

**AMENDMENT OF OTHER TRANSACTION AGREEMENT (OTA)**

**OTHER TRANSACTION FOR ADVANCED RESEARCH (OTAR)**

**BETWEEN**

**JANSSEN RESEARCH & DEVELOPMENT LLC  
920 ROUTE 202  
RARITAN, NJ 08869, USA**

**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**

**INFLUENZA PORTFOLIO AND OTHER EMERGING PATHOGENS DEVELOPMENT CANDIDATES**

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Amendment No. 0006

Effective Date of Amendment: Upon Last Signature in Section III

Other Transaction Agreement No. HHSO100201700018C

Effective Date of Agreement: August 15, 2017

Except as provided in this Amendment, all terms and conditions of the Agreement, as heretofore changed, remain unchanged and in full force and effect.

*[Remainder of this Page Intentionally Left Blank; See Next Page for Description]*

I. AMENDMENT PURPOSE

By the Parties' mutual agreement and within the existing Agreement's general scope, this Amendment No. 0006 bilaterally:

- i. adds an additional asset to develop a vaccine in response to the current novel coronavirus ("2019-nCoV") outbreak,
- ii. incorporates a realigned budget structure around (b)(4) and the 2019-nCoV asset. This structure aligns with (b)(4)  
(b)(4)
- iii. updates the Statement of Work (Exhibit-A) to reflect 2019-nCoV work packages. The 2019-nCoV asset work packages 6.1 – 6.7 (CLINs 0001- 0007) as described on the Exhibit-A, Statement of Work are considered added and funded (b)(4) (b)(4) work packages as of the date of this amendment. Work Package 6.7 is an option to be exercised at a future date based on (i) JOC recommendation, (ii) availability of funding and (iii) a signed amendment between the Parties,
- iv. modifies the PMO steering committee and USG agreement team to add the respective Technical Leads for this 2019-nCoV Vaccine development, and (b)(4)
- v. (b)(4)

II. AMENDMENTS TO AGREEMENT

A. Incorporate new budget and workplan structure to reflect the new 2019-nCoV asset and redirected (b)(4)

- 1) Pursuant to Agreement Article VI(C), the budget allocation summary of assets is hereby replaced to incorporate the following.

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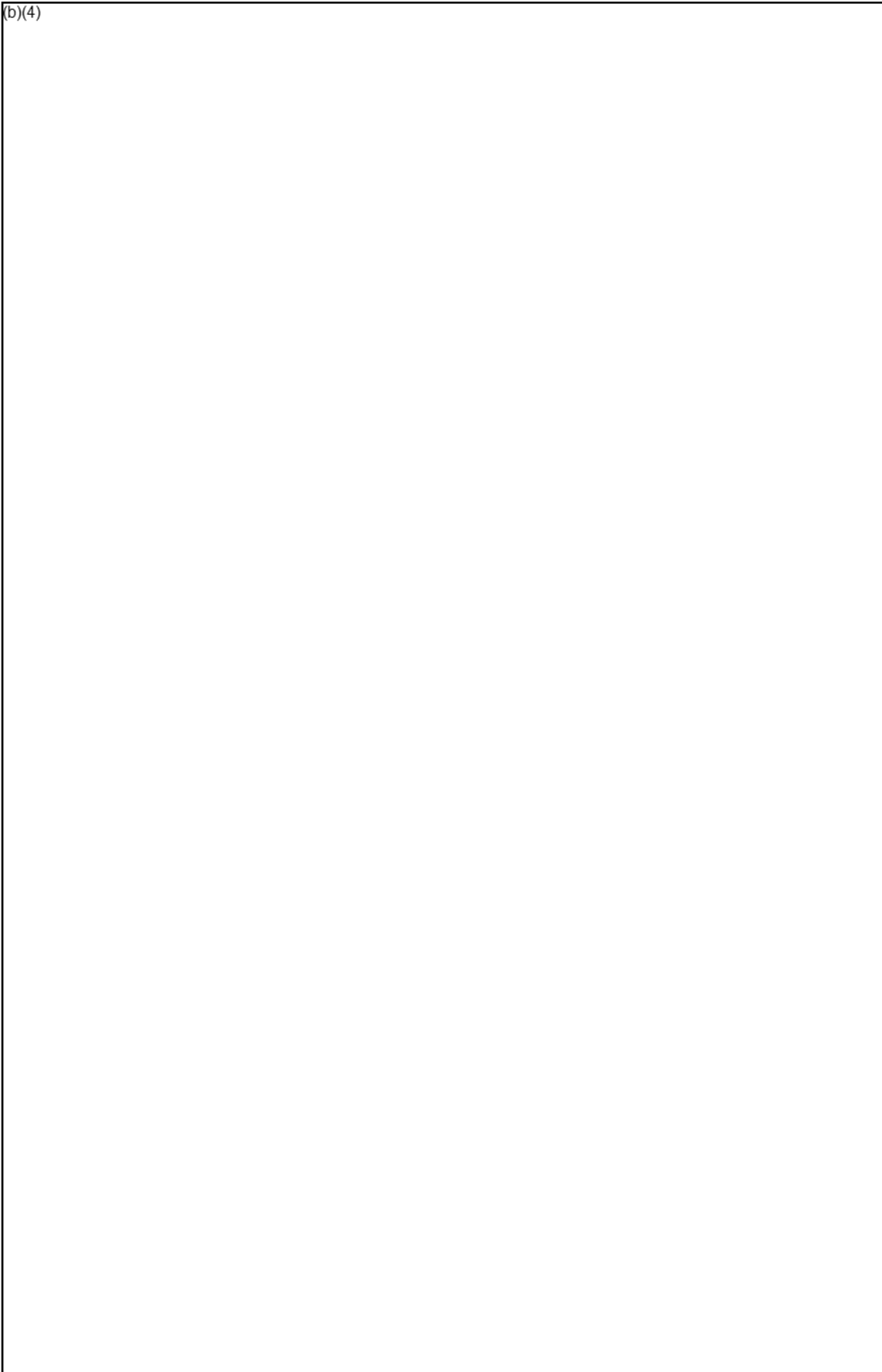
(b)(4)



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(b)(4)

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- 2) Exhibit B budget allocation summary provide details for the budget restructuring are incorporated and attached to this Amendment 0006.

(b)(4)

(b)(4)

B. Updated the Statement of Work

- 1) The Statement of Work shall be replaced to reflect the new asset structure. The updated SOW for incorporation in the OTA is included in Exhibit A.

C. Update of Recipient's Key Personnel and the Government's personnel working under the Agreement

- 1) Article IV *Management of the Project* Section A (3) *Organizational Chart* is deleted and replaced with the following:

(b)(6)

(b)(4)

(b)(4)



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III. SIGNATURES

Acknowledged, accepted, and agreed for

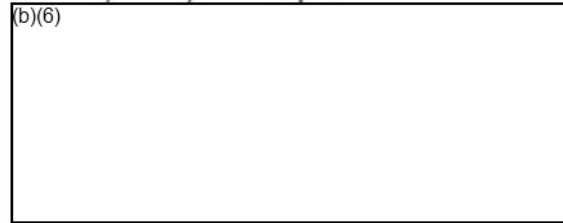
JANSSEN RESEARCH & DEVELOPMENT, LLC

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES  
OFFICE OF THE ASSISTANT SECRETARY FOR  
PREPAREDNESS & RESPONSE

(b)(6)



(b)(6)



DATE: 2/11/2020

**ATTACHMENT 1: TASK DESCRIPTION DOCUMENT (SOW)**

Overall Objectives and Scope

Seasonal and pandemic influenza remains one of the most important public health threats despite current vaccine and therapeutic options. The Consortium is developing a broad portfolio of innovative and novel countermeasures against influenza and other emerging infectious diseases comprising small molecules, biologics and vaccines. The portfolio employs (b)(4) modes of action complementary to current Standard of Care treatments to develop single or combination therapies that have the potential to increase therapeutic benefit and preclude the rapid emergence of drug resistance. The (b)(4) aims to (b)(4) the influenza vaccine field by providing broad protection for both seasonal and pandemic influenza.

Specifically, this Agreement includes: an influenza (b)(4) that is now ready for (b)(4)

(b)(4) influenza A or B

(b)(4); and (b)(4)

In addition, Recipient may propose to augment the portfolio by replacing molecules listed in this SOW with backup molecules from their ongoing research programs. With support from the JOC, the Consortium may also consider in-licensing drug or vaccine candidates to supplement the Program's portfolio of emerging infectious disease medical countermeasures in the Field. Recipient may also add Consortium Members as may be appropriate or complimentary to the performance and goals of this Agreement.

(b)(4)



(b)(4)

(b)(4)

6 Novel Coronavirus ("2019-nCoV") Vaccine

**6.1 Antigen design, manufacturability testing and preMVS manufacturing**

*Activities*

- Several designs based on the 2019-nCoV spike sequence will be made and (b)(4) at multiple CROs

- Ad26 research batches encoding the different spike variants (b)(4)

(b)(4)

(b)(4)

(b)(4)

- Several critical reagents such as expression plasmids, soluble proteins, peptide pools and detection antibodies will be generated or ordered

(b)(4)

(b)(4)

## 6.2 pre-clinical immunology and protective efficacy

### *Activities*

(b)(4)

(b)(4)

## 6.3 CMC development

### *Activities*

(b)(4)

- (b)(4) method development will occur to make insert specific assays fit for purpose.

(b)(4)

*Activities*

- Setup of immunological assays
  - (b)(4)
- Writing of protocol elements document (PED)
- Protocol writing
- Writing and submission of preIND document
- Writing and submission of IND documents

(b)(4)

**6.5 GLP Toxicology**

*Activities*

- A GLP Toxicity study will be performed (b)(4)
- (b)(4)
- (b)(4)

(b)(4)

**6.6 GMP manufacturing**

*Activities*

- Master Virus Seed manufacturing and release
- Drug substance manufacturing at appropriate scale (b)(4)
- Drug product manufacturing and release (b)(4)

(b)(4)

(b)(4)

**6.7 Ph1 clinical trial – OPTION Work Package**

*Activities*

- Randomized, placebo-controlled, double blind study in healthy adult volunteers
- Primary objective will be assessment of safety and reactogenicity. Secondary and exploratory endpoints will evaluate vaccine-induced immunogenicity.

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

(b)(4) will be enrolled at (b)(4) to allow additional exploratory immunogenicity analysis, including potentially passive transfer studies if such model can be developed.

(b)(4)

## 7 Project Management

(b)(4)

### 7.1 Joint Oversight Committee

The Joint Oversight Committee (JOC) is the larger decision-making body that provides guidance, direction and control to the projects to ensure execution of the projects according to the SOW. The JOC will discuss and approve any changes to the SOW. To that extent, the JOC will meet at critical decision points in the program, but no less than two times per year, preferably face to face or alternatively by WebEx or telephone conference. Ad hoc meetings will be organized when urgent matters arise. The JOC will consist of voting and non-voting members from BARDA and Janssen. Additional, non-voting members can be assigned or invited on an ad hoc basis. Decisions to reprioritize specific projects and resources as the need arises will be taken by consensus. In case such a decision cannot be reached in the JOC, the decision will be escalated to one BARDA and one Janssen senior management member identified at the start of the project.

### 7.2 PMO Steering Committee

The PMO (Program Management Organization) steering committee has dual responsibilities. One area of responsibility is the communication and coordination with BARDA regarding day to day management and execution of the project e.g. organizing meetings on a regular agreed basis. In addition, the PMO Steering Committee will coordinate all SOW activities and provide the technical and administrative infrastructure to ensure efficient planning, initiation, implementation, direction, management and completion of all tasks. This will be coordinated by the Project Manager Leader (PML). The Steering Committee will assess progress and where needed will work out strategic changes to be decided upon by the JOC. The Steering Committee consists of a group of dedicated and specialized Project Management experts, key personnel and additional specific expertise for the functions that are required for executing the specific work scope for each proposed asset area.

### 7.3 Asset Project Management

These WPs include the Program Management activities associated with each of the assets. Each asset will have an (b)(4) who will oversee their specific (b)(4) requirements. This includes conducting frequent and regular (b)(4) meetings to ensure the accurate developing and tracking of the budget, timeline and resource plan. The (b)(4) (b)(4) team of each asset will also include relevant functional (b)(4) and a (b)(4). Each asset will also have an (b)(4) who will oversee their specific Technical requirements. This includes conducting frequent and regular (b)(4) meetings to define the overall development strategy. The (b)(4) of each asset will include Technical Lead, Preclinical Leader, Clinical Leader, the CMC Leader and, the Regulatory Leader. Additional expertise

required for executing asset-specific work possibly including subcontractors may be added as part of (b)(4) and (b)(4)



(b)(4)