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. 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.

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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 non-severable independent 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

v. adds the essential considerations.

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)

[redacted]

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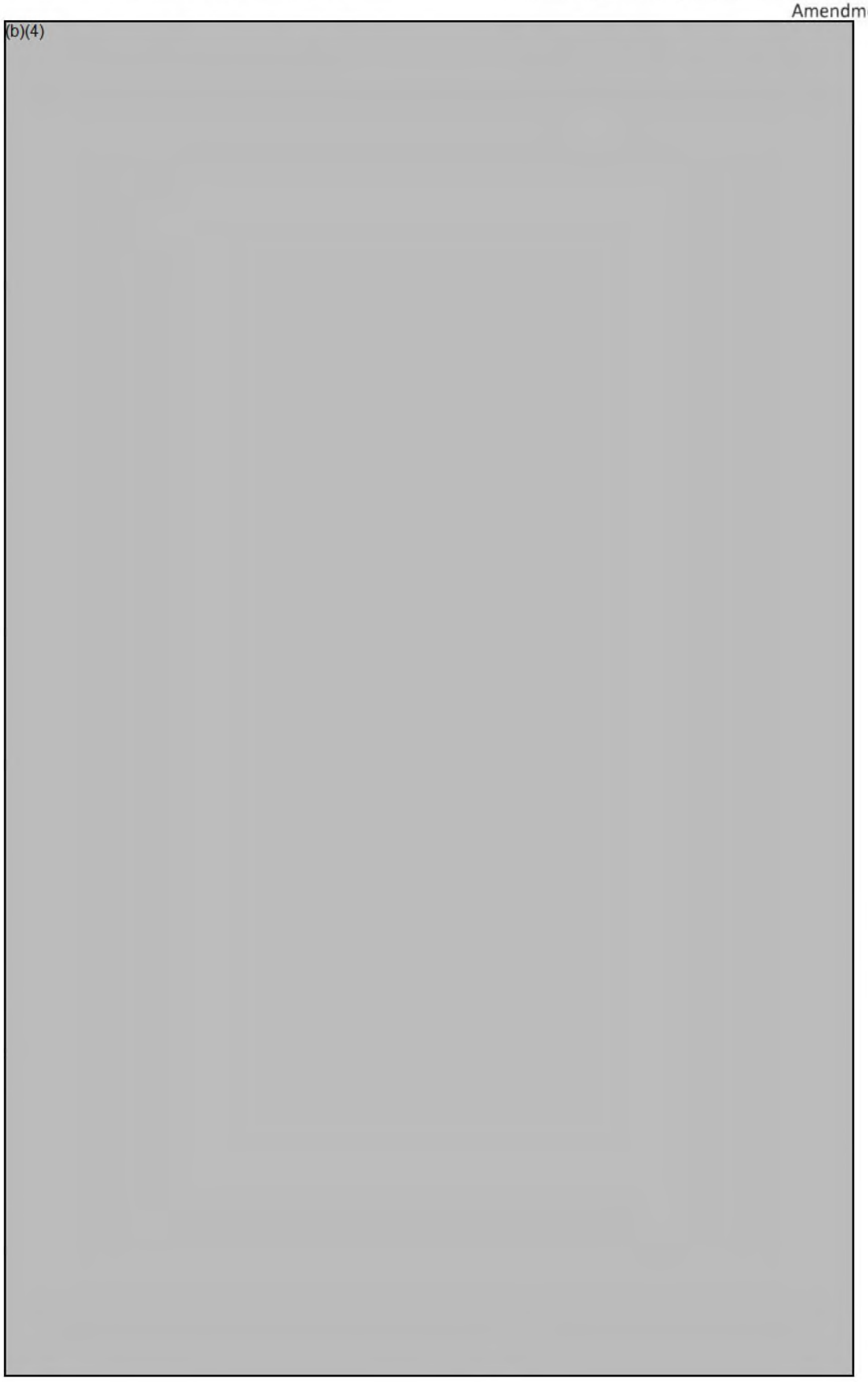
(b)(4)



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)(4)

D. Due to the urgency presented by the current threat and to assure Janssen is able to expeditiously and compliantly execute the SOW, BARDA/ASPR agree to exercise their statutory authority to the maximum extent practical to negotiate additional terms and waivers of existing OTA terms, laws and regulations, as listed below or as may arise during performance of this additional work, to enable Janssen, as a nontraditional government contractor, to execute performance consistent with its commercial practices. These provisions represent the underlying assumptions upon which the estimated cost and schedule have been developed.

1. Adherence to commercial practices when engaging subcontractors, including relief from flow down provisions that otherwise may apply.

(b)(4)

3. As it is not known at this time what the final composition and manufacturing technology of the vaccine shall be, any IP (patent or technical data)rights (including third party rights) that are needed to fully launch/deploy the final vaccine will be subject to pre-existing obligations and as well as negotiation by the appropriate parties at that time. The final negotiated rights shall, at a minimum, be consistent with the USG's IP rights specified under Articles IX and X of the OTA.

4. Due to the emerging nature of this threat, it is not possible to know the full extent of the threat, its impact, or the necessary resources required to control the virus. To the extent other parties, such as other agencies, international organizations, governments or NGOs, seek Janssen's participation in the effort to develop solutions to counter the threat of the coronavirus, BARDA will not place undue restrictions on Janssen's ability to collaborate with these other parties, including receipt of funding, use of Janssen's technology, or any other support or collaboration that Janssen determines is needed. BARDA's intellectual property rights will be consistent with the terms within Articles IX and X of the OTA.

5. Reporting Requirements of the above referenced OTAs will include only those requirements necessary to maintain sufficient updating during this dramatically accelerated vaccine development program.

6. To expedite the negotiation of 3rd party agreements and consistent with BARDA's flexibilities, the Government's right to audit financial records be limited to the records of those Parties that are relevant for performance of this Agreement for a period not to exceed three years after the expiration of the term of this Agreement.

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III. SIGNATURES

Acknowledged, accepted, and agreed for

JANSSEN RESEARCH & DEVELOPMENT, LLC

(b)(6)

DATE: 2/11/20

U.S. DEPART[illegible] HEALTH & HUMAN SERVICES
OFFICE [illegible] SECRETARY FOR
[illegible]SE
B[illegible] & DEVELOPMENT

(b)(6)

BY: [illegible]
NAME[illegible]
ITS: OTA[illegible]
DATE: 2[illegible]

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

Page 009

Withheld pursuant to exemption

(b)(4)

of the Freedom of Information Act

(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)

- 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

(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)

6.4 Clinical development

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
- Contracting with CRO clinical site

(b)(4)

6.5 GLP Toxicology

Activities

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

(b)(4)

6.6 GMP manufacturing

Activities

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

(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) 20+5 (b)(4) 125 subjects (b)(4)
  25 (b)(4)
  (b)(4)

(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) 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)

Page 017

Withheld pursuant to exemption

(b)(4)

of the Freedom of Information Act

The information provided herein is considered JRD, LLC trade secrets, commercial or financial information that JRD, LLC customarily holds close and treats as confidential. The information is being provided under the assurance that the U.S. Department of Health and Human Services and all of its agencies, including the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, will maintain the confidentiality of the information under the Trade Secrets Act, Procurement Integrity Act, other applicable statutes, regulations, rules, case law contractual provisions, protective orders or otherwise and as such, the information provided herein is exempt from disclosure under Exemption 4 of the Freedom of Information Act ("FOIA").

AMENDMENT OF OTHER TRANSACTION AGREEMENT (OTA)

OTHER TRANSACTION FOR ADVANCED RESEARCH (OTAR)

BETWEEN

Other Transaction Agreement

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. 0007

Effective Date of Modification: Upon Last Signature in Section III

Total Amount of the Agreement is increased by (b)(4) from (b)(4) to (b)(4) (Includes Recipient and Government Funding).

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

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

Current Government commitment: with the addition and authorization of WPs 7.1 – 7.4.3, 7.5.1 and 7.6.1, the total Funds Obligated is increased by (b)(4) from $(b)(4) to (b)(4)

Current Recipient commitment: with the addition and authorization of WPs 7.1 – 7.4.3, 7.5.1 and 7.6.1, the total Recipient Funds Obligated is increased by (b)(4) from $(b)(4) to (b)(4)

Period of Performance:

- The Period of Performance of this agreement is extended to from April 30, 2023 to December 31, 2024.

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

Line of Accounting and Appropriation:

Work Packages	Title	Requisition (OS)	CAN	Obj.Class	Amt. (Govt Share)	Changed
Base Period	Base/Initial – Initial Award (August 15, 2017 – December 31, 2018)	(b)(4)				
Option Period Number 1	Option Period Number 1, January 1, 2019 – December 31, 2019	(b)(4)				
WP 6.1 – 6.7	COVID-19 - Vaccines discovery thru Phase 1 Trial.				(b)(4)	Redistributed via modification (b)(4)

WP 7.1 – 7.4.3, 7.5.1 and 7.6.1	COVID-19 TX Antiviral Discovery and Clinical Development (through Phase 2b Trials)	OS256087	199COV2	25103	(b)(4)	Added via this modification
Total					(b)(4)	

I. AMENDMENT PURPOSE

During the March 10, 2020 JOC the JOC made decisions regarding both the COVID-19 vaccine work as amended to the Influenza and Emerging Pathogens OTA, OTA number HHSO100201700018C ("Flu" OTA), by Amendment 0006 and work to be added to the Flu OTA involving COVID-19 Antiviral work. In order to ensure clarity, this Amendment 0007 only discusses items related to the JOC's March 10, 2020 decision and recommendation involving the COVID-19 Antiviral work.

By the Parties' mutual agreement and within the existing Agreement's general scope, this Amendment No. 0007 bilaterally:

i. implements the JOC decision and recommendation of March 10, 2020 to place the next phases of the COVID-19 Antiviral program under this Flu OTA. As such, based on the JOC decision and recommendation, this Amendment 0007 to the Flu OTA, hereby adds Work Packages (WP) 7.1 – 7.6.2, COVID-19 TX Antiviral Discovery and Clinical Development to this OTA.

ii. incorporates an updated (b)(4) to (i) add COVID-19 TX Antiviral Discovery and Clinical Development (WPs 7.1 – 7.6.2), and (ii) (b)(4) (b)(4) 2019-nCoV Vaccines (WPs 6.1 – 6.7 activities). Exhibit B Budget Allocations is provided and includes additional information.

iii. updates the Statement of Work (Exhibit-A) to reflect COVID-19 TX Antiviral Discovery and Clinical Development, Work Packages (WP) 7.1 – 7.6.2. The COVID-19 Antiviral Discovery and Clinical Development, Work Packages (WP) 7.1 – 7.4.3 (Clinical Phase 2b Study), 7.5.1 (Regulatory though Phase 2b clinical study) and 7.6.1 (Project Management through to Phase 2b clinical study) as described on 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 7.4.4 (Clinical Phase 3 Study), WP 7.5.2 (Regulatory for Phase 3 and registration) and WP 7.6.2 (Project Management for Phase 3 and registration) are identified as Options 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. Within Agreement Number HHSO100201700018C, Article IV Management of the Project the following updates are made:

a. Section A (3) Organizational Chart, is updated to include the respective Technical Leads for the COVID-19 program

b. Within Section B, Project Committees and Meetings, paragraph 5. "Cost Share Determination (CSD) Meeting" is added.

II. AMENDMENTS TO AGREEMENT

A. Incorporate new Cost Share Estimates/Budget Summary and Budget Allocation/Workplan Structure to reflect the new COVID-19 TX Antiviral Discovery and Clinical Development 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 0007. Please note that work packages (b)(4) (b)(4) to the 2019-nCoV activities. (b)(4)

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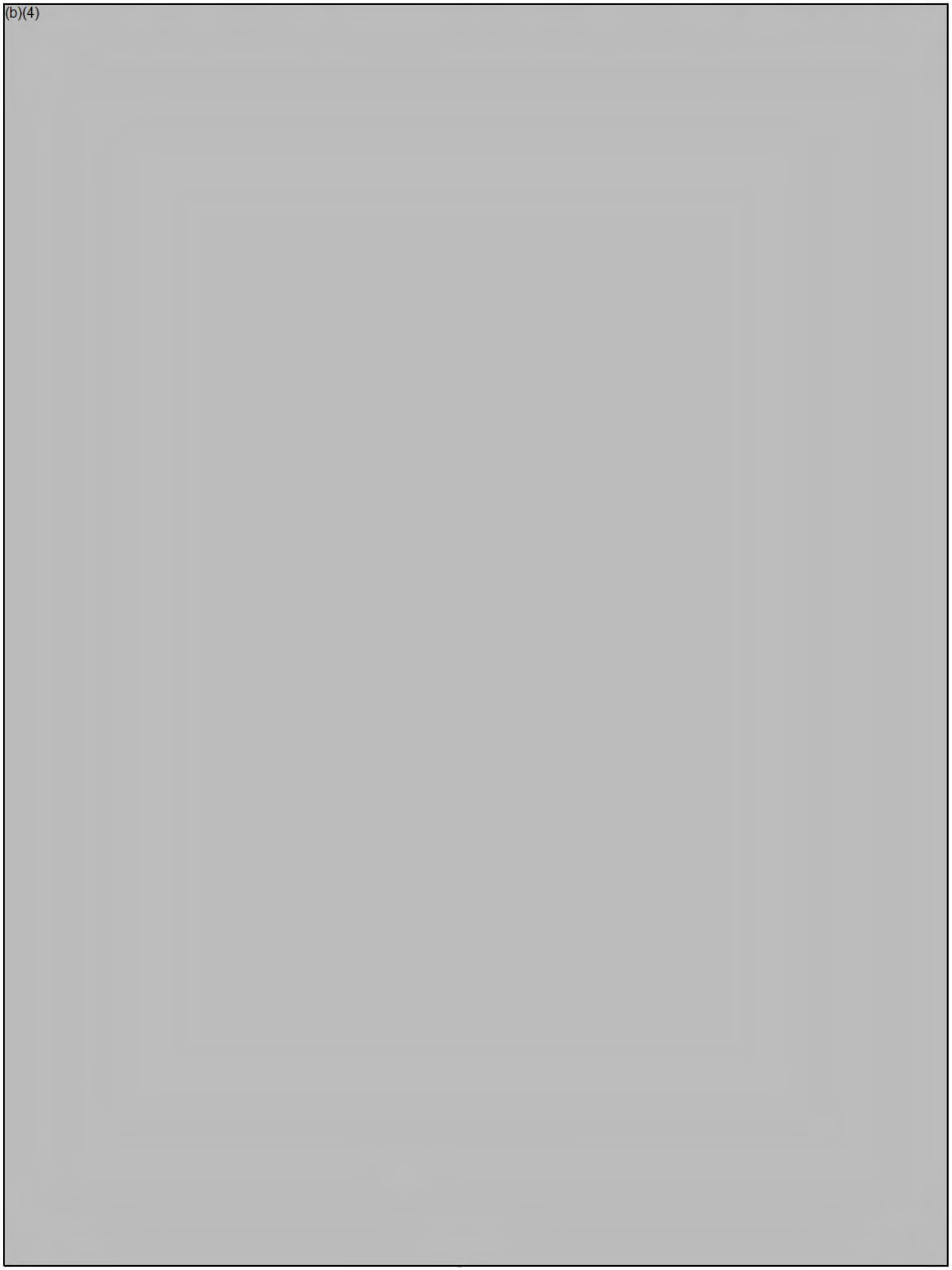
(b)(4)

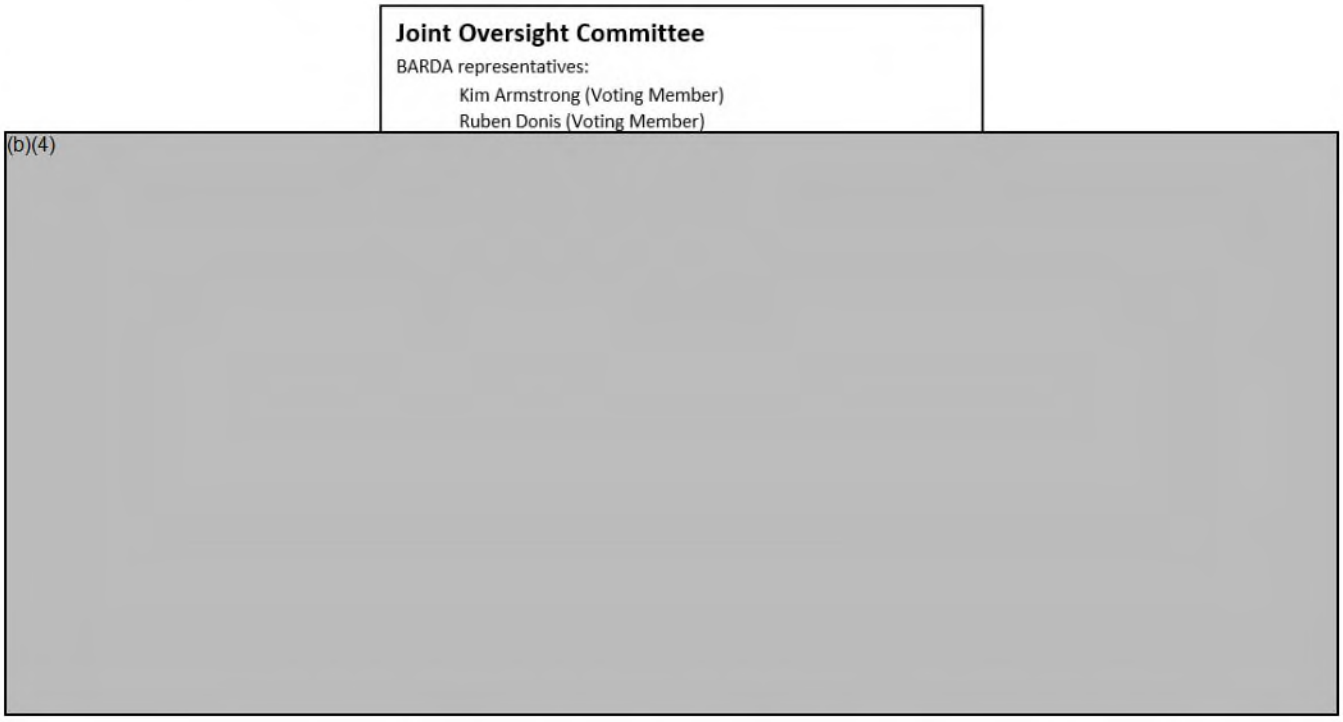


B. Updated the Statement of Work

1) The Statement of Work shall be replaced to reflect the new COVID-19 TX Antiviral Discovery and Clinical Development, Work Packages (WP) 7.1 – 7.6.2. The updated SOW for incorporation in the OTA is included in Exhibit A.

C. Article IV Management of the Project, the following updates are made:

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



2) Article IV Management of the Project, Section B, Project Committees and Meetings, paragraph 5. "Cost Share Determination (CSD) Meeting" is added:

5. Cost Share Determination (CSD) Meeting: Either by conference call or in person, the OTAO, and/or the OTAS, OTTR and the PI/PML/Business Interface will discuss and review cost share contributions of the Agreement. During this meeting, the PI/PML/Business Interface will discuss assets progression to date and provide an update on the commercial viability of portfolio assets. These meetings will be held on annual basis and may be scheduled on an ad-hoc basis after the receipt of study data, FDA feedback and/or future public health scenarios that will guide in the activation of future elements of the Agreement. The recipient will submit to the Government meeting minutes and a revised budget (if applicable) as result of discussions.

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

III. SIGNATURES

Acknowledged, accepted, and agreed for

JANSSEN RESEARCH & DEVELOPMENT, LLC

(b)(6)

DATE: 3/20/20.

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS & RESPONSE
BIOMEDICAL ADVANCED RESEARCH & DEVELOPMENT AUTHORITY

BY: Wendell Conyers -S Digitally signed by Wendell Conyers -S Date: 2020.03.20 17:53:40 -04'00'

NAME: WENDELL CONYERS
ITS: OTHER TRANSACTION AGREEMENT OFFICER
DATE:

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 (b)(4) inhibitor that is now ready for (b)(4)
(b)(4)
influenza A or B viruses; (b)(4)
(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.

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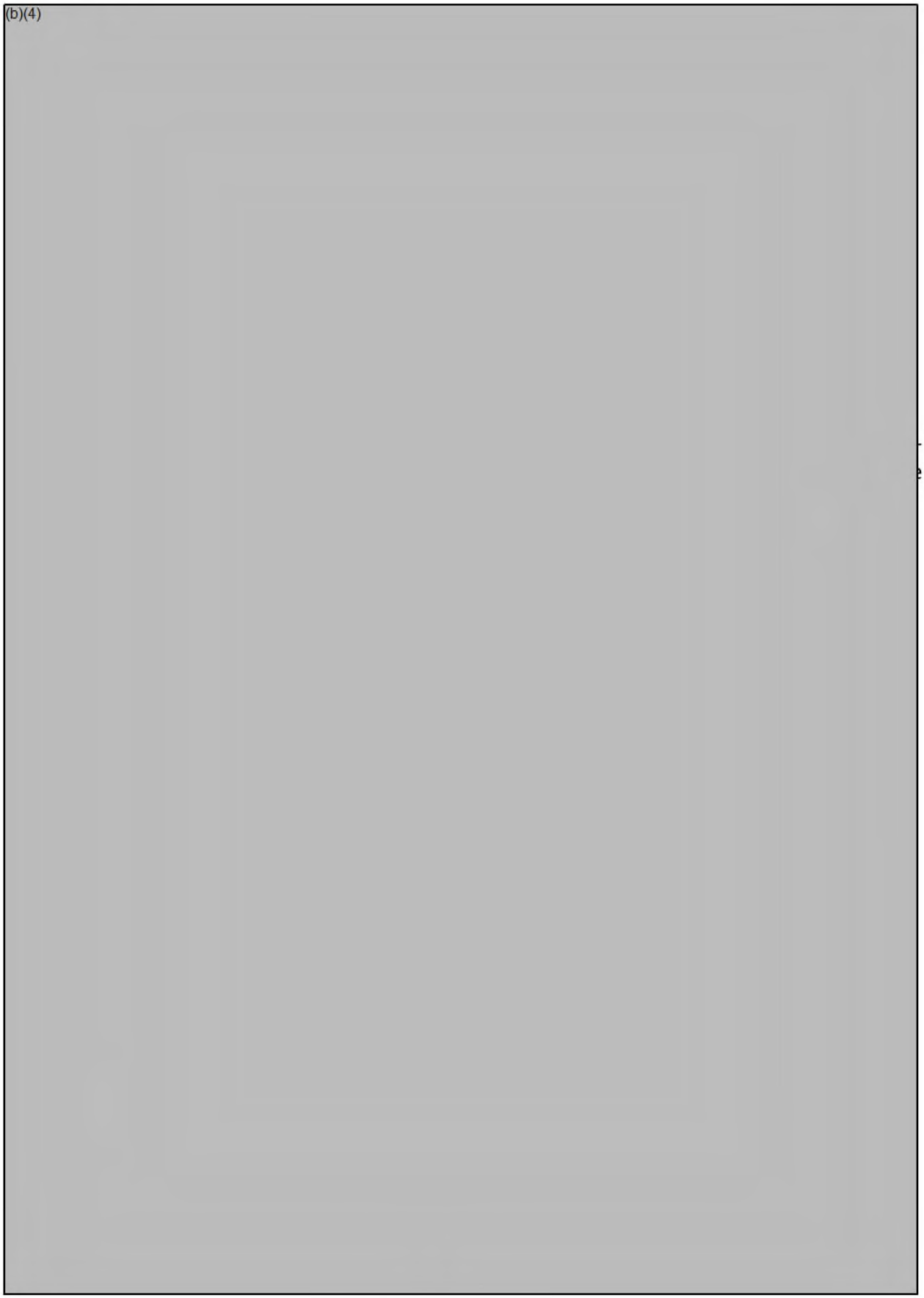
(b)(4)

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

6.2 pre-clinical immunology and protective efficacy

Activities

(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)

6.4 Clinical development

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
- Contracting with CRO clinical site

(b)(4)

(b)(4)

6.5 GLP Toxicology

Activities

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

(b)(4)

(b)(4)

6.6 GMP manufacturing

Activities

- Master Virus Seed manufacturing and release
- Drug substance manufacturing at appropriate scale in a (b)(4)
(b)(4)
- Drug product manufacturing (b)(4)
and release
- DS and DP stability analysis

(b)(4)

(b)(4)

6.7 Ph1 clinical trial

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) 20+5 subjects (b)(4) 125 subjects (b)(4) 25 (b)(4) subjects (b)(4)

(b)(4)

(b)(4)

(b)(4)

7 COVID-19 Antiviral Discovery and Clinical Development

Outlined below is the full development program for a typical hit from screening a library of compounds that have not been clinically tested in humans for any uses. Steps described below cover (b)(4) (b)(4) (b)(4) Described activities are therefore subject to change upon data-driven decision.

In case a (b)(4) (b)(4) the development program could be significantly accelerated. Depending on the availability of e.g. (b)(4) (b)(4) upon joint decision.

WP 7.1 Continuation (b)(4)

Depending on the nature of the identified (b)(4) additional efforts may need to be undertaken to (b)(4) (b)(4)

WP 7.2 Lead and Late Lead Optimization

The purpose of (b)(4) (b)(4) (b)(4) and a go-no go decision will be taken whether or not to move to pre-clinical development.

WP 7.3 Pre-Clinical development

This phase includes studies in s (b)(4) (b)(4) This may include, but not be limited to (b)(4) (b)(4)

This phase will also include (b)(4) and Phase 1 clinical trials, including stability studies. It may also include pre-formulation for Phase 1 clinical trials.

Phase 1 first-in-human formulation development will follow the (b)(4) (b)(4) (conditional to JOC approval). Based on the result of the formulation development work, clinical study materials packaging, labeling and distribution will start and clinical pharmacy manual of Phase 1 trial will be developed.

WP 7.4 Clinical development

WP 7.4.1 Clinical Phase 1

This stage includes a first-in-human clinical Phase 1 and may include additional supportive clinical Phase 1 studies as well.

7.4.2 Clinical Phase 2a Study

(b)(4), this stage may include a clinical Phase 2a study to investigate the therapeutic efficacy and safety of the drug in (b)(4) (b)(4) This Phase 2a study may or may not include (b)(4) depending on available data for the asset selected.

7.4.3 Clinical Phase 2b Study

Depending on the available data of the asset and the results of the Ph2a study, a confirmatory Ph2b study can be performed as a separate study, or in an a(b)(4)

This stage also includes further Drug Substance and Drug Product development for Phase 2 studies.

These (b)(4) will continue in the next phases:

- (b)(4)
- Registration and Validation phase

Clinical Phase 3 - OPTION

7.4.4 Clinical Phase 3 – (Option)

This stage may include one or more clinical Phase 3 trials in (b)(4)

(b)(4)

WP 7.5 Regulatory

WP 7.5.1 Regulatory through to Phase 2b clinical study

Janssen intends to seek regulatory and scientific advice from the regulatory authorities throughout the development of the project, (b)(4)

(b)(4)

WP 7.5.2 Regulatory from Phase 3 and registration

Janssen will continue to seek regulatory and scientific advice from the regulatory authorities throughout Phase 3 of the project. (b)(4)

(b)(4)

8 Project Management

Coordinating project management has been brought under WP 5.6 as per JOC memo 4 (initially in 1.6) and subsequently adjusted to reflect new Assets.

8.1 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.

8.2 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.

8.3 Asset Project Management (WP 2.5, WP 5.5, WP 7.6.1 and 7.6.2)

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 functiona (b)(4) and a (b)(4) Each asset will also have an Asset Technical Lead 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)

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(b)(4)

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The information provided herein is considered JRD, LLC trade secrets, commercial or financial information that JRD, LLC customarily holds close and treats as confidential. The information is being provided under the assurance that the U.S. Department of Health and Human Services and all of its agencies, including the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, will maintain the confidentiality of the information under the Trade Secrets Act, Procurement Integrity Act, other applicable statutes, regulations, rules, case law contractual provisions, protective orders or otherwise and as such, the information provided herein is exempt from disclosure under Exemption 4 of the Freedom of Information Act ("FOIA").

(b)(4)

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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 plus (b)(4) cost share adjustment from (b)(4) to (b)(4) (Includes Recipient and Government Funding).

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

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

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 increased by (b)(4) from (b)(4) to (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 and therapeutic candidates 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 6.11 (Pediatric Study) and 6.12 (High-risk Populations are identified as Options to be exercised at a future date based on (i) JOC recommendation, (ii) availability of funding and (iii) a signed amendment between the Parties.

vii. updates the Essential Considerations in 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. Essential Considerations as added via Amendment 0006 and amended herein and made applicable to Amendments 0007 (COVID-19 Antiviral) and 0008 (COVID-19 Vaccines):

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

i. Recipient will adhere to commercial practices when engaging subcontractors, including, if necessary, relief from OTA flow down provisions that otherwise may apply;

ii. Recipient will use reasonable efforts to include rights for BARDA consistent with its IP rights specified under Articles IX and X of the OTA in negotiations with third parties controlling such IP rights. In the circumstance that 1) a sub-contractor is not willing to agree to the flow-down terms regarding IP and data rights in Articles IX and X of the Flu OTA, and 2) the sub-contractor's proposed terms are materially less than the scope of the flow-down IP and data rights in Articles IX and X of the Flu OTA, then Recipient will confer with BARDA (OTAO, OTTR, and Respective Asset Lead) in writing (email is acceptable) to gain alignment on the sub-contractor IP and data rights that BARDA believes are necessary in the specific instance. Such alignment on BARDA's concerns with Recipient's sub-contractor's IP and data rights shall be provided within a reasonable timeframe based upon the urgency of the situation at that time. If alignment on sub-contractor IP and data rights reaches an impasse and BARDA is unable to accept any lesser rights than those for which it is entitled to under the Flu OTA, Recipient and BARDA agree that no government funds shall be used for the impacted scope of work, however, Recipient may proceed at its own cost. Such activities conducted at Recipient's own cost are not subject to the terms and conditions of this OTA; however, any impacted deliverables will be aligned to ensure program continuity;

iii. BARDA shall not restrict Recipient's engagement or collaboration with other parties, such as other agencies, international organizations, governments or NGOs, seeking Recipient's participation in the effort to develop solutions to counter the threat of the coronavirus, including receipt of funding (to the extent that Recipient is not receiving funding from multiple sources for the exact same work it is performing here under), use of Recipient's technology, or any other support or collaboration that Recipient determines is needed; and

iv. Reporting Requirements of the above referenced OTAs will include only those requirements necessary to maintain sufficient updating during these dramatically accelerated development programs.

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

Joint Oversight Committee
BARDA representatives:
Kim Armstrong (Voting Member)
Ruben Donis (Voting Member)

(b)(4)

E. Article XIII: Subcontracting is amended to add a supplemental section for COVID-19 initiatives;

(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
(b)(6)	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: 3/27/20	DATE:

The information provided herein is considered JRD, LLC trade secrets, commercial or financial information that JRD, LLC customarily holds close and treats as confidential. The information is being provided under the assurance that the U.S. Department of Health and Human Services and all of its agencies, including the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, will maintain the confidentiality of the information under the Trade Secrets Act, Procurement Integrity Act, other applicable statutes, regulations, rules, case law contractual provisions, protective orders or otherwise and as such, the information provided herein is exempt from disclosure under Exemption 4 of the Freedom of Information Act ("FOIA").

ATTACHMENT 1: TASK DESCRIPTION DOCUMENT (SOW)

Overall Objectives and Scope

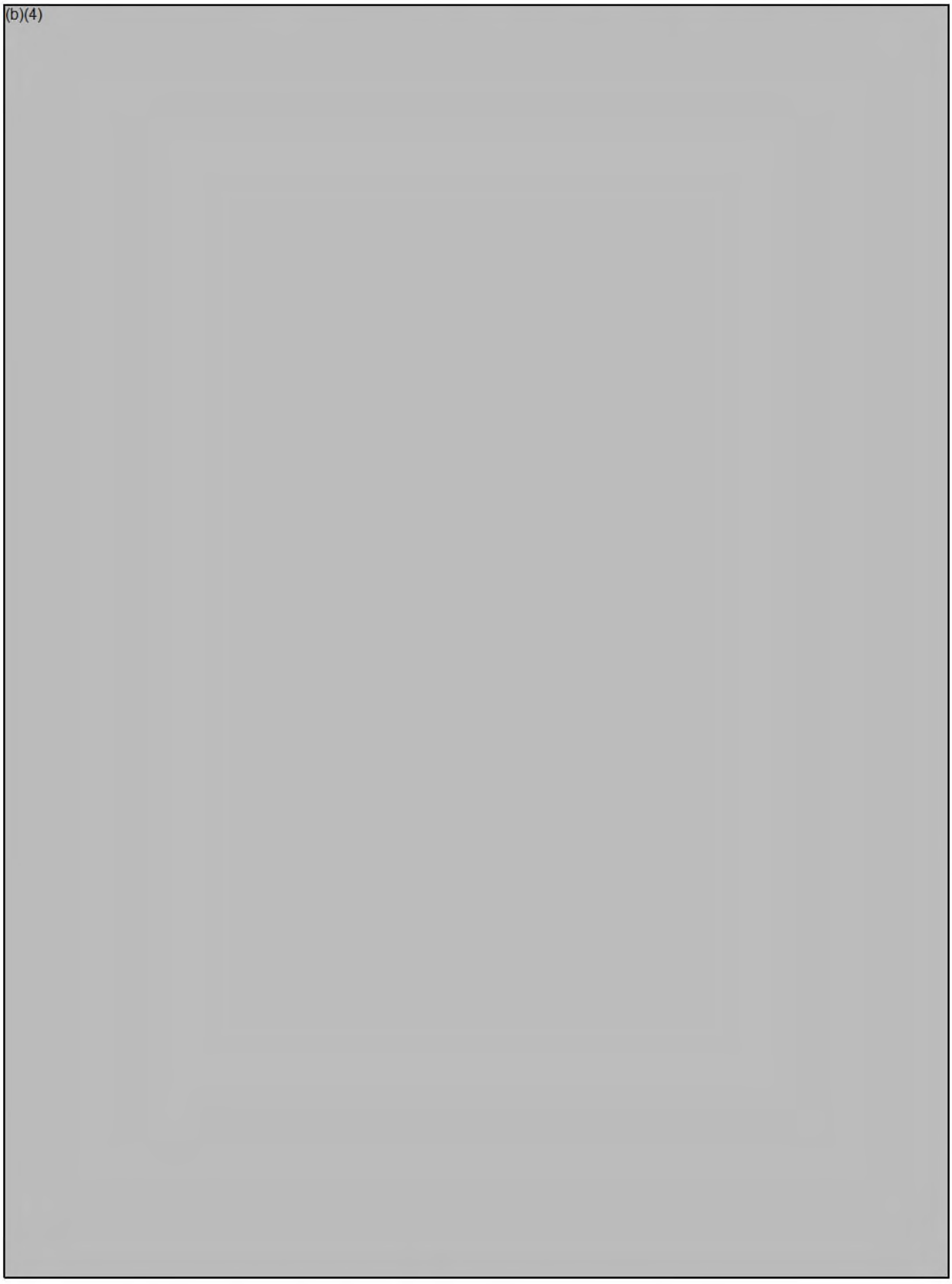
Seasonal and pandemic influenza remains one of the most important public health threats despite current vaccine and therapeutic options. The Consortium is developing a broad portfolio of innovative and novel countermeasures against influenza and other emerging infectious diseases comprising small molecules, 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) a (b)(4) influenza A or B viruses; a (b)(4) (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

- DNA encoding for several designs of the SARS-CoV-2 spike protein will be (b)(4) t multiple CROs
- Research batches of Ad26 vectors with (b)(4) (b)(4) of the spike protein (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)

WP6.2 Pre-Clinical Immunology (Performed at Janssen or (b)(4)

Activities

(b)(4)

(b)(4)

(b)(4)

WP6.3 CMC Development until First in Human ("FIH")

Activities

(b)(4)

- (b)(4) method development will occur to make insert specific assays fit for purpose.
- (b)(4) the PER.C6® (b)(4) (b)(4) Ad26-based COVID-19 vaccine. (b)(4) (b)(4) PER.C6® cell line (b)(4) (b)(4) PER.C6® (b)(4)

(b)(4)

WP6.4 Clinical Development and Regulatory Activities to Start First in Human Study

Activities

- Setup of immunological assays at CROs or at Janssen:
  (b)(4)
- Writing of protocol elements document (PED)
- Protocol writing
- Writing and submission of preIND document
- Writing and submission of IND documents
- Contracting with vendors

- Contracting with clinical sites

(b)(4)

WP6.5 GLP Toxicology

Activities

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

(b)(4)

WP6.6 GMP Manufacturing to Enable Clinical Trials

Activities until First in Human ("FIH")

- Master Virus Seed manufacturing and release

(b)(4)

WP6.7 Phase 1/2a Clinical Trial

Activities

- Randomized, placebo-controlled, (b)(4) double blind study in healthy adult volunteers 18-55yrs, 65 and older.

- Primary objective will be assessment of safety and reactogenicity. Secondary and exploratory endpoints will evaluate vaccine-induced immune responses to SARS-CoV-2.

(b)(4)

- (b)(4) 18-55 yr old, (b)(4)

(b)(4) 50 subjects (b)(4) 18-55 yr, (b)(4)

(b)(4)

(b)(4) 65 or older (b)(4)

(b)(4)

(b)(4)

- (b)(4) aged 18-55 adults (b)(4)

(b)(4)

WP6.8 CMC Development and GMP Manufacturing Process to Enable Large Scale Manufacturing and Launch to Support the Regulatory Filing

Activities;

(b)(4)

- PPQ for both DS and DP will be executed.
- (b)(4)
- Studies to enable launch and support licensure will be assessed and executed as appropriate.
- (b)(4)

(b)(4)

(b)(4)

WP6.9 Toxicology Studies

A Phase 1 enabling GLP toxicology study is described under WP6.5. (b)(4)

(b)(4)

Activities

- Conduct developmental and reproductive toxicity (DART) study

(b)(4)

(b)(4)

WP6.10 Phase 3 Study Adults

A variety of factors including manufacturing and CMC considerations, preclinical data, the state of the COVID-19 pandemic and primarily the safety and the immunogenicity of the vaccine as demonstrated in (b)(4) will be considered before proceeding to Phase 3 studies. (b)(4)

(b)(4)

The Phase 3 pivotal efficacy study, (b)(4) will be a randomized placebo-controlled study in adults a (b)(4)

(b)(4)

(b)(4)

International agencies are contemplating comparative trials between vaccine candidates and this will be considered at the time of proceeding to Phase 3.

OPTION - WP6.11 Pediatric Study

Clinical studies with immunologic endpoints will be performed in children (b)(4)
Sample size will be calculated (b)(4)
(b)(4)

OPTION - WP6.12 High-risk Populations

(b)(4)

WP6.13 Other Clinical Studies

Phase 3 Consistency Lot Study

A Phase 3 consistency lot trial comparing (b consecutive manufactured lots of the vaccine plus potentially a lot used in the Phase 3 efficacy trial (if consistency lot material is not utilized in the efficacy trial) will be performed. The objective of the study is to demonstrate that the immune responses to the (b)(4) lots are non-inferior to each other based on a margin acceptable to regulatory agencies. (b)(4)
(b)(4)

Phase 3 End Expiry Study

A Phase 3 end expiry study will be performed to determine that the vaccine at the end of the shelf life is still immunogenic at a level that it elicits immune responses that are expected to be protective. (b)(4)
(b)(4) The vaccine will then be tested at a dose that is consistent with this model for the end of shelf life, taking assay variation and stability into account. (b)(4)
(b)(4)

(b)(4)

Phase 3 Concomitant Use Trial

Phase 3 concomitant use trials may be performed. (b)(4)

(b)(4)

WP6.14 Regulatory Support

Activities to establish an IND for an Ad26-based COVID-19 vaccine will involve an arrangement of a pre-IND meeting with CBER before the intended IND submission (b)(4)

(b)(4)

The pre-IND and IND preparation to enable Phase 1 will be led by RA. Further regulatory activities beyond Phase I are interactions with FDA to support the development of the vaccine up to regulatory submission (to be discussed: pre-EUA and/or BLA submission, or other pathways as per Agency's guidance). This involves an end-of-Phase 2 meeting and a pre-BLA meeting. Type C meetings will be scheduled on an as-needed basis. Pediatric requirements will be discussed as per Agency's requirements.

Annual reports will be prepared and submitted to CBER according to the foreseen timelines after the IND comes into effect. Development of regulatory intelligence with respect to development and licensing of a COVID-19 vaccine will carefully be monitored.

Discussions with other regulatory Agencies as required by the program and in particular to allow for a harmonized approach from a CMC, non-clinical and clinical development perspective, and facilitate multi-country trials as required per discussion with the Agencies, may also have to be conducted and will then be covered under WP6.14.

WP6.15 Project Management Support

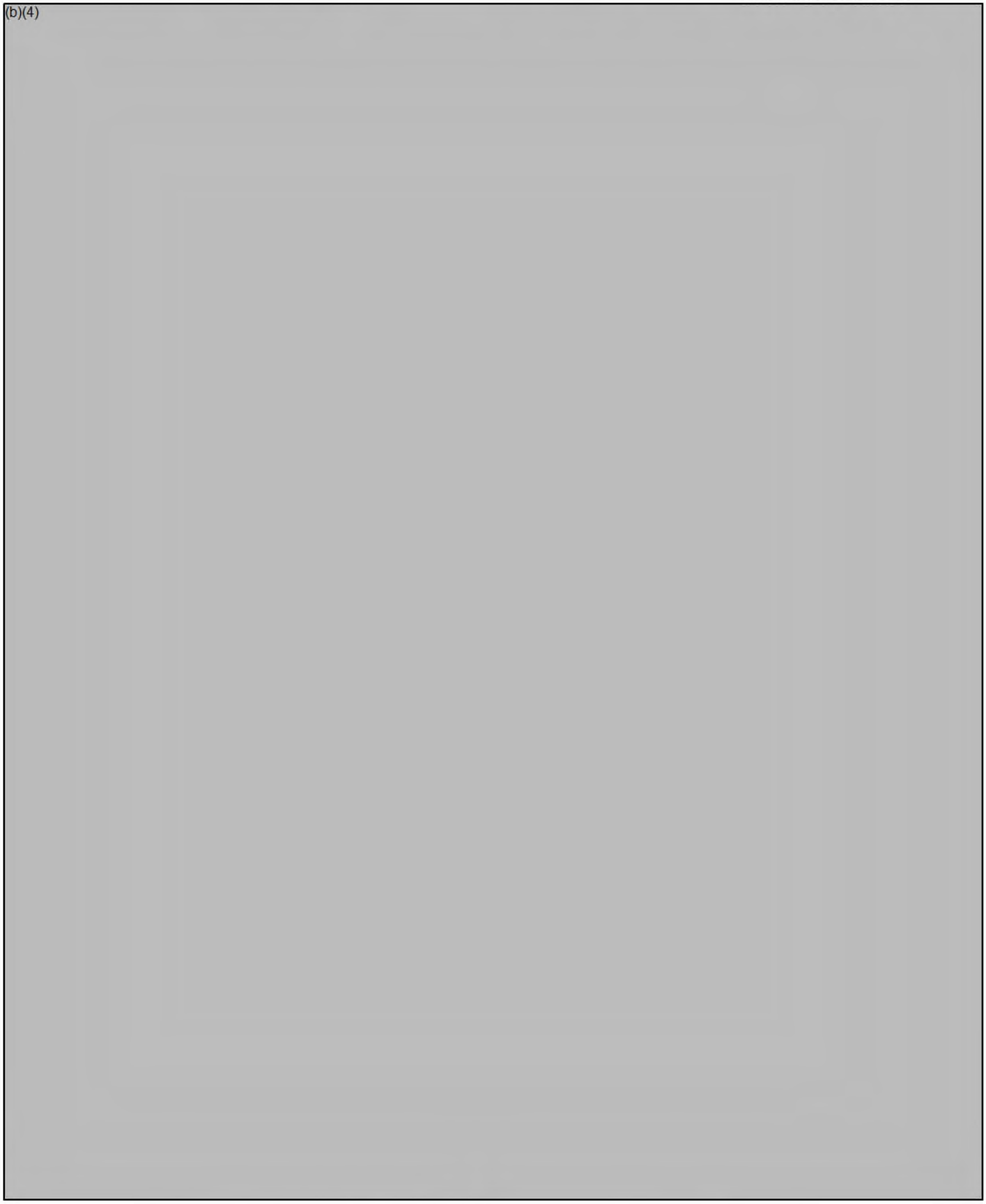
This WP includes the Program Management activities associated with development of an Ad26-based COVID-19 vaccine. The program will have an (b)(4) (b)(4)) who will oversee their specific (b)(4) requirements. This includes conducting frequent and regular (b)(4) meetings to ensure the accurate developing and tracking of the budget, timeline and resource plan. The (b)(4) team of each asset will also include relevant functional (b)(4) and a(b)(4) (b)(4) The Program will also have an (b)(4) who will oversee their specific Technical requirements. This includes conducting frequent and regular (b)(4) (b)(4) meetings to define the overall development strategy. The (b)(4) of each asset will include, but is not limited to, the Technical Lead, Preclinical Leader, Clinical Leader, the CMC Leader and, the Regulatory Leader. Clinical Team and Trial teams will oversee clinical program and trial execution. These teams include operational staff, Operational Leader sand representatives of operational departments such as data management; GCO; medical writing, programming, stats. Additional expertise required for executing asset-specific work possibly including subcontractors may be added as part of (b)(4) and (b)(4)

WP6.16 Dissecting the Evolution of SARS-CoV-2 and Specific Humoral and Cellular Immunity Following Infection

Activities

- The understanding of the roles that (b)(4) responses to SARS-CoV-2 are thought to play in protection, disease resolution, or enhancement of disease are evolving with the assessment of patients with varying disease outcomes. (b)(4) (b)(4)
- Identification of antigen-specific biomarkers of disease trajectory (survival, disease, death) and SARS-CoV-2 specific immune responses against the virus by s(b)(4) approaches (b)(4) using samples from previously and prospectively collected, longitudinal cohorts at the (b)(4) (b)(4)

(b)(4)



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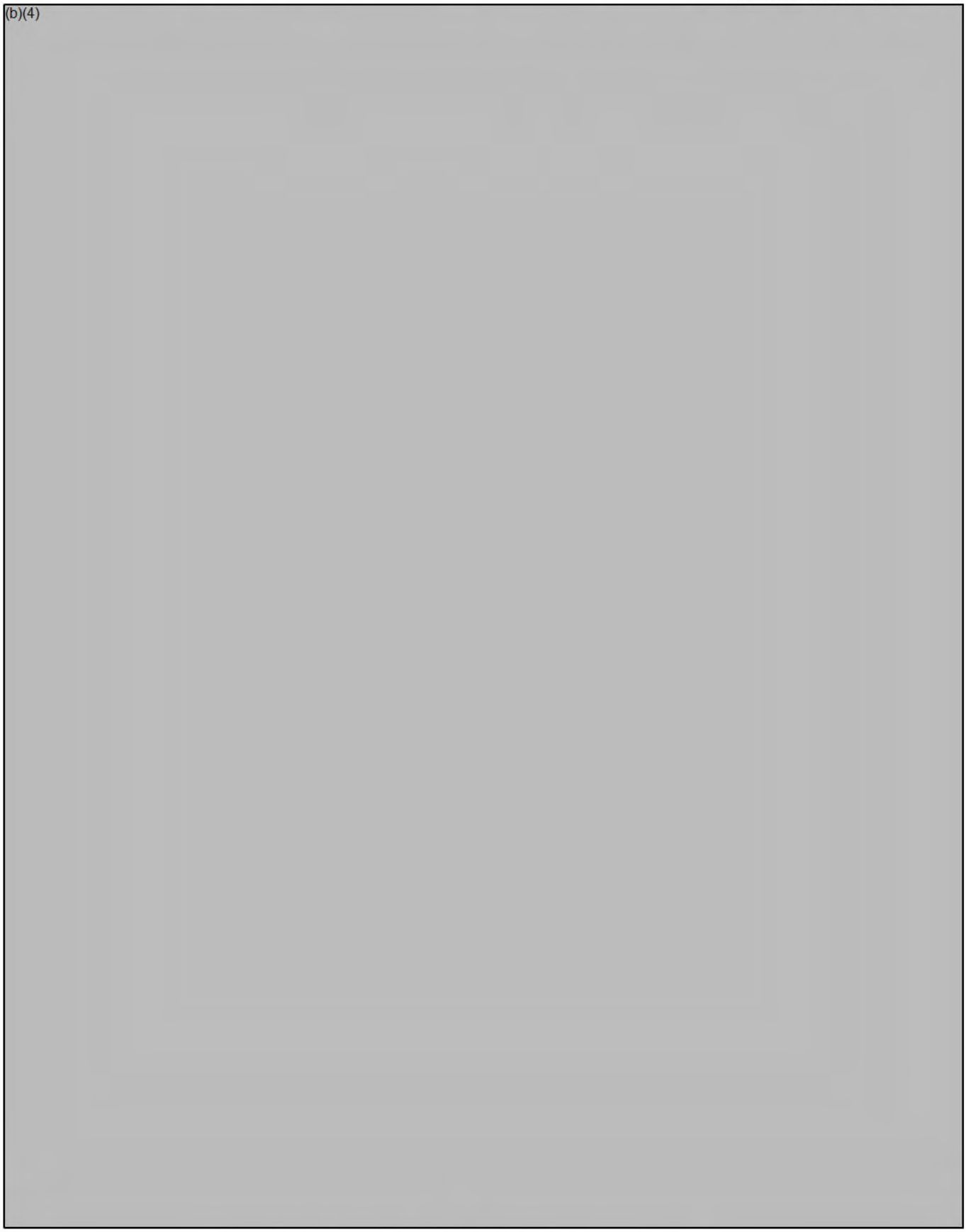

(b)(4)

8 Project Management

(b)(4)

8.1 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.

8.2 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.

8.3 Asset Project Management (WP 2.5, WP 5.5, WP 6.15, WP 7.6.1, and 7.6.2)

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 Project [(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)

(b)(4)

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(b)(4)

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

Agreement No.: HHSO100201700018C

Total Amount of the Agreement: [redacted] (INCLUDES RECIPIENT AND GOVERNMENT FUNDING)

Total Estimated Government Funding of the Agreement: [redacted]

Total Estimated Recipient Funding of the Agreement: [redacted]

Funds Obligated: [redacted]

Effective Date of Agreement: August 15, 2017

Period of Performance: August 15, 2017 – August 14, 2022

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:

[redacted]

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 the JANSSEN RESEARCH & DEVELOPMENT, LLC, hereinafter called the Recipient, pursuant to and under U.S. Federal law.

FOR JANSSEN RESEARCH & DEVELOPMENT, LLC	**FOR THE UNITED STATES OF AMERICA OFFICE OF ACQUISITION MANAGEMENT, CONTRACTS, AND GRANTS, ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE**
[redacted]	
(Name, Title) 8/13/17 (Date)	(Name, Title) (Date)

Agreement No.: HHSO100201700018C

Total Amount of the Agreement (b)(4) INCLUDES RECIPIENT AND GOVERNMENT FUNDING)

Total Estimated Government Funding of the Agreement: (b)(4)

Total Estimated Recipient Funding of the Agreement: (b)(4)

Funds Obligated: (b)(4)

Effective Date of Agreement: August 15, 2017

Period of Performance: August 15, 2017 – August 14, 2022

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:

(b)(4)

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FOR JANSSEN RESEARCH & DEVELOPMENT, LLC	**FOR THE UNITED STATES OF AMERICA OFFICE OF ACQUISITION MANAGEMENT, CONTRACTS, AND GRANTS, ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE**
_____	_____
(Signature)	(Signature)
_____	_____
(Name, Title) (Date)	(Name, Title) (Date)

Table of Contents

ATTACHMENTS

ARTICLE I: SCOPE OF THE AGREEMENT

A. Background

Seasonal and pandemic influenza remains among the most important public health threats despite current therapeutic options. Janssen Pharmaceutical Companies have developed a broad portfolio of innovative and unique small molecules, biologics and vaccines countermeasures against a broad range of threat agents. Those companies have come together to form a Consortium, and this Agreement is intended to cover efforts by the Consortium Members to work together with BARDA to further develop their collective portfolio of potential countermeasures against influenza and medical countermeasures against other emerging infectious diseases. A single Janssen Company, Janssen Research and Development, LLC is designated as the Recipient of this Agreement.

The current portfolio envisioned under this Agreement includes: an influenza (b)(4) now ready for (b)(4) (b)(4) influenza A or B viruses; a (b)(4) (b)(4) (b)(4) This portfolio employs (b)(4) modes of action that are complementary to current standard-of-care treatments, and may be useful in developing 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.

Collaboration between BARDA and the Consortium Members under this Agreement will provide the parties the flexibility to execute a portfolio approach to funding in the complex and uncertain environment of drug development. To maximize the potential to achieve the objectives of this Agreement, other medical countermeasure candidates that Consortium Members develop or in-license during the term of the Agreement may be considered by the Joint Oversight Committee (JOC) for inclusion in the portfolio.

B. Definitions

Affiliate: Any entity that controls, is controlled by, or is under common control with, a party to this Agreement. In this context, "control" shall mean (1) ownership by one entity, directly or indirectly, of at least fifty percent (50%) of the voting stock of another entity; or (2) power of one entity to direct the management or policies of another entity, by contract or otherwise.

Agreement: The body of this Agreement and all attachments and modifications thereto, including Attachments 1 – 3 are expressly incorporated in and made a part of the Agreement.

Consortium: That group of Consortium Members that are: (i) Affiliates of one another; and (ii) have agreed with one another to collaborate to perform the objectives and obligations set forth in this Agreement.

Consortium Member: Janssen Research and Development, LLC (JRD), Janssen Pharmaceuticals, Inc. (JPI), Janssen Vaccines & Prevention B.V.(JV&P), Alios BioPharma, Inc. (Alios), and any legal entity, U.S.

or ex-U.S., that has been identified by Recipient as a member of the Consortium during performance of the Agreement.

Data: Recorded information first created in performance of the Program, regardless of form or method of recording, which includes but is not limited to, technical data and software, but does not include Subject Inventions, trade secrets, clinical data, or financial, administrative, cost, pricing or management information.

Effective Date: The date of execution of this Agreement by the Parties. If this Agreement is executed in counterparts, the Effective Date shall be the date of the last signature.

Field: Means the development and use as a prophylactic and/or therapeutic to treat respiratory illnesses, including influenza.

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 which are owned or substantially controlled by foreign governments, firms, institutions, or individuals.

Government: The United States of America, as represented by HHS/BARDA. For purposes of this Agreement, the Government and HHS and BARDA may be used interchangeably.

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

Know-How: Information, practical knowledge, techniques, and skill development created by Recipient in performance of the Program necessary for the Practical Application of a Subject Invention within the Field.

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. The 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 Data outside the Government, use Data for competitive procurement or manufacture, release or disclose Data for commercial purposes, or authorize Data to be used by another party.

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 executes agreement modifications on behalf of the Other Transaction Agreement Officer

Other Transaction Agreement Technical Representative (OTTR): Is the primary government official for all technical matters on the agreement

Party: Either Recipient and Government, and "Parties" means both Recipient and Government.

Practical Application: With respect to a Subject Invention, to manufacture, in the case of a composition of 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 so as to establish that the Subject Invention is capable of being utilized.

Program: Research and development that is conducted by the Consortium under this Agreement, as set forth in Article I., section C, and is funded by BARDA or by Binding Cost Share by Recipient.

Property: Any tangible personal property other than property actually consumed during the execution of work in performance of the Program.

Recipient: Janssen Research & Development, LLC ("JRD") acting on its own behalf and on behalf of the Consortium and each Consortium Member.

Subject Invention: Any Invention that (i) has utility in the Field; and (ii) where the conception of such Invention and either (a) the first actual reduction to practice or (b) constructive reduction to practice of such Invention occurs in performance of the Program.

Subject Invention (SI) Intellectual Property Rights: Patent rights controlled by Recipient that are necessary to practice the Subject Invention in the Field.

Technology: Discoveries, innovations and Know-How, whether patentable or not, 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 first created in the Program and that have not been disclosed to the public, but does not include any Subject Invention.

Under this Agreement: Means activities conducted pursuant to this Agreement that are BARDA funded or Binding Cost Share by Recipient.

C. Scope

1. The Consortium Members shall perform an advanced research and development program to develop single or combination therapies that have the potential to increase therapeutic benefit, and preclude the rapid emergence of drug resistance for influenza and medical countermeasures against threat agents. Specifically, this Agreement includes: an influenza (b)(4) that is now ready for (b)(4) (b)(4) influenza A or B viruses; a (b)(4) (b)(4) The research shall be carried out in accordance with one or more Statements of Work ("SOW"). The SOW is incorporated in this Agreement as Attachment 1 and may be modified with the

approval of the JOC and OTAO. Consortium Members shall submit or otherwise provide all documentation required by Attachment 2, Report Requirements.

2. Recipient shall be paid for work performed under this Agreement upon submission of invoices on a quarterly basis. The agreement payments will be based upon accumulation of expenses incurred by the Consortium Members.

3. The Government and Recipient anticipate that the work described in the SOW of this Agreement can only be accomplished with an estimated Consortium aggregate resource contribution of (b)(4), which represents a (b)(4) share of the total estimated project costs from the effective date of this Agreement through sixty (60) months thereafter. By entering into this Agreement, Recipient intends and shall undertake to cause these funds to be provided to the Consortium Members for the purpose of performing the obligations described in this Agreement. If either HHS or Consortium is unable to provide its respective total contribution, the other Party may reduce its project funding by a proportional amount.

4. The Government will have access to research results and certain rights in data and patents as stated in this Agreement. HHS and Recipient are bound to each other by a duty of good faith and will utilize commercially reasonable efforts in achieving the goals of the Program.

5. This Agreement is an "other transaction" pursuant to 10 U.S.C. § 2371 and Sections 319L(c)(4)(B) and 319L(c)(4)(D) of the Pandemic and All-Hazards Preparedness Act, P.L. 109-417. The Parties agree that the principal purpose of this Agreement is to support commercially reasonable efforts in achieving the goals of the Program, and not for the acquisition of property or services for the direct benefit or use of the Government.

ARTICLE II: TERM

A. Term of this Agreement:

The Agreement commences on the date of the last signature hereto and continues for a twelve-month period (the "Base Period") with an option to extend the term of the Agreement on four (4) occasions for an additional twelve months on each occasion (each, an "Option"). The Government will provide the Recipient a preliminary written notice of its desire to exercise each option at least ninety (90) days before the expiration of (i) one year following the commencement of the Agreement (for the first Option) and (ii) each Option term thereafter, as applicable. The preliminary notice does not commit the Government to an extension; however, if the Government issues a preliminary notice to Recipient and subsequently elects not to proceed to exercise the Option, the Government shall notify Recipient of this decision not less than thirty (30) days prior to expiration of the term. The Recipient may decline any Option and such declination will be treated as a termination and Recipient shall act in accordance with the terms in Section B. The Parties may also agree mutually to extend the term of this Agreement and its options by written agreement on or before the expiration of the Agreement.

B. Termination Provisions

Either Party may terminate this Agreement by providing ninety (90) days written notice to the other Party, provided that such written notice is preceded by consultation between the Parties at the level of the JOC. In the event of a termination of the Agreement, it is agreed that disposition of Data developed under this Agreement, shall be in accordance with the provisions set forth in Article VIII, Data Rights. The Government and the Recipient will negotiate in good faith a reasonable and timely adjustment of all outstanding issues between the Parties resulting from 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 VI, Disputes. The Government has no obligation to pay the Recipient for activities performed after the date of contract termination with the exception of any non-cancellable obligations which may have been entered into in the course of performing the approved scope of work. For purposes of this clause, termination expenses shall be those expenses identified in Federal Acquisition Regulation 31.205-42 but do not include re-procurement costs.

C. Extending the Term

The Parties may extend by mutual written agreement the term of this Agreement if funding availability and research opportunities reasonably warrant. Any extension shall be formalized through modification of the Agreement by the OTAO and the Consortium Project Management Lead (PML). If the Recipient desires an extension to the period of performance 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: AMENDMENTS

A. Recommendations for Modifications

As a result of quarterly meetings, JOC meetings 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, excluding minor modifications discussed below, 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 PML to the OTTR with a copy to the ASPR OTAO and OTAS. This letter will detail the technical, chronological, and financial impact (if any) of the proposed modification to the Program.

B. Minor Modifications

Notwithstanding the foregoing, minor non-material Agreement modifications that do not affect the obligations of Recipient or Consortium Members, the Government or the terms and conditions of this Agreement (e.g. changes in the paying office or appropriation data, Government or the Recipient's changes to personnel identified in the Agreement, etc.), may be made by either Party with one (1) working-day written notice to the other Party. Failure of the other party to respond will be deemed concurrence that subject modification is non-material. If Parties do not reach agreement as to whether a modification is minor, then the process identified in Section C shall apply.

C. Modifying the Agreement

The OTAO and OTAS shall be responsible for agreeing to any modifications to this Agreement on behalf of the Government. The Principal Investigator (PI) and PML shall be responsible for agreeing to any modifications to this Agreement on behalf of the Consortium. No modification, however, is effective unless in writing and signed by the Parties.

ARTICLE IV: MANAGEMENT OF THE PROJECT

A. Project Organization and management Structure

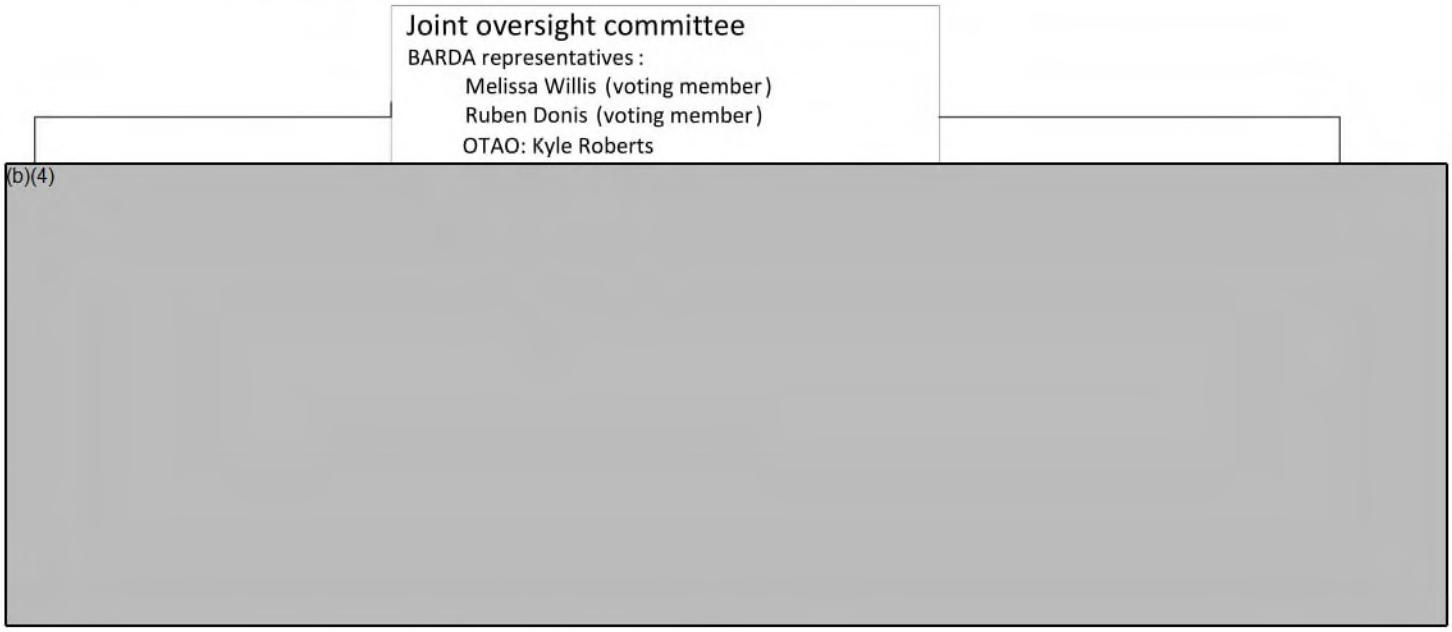
1. Joint Oversight Committee: The Joint Oversight Committee (JOC) is the higher-level decision making body that provides guidance, direction and control to the Program Management Organization (PMO) Steering Committee to ensure execution of the projects according to the SOW. The JOC shall have representation from both BARDA and the Recipient and shall discuss and jointly approve changes to the SOW. The responsibility of the JOC is to mutually interrogate risks and progress of assets covered under this Agreement, endorse potential new assets and agree on allocation of funding across activities covered under the Agreement. Any addition or removal of assets or Consortium Members, agreed upon by the JOC for inclusion under this Agreement shall be added by modification.

The JOC will recommend the strategy to be covered under this Agreement during the subsequent funding period, as well as how Government funding will be allocated across these activities. The recommendations will be submitted, as appropriate, to the relevant Consortium governance board(s) for endorsement and decision (b)(4) (b)(4) (b)(4) Similar procedures will be implemented by the Government. If endorsed by the relevant Consortium governance boards and by BARDA, the recommendations will be incorporated into the SOW and this Agreement through modifications as described in ARTICLE III.

2. PMO Steering Committee: The PMO steering committee has dual responsibilities. First, it is responsible for communication and coordination with BARDA regarding day to day management and execution of the project; *e.g.* organizing meetings on a regular, agreed-upon basis. Second, 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, including the establishment of the Compound Development Teams (CDT). These SOW activities will be coordinated by the Project Manager Leader (PML). The Steering Committee will assess progress and, where needed, will propose strategic technical changes to be decided upon by the JOC. The Steering Committee consists of a group of dedicated and specialized project management experts, key personnel (shown below) and additional specific expertise for the functions that are required for executing the specific work scope for each proposed asset

area. The PMO Steering Committee will prepare for and participate in quarterly review meetings in conjunction with the BARDA Technical Team including the OTTR, as further described in Section B of this Agreement.

3. Organizational Chart



B. Project Committees and Meetings

1. Joint Oversight Committee (JOC). 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 or prior to the exercising of an Option. The JOC will consist of two (2) voting members each from the Consortium and BARDA and non-voting members from the Consortium and BARDA, or other additional Consortium or U.S. Government Members (non-voting) as may be required. Additional, non-voting members may be assigned or invited by Recipient on an ad-hoc basis. Decisions to reprioritize specific projects and resources within the scope of this Agreement 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 Consortium senior management member identified at the start of the project.

2. Kick-off and Quarterly PMO Steering Committee. A Kick-off meeting will be held within thirty (30) days of Agreement Effective Date; the Consortium will provide an updated Program Plan for the base period within forty-five (45) days of Kick-off meeting. The Consortium, the OTAO and/or OTAS and BARDA shall participate in Project Meetings to coordinate the performance of the Agreement. These meetings may include face-to-face

meetings in Washington, D.C. or at work sites of the Consortium Members. Such meetings may include, but are not limited to, meetings with the Consortium Members to discuss study designs, site visits to Consortium Member facilities, and meetings with the Consortium and HHS officials to discuss the technical, financial, regulatory and ethical aspects of the program. These meetings will also formulate and endorse the activities for the subsequent three months. In order to facilitate review of agreement activities, it is expected that the Consortium will provide data, reports, and presentations to groups of outside experts (subject to appropriate agreements to protect confidential or proprietary data) and Government personnel as requested by the OTTR. The PML shall provide an itinerary and agenda at least five (5) business days in advance of a face-to-face meeting. Subject to other provisions specified in this Agreement (see for example Attachment 2), the PML/PI shall notify the OTTR and OTAO of formal and informal correspondence with the Food and Drug Administration (FDA) or other regulatory agencies as specified in Attachment 2.

3. Integrated Program Review (IPR) Meetings. On an annual basis or by an event-driven need, and with a minimum of sixty (60) days advanced notice, prior to the exercise of additional effort to the Agreement, the Government may invite the Consortium to give a presentation at an Integrated Program Review Meeting attended by BARDA and invited interagency representatives. The Consortium will present data generated under the Agreement over the past year. Progress against portfolio progress milestones will be assessed. Successes and challenges of the program will be discussed and plans for the coming year will be presented.

4. Bi-Weekly Teleconferences. A conference call between the OTTR, OTAS and/or OTAO and the Consortium PI/PML shall occur every two weeks or as required, if an urgent matter should arise. During this call, the PI/PML will discuss the activities during the reporting period, any problems that have arisen, and the key activities planned for the ensuing reporting period. The PI/PML 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. On an as needed basis, the OTTR or PI/PML may assign this responsibility to a delegate.

C. Document Review: The PI/PML shall provide the Government sufficient opportunity to review study protocols, reports, and FDA correspondence. The Government's comments on these documents will be viewed as 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 shall be referred to the following representatives of the Parties:

Government Points of Contact:

Other Transaction Agreement Officer (OTAO):

(NAME) Kyle Roberts

(TITLE) Section Chief, Influenza and Emerging Disease

(PHONE NUMBER) (202) 260-0747

(EMAIL) Kyle.Roberts@hhs.gov

Other Transaction Agreement Specialist (OTAS):

(NAME) Kevin Nilles

(TITLE) Contract/Agreement Specialist

(PHONE NUMBER) (202) 245-0969

(EMAIL) Kevin.Nilles@hhs.gov

Other Transaction Agreement Technical Representative (OTTR):

(NAME) Kimberly Armstrong

(TITLE) Health Scientist, Influenza and Emerging Diseases Division

(PHONE NUMBER) (202)260-0130

(EMAIL) Kimberly.Armstrong@hhs.gov

Alternate OTTR:

(NAME) Karl Erlandson

(TITLE) Health Scientist, Influenza and Emerging Diseases Division

(PHONE NUMBER) (202) 692-4676

(EMAIL) Karl.Erlandson@hhs.gov

Recipient Points of Contact:

ARTICLE VI: COST SHARING

A. **Acknowledgement:** The terms of this Article VI apply to the cost sharing principles as described below. The Parties acknowledge that the activities included under this agreement may change at any time due to alterations in development strategy, risk mitigation approaches, technical challenges, or any other circumstance. Any modification will be subject to these cost sharing principles unless otherwise agreed by the JOC. As such, any projection of shared costs or resources will be estimates and will be non-binding, with the exception of the Base Period costs discussed in Sections B and C below.

B. **Allowable Costs:** The Recipient's binding cost share will consist of reimbursable expenses including direct labor dollars charged in the performance of activities covered under the SOW, the indirect dollars (fringe, overhead and G&A) applicable to the direct labor and material costs, and subcontractor, consultant, and other costs. No fee or profit is allowable. These costs will reasonably relate to the activities conducted under the SOW. Budgets will be updated at least once a year to reflect changes to Consortium Members' indirect rates, which are updated annually and shall be set at government-approved provisional rates for the forthcoming year. Direct labor will be charged based on effort reports from Consortium personnel who will track their time in the Consortium Member's standard timekeeping system. These personnel allocate their effort to specific projects and activities, but the time can be recorded per standard

practices of Consortium Members, and does not require manager review or approval. No reconciliation of costs shall occur.

Charges made under this Agreement shall include:

1. Direct materials and supplies that are used in the performing of the work provided for under the Agreement, including those purchased for subcontracts and purchase orders.

2. Labor, including supervisory, that is properly chargeable directly to the contract, and inclusive of fringe benefits

3. Indirect Costs

Other items as agreed upon by the Parties may be included by modification to this Agreement.

C. Global Cost Share: The Global Cost represents the estimated total cost for activities under the SOW that support the development of the assets described above during the term of the within the base and option periods of the Agreement. The Recipient Global Cost Share of (b)(4) represents the Recipient's estimated contribution as a percentage of the Global Cost during the Base Period of the Agreement. The table as shown below represents the Recipient's total estimated cost share under the SOW for the Base Period and the proposed option periods of this Agreement. As stated above, the Recipient's and BARDA global cost share, with the exception of the Base Period estimate, is non-binding and may vary during the performance of the Agreement with the addition or removal of an asset, a significant change in the development plan of an asset, or by funding allocation decisions that are made by the Joint Oversight Committee. The cost share estimates would need to be re-established under any of these scenarios. The Recipient agrees to at a minimum match the Government funding.

Recipient Global Cost Share Estimates for the activities covered under the SOW:

(b)(4)

D. Financial Reporting: In lieu of earned value management reporting Consortium will provide quarterly Business Status report found in Attachment 2, A.2. Additionally at least once a year, in alignment with the timing of a JOC meeting and the timing for exercise of options, Recipient will provide financial information to the OTAO identifying the total charges made during the performance of this Agreement with a budget update for future periods. This report is for informational purposes only. Consortium Members' accounting for government-reimbursed and Recipient costs shall be in accordance with Consortium Members' accounting practices but must comply with Generally Accepted Accounting Principles or other international standards. Consortium Members' accounting practices in determining total actual costs are not required to comply with the Cost Accounting Standards or the cost principles at Federal Acquisition Regulation Subpart 31.

ARTICLE VII: OBLIGATION AND PAYMENT

A. Obligation

1. The Government's obligation to make payments to Recipient is limited to only those funds described in the Agreement or by modification to the Agreement. The Government is obligated to fund the amount of (b)(4) (b)(4) The Government and Recipient are not obligated to fund work that is to be performed during the Option periods until an Option is exercised. Recipient is not obligated to perform work beyond that which has been funded by the Government.

2. If modification of the payment terms or schedule becomes necessary in performance of this Agreement, pursuant to Article III, section C, the ASPR OTAO and PML/PI Administrator shall execute a revised Statement of Work consistent with the then current Program Plan.

B. Payments

Recipient has an established and agrees to maintain an accounting system which complies with Generally Accepted Accounting Principles and international standards as required, and shall ensure that appropriate arrangements have been made for receiving, distributing and accounting for the funds dispersed under this Agreement. An acceptable accounting system is one in which all cash receipts and disbursements are controlled and documented properly.

Properly prepared invoice(s) shall be submitted by Recipient for payment not more than once per quarter in Adobe Acrobat (.pdf) format. The invoice shall be uploaded to a shared electronic file server, with an email copy to the OTAO, OTAS and OTTR cited below. The invoice shall be accompanied by adequate documentation as may be required to support the payment. After verification of the accomplishment of the work, the OTAS and OTTR will forward the invoice(s) to the payment office. Each invoice must contain the following information in order to be deemed properly prepared:

a. Name and address of Contractor

b. Invoice Date and Invoice Number

c. Agreement Number

d. Description, quantity, unit of measure, unit price, and extended price

e. Recipient Cost Share

f. Name and address of OTAR official to whom voucher is to be sent

g. Name, title, phone number, and mailing address of person to notify in the event of a defective invoice.

h. Taxpayer Identification Number (TIN)

i. Electronic Funds transfer (EFT) banking information

Documents should be delivered electronically to the OTAO, OTAS and OTTR. Unless otherwise specified by the OTAO all deliverables and reports furnished to the Government under the resultant Agreement (including invoices) shall be addressed to the OTAO, OTAS and OTTR.

Quarterly invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the Government.

The Recipient will convert foreign currency costs to US Dollars each quarter using the spot exchange rate published by Reuters at 4 PM ET on the last working day of each quarter.

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

The Government will pay all proper invoices in US dollars 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 and funds identified as Recipient contributions are to be used solely for Agreement-related expenditures that are reasonable in nature and amount, and allocable to this Agreement.

D. Financial Records and Reports:

The Recipient shall maintain adequate records to account for its expenditure of all funding under this Agreement. Upon completion or termination of this Agreement, whichever occurs earlier, the Recipient Administrator shall furnish to the OTAO a copy of the Final Report required by Attachment 2, Part E. Recipient's relevant financial records are subject to examination or audit by the Government for a period not to exceed three (3) years after expiration of the term of this Agreement. The OTAO or designee shall be provided direct access to sufficient records and information of Recipient, to ensure accountability for funding under this Agreement. Such audit, examination, or access shall be performed during business hours on business days upon prior written notice and shall be subject to the security requirements of the audited party.

E. Comptroller General Access to Records

To the extent that the total Government payment under this Agreement exceeds $5,000,000, the Comptroller General, at its discretion, shall have access to and the right to examine records of any Consortium Member participating in the performance of this Agreement for a period of three (3) years after final payment is made. This requirement shall not apply with respect to any Consortium Member that participates in the performance of the Agreement that has not entered into any other Agreement (contract, grant, cooperative agreement, or "other transaction") that provides for access by a Government entity in the year prior to the date of this Agreement. This paragraph only applies to any record that was created or maintained in the ordinary course of business or pursuant to a provision of law in the performance of the Agreement.

ARTICLE VIII: 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

1. Any claim or dispute between HHS and Consortium 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 under this Article.

2. Whenever legal disputes or claims arise, the Parties shall attempt to resolve the issue(s) by discussion and come to mutual agreement on a resolution as soon as practicable. In no event shall a dispute, disagreement or misunderstanding that arose more than three (3) months prior to the notification made under sub-section B.3 of this article constitute the basis for relief under this article unless one level above the OTAO, in the interests of justice, waives this requirement.

3. 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.

4. 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.3 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 resolve the issue(s) and notify the Parties in writing. Such resolution shall be final and binding.

5. 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.

C. Escalation Procedure for Technical Matters

In the event of a technical disagreement the procedures for resolution are depicted in Attachment 3, Technical Escalation Procedure

D. Limitation of Damages

Claims for damages of any nature whatsoever pursued under this Agreement shall be limited to direct damages only up to the aggregate amount of HHS funding disbursed as of the time the dispute arises. In no event shall either Party be liable for claims for consequential, punitive, special and incidental damages, claims for lost profits, or other indirect damages.

ARTICLE IX: PATENT RIGHTS

A. Allocation of Principal Rights

Unless Recipient notifies the Government that Recipient does not intend to retain title, Recipient or its designee shall retain the entire right, title, and interest throughout the world to each Subject Invention consistent with the provisions of this Article and 35 U.S. § 202.

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

1. Recipient shall identify Subject Inventions in an annual report and the final report, which shall be in sufficiently complete technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological, or electrical characteristics of the Subject Invention.

2. If Recipient determines that neither it nor its designee intends to file any patent applications on a Subject Invention, Recipient shall notify HHS, in writing, within two (2) years of disclosure of such Subject Invention to HHS. 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 HHS to a date that is no more than sixty (60) calendar days prior to the end of the statutory period.

3. Recipient shall file its initial patent application on a Subject Invention to which it retains title prior to the end of the statutory period wherein valid patent protection can be obtained in the United States after a publication, or sale, or public use. Recipient may elect to file patent applications in additional countries (including the European Patent Office and the Patent Cooperation Treaty) at its discretion.

C. Conditions When the Government May Obtain Title

Upon HHS's written request, Recipient shall convey title to HHS:

1. Of any Subject Invention, if Recipient fails to disclose the Subject Invention within the times specified in section B of this Article; provided, that HHS may only request title within sixty (60) calendar days after learning of the failure of Recipient to disclose within the specified times. For the avoidance of doubt, disclosure under this paragraph shall be deemed to have occurred at the time of Recipient's notification to the Government of a Subject Invention regardless of whether such disclosure meets the standards set forth in Article IX.B.1 above.

2. Of a patent application or patent that claims a Subject Invention, as the case may be, in any country in which Recipient decides not to continue the prosecution of such patent application, or to pay the maintenance fees on or defend in reexamination or opposition proceedings such a patent.

D. Minimum Rights to Consortium and Protection of Consortium's Right to File

1. Recipient shall retain a nonexclusive, royalty-free license throughout the world in each Subject Invention to which the Government obtains title under IX. C. The Recipient license extends to the Recipient's Affiliates, and includes the right to grant licenses of the same scope to the extent that Recipient was legally obligated to do so at the time the Agreement was awarded or at the time of the Subject Invention was invented. The license is transferable only with the approval of HHS, except when transferred to the successor of that part of the business to which the Subject Invention pertains. HHS approval for license transfer shall not be unreasonably withheld.

2. The Recipient license may be modified by HHS to the extent necessary to achieve diligent Practical Application of the Subject Invention pursuant to an application for an exclusive or non-exclusive license submitted consistent with appropriate provisions at 37 CFR Part 404. .

3. Before modification of the license, HHS shall furnish Recipient a written notice of its intention to modify the license, and Recipient shall be allowed sixty (60) 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 modified.

E. Action to Protect the Government's Interest

1. Recipient agrees to execute or to have executed and promptly deliver to HHS 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 HHS when requested under section D of this Article and to enable the Government to obtain patent protection throughout the world in that Subject Invention.

2. 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 in order that Recipient can comply with the disclosure provisions of section C of this Article. Recipient shall instruct employees, through employee agreements or other suitable educational programs, on the importance of reporting Subject Inventions in sufficient time to permit the filing of patent applications prior to U. S. or foreign statutory bars.

3. Recipient shall notify HHS of any decisions not to continue the prosecution of a patent application claiming a Subject Invention, pay maintenance fees on a patent claiming a Subject Invention, or defend in a reexamination or opposition proceedings on a patent claiming 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.

4. Recipient shall include, within the specification of any United States patent application and any patent issuing thereon claiming a Subject Invention, the following

statement: "This invention was made with Government support under Agreement HHSO100201700018C, awarded by HHS. The Government has certain rights in the invention."

F. Lower Tier Agreements

Recipient shall include this Article, suitably modified, to identify the Parties, in all subcontracts or lower tier agreements, regardless of tier, for experimental, developmental, or research work under this Agreement.

G. Reporting on Utilization of Subject Inventions

1. Recipient shall submit, during the term of the Agreement, an annual report on the utilization of Subject Inventions or on efforts at obtaining such utilization that are being made by or on behalf Recipient or its licensees or assignees. Such reports will 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 shall provide additional reports as may be requested by HHS in connection with any march-in proceedings undertaken by HHS in accordance with section H of this Article. Consistent with 35 U.S.C. § 202(c) (5), HHS agrees it shall not disclose such information to persons outside the Government without permission of Recipient.

2. All required reporting shall be submitted to the OTAS, OTAO, and OTTR.

3. Where the Subject Invention is a drug or a vaccine, or a method of manufacturing, administering or using a drug or vaccine, Practical Application is achieved with respect to:

a. such drug or vaccine, if (b)(4) (b)(4) or

b. such method of use, if the method of use is employed in manufacture, administration or use of such drug or vaccine in connection v(b)(4) (b)(4)

4. Failure to complete a(b)(4) does not per se constitute a failure to achieve Practical Application.

H. March-in Rights

Recipient agrees that, with respect to any Subject Invention in which it has retained title, HHS may request Recipient, an assignee, or exclusive licensee of a Subject Invention to grant a non-exclusive license within the Field to a responsible third party, upon terms that are reasonable under the

circumstances. If Recipient, assignee, or exclusive licensee refuses such a request, HHS has the right to require Recipient to grant such a license if HHS determines that:

1. Such action is necessary because Recipient or assignee has not taken steps, consistent with the intent of this Agreement, to achieve Practical Application of the Subject Invention; or

2. Such action is necessary to alleviate the following urgent health or safety needs that effect the United States and that are not reasonably satisfied by Recipient, assignee, or their licensees:

a. declaration for Public Health Emergency by the Secretary of HHS;

b. determination that there is a significant potential for a public Health emergency that has a significant potential to effect a national or health security of U.S. citizens as determined by the Secretary of HHS; or

c. declaration by WHO Director General of a public health emergency of international concern.

3. Where the circumstances described in subsection H.2 are met, Recipient will act promptly to negotiate in good faith with the responsible third party a non-exclusive license on terms that are reasonable under the circumstances under the SI Intellectual Property Rights it controls at the time to make, have made, use, sell, offer for sale and import the relevant Subject Invention in the Field to the extent necessary to alleviate the public health emergency in the United States.

ARTICLE X: DATA RIGHTS

A. Allocation of Principal Rights

1. The Government will receive Limited Rights in Data delivered in the performance of the SOW that is marked with the "Limited Rights" legend required by section C below. Any delivered Data which is part of a patent application claiming a Subject Invention will be subject to the disclosure and release restrictions set forth in Article IX, section B of this Agreement.

2. Data in any document which is a part of a patent application that would disclose a Subject Invention will be subject to Limited Rights until publication of patent application in accordance with Article IX of this Agreement.

3. Recipient agrees to retain and maintain in good condition all Data necessary to achieve Practical Application of any Subject Invention in accordance with the Recipient's established record retention practices. In the event of exercise of the Government's March-in Rights as set forth under Article X, Recipient agrees, upon written request and with adequate additional support from the Government, as mutually agreed between

the Parties, to deliver Data necessary to achieve Practical Application within one-hundred and twenty (120) calendar days from the date of the written request.

4. 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. IDENTIFICATION AND DISPOSITION OF DATA

Recipient shall keep copies of all Data required by the Food and Drug Administration (FDA) relevant to this Agreement for the time specified by the FDA and provide such Data to OTAO. HHS reserves the right to review any other Data determined by HHS to be relevant to this Agreement. Recipient shall provide regulatory data to the OTTR and OTAS in accordance with Attachment 2: Reporting Requirements.

C. Marking of Data

Pursuant to section A above, any Data delivered under this Agreement shall be marked with the following legend or similar:

> *"LIMITED RIGHTS: The Government's right to use, modify, reproduce, perform, display or disclose this Data is restricted by Agreement XX-X-XXXX between the Government and Recipient, and those restrictions do not permit disclosure to any party outside the Government without prior agreement of Recipient. Any reproduction of this Data or portions thereof must be marked with this legend."*

D. Lower Tier Agreements

Recipient shall include this Article, suitably modified to identify the Parties, in all subcontracts or lower tier agreements, regardless of tier, for experimental, developmental, or research work performed under this Agreement.

ARTICLE XI: FOREIGN ACCESS TO TECHNOLOGY:

(a) Except as authorized by the Office of Foreign Assets Control (OFAC) in the Department of the Treasury, the Contractor shall not acquire, for use in the performance of this contract, any supplies or services if any proclamation, Executive order, or statute administered by OFAC, or if OFAC's implementing regulations at 31 CFR chapter V, would prohibit such a transaction by a person subject to the jurisdiction of the United States.

(b) Except as authorized by OFAC, most transactions involving Cuba, Iran, and Sudan are prohibited, as are most imports from Burma or North Korea, into the United States or its outlying areas. Lists of entities and individuals subject to economic sanctions are included in OFAC's List of Specially Designated Nationals and Blocked Persons at http://www.treas.gov/offices/enforcement/ofac/sdn/. More information about these restrictions, as well as updates, is available in the OFAC's regulations at 31 CFR chapter V and/or on OFAC's website at http://www.treas.gov/offices/enforcement/ofac.

(c) The Contractor shall insert this clause, including this paragraph (c), in all subcontracts.

ARTICLE XII: TITLE TO AND DISPOSITION OF PROPERTY

A. Title to Property

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. Title to this Property shall also vest in Recipient and HHS upon acquisition in accordance with the cost share of the acquisition. Recipient shall be responsible for the maintenance, repair, protection, and preservation of all Property at its own expense.

B. Disposition of Property

At the completion of the term of this Agreement, items of Property with an acquisition value greater than $50,000 shall be disposed of in the following manner:

1. Purchased in full by Recipient at a price that the parties agree represents fair market value of the property at the time of purchase with an agreed upon markdown due to the Recipients care of the property, with the proceeds of the sale being returned to HHS; or

2. Transferred to a Government research facility with title and ownership being transferred to the Government; or

3. Donated to a mutually agreed university or technical learning center for research purposes; or

4. Any other HHS-approved disposition procedure.

(b)(4)

(b)(4)

ARTICLE XIV: CIVIL RIGHTS ACT

Performance of this Agreement in the US 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. Recipient has signed an Assurance of Compliance with the nondiscriminatory provisions of the Act.

ARTICLE XV: EXECUTION

This Agreement constitutes the entire agreement of the Parties and supersedes all prior and contemporaneous agreements, understandings, negotiations and discussions among the Parties, whether oral or written, with respect to the subject matter hereof. This Agreement may be revised only by written consent of Recipient and the ASPR 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.

ARTICLE XVI: SPECIAL CLAUSES

A. Inspection and Acceptance

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

2. For the purpose of this Section, the designated OTTR is the authorized representative of OTAO. The OTTR will assist in resolving technical issues that arise during performance. The OTTR; however, is not authorized to change any OTA terms or authorize any changes in the Statement of Work or modify or extend the period of performance, or authorize reimbursement of any costs incurred during performance.

3. Inspection and acceptance will be performed at the Recipient's facilities or at:

Biomedical Advanced Research and Development Authority (BARDA) and/or Office of Acquisition Management, Contracts, and Grants (AMCG) under the Office of the Assistant Secretary for Preparedness and Response U.S. Department of Health and Human Services

B. PROTECTION OF HUMAN SUBJECTS

1. The Recipient agrees that the rights and welfare of human subjects involved in research under this contract 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 at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR Part 46 and the Assurance of Compliance.

2. The Recipient shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The Parties hereto agree that the Recipient retains the right to control and direct the performance of all work under this contract. Nothing in this contract shall be deemed to constitute the Recipient or any sub Recipient, agent or employee of the Recipient, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Recipient agrees that it has entered into this contract 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.

3. If at any time during the performance of this contract, the ASPR OTAO's determines, in consultation with the OHRP, OPHS, ASH, that the Consortium is not in compliance with any of the requirements and/or standards stated in paragraphs (1) and (2) above, the HHS OTAO's may immediately suspend, in whole or in part, work and further payments under this contract until the Recipient corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Consortium fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the ASPR OTAO's may, in consultation with OHRP, OPHS, ASH, terminate this contract in a whole or in part, and the Recipient's name may be removed from the list of those consortiums with approved Health and Human Services Human Subject Assurances.

C. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

1. The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Recipient in full compliance with applicable federal, state and local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

2. The Recipient shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were

obtained with prior approval by the Office for Human Research Protections (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.

3. Provision by the Recipient to the ASPR 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).

D. 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 and http://grants1.nih.gov/grants/guide/notice-files/not93-235.html and any subsequent revisions to this NIH Guide to Grants and Contracts ("Guide") Notice. The Recipient shall make available, for audit by the Secretary, HHS, the physician statements and informed consents required by 42 USC 289g-1(b) and (c), or ensure HHS access to those records, if maintained by an entity other than the Recipient.

E. NEEDLE EXCHANGE

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

F. CARE OF LIVE VERTEBRATE ANIMALS

1. Before undertaking performance of any contract involving animal related activities, the Recipient shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR 2.25 through 2.28. Recipient shall furnish evidence of the registration to the Contracting Officer.

2. The Recipient agrees that the care and use of any live vertebrate animals used or intended for use in the performance of this contract will conform with the PHS Policy on Humane Care of Use of Laboratory Animals, the current Animal Welfare Assurance, the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources 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 be used.

3. If at any time during performance of this contract, the ASPR OTAO's determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Recipient is not in compliance with any of the requirements and/or standards stated in paragraphs (1) through (3) above, the ASPR OTAO's may immediately suspend, in whole or in part, work and further payments under this contract 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 Contracting Officer's written notice of suspension, the ASPR OTAO's may, in consultation with OLAW, NIH, terminate this contract in whole or in part, and the Recipient's name may be removed from the list of those consortiums with approved PHS 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. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737.

Office of Laboratory Animal Welfare Number _____ (FILL IN)

G. 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

H. PROTECTION OF PERSONNEL WHO WORK WITH NONHUMAN PRIMATES

All 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: http://www1.od.nih.gov/oma/manualchapters/intramural/3044-2/

I. INFORMATION ON COMPLIANCE WITH ANIMAL CARE REQUIREMENTS

Registration with the U. S. Dept. of Agriculture (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.), http://www.nal.usda.gov/awic/legislat/awa.htm.

The Public Health Service (PHS) Policy is administered by the Office of Laboratory Animal Welfare (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.

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 http://www.nap.edu/readingroom/books/labrats/ and that they comply with the regulations (9 CFR, Subchapter A) http://www.nal.usda.gov/awic/legislat/usdaleg1.htm issued by the U.S. Department of Agriculture (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.

J. APPROVAL OF REQUIRED ASSURANCE BY LAW

Under governing regulations, federal funds which are administered by the Department of Health and Human Services, Office of Biomedical Advanced Research and Development Authority (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. 2316 and 9 CFR Sections 2.25-2.28 is submitted within 30 days of the date of this award and approved by the Office of Laboratory Animal Welfare (OLAW). Each performance site (if any) must also assure compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28 with the following restriction: Only activities which 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 the Recipient or individual performance sites pending OLAW approval of their respective assurance of compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28. Additional information regarding OLAW may be obtained via the Internet at http://grants2.nih.gov/grants/olaw/references/phspol.htm

K. 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 prime or subcontract awards to domestic institutions who possess, use, and/or transfer Select Agents under this contract, the institution must complete registration with the Centers for

Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS) or the Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA), as applicable, before performing work involving Select Agents, in accordance with 42 CFR 73. No Government funds can be used for work involving Select Agents, as defined in 42 CFR 73, if the final registration certificate is denied.

For prime or subcontract awards to foreign institutions who possess, use, and/or transfer Select Agents under this contract, the institution must provide information satisfactory to the Government that a process equivalent to that described in 42 CFR 73 (http://www.cdc.gov/od/sap/docs/42cfr73.pdf) 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, 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 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 contracting officer, the consortium 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 consortium 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 the contract.

Listings of HHS 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/.

L. MANUFACTURING STANDARDS

The Current Good Manufacturing Practice Regulations (cGMP) (21 CFR 210-211) will be the standard applied for manufacturing, processing and packing of any products to be administered to human subjects under this Agreement.

If at any time during the life of this contract, the Recipient fails to comply with cGMP in the manufacturing, processing and packaging of the products and such failure results in a material adverse effect on the safety, purity or potency of the products (a material failure) as identified by CBER and CDER, the Recipient shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure. If the Recipient fails to take such an action within the thirty (30) calendar day period, then the contract may be terminated.

M. PRODUCT APPROVAL

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

N. ANTI-BRIBERY AND ANTI-CORRUPTION

HHS acknowledges that it has received and read Recipient's 'Prevention of Corruption - Third Party Guidelines'. 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 XVI Section M.

O. GOVERNMENT OBSERVER IN RECIPIENT FACILITY

With seven (7) days advance notice to the Recipient in writing from the OTAO/OTAS, the Government may place an observer in a Recipient facility, who shall be subject to Recipient's policies and procedures regarding security and facility access at all times while in the Recipient'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 disclosed to that person in the course of employment or official duties performed while stationed in a Recipient facility.

P. 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 HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll-free number is 1-800-HHS-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

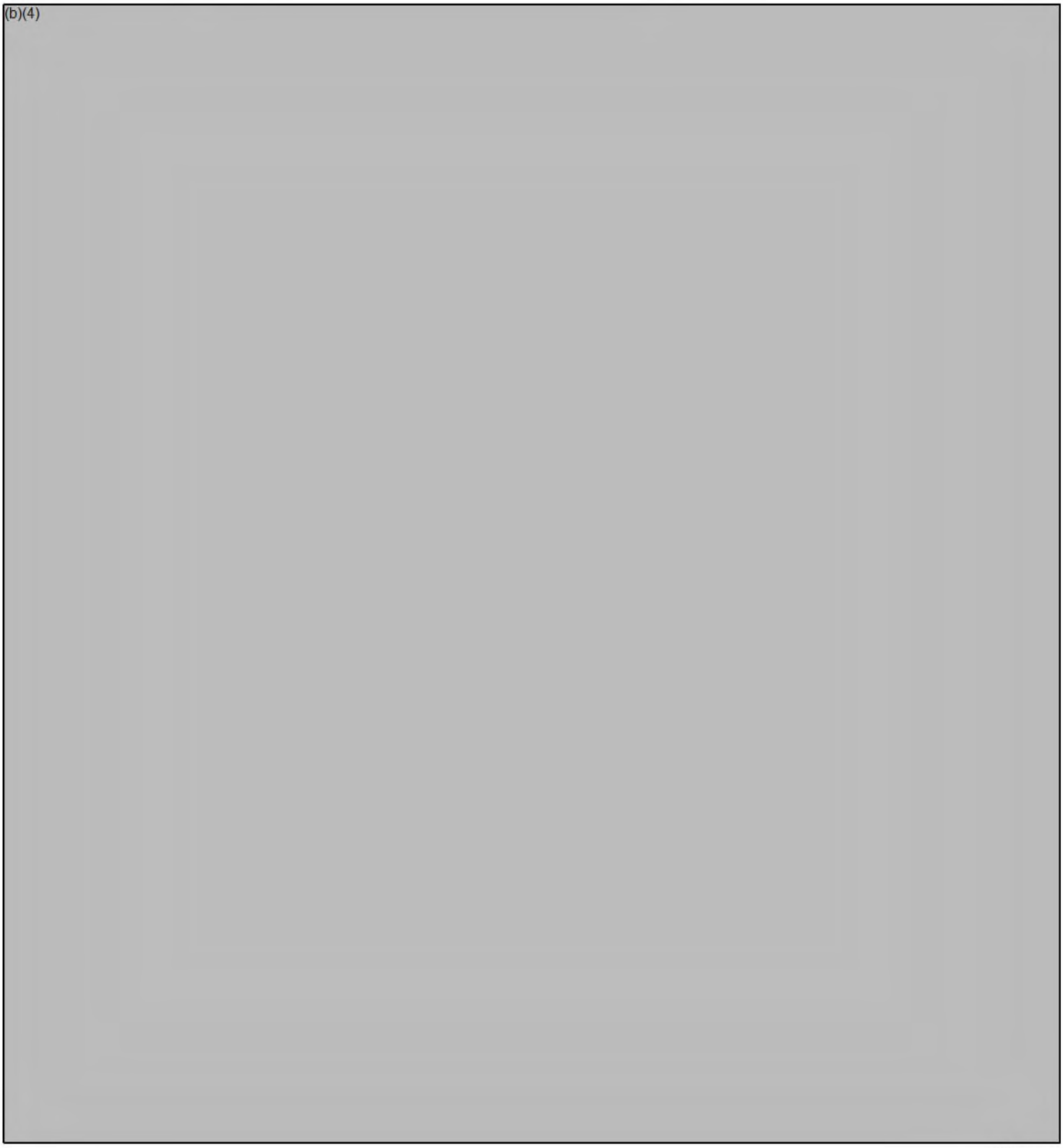
Q. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The Recipient acknowledges that U.S. Executive Orders and Laws, including but not limited to E.0.13224 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. This clause must be included in all subcontracts issued under this Agreement.

ARTICLE XVII: TRANSFERS & ASSIGNMENTS

Any transfer or assignment will be conducted in a manner 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, the "Anti-Assignment Act"). In the event there is a transfer to an independent 3rd Party who is not a consortium member, then the provisions of FAR 42.1204 would apply.

ATTACHMENT 1: (b)(4)



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Withheld pursuant to exemption

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of the Freedom of Information Act

Non-clinical studies may include, but not be limited to: optimization of prodrugs of AL-073 and AL121 for intravenous administration, animal efficacy studies, non-GLP pk/toxicology studies in rats and dogs, a GLP toxicology program, and non-clinical ADME characterization.

4.2 Clinical – First-in-human Phase 1 Study

4.3 CMC

CMC activities may include, but not be limited to: API stable crystalline form screen, non-GMP synthesis, GMP synthesis of API and stability study, pre-formulation and formulation development for phase 1 clinical trial, injectable dosage form formulation development, GMP manufacture of clinical trial material and stability study, and lyophilized powder development.

4.4 Regulatory

Recipient intends to seek regulatory and scientific advice from the regulatory authorities throughout the development of the project as appropriate.

5 Project Management

5.1 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.

5.2 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.

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of the Freedom of Information Act

ATTACHMENT 2: REPORT REQUIREMENTS

Item Description	Delivery Date	Deliver To
1. Monthly Technical Progress Report describing project progress over the previous month.	The 15th of each month	OTAO/OTAS and OTTR via e-mail. Additionally, email invoices to PSC_Invoices@psc.hhs.gov
2. Quarterly Invoices	Within 60 calendar days of the end of each quarter	
3. Bi-Weekly Conference Call Minutes	Proposed agenda 2 business days prior to call. Minutes within 7 business days following each conference call	
4. Quarterly PMO Steering Committee / Site Visit Minutes	Within 10 business days following each PMO Steering Committee /site visit	
5. Bi-annually Joint Oversight Committee minutes	Within 10 business days following each Joint Oversight Committee	
6. Portfolio Progress Milestone Presentation. Annual or event driven review of program	No later than 10 business days before Milestone Review at Joint Oversight Committee	
7. 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
8. Study Reports for each non-clinical or clinical trial	No later than 15 business days before submission to the FDA*	
9. Manufacturing Campaign Reports for contract funded clinical trial material and registration lots	No later than 15 business days before submission to the FDA*	
10. Technical Documents from contract funded activities such as Process Development Report, Assay Validation Plan/Report, Assay Technology Transfer	Within 10 business days upon request by CO/COR or 15 business days prior to submission to FDA*	
11. 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	

12. 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	
13. Memo with Date and Time of Scheduled Meetings with FDA. BARDA reserves the right to attend FDA meetings relevant to contract funded activities	As soon as possible after scheduling	
14. Communications from FDA related to contract funded activities	Within 2 business days of receipt from FDA	
15. Minutes for Formal Meetings with FDA	Within 2 business days of receipt from FDA	
16. 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 risks	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 Funds	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 Trial Database	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

A. Monthly Report

On or before ninety (90) calendar days after the effective date of the Agreement and monthly thereafter throughout the term of the Agreement, Recipient shall submit or otherwise provide

a monthly report. Two (2) copies shall be submitted or otherwise provided to the HHS Program Manager (or OTTR), one (1) copy shall be submitted or otherwise provided to the ASPR OTAO. The report will have two (2) major sections.

1. Technical Status Report. The technical status report will detail technical progress to date and report on all problems, technical issues, major developments, and the status of external collaborations during the reporting period.

2. Business Status Report. The Business Status Report will be provided on a quarterly basis consistent with the invoice cycle. The business status report shall provide summarized details of the resource status of this Agreement, including the status of Recipient contributions. This report will include a quarterly accounting of current expenditures as outlined in the Annual Program Plan. Any major deviations, over plus or minus 10%, shall be explained along with discussions of the adjustment actions proposed. The report will also include an accounting of any interest earned on Government funds. Recipient is reminded that interest in amounts greater than $250 per year is not expected to accrue under this Agreement. In the event that this interest does accrue on Government funds, Recipient is required to provide an explanation for the accrual in the business report. Depending on the circumstances, the Payable Milestones may require adjustment.

B. ANNUAL PROGRAM PLAN DOCUMENT, as necessary

Recipient shall submit or otherwise provide to the OTTR and OTAO one (1) copy each of a report which describes the Annual Program Plan. This document shall be submitted not later than thirty (30) calendar days following the Integrated Program Review as described in Article IV, Section B.

C. SPECIAL TECHNICAL REPORTS

As agreed to by Recipient and the OTTR , Recipient shall submit or otherwise provide to the OTTR and OTAO one (1) copy each of special reports on significant events such as significant target accomplishments by Recipient, significant tests, experiments, or symposia.

D. FINAL REPORT

1. Recipient shall submit or otherwise provide a Final Report making full disclosure of all major developments by Recipient and Subject Inventions upon completion of the Agreement or within sixty (60) calendar days of termination of this Agreement. With the approval of the OTAO, reprints of published articles may be attached to the Final Report. Two (2) copies shall be submitted or otherwise provided to the OTTR; one (1) copy shall be submitted or otherwise provided to the OTAO. One (1) copy shall be submitted to the National Technical Information Center, Attn: DTIC-BCS, 8725 John J. Kingman Road, Suite 0944, Fort Belvoir, VA 22060-0944.

2. The Final Report shall be marked with a distribution statement to denote the extent of its availability for distribution, release, and disclosure without additional approvals or authorizations. The Final Report shall be marked on the front page in a conspicuous place with the following marking:

"DISTRIBUTION STATEMENT B. Distribution authorized to U.S. Government agencies only to protect information not owned by the U.S. Government and protected by a consortium's "limited rights" statement, or received with the understanding that it not be routinely transmitted outside the U.S. Government. Other requests for this document shall be referred to ASPR/OTAO."

E. EXECUTIVE SUMMARY

Recipient shall submit a one to two page executive-level summary of the major accomplishments of the Agreement and the benefits of using the "other transactions" authority pursuant to 10 U.S.C. § 2371and Sections 319L(c)(4)(B) and/or 319L(c)(4)(D) of the Pandemic and All-Hazards Preparedness Act, P.L. 109-417 upon completion of the Agreement. This summary shall include a discussion of the actual or planned benefits of the technologies for both the military and commercial sectors. Two (2) copies shall be submitted to the ASPR OTAO.

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Withheld pursuant to exemption

(b)(6)

of the Freedom of Information Act

BARDA Escalation Procedure Diagram: