

OTHER TRANSACTION FOR ADVANCED RESEARCH (OTAR)
BETWEEN
GENENTECH, INC
1 DNA WAY
SOUTH SAN FRANCISCO, CA 94080
AND
THE UNITED STATES OF AMERICA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY
O'NEILL HOUSE OFFICE BUILDING
WASHINGTON, DC 20515

CONCERNING
GENENTECH UMBRELLA AGREEMENT

(b)(4)

Date: March 27, 2020

Agreement No.: HHSO100201800036C

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:

CLIN	Title	Start	End
(b)(4)			

Authority: 10 USC 2371 and Sections 319(c) (4) (B) and/or 319L(c) (4) (D) of the Pandemic and All-Hazards Preparedness Act, P.L. 109-417, 319L(c)(5) of the Public Health Service Act, 42 USC 247d-7e(c)(5).

Line of Accounting and Appropriation:

(b)(4)

(b)(4)



PURPOSE: The purpose of this modification is to accomplish the following:

(b)(4)



This Agreement is entered into between the United States of America, hereinafter called the "Government", represented by the Department of Health and Human Services (HHS) and Genentech, 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".

Signatures	
For GENENTECH, INC.	FOR THE UNITED STATES OF AMERICA ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE, BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY (BARDA), DIVISION OF CONTRACT MANAGEMENT AND ACQUISITIONS
(b)(6)	George J. Keane Jr -S Digitally signed by George J. Keane Jr -S Date: 2020.03.27 19:35:30 -04'00'
(b)(6)	George J. Keane, Jr., Other Transactions Agreement Officer, ASPR/BARDA/DCMA Date:
(b)(6) North America Date: March 27, 2020	

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ARTICLE VI: COST SHARING

ARTICLE VI: COST SHARING, is modified to revise and replace the entire Article VI with the following:

- A. The terms of this Article VI apply to the cost sharing for (b)(4).
(b)(4) This framework may be applied by mutual agreement to any of the Options or to any modification to the effort required under the (b)(4).
(b)(4) The Parties acknowledge that the exercise of Options will be subject to the availability of funding.
- B. Recipient estimates that the cost of completing the (b)(4).
(b)(4) This amount reflects Recipient's estimate and may overstate or understate the actual cost of completing the (b)(4).

(b)(4)

1. (b)(4)
2. (b)(4)
3. (b)(4)
4. (b)(4)
5. (b)(4)
6. (b)(4)

1. TOTAL PROJECT COST SUMMARY FOR BASE PERIODS AND OPTION PERIODS

	IEID:	IEID: BALOXAVIR					
	(b)(4)						
DIR. LABOR							
FRINGE							
OVERHEAD							
SUBCONTR.							
MATERIALS							
DIR. TRAVEL							
OTHER DIR. COSTS							
G&A							
TOTAL COSTS							

2. COST SHARE FOR BASE PERIOD AND OPTION PERIODS – RECIPIENT

	IEID:	IEID: BALOXAVIR					
	(b)(4)						
DIR. LABOR							
FRINGE							
OVERHEAD							
SUBCONTR.							
MATERIALS							
DIR. TRAVEL							
OTHER DIR. COSTS							
G&A							
TOTAL COSTS							

3. COST SHARE FOR BASE PERIOD AND OPTION PERIODS – U.S. Government

	IEID:	IEID:					
	(b)(4)	(b)(4)					
DIR. LABOR							
FRINGE							
OVERHEAD							
SUBCONTR.							
MATERIALS							
DIR. TRAVEL							
OTHER DIR. COSTS							
G&A							
TOTAL COSTS							

4. PROJECTED FUNDING PROFILE

CLIN	TYPE	SEGMENT	AREA	TOTAL PROGRAM	TOTAL GOVERNMENT SHARE	EXERCISED GOVERNMENT SHARE
(b)(4)						

C.

D. Recipient will provide a Financial Status Report to the Government, which will, among other things, identify the total actual costs of performing this Agreement. This report is for informational purposes only. Recipient's accounting for Government-reimbursed and Recipient costs shall be in accordance with the Recipient's accounting practices but must comply with International Financial Reporting Standards (IFRS) (b)(4)

(b)(4)

E. For purposes of the Financial Status Report, Recipient shall (b)(4)

(b)(4)

F. Recipient's entitlement to reimbursement for approved costs under this Agreement is not contingent upon Recipient's cost share equaling any specific ratio or percentage of total costs. The Parties' remedy to address the total cost exceeding or falling below the estimated total cost to perform the SOW is to agree to a mutual modification of the Agreement or a termination of the Agreement.

ARTICLE VII: SPECIAL CLAUSES

The following text is appended to Article VII: SPECIAL CLAUSES

R. (b)(4)

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(b)(4)



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ATTACHMENT 1: STATEMENT OF WORK (Revised)

ATTACHMENT 1: STATEMENT OF WORK, is modified to revise and replace ATTACHMENT 1 with the following:

Dated: March 27, 2020

Recipient: Genentech, Inc.

ATTACHMENT 1. Statement of Work

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

(b)(4)



1.1.1. IEID CLIN Summary Table

(b)(4)



(b)(4)

Block 14

(b)(4)

(b)(4)

Contractor will create a framework for Contractor and BARDA to collaborate through their Alliance Management team. Contractor will develop a schedule for meetings that are designed to ensure collaboration between BARDA and Contractor on areas of mutual interest and progress towards the project objectives. Contractor will manage day-to-day communication and reporting to BARDA for funded projects.

(b)(4)

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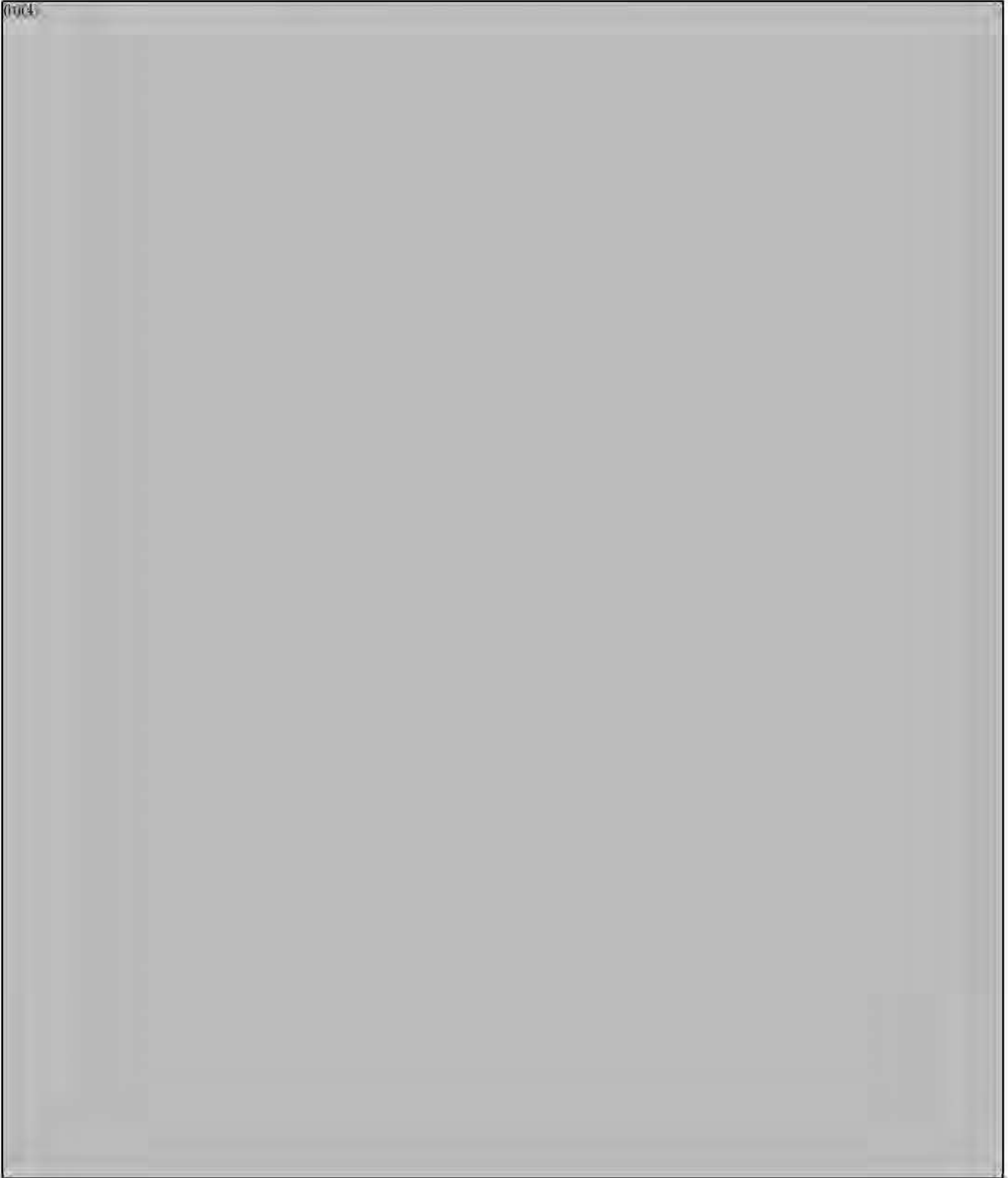
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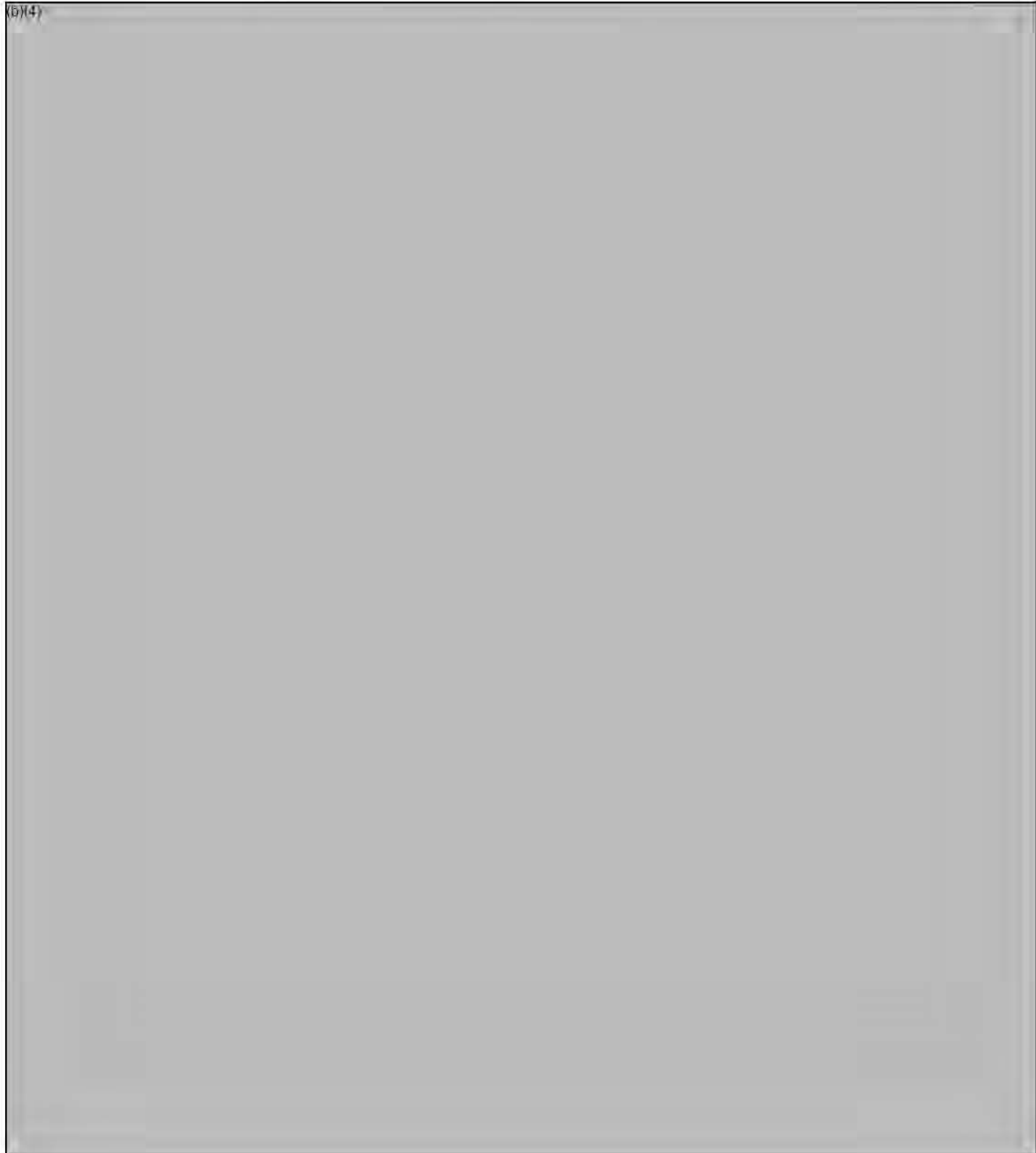
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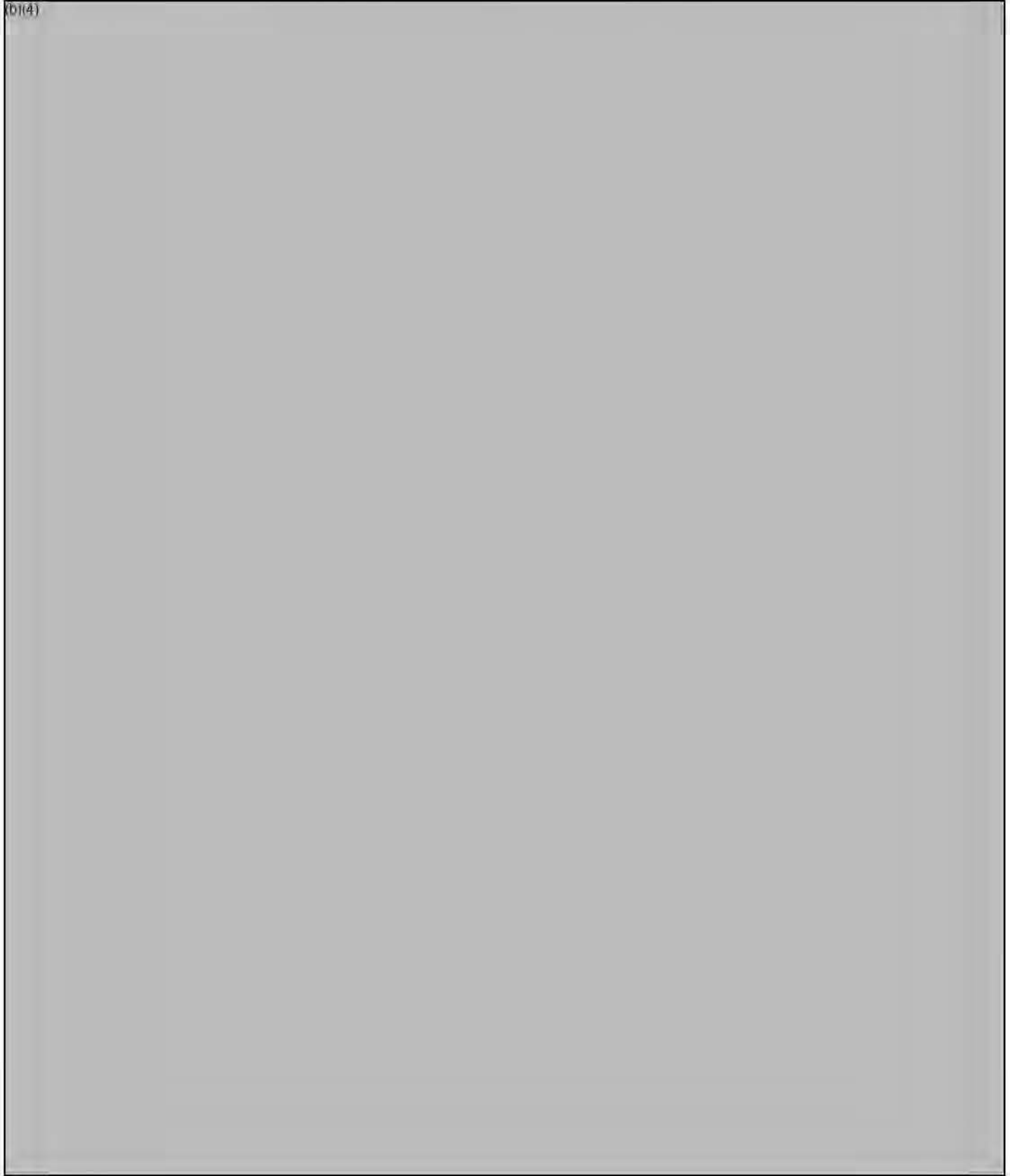
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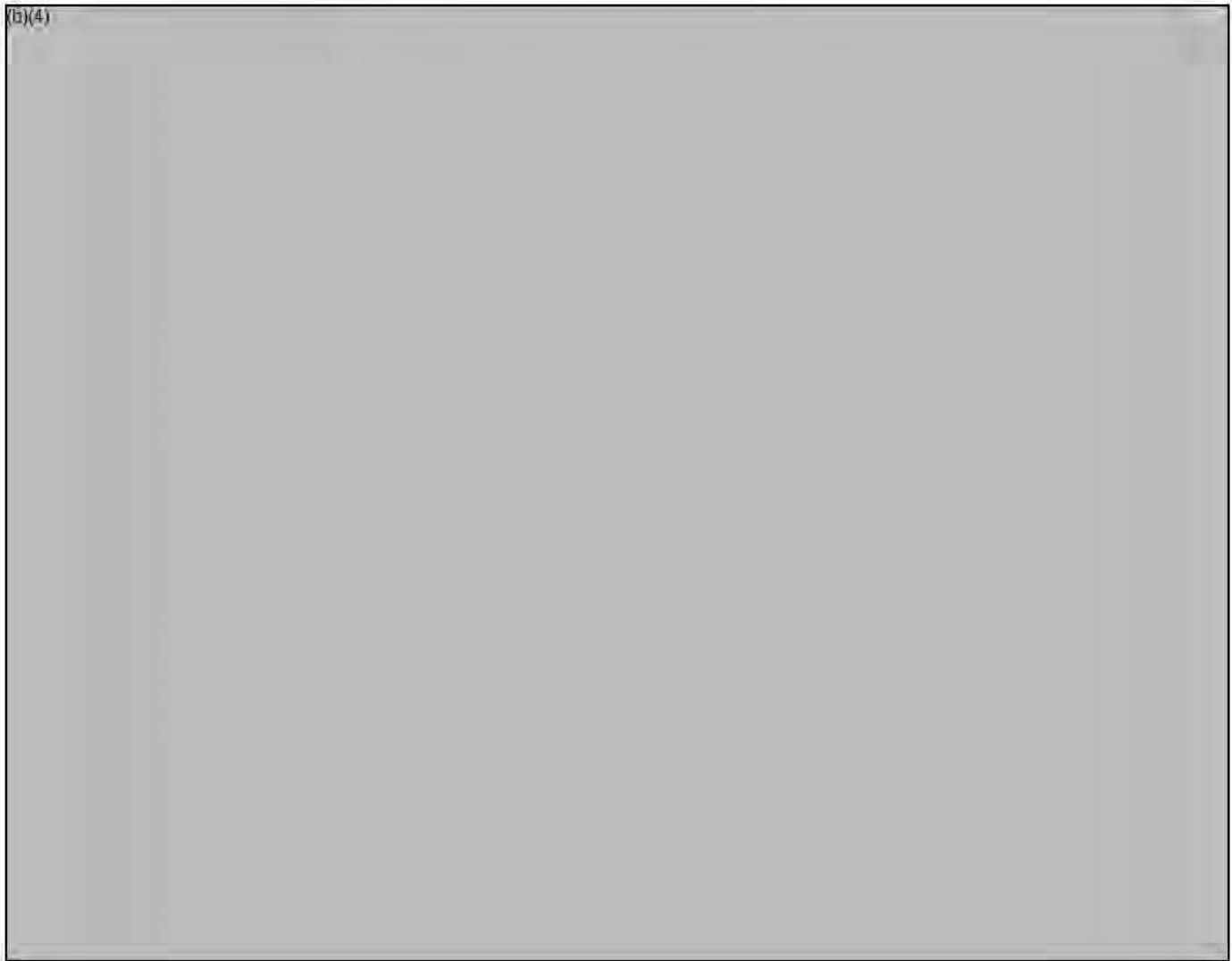
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(b)(4)



ATTACHMENT 2. REPORTING REQUIREMENTS

ATTACHMENT 2: REPORTING REQUIREMENTS, is modified by appending the following table to section D. Deliverables.

1. Delivery of the following items shall only be required for (b)(4)

#	Type of Deliverable	Frequency/ Time Periods	Description of Deliverable	Reporting Procedures	Quantity/ Forms
1.	Daily project status update	Daily, except for weekends and Federal holidays, or as agreed by the two parties	<p>Upon request of the Government, the Recipient shall provide by email a daily update to BARDA project staff.</p> <p>(b)(4)</p> <p>Upon request of the Government, updates may also occur on weekends and on federal holidays, provided at least 24 hours' notice.</p>	<p>Update will be provided to OTTR by email.</p> <p>Upon request of the Government, Recipient may participate in teleconferences, as mutually agreed.</p> <p>No agenda or meeting minutes will be required.</p>	1 Electronic Copy by Email to OTTR
2	Product Development	Within one month of	(b)(4)	Recipient will submit Product Development	1 Electronic Copy to OTTR

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#	Type of Deliverable	Frequency/ Time Periods	Description of Deliverable	Reporting Procedures	Quantity/ Forms
	Source Material and Manufacturing Report	contract award and with substantive changes	(b)(4)	<p>Source Material Report within one month of contract award, within 30 days of substantive changes made to sources and/or materials, or on the 6th month anniversary of the work package being approved (OT modification).</p> <p>The Government will provide written comments to the Product Development Source Material and Manufacturing Report within 15 business days of receipt.</p> <p>Recipient will address, in writing, any concerns raised by BARDA.</p> <p>The Recipient is not required to change its methods or processes based on BARDA's concerns and/or recommendations.</p>	and OTAS by Email; Upload to eRoom.
3	Recipient Locations	Within 5 business days of contract award and substantive changes	(b)(4)	<p>Within 5 business days of contract award.</p> <p>Within 5 business days after a substantive location or capabilities change.</p>	1 Electronic Copy to OTTR and OTAS by Email; Upload to eRoom.