

OTHER TRANSACTION FOR ADVANCED RESEARCH (OTAR)

Agreement No.: HHSO100201800012C

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

(b)(4)

Modification No. 0004

Effective Date of Modification: Upon Last Signature in Section III

Total Amount of the Agreement: is left unchanged at

(b)(4)

Government Funding of the Agreement: is left unchanged at

(b)(4)

Total Estimated Recipient Funding of the Agreement: is left unchanged at

(b)(4)

Funds Obligated: with the exercise of

(b)(4)

the total Funds Obligated is increased by

(b)(4)

from

(b)(4)

to

(b)(4)

Period of Performance:

- Period of Performance for added (b)(4) (COVID-19 Antiviral Library screening scope) - effective date of Modification through 31 July 2020.
- Period of Performance for (b)(4) May 1, 2020 through 31 March 31, 2021.

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

Line of Accounting and Appropriation:

CLIN	Title	Requisition (OS)	CAN	Obj.Class	Amt. (Govt Share)	Changed
(b)(4)	(b)(4)	(b)(4)				
	COVID-19 Antiviral Library screening scope					
	(b)(4)					
Total						

I. **AMENDMENT PURPOSE:** The purpose of this modification is to accomplish the following:

- a. (b)(4)
- b. In response to the current novel coronavirus ("COVID-19") outbreak, adds an additional Asset (b)(4) COVID-19 Antiviral program) to perform compound library screening to identify and develop new biological and chemical entities with anti-coronavirus effect,
- c. incorporates a realigned Global Cost Share around (b)(4) (b)(4) Antiviral program asset. This structure aligns with decisions made at the joint BARDA Flu OTA, CBRN

(TPOm) and Janssen JOC committee member meeting on February 3, 2020. The redirected funding and associated tasks from the (b)(4) are subject to future government funding and JOC recommendations,

- d. updates the Statement of Work (Attachment 1) to adjust current (b)(4) work scope to better align work packages to achieve program objectives while also supporting the redirection of funding in support of the COVID-19 Antiviral activities being added to the agreement. This updated SOW also includes the COVID-19 Antiviral Program, work packages, 10.1 and 10.2. These additional Antiviral Program work packages are considered added and funded non-severable independent work packages as of the date of this amendment. For additional clarity, CLIN 0001A (b)(4) will have corresponding tasks performed under WP 10.1 High Throughput Screening (HTS) of Janssen Libraries will be at an (b)(4) cost share and tasks performed under (WBS 10.2) HTS of non-Janssen libraries will be at an (b)(4) cost share
- e. modifies the Project Organization and Management Structure, Organization Chart to add the respective COVID-19 Antiviral BARDA and Janssen Technical Representatives, and reflect other recent changes and additions; and,
- f. adds the essential considerations in paragraph II.d below.

II. AMENDMENT CHANGES

- a. Article VI Cost Sharing, paragraph C, Global Cost Share schedule is deleted and replaced with the following:

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Cost Share Estimates for the activities covered under the SOW for (b)(4)

(b)(4) COVID-19 Antiviral program):

(b)(4)

Cost Estimates to Establish and Operate (b)(4)

(b)(4)

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Cost Share Estimates for the activities covered under the SOW for (b)(4) (COVID-2019 Antiviral Activities)- (b)(4)

(b)(4)

b. Updated the Statement of Work

1. The Statement of Work shall be replaced to reflect adjustments to the (b)(4) work packages and update to include the new asset structure. The updated SOW for incorporation in the OTA is included in Attachment 1.

c. Article IV, Management of the Program, Organization Chart is deleted and replaced with the updated chart as shown below

(b)(4)

d. Essential Considerations - 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.

2. (b)(4)

(b)(4)

3. As it is not known at this time what the final composition and manufacturing technology of the therapeutic product shall be, any IP (patent or technical data) rights (including third party rights) that are needed to fully launch/deploy the final therapeutic product may be subject to pre-existing or other 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 therapeutic 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)



U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS & RESPONSE

BIOMEDICAL ADVANCED RESEARCH & DEVELOPMENT AUTHORITY

BY:

A handwritten signature in blue ink, which appears to read "Jeffrey Q. Benford", is written over a horizontal line.

NAME: JOFFREY Q. BENFORD

ITS: OTHER TRANSACTION AGREEMENT OFFICER

DATE:

2/14/2020

ATTACHMENT 1: STATEMENT OF WORK (SOW)

STATEMENT OF WORK – PREAMBLE

Independently, and not as an agent of the government, the recipient shall furnish all necessary services; qualified professional, technical, and administrative personnel; and material, equipment, and facilities not otherwise provided by the government under the terms of this Agreement as needed to perform the tasks set forth below. The government reserves the right to modify the budget, progress, schedule, or milestones to add or delete processes, schedules, or deliverables if the need arises. Because of the nature of this research and development (R&D) agreement and the complexities inherent in this and prior programs, at designated milestones the government will evaluate whether work should be redirected or removed, or whether schedule or budget adjustments should be made. The government will collaborate with the recipient to arrive at mutually agreeable potential future decisions to change the product, process, schedule, or events to add or delete part or all of these elements as the need arises.

(b)(4)




The potential programs/platforms or technology that may be developed or otherwise supported under this OTA have novel modes of action with the potential to address areas of high unmet medical need for biodefense in the areas of treatment, detection and response.

The Recipient may propose to augment the portfolio by replacing molecules or devices listed in this SOW with backup molecules or devices from their ongoing research programs. With support from the JOC, the Consortium may also consider in-licensing or other approaches to access, promote, support and/or develop drugs, devices, or vaccine candidates to supplement the Program's portfolio of 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.

Objectives for Agreement Lead Asset – (b)(4)

(b)(4)



Other Potential Assets for Agreement

Other potential Assets may include but are not limited to the following:

(b)(4)



Goals:



Deliverables:

Goals:



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of the Freedom of Information Act

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(b)(4)



(b)(4) **Corona Virus ("COVID-19") (WBS – Task 10)**

The goal of this Task is to develop a therapy for the treatment of patients infected with CoV infection. Therefore, High Throughput Screening (HTS) of drug libraries will be performed. These libraries contain approved (b)(4)

(b)(4)

This task was added to this OTA in 1Q20 and resides in (b)(4) for the (b)(4) (b)(4) (b)(4) is being redirected to this Task subject to future government funding and JOC recommendations.

High Throughput Screening (HTS) of Janssen drug libraries (WBS 10.1)

An HTS CoV assay will be implemented to assess the antiviral activities of libraries of compounds against CoV (b)(4)

(b)(4)
(b)(4) This screening assay will be performed at the BSL-3 lab of (b)(4) (b)(4) Rega Institute, University of Leuven).

This lab is equipped with a Box-in-a-lab HTS platform enabling the screening of highly pathogenic pathogens in a BSL3 (b)(4)

(b)(4)

Deliverable: Report summarizing the results of the HTS activities

High Throughput Screening (HTS) of non-Janssen drug libraries (WBS 10.2)

An HTS CoV assay may be implemented to assess the antiviral activities of against non-Janssen libraries of compounds against CoV. (b)(4)

(b)(4)

(b)(4) This screening assay will be performed at the BSL-3 lab of (b)(4) Rega Institute, University of Leuven).

Deliverable: Report summarizing the results of the HTS activities

OTA Review Meetings

- Participate in regular meetings to coordinate and oversee the effort. Such meetings may include, but are not limited to, meeting to discuss manufacturing progress, assay development, preclinical/clinical studies and regulatory progress.
- Participate in teleconferences every two weeks to review technical progress. Teleconferences or additional face-to-face meetings shall be more frequent at the request of BARDA.

(b)(4)



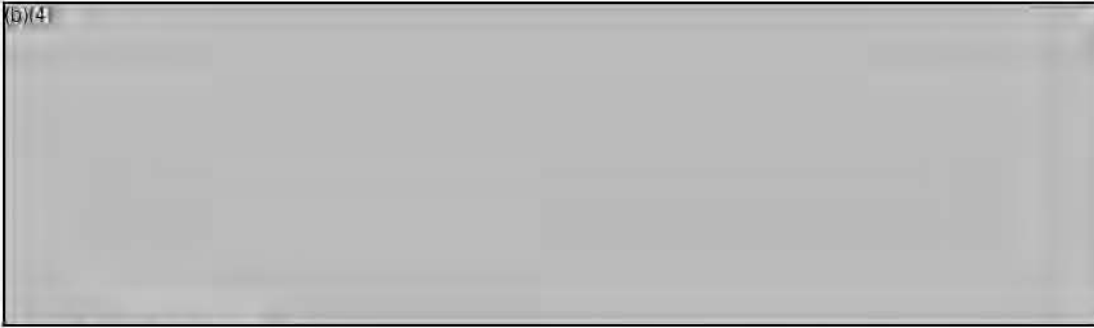
Monthly and Annual Reports

Deliver Project Status Reports on a monthly basis. The reports shall address the items below cross referenced to the WBS, SOW and IMS:

Executive summary highlighting the progress, issues, and relevant activities in manufacturing, nonclinical, clinical, and regulatory;

Progress in meeting OTA milestones, detailing the planned progress and actual progress during the reporting period, explaining any differences between the two and corrective steps;

(b)(4)



Data Management

Develop and implement data management and quality control systems/procedures, including transmission, storage, confidentiality, and retrieval of all OTA data.

(b)(4)



EARLY-MID-STAGE ACTIVITIES

(b)(4)

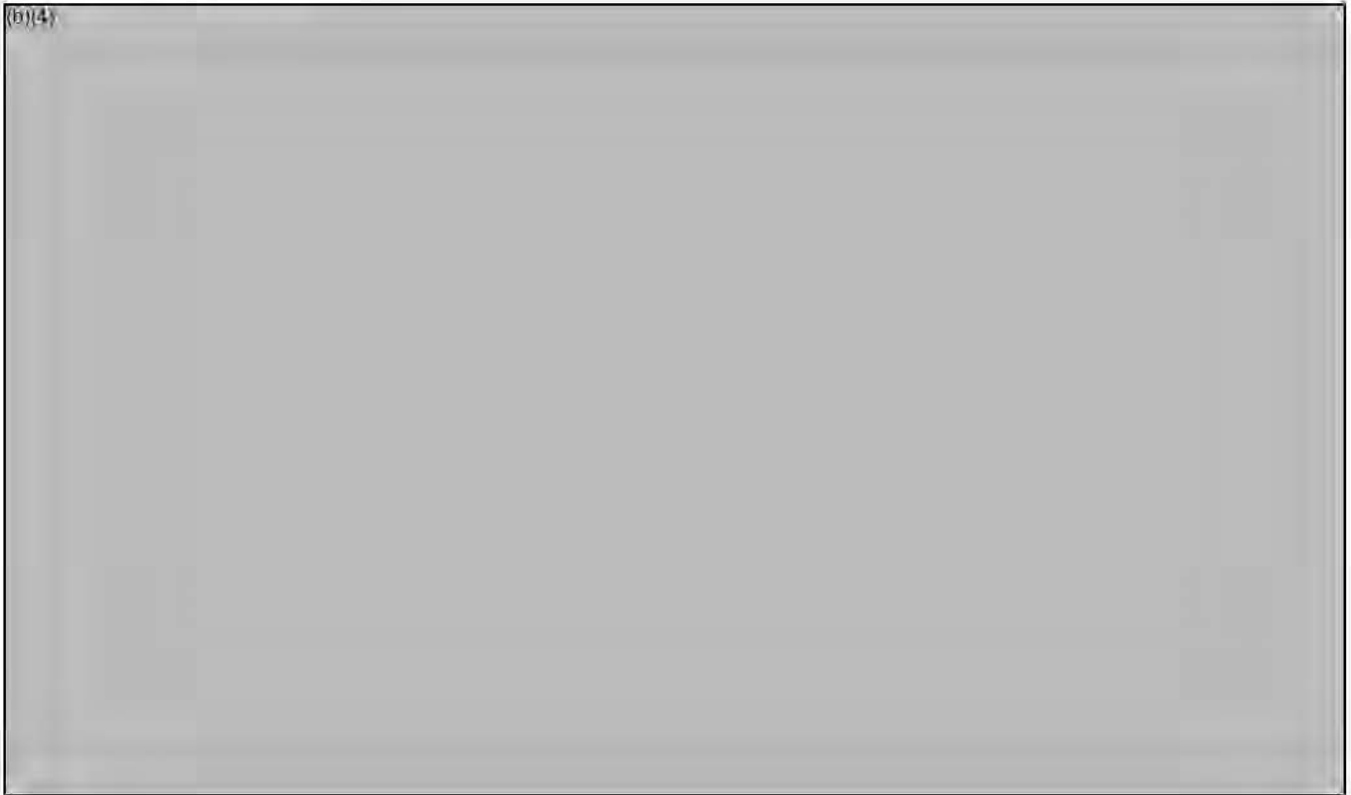


(b)(4)



MID-STAGE ACTIVITIES

(b)(4)



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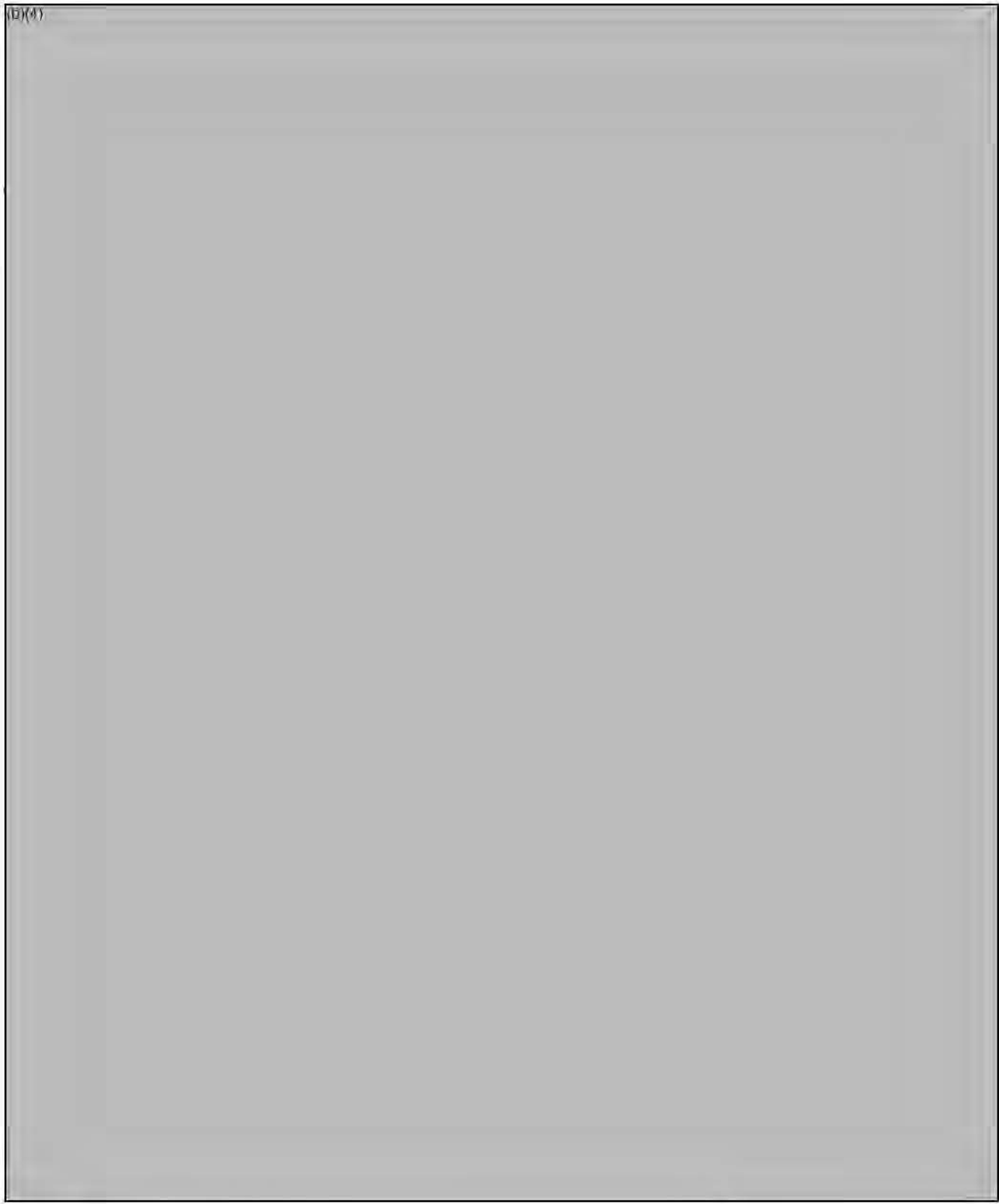
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- (b)(4)
- BARDA POCs for reporting/status updates etc.

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Task 10.1	High throughput screening of Janssen libraries for Corona Virus activity	Report summarizing the outcome of the High Throughput Screening activities
Task 10.2	High throughput screening of non-Janssen libraries for Corona Virus activities.	Report summarizing the outcome of the High Throughput Screening activities

(b)(4)

CLIN 0001A	High Throughput Screening (HTS) of Janssen Libraries (WBS	Modification start	Report summarizing the outcome of the High Throughput Screening activities	<ul style="list-style-type: none">• If Hits are identified this will be reviewed by the JOC for a decision on further activities	New CLIN with scope estimated costs to be
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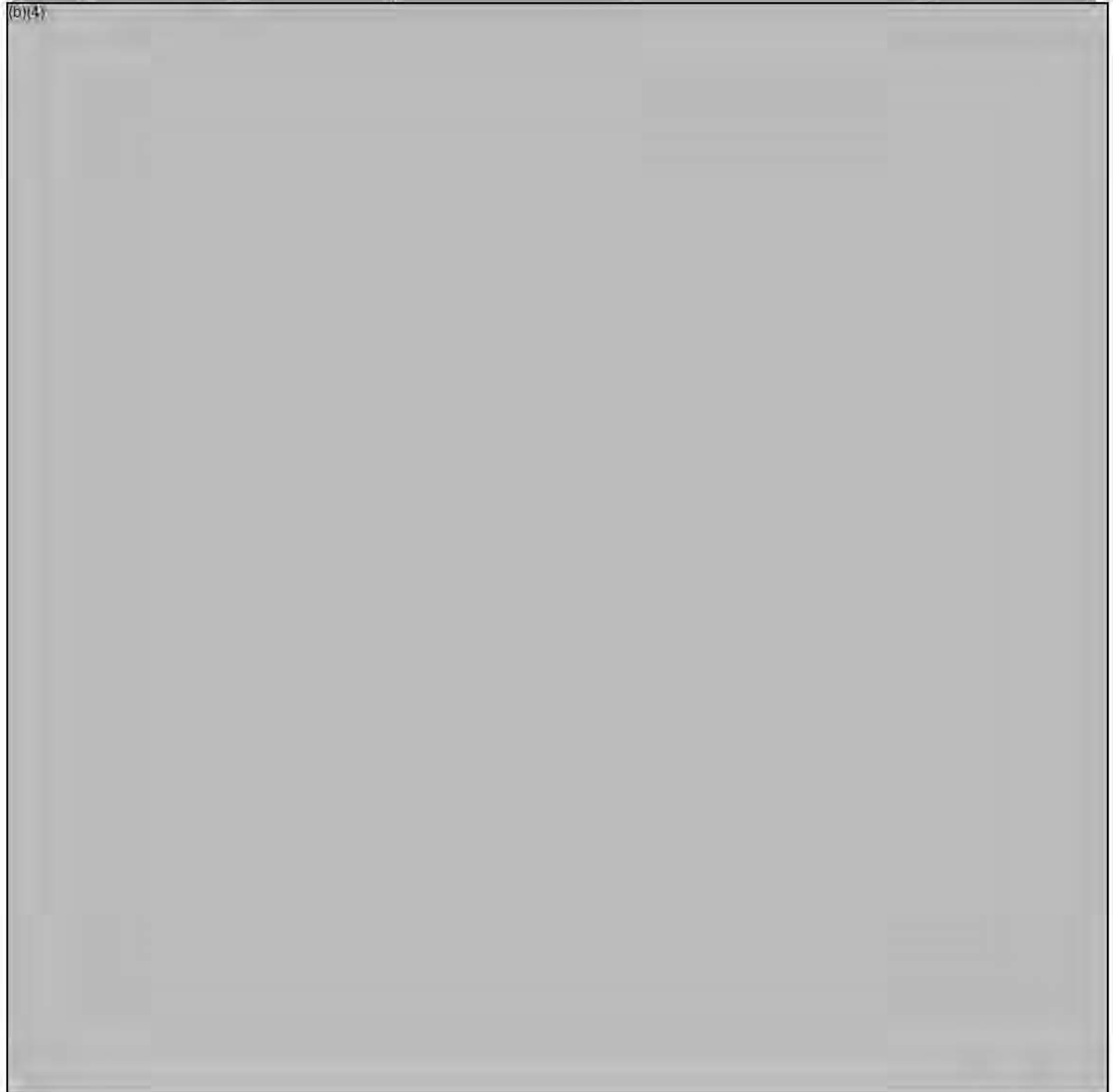
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10.1) and non-Janssen libraries (WBS 10.2)

defined and negotiated

(b)(4)



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