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AMENDMENT OF OTHER TRANSACTION AGREEMENT (OTA)

OTHER TRANSACTION FOR ADVANCED RESEARCH (OTAR)

Agreement Number HHSO100201700018C

Effective Date of Agreement: August 15, 2017

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

Amendment No. 0008

Effective Date of Modification: Upon Last Signature in Section III

Total Amount of the Agreement is increased by (b)(4) for addition COVID scope (b)(4)
(b)(4) cost share adjustment from (b)(4) to (b)(4)
(b)(4) (Includes Recipient and Government Funding).

Government Share of Total Amount of the Agreement is increased by (b)(4) from (b)(4)

Recipient Share of Total Amount of the Agreement is increased by (b)(4) for scope increase (b)(4)
(b)(4) cost share adjustment from (b)(4)

Current Government commitment: with the scope/cost estimate adjustment to Work Packages (“WP”) 6.1 - 6.7 and the addition and authorization of WPs 6.8 – 6.10 and 6.13 – 6.16, the total Funds Obligated is increased by \$456,237,081 from \$233,288,786 to \$689,525,867.

Current Recipient commitment: with the scope/cost estimate adjustment to WPs 6.1 - 6.7, the addition and authorization of WPs 6.8 – 6.10 and 6.13 – 6.16 of (b)(4) and the (b)(4) (b)(4) the total Recipient Funds Obligated is (b)(4)

Authority: Section 319L(C)(5) of the Public Health Service Act, 42 USC 247d-7e(C)(5).

Line of Accounting and Appropriation:

(b)(4)

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I. AMENDMENT PURPOSE

This Amendment seeks to utilize Recipient's expertise to perform research and development for vaccine (b)(4) for the current COVID-19 pandemic and declared public health emergency.

By the Parties' mutual agreement and within the existing Agreement's general scope, this Amendment No. 0008 bilaterally:

- i. replenishes funding (b)(4) to the COVID-19 vaccine efforts added to Amendment 0006;
- ii. incorporates the scope of work previously added via Amendment 0006 for Pre-clinical thru Clinical Phase 1 Study, WPs 6.1 - 6.7, which will be removed from Amendment 0006 and will be added to this Amendment 0008;
- iii. adjusted Work Packages 6.1 - 6.7 to reflect an updated scope and budget;
- iv. exercises Work Package 6.7;
- v. adds Work Packages 6.8 - 6.16;
- vi. updates the Statement of Work (Exhibit-A) to reflect COVID-19 Vaccine, Work Packages (WP) 6.1 – 6.16. The COVID-19 Vaccine Work Packages 6.1 – 6.10 and 6.13 – 6.16 as described in the Exhibit-A, Statement of Work are considered added and funded non-severable independent work packages as of the date of this amendment. Work Packages (b)(4)
- vii. updates the (b)(4) paragraph II.C. below;
- viii. Article IV: Management of the Project, Section A (3) Organizational Chart, is updated to include the respective Technical Leads for the COVID-19 program;
- ix. (b)(4)
- x. Within Agreement Number HHSO100201700018C, Article XVI: Special Clauses the Section R, Public Readiness and Emergency Preparedness Act ("PREP ACT") Coverage, is added.

II. AMENDMENTS TO AGREEMENT

A. Incorporate new Cost Share Estimates/Budget Summary and Budget Allocation/Workplan Structure (Exhibit B) to reflect the COVID-19 Vaccine estimated costs and cost shares.

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

(b)(4)

2) Budget Allocation/Workplan Structure (also included as Exhibit B) reflects the budget allocation summary and provides details for the budget incorporated in this Amendment 0008. This updated Exhibit B reflects the adjusted WPs 6.1 – 6.7 cost estimates, adds the new WPs (6.8 - 6.16) and replenishes funding

(b)(4)

(b)(4)

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(b)(4)

- B. Updated the Statement of Work - The Statement of Work shall be replaced to reflect the new COVID-19 Vaccine, Work Packages (WP) 6.1 – 6.16. The updated SOW for incorporation in the OTA is included in Exhibit A.

C.

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(b)(4)

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

(b)(4)



E.

(b)(4)



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F. Article XVI: Special Clauses the following clauses are added:

- i. Section R, Public Readiness and Emergency Preparedness Act ("PREP ACT") Coverage, is added:

R. Public Readiness and Emergency Preparedness Act ("PREP ACT") Coverage

The Federal Government may not use, or authorize the use of, any products or materials provided under either this agreement or any future purchase from Recipient's domestic manufacturing capacity unless such use occurs in the United States and is protected from liability under a declaration issued under the Public Readiness and Emergency Preparedness Act, 42 U.S.C. § 247d-6d.

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

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
Biomedical Advanced Research &
Development Authority

BY: James Harris -S Digitally signed by James Harris -S
Date: 2020.03.27 16:47:10 -04'00'

NAME: James Harris

ITS: Other Transaction Agreement Officer

DATE:

(b)(6)

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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) and (b)(4) influenza A or B viruses; a (b)(4) (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)

6.1 Antigen design, manufacturability testing and preMVS manufacturing

Activities

- DNA encoding for several designs of the SARS-CoV-2 spike protein will be (b)(4) at multiple CROs
- Research batches of Ad26 vectors (b)(4) of the spike protein (b)(4)
- (b)(4)
- (b)(4)
- (b)(4)
- The PreMVS, with selected antigen, will be released based on the following assays:

(b)(4)

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

(b)(4)

WP6.2 Pre-Clinical Immunology (Performed at Janssen or

(b)(4)

Activities

(b)(4)

(b)(4)

