DEPARTMENT OF THE ARMY
U.S. ARMY CONTRACTING COMMAND – NEW JERSEY
PICATINNY ARSENAL, NEW JERSEY 07806-5000

REPLY TO
ATTENTION OF

18 April 2020

Army Contracting Command – New Jersey
ACC-NJ, Building 9
Picatinny Arsenal, NJ 07806

SUBJECT: Technical Direction Letter for Medical CRBN Defense Consortium (MCDC), Request for Prototype Proposals (RPP) 19-02, Sub-Objective 19-02 Definitized Ceiling Increase Modification for "SAB DiversitAb™ Rapid Response Antibody Platform"

REF: Request for Updated Proposal Submitted in Response to RPP-19-02 under OTA W15QKN-16-9-1002 for Sub-Objective 19-02 Modification, dated 24 March 2020

Advanced Technology International
ATTN: (b) (6), Senior Contracts Manager
315 Sigma Drive
Summerville, SC 29486

Dear (b) (6)

The Army Contracting Command – New Jersey (ACC-NJ), in supporting the Joint Project Manager – Medical Countermeasure Systems (JPM-MCS), issued a Request for Proposal Update under MCDC RPP-19-02, Sub-Objective 19-02 on 24 March 2020 to Advanced Technology International, for distribution to SAB Biotherapeutics, Inc. This request would allow SAB to proceed with revisions to current project tasks, as well as incorporate Coronavirus Disease 2019 (COVID-19) tasks. The Government received the undefinitized Rough Order of Magnitude (ROM) proposal update on 30 March 2020, and reviewed the costs and documentation accordingly. Based on the acceptable ROM proposal update, the Government issued an Undefinitized Project Agreement Modification (UPAM) on 30 March 2020. In order to definitize the UPAM, the Government received a proposal update on 16 April 2020, and evaluated the costs and documentation accordingly. Based on the acceptable update of SAB's proposal, the Government is increasing the Project Agreement Ceiling value by (b) (4), from (b) (4) to (b) (4) The Government is also increasing the MCDC CMF Administrative Cost Ceiling increased by (b) (4), from (b) (4) to (b) (4). Please see the below table for additional details.

	MCDC1902-007 Current Ceiling	MCDC1902-007 Proposed Increase ((b) (4) admin cost rate)	MCDC1902-007 Revised Ceiling
Member Ceiling	(b) (4)		
MCDC Admin Cost	(b) (4)		
MCDC Admin Fee	(b) (4)		
Total	(b) (4)		

Work will be performed in accordance with the SOW, entitled, "Encl 3_MCDC1902-007_SOW_PUL3 SAB_ SS edits 4-15-20" (See Attachment 1). SAB should utilize the not-to-exceed existing obligation amount of $15,421,972.84 to continue work on the project. More specifically, COVID-19 work shall be tracked separately using the funding obligated via modification P00063. This Project Agreement is

anticipated to be incrementally funded. The Government reserves the right to award future milestones/fund additional months of project tasks. If the Government decides to do so, the MCDC member will be notified via ATI. The Government's liability will never exceed the current amount of funding obligated under the Project Agreement. The Project Agreement Holder shall notify ATI when they are approaching 75% of current funding obligated in incurred costs by written notice.

The prime contractor is considered a small business, nontraditional defense contractor, or nonprofit research institution and determined to be providing a significant contribution. The affirmation of business status certifications submitted as part of the proposal are hereby incorporated into the agreement. The contractor shall notify the MCDC CMF of any deviation from the final proposed affirmation of business status certifications that would affect the contributions of the small business, nontraditional defense contractor, or nonprofit research institution as proposed.

In accordance with 10.U.S.C. 2371b(f), and upon a determination that the prototype project for this transaction has been successfully completed, this competitively awarded prototype OTA may result in the award of a follow-on production contract or transaction without the use of competitive procedures.

Points of Contact:

Agreements Specialist:
(b) (6)
E-mail: (b) (6)
Phone: (b) (6)

Agreements Officer:
(b) (6)
E-mail: (b) (6)
Phone: (b) (6)

Regards,

X (b) (6)

(b) (6)
Agreements Officer
Signed by: (b) (6)

Attachments:
Attachment 1: "Encl 3_MCDC1902-007_SOW_PUL3 SAB_ SS edits 4-15-20"

DEPARTMENT OF THE ARMY
U.S. ARMY CONTRACTING COMMAND – NEW JERSEY
PICATINNY ARSENAL, NEW JERSEY 07806-5000

REPLY TO
ATTENTION OF

05 June 2020

Army Contracting Command – New Jersey
ACC-NJ, Building 9
Picatinny Arsenal, NJ 07806

SUBJECT: Technical Direction Letter for Medical CRBN Defense Consortium (MCDC), Request for Prototype Proposals (RPP) 19-02, Sub-Objective 19-02 Ceiling Increase Modification for "SAB DiversitAb™ Rapid Response Antibody Platform"

REF: Request for Updated Proposal Submitted in Response to RPP-19-02 under OTA W15QKN-16-9-1002 for Sub-Objective 19-02 Modification, dated 31 May 2020

Advanced Technology International
ATTN: (b) (6), Sr. Contracts Manager
315 Sigma Drive
Summerville, SC 29486

Dear (b) (6)

The Army Contracting Command – New Jersey (ACC-NJ), in supporting the Joint Project Manager – Medical Countermeasure Systems (JPM-MCS), issued a Request for Proposal Update under MCDC RPP-19-02, Sub-Objective 19-02 on 31 May 2020 to Advanced Technology International, for distribution to SAB Biotherapeutics, Inc. (SAB). This request would allow SAB to proceed with revisions to incorporate additional Stage 4 tasks, in support of the Coronavirus Disease 2019 (COVID-19) pandemic. The Government received the proposal update on 05 June 2020, and evaluated the costs and documentation accordingly. Based on the acceptable update of SAB's proposal, the Government is increasing the Project Agreement ceiling value by (b) (4) from (b) (4) to (b) (4). The Government is also increasing the MCDC CMF Administrative Cost Ceiling by (b) (4), from (b) (4) to (b) (4). Please see the below table for additional details.

	MCDC1902-007 Current Ceiling	MCDC1902-007 Proposed Increase ((b) (4) admin cost)	MCDC1902-007 Revised Ceiling
Member Ceiling	(b) (4)		
MCDC Admin Cost	(b) (4)		
MCDC Admin Fee	(b) (4)		
Total	(b) (4)		

Work will be performed in accordance with the SOW, entitled, "Encl 3_MCDC1902-007_M06_03JUN2020_v8_FINAL_CLEAN" (See Attachment 1). SAB should utilize the not-to-exceed existing obligation amount of $53,204,934.13 to continue work on the project. More specifically, COVID-19 work shall be tracked separately using the funding obligated via modification P00069. This Project Agreement is anticipated to be incrementally funded. The Government reserves the right to award future milestones/fund additional months of project tasks. If the Government decides to do so, the MCDC member will be notified via ATI. The Government's liability will never exceed the current amount of funding

obligated under the Project Agreement. The Project Agreement Holder shall notify ATI when they are approaching 75% of current funding obligated in incurred costs by written notice.

For future changes under this project, it is anticipated that SAB will be required to respond expeditiously with cost proposal updates. Based on this, it is requested that SAB be prepared to submit any future cost proposal updates in accordance with the Government instructions, in terms of a proper cost element breakout. While the Government will consider alternate forms of support, this information is necessary in order to conduct a proper review and analysis of any additional costs. While this rapid pace of contracting is not the preferred approach, it certainly is necessary to support COVID-19 efforts.

The prime contractor is considered a small business, nontraditional defense contractor, or nonprofit research institution and determined to be providing a significant contribution. The affirmation of business status certifications submitted as part of the proposal are hereby incorporated into the agreement. The contractor shall notify the MCDC CMF of any deviation from the final proposed affirmation of business status certifications that would affect the contributions of the small business, nontraditional defense contractor, or nonprofit research institution as proposed.

In accordance with 10.U.S.C. 2371b(f), and upon a determination that the prototype project for this transaction has been successfully completed, this competitively awarded prototype OTA may result in the award of a follow-on production contract or transaction without the use of competitive procedures.

Points of Contact:

Agreements Specialist:
(b) (6)
E-mail: (b) (6) l
Phone: (b) (6)

Agreements Officer:
(b) (6) ard
E-mail: (b) (6)
Phone: (b) (6)

Regards,

X (b) (6)

(b) (6)
Agreements Officer
Signed by: (b) (6)

Attachments:
Attachment 1: "Encl 3_MCDC1902-007_M06_03JUN2020_v8_FINAL_CLEAN"

Attachment A
Statement of Work

For
SAB DiversitAb™ Rapid Response Antibody Platform

RPP #: RPP-19-02
Sub-Objective Area: (TRE/PRE-19-02): Development and Testing (b) (4) Medical Countermeasure (MCM) (b) (4)
Consortium Member: SAB Biotherapeutics, Inc.
Title of Proposal: SAB DiversitAb™ Rapid Response Antibody Platform
Requiring Activity: Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) - Enabling Biotechnologies (EB)

1.0 INTRODUCTION, SCOPE, AND OBJECTIVES

1.1 Introduction

The recent acceleration in the evolution of biotechnology has significantly altered the biological and chemical weapons threat landscape. The advent of modern synthetic biology and its associated tools and methods has significantly reduced financial and educational barriers to the modification and design of biological organisms and toxins. In response to this changing threat environment, the US Department of Defense (DoD) through the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) has established a new office for Enabling Biotechnologies (JPEO-EB), to integrate platform Medical Countermeasures (MCM) development technologies (b) (4)

SAB Biotherapeutics will support the JPEO-EB program in developing a rapid response Antibody (Ab) (b) (4) The proposed project will support the development of a MCM production capability (b) (4) to enable Food and Drug Administration (FDA) concurrence with MCM use prior to full FDA licensure in an emergency scenario. (b) (4) , allows SAB to meet DoD requirements (b) (4)

1.2 Scope

SAB, as part of this prototype project, will develop (b) (4) antibody-based MCMs for biological and chemical threats. (b) (4) to meet the DoD's requirement (b) (4)

(b) (4)

(b) (4)

(b) (4)

the Project Agreement language will supersede and control the relationship of the parties.

1.3 Objective

SAB will undertake all activities required to (b) (4)
technology to provide the US Department of Defense (b) (4)
medical countermeasure antibodies against threats of interest. (b) (4)

(b) (4)

(b) (4)

This is a prototype project because the contractor will develop physical models of a(b) (4)
to evaluate the technical feasibility of(b) (4)

The system shall deliver DP(b) (4)

In accordance with 10 U.S.C. § 2371b(f), and upon a determination that the prototype project for this transaction has been successfully completed, this competitively awarded prototype OTA may result in the award of a follow-on production contract or transaction without the use of competitive procedures.(b) (4)

2.0 APPLICABLE REFERENCES

N/A

3.0 REQUIREMENTS

The numbers preceding the following tasks are equivalent to the associated Work Breakdown Structure (WBS) reference.

1.0 (b) (4)

1.1 Program Management

(b) (4)

1.1.1 JPEO-EB Project Management

(b) (4)

1.1.2 Internal Program Management

(b) (4)

1.1.3 Collaborator/Contractor Management

(b) (4)

1.1.4 Advisor/Consultant Management

(b) (4)

1.2 Regulatory and Quality

1.2.1 Cooperative Evaluation with JPEO-EB and ONE-RAQA

(b) (4)

1.2.2 Regulatory

1.2.2.1 (b) (4)

1.2.2.2 (b) (4)

1.2.2.3 (b) (4)

[redacted]

1.2.2.4 (b) (4)

[redacted]

1.2.3 Quality

1.2.3.1 (b) (4)

[redacted]

1.2.3.2 (b) (4)

[redacted]

1.2.3.3 (b) (4)

[redacted]

1.3 Upstream Manufacturing

(b) (4)

[redacted]

(b) (4)

(b) (4)

1.4 Downstream Manufacturing

(b) (4)

(b) (4)

1.5 (b) (4) Development (b) (4)

(b) (4)

(b) (4)

2.0 (b) (4)

2.1 Program Management

(b) (4)

2.1.1 JPEO-EB Project Management

(b) (4)

2.1.2 Internal Program Management

(b) (4)

2.1.3 Collaborator/Contractor Management

(b) (4)

2.1.4 Advisor/Consultant Management

(b) (4)

2.2 Regulatory and Quality

2.2.1 (b) (4)

2.2.2 Regulatory

2.2.2.1 (b) (4)

(b) (4)

2.2.2.1.1 (b) (4)

2.2.2.1.2 (b) (4)

2.2.2.1.3 (b) (4)

2.2.2.1.4 (b) (4)

(b) (4)

2.2.3 Quality

2.2.3.1 (b) (4)

2.2.3.2 (b) (4)

2.2.3.3 (b) (4)

(b) (4)

2.3 Upstream Manufacturing

The awardee shall produce (b) (4), sufficient to demonstrate the ability to execute activities (b) (4)

2.3.1 (b) (4)

2.3.2 (b) (4)

2.3.3 (b) (4)

2.3.4 (b) (4)

2.3.5 (b) (4)

2.4 Downstream Manufacturing

(b) (4)

2.4.1 (b) (4)

(b) (4)

2.4.2 (b) (4)

2.4.3 (b) (4)

2.4.4 (b) (4)

2.4.5 (b) (4)

2.4.6 (b) (4)

2.5 (b) (4)

2.5.1 (b) (4)

2.5.2 (b) (4)

2.5.3 (b) (4)

2.6 (b) (4)

2.6.1 (b) (4)

2.6.2 (b) (4)

3.0 (b) (4)

3.1 Program Management

(b) (4)

3.1.1 (b) (4)

3.1.2 Internal Program Management

(b) (4)

3.1.3 Collaborator/Contractor Management

(b) (4)

3.1.4 Advisor/Consultant Management

(b) (4)

3.2 Regulatory and Quality

3.2.1 (b) (4)

3.2.2 Regulatory

(b) (4)


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

(b) (4)

3.2.3 Quality

(b) (4)

3.3 Upstream Manufacturing

(b) (4)

(b) (4)

3.4 Downstream Manufacturing

(b) (4)

3.4.1 (b) (4)

3.4.2 (b) (4)

3.4.3 (b) (4)

3.4.4 (b) (4)

3.4.5 (b) (4)

(b) (4)

[redacted]

3.5 Non-Clinical

(b) (4)

3.5.1 (b) (4)

[redacted]

3.5.2 (b) (4)

[redacted]

3.5.3 (b) (4)

[redacted]

3.5.4 (b) (4)

[redacted]

3.6 Clinical

3.6.1 (b) (4)

[redacted]

3.6.2 (b) (4)

[redacted]

3.6.3 (b) (4)

(b) (4)

4.0 (b) (4)

4.1 Program Management

(b) (4)

4.1.1 (b) (4)

4.1.2 (b) (4)

4.1.3 (b) (4)

4.1.4 (b) (4)

4.2 Regulatory and Quality

4.2.1 (b) (4)

4.2.2 Regulatory

(b) (4)

(b) (4)

(b) (4)

4.2.3 Quality

4.2.3.1 (b) (4)

4.2.3.2 (b) (4)

4.2.3.3 (b) (4)

4.3 Upstream Manufacturing

(b) (4)

4.3.1 (b) (4)

4.3.2 (b) (4)

(b) (4)

4.3.3 (b) (4)

4.3.4 (b) (4)

4.4 Downstream Manufacturing

(b) (4)

4.4.1 (b) (4)

4.4.2 (b) (4)

4.4.3 (b) (4)

4.4.4 (b) (4)

4.4.5 (b) (4)

4.5 (b) (4)

4.5.1 (b) (4)

4.5.2 (b) (4)

4.6 Non-Clinical

(b) (4)

4.6.1 (b) (4)

4.6.2 (b) (4)

4.6.3 (b) (4)

4.6.4 (b) (4)

4.6.5 (b) (4)

4.7 (b) (4)

4.7.1 (b) (4)

4.7.2 (b) (4)

4.7.3 (b) (4)

4.7.4 (b) (4)

(b) (4)

4.8 Clinical

4.8.1 (b) (4)

4.8.2 (b) (4)

4.8.3 (b) (4)

(b) (4)

4.9 (b) (4)

4.9.1 (b) (4)

(b) (4)

4.9.2 (b) (4)

4.9.3 (b) (4)

(b) (4)

4.10 (b) (4)

4.10.1 Regulatory

(b) (4)

(b) (4)

4.10.2 (b) (4)

4.0 DELIVERABLES

(b) (4)

1.1 (b) (4)

1.2 (b) (4)

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2.1 (b) (4)

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4.10 (b) (4)

4.11 (b) (4)

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4.12 (b) (4)

4.13 (b) (4)

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4.15 (b) (4)

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4.26 (b) (4)

4.27 (b) (4)

(b) (4)

(b) (4)

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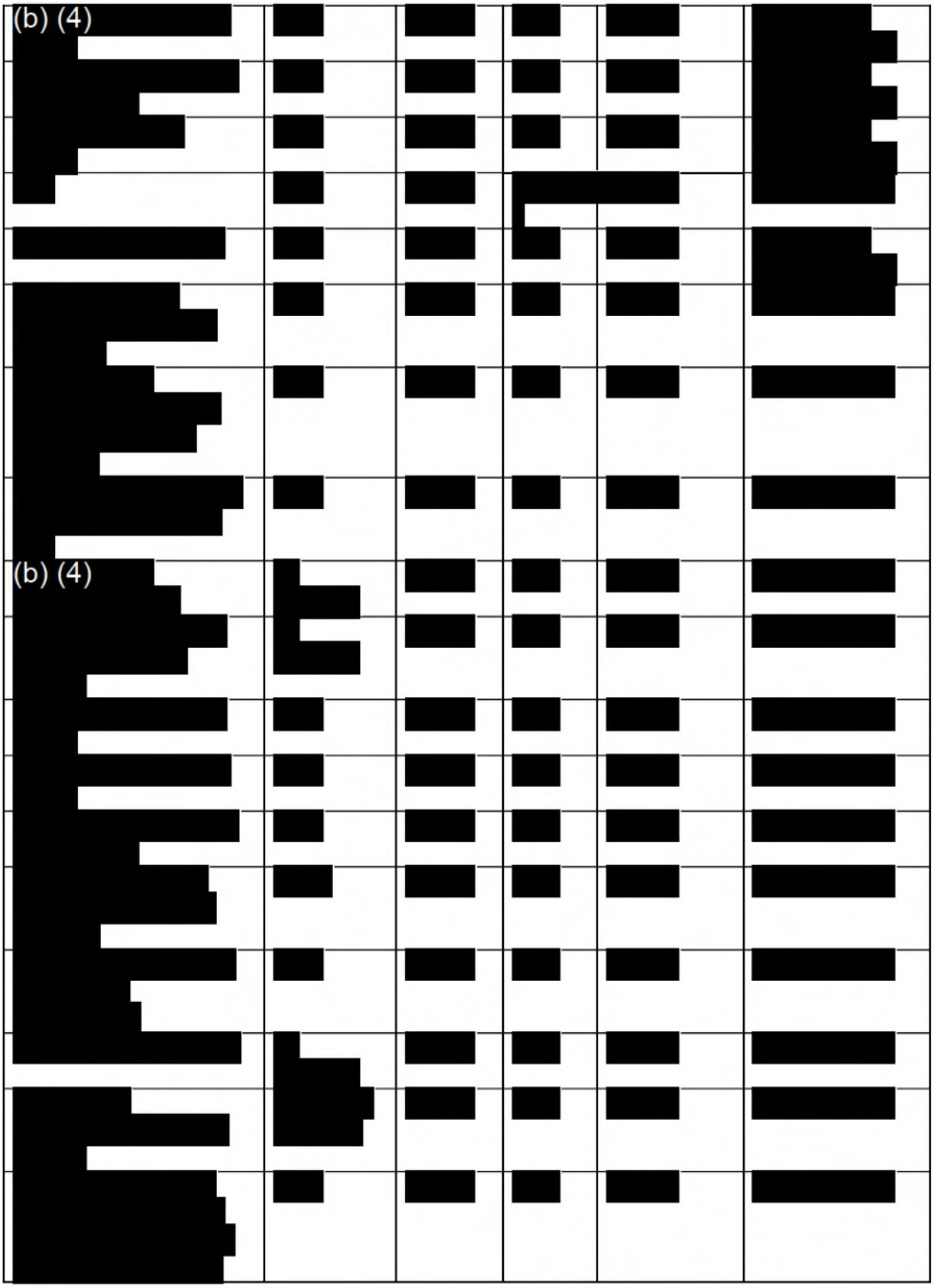
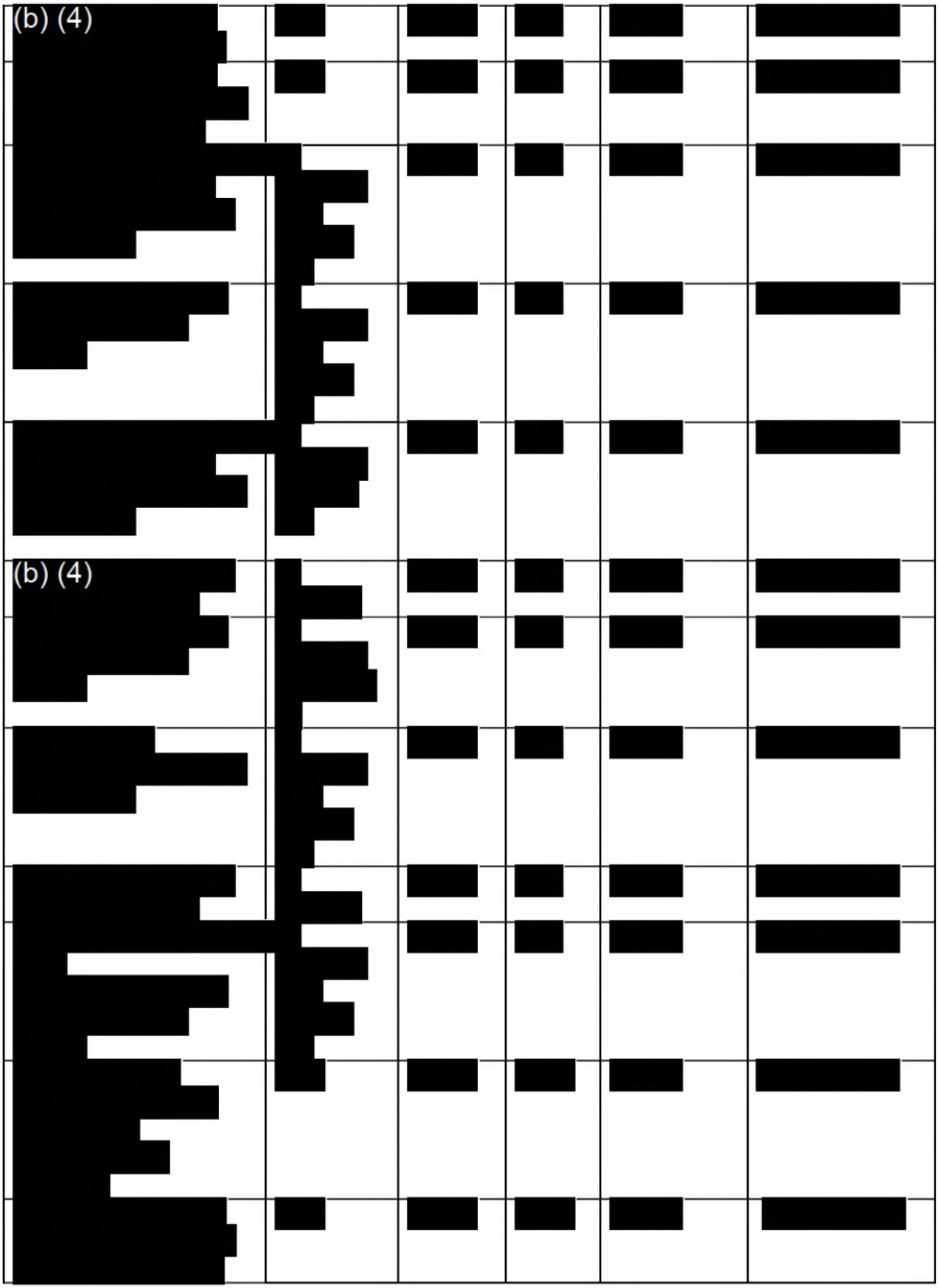
(b) (4)

Deliverable	Frequency	Schedule	SOW Ref	Government Role	Data Rights
Manufacturing Campaign Report	Once	Stage 1	1.4.5	Review	Limited Rights
Certificate of Analysis for Released Drug Substance	Once	Stage 1	1.4.5	Review	Limited Rights
Pre-IND Meeting Package and Meeting Summary	Once	Stage 2	2.2.2.1	Review	Limited Rights
Manufacturing Campaign Report	Once	Stage 2	2.4.6	Review	Limited Rights
Certificate of Analysis for Released Drug Product	Once	Stage 2	2.4.6	Review	Limited Rights
Pre-IND Meeting Package and Meeting Summary	Once	Stage 3	3.2.2.1	Review	Limited Rights
Certificate of Analysis for Released Drug Product	Once	Stage 3	3.4.5	Review	Limited Rights
(b) (4)					


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


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


(b) (4)

(b) (4)			
		Total (CPFF):	(b) (4)
		Period of Performance:	**48 Months**

(b) (4)

(b) (4)

(b) (4)

[redacted]

(b) (4)

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[redacted]

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(b) (4)

(b) (4)

[redacted]

DEPARTMENT OF THE ARMY
U.S. ARMY CONTRACTING COMMAND – NEW JERSEY
PICATINNY ARSENAL, NEW JERSEY 07806-5000

REPLY TO
ATTENTION OF

23 November 2020

Army Contracting Command – New Jersey
ACC-NJ, Building 9
Picatinny Arsenal, NJ 07806

SUBJECT: Technical Direction Letter for Medical CRBN Defense Consortium (MCDC), Request for Prototype Proposals (RPP) 19-02, Sub-Objective 19-02, Definitization of the Ceiling Increase Modification for "SAB DiversitAb™ Rapid Response Antibody Platform"

REF: Request for Updated Proposal Submitted in Response to RPP-19-02 under OTA W15QKN-16-9-1002 for Sub-Objective 19-02 Modification, dated 15 June 2020

Advanced Technology International
ATTN: (b) (6), Sr. Contracts Manager
315 Sigma Drive
Summerville, SC 29486

Dear (b) (6),

The Army Contracting Command – New Jersey (ACC-NJ), in supporting the Joint Project Manager – Medical Countermeasure Systems (JPM-MCS), issued a Request for Proposal Update under MCDC RPP-19-02, Sub-Objective 19-02 on 15 June 2020 to Advanced Technology International, for distribution to SAB Biotherapeutics, Inc. This request would allow SAB to proceed with optional Stage 4 manufacturing tasks, in support of Coronavirus Disease 2019 (COVID-19). The Government received the undefinitized Rough Order of Magnitude (ROM) proposal update on 18 June 2020, and issued an Undefinitized Project Agreement (UPA) on 23 June 2020. In order to definitize the UPA, the Government finalized an analysis of the cost proposal on 02 November 2020, which focused on evaluation of the cost components and documentation. Based on the acceptable update of SAB's proposal, the Government is definitizing the Project Agreement modification. Please see the below table for additional details on the ceiling adjustment.

	MCDC1902-007 Current Ceiling	MCDC1902-007 Proposed ALIN 02 Definitization Adjustment (b) (4) Admin Cost)	MCDC1902-007 Revised Ceiling
Member Ceiling	(b) (4)		
MCDC Admin Cost	(b) (4)		
MCDC Admin Fee	(b) (4)		
Total	(b) (4)		

Work will be performed in accordance with the SOW, entitled, "Encl 3_MCDC1902-007 SOW_PUL_05" (See Attachment 1). SAB should utilize the not-to-exceed existing obligation to continue work on the project, as detailed in the MCDC OTA Award Tracker. More specifically, COVID-19 work shall be tracked separately using the funding obligated via modification P00072. This Project Agreement is anticipated to be incrementally funded. The Government reserves the right to award future milestones/fund additional

months of project tasks. If the Government decides to do so, the MCDC member will be notified via ATI. The Government's liability will never exceed the current amount of funding obligated under the Project Agreement. The Project Agreement Holder shall notify ATI when they are approaching 75% of current funding obligated in incurred costs by written notice.

The prime contractor is considered a small business, nontraditional defense contractor, or nonprofit research institution and determined to be providing a significant contribution. The affirmation of business status certifications submitted as part of the proposal are hereby incorporated into the agreement. The contractor shall notify the MCDC CMF of any deviation from the final proposed affirmation of business status certifications that would affect the contributions of the small business, nontraditional defense contractor, or nonprofit research institution as proposed.

In accordance with 10.U.S.C. 2371b(f), and upon a determination that the prototype project for this transaction has been successfully completed, this competitively awarded prototype OTA may result in the award of a follow-on production contract or transaction without the use of competitive procedures.

In addition, ATI is advised of the implementation guidance for Section § 889(a)(1)(B) of the John S. McCain National Defense Authorization Act (NDAA) for Fiscal Year 2019 (Pub. L. 115–232), which prohibits executive agencies from entering into, extending, or renewing a contract with an entity that uses any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. While the interim rule and Defense Pricing and Contracting (DPC) implementation memorandum are directed to FAR-based contracts, the § 889(a)(1)(B) prohibition went into effect August 13, 2020, and applies to Other Transactions (OTs) for Prototype Projects under § 2371b of title 10, United States Code (U.S.C.). Any OT for Prototype Project agreement on or after August 13, 2020 must contain an article for the Prohibition on the Use of Certain Telecommunications and Video Surveillance Services or Equipment that requires the offeror to represent if it uses any equipment, system, or service that uses covered telecommunications equipment or services.

ATI must receive § 889(a)(1)(B) Certification from the MCDC member prior to executing any new project agreements or modification to an existing project agreement. A copy of the certification should be provided to the undersigned.

Points of Contact:

Agreements Specialist:
(b) (6)
E-mail: (b) (6)
Phone: (b) (6)

Agreements Officer:
(b) (6)
E-mail: (b) (6)
Phone: (b) (6)

Regards,

X (b) (6)

(b) (6)
Agreements Officer
Signed by: (b) (6)

Attachments:
Attachment 1: Encl 3_MCDC1902-007 SOW_PUL_05

DEPARTMENT OF THE ARMY
U.S. ARMY CONTRACTING COMMAND – NEW JERSEY
PICATINNY ARSENAL, NEW JERSEY 07806-5000

REPLY TO
ATTENTION OF

09 December 2020

Army Contracting Command – New Jersey
ACC-NJ, Building 9
Picatinny Arsenal, NJ 07806

SUBJECT: Technical Direction Letter for Medical CRBN Defense Consortium (MCDC), Request for Prototype Proposals (RPP) 19-02, Sub-Objective 19-02 Ceiling Increase Modification for "SAB DiversitAb™ Rapid Response Antibody Platform"

REF: Request for Updated Proposal Submitted in Response to RPP-19-02 under OTA W15QKN-16-9-1002 for Sub-Objective 19-02 Modification, dated 01 December 2020

Advanced Technology International
ATTN: (b) (6), Sr. Contracts Manager
315 Sigma Drive
Summerville, SC 29486

Dear (b) (6),

The Army Contracting Command – New Jersey (ACC-NJ), in supporting the Joint Project Manager – Medical Countermeasure Systems (JPM-MCS), issued a Request for Proposal Update under MCDC RPP-19-02, Sub-Objective 19-02 on 01 December 2020 to Advanced Technology International, for distribution to SAB Biotherapeutics, Inc. (SAB). This request would allow SAB to proceed with revisions to increase manufacturing runs and enhance scope for pre-clinical and clinical development of the Stage 4 tasks. The Government received the proposal update on 01 December 2020, and evaluated the costs and documentation accordingly. Based on the acceptable update of SAB's proposal, the Government is increasing the Project Agreement ceiling value by (b) (4) from (b) (4) to (b) (4). The Government is also increasing the MCDC CMF Administrative Cost Ceiling by (b) (4), from (b) (4) to (b) (4). The ceiling will be updated appropriately via a future prime modification. Please see the below table for additional details.

	MCDC1902-007 Current Ceiling	MCDC1902-007 Proposed Increase	MCDC1902-007 Revised Ceiling
Member Ceiling	(b) (4)		
MCDC Admin Cost	(b) (4)		
MCDC Admin Fee	(b) (4)		
Total	(b) (4)		

Work will be performed in accordance with the SOW, entitled, "Encl 1_MCDC1902-007 SOW_PUL06 07DEC20" (See Attachment 1). SAB should utilize the not-to-exceed existing obligation amounts within their agreement to continue work on the project. More specifically, COVID-19 work shall be tracked separately, as indicated in the MCDC OTA Award Tracker. This Project Agreement is anticipated to be incrementally funded. The Government reserves the right to award future milestones/fund additional months of project tasks. If the Government decides to do so, the MCDC member will be notified via ATI. The Government's liability will never exceed the current amount of funding obligated under the Project

Agreement. The Project Agreement Holder shall notify ATI when they are approaching 75% of current funding obligated in incurred costs by written notice.

For future changes under this project, it is anticipated that SAB will be required to respond expeditiously with cost proposal updates. Based on this, it is requested that SAB be prepared to submit any future cost proposal updates in accordance with the Government instructions, in terms of a proper cost element breakout. While the Government will consider alternate forms of support, this information is necessary in order to conduct a proper review and analysis of any additional costs. While this rapid pace of contracting is not the preferred approach, it certainly is necessary to support COVID-19 efforts.

The prime contractor is considered a small business, nontraditional defense contractor, or nonprofit research institution and determined to be providing a significant contribution. The affirmation of business status certifications submitted as part of the proposal are hereby incorporated into the agreement. The contractor shall notify the MCDC CMF of any deviation from the final proposed affirmation of business status certifications that would affect the contributions of the small business, nontraditional defense contractor, or nonprofit research institution as proposed.

In accordance with 10.U.S.C. 2371b(f), and upon a determination that the prototype project for this transaction has been successfully completed, this competitively awarded prototype OTA may result in the award of a follow-on production contract or transaction without the use of competitive procedures.

Points of Contact:

Agreements Specialist:
(b) (6)
E-mail: (b) (6)
Phone: (b) (6)

Agreements Officer:
(b) (6)
E-mail: (b) (6)
Phone: (b) (6)

Regards,

X (b) (6)

(b) (6)
Agreements Officer
Signed by: (b) (6)

Attachments:
Attachment 1: "Encl 1_MCDC1902-007 SOW_PUL06 07DEC20"

Attachment A
Statement of Work
For
SAB DiversitAb™ Rapid Response Antibody Platform

RPP #: RPP-19-02
Sub-Objective Area: (TRE/PRE-19-02): Development and Testing (b) (4) Medical Countermeasure (MCM) (b) (4)
Consortium Member: SAB Biotherapeutics, Inc.
Title of Proposal: SAB DiversitAb™ Rapid Response Antibody Platform
Requiring Activity: Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND)- Enabling Biotechnologies (EB)

1.0 INTRODUCTION, SCOPE, AND OBJECTIVES

1.1 Introduction

The recent acceleration in the evolution of biotechnology has significantly altered the biological and chemical weapons threat landscape. The advent of modern synthetic biology and its associated tools and methods has significantly reduced financial and educational barriers to the modification and design of biological organisms and toxins. In response to this changing threat environment, the US Department of Defense (DoD) through the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) has established a new office for Enabling Biotechnologies (JPEO-EB), to integrate platform Medical Countermeasures (MCM) development technologies (b) (4)

SAB Biotherapeutics will support the JPEO-EB program in developing a rapid response Antibody (Ab) (b) (4) The proposed project will support the development of a MCM production capability (b) (4) to enable Food and Drug Administration (FDA) concurrence with MCM use prior to full FDA licensure in an emergency scenario. (b) (4) allows SAB to meet DoD requirements (b) (4)

1.2 Scope

SAB, as part of this prototype project, will develop (b) (4) antibody-based MCMs for biological and chemical threats, (b) (4) to meet the DoD's requirement (b) (4)

(b) (4) [redacted]

(b) (4) [redacted]

(b) (4) [redacted]

(b) (4) [redacted]

(b) (4) [redacted]

(b) (4) [redacted] the Project Agreement language will supersede and control the relationship of the parties.

1.3 Objective

SAB will undertake all activities required to (b) (4) [redacted] technology to provide the US Department of Defense (b) (4) [redacted] medical countermeasure antibodies against threats of interest. (b) (4) [redacted]

(b) (4)

(b) (4)

(b) (4)

This is a prototype project because the contractor will develop physical models of (b) (4) to evaluate the technical feasibility of (b) (4) The system shall deliver DP (b) (4)

In accordance with 10.U.S.C.§ 2371b(f), and upon a determination that the prototype project for this transaction has been successfully completed, this competitively awarded prototype OTA may result in the award of a follow-on production contract or transaction without the use of competitive procedures. (b) (4)

2.0 APPLICABLE REFERENCES

N/A

3.0 REQUIREMENTS

The numbers preceding the following tasks are equivalent to the associated Work Breakdown Structure (WBS) reference.

1.0 (b) (4)

1.1 Program Management

(b) (4)

1.1.1 JPEO-EB Project Management

(b) (4)

1.1.2 Internal Program Management

(b) (4)

1.1.3 Collaborator/Contractor Management

(b) (4)

1.1.4 Advisor/Consultant Management

(b) (4)

1.2 Regulatory and Quality

1.2.1 Cooperative Evaluation with JPEO-EB and ONE-RAQA

(b) (4)

1.2.2 Regulatory

1.2.2.1 (b) (4)

(b) (4)

1.2.2.2 (b) (4)

1.2.2.3 (b) (4)

1.2.2.4 (b) (4)

1.2.3 Quality

1.2.3.1 (b) (4)

1.2.3.2 (b) (4)

1.2.3.3 (b) (4)

1.3 Upstream Manufacturing

(b) (4)

(b) (4)

(b) (4)

1.4 Downstream Manufacturing

(b) (4)

(b) (4)

1.5 (b) (4) Development (b) (4)

(b) (4)

2.0 (b) (4)

2.1 Program Management

(b) (4)

2.1.1 JPEO-EB Project Management

(b) (4)

2.1.2 Internal Program Management

(b) (4)

2.1.3 Collaborator/Contractor Management

(b) (4)

2.1.4 Advisor/Consultant Management

(b) (4)

2.2 Regulatory and Quality

2.2.1 (b) (4)

2.2.2 Regulatory

2.2.2.1 (b) (4)

2.2.2.1.1 (b) (4)

2.2.2.1.2 (b) (4)

2.2.2.1.3 (b) (4)

2.2.2.1.4 (b) (4)

(b) (4)

2.2.3 Quality

2.2.3.1 (b) (4)

2.2.3.2 (b) (4)

2.2.3.3 (b) (4)

2.3 Upstream Manufacturing

The awardee shall produce (b) (4), sufficient to demonstrate the ability to execute activities (b) (4)

2.3.1 (b) (4)

2.3.2 (b) (4)

2.3.3 (b) (4)

2.3.4 (b) (4)

2.3.5 (b) (4)

2.4 Downstream Manufacturing

(b) (4)

2.4.1 (b) (4)

2.4.2 (b) (4)

2.4.3 (b) (4)

(b) (4)

2.4.4 (b) (4)

2.4.5 (b) (4)

2.4.6 (b) (4)

2.5 (b) (4)

2.5.1 (b) (4)

2.5.2 (b) (4)

2.5.3 (b) (4)

2.6 (b) (4)

2.6.1 (b) (4)

(b) (4)

2.6.2 (b) (4)

3.0 (b) (4)

3.1 Program Management

(b) (4)

3.1.1 (b) (4)

3.1.2 Internal Program Management

(b) (4)

3.1.3 Collaborator/Contractor Management

(b) (4)

3.1.4 Advisor/Consultant Management

(b) (4)

3.2 Regulatory and Quality

3.2.1 (b) (4)

3.2.2 Regulatory

(b) (4)

(b) (4) [redacted]

(b) (4)

[redacted]

3.2.3 Quality

(b) (4)

[redacted]

3.3 Upstream Manufacturing

(b) (4)

[redacted]

(b) (4)

3.4 Downstream Manufacturing

(b) (4)

3.4.1 (b) (4)

3.4.2 (b) (4)

3.4.3 (b) (4)

3.4.4 (b) (4)

3.4.5 (b) (4)

3.5 Non-Clinical

(b) (4)

3.5.1 (b) (4)

3.5.2 (b) (4)

3.5.3 (b) (4)

3.5.4 (b) (4)

3.6 Clinical

3.6.1 (b) (4)

(b) (4)

3.6.2 (b) (4)

3.6.3 (b) (4)

4.0 (b) (4)

4.1 Program Management

(b) (4)

4.1.1 (b) (4)

4.1.2 (b) (4)

4.1.3 (b) (4)

4.1.4 (b) (4)

(b) (4)

4.2 Regulatory and Quality

4.2.1 (b) (4)

4.2.2 Regulatory

(b) (4)

(b) (4)

4.2.3 Quality

(b) (4)

4.3 Upstream Manufacturing

(b) (4)

4.3.1 (b) (4)

4.3.2 (b) (4)

4.3.3 (b) (4)

4.3.4 (b) (4)

(b) (4)

4.4 Downstream Manufacturing

(b) (4)

4.4.1 (b) (4)

4.4.2 (b) (4)

4.4.3 (b) (4)

4.4.4 (b) (4)

4.4.5 (b) (4)

4.5 (b) (4)

4.5.1 (b) (4)

4.5.2 (b) (4)

4.6 Non-Clinical

(b) (4)

4.6.1 (b) (4)

4.6.2 (b) (4)

4.6.3 (b) (4)

4.6.4 (b) (4)

4.6.5 (b) (4)

Go/No-Go (Optional Trial Task):

4.7 Clinical

4.7.1 (b) (4)

4.7.2 (b) (4)

(b) (4)

4.7.3 (b) (4)

4.0 DELIVERABLES

(b) (4)

1.1 (b) (4)

1.2 (b) (4)

(b) (4)

2.1 (b) (4)

2.2 (b) (4)

2.3 (b) (4)

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3.1 (b) (4)

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4.5 (b) (4)

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4.8 (b) (4)

4.9 (b) (4)

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(b) (4)

(b) (4) [redacted]

(b) (4) [redacted]

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4) [redacted]

[redacted]

[redacted]

[redacted]

Deliverable	Frequency	Schedule	SOW Ref	Government Role	Data Rights
Certificate of Analysis for Released Drug Substance	Once	Stage 1	1.4.5	Review	Limited Rights
Pre-IND Meeting Package and Meeting Summary	Once	Stage 2	2.2.2.1	Review	Limited Rights
Certificate of Analysis for Released Drug Product	Once	Stage 2	2.4.7	Review	Limited Rights
Pre-IND Meeting Package and Meeting Summary	Once	Stage 3	3.2.2.1	Review	Limited Rights
Certificate of Analysis for Released Drug Product	Once	Stage 3	3.4.5	Review	Limited Rights
(b) (4) [redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
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(b) (4) [redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
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(b) (4) [redacted]

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(b) (4) [redacted]	[redacted]	[redacted]	[redacted]
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[redacted]			
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[redacted]	[redacted]	[redacted]	[redacted]

(b) (4)			
		(b) (4)	(b) (4)
		Total (CPFF):	(b) (4)
		Period of Performance:	**48 Months**

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)				

(b) (4)				

(b) (4)

(b) (4)

(b) (4)

(b) (4) [redacted]

11.0 AOR AND ALTERNATE AOR CONTACT INFORMATION:

AOR

NAME: (b) (6) [redacted]
MAILING ADDRESS: JPEO-EB
EMAIL: (b) (6) [redacted]
PHONE: (b) (6) [redacted]

Alternate AOR

NAME: (b) (6) [redacted]
MAILING ADDRESS: JPEO-EB
EMAIL: (b) (6) [redacted]
PHONE: (b) (6) [redacted]

Attachment A
Statement of Work
For
SAB DiversitAb™ Rapid Response Antibody Platform

RPP #: RPP-19-02
Sub-Objective Area: (TRE/PRE-19-02): Development and Testing (b) (4) Medical Countermeasure (MCM) (b) (4)
Consortium Member: SAB Biotherapeutics, Inc.
Title of Proposal: SAB DiversitAb™ Rapid Response Antibody Platform
Requiring Activity: Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND)- Enabling Biotechnologies (EB)

1.0 INTRODUCTION, SCOPE, AND OBJECTIVES

1.1 Introduction

The recent acceleration in the evolution of biotechnology has significantly altered the biological and chemical weapons threat landscape. The advent of modern synthetic biology and its associated tools and methods has significantly reduced financial and educational barriers to the modification and design of biological organisms and toxins. In response to this changing threat environment, the US Department of Defense (DoD) through the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) has established a new office for Enabling Biotechnologies (JPEO-EB), to integrate platform Medical Countermeasures (MCM) development technologies (b) (4)

SAB Biotherapeutics will support the JPEO-EB program in developing a rapid response Antibody (Ab) (b) (4) The proposed project will support the development of a MCM production capability (b) (4) to enable Food and Drug Administration (FDA) concurrence with MCM use prior to full FDA licensure in an emergency scenario. (b) (4) allows SAB to meet DoD requirements (b) (4)

1.2 Scope

SAB, as part of this prototype project, will develop a (b) (4) antibody-based MCMs for biological and chemical threats, (b) (4) to meet the DoD's requirement (b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

the Project Agreement language will supersede and control the relationship of the parties.

1.3 Objective

SAB will undertake all activities required to (b) (4) technology to provide the US Department of Defense (b) (4) medical countermeasure antibodies against threats of interest. (b) (4)

(b) (4)

- [redacted]
- [redacted]
- [redacted]

[redacted]

(b) (4)

[redacted]

This is a prototype project because the contractor will develop physical models of (b) (4) to evaluate the technical feasibility of (b) (4) The system shall deliver DP (b) (4) [redacted]

In accordance with 10.U.S.C.§ 2371b(f), and upon a determination that the prototype project for this transaction has been successfully completed, this competitively awarded prototype OTA may result in the award of a follow-on production contract or transaction without the use of competitive procedures. (b) (4) [redacted]

2.0 APPLICABLE REFERENCES

N/A

3.0 REQUIREMENTS

The numbers preceding the following tasks are equivalent to the associated Work Breakdown Structure (WBS) reference.

1.0 (b) (4)

1.1 Program Management

(b) (4)

1.1.1 JPEO-EB Project Management

(b) (4)

1.1.2 Internal Program Management

(b) (4)

1.1.3 Collaborator/Contractor Management

(b) (4)

1.1.4 Advisor/Consultant Management

(b) (4)

1.2 Regulatory and Quality

1.2.1 Cooperative Evaluation with JPEO-EB and ONE-RAQA

(b) (4)

1.2.2 Regulatory

1.2.2.1 (b) (4)

1.2.2.2 (b) (4)

1.2.2.3 (b) (4)

(b) (4)

1.2.2.4 (b) (4)

1.2.3 Quality

1.2.3.1 (b) (4)

1.2.3.2 (b) (4)

1.2.3.3 (b) (4)

1.3 Upstream Manufacturing

(b) (4)

(b) (4)

(b) (4) [redacted]

1.4 Downstream Manufacturing

(b) (4) [redacted]

1.5 (b) (4) Development (b) (4) [redacted]

(b) (4) [redacted]

(b) (4)

2.0 (b) (4)

2.1 Program Management

(b) (4)

2.1.1 JPEO-EB Project Management

(b) (4)

2.1.2 Internal Program Management

(b) (4)

2.1.3 Collaborator/Contractor Management

(b) (4)

2.1.4 Advisor/Consultant Management

(b) (4)

2.2 Regulatory and Quality

2.2.1 (b) (4)

2.2.2 Regulatory

2.2.2.1 (b) (4)

(b) (4)

2.2.2.1.1 (b) (4)

2.2.2.1.2 (b) (4)

2.2.2.1.3 (b) (4)

2.2.2.1.4 (b) (4)

(b) (4)

2.2.3 Quality

2.2.3.1 (b) (4)

2.2.3.2 (b) (4)

2.2.3.3 (b) (4)

(b) (4)

2.3 Upstream Manufacturing

The awardee shall produce (b) (4) sufficient to demonstrate the ability to execute activities (b) (4)

2.3.1 (b) (4)

2.3.2 (b) (4)

2.3.3 (b) (4)

2.3.4 (b) (4)

2.3.5 (b) (4)

2.4 Downstream Manufacturing

(b) (4)

2.4.1 (b) (4)

(b) (4)

2.4.2 (b) (4)

2.4.3 (b) (4)

2.4.4 (b) (4)

2.4.5 (b) (4)

2.4.6 (b) (4)

2.5 (b) (4)

2.5.1 (b) (4)

2.5.2 (b) (4)

2.5.3 (b) (4)

2.6 (b) (4)

2.6.1 (b) (4)

2.6.2 (b) (4)

3.0 (b) (4)

3.1 Program Management

(b) (4)

3.1.1 (b) (4)

3.1.2 Internal Program Management

(b) (4)

3.1.3 Collaborator/Contractor Management

(b) (4)

3.1.4 Advisor/Consultant Management

(b) (4)

3.2 Regulatory and Quality

3.2.1 (b) (4)

3.2.2 Regulatory

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

3.2.3 Quality

(b) (4)

3.3 Upstream Manufacturing

(b) (4)

(b) (4) [redacted]

3.4 Downstream Manufacturing

(b) (4) [redacted]

3.4.1 (b) (4) [redacted]

3.4.2 (b) (4) [redacted]

3.4.3 (b) (4) [redacted]

3.4.4 (b) (4) [redacted]

3.4.5 (b) (4) [redacted]

(b) (4)

3.5 Non-Clinical

(b) (4)

3.5.1 (b) (4)

3.5.2 (b) (4)

3.5.3 (b) (4)

3.5.4 (b) (4)

3.6 Clinical

3.6.1 (b) (4)

3.6.2 (b) (4)

3.6.3 (b) (4)

(b) (4)

4.0 (b) (4)

4.1 Program Management

(b) (4)

4.1.1 (b) (4)

4.1.2 (b) (4)

4.1.3 (b) (4)

4.1.4 (b) (4)

4.2 Regulatory and Quality

4.2.1 (b) (4)

4.2.2 Regulatory

(b) (4)

(b) (4)

4.2.3 Quality

4.2.3.1 (b) (4)

4.2.3.2 (b) (4)

4.2.3.3 (b) (4)

4.3 Upstream Manufacturing

(b) (4)

4.3.1 (b) (4)

4.3.2 (b) (4)

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4.3.3 (b) (4)

4.3.4 (b) (4)

4.4 Downstream Manufacturing

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4.4.1 (b) (4)

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4.4.5 (b) (4)

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4.5.1 (b) (4)

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4.6 Non-Clinical

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4.6.2 (b) (4)

4.6.3 (b) (4)

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4.7.3 (b) (4)

4.7.4 (b) (4)

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4.8 Clinical

4.8.1 (b) (4)

4.8.2 (b) (4)

4.8.3 (b) (4)

4.9 (b) (4)

4.9.1 (b) (4)

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4.9.2 (b) (4)

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4.0 DELIVERABLES

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(b) (4) [redacted]

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Deliverable	Frequency	Schedule	SOW Ref	Government Role	Data Rights
Manufacturing Campaign Report	Once	Stage 1	1.4.5	Review	Limited Rights
Certificate of Analysis for Released Drug Substance	Once	Stage 1	1.4.5	Review	Limited Rights
Pre-IND Meeting Package and Meeting Summary	Once	Stage 2	2.2.2.1	Review	Limited Rights
Manufacturing Campaign Report	Once	Stage 2	2.4.6	Review	Limited Rights
Certificate of Analysis for Released Drug Product	Once	Stage 2	2.4.6	Review	Limited Rights
Pre-IND Meeting Package and Meeting Summary	Once	Stage 3	3.2.2.1	Review	Limited Rights
Certificate of Analysis for Released Drug Product	Once	Stage 3	3.4.5	Review	Limited Rights
(b) (4) [redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
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(b) (4)			
		Total (CPFF):	(b) (4)
		Period of Performance:	48 Months

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(b) (4) [redacted]

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(b) (4) [redacted]

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(b) (4) [redacted]	[redacted]	[redacted]	[redacted]	[redacted]
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[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

(b) (4)				

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(b) (4)

Attachment A
Statement of Work
For
SAB DiversitAb™ Rapid Response Antibody Platform

RPP #: RPP-19-02
Sub-Objective Area: (TRE/PRE-19-02): Development and Testing (b) (4) Medical Countermeasure (MCM) (b) (4)
Consortium Member: SAB Biotherapeutics, Inc.
Title of Proposal: SAB DiversitAb™ Rapid Response Antibody Platform
Requiring Activity: Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) - Enabling Biotechnologies (EB)

1.0 INTRODUCTION, SCOPE, AND OBJECTIVES

1.1 Introduction

The recent acceleration in the evolution of biotechnology has significantly altered the biological and chemical weapons threat landscape. The advent of modern synthetic biology and its associated tools and methods has significantly reduced financial and educational barriers to the modification and design of biological organisms and toxins. In response to this changing threat environment, the US Department of Defense (DoD) through the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) has established a new office for Enabling Biotechnologies (JPEO-EB), to integrate platform Medical Countermeasures (MCM) development technologies (b) (4)

SAB Biotherapeutics will support the JPEO-EB program in developing a rapid response Antibody (Ab) (b) (4) The proposed project will support the development of a MCM production capability (b) (4) to enable Food and Drug Administration (FDA) concurrence with MCM use prior to full FDA licensure in an emergency scenario. (b) (4) allows SAB to meet DoD requirements (b) (4)

1.2 Scope

SAB, as part of this prototype project, will develop a (b) (4) antibody-based MCMs for biological and chemical threats, (b) (4) to meet the DoD's requirement (b) (4)

(b) (4)

(b) (4) [redacted]

(b) (4) [redacted] the Project Agreement language will supersede and control the relationship of the parties.

1.3 Objective

SAB will undertake all activities required to (b) (4) [redacted] technology to provide the US Department of Defense (b) (4) [redacted] medical countermeasure antibodies against threats of interest. (b) (4) [redacted]

(b) (4)

- [redacted]
- [redacted]
- [redacted]

[redacted]

(b) (4)

[redacted]

This is a prototype project because the contractor will develop physical models of (b) (4) to evaluate the technical feasibility of (b) (4) The system shall deliver DP (b) (4) [redacted]

In accordance with 10.U.S.C.§ 2371b(f), and upon a determination that the prototype project for this transaction has been successfully completed, this competitively awarded prototype OTA may result in the award of a follow-on production contract or transaction without the use of competitive procedures. (b) (4) [redacted]

2.0 APPLICABLE REFERENCES

N/A

3.0 REQUIREMENTS

The numbers preceding the following tasks are equivalent to the associated Work Breakdown Structure (WBS) reference.

1.0 (b) (4)

1.1 Program Management

(b) (4)

1.1.1 JPEO-EB Project Management

(b) (4)

1.1.2 Internal Program Management

(b) (4)

1.1.3 Collaborator/Contractor Management

(b) (4)

1.1.4 Advisor/Consultant Management

(b) (4)

1.2 Regulatory and Quality

1.2.1 Cooperative Evaluation with JPEO-EB and ONE-RAQA

(b) (4)

1.2.2 Regulatory

1.2.2.1 (b) (4)

1.2.2.2 (b) (4)

1.2.2.3 (b) (4)

(b) (4)

1.2.2.4 (b) (4)

1.2.3 Quality

1.2.3.1 (b) (4)

1.2.3.2 (b) (4)

1.2.3.3 (b) (4)

1.3 Upstream Manufacturing

(b) (4)

(b) (4) [redacted]

1.4 Downstream Manufacturing

(b) (4) [redacted]

1.5 (b) (4) Development (b) (4) [redacted]

(b) (4) [redacted]

(b) (4)

2.0 (b) (4)

2.1 Program Management

(b) (4)

2.1.1 JPEO-EB Project Management

(b) (4)

2.1.2 Internal Program Management

(b) (4)

2.1.3 Collaborator/Contractor Management

(b) (4)

2.1.4 Advisor/Consultant Management

(b) (4)

2.2 Regulatory and Quality

2.2.1 (b) (4)

2.2.2 Regulatory

2.2.2.1 (b) (4)

(b) (4)

2.2.2.1.1 (b) (4)

2.2.2.1.2 (b) (4)

2.2.2.1.3 (b) (4)

2.2.2.1.4 (b) (4)

(b) (4)

2.2.3 Quality

2.2.3.1 (b) (4)

2.2.3.2 (b) (4)

2.2.3.3 (b) (4)

(b) (4)

2.3 Upstream Manufacturing

The awardee shall produce (b) (4), sufficient to demonstrate the ability to execute activities (b) (4)

2.3.1 (b) (4)

2.3.2 (b) (4)

2.3.3 (b) (4)

2.3.4 (b) (4)

2.3.5 (b) (4)

2.4 Downstream Manufacturing

(b) (4)

2.4.1 (b) (4)

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2.4.3 (b) (4)

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2.4.6 (b) (4)

2.5 (b) (4)

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2.5.2 (b) (4)

2.5.3 (b) (4)

2.6 (b) (4)

2.6.1 (b) (4)

2.6.2 (b) (4)

3.0 (b) (4)

3.1 Program Management

(b) (4)

3.1.1 (b) (4)

3.1.2 Internal Program Management

(b) (4)

3.1.3 Collaborator/Contractor Management

(b) (4)

3.1.4 Advisor/Consultant Management

(b) (4)

3.2 Regulatory and Quality

3.2.1 (b) (4)

3.2.2 Regulatory

(b) (4)

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3.2.3 Quality

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3.3 Upstream Manufacturing

(b) (4)

(b) (4) [redacted]

3.4 Downstream Manufacturing

(b) (4) [redacted]

3.4.1 (b) (4) [redacted]

3.4.2 (b) (4) [redacted]

3.4.3 (b) (4) [redacted]

3.4.4 (b) (4) [redacted]

3.4.5 (b) (4) [redacted]

(b) (4)

3.5 Non-Clinical

(b) (4)

3.5.1 (b) (4)

3.5.2 (b) (4)

3.5.3 (b) (4)

3.5.4 (b) (4)

3.6 Clinical

3.6.1 (b) (4)

3.6.2 (b) (4)

3.6.3 (b) (4)

(b) (4)

4.0 (b) (4)

4.1 Program Management

(b) (4)

4.1.1 (b) (4)

4.1.2 (b) (4)

4.1.3 (b) (4)

4.1.4 (b) (4)

4.2 Regulatory and Quality

4.2.1 (b) (4)

4.2.2 Regulatory

(b) (4)

(b) (4)

4.2.3 Quality

4.2.3.1 (b) (4)

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4.2.3.3 (b) (4)

4.3 Upstream Manufacturing

(b) (4)

4.3.1 (b) (4)

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4.4 Downstream Manufacturing

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4.6 Non-Clinical

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4.8 Clinical

4.8.1 (b) (4)

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4.0 DELIVERABLES

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Deliverable	Frequency	Schedule	SOW Ref	Government Role	Data Rights
Manufacturing Campaign Report	Once	Stage 1	1.4.5	Review	Limited Rights
Certificate of Analysis for Released Drug Substance	Once	Stage 1	1.4.5	Review	Limited Rights
Pre-IND Meeting Package and Meeting Summary	Once	Stage 2	2.2.2.1	Review	Limited Rights
Manufacturing Campaign Report	Once	Stage 2	2.4.6	Review	Limited Rights
Certificate of Analysis for Released Drug Product	Once	Stage 2	2.4.6	Review	Limited Rights
Pre-IND Meeting Package and Meeting Summary	Once	Stage 3	3.2.2.1	Review	Limited Rights
Certificate of Analysis for Released Drug Product	Once	Stage 3	3.4.5	Review	Limited Rights
(b) (4) [redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
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		Total (CPFF):	(b) (4)
		Period of Performance:	48 Months

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