

MODIFICATION 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
ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE
O'Neill House Office Building
WASHINGTON, DC 20201

CONCERNING

INFLUENZA PORTFOLIO AND OTHER EMERGING PATHOGENS DEVELOPMENT CANDIDATES

Modification No.: 0001

Date of Modification:

Effective Date of Modification:

Agreement No.: HHSO100201700018C

PR No.: N/A

Total Amount of the Agreement: **\$546,000,000** (INCLUDES RECIPIENT AND GOVERNMENT FUNDING)

Total Estimated Government Funding of the Agreement: \$273,000,000

Total Estimated Recipient Funding of the Agreement: **\$273,000,000**

Funds Obligated: \$43,588,145

Effective Date of the Agreement: August 15, 2017

Authority: 10 USC 2371 and Sections 319L(c) (4) (B) and/or 319L(c) (4) (D) of the Pandemic and All-Hazards Preparedness Act, P.L. 109-417

Line of Accounting and Appropriation: unchanged

Description/Purpose of modification: The purpose of the modification is to add ARTICLE XVIII: CONFIDENTIALITY to the other transaction. No other changes are agreed to at this time.

This bi lateral modification is entered into by mutual agreement of parties and pursuant to the terms of the OTA. All agreement terms and conditions are changed to be consistent with the description of modification listed above. All other terms and conditions remain the same.

1. ARTICLE I: SCOPE OF THE AGREEMENT, SECTION B Definitions - The following definitions shall be added to the OTAT Agreement in Article IB.

"Business day: A business day is any day that is not a Saturday or Sunday; a Federal holiday in the United States; a bank holiday or national public holiday in Belgium; or a bank holiday or national public holiday in The Netherlands.

Confidential Information: information or data of a personal nature about an individual, or proprietary information or data submitted to the Government by or on behalf of Recipient, its affiliates or other third parties or by the Government to the Recipient in connection with, or during performance of the OTAR Agreement, whether or not either party required or requested that such information be submitted."

2. ADD the following article after ARTICLE XVII: TRANSFERS & ASSIGNMENTS

"ARTICLE XVIII: CONFIDENTIALITY.

It is recognized by the parties that success of the OTAR is enhanced by sharing of Confidential Information to inform the Government and Recipient of developments outside of, but potentially relevant to, the scope of work being performed under the OTAR Agreement. The parties may use Confidential Information submitted hereunder for purposes of the OTAR, but for no other purpose.

Confidential Information shall be subject to the same prohibitions on disclosure as provided for under FAR Part 24.202 and shall not be disclosed by the Government or its representatives or Recipient without the prior written consent of the providing party except to the extent such disclosure is required by law. Further, any reproduction of Confidential Information or portions thereof that is disseminated within the Government or Recipient, shall be shared strictly on a need to know basis for the purposes of the OTAR, and is subject to the restrictions of this provision.

In addition to the above, Confidential Information is subject to the protections of the Trade Secrets Act as well as any other remedies available under this Agreement or the law.

In order to be subject to the provisions of this Article XVIII, the providing party shall identify Confidential Information as confidential or proprietary at the time of disclosure, either by separate written communication or by use of an appropriate stamp or legend; or shall provide written notice to the receiving party within thirty (30) days of disclosure of the information's confidential or proprietary nature. Any disclosure of Confidential Information by either party or its representatives prior to receipt of such notice of its confidential or proprietary nature shall not constitute a breach of this Article XVIII.

Recipient shall mark Confidential Information with the following legend or similar:

"Confidential and Proprietary. This information is confidential and proprietary. The receiving party may not use, modify, reproduce, perform, display or disclose this information except within the receiving party's organization on a need to know basis for the purposes of Agreement HHSO100201700018C, and may not disclose to any party outside the receiving party's organization without prior agreement of the providing party. Any reproduction of this information or portions thereof must be marked with this legend."

Confidential Information shall also include the following information provided to the Government prior to the effective date of this modification, whether or not marked as confidential or proprietary, provided that any disclosure of such information by Government or its representatives prior to the effective date of this modification shall not constitute a breach of this Article XVIII:

- Powerpoint presentations sent on September 14, 2017 and related to Uniflu and
Coronavirus
- Manuscript related to UNJ-445 and sent on October 12, 2017

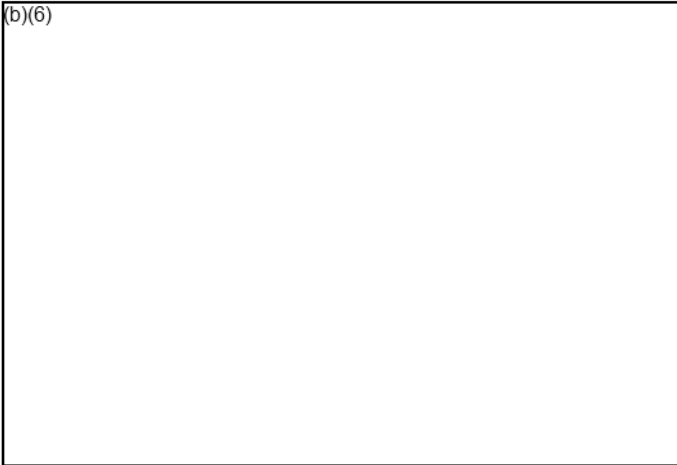
- (b)(4) sent on December 1, 2017
- (b)(4) sent on September 28, 2017

The obligations of this Article XVIII shall survive expiration or termination of the OTAR."

FOR Janssen R&D LLC

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

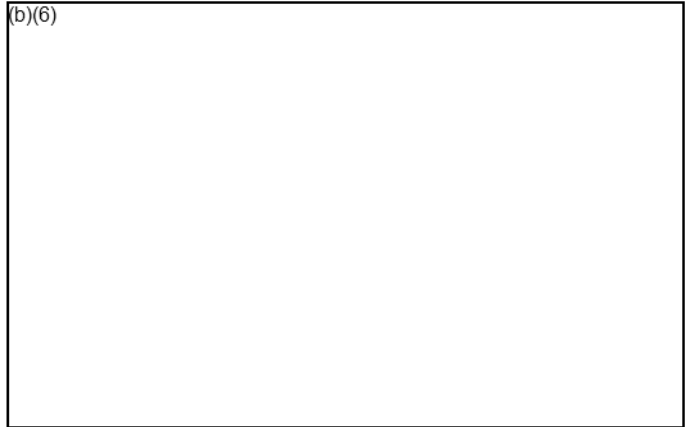
(b)(6)



(Name, Title)

(Date)

(b)(6)



(Name, Title)

(Date)

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

Amendment No. 0002

Effective Date of Amendment: Upon Last Signature in Section IV

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.

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I. AMENDMENT PURPOSE

By the Parties' mutual agreement, this Amendment makes bilateral changes within the general scope of the existing Agreement to (i) (b)(4)

(b)(4) (ii) extend the Base Period's term until December 31, 2018 to conform the Agreement to the Recipient's accounting period, (iii)

(b)(4)

(b)(4) (v) update the Recipient's Key Personnel and the Government's personnel working under the Agreement, and (v) make conforming changes to those ends.

II. AMENDMENTS TO AGREEMENT

A. Article II *Term* Section A *Term of this Agreement* is changed in the first paragraph by deleting the first sentence and replacing it with the following:

The Agreement commences on the date of the last signature hereto and continues for a sixteen and one-half (16 ½) month period (the "Base Period") with an option to extend the term of the Agreement on three (3) occasions for an additional twelve months on each occasion and, additionally, on one (1) last occasion for an additional seven and one-half (7 ½) months (each of the four extensions hereinafter referred to as an "Option").

B. Pursuant to Article II *Term* Section C *Extending the Term*, and independently of any Option, the Base Period's expiration date is extended by four and one-half (4 ½) months from August 14, 2018 to December 31, 2018. As of this Amendment No. 0002, the Parties acknowledge that, during that extended Base Period, funds remain available and research opportunities exist.

C. For clarity, the Agreement's potential Period of Performance, including all Options, that is set forth on the Agreement's Signature Page remains unchanged at "August 15, 2017 – August 14, 2022."

D. Article IV *Management of the Project* is changed in Section A.3 *Organizational Chart* by

1. adding (b)(6) as a second Project Management Leader (PML) to the Joint oversight committee and the PMO steering committee; and
2. replacing (b)(6) with (b)(6) as the Co-Principal Investigator on the Joint oversight committee and the PMO steering committee.
3. replacing (b)(6) with (b)(6) as non-voting JOC member.
4. replacing (b)(6) with (b)(6) as voting JOC member

E. Article V *Agreement Administration* is changed by

1. revising the Paragraph entitled "Government Points of Contact" as follows:

a. Other Transaction Agreement Specialist (OTAS)'s phone number is

+1 (b)(6)
[Redacted]

2. revising the Paragraph entitled "Recipient Points of Contact" by

a. adding the following as the second Recipient Program Management Lead (PML):

(NAME) (b)(6)
(TITLE) (b)(6)
(PHONE) [Redacted]
(EMAIL) [Redacted]

b. adding the following as the Recipient's Co-Principal Investigator (Co-PI):

(NAME) (b)(6)
(TITLE) (b)(6)
(b)(6)
(PHONE NUMBER) (b)(6)
(EMAIL) (b)(6)

F. Article VI *Cost Sharing* is changed in Section C *Global Cost Share* by

(b)(4)
[Redacted]

G.

(b)(4)

H. Attachment 3 *Escalation Procedure Diagram* is changed by

1. deleting from the Janssen Escalation Procedure Diagram (b)(6) as a member of the first level of escalation resolution; and
2. indicating in the Janssen Escalation Procedure Diagram that (b)(6) is co-PI and voting member; and
3. adding (b)(6) to the Janssen Escalation Procedure Diagram as a member of the first level of escalation resolution and non-voting member of the JOC; and
4. replacing (b)(6) in the Janssen Escalation Procedure Diagram, as a member of the second level of escalation resolution; and
5. replacing (b)(6) in the Janssen Escalation Procedure Diagram, as third level of escalation resolution; and

- 6. revising in the BARDA Escalation Procedure Diagram Ruben Donis’s title from “Acting Director” to “Deputy Director” in the first level of escalation resolution.

III. Total funds obligated to this Agreement by the Government remain unchanged at

\$43,588,145. (b)(4)

(b)(4)

IV. 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: _____	BY: _____
NAME:	NAME:
ITS:	ITS:
DATE:	DATE:

member of the second level of escalation resolution; and

5. replacing (b)(6) in the Janssen Escalation Procedure Diagram, as third level of escalation resolution; and

6. revising in the BARDA Escalation Procedure Diagram Ruben Donis's title from "Acting Director" to "Deputy Director" in the first level of escalation resolution.

III. Total funds obligated to this Agreement by the Government remain unchanged at \$43,588,145.

(b)(4)

(b)(4)

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

(b)(6)

(b)(6)

ME

TE:

JANSSEN RESEARCH & DEVELOPMENT, LLC

Other Transaction

Agreement No. HHSO100201700018C

Amendment No. 0002

EXHIBIT A

(b)(4)

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

Amendment No. 0003

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. 0003 bilaterally (i) ^{(b)(4)}

(b)(4)

(iii) update the Recipient's Key Personnel

and the Government's personnel working under the Agreement, and (iv) make administrative changes..

II. AMENDMENTS TO AGREEMENT

A. Exercise Option Period No. 1

- 1) Pursuant to Agreement Article II(A), Option Period No. 1 is hereby exercised, thereby extending the Agreement's expiry by one (1) year from December 31, 2018 to December 31, 2019.
- 2) Exhibit A Joint Oversight Committee – Decision Document (June 28, 2018), which evidences the agreement with the updated Option 1 budget, is incorporated and attached to this Amendment No. 0003.
- 3) For clarity, the Agreement's *potential* Period of Performance, including every Option, that is set forth on the Agreement's Signature Page remains unchanged at "August 15, 2017–August 14, 2022."

B. ^{(b)(4)} Under This Agreement

- 1) Pursuant to Agreement Amendment No. 0002 Section II(G)(2) ^{(b)(4)}

(b)(4)

2)

C. ^{(b)(4)}

1)

2)

