73, if the final registration certificate is denied.

For Recipient or Sub-Recipient awards to foreign institutions who possess, use, and/or transfer Select Agents under this Agreement, the institution must provide information satisfactory to the Government that a process equivalent to that described in 42 CFR Part 73 for U.S. institutions is

in place and will be administered on behalf of all Select Agent work sponsored by these funds before using these funds for any work directly involving the Select Agents. The Recipient must provide information addressing the following key elements appropriate for the foreign institution: safety, security, training, and procedures for ensuring that only approved/appropriate individuals have access to the Select Agents, and any applicable laws, regulations and policies equivalent to 42 CFR Part 73. The Government will assess the policies and procedures for comparability to the U.S. requirements described in 42 CFR Part 73. When requested by the OTAO, the Recipient shall provide key information delineating any laws, regulations, policies, and procedures applicable to the foreign institution for the safe and secure possession, use, and transfer of Select Agents. This includes summaries of safety, security, and training plans, and applicable laws, regulations, and policies. For the purpose of security risk assessments, the Recipient must provide the names of all individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals have access to Select Agents under this Agreement.

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

i. Manufacturing Standards

The Recipient agrees to comply with cGMP guidelines (21 CFR Parts 210-211, 600) for manufacturing, processing and packing of drugs, chemicals, biological, and reagents.

The Recipient agrees to advise the Government OTAO and OTTR promptly of any relocation of the Recipient's prime manufacturing facility or the relocation of any subconsortium's facility during the term of this Agreement. The Recipient also agrees to advise the Government OTAO and OTTR immediately if at any time during the term of this Agreement, the items under this Agreement fail to comply with cGMP guidelines and/or the facility receives a negative FDA Quality Assurance Evaluation (Form 483).

The Current Good Manufacturing Practice Regulations (cGMP) (21 CFR 210-211) will be the standard applied for manufacturing, processing and packing of a therapeutic product under this Agreement unless otherwise agreed upon or as required by the development process (e.g., lab scale experimental manufacturing and pilot scale manufacturing).

If at any time during the life of this Agreement, the Recipient fails to comply with cGMP in the manufacturing, processing and packaging of a therapeutic product under this Agreement and such failure results in a material adverse effect on the safety, purity or potency of this therapeutic product (a material failure) as identified by CDER, the Recipient shall have sixty (60) calendar days from the time such material failure is identified to initiate corrective action designed to cure such material failure within three (3) months. If the Recipient fails to initiate such an action within the sixty (60) calendar day period, then the Agreement may be terminated.

j. Anti-Bribery and Anti-Corruption

Each Party agrees to perform its obligations under this Agreement in accordance with the applicable anti-bribery and anti-corruption laws of the territory in which such Party conducts business with the other Party as set forth herein. Each Party shall be entitled to exercise its termination right, under and in accordance with the terms of this Agreement, to terminate this

Agreement immediately on written notice to the other Party, if the other Party fails to perform its material obligations in accordance with this Article VIII K.j.

k. Salary Rate Limitation

i. Pursuant to the current and applicable prior HHS appropriations acts, payment of the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II in effect on the date Government funding was initially obligated to this Agreement is an unallowable cost under this Agreement and shall be addressed in accordance with Article.

ii. For purposes of the salary rate limitation, the terms "direct salary," "salary", and "institutional base salary", have the same meaning and are collectively referred to as "direct salary", in this clause. An individual's direct salary is the annual compensation that the Recipient pays for an individual's direct effort (costs) under the OTAR. Direct salary excludes any income that an individual may be permitted to earn outside of duties to the Recipient. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative [F&A] costs).

Note: The salary rate limitation does not restrict the salary that an organization may pay an individual working under an Government contract, order, or OTAR; it merely limits the portion of that salary that may be paid with Federal funds.

iii. The salary rate limitation also applies to individuals under Sub-Recipient Agreements except to the extent that that a Sub-Recipient Agreement is awarded on a fixed-price basis without analysis of labor costs. If this is a multiple-year OTAR, it may be subject to unilateral modification by the OTAO to ensure that an individual is not paid at a rate that exceeds the salary rate limitation provision established in the HHS appropriations act in effect when the expense is incurred regardless of the rate initially used to establish Agreement funding.

iv. See the salaries and wages pay tables on the U.S. Office of Personnel Management Web site for Federal Executive Schedule salary levels that apply to the current and prior periods.

l. Person-In-Plant

With seven (7) business days advance notice to the Recipient in writing from the OTAO/OTAS, the Government may place a person-in-plant in Recipient, Sub-Recipient, or Affiliates facility for activities associated with this Agreement. That Person-In-Plant shall be subject to the Recipient, Sub-Recipient, and/or Affiliate's policies and procedures regarding security and facility access at all times while in the Recipient, Sub-Recipient, and/or Affiliate's facility. As determined by federal law, no Government representative shall publish, divulge, disclose, or make known in any manner, or to any extent not authorized by law, any information coming to him in the course of employment or official duties, while stationed in a Recipient, Sub-Recipient, and/or Affiliate's plant.

m. Reporting Matters Involving Fraud, Waste and Abuse

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

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

n. Prohibition on Recipient Involvement with Terrorist Activities

The Recipient acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Recipient to ensure compliance with these Executive Orders and Laws. The Recipient shall ensure that its Affiliate agreements and Sub-Recipient Agreements regardless of tier, for experimental, developmental, or research work entered into after the Effective Date and submitted for reimbursement under this Agreement, are consistent with this subparagraph n.

o. Materials Transfer Agreement

For distribution to third parties (*i.e.* any Party outside of the Consortium) of any material developed under this Agreement, the Recipient must provide BARDA and AMCG notice of the transfers in the Recipient's monthly technical report.

p. Inspection and Acceptance

i. The OTAO or the duly authorized representative will perform inspection and acceptance of materials and services to be provided under this Agreement.

ii. For the purposes of this Paragraph, the designated OTTR is the authorized representative of OTAO. The OTTR will assist in resolving technical issues that arise during performance of the Agreement. The OTTR; however, is not authorized to change any Agreement terms or authorize any changes in the SOW or modify or extend the Period of Performance, or authorize reimbursement of any costs incurred during performance of the Agreement.

iii. Inspection and acceptance will be performed at Recipient or Sub-Recipient's facilities or at:

Biomedical Advanced Research and Development Authority/Office of Acquisition Management, Contracts, and Grants (AMCG)
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
200 C Street, SW
Washington, D.C. 20515

L. TRANSFERS & ASSIGNMENTS

All transfers and/or assignment will be conducted in a manner that is consistent with the Assignment of Claims Act (31 U.S. Code § 3727) and the **prohibition on transfer of contract and certain allowable assignments (**41 U.S.C.A. § 6305). Notwithstanding the foregoing, the Recipient may assign this Agreement to its Corporate Affiliates after providing the Government with 30 calendar days' advance notice and Government agrees to such assignment.

M. ENTIRE AGREEMENT

Unless otherwise specifically provided, this Agreement and its Attachments embodies the entire understanding between the Parties, and any prior or contemporaneous representations, either oral or written, are superseded. No amendments or changes to this Agreement, including without limitation, changes in the SOW, total estimated cost, and period of performance, shall be effective unless made in writing and signed by authorized representatives of the Parties.

ATTACHMENT 1:
STATEMENT OF WORK ((b)(4)

1. EXECUTIVE SUMMARY

(b)(4)

2. STATEMENT OF WORK

2.1. Preamble

(b)(4)

Withheld pursuant to exemption

(b)(4)

of the Freedom of Information Act

Withheld pursuant to exemption

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of the Freedom of Information Act

Note: On the preceeding three pages of this award (i.e. Standard Form 26), the term "Contractor" is included to refer to Regeneron. It is agreed that this is an award made under Other Transaction Authority and the term "Contractor" is only included above as it is system generated. The term "Recipient" is used hereafter.

ATTACHMENT 2:
REPORTING REQUIREMENTS

REPORT DELIVERABLES

Unless otherwise specified by the OTAO, delivery of reports to be furnished to the Government under this Agreement (including invoices), shall be delivered electronically along with a concurrent email notification in accordance with Article VII, Paragraph B.

For electronic delivery of final versions of the deliverables listed below, the Recipient shall upload documents into the appropriate folder on (b)(4) ("eRoom") which is the designated USG file sharing system. The USG shall provide two Recipient representatives authorized log in access to the file share program. Each representative must complete a mandatory training provided by the USG prior to gaining user access. A notification email should be sent to the OTAO, OTAS, and OTTR upon electronic delivery of any documents in accordance with Article VII, Paragraph B.

DELIVERABLES

Successful performance of the Agreement shall be deemed to occur upon performance of the work set forth in the SOW set forth in Attachment 1 of this Agreement and upon delivery, as required by the SOW or elsewhere in this Agreement, by the OTAO, or the duly authorized representative of the OTAO, of the following items in accordance with the stated delivery schedule on the following pages:

Item Description	Delivery Date	Deliver To
1. Monthly Technical Progress Report describing project progress over the previous month. **Business status update** will be provided on a quarterly basis consistent with the invoice	The 15th of each month	OTAO/OTAS and OTTR via e-mail. Additionally, email invoices to (b)(4) and mail hard copy of invoice only as directed by OTAO.
2. (b)(4) Invoices	(b)(4)	
3. Bi-Weekly (i.e. Every two weeks or as-aeeded) Conference Call Minutes	Proposed agenda 2 business days prior to call. Minutes within 7 business days following each conference call	
4. Bi-annually Joint Oversight Committee minutes	Within 10 business days following each Joint Oversight Committee	
5. Portfolio Progress Milestone Presentation. Annual or event driven review of program	No later than 10 business days before Milestone Review at Joint Oversight Committee	

6. Study Protocols for each non-clinical or clinical trial	No later than 10 business days before submission to the FDA*	OTAO/OTAS and OTTR via e-mail and, if requested, CD-ROM
7. Study Reports for each non-clinical or clinical trial	No later than 15 business days before submission to the FDA*	
8. Manufacturing Campaign Reports for contract funded clinical trial material and	No later than 15 business days before submission to the FDA*	
9. Technical Documents from contract funded activities such as Process Development Report, Assay Validation Plan/Report, Assay	Within 10 business days upon request by OTAO/OTTR or 15 business days prior to submission to FDA*	
10. QA Audit Reports including findings, results and next steps. BARDA reserves the right to participate in the audits.	Within 5 business days of report completion	
11. Formal FDA Submissions of any kind pertaining to the scope of the project as necessary during Contract performance	No later than 10 business days before submission to the FDA* BARDA will coordinate with Contractor for reviewing NDA sections	
12. Memo with Date and Time of Scheduled Meetings with FDA. BARDA reserves the right to attend FDA meetings relevant	As soon as possible after scheduling	
13. Communications from FDA related to contract funded	Within 2 business days of receipt from FDA	
14. Minutes for Formal Meetings with FDA	Within 2 business days of receipt from FDA	

15. Draft Final Report	No later than 45 business days prior to contract expiration	OTAO/OTAS and OTTR via e-mail.
16. Final Report	No later than contract expiration	
17. Incident Report for any critical programmatic concerns, risks or potential	Within 96 hours of incident	OTAO/OTAS and OTTR via e-mail or telephone
18. Raw Data and Analysis Pertaining to Scope of the Project Generated Using USG	Within a reasonable time after request within industry standards	OTAO/OTAS via e-mail
19. Weekly Clinical Report during Active Enrollment Periods	The Monday following the week being reported	OTTR via email
20. Clinical Site Enrollment Reporting and Updates to support the BARDA Clinical	Submitted monthly as part of technical report	
21. Quality Agreements with Subcontractors	Within 10 business days upon request by OTAO/OTTR	OTAO/OTAS and OTTR via e-mail
22. Publications/Presentations	No later than 30 calendar days before submission for publications and 15 calendar days for presentations	OTAO/OTAS and OTTR via email

23. Financial Status Report. (b)(4)	(b)(4)	OTAO/OTAS and OTTR via email

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