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

REPLY TO
ATTENTION OF

06 July 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) 20-08, Objective TRE-PRE-20-08 for "Large-Scale Manufacturing of Antibodies Directed to SARS-CoV-2" (Regeneron Pharmaceuticals, Inc.)

REF: Regeneron Request for Technical Direction Letter, RPP 20-08 under OTA W15QKN-16-9-1002 for Objective TRE-PRE-20-08, dated 30 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 MCDC RPP 20-08 on 17 May 2020. Members of the MCDC submitted proposals in accordance with this RPP. The Government received and evaluated all proposal(s) submitted and a Basis of Selection has been executed, selecting Regeneron as the awardee. The Government requests that a Firm-Fixed-Price Project Agreement be issued to Regeneron to award this proposal under Other Transaction Agreement W15QKN-16-9-1002, to be performed in accordance with the attached Government Statement of Work (SOW).

Based upon the acceptable update of Regeneron's proposal for "Large-Scale Manufacturing of Antibodies Directed to SARS-CoV-2" and 1) The Project Agreement Recipient's concurrence with the requirements included in the Government SOW; 2) An acceptable milestone schedule that meets SOW requirements, and; 3) The cost proposal that has been analyzed and negotiated by the Government, you are hereby directed to issue a Project Agreement to Regeneron for the subject project. The total project value has been determined fair and reasonable and Regeneron's proposal has been selected IAW the above referenced Basis of Selection.

The total approved cost to the Government for this effort is not to exceed $450,392,000.00. The break-out of the costs is as follows: $450,262,000.00 to perform project efforts included in the SOW and $130,000.00 for the Consortium Management Firm (CMF) Administrative Cost. The CMF Administrative Cost and Fee was approved as a "Special Allocation" for Operation Warp Speed (OWS) Prototype Projects executed under the MCDC OTA. The effort currently has $450,392,000.00 of available funding, comprised of $450,262,000.00 for the Project Agreement and $130,000.00 for the CMF. PAH COVID-19 work shall be tracked separately using the funding obligated via

modification P00074. In alignment with the special allocation conditions, it is noted that this project has a period of performance of twelve (12) months, with a projected completion date of 30 June 2021. A customized clause for the special allocation, will be incorporated into the funding modification for this prototype project.

The PAH 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.

The Government and Advanced Technology International ("ATI") hereby agree and confirm that (a) ATI, in its capacity as the Consortium Management Firm under the Medical CBRN Defense Consortium (MCDC) Other Transaction Agreement No. W15QKN-16-9-1002 (the MCDC Agreement), has the authorization to enter into the Medical CBRN Defense Consortium Base Agreement No. 2020-504 and the Statement of Work (collectively, the "Regeneron Agreement") with Regeneron on behalf of the Government, (b) the Government is and shall be bound by its obligations set forth in the Regeneron Agreement, and the MCDC Agreement is hereby amended to incorporate these obligations in the MCDC Agreement, as that Agreement relates to Regeneron, and (c) Regeneron is an intended third-party beneficiary of such obligations that can enforce them directly against the Government, and (d) in the event of any conflict between the Regeneron Agreement, on the one hand, and the MCDC Agreement, on the other hand, the Regeneron Agreement shall control and take precedence.

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: MCDC2008-005 - Regeneron - 7-3-2020
Attachment 2: OPSEC Language Addendum
Attachment 3: MCDC OTA Special Allocation Letter

(b) (6)

ATI Signatory

Statement of Work
For
Large-Scale Manufacturing of Antibodies Directed to SARS-CoV-2

RPP #: RPP-20-08
Project Identifier: MCDC OTA 2008-005, W15QKN-16-9-1002
Consortium Member: Regeneron Pharmaceuticals, Inc.
Title of Proposal: Large-Scale Manufacturing of Antibodies Directed to SARS-CoV-2

1.0 INTRODUCTION, SCOPE, AND OBJECTIVES

A. Preamble

Regeneron Pharmaceuticals, Inc. (referred to herein as "Regeneron", "Offeror", "Contractor" or "Recipient") has demonstrated experience with rapid scale-up of biopharmaceutical programs. Our excellent history of receiving development scale processes from Research and Development (R&D) laboratories, and then expanding to clinical or commercial Good Manufacturing Practice (GMP) scale production, is well documented. Greater than 65 processes have been transferred since 2008 with a success rate of 100%. We have consistently demonstrated our ability to expedite the delivery of high quality, safe and efficacious products (Ebola therapeutic) in partnership with the Government (anti-MERS, anti-Ebola).

Fully human monoclonal antibodies (mAbs) are molecules with high potency, predictable Pharmacokinetics (PK), and limited off-target toxicity, and thus provide attractive types of therapeutics for emerging diseases. Importantly, we have repeatedly demonstrated that candidate mAb-based drugs to prevent and/or treat emerging infections, can be rapidly obtained from Regeneron's proprietary VelocImmune® mice. Further, our ability to concurrently generate isogenic cell lines that are optimized for rapid antibody scale up and manufacturing using our proprietary Chemistry, Manufacturing, and Controls (CMC) platform technologies, have facilitated both testing of our mAbs in preclinical models and subsequent development of these mAbs into drugs suitable for human testing. In the process of completing many of these activities we have collaborated with other entities (including BARDA, Research Institutes, Government Laboratories and Universities). Our manufacturing has been designed to be paired with our proprietary VelocImmune® R&D technology, that is a proven process to rapidly take a research concept from the bench, into large scale production, with the ability to delivery medicines to patients.

The Government has advised Regeneron that it is appropriate for the project described in this Project Agreement to be performed through the Medical CBRN Defense Consortium (MCDC), under the authority of the MCDC Other Transaction Agreement No. W15QKN-16-9-1002. Regeneron is amenable to performing the project pursuant to such authority, based on the advice of the Government, and due to the unprecedented circumstances of the Coronavirus Disease 2019 (COVID-19) pandemic and, accordingly, the parties have entered into this Project Agreement.

B. Overall Objectives and Scope

This project is defined by discrete work segments for the continuous manufacture of drug substance, formulated drug substance and filled, packaged and labeled drug product, in accordance with a mutually agreed schedule.

Pursuant to this project, Regeneron will manufacture and sell drug product to the applicable United States (U.S.) Federal Government agency, for distribution in the U.S. All manufacturing described herein will be compliant with Food and Drug Administration (FDA) current Good Manufacturing Oractices (cGMP), as 21 CFR 210 and 211.

1.1 Introduction

The objective is to conduct the manufacturing production activities described in this proposal for prototypes consisting of novel, proprietary mAb therapeutics and prophylactics, to reduce pathology of COVID-19 disease and/or prevent development of disease when administered prophylactically.

1.2 Scope

These manufacturing production activities will include manufacturing at-scale, filling and finishing, and storage and shipping of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)-specific monoclonal antibodies (referred to herein as the "prototype", the "prototype product", the "product" or "drug product") for treatment and/or prophylaxis against COVID-19.

1.3 Definition of the Prototype Project

Consistent with USG objectives, Regeneron will employ its proprietary manufacturing technology and processes, in a manner compliant with applicable laws and regulations, including 21 CFR 210 and 211 and the Drug Supply Chain Security Act, to manufacture the prototype product. This effort constitutes a prototype project because it will be used to evaluate the technical feasibility of manufacturing the prototype product during the ongoing COVID-19 pandemic. In addition, this is a prototype project because Regeneron will demonstrate, and prove-out the at-scale, multi-lot proprietary manufacturing activities of Regeneron in order to assess the feasibility of these activities to support the necessary quantity of the prototype product to treat the U.S. population. Successful completion of the prototype project will demonstrate Regeneron's capability to (i) rapidly manufacture product, which can be further scaled-up to meet mutually agreed to surge requirements with little advance notification and (ii) facilitate the Government's ability to stockpile and distribute large quantities of the drug product to respond when needed, including for use in clinical studies, under an Emergency Use Authorization (EUA), or pursuant to other clearance from the U.S. FDA. For clarity, any manufacturing and supply of drug product in excess of the specific quantities set forth in Section 4.0 of this Statement of Work, shall be subject to a separate mutual agreement between Regeneron and the Government.

The scope of effort supported by this agreement is further clarified in Section 1.4. It is important to note that nonclinical and clinical studies for the prototype are being conducted by Regeneron outside of this agreement. The results of those studies may be used to develop use case scenarios and, in turn, inform the USG's deployment strategy as it relates to product manufactured under this agreement; however, such results (including the degree to which the data are "positive" or "negative") shall not be a factor in this prototype project.

1.4 Objective

- Conduct its proprietary manufacturing production activities described in this proposal for prototypes consisting of novel, proprietary mAb therapeutics and prophylactics, to reduce pathology of COVID-19 disease and/or prevent development of disease when administered prophylactically.
- The prototypes will include one or more of the following, as mutually agreed between Offeror and the Government:
    - the mAbs known as REGN10987 and REGN10933, as a cocktail;
    - Other mAbs (as monotherapies or a cocktail) as agreed to by bilateral modification between Offeror and the Government.
- The deliverables will be the products listed above (i.e., REGN10987 and REGN10933), in the form of bulk formulated drug substance and/or filled and finished product in vials, as mutually agreed between Offeror and the Government, packaged and labeled drug product, results, reports and records associated with generation of data demonstrating quality and control.
- The products will be delivered in the form and quantity to be agreed between Offeror and the Government. It is expected that the prototypes will be stored by Offeror until such time as (a) they can be used for pre-clinical or clinical development purposes under an Investigational New Drug application (IND), or (b) upon the FDA's grant of an EUA under Section 564 of the Food, Drug and Cosmetic Act (FD&C Act), or full marketing approval under a full Biologics License Application (BLA) under Section 351(a) of the Public Health Service Act (PHSA).

1.5 Follow-on Activity

In accordance with 10.U.S.C. 2371b(f), and upon successful demonstration of the prototype, or at the accomplishment of particularly favorable or unexpected results achieved outside of this Agreement that would justify transitioning to production (e.g., EUA or BLA), additional at-scale manufacturing of up to 800,000 treatment courses, supported by a mutually agreed upon follow-on production contract or Other Transaction Agreement, may be awarded to Regeneron, without further competition, to partially or completely meet the USG objective of supplying a safe and effective COVID-19 therapeutic or prophylactic treatment courses to ensure nationwide access. For clarity, any manufacturing and supply of drug product in excess of the specific quantities set forth in Section 4.0 of this Statement of Work shall be subject to a mutually-agreed upon separate agreement between Regeneron and the Government. For further clarity, neither party shall be obligated to negotiate or enter into such a separate agreement for follow-on production.

During the performance of the prototype project, the Government and contractor may negotiate the scope and price of follow-on production.

2.0 APPLICABLE REFERENCES

Current Good Manufacturing Practices, 21 CFR 210, 211

3.0 REQUIREMENTS

3.1 Technical

- The Offeror's technical approach is expected to be similar, but not duplicative, to its manufacturing activities under its current agreements with the Biomedical Advanced Research and Development Authority (BARDA), including contract # HHSO100201700016C, and will include the following:
    - Drug Substance, Formulated Drug Substance, Drug Product (DS/FDS/DP) quality and control.
        - Regeneron will apply statistical process analysis to continuously qualify in-process controls and release parameters.
        - The manufacturing process will be evaluated against parameters that are correlated to process performance and product quality. Ranges for the performance of each unit operation will be established through process development recommended ranges, the generation of statistical limits based on small-scale studies, and/or continuous commercial-scale manufacturing experience. These ranges will be monitored during the execution of quality and control, and are designed to ensure that the process is in a state of control and to ensure that the manufacturing process operates in a consistent and reproducible manner. The quality and control runs will also confirm that the process and product impurity profiles are within limits, demonstrate the consistent removal of impurities, and demonstrate that the process is capable of operating within acceptable microbiological control limits. Additional sampling and testing beyond that needed to assess process performance, may be completed to further process understanding.
        - *Intermediate Hold Time Validation*: Intermediate hold time validation to be performed via combination of at scale and small scale executions:
            - Microbial Control: Where appropriate, microbial control data from at scale hold time studies, will be leveraged from historical validation runs with molecules which have similar equipment and sanitization procedures.
            - Chemical Stability: Chemical stability will be demonstrated using data from laboratory scale hold time studies performed for each of the prototypes, using material obtained from in-process pools from the 10,000 L manufacturing executions.

- *Media, Feed and Buffer Mixing Validation*: Preparation of buffers and media will be validated at commercial-scale. These validation studies will demonstrate that the preparation process consistently produces solutions meeting predefined limits for parameters indicative of homogeneity, such as pH, conductivity, osmolality, and turbidity. Where vessels of equivalent design and construction exist within the manufacturing facility, validation of media and buffer preparation will be performed on one representative vessel on at least three consecutive and successful executions.
- *Medium Storage Validation*: Medium storage validation will be separated into preparation hold and post-filtration storage, and has two components: microbial control and chemical stability. Pre-filtration microbial control is specific to the raw materials and the environment, and post-filtration microbial control is specific to each storage container and the ability of the storage container to maintain a microbial free condition. Maximum storage times for medium solutions with respect to microbial control will be validated as necessary at commercial scale, through preparation and storage of medium for extended storage times pre- and post-filtration. Validation will be achieved by demonstrating microbial control for a number of consecutive attempts established in the relevant validation protocol. Solutions will be prepared, stored for defined periods and tested for bioburden and endotoxin. Chemical stability of medium may be performed at small-scale to demonstrate storage conditions maintain integrity of chemical components. Bracketing approaches may be used to cover the different feeds and medium used, provided the individual protocol justifies the bracket.
- *Buffer Storage Validation:* Buffer storage validation is separated into preparation hold and post-filtration storage, and has two components: microbial control and chemical stability. Preparation holds are dependent on the solution composition. The worst- case solution for growth is determined using a risk-based approach, and post-filtration microbial control is specific to each vessel and the ability of a vessel to maintain a microbial free condition. Maximum storage times for buffer solutions will be validated as necessary at commercial-scale for microbial control, through preparation and storage of a non-growth inhibiting buffer for extended storage times pre- and post-filtration. Validation will be achieved by demonstrating microbial control for a number of consecutive attempts established by the protocol. Buffer hold validation in stainless steel vessels will require ongoing evaluation and monitoring; however, buffer hold validation in disposable bioprocess containers may be shortened, if appropriate, by a bracketing approach. Solutions will be prepared, held and monitored over time for bioburden, endotoxin. Chemical stability of buffers may be performed at small-scale to demonstrate that storage conditions maintain integrity of chemical components. Bracketing approaches may be used to cover the large number of buffers used, provided the individual protocol justifies the bracket.

- *Chromatography Column Sanitization and Storage Validation*: Any newly required studies will be performed to validate the cleaning and storage procedures for (b) (4) chromatography columns used in the manufacture of the prototypes. In addition, the maximum allowable storage period following cleaning will be established for each of the chromatography resins.

- *Chromatography Column Cleaning Validation*: The efficacy of the solutions used to clean the chromatography columns will be examined as necessary over three consecutive executions during commercial scale manufacturing of each of the prototypes. The effectiveness of the cleaning procedures will be assessed by sampling the post cleaning (post-use) Water for Injection (WFI) flush effluent; at approximately (b) (4) into the flush for bioburden and endotoxin levels (the purpose of which is to demonstrate microbial control). In addition, Total Organic Carbon (TOC) will be measured to verify the absence of lot to lot protein carry over.

- *Chromatography Column Storage Validation*: The efficacy of the solutions used to store the chromatography columns will be examined, as necessary, over three consecutive executions during commercial scale manufacturing of each of the prototypes. The effectiveness of the cleaning and storage procedures will be assessed by sampling the post storage (pre-use) WFI flush effluent for bioburden, endotoxin levels and TOC. The maximum allowable storage period for each column will be established based on the shortest of the three consecutive executions for which the column remained in the storage solution.

- *Establishment of In-Process Control (IPC) Program*: The IPC program will utilize Statistical Process Control (SPC) to monitor critical and general process parameters, and critical and general quality attributes for each lot manufactured. On completion of quality and control activities, the IPC development report will establish the set of parameters and attributes to be monitored, and justify appropriate action limits for each. Upon approval of the development report, a Process Performance Monitoring (PPM) Plan will be generated containing the list of IPCs, historical data, selection of monitoring tools and response to signal strategy, statistical summary, and visualization of the IPCs. The IPC development report and PPM Plan will be further updated as laboratory and production scale characterization and validation data is gained, once defined production milestones are achieved, and then annually afterward. The annual updates will assess the overall state of process control and include process capability analysis and assessment of evidence of special cause variation for all applicable IPCs. Process data for individual lots will be monitored through (b) (4) PPM meetings, where any trend signals are identified and responded to. These meetings will be attended by subject matter experts from departments including, but

not limited to, (b) (4)

- **Master Cell Bank (MCB) Genetic Characterization**: (b) (4)

- **Working Cell Bank (WCB) Genetic Characterization**: (b) (4)

- **DS/FDS/DP Registration Stability**: Stability studies for DS/FDS/DP will be initiated and executed according to stability protocols, International Council for Harmonisation (ICH) guidelines and internal procedures. Quality and control lots will be stored and monitored at the routine long term storage condition per the Specification for (b) (4) Samples will also be stored and monitored at Accelerated (b) (4) condition for 6 months, and Stress (b) (4) condition for (b) (4) for the evaluation and identification of degradation pathways of the molecule. Stability studies performed on the quality and control lots will support the shelf life of each prototype, and confirm that the manufacturing process is suitable for commercial-scale manufacture. All testing will be conducted in a GMP Quality Control (QC) Laboratory. Any Out of Specification (OOS) or Out of Trend (OOT) results will be investigated.

- **DS/FDS/DP Shipping Validation**: Shipping Validation by actual transport will be performed on the DS/FDS/DP of each prototype to cover a distance and duration that will exceed routine shipment to the intended fill site. Successful shipping validation of intended shipping lanes is based on the ability of the container to maintain the product at a specified temperature, to preserve product quality, and meet specifications.

- **DS/FDS/DP Photostability Studies**: To determine overall photosensitivity of DS/FDS/DP per ICH requirements, a study will be performed at (b) (4) under (b) (4) and (b) (4) light. Samples will be oriented for maximum light exposure using container closures designed for direct exposure, immediate pack/marketing pack, and a foil covered control. Testing will then be performed on (b) (4) sample sets for stability indicating attributes.

- **QC Reference Standard Production and Stability**: Reference standards for the individual DS/FDS/DP GMP lots will be generated according to internal standard

operating procedures. The DS/FDS/DP for each prototype will be filled as a product reference standard. The first manufactured lot (lead lot) will be sub-aliquoted into single use vials, stored and routinely monitored at (b) (4) by Offeror's Quality Control personnel. The reference standard will be qualified prior to use, according to specifications. A Certificate of Qualification (CofQ) will be issued for each individual reference standard at the time of initial qualification and following recertification testing. A stability study to monitor the critical quality attributes of each reference standard will also be conducted.

- **Assay Validation**: Will be performed as necessary to support any applicable EUA or other regulatory requirements.
- **Manufacturing**: Following the completion of the activities described above, Offeror will manufacture prototypes at scale in order to achieve the intended scope of the contract.
- **Label/Pack**: Labeling and packaging of investigational product for clinical studies or for use under an EUA or approval, will be completed at a GMP contract manufacturing organization managed by Offeror's External Manufacturing group.
- **Storage**: Packaged and labeled material storage will be managed by Offeror's External Manufacturing group.

3.2 Management and Reporting

3.2.1 Program Management

Below are the individuals currently assigned to key roles on the project team. Regeneron reserves the right to make personnel changes which will be communicated accordingly.

a. Regeneron will manage, integrate and coordinate all activities, including utilizing Regeneron's state-of-the-art technical and administrative infrastructure to ensure efficient planning, initiation, implementation and direction of contracted activities.

b. The (b) (4), is responsible for guiding the project approach and scope of this Program.

c. (b) (4), will serve as Lead PI for this Program. The PI will be responsible for project management, communication, tracking, monitoring and reporting on status and progress, and modification to the project requirements and timelines, including any projects undertaken by subcontractors.

d. A (b) (4), will be responsible for monitoring and tracking day-to-day progress and timelines, coordinating communication and project activities, costs incurred, and program management for this Program. The contract deliverables list identifies all contract deliverables and reporting requirements for this contract.

e. (b) (4), will provide development of compliant subcontracts, consulting, and other legal agreements.

f. (b) (4), will be responsible for financial management and reporting on all activities conducted by Regeneron and any subcontractors.

g. A (b) (4), will be responsible for facilitating the development of integrated CMC plans and for monitoring and tracking the progress of the CMC milestones.

h. A (b) (4), will be responsible for management of batch disposition, oversight of discrepancy investigations, and to ensure all released product conforms to GMP standards.

i. A (b) (4), will be responsible for analytical method development, method transfer and specification development.

j. A (b) (4), will be responsible for ensuring Regeneron quality, preclinical, and clinical drug development programs are conducted in compliance with regulations governing pharmaceutical drug development, and with project specific regulatory commitments/requirements ,and will serve as the liaison for communications with the US Food and Drug Administration.

k. Regeneron shall provide Quarterly Progress Reports, which shall include a description of the activities during the reporting period and the activities planned for the ensuing reporting period.

l. Regeneron shall provide Annual Progress Reports, which shall include a summation of the activities during the reporting period, and the activities planned for the ensuing reporting period.

m. Regeneron shall provide Draft and Final Reports, which shall include a summation of the work performed and results obtained for execution of various studies or technical work packages during the entire contract period of performance. This report shall describe the results achieved.

n. Regeneron shall participate in regular meetings to coordinate and oversee the contract effort, as directed by a single point of contact established by the Government. Such meetings may include, but are not limited to, meetings of Regeneron and subcontractors to discuss clinical manufacturing progress, product development, scale-up manufacturing development, preclinical/clinical study designs and regulatory issues, meetings with individual contractors and other Health and Human Services (HHS) officials to discuss the technical, regulatory, and ethical aspects of the program, and meetings with technical consultants to discuss technical data provided by Regeneron. Regeneron shall also consult with the Government as required in connection with meetings and submissions to regulatory agencies, including the FDA. The Government will establish a single point of contact for regular meetings and coordinate all requests for information through such point of contact, such that Regeneron shall not be required to attend multiple meetings with different Government agencies for the same (or similar) subject matter, or respond to multiple requests for information or materials concerning the same (or similar) subject matter.

o. Regeneron shall participate in teleconferences at an agreed upon frequency between Regeneron and -to review technical progress.

3.2.2 Integrated Master Schedule (IMS)

Regeneron will provide an Integrated Master Schedule within (b) (4) of the award, and shall update such schedule to reflect any material changes. Within an agreed upon timeframe of the effective date of the contract, Regeneron will make any agreed upon changes between Regeneron and Agreements Officer and/or Project Officer at the the Government. The IMS shall be incorporated into the contract and will be used to monitor performance of the contract. Regeneron shall include the key milestones and Go/No-Go decision gates. The IMS for the period of performance will be accepted by the Government within (b) (4) of the Government's receipt of such IMS.

3.2.3 Reporting

On completion of a stage of the product development, as defined in the agreed upon IMS and Integrated Master Plan, Regeneron shall prepare and submit to the Project Officer and the Agreements Officer, reports from time to time that contain (i) reasonable detail, documentation and analysis to support successful completion of the stage according to the predetermined qualitative and quantitative criteria, and (ii) a description of the next stage of product development to be initiated, and a request for approval to proceed to the next stage of product development.

3.2.4 Data Management

Regeneron will utilize existing systems to implement data management and quality control systems/procedures, including transmission, storage, confidentiality, and retrieval of contract data. Provide analysis of data generated with contract funding to the Project Officer or Agreements Officer, upon request.

3.2.5 Technical and Financial Reporting

Technical Reports are described in Section 3.3.1 k., l. and m. They are also listed in the milestone schedule and deliverables table in Section 5 of this Statement of Work.

For Financial Reporting, firm fixed price invoices will be submitted on a quarterly basis as described in Section 5 below. Invoices will include data and technical reports sufficient to support the accomplishment of each milestone, as appropriate, during the invoicing period. Regeneron will provide quarterly Financial Status Reports outlining billed vs. budgeted activity for each period, and in aggregate for the contract.

4.0 DELIVERABLES

Offeror assumed (b) (4); Filled/Finished Drug Product Deliveries (b) (4). Regeneron shall have the right to provide deliverables directly to the Government and not to the Consortium Management Firm (CMF).

Deliverable Table (June 2020 - June 2021)

Deliverable	Due Date	Total Program Funds	Data Rights
Project Kick-Off; Deliverable	(b) (4)	(b) (4)	*Specially Negotiated
DS/FDS Bulk GMP Lot (b) (4)			*Specially Negotiated
DS/FDS Bulk GMP Lot (b) (4)			*Specially Negotiated
DS/FDS Bulk GMP Lot (b) (4)			*Specially Negotiated
Fill Product (b) (4)			*Specially Negotiated
Fill Product (b) (4)			*Specially Negotiated
Fill Product (b) (4)			*Specially Negotiated
Package/Label Product			*Specially Negotiated
Storage of Drug Product in VMI (b) (4)			*Specially Negotiated
Storage of Drug Product in VMI (b) (4)			*Specially Negotiated
Storage of Drug Product in VMI (b) (4)			*Specially Negotiated
Storage of Drug Product in VMI (b) (4)			*Specially Negotiated
Quarterly Technical and Business Status Report, see above for submission schedule			*Specially Negotiated
Annual Technical and Business Status Report, see above for submission schedule			*Specially Negotiated
Quarterly Technical and Business Status Report, see above for submission schedule			*Specially Negotiated
(b) (4)			Limited Rights

Deliverable	Due Date	Total Program Funds	Data Rights
		$450,262,000 (FFP)	

*Upon payment, delivery and acceptance in accordance with the terms of this Project Agreement, the Government will have title to the product produced under this Statement of Work. The Government will have the rights described below in Section 7.3 to technical data disclosed under this Statement of Work.

** Packaging and labeling of product will be performed following the determination of the use of the applicable drug product (e.g., for clinical trials or for distribution under an EUA or BLA).

5.0 MILESTONE PAYMENT SCHEDULE; TERMINATION COSTS

Milestone #	Milestone Description (Deliverable Reference)	Due Date	Total Program Funds
5.1	(b) (4) Drug Substance Deliverables (b) (4) of Drug Substance)	(b) (4)	(b) (4)
5.2	(b) (4) Drug Substance Deliverables (b) (4) of Drug Substance)		
5.3	(b) (4) Drug Product Deliverables (Fill/Finish for (b) (4) of Drug Substance)		
5.4	(b) (4) Drug Substance Deliverables (b) (4) of Drug Substance)		
5.5	(b) (4) Drug Product Deliverables (Fill/Finish for (b) (4) of Drug Substance)		
5.6	Quarterly Technical and Business Status Report, Reference 3.3.1.k		
5.7	Annual Technical and Business Status Report, Reference 3.3.1.l		
5.8	Storage of Drug Product in VMI (b) (4)		
5.9	Storage of Drug Product in VMI (b) (4)		
5.10	Storage of Drug Product in VMI (b) (4)		
5.11	Storage of Drug Product in VMI (b) (4)		
	Total (Include Payment Type; FFP):		**$450,262,000**
	Period of Performance:		**June 2020 – June 2021**

The overall price is fixed price at $450,262,000. Milestone payments will be made quarterly as set forth in the table above, corresponding to the deliverables and any 3rd party commitments Regeneron needs to make. In the event the deliverables in a given quarter are less than or exceed the projected quantity, the milestone payment for such quarter will be equitably adjusted based on the shortfall or excess amount, as applicable, however the price will not exceed $450,262,000 Milestone payment terms will be net 30 days.

Total pricing is a firm fixed price per lot, (b) (4) [redacted]. Regeneron will deliver (b) (4) [redacted]

(b) (4) of filled/finished drug product. Regeneron will be entitled to full payment for drug product upon delivery/acceptance (as described herein) of filled/finished drug product, prior to packaging and labeling. However, Regeneron shall be responsible for the packaging and labeling of product at no additional cost following the determination of the use of such drug product (e.g., for clinical trials or for distribution under an EUA or BLA). Drug product will comply with the Drug Supply Chain Security Act serialization and tracking requirements. Drug product will not be co-formulated, except as otherwise mutually agreed by the parties. Unless and until otherwise mutually agreed, the drug product produced under this Statement of Work will be filled for therapeutic use. In order to change this allocation, Regeneron will require at least (b) (4) (b) (4) prior written notice, in order to meet Regeneron's notification requirements to its fill/finish subcontractor. Regeneron will provide the Government with the timeline for fill/finish activities, including the dates by which the parties must determine the allocation of fill/finish activities. Notwithstanding the foregoing, as part of this Project Agreement, Regeneron will have the right to utilize material and capacity supported by this agreement to fill up to (b) (4) (b) (4), as well as any additional drug product mutually agreed upon by Regeneron and the Government (with respect to which use the Government will not unreasonably withhold consent.

In the event this Statement of Work is terminated prior to completion, termination costs recoverable by Regeneron under Section 2.04 of the MCDC Base Agreement, shall include the following: the full contract price for any drug product manufactured and not yet paid for; a pro-rated portion of the contract price for drug substance or drug product that is in process, based on the stage of production, (b) (4), and raw materials that Regeneron purchased (or is obligated to purchase) that cannot be allocated to other products.

6.0 STORAGE AND SHIPPING PROVISIONS

Upon acceptance by the Agreements Officer Representative of any lot of antibodies under this contract, title to such antibodies will transfer as follows: upon delivery of drug product to vendor-managed inventory and the Government's corresponding written acceptance of the delivery of each such lot of drug product. The Government shall accept product that conforms to contract requirements based on a Certificate of Analysis (COA) provided by Regeneron. The Government's acceptance of product will be (b) (4) provide written notice of acceptance or rejection (b) (4) (b) (4) Unless otherwise mutually agreed upon by the parties, drug product shall be shipped to the Government within the continental United States. Regeneron will (b) (4) for all product stored as vendor-managed inventory. To the extent that Regeneron is responsible for the correction, repair or replacement of Government property held in vendor-managed inventory (b) (4) the Government will (b) (4) of such property. Vendor-managed storage of product manufactured under this agreement is supported through (b) (4) and, as such, the Government must either (a) take possession on or before this date and provide Regeneron with disposition instructions in sufficient time to transfer physical material from Regeneron by this date or (b) bilaterally modify this agreement to extend the period of vendor management of storage prior to this date.

The Government understands that prices identified in this contract include (b) (4) applicable to material that will become Government property, including product stored as vendor-managed inventory.

7.0 PATENT RIGHTS; DATA RIGHTS; PREP ACT AND TRANSPARENCY

Article X, ("PATENT RIGHTS") and Article XI. ("DATA RIGHTS") of Other Transaction Agreement number W15QKN-16-9-1002 shall not apply to this Project Agreement and are hereby replaced for the purpose of this Project Agreement, with this Section 7.0 (including Sections 7.1-7.4 and the Definitions Appendix).

Definitions:

Capitalized terms used in this Section 7.0 (including Sections 7.1-7.4) shall have the meanings ascribed to such terms in the Definitions Appendix to this Project Agreement.

For purposes of this Project Agreement, all rights of the Government in and to Data or Subject Inventions are granted solely to The United States of America, as represented by the Department of Health & Human Services, Office of the Assistant Secretary for Preparedness & Response ("ASPR"), Office of Biomedical Advanced Research and Development ("BARDA") (represented by Office of Acquisition Management, Contracts and Grants (AMCG)) and to no other agency of the United States of America (including JPEO) or representative of any such other agency (including the CMF). The parties acknowledge that Regeneron is permitted to communicate solely with BARDA regarding the matters described in this Section 7.0 (including Sections 7.1-7.4) and is not obligated to communicate with any other Government agency or representative regarding such matters.

7.1 BACKGROUND INTELLECTUAL PROPERTY

Each party acknowledges that it has no rights to the other party's inventions, discoveries, know-how, Data, technology or intellectual property generated, discovered, conceived or reduced to practice prior to or otherwise outside of this Statement of Work (also referred to herein as, this "Project Agreement" or this "Agreement"), and any improvements or modifications thereto, including, without limitation, the background intellectual property (and improvements/modifications) for the Government and Regeneron described below, as follows:

Government Background Intellectual Property. None.

Contractor Background Intellectual Property: Includes, but is not limited to, (b) (4)
[redacted]
:

63/004,312, filed April 2, 2020 "Anti-SARS-CoV-2-Spike Glycoprotein Antibodies and Antigen-Binding Fragments"

(b) (4)

63/014,687, filed April 23, 2020 "Anti-SARS-CoV-2-Spike Glycoprotein Antibodies and Antigen-Binding Fragments"

(b) (4)

63/025,949, filed May 15, 2020 "Anti-SARS-CoV-2-Spike Glycoprotein Antibodies and Antigen-Binding Fragments"

(b) (4)

(b) (4)

63/034,865, filed June 4, 2020 "Anti-SARS-CoV-2-Spike Glycoprotein Antibodies and Antigen-Binding Fragments"

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

No party relinquishes rights in any of its background intellectual property to any other party under this contract.

Either Party may update its disclosure of background intellectual property under this Section 7.1 upon written notice to the other Party.

7.2 PATENT RIGHTS

a. Allocation of Principal Rights

The parties agree that the Bayh-Dole statute does not apply to this Project Agreement. Ownership of inventions Made in the performance of this Project Agreement shall follow inventorship, and inventorship shall be determined in accordance with United States patent laws. With respect to any Subject Invention Made (in whole or in part) by or on behalf of Regeneron, unless Regeneron shall have notified the Government (in accordance with Subparagraph b. below) that Regeneron does not intend to properly disclose and elect title to a Subject Invention, Regeneron shall retain the entire right, title, and interest throughout the world to such Subject Invention, and the Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the Subject Invention throughout the world. This license does not include the right to use or allow others to use the Subject Invention for commercial purposes. If Regeneron does not properly disclose and elect title to any such Subject Invention (in accordance with Subparagraph b. below), then the Government may exercise its rights to seek ownership of such Subject Invention, pursuant to clause 7.2.c. below.

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

i. Regeneron shall disclose in writing each Subject Invention to the OTTR within 12 months after the inventor discloses it in writing to Regeneron personnel responsible for patent matters. The disclosure shall identify the inventor(s) and this Project Agreement under which the Subject Invention was made. It shall be sufficiently complete in technical detail to convey a clear understanding of the Subject Invention. The disclosure shall also identify any publication, on sale (i.e., sale or offer for sale), or public use of the Subject Invention, or whether a manuscript describing the Subject Invention has been submitted for publication and, if so, whether it has been accepted for publication. In addition, after disclosure to the Government funding agency (HHS/BARDA), Regeneron shall promptly notify the OTTR of the acceptance of any manuscript describing the Subject Invention for publication and any on sale or public use.

ii. Regeneron shall elect in writing whether or not to retain ownership of any Subject Invention by notifying the OTTR within 2 years of disclosure to the Government funding agency. However, in any case where publication, on sale, or public use has initiated the 1-year statutory period during which valid patent protection can be obtained in the United States, the period for election of title may be shortened by the agency to a date that is no more than 60 calendar days prior to the end of the statutory period.

iii. Regeneron shall file either a provisional or a non-provisional patent application for an elected Subject Invention within 1 year after election of title. However, in any case where a publication, on sale, or public use has initiated the 1-year statutory period during which valid patent protection can be obtained in the United States, Regeneron shall file the application prior to the end of that statutory period. If Regeneron files an initial provisional application, it shall file a non-provisional application within 10 months of the filing of the initial provisional application. Regeneron shall include a Government Support Clause (GSC) within the specification of any United States patent applications and any patent issuing thereon covering a subject invention.

iv. Regeneron may request extensions of time for disclosure, election, or filing under subparagraphs (b)(i), (b)(ii) and (b)(iii) of this clause. An extension of time for each deadline, may be granted at the discretion of the Government funding agency.

v. If Regeneron determines that it does not intend to elect to retain title to any such Subject Invention, Regeneron shall notify the Government, in writing, within two (2) years of disclosure to the Government. 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 the Government to a date that is no more than sixty (60) calendar days prior to the end of the statutory period.

c. Conditions When the Government May Obtain Title

Upon the Government's written request, Regeneron shall convey title to any Subject Invention to the Government funding agency if Regeneron fails to disclose the Subject Invention or elects not to retain title to the Subject Invention within the times specified in Subparagraph b of Section 7.2. The Government may request title after learning of the failure of Regeneron to disclose or elect within the specified times for an unlimited time. The Government funding agency may request title upon Regeneron's omission to timely file patent applications in any country. The Government funding agency may request title in any country in which Regeneron decides to discontinue prosecution.

d. Rights to Regeneron and Protection of Regeneron's Right to File

Regeneron shall retain a fully paid up, sub-licensable, nonexclusive, royalty-free license throughout the world in each Subject Invention to which the Government obtains title. Regeneron license extends to Regeneron's subsidiaries and other affiliates (outside this Agreement), if any, within the corporate structure of which Regeneron is a party and includes the right to grant licenses of the same scope to the extent that Regeneron was legally obligated or permitted to do so at the time the Project Agreement was executed. The license is otherwise transferable only with the approval of the Government, except when transferred to an Affiliate or successor of that part of Regeneron's business to which the Subject Invention pertains. The Government approval for license transfer shall be provided on a timely basis (and in no event later than 90 calendar days following Regeneron's request) and shall not be unreasonably withheld.

i. The Regeneron license may be revoked or modified by the Government to the extent necessary to achieve expeditious Practical Application of the Subject Invention pursuant to an application for an exclusive or nonexclusive license submitted consistent with appropriate provisions at 37 CFR Part 404. Regeneron's license shall not be revoked in that field of use or the geographical areas in which Regeneron has achieved Practical Application of the Subject Invention and continues to make the benefits of the Subject Invention accessible to the public.

ii. Before revocation or modification of Regeneron's license, the Government shall furnish Regeneron with a written notice of its intention to revoke or modify the license, which notice shall include a detailed explanation of the

reasons for such revocation or modification, and Regeneron shall be allowed thirty (30) 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 revoked or modified.

e. Action to Protect the Government's Interest

Regeneron agrees to execute or to have executed and promptly deliver to the Government all instruments necessary to (i) establish or confirm the rights the Government has throughout the world in those Subject Inventions to which Regeneron elects to retain title, and (ii) convey title to the Government when requested under Subparagraph c of this Section 7.2 and to enable the Government to obtain patent protection throughout the world in that Subject Invention.

i. Regeneron 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 Regeneron, each Subject Invention made under this Agreement so Regeneron can comply with the disclosure provisions of this Section 7.2. Regeneron shall use reasonable efforts to instruct employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

ii. Regeneron shall notify the Government of any decisions not to continue the prosecution of a patent application for a Subject Invention, pay maintenance fees, or defend in a reexamination or opposition proceedings on a patent of 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.

Regeneron shall include, within the specification of any United States patent application and any patent issuing thereon covering a Subject Invention, the following statement: "This invention was made with Government support under Agreement **MCDC2020-504**, awarded by the U.S. Department of Health and Human Services. The Government has certain rights in the invention."

f. Lower Tier Agreements

Regeneron shall ensure that its Affiliate agreements and Sub-Recipient Agreements regardless of tier, for experimental, developmental, or research work entered into after the Effective Date and submitted for reimbursement under this Agreement, contain invention reporting and assignment requirements sufficient to permit Regeneron to comply with this Section 7.2.

g. Reporting on Utilization of Subject Inventions

i. Regeneron agrees to submit, during the term of this Project Agreement, an annual report on the utilization of a Subject Invention or on efforts at obtaining such utilization that is being made by Regeneron or its licensees or assignees. Such reports shall 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. Regeneron also agrees to provide additional reports as may be requested by the Government in connection with any march-in proceedings undertaken by the Government in accordance with Subparagraph h of this Section 7.2. Consistent with 35 U.S.C. § 202(c)(5), the Government agrees it shall not disclose such information to persons outside the Government without permission of Regeneron.

ii. All required reports shall be submitted to the e-room, OTAS, OTAO, and OTTR.

h. Compulsory Licensing Rights

Regeneron agrees that, with respect to any Subject Invention in which it has retained title, the Government has the right to require Regeneron, an assignee, or exclusive licensee of a Subject Invention to grant a non-exclusive license to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if Regeneron, assignee, or exclusive licensee refuses such a request, the Government has the right to grant such a license within the Field itself *only* if the Government determines that:

i. Action is necessary to alleviate the following health or safety needs that may affect the United States and Regeneron (itself or through its assignee, subcontractor or licensee) is unwilling or unable to manufacture or supply the Subject Invention to address such needs:
   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 affect 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.

7.3 DATA RIGHTS

a. Allocation of Principal Rights

i. For Data produced under this SOW including Computer Software, to the extent developed with Government funds provided under this SOW, except as expressly provided elsewhere in this Project Agreement (including Section 7.3.b.), Regeneron grants to the Government a paid-up, nonexclusive, nontransferable, irrevocable, worldwide license in such Data (a) to exercise Government Purpose Rights for a period of ten (10) years following the production of such Data, (b) to exercise Unlimited Rights following the expiration of such ten (10)- year period. For Data produced under this Project Agreement, excluding Computer Software, to the extent developed with private funds and for other Data designated by Regeneron as "Limited Rights Data", Regeneron grants to the Government a paid-up,

nonexclusive, nontransferable, irrevocable, worldwide license in such Data to exercise Limited Rights. The Government will not obtain any rights in Computer Software produced under this Project Agreement to the extent developed with private funds. For certificates of analysis and batch records pertaining to drug product purchased under this Project Agreement, the Government shall have Unlimited Rights.

ii. Regeneron agrees to retain and maintain in good condition all Data produced under this Project Agreement and necessary to achieve Practical Application of any Subject Invention in accordance with Regeneron's established record retention practices. In the event of an exercise of the Government's compulsory licensing rights as set forth under Section 7.2.h., Regeneron agrees, upon written request from the Government, to deliver at no additional cost to the Government, all existing Data produced under this Project Agreement necessary to achieve Practical Application of the relevant Subject Invention within sixty (60) calendar days from the date of the written request.

iii. Regeneron's right to use Data is not restricted and includes the right under Regeneron'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. Proprietary Manufacturing Data

Notwithstanding anything to the contrary in this Project Agreement, Regeneron retains all rights in and to Data relating to or comprising Regeneron's proprietary manufacturing technology and processes, including any trade secrets, Chemistry, Manufacturing and Controls information (CMC Data), and Data concerning or arising from test method development, device or delivery system development, assay development, formulation, quality assurance/quality control development, technology transfer, process development and scale-up and cell-line development, and the Government shall have no rights to use such Data independently from this Agreement or to disclose such Data to any third party. Regeneron may designate certain Data concerning its manufacturing activities as Limited Rights Data, in which case the Government shall have Limited Rights in and to such Data. Regeneron will use reasonable efforts to mark any Limited Rights Data delivered under this Project Agreement with appropriate Limited Rights markings.

c. Identification and Disposition of Data

Regeneron shall keep copies of all Data relevant to this Project Agreement as required by the Food and Drug Administration (FDA) for the time specified by the FDA. The Government reserves the right to review any other data determined by the Government to be relevant to this Agreement. The Government further acknowledges that Regeneron holds the commercialization rights for all products developed under this Agreement in the U.S. and will be responsible for their registration with the FDA. This provision is subject to any applicable limitations on the Government's rights under Article VIII.B.a-b of the BARDA OTA.

7.4 REGULATORY RIGHTS

The Contractor agrees to the following:

a. Regulatory Data. Regeneron shall provide to the OTTR and OTAS copies of formal FDA submissions pertaining to the scope of the project, no later than 10 business days before submission to the FDA. For clarity, CMC Data included in such submissions shall be subject to Section 7.3.b.

b. Rights of Reference. Upon mutual agreement, Regeneron will grant to the Government a right of reference to any Regulatory Application submitted in support of this Project Agreement, solely for the purpose of the Government conducting a clinical trial with the drug product supplied under this Project Agreement under a protocol approved by Regeneron for performance by the Government. In such a case, Regeneron agrees to provide a letter of cross-reference to the Government and file such letter with the appropriate FDA office. Nothing in this paragraph reduces the Government's data rights as articulated in other provisions of this award.

c. Clause 7.4.b. will survive the acquisition or merger of the Contractor by or with a third party. This clause will survive the expiration of this contract.

7.5 PREP Act Coverage. It is the intent of the Parties that the drug product provided pursuant to this Agreement be covered by the March 10, 2020 declaration under the Public Readiness and Emergency Preparedness Act (PREP Act), 42 U.S.C. § 247d-6d, 85 Fed Reg. 15,198 (March 17, 2020), or any amendments thereto that provides liability protection for such use. Based on an independent review by each of the Parties of the PREP Act Declaration issued by DHHS on March 10, 2020, pursuant to section 319F-3 of the Public Health Service Act (42 U.S.C. 247d-6d), and a related advisory opinion issued by the DHHS Office of General Counsel on April 14, 2020, the Parties believe that Regeneron is a covered person eligible for immunity under the PREP Act for activities related to medical countermeasures against COVID-19. To the extent DoD or BARDA is authorized to do so as an Authority Having Jurisdiction, the Government designates Regeneron as a covered person eligible for immunity under the PREP Act Declaration issued by DHHS on March 10, 2020, pursuant to section 319F-3 of the Public Health Service Act (42 U.S.C. 247d-6d), for activities related to medical countermeasures against COVID-19. The Government further warrants that the drug product provided pursuant to this Project Agreement will not be (a) sold to any entity nor will it be returned after acceptance under the terms of this contract or (b) distributed or used, or authorized for distribution or use, outside the United States or to the extent such activities are not protected from liability under an active PREP Act declaration.

7.6 Transparency. To the extent permitted under applicable laws, the Government will provide Regeneron in a timely manner copies of reports concerning this Project Agreement that are provided to other Government agencies or legislative or executive branches of the government.

8.0 SECURITY

The security classification level for this effort is UNCLASSIFIED.

9.0 MISCELLANEOUS REQUIREMENTS (SAFETY, ENVIRONMENTAL, ETC.)

N/A

10.0 GOVERNMENT FURNISHED PROPERTY/MATERIAL/INFORMATION

None

11.0 AGREEMENTS OFFICER'S REPRESENTATIVE (AOR) AND ALTERNATE AOR CONTACT INFORMATION

AOR

NAME: (b) (6)
EMAIL: (b) (6)
PHONE: (b) (6)
AGENCY NAME/DIVISION/SECTION: HHS/ASPR/BARDA

Alternate AOR

NAME:
MAILING ADDRESS:
EMAIL:
PHONE:
AGENCY NAME/DIVISION/SECTION:

Requiring Activity:
US Department of Health & Human Services (HHS), Assistant Secretary for Preparedness and Response (ASPR), Biomedical Advanced Research and Development Authority (BARDA)

Definitions Appendix

Computer Software:

To perform and further this Project Agreement:

Computer programs that comprise a series of instructions, rules, routines, or statements, regardless of the media in which recorded, that allow or cause a computer to perform a specific operation or series of operations; and

Recorded information comprising source code listings, design details, algorithms, processes, flow charts, formulas, and related material that would enable the computer program to be produced, created, or compiled.

Does not include computer databases or computer software documentation.

Data: Means recorded information, regardless of form or the media on which it may be recorded. The term includes technical data and Computer Software. The term does not include information incidental to contract administration, such as financial, administrative, cost or pricing, or management information.

Field: The development of anti-pathogen assets to treat, diagnose or prevent emerging infectious diseases.

Government: The United States of America, as represented by the Department of Health & Human Services ("Government"), Office of the Assistant Secretary for Preparedness & Response ("ASPR"), Office of Biomedical Advanced Research and Development ("BARDA") (represented by Office of Acquisition Management, Contracts and Grants (AMCG)).

Government Purpose: Any activity in which the United States Government is a party, including cooperative agreements with international or multi-national defense organizations, or sales or transfers by the United States Government to foreign governments or international organizations. Government purposes include competitive procurement, but do not include the rights to use, modify, reproduce, release, perform, display, or disclose technical data for commercial purposes or authorize others to do so.

Government Purpose Rights: The rights by Government to—

1. Use, modify, reproduce, release, perform, display, or disclose technical data within the Government without restriction; and

2. Release or disclose technical data outside the Government and authorize persons to whom release or disclosure has been made to use, modify, reproduce, release, perform, display, or disclose that data for United States Government Purpose.

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

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. 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 the Data outside the Government, use the Data for competitive procurement or manufacture, release or disclose the data for commercial purposes, or authorize the Data to be used by another party. The Parties shall maintain the confidentiality of all Data subject to or designated as falling within Limited Rights.

Limited Rights Data: Data, other than Computer Software, that embody trade secrets or are commercial or financial and confidential or privileged, to the extent that such Data pertain to items, components, or processes developed at private expense, including minor modifications.

Made: The conception or first actual reduction to practice of the invention as defined in this Agreement.

Option: An option, entered into by bilateral agreement pursuant to a Statement of Work and budget, by which, for a specified time, the Government may elect to purchase additional supplies or services called for by the Agreement.

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 assists and represents the OTAO. The OTAO is the only official who can bind the Government.

Other Transaction Agreement Technical Representative ("OTTR"): Is the primary Government official for all technical matters on the Agreement.

Practical Application: With respect to a Subject Invention, to manufacture, in the case of a composition or 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 as to establish that the Subject Invention is capable of being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public for a regulatory approved product.

Subject Invention: Any Invention Made in the performance of work under this Agreement within the Field for which Recipient pursues a patent.

Sub-Recipient: Akin to a subcontractor. Any supplier, distributor, vendor, or firm that furnishes supplies or services to or for the Recipient, an Affiliate, or a Sub-Recipient. A Sub-Recipient differs from an Affiliate in that Sub-Recipients are not listed as an Affiliate in Attachment 3 and may be used to execute tasks under the SOW by Recipient or Affiliate.

Sub-Recipient Agreement: Any contract entered into by a Sub-Recipient to furnish supplies or services for performance of this Agreement. This term describes an agreement with a 1st-Tier Sub-Recipient, except as expressly noted in this Agreement.

ARTICLE XVII. SECURITY & OPSEC

The below language shall be used as Paragraph 6 of Article XVII in Regeneron's Base Agreement.

(6) Access and General Protection/Security Policy and Procedures. This standard language text is applicable to ALL PAH employees working on critical program information or covered defense information related to Operation Warp Speed (OWS), and to those with an area of performance within an Army controlled installation, facility or area. PAH employees shall comply with applicable installation, facility and area commander installation/facility access and local security policies and procedures (provided by government representative). The PAH also shall provide all information required for background checks necessary to access critical program information or covered defense information related to OWS, and to meet installation access requirements to be accomplished by installation Provost Marshal Office, Director of Emergency Services or Security Office. The PAH workforce must comply with all personal identity verification requirements as directed by DOD, HQDA and/or local policy. In addition to the changes otherwise authorized by the changes clause of this agreement, should the Force Protection Condition (FPCON) at any individual facility or installation change, the Government may require changes in PAH security matters or processes.