OTHER TRANSACTION AUTHORITY FOR PROTOTYPE
AGREEMENT BETWEEN

60 Degrees Pharmaceuticals, LLC. (Awardee)
1025 Connecticut Ave NW Ste 1000
Washington, DC 20036-5417
DUNS: 079146968
CAGE Code: 71D06
And
NATICK CONTRACTING DIVISION (Government)
110 Thomas Johnson Dr.
Frederick, MD 21702

Effective Date:

Agreement No.: W911QY-21-9-0011

Total Amount of the Agreement: $4,999,814.00

Awardee	**Government**
(b) (6)	(b) (6)
Signature	**Signature**
(b) (6)	(b) (6)
Printed Name	Printed Name
CEO	**Agreements Officer**
Title	Title
4 December 2020	4 December 2020
Date	Date

This Other Transaction Authority for Prototype Agreement is entered into between the United States of America, hereinafter called the "Government", pursuant to and under U.S. Federal law, and 60 Degrees Pharmaceuticals LLC. a small business, non-traditional defense contractor, hereinafter called the "Awardee". The United States of America and Awardee are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

WHEREAS, the Awardee is eligible for an Other Transaction Authority for Prototype Agreement in accordance with 10 USC § 2371b(d)(1)(A) as amended by the National Defense Authorization Act for Fiscal Year 2018 as they are non-traditional defense contractor, as confirmed by their attestation;

WHEREAS, in accordance with 10 U.S.C. 2371b, The Department of Defense currently has authority to award "other transactions" (OTs) in certain circumstances for prototype projects that are directly relevant to enhancing the mission effectiveness of military personnel and the supporting platforms, systems, components, or materials proposed to be acquired or developed by the Department of Defense, or to improvement of platforms, systems, components, or materials in use by the Armed Forces. To the maximum extent practicable, competitive procedures shall be used when entering into agreements to carry out projects under subsection (a);

WHEREAS, a prototype project can generally be described as a proof of concept, model, reverse engineering to address obsolescence, pilot, novel application of commercial technologies for defense purposes, agile development activity, creation, design, development, demonstration of technical or operational utility, or combinations of the foregoing;

WHEREAS, this Agreement meets the criteria for a prototype project;

NOW THEREFORE, the Parties have agreed as follows:

ARTICLE 1. Scope.

A. This Other Transaction Authority for Prototypes Agreement (the "Agreement") is entered into between the Government and the Awardee on the Effective Date set forth above. For the avoidance of doubt, this Agreement is entered into pursuant to 10U.S.C. § 2371b and is not a procurement contract governed by the Federal Acquisition Regulation (FAR), a grant, or cooperative agreement. The FAR and the Defense Federal Acquisition Regulation Supplement (DFARS) apply only as specifically referenced herein. This Agreement is not intended to be, nor will it be construed as, forming, by implication or otherwise, a partnership, a corporation, or other business organization. This Agreement is not subject to the Bayh-Dole Act, 35 U.S.C. §§ 200- 12.

B. The Parties agree that the ultimate purpose of this Agreement is to deliver (b) (4) with an FDA Emergency Use Authorization (EUA) approved as a countermeasure against COVID-

19 (hereinafter referred to as the "the Prototype or Protoype Project." The objectives include; all activities for a Phase II clinical trial to assess the safety and efficacy of (b) (4) for the treatment of mild to moderate COVID-19 disease. The Awardee shall develop the Prototype Project as described in the Awardee's Statement of Work (SOW), which is incorporated herein and attached hereto as Appendix A.

C. Upon the Government's determination that the Prototype Project under this Agreement has been successful and meets the key technical requirements listed in the SOW, or at the accomplishment of particularly favorable or unexpected results related to the safety or efficacy of the product that justify transition to production, this Agreement may result in the award of a follow on production without the use of competitive procedures pursuant to 10 U.S.C. 2371b(f) for a quantity up to 10 Million courses of treatment executed under a separate agreement or contract.

ARTICLE 2. Term and Termination.

A. Term: The Term of this Agreement commences upon the Effective Date and extends through final payment. This Agreement is anticipated to end 12 months after the Effective Date, subject to completion of the Prototype Project. A transaction for the Prototype Project is complete upon the written determination of the appropriate official for the matter in question that efforts conducted under a Prototype OT: (1) met the key technical goals of a project or (2) accomplished a particularly favorable or unexpected result that justifies the completion of the prototype.

B. Termination for Convenience: The Government may terminate this Agreement for any or no reason by providing at least thirty (30) calendar days' prior written notice to the Awardee. The Government and Awardee will negotiate in good faith a reasonable and timely adjustment of all outstanding issues between the Parties as a result of termination by the Government for convenience, consistent with the terms of this Agreement.

C. Termination for Cause: If the Awardee materially fails to comply with the provisions of this Agreement, the Other Transaction Agreement Officer (OTAO), after issuance of a cure notice and failure of the Awardee to cure the defect (i) within ten (10) calender days (if defect cannot be cured within ten (10) calender days, take reasonable action to cure within ten (10) calender days),or (ii) the time allowed by the OTAO after Awardee's receipt of the cure notice, whichever is longer; the Government may take one or more of the following actions as appropriate:

(i) temporarily withhold payments pending correction of the deficiency,
(ii) disallow all or part of the cost of the activity or action not in compliance,
(iii)wholly or partly suspend or terminate this Agreement,
(iv)withhold further funding,
(v) require Awardee to pay repurchase costs as defined in Article 2C1, Repurchase Against

Contractors Account, or
(vi) take any other legally available remedies.

For the avoidance of doubt, Awardee is not in breach of this Agreement for the failure of Awardee to produce a successful Prototype Project provided Awardee complies with the other provisions of this Agreement.

If, after the Agreement is terminated for Cause, it is determined that the Awardee had not materially failed to comply with the provisions of this Agreement ("cause"), or that the material failure was excusable, the rights and obligations of the parties shall be the same as if the termination had been issued for the convenience of the Government under Article 2.B.

Notwithstanding this Article 2.C, the Government's rights and Awardee's obligations under this paragraph will cease to exist if the Government terminates this Agreement for any reason other than for Awardee's failure to materially comply with the terms of this Agreement.

D. Survival: In the event of Termination, all rights, obligations, and duties hereunder, which by their nature or by their express terms extend beyond the expiration or termination of this Agreement, including but not limited to warranties, indemnifications, intellectual property (including rights to and protection of Intellectual Property and Proprietary Information), and product support obligations shall survive the expiration or termination of this Agreement.

ARTICLE 3. Project Management.

A. Program Governance: The Awardee is responsible for the overall management of the project development program and related program decisions. The Awardee will likewise be the FDA sponsor of any regulatory application contemplated by this agreement. The Government will have continuous involvement with the Awardee. The Awardee shall provide access to project results in accordance with the Awardee's Project Timeline located in Appendix A.

B. Project Managers: The Awardee and the Government will each designate a Project Manager responsible for facilitating the communications, reporting, and meetings between the Parties. Each Party will also designate an alternate to the Project Manager, in case the primary Project Manager is unavailable. See Project Manager/Alternate Project Manager point of contact information for each respective party below:
Awardee Project Managers

Primary Project Manager:	Alternate Project Manager:
(b) (6)	

(b) (6)

Government Project Managers (GPM)

Primary Project Manager:	Alternate Project Manager:
(b) (6)	

C. Key Personnel: The Awardee's organization shall be established with authority to effectively develop the Prototype. This organization shall become effective upon execution of this Agreement and its integrity shall be maintained until completion or acceptance of the effort by the Government. The key personnel listed in Appendix C are considered to be critical to the successful performance of this Agreement. Prior to replacing these key personnel, the Awardee shall provide written notification to the OTAO with an opportunity to approve, the approval of which will not be unreasonably withheld. The Awardee shall demonstrate that the qualifications of the proposed substitute personnel are generally equivalent to or better than the qualifications of the personnel being replaced.

D. Subaward Approval: Modifications to subawards and/or new subcontracts under this Agreement that could reasonably impact the technical approach proposed and accepted by the Government require the approval of the OTAO prior to being executed.

E. The OTAO has assigned an Agreements Officer's Representative (AOR) for this agreement. The Awardee will receive a copy of the written designation outlining the roles and responsibilities of the AOR and specifying the extent of the AOR's authority to act on behalf of the OTAO. The AOR is not authorized to make any commitments or changes that will affect price, quality, quantity, delivery, or any other term or condition of the contract.

ARTICLE 4. Agreement Administration.

In no event shall any understanding or agreement, modification, change order, or other matter in deviation from the terms of this Agreement between the Awardee and a person other than the OTAO be effective or binding upon the Government. All such actions must be formalized by a proper contractual document executed by the OTAO.

Government Representatives:
Other Transaction Agreements Officer (OTAO)
(b) (6)
ACC-APG-Fort Detrick

110 Thomas Johnson Dr.
Frederick, MD 21702
(b) (6)

Other Transaction Agreement Specialist (OTAS)
(b) (6)
ACC-APG-Fort Detrick
110 Thomas Johnson Dr.
Frederick, MD 21702
(b) (6)

Agreements Officer Representative (AOR):
(b) (6)
COVID-19 Repurposing PM
Joint Project Manager - Chemical, Biological, Radiological, and Nuclear Medical (JPM CBRN Medical)
1564 Freedman Drive
Fort Detrick, MD 21702
(b) (6)

Awardee Representatives:
(b) (6)
Chief Medical Officer
60 Degrees Pharmaceuticals, LLC
Email:
(b) (6)

ARTICLE 5. Performance Objectives and Changes.

A. Statement of Work (SOW): The SOW, Appendix A, describes the scope of activities that will be undertaken by the Awardee to achieve the objective.

B. Recommendations for Modifications: At any time during the term of this Agreement, progress

or results may indicate that a change in the SOW would be beneficial to the project objectives. Recommendations for modifications, including justifications to support any changes to the SOW, will be documented in a letter and submitted by Awardee to the GPM with a copy to the OTAO. This letter will detail the technical, chronological and financial impact, if any, of the proposed modification to the project. Any resultant modification is subject to the mutual agreement of the Parties. The Government is not obligated to pay for additional or revised costs unless and until this Agreement is formally revised by the OTAO and made part of this Agreement. Any modification to this Agreement to account for recommended changes in the SOW or Payable Milestones will be considered a supplemental agreement.

C. Review of Recommendations: The OTAO will be responsible for the review and verification of any recommendations to revise or otherwise modify the Agreement, the SOW, the milestone payments, or other proposed changes to the terms and conditions of this Agreement.

D. Minor Modifications: The Government may make minor or administrative Agreement modifications unilaterally (e.g., changes in the paying office or appropriation data, changes to Awardee personnel proposed by Awardee, etc.).

E. Amending the Agreement: The Government will be responsible for effecting all modifications to this Agreement, with the concurrence of the Awardee for modifications that are not minor or administrative. Administrative and material matters under this Agreement will be referred to OTAO.

F. Modification Communications: No other communications, whether oral or in writing, that purport to change this Agreement are valid.

G. Government Property: If applicable, terms and conditions applicable to Government Property shall be incorporated through Appendix D.

E. Disputes: For any disagreement, claim, or dispute arising under this Agreement, the parties shall communicate with one another in good faith and in a timely and cooperative manner. Whenever disputes, disagreements, or misunderstandings arise, the parties shall attempt to resolve the issue by discussion and mutual agreement as soon as practicable. Failing resolution by mutual agreement, the aggrieved party shall request a resolution in writing from the OTAO. The OTAO will review the matter and render a decision in writing within sixty (60) calendar days. Thereafter, either party may pursue any right or remedy provided by law in a court of competent jurisdiction as authorized by 28 U.S.C. 1491, or 41 U.S.C. Chapter 71 using the procedures set forth in FAR 52.233-1, Disputes. Alternately, the parties may agree by mutual consent to explore and establish and Alternate Disputes Resolution procedure to resolve this dispute. The Awardee shall proceed diligently with performance under this agreement pending resolution of the dispute.

ARTICLE 6. Inspection/Acceptance

A. Inspection: The Government has the right to inspect and test all work called for by the agreement, to the extent practicable at all places and times, including the period of performance, and in any event before acceptance. With reasonable notice, the Government may also inspect the premises of the Awardee or any subawardee engaged in agreement performance. The Government shall perform inspections and tests in a manner that will not unduly delay the work. If the Government performs any inspection or test on the premises of the Awardee or a subawardee, the Awardee shall furnish and shall require subawardees to furnish, at no increase in agreement price, all reasonable facilities and assistance for the safe and convenient performance of these duties. Except as otherwise provided in the Agreement, the Government shall bear the expense of Government inspections or tests made at other than the Awardee's or subawardee's premises.

B. The Government shall accept or reject the work as promptly as practicable after completion/delivery, unless otherwise specified in the Agreement. Government failure to inspect and accept or reject the work shall not relieve the Awardee from responsibility, nor impose liability on the Government, for nonconforming work. Work is nonconforming when it is defective in material or workmanship or is otherwise not in conformity with Agreement requirements. The Government has the right to reject nonconforming work.

ARTICLE 7. Financial Matters

A. This Agreement is an expenditure type Other Transaction Authority agreement. The payments provided under this Agreement are intended to compensate the Awardee on a cost basis for performance under this Agreement. The Awardee shall provide its commercially reasonable efforts to complete a Prototype Project based on the estimated cost. Payments are based on amounts generated from the Awardee's financial or cost records.

B. Payment. Payments are based on amounts generated from the Awardee's financial or cost records. The Awardee shall be reimbursed for each element identified in the awarded cost proposal, executed and accomplished in accordance with the performance schedule set forth in Appendix B. The schedule is predicated upon the Government's fiscal year, which begins on October 1 of each year, and ends on September 30 of the subsequent calendar year.

C. Obligation. Under no circumstances shall the Government's financial obligation exceed the amount obligated in this Agreement or by amendment to the Agreement. The amount of Government funds obligated by this Agreement and available for payment is set forth in the supplemental administration (PD2 generated) version of the agreement, and any subsequent modifications. The Government may incrementally fund this agreement.

D. The Government is not obligated to provide payment to the Awardee for amounts in excess of the amount of obligated funds allotted by the Government.

E. . The Government shall pay the Awardee, upon submission of proper invoices, the costs stipulated in Article 7B of this Agreement, less any deductions provided in this Agreement. Payments will be made within thirty (30) calendar days of receipt of a request for payment.

F. Prior written approval by the OTAO, or the AOR, is required for all travel directly and identifiably funded by the Government under this agreement. The Awardee shall present to the OTAO or AOR, an itinerary for each planned trip, showing the name of the traveler, purpose of the trip, origin/destination, dates of travel, and estimated cost broken down by line item as far in advanced of the proposed travel as possible, but no less than two weeks before travel is planned to commence. In the event that emergency travel is required (e.g. in the event of an outbreak) that would make two weeks' notice impractical, travel requests may be submitted to the Government for an expedited review. Emergency travel requests shall be labelled as such and shall include a brief summary of the emergency situation and rationale for expedited review.

G. WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS

(a) Definitions. As used in this clause--

Department of Defense Activity Address Code (DoDAAC) is a six position code that uniquely identifies a unit, activity, or organization.

Document type means the type of payment request or receiving report available for creation in Wide Area WorkFlow (WAWF).

Local processing office (LPO) is the office responsible for payment certification when payment certification is done external to the entitlement system.

(b) Electronic invoicing. The WAWF system is the method to electronically process vendor payment requests and receiving reports, as authorized by DFARS 252.232- 7003, Electronic Submission of Payment Requests and Receiving Reports.

(c) WAWF access. To access WAWF, the Awardee shall (i) have a designated electronic business point of contact in the System for Award Management at https://www.acquisition.gov; and (ii) be registered to use WAWF at https://wawf.eb.mil/ following the step-by-step

procedures for self-registration available at this website.

(d) WAWF training. The Awardee should follow the training instructions of the WAWF Web-Based Training Course and use the Practice Training Site before submitting payment requests through WAWF. Both can be accessed by selecting the "Web Based Training" link on the WAWF home page at https://wawf.eb.mil/.

(e) WAWF methods of document submission. Document submissions may be via Web entry, Electronic Data Interchange, or File Transfer Protocol.

(f) WAWF payment instructions. The Awardee must use the following information when submitting payment requests and receiving reports in WAWF for this Agreement:

(1) Document type. The Awardee shall use the following document type: Voucher

(2) Inspection/acceptance location. The Awardee shall select the following inspection/acceptance location(s) in WAWF, as specified by the contracting officer.

(3) Document routing. The Awardee shall use the information in the Routing Data Table below only to fill in applicable fields in WAWF when creating payment requests and receiving reports in the system.

Routing Data Table

Pay Official DoDAAC	**HQ0490**
Issue By DoDAAC	**W911QY**
Admin DoDAAC	**W911QY**
Inspect By DoDAAC	**W56XNH**

(4) Payment request and supporting documentation. The Awardee shall ensure a payment request includes appropriate contract line item and subline item descriptions of the work performed or supplies

delivered, costs, fee (if applicable), and all relevant back- up documentation in support of each payment request.

(5) WAWF email notifications. The Awardee shall enter the email address identified below in the "Send Additional Email Notifications" field of WAWF once a document is submitted in the system.

H. WAWF point of contact.

1. The Awardee may obtain clarification regarding invoicing in WAWF from the following contracting activity's WAWF point of contact.
See above.

2. For technical WAWF help, contact the WAWF helpdesk at 866-618-5988.
(End of Clause)

H. Comptroller General Access to Records: To the extent that the total Government payments under this Agreement exceed $5,000,000, the Comptroller General, at its discretion, shall have access to and the right to examine records of any Party to the Agreement or any entity that participates in the performance of this Agreement that directly pertain to, and involve transactions relating to, the Agreement for a period of three (3) years after final payment is made. This requirement shall not apply with respect to any Party to this Agreement or any entity that participates in the performance of the Agreement, or any subordinate element of such Party or entity, that has not entered into any other agreement (contract, grant, cooperative agreement, or "other transaction") that provides for audit access by a government entity in the year prior to the date of this Agreement. This paragraph only applies to any record that is created or maintained in the ordinary course of business or pursuant to a provision of law. The terms of this paragraph shall be included in all sub-agreements to the Agreement other than sub-agreements with a component of the U.S. Government. The Comptroller General may not examine records pursuant to a clause included in an agreement more than three years after the final payment is made by the United States under the agreement.

ARTICLE 8. Report and Data Requirements

A. Weekly Teleconferences and Communication

Awardee shall conduct weekly teleconferences with the Government throughout the performance of the Agreement to discuss tasks accomplished and direction for the upcoming tasks. Awardee shall provide agendas and read-ahead material as required two days prior to the meetings and shall provide minutes of each meeting to the Government. Awardee shall include key subcontractors as attendees at these teleconferences when applicable. The Awardee shall provide meeting minutes within three (3) business days after each formal scheduled meeting/teleconference conducted with JPEO Medical.

B. Monthly Progress Reports

The Awardee shall submit a Monthly Progress report within twenty (20) calendar days after the

end of each month of performance. The report shall contain the technical progress made during the previous period and the updated resource loaded Integrated Master Schedule (IMS) in Microsoft Project format. The schedule update shall include the explanation for any changes in the schedule, and drivers for the changes, as applicable. The report should also address any concerns that would impact the performance, schedule, or cost planned for the effort. The Awardee shall report risk matrix format to include risk mitigation strategies. Note: Any identified changes require formal notification to the OTAO in accordance with the Agreement provisions.

In addition, the Monthly Progress Report shall contain regular status updates of all Intellectual Property (IP) license(s) related to the effort to ensure that all license(s) are in good standing as the project progresses. In the event of any change in IP license(s) status or potentially imminent change in status, the Awardee shall immediately contact the OTA and GPM in writing.

The Government will have ten (10) calendar days to respond to the report with any comments and the Awardee will have an additional five (5) calendar days to revise the report or respond to those comments.

C. Monthly Financial Status Report

The Awardee shall submit a Monthly Financial Status Report no later than twenty (20) calendar days after the end of each month of performance. The Government will have ten (10) calendar days to respond to the report with any comments and the Awardee will have an additional ten (10) calendar days to revise the report or respond to those comments. Reports will cover work performed monthly for the duration of the Period of Performance (PoP).

In addition, the Financial Status Report shall include expenditure forecasts with both the monthly planned accrual and the cumulative total. Expenditure forecast submissions shall include analysis of the cost drivers for Estimate to Complete changes, if any, from the previous projection. The Awardee shall provide all submissions in Excel format, including all formulas.

D. Expenditure Forecasts

The Awardee shall submit the first expenditure forecast within thirty (30) calendar days after receiving the project award. An updated forecast shall be submitted within fifteen (15) calendar days of any project modifications that modify the PoP or the cost of the prototype. Expenditure forecast submissions shall include analysis of the cost drivers for Estimate to Complete changes, if any, from the previous projection. The Awardee shall provide all submissions in Excel format, including all formulas.

E. Final report

A Final Report shall be prepared at the end of the effort by the Awardee. The Final Report shall narrate a complete summary of the project execution and associated results obtained. The narration will include outstanding problems and their potential solutions, problems solved during the course of the agreement, and the solutions to the solved problems. The Final Report shall demonstrate how the prototype was developed and advanced.

The Awardee shall submit a Draft Final Report by the forty-fifth (45th) calendar day following the end of the project. The Government shall provide comments to the Awardee by the thirtieth (30th) calendar day following receipt of the Awardee's Draft Final Report. The Awardee shall submit the Final Report on the thirtieth (30th) calendar day after receipt.

F. Ad Hoc Meetings

In addition to the monthly meetings and written quarterly program updates, additional ad hoc meetings to address specific issues or to convey time-sensitive updates or scientific data related to the program will be held.

G. Patents - Reporting of OTA Invention: The Awardee shall report any OTA Inventions in accordance with the terms and conditions of this Other Transaction Agreement (OTA).

H. Miscellaneous Data Submissions

If applicable, the Awardee must submit to the Government all Point Papers, Briefings, Technical Performance Plans , Program Development Plans (PDP), target product profile (TPP), Regulatory Strategy, Technology Transfer Report and Gap Analysis, Formulation Development, Feasibility and Optimization Reports, United States Army Medical Research and Material Command Animal Care and Use Review Office (USAMRMC ACURO) Approvals, Human Resources Operations Branch (HROB) Approvals, Technical Presentations and Publications, and any formal technical reports that have been prepared for eventual submission to FDA or other regulatory agencies. Examples include the following reports related to: pharmaceutical development, manufacturing development, manufacturing validation, completed batch records, certificates of analysis, analytical development and validation, drug substance and product stability, nonclinical testing, and clinical testing.
Examples include clinical performance and clinical quality documentation.

I. Work Breakdown Structure ("WBS")
Three-level WBS with costs and schedule (top level is program, level two (2) is phase, level three (3) are major tasks). For WBS level two (2), show breakdown for labor, material, and other indirect costs.

WBS shall be updated annually or thirty (30) calendar days after a Statement of Work modification. Government review/approval is fifteen (15) calendar days after receipt of first submittal. Provide changes to draft within ten (10) calendar days of such request. Provide final document within ten (10) calendar days after approval of changes is received.

J. Integrated Master Schedule

The Awardee shall provide within thirty (30) calendar days after project award an IMS in Microsoft Project format. Any updates to the IMS shall be included in the quarterly progress reports.

Submission shall be thirty (30) calendar days after the end of each month of performance. The Government will have ten (10) calendar days to respond to the report with any comments and the performer will have an additional five (5) calendar days to revise the schedule or respond to those comments.

K. Incident Report.

The Awardee shall report any incident to the Government that could result in more than a one month delay in schedule from the most recent IMS critical path delivered to the Government. Telephonically contact the GPM within one day of incident. A written summary report shall be submitted within three (3) business days of an incident, to include, what happened, what was the impact, if there are any available corrective actions and a time line for when the corrective actions would be in place.

L. Quality Management Plan.

Quality Management Plan. Awardee will, in the level of detail and format that the Awardee selects (provided such format provides a reasonable and industry-standard level of detail), provide a quality management plan which may include, but is not limited to, the company's quality policy and objectives, management review, competencies and training, process document control, feedback, evaluation, corrective action and preventive action, process improvement, measurement, and data analysis processes and vendor qualification process. The framework is normally divided into infrastructure, senior management responsibility, resource management, lifecycle management, quality management system evaluation, and procedures to notify the Government when issues arise.

M. Awardee Locations

The Awardee shall submit detailed data regarding locations where work will be performed under this Agreement, including addresses, points of contact, and work performed per location, to

include sub-awardees.

Awardee will submit Work Locations Report:

- Within 5 days of Agreement award
- Within 30 business days after a substantive location or capabilities change
- Within 2 business days of a substantive change if the work performed supports medical countermeasure development that addresses a threat that has been declared a Public Health Emergency by the HHS Secretary or a Public Health Emergency of International Concern (PHEIC) by the WHO

ARTICLE 9. Most Favored Customer

A. (b) (4)

C. This Article applies only to products sold in the (b) (4) related to COVID-19.

ARTICLE 10. Confidential Information

A. Definitions

i. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

ii. The Agreements Officer and the Awardee may, by mutual consent, identify elsewhere in this Agreement specific information and/or categories of information which the Government will furnish to the Awardee or that the Awardee is expected to generate which is confidential. Similarly, the Agreements Officer and the Awardee may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

iii. If it is established elsewhere in this Agreement that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Awardee will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

iv. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

v. Whenever the Awardee is uncertain with regard to the proper handling of material under the Agreement, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Awardee shall obtain a written determination from the Agreements Officer prior to any release, disclosure, dissemination, or publication.

vi. Agreements Officer Determinations will reflect the result of internal coordination with appropriate program and legal officials.

vii. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

All above requirements MUST be passed to all Sub-awards.

ARTICLE 11. Intellectual Property Rights

Awardee represents that the rights held by or granted to Awardee, including all intellectual property licenses, are sufficient to enable Awardee to perform its oblications under this Agreement

A. **Background IP and Materials**. Regardless of any other clause in this Agreement, the Awardee and the Government each retain any intellectual property (IP) rights to their own materials, data, technology, information, documents, or know-how—or potential rights, such as issued patents, patent applications, invention disclosures, or other written documentation—that exist prior to execution of this Agreement or are developed outside the scope of this Agreement (Background IP). Additionally, during the term of this Agreement, neither Party to the Agreement will enter

into an agreement with any contract manufacturer or other third party, other than a Government-approved subawardee, whereby the third party will obtain rights in OTA Inventions or Study Data, as those terms are defined in this Agreement, absent the mutual consent of the Parties, such consent not to be unreasonably withheld, conditioned or delayed.

B. **Awardee's Background IP**. Awardee warrants that it has filed patent application(s), has issued patents, or is the assignee of issued patent(s) listed below which contain claims that are related to research contemplated under this Agreement. No license(s) to any patent applications or issued patents identified as Background IP shall be granted under this Agreement.

PSBN	(b) (4)		

C. **Government's Background IP**. The Government warrants that it has no Background IP and therefore lists "None".

D. **OTA Inventions.** Ownership of any invention, regardless of whether it is not patentable, or is patentable under U.S. patent law that is conceived or first reduced to practice under this Agreement ("OTA Invention") will follow inventorship in accordance with U.S. patent law. The Bayh-Dole Act, 35 U.S.C. §§ 200-212 does not apply to this Agreement and, as such, title to inventions will accrue to the inventor or inventor-organization. The Parties represent and warrant

that each inventor will assign his or her rights in any such inventions to his or her employing organization. If either an Awardee employee or a Government employee makes a sole OTA Invention, the entire rights to that OTA Invention will be respectively assigned to the Awardee or the Government. If an Awardee employee and a Government employee jointly make an OTA invention, it will be owned jointly by the Awardee and the Government. Ownership of inventions made in whole or in part with subawardee or collaborator employees, including employees of other components of the Government, will be determined solely pursuant to an agreement between the Awardee and the applicable subawardee or collaborator.

E. Patent Applications. Each Party shall report any Agreement Inventions to the other Party within 60 days of the time the inventor discloses it in writing to its personnel responsible for patent matters. The Parties will respectively have the option to file a patent application claiming any OTA Invention made solely by their respective employees. The Parties will consult with each other regarding the options for filing a patent application claiming a joint OTA Invention. Within forty-five (45) calendar days of being notified of the discovery of an OTA invention or filing a patent application covering an OTA Invention, each Party will provide notice of such discovery or filing to the other Party. The Parties will reasonably cooperate with each other in the preparation, filing, and prosecution of any patent application claiming an OTA Invention. Any Party filing a patent application will bear expenses associated with filing and prosecuting the application, as well as maintaining any patents that issue from the application, unless otherwise agreed by the Parties.

F. Patent Prosecution. Awardee agrees to take responsibility for the preparation, filing, prosecution, and maintenance of any and all patents and patent applications listed as Awardee Background IP that are relevant to the work performed under this Agreement. Awardee shall keep the Government reasonably advised on the status of Awardee Background IP by providing an annual report on the status of Awardee Background IP. Prior to acting on a decision by Awardee to abandon or not file in any country a patent or patent application covering an OTA Invention, which is defined below, Awardee shall so inform the Government in a timely manner to allow Awardee to thoughtfully consider the Government's comments regarding such a proposed decision. Nothing in this ARTICLE shall restrict the Government in its preparation, filing, prosecution and maintenance of a patent or patent application covering an OTA Invention solely owned by it.

G. Patent Indemnity. The Awardee shall indemnify the Government and its officers, employees and agents against liability, including costs, for actual or alleged direct or contributory infringement of, or inducement to infringe, any United States or foreign patent, trademark or copyright, arising out of this Agreement, provided the Awardee is reasonably notified of such claims and proceedings.

H. Patent Enforcement. Awardee will have the first option to enforce any patent rights covering an OTA Invention owned jointly by the Parties or solely by Awardee, at Awardee's expense. If Awardee chooses not to exercise this option, the Government may enforce patent rights covering a joint OTA Invention only with Awardee's prior written approval.

I. Licenses. The Awardee asserts that no Government funding was used to finance, develop or acquire the Background IP identified in Article 11.B. above. Therefore, Recipient does not grant to the Government any license to the Background IP identified in Article 11.B above. Upon the Awardee's request, the Government agrees to enter into good faith negotiations with the Awardee regarding the Awardee's receipt of a nonexclusive commercialization license covering the Government's interest in any OTA Invention made solely by a Government employee. Any OTA Invention made solely by an Awardee employee is subject to a nonexclusive, nontransferable, irrevocable, paid-up license for the Government to practice and have practiced the OTA Invention on behalf of the Government.

J. Executive Order No. 9424 of 18 February 1944 requires all executive Departments and agencies of the Government to forward through appropriate channels to the Commissioner of Patents and Trademarks, for recording, all Government interests in patents or applications for patents.

ARTICLE 12. Data Rights

A. Background Data. "Background Data" shall mean all technical data, as defined in 22 C.F.R. § 120.10, that exists prior to execution of this Agreement, or are developed outside the scope of this Agreement. Recipient's Background Data includes, but is not limited to, the following technical data, to the extent such data exists prior to execution of this Agreement or is developed outside the scope of this Agreement.

*(b) (4)

B. Subject Data. All data generated in connection with the performance of the studies under this Agreement, or that arises out of the use of any materials or enabling technology provided or used by the Awardee in the performance of this Agreement, other Awardee materials or Awardee confidential information, whether conducted by the Government or the Awardee (collectively, the "Subject Data"), shall be owned by the Awardee.

The USG shall have an "Unlimited rights" licensed (as defined by DFARS 252.227-7013) to any Subject Data.
Any background technical data delivered with less than unlimited rights shall be subject to a "Government Purpose Rights" (GPR) license (as defined by DFARS 252.227-7013); subject to negotiation for any data delivered with less than GPR. The U.S. Government may purchase, under a separate agreement or modification of this agreement, a license for greater use of background technical data as necessary. Such agreement will be negotiated in good faith at customary industry rates and under reasonable terms and conditions.

The Awardee agrees to retain and maintain in good condition until seven (7) years after completion or termination of this Agreement, all data generated under this Agreement. In the event of exercise of the Government's rights as potentially granted under paragraph 2.C, the Awardee agrees to deliver at no additional cost to the Government, all data, in Awardee's possession and developed under this Agreement, necessary to develop the Prototype within sixty (60) calendar days from the date of the written request.

C. Marking of Data: The Awardee will mark any data delivered under this Agreement with the following legend:

"Use, duplication, or disclosure is subject to the restrictions as stated in Agreement No. W911QY-21-9-0011 between the Government and the Awardee."

Any rights that the Awardee or the Government may have in data delivered under this Agreement, whether arising under this Agreement or otherwise, will not be affected by Awardee's failure to

mark data pursuant to this Article.

Any distribution markings shall be established by the Government Project Manager and incorporated prior to distribution.

D. All Subject Data meeting the definitions of "Technical Data" and "Software" (each term as defined under DFARS 252.227- 7013) which shall be delivered under this Agreement with less than unlimited rights shall be identified in reasonable specificity and particular rights granted (Government Purpose, Limited or Restricted (all as defined in DFARS 252.227-7013)) prior to entering into the Agreement. All other Technical Data and Software developed under funding of this agreement shall be delivered with unlimited rights as provided for within this Article.

ARTICLE 13. Regulatory Rights

This agreement includes research with an drug, biologic or medical device that is regulated by the U.S. Food and Drug Administration (FDA), and requires FDA pre-market approval or clearance before commercial marketing may begin for the COVID-19 indication. It is expected this agreement will result in the FDA clearance and commercialization of product(s) for the treatment of COVID 19 infection.The Awardee is the Sponsorof the Regulatory Application (an Investigational New Drug Application (IND), Investigational Device Exemption (IDE), New Drug Application (NDA), Biologics License Application (BLA), Premarket Approval Application (PMA), or 510(k) pre-market notification filing (510(k)) or another regulatory filing submitted to FDA), that controls research under this agreement. The Sponsor- of the Regulatory Application to FDA (as the terms "sponsor", "sponsor-investigator", and "applicant" are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20), has certain standing before the FDA that entitles him to exclusive communications related to the Regulatory Application.

The Awardee agrees to the following:

A. **Government Regulatory Representatives**: The Senior Director Medical Regulatory (SDMR) is the JPEO-CBRND and DTRA-JSTO representative for all regulatory and quality activities. The Awardee shall coordinate with the SDMR prior to communicating or meeting with the FDA, or other regulatory authorities, as appropriate for this OTA Project. The Awardee shall invite the SDMR to observe all FDA meetings and regulatory discussions applicable to this OTA Project.

B. **Obligations of the Sponsor-Investigator and SDMR**:The IND Sponsor-Investigator shall submit a letter to FDA indicating the SDMR as a co-contact and that FDA is authorized to contact SDMR for DoD regulatory/policy input, as needed for this development effort. This notice could be part of the PL 115-92 authorization letter described below. In this circumstance and to the maximum extent practicable, the Government will include the Sponsor in any and all meetings and correspondence with the FDA. If it is not practicable to include the Sponsor in any

interaction with the FDA, the Government will provide a summary of the interaction to the Sponsor within ten (10) business days.

C. **Regulatory Submissions**: The Awardee will provide to the Government all data, including top-line summaries and key conclusions from all studies supporting the regulatory filing and commercial approval to the extent that such data, summaries, and conclusions are funded by this Agreement. In addition, the Awardee will offer the Government the opportunity to review and provide comments on a final draft of regulatory submissions, which include data funded by this Agreement. The Government will review any such submissions (i.e., the IND) promptly upon receipt. The Awardee will reasonably consider any comments provided by the Government, and prior to submission will provide notification to the Government of any additional edits or revisions. The Awardee will keep the Government apprised of planned FDA meetings and post-meeting outcomes relating to activities funded by this Agreement.

D. **Regulatory Communications**: The Awardee will provide the Government with copies of all communications, both formal and informal, to or from FDA, regarding the Technology within 48 hours, and ensure that the Government representatives are invited to participate in any formal or informal Sponsor-Investigator meetings with FDA, as appropriate for this OTA Project;

E. **Public Law 115-92 Sponsor Authorization Letter/ DoD Medical Product Priority**: Public Law 115-92 allows the DoD to request, and FDA to provide, assistance to expedite development of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel. The Awardee recognizes that only the DoD can utilize Public Law 115-92. As such, the Awardee will work proactively with the SDMR to leverage this law to its maximum potential under this Project Agreement.

   (i) The Awardee shall submit to the Government, within thirty (30) days of project award, a fully executed sponsor authorization letter enabling FDA to disclose information to JPEO-CBRND and its Government support contractors related to the proposed product under Public Law 115-92. A template for the sponsor authorization letter was included in Appendix E.

   (ii) JPEO-CBRND shall formally submit the executed letter to the FDA under the Regulatory Application, only if the proposed product becomes a DoD medical product priority under Public Law 115-92.

   (iii) If the product becomes a DoD medical product priority, to the maximum extent practicable, JPEO-CBRND will include the Awardee in any and all meetings and correspondence conducted with the FDA under Public Law 115-92. If it is not practicable to include the Awardee in any Public Law 115-92 interaction with the FDA regarding the product (for example, discussions conducted at quarterly or semi-annual DoD-FDA meetings mandated by the Public Law), JPEO-CBRND will provide a summary of the interaction to the Awardee within ten (10) business days.

   (iv) **Deliverable(s)**: Public Law 115-92 Sponsor Authorization Letter.

F. **Rights of Reference**. Recipient hereby grants to the Government and its permitted sublicensees a limited "right of reference or use" (as that term is defined in 21 C.F.R. § 314.3(b), as amended

from time to time) to Recipient's filings to the FDA in connection with the Regulatory Application strictly for COVID-19 or other Material Threat (as defined at Section 319 of the Public Health Service Act) purposes. The Recipient shall provide appropriate notification of the Government's access and reference rights to the applicable regulatory authorities requested by the Government for the limited purposes described above. Recipient agrees to provide a letter of cross-reference to the Government and file such letter with the appropriate FDA office. The USG will agree to any reasonable request for information connected to its reliance on the right of reference provided under this Section. This provision is in addition to any rights in technical data described earlier in this document.

G. **Product Development Failure:**

1. The Parties acknowledge the Government's need to develop a COVID-19 treatment to protect the United States population and the Government's significant funding assessing the safety and efficacy of t(b) (4) for the treatment of COVID-19 under this Agreement. In the event of certain product development failures the Government shall have the remedy described in this section to meet the needs of the public health or national security. This remedy is not available as a result of a Termination for Convenience under Article 2(B) of this Agreement. This remedy is only available to the Government if and when any of the following conditions occur:

   (i) This Agreement is terminated for cause under Article 2(C) of this Agreement;
   (ii) Awardee gives notice, required to be submitted to the Government no later than 30 business days, following any formal management decision to terminate the prototype project;
   (iii) Awardee gives written notice, required to be submitted to the Government no later than 15 business days, of any filing that anticipates Federal bankruptcy protection.

2. If one or more of the conditions listed above occur, the Awardee, upon the request of the Government, shall provide the following items necessary for the Government to pursue FDA licensure/authorization and manufacturing of the Technology with a third party, whereby the third party may non-exclusively sell the Technology only to the U.S. Government for treatment of patients with COVID-19 [all other commercial purposes are excluded from the below provisions]:

   (i) a writing evidencing a non-exclusive, nontransferable, irrevocable (except for cause), license to practice or have practiced for or on behalf of the U.S. Government any 60P patent, IP, copyright, technical data, or regulatory information held by Awardee that relates to the prototype project necessary to manufacture or commercialize the Technology. The parties agree to negotiate in good faith at customary industry rates and under reasonable terms and conditions; to enable a third party to continue to develop t(b) (4)
   necessary FDA regulatory filings or authorizations related to COVID 19 which are owned

or controlled by 60P related to the Technology and any confirmatory instrument pertaining thereto; and

(iii) any outstanding Deliverables contemplated or materials purchased under this Agreement.

3. This clause will survive the acquisition or merger of the Awardee by or with a third party. This clause will also be included in any subcontracts/sub-agreements relating to the development of the Technology as appropriate for this OTA Project. This clause will survive for 1 year after the Government elects to discontinue funding the development or procurement of this product for the indication identified in this OTA project.

ARTICLE 14: REGULATORY COMPLIANCE

A. The manufacturing described in the Statement of Work will comply with Current Good Manufacturing Practices (cGMP) regulations at 21 CFR 210 and 211. Production shall occur using cGMP validated manufacturing process, fully compliant with 21 CFR 210 and 211, for bulk drug substance and fill and finished drug product, with a ramp-up capacity that provides doses sufficient for the government to treat the US population.

B. Production and distribution shall comply with applicable provisions of the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov 27, 2013), taking into account FDA's regular guidance for the COVID-19 public health response.

C. Any clinical trials described in the Statement of Work will comply with ICH and FDA Good Clinical Practices (GCP) regulations at 21 CFR Part 11, 50, 54 and 56.

D. All clinical sites and IRBs utilized in the clinical trial described in the Statement of Work are required to register with the Office for Human Research Protections (OHRP) and receive Federal Wide Assurance (FWA) numbers in accordance with human subject protections regulations 45 C.F.R 46.103.

ARTICLE 15. Foreign Access to Data.

A. Export Compliance: The Parties will comply with any applicable U.S. export control statutes or regulations in performing this Agreement.

ARTICLE 16. Scientific Publications and Press Releases.

A. The Awardee shall not release any reports, manuscripts, press releases, or abstracts about

the work being performed under this Agreement without written notice in advance to the Government.

B. Unless otherwise specified in this Agreement, the Awardee may publish the results of its work under this contract. The Awardee shall promptly send a copy of each submission to the AOR for security review prior to submission. The Awardee shall also inform the AOR when the abstract article or other publication is published, and furnish a copy of it as finally published.

C. Unless authorized in writing by the AO, the Awardee shall not display Government logos including Operating Division or Staff Division logos on any publications.

D. The Awardee shall not reference the products(s) or services(s) awarded under this contract in commercial advertising, as defined in FAR 31.205-1, in any manner which states or implies Government approval or endorsement of the product(s) or service(s) provided.

E. The Awardee shall include this clause, including this section (d) in all subawards where the subawardee may propose publishing the results of its work under the subaward. The Awardee shall acknowledge the support of the Government whenever publicizing the work under this Agreeement in any media by including an acknowledgement substantially as follows:

"This project has been funded in whole or in part by the U.S. Government under Agreement No. W911QY-21-9-0011. The US Government is authorized to reproduce and distribute reprints for Governmental purposes notwithstanding any copyright notation thereon."

ARTICLE 16. Miscellaneous Clauses.

A. No Consent. Nothing in the terms of this Agreement constitutes express or implied Government authorization and consent for Awardee or its subawardee(s) to utilize, manufacture or practice inventions covered by United States or foreign patents in the performance of work under this Agreement.

B. Patent Infringement. Each Party will advise the other Party promptly and in reasonable written detail, of each claim or lawsuit of patent infringement based on the performance of this Agreement. When requested by either Party, all evidence and information in possession of the Party pertaining to such claim or lawsuit will be provided to the other at no cost to the requesting Party.

C. Limitation of Liability. In no event will either Party be liable to the other Party or any third party claiming through such Party for any indirect, incidental, consequential or punitive damages, or claims for lost profits, arising under or relating to this Agreement, whether based in contract, tort or otherwise, even if the other Party has been advised of the possibility of such damages.

D. Disclosure of Information. Performance under this Agreement may require the Awardee to access non-public data and information proprietary to a Government agency, another Government

Contractor or of such nature that its dissemination or use other than as specified in the work statement would be adverse to the interests of the Government or others. Neither the Awardee, nor Awardee personnel, shall divulge nor release data nor information developed or obtained under performance of this Agreement, except as authorized by Government personnel or upon written approval of the AO in accordance with OWS or other Government policies and/or guidance. The Awardee shall not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as specified in this Agreement, or any information at all regarding this agency.

The Awardee shall comply with all Government requirements for protection of non-public information. Unauthorized disclosure of nonpublic information is prohibited by the Government's rules. Unauthorized disclosure may result in termination of the Agreement, replacement of an Awardee employee, or other appropriate redress. Neither the Awardee nor the Awardee's employees shall disclose or cause to be disseminated, any information concerning the operations of the activity, which could result in, or increase the likelihood of, the possibility of a breach of the activity's security or interrupt the continuity of its operations.

No information related to data obtained under this contract shall be released or publicized without the prior written consent of the AOR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity' for submission to any securities exchange on which the Awardee's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

E. Force Majeure. Neither Party will be liable to the other Party for failure or delay in performing its obligations hereunder if such failure or delay arises from circumstances beyond the control and without the fault or negligence of the Party (a Force Majeure event). Examples of such circumstances are: pandemic, authorized acts of the government in either its sovereign or contractual capacity, war, insurrection, freight embargos, fire, flood, or strikes. The Party asserting Force Majeure as an excuse must take commercially reasonable steps to minimize delay or damages caused by unforeseeable events.

F. Essential Critical Infrastructure. The Government expressly designates Awardee, for entire duration of this Agreement, as performing work on Essential Critical Infrastructure pursuant to the U.S. Department of Homeland Security guidance and applicable U.S. Department of Defense guidance. See, e.g., https://www.dhs.gov/coronavirus/cybersecurity-and-critical-infrastructure.

G. Severability. If any provision of this Agreement, or the application of any such provision to any person or set of circumstances, is determined to be invalid, unlawful, void or unenforceable to any extent, the remainder of this Agreement, and the application of such provision to persons or

circumstances other than those as to which it is determined to be invalid, unlawful, void or unenforceable, will not be impaired or otherwise affected and will continue to be valid and enforceable to the fullest extent permitted by law.

H. Choice of Law. This Agreement and the resolution of disputes hereunder will be governed, construed, and interpreted by the statutes, regulations, and/or legal precedent applicable to the Government of the United States of America. Unless explicitly stated, the Parties do not intend that this Agreement be subject to the Federal Acquisition Regulation either directly or indirectly or by operation of law. When a specific FAR requirement is incorporated by reference in this Agreement, the text of the clause alone will apply without application or incorporation of other provisions of these regulations.

I. Order of Precedence. In the event of a conflict between the terms of this Agreement and the attachments incorporated herein, the conflict shall be resolved by giving precedence in descending order as follows: (i) the Articles of this Agreement, and the Appendices to the Agreement.

J. FAR 52.204-25 Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment incorporated by reference.

K. Access and General Protection/Security Policy and Procedures. This standard language text is applicable to ALL employees working on critical information related to Operation Warp Speed (OWS), and to those with an area of performance within a Government controlled installation, facility or area. Employees shall comply with applicable installation, facility and area commander installation/facility access and local security policies and procedures (provided by government representative). The performer also shall provide all information required for background checks necessary to access critical information related to OWS, and to meet Government installation access requirements to be accomplished by installation Director of Emergency Services or Security Office. The workforce must comply with all personnel identity verification requirements as directed by the Government and/or local policy. In addition to the changes otherwise authorized by the changes clause of this agreement, should the security status of OWS change the Government may require changes in performer security matters or processes. In addition to the industry standards for employment background checks, The Contractor must be willing to have key individuals, in exceptionally sensitive positions, identified for additional vetting by the United States Government.

L. Organizational Conflicts of Interest. Performance under this Agreement may create an actual or potential organizational conflict of interest such as are contemplated by FAR Part 9.505-General Rules. The Awardee shall not engage in any other contractual or other activities which could create an organizational conflict of interest (OCI). This provision shall apply to the prime

Awardee and all sub-awardees. This provision shall have effect throughout the period of performance of this Agreement, any extensions thereto by change order or supplemental agreement, and for two (2) years thereafter. The Government may pursue such remedies as may be permitted by law or this contract, upon determination that an OCI has occurred.

The work performed under this Agreement may create a significant potential for certain conflicts of interest, as set forth in FAR Parts 9.505-1, 9.505-2, 9.505-3, and 9.505-4. It is the intention of the parties hereto to prevent both the potential for bias in connection with the Awardee's performance of this Agreement, as well as the creation of any unfair competitive advantage as a result of knowledge gained through access to any non-public data or third party proprietary information.

The Awardee shall notify the Agreements Officer immediately whenever it becomes aware that such access or participation may result in any actual or potential OCI. Furthermore, the Awardee shall promptly submit a plan to the Agreements Officer to either avoid or mitigate any such OCI. The Agreements Officer will have sole discretion in accepting the Awardee's mitigation plan. In the event the Agreements Officer unilaterally determines that any such OCI cannot be satisfactorily avoided or mitigated, other remedies may be taken to prohibit the Awardee from participating in Agreement requirements related to OCI.

Whenever performance of this Agreement provides access to another Contractor's proprietary information, the Awardee shall enter into a written agreement with the other entities involved, as appropriate, in order to protect such proprietary information from unauthorized use or disclosure for as long as it remains proprietary; and refrain from using such proprietary information other than as agreed to, for example to provide assistance during technical evaluation of other Awardees' offers or products under this Agreement. An executed copy of all proprietary information agreements by individual personnel or on a corporate basis shall be furnished to the AO within fifteen (15) calendar days of execution.

M. Institutional Responsibility Regarding Investigator Conflicts of Interest. The Institution (includes any Contractor, public or private, excluding a Federal agency) shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Investigators (defined as the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded under Government contracts, or proposed for such funding, which may include, for example, collaborators or consultants) will not be biased by any Investigator financial conflicts of interest. 45 CFR Part 94 is available at the following Web site:
http://www.ecfr.gov/cgiin/textidx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5

&view=text&node=45:1.0.1.1.51&idno=

As required by 45 CFR Part 94, the Institution shall, at a minimum:

a. Maintain an up-to-date, written, enforceable policy on financial conflicts of interest that complies with 45 CFR Part 94, inform each Investigator of the policy, the Investigator's reporting responsibilities regarding disclosure of significant financial interests, and the applicable regulation, and make such policy available via a publicly accessible Web site, or if none currently exist, available to any requestor within five business days of a request. A significant financial interest means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. Included are payments and equity interests;
2. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest; or
3. Intellectual property rights and interests, upon receipt of income related to such rights and interest.

Significant financial interests do not include the following:

1. Income from seminars, lectures, or teaching, and service on advisory or review panels for Government agencies, Institutions of higher education, academic teaching hospitals, medical centers, or research institutes with an Institution of higher learning; and
2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

b. Require each Investigator to complete training regarding the Institution's financial conflicts of interest policy prior to engaging in research related to any Government funded

contract and at least every four years. The Institution must take reasonable steps [see Part 94.4(c)] to ensure that investigators working as collaborators, consultants or subcontractors comply with the regulations.

c. Designate an official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the Government funded research.

d. Require that each Investigator who is planning to participate in the Government funded research disclose to the Institution's designated official(s) the Investigator's significant financial interest (and those of the Investigator's spouse and dependent children) no later than the date of submission of the Institution's proposal for Government funded research. Require that each Investigator who is participating in the Government funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Institution during the period of the award as well as within thirty days of discovering or acquiring a new significant financial interest.

e. Provide guidelines consistent with the regulations for the designated official(s) to determine whether an Investigator's significant financial interest is related to Government funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to Government funded research when the Institution, thorough its designated official(s), reasonably determines that the significant financial interest: Could be affected by the Government funded research; or is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists when the Institution, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the Government funded research.

f. Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subcontractor Investigator. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report pursuant to Part 94.5(a).

g. Provide initial and ongoing FCOI reports to the Contracting Officer pursuant to Part 94.5(b).

h. Maintain records relating to all Investigator disclosures of financial interests and the

Institution's review of, and response to, such disclosures, and all actions under the Institution's policy or retrospective review, if applicable, for at least 3 years from the date of final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.

i. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.

j. Complete the certification in Section K - Representations, Certifications, and Other Statements of Contractors titled "Certification of Institutional Policy on Financial Conflicts of Interest".

If the failure of an Institution to comply with an Institution's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the Government funded research, the Institution must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will consider the situation and, as necessary, take appropriate action or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the Government funded research project.

The Contracting Officer and/or Government may inquire at any time before, during, or after award into any Investigator disclosure of financial interests, and the Institution's review of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of a financial conflict of interests. The Contracting Officer may require submission of the records or review them on site. On the basis of this review of records or other information that may be available, the Contracting Officer may decide that a particular financial conflict of interest will bias the objectivity of the Government funded research to such an extent that further corrective action is needed or that the Institution has not managed the financial conflict of interest in accordance with Part 94.6(b). The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that Government funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution, the Institution shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

ARTICLE 17. Human Subjects.

A. Definitions. As used in this clause -

a) Assurance of compliance means a written assurance that an institution will comply with requirements of 32 CFR Part 219, as well as the terms of the assurance, which the Human Research Protection Official determines to be appropriate for the research supported by the Department of Defense (DoD) component (32 CFR 219.103).

b) Human Research Protection Official (HRPO) means the individual designated by the head of the applicable DoD component and identified in the component's Human Research Protection Management Plan as the official who is responsible for the oversight and execution of the requirements of this clause, although some DoD components may use a different title for this position.

c) Human subject means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. (32 CFR 219.102(e)). For example, this could include the use of human organs, tissue, and body fluids from individually identifiable living human subjects as well as graphic, written, or recorded information derived from individually identifiable living human subjects.

d) Institution means any public or private entity, or department or agency (including federal, state, and other agencies). (32 CFR 219.102(f)).

e) Institutional Review Board (IRB) means a board established in accord with and for the purposes expressed in 32 CFR Part 219 (32 CFR 219.102(g)).

f) IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements (32 CFR 219.102(h)).

g) Research means a systematic investigation, including research, development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of 32 CFR Part 219, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities (32 CFR 219.102(l)).

B. The Awardee shall oversee the execution of the research to ensure compliance with this

clause. The Awardee shall comply fully with 32 CFR Part 219 and DoD Instruction 3216.02, applicable DoD component policies, 10 U.S.C. 980, and, when applicable, Food and Drug Administration policies and regulations.

C. The Awardee shall not commence performance of research involving human subjects that is covered under 32 CFR Part 219 or that meets exemption criteria under 32 CFR 219.104, or expend funding on such effort, until and unless the conditions of either the following paragraph (c)(1) or (c)(2) have been met:

a) The Awardee furnishes to the HRPO, with a copy to the Agreements Officer, an assurance of compliance and IRB approval and receives notification from the OTAO that the HRPO has approved the assurance as appropriate for the research under the Statement of Work and also that the HRPO has reviewed the protocol and accepted the IRB approval for compliance with the DoD component policies. The Awardee may furnish evidence of an existing assurance of compliance for acceptance by the HRPO, if an appropriate assurance has been approved in connection with previous research. The Awardee shall notify the OTAO immediately of any suspensions or terminations of the assurance.

b) The Awardee furnishes to the HRPO, with a copy to the OTAO, a determination that the human research proposed meets exemption criteria in 32 CFR 219.104and receives written notification from the OTAO that the exemption is determined acceptable. The determination shall include citation of the exemption category under 32 CFR 219.104 and a rationale statement. In the event of a disagreement regarding the Awardee's furnished exemption determination, the HRPO retains final judgment on what research activities or classes of research are covered or are exempt under the agreement.

D. DoD staff, consultants, and advisory groups may independently review and inspect the Awardee's research and research procedures involving human subjects and, based on such findings, DoD may prohibit research that presents unacceptable hazards or otherwise fails to comply with DoD procedures.

E. Failure of the Awardee to comply with the requirements of this clause will result in the issuance of a stop-work order to immediately suspend, in whole or in part, work and further payment under this Agreement, or will result in other issuance of suspension of work and further payment for as long as determined necessary at the discretion of the OTAO.

F. The Awardee shall include the substance of this clause, including this paragraph (f), in all subcontracts that may include research involving human subjects in accordance with 32 CFR Part 219, DoD Instruction 3216.02, and 10 U.S.C. 980, including research that meets exemption criteria under 32 CFR 219.104. This clause does not apply to subcontracts that involve only the use of cadaver materials.

Appendix A Statement of Work

The Awardee plans to execute the program in accordance with the statement of work provided below. The plan is to accomplish the entire project based on the schedule prescribed in this agreement. Completion dates are expressed in Appendix B. The numbering scheme below is adopted from the Awardee's Statement of Work as included in its proposal. Only the sections of the proposal included in this Appendix A are made a part of this Agreement.

1.0 SCOPE, AND OBJECTIVES

1.2 Scope

The project objective is to provide a clinical trial to rapidly test repurposed FDA-approved (b) (4) in order to determine the safety and efficacy of the drug for treatment of COVID-19 outpatients. (b) (4)

The regulatory objective is to provide a therapeutic with clinical data to support a use under an EUA under aegis of FDA review.

The 60P team will coordinate, conduct, and manage all communications (written, oral, email) with the FDA, including scheduling and holding of formal and informal meetings, maintain written records of all communications to and from the FDA, and prepare all documents for submission to the FDA. In addition, the 60P team will maintain clinical trial master file and prepare all clinical trial documents.

The project management objectives include participation in biweekly Integrated Product Teams (IPT) or as required, providing technical reporting of project accomplishments, risks and/or issues and providing mitigation plans. The 60P team will prepare quarterly and annual progress reports, agendas and minutes from IPT meetings, technical and financial expenditure forecasts and an Integrated Master Schedule (IMS). At the conclusion of the clinical trial, a clinical study report will be prepared according to ICH guidelines.

1.3 Objective

(b) (4)

(b) (4)

2.0 APPLICABLE REFERENCES

21 CFR Part 312 - Investigational New Drug Application

45 CFR Part 46: Federal Policy for the Protection of Human Subjects ('Common Rule')

21 CRF Part 50: Protection of Human Subjects

ICH Guideline E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) Guidance for Industry

ICH Guideline E3: Structure and Content of Clinical Study Reports

3.0 REQUIREMENTS

3.1 Regulatory Planning

(b) (4)

- (b) (4)

3.2 Clinical Trial Planning

(b) (4)

3.2.1 Study Documents Preparation

(b) (4)

- (b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

3.2.3 Data Management System

(b) (4)

as well as reviews by data management staff, will be defined and explained. Database (b) (4)

3.3 Regulatory Execution

(b) (4)

(b) (4)

- (b) (4)

(b) (4)

drug

(b) (4)

(b) (4)

(b) (4)

- (b) (4)

(b) (4)

(b) (4)

(b) (4)

4.0 DELIVERABLES

All data deliverables will be provided in electronic format. The following tables provides a list of deliverables considered a standard part of a clinical trial under this contract.

Deliverables

Del. #	Deliverable Description	Due Date	SOW Reference	Government Role
(b) (4)				

Del. #	Deliverable Description	Due Date	SOW Reference	Government Role
(b) (4)				

Del. #	Deliverable Description	Due Date	SOW Reference	Government Role (b) (4)

Appendix B
Project Schedule/Milestone Payment Schedule

The Government shall pay the Awardee, upon the submission of proper invoices or vouchers, the prices stipulated in this Agreement for supplies delivered and accepted or services rendered and accepted, less any deductions provided in this Agreement.
Expenditures shall be submitted based on the awarded budget. Federal funds are to be used only for costs that a reasonable and prudent person would incur in carrying out the prototype project. The Awardee must maintain a financial system capable of identifying costs applicable to this Agreement, compliant with Cost Principles (48 CFR Part 31) and/or the Cost Accounting Standards (CAS) (48 CFR Part 99). An invoice will be submitted through Wide Area Work Flow (WAWF) in accordance with agreement requirements. Final payment of the Agreement shall be determined upon mutual agreement and settlement of any outstanding costs.

The Awardee shall proceed with the performance in accordance with the terms and conditions of this Agreement and its Appendices. However, the Government may require the Awardee to cease performance at any time prior to the commencement of any milestone or task. Such notice to cease performance must be from the OTAO and be in writing, of which email is an acceptable form.

The Parties acknowledge that the nature of this Prototype Project requires flexibility and the ability to react to changing circumstances. Although the Statement of Work sets the scope for activities the Government may require under this Agreement, it is not intended to, and does not, prescribe with specificity each task that Awardee will perform.

The Awardee will be responsible for submission of SOW's, quotes, and proposals for cost, performance, and schedule for those efforts not already identified, priced or otherwise negotiated. Government approval will be required prior to incurring costs. In addition, subawards not already negotiated, will require Government review and determination of reasonableness.

Appendix C
Key Personnel

1. Awardee's Organization and Key Personnel.

The Awardee's organization shall be established with authority to effectively accomplish the objectives of the Statement of Work. This organization shall become effective upon award of the Agreement and its integrity shall be maintained for the duration of the effort.

The key personnel listed below are considered to be critical to the successful performance of this Agreement. Prior to replacing these key personnel, the Awardee shall obtain the written consent of the OTAO. In order to obtain such consent, the Awardee shall provide advance notice of the proposed changes and shall demonstrate that the qualifications of the proposed substitute personnel are generally equivalent to or better than the qualifications of the personnel being replaced.

Prior to permanently removing any of the specified individuals to other contracts, the Awardee shall provide the OTAO not less than thirty (30) calendar days advance notice and shall submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on the program. No reassignment shall be made by the Awardee without written consent of the OTAO. The "Key Personnel" list presented in Table 2 below may be amended from time to time during the course of the Agreement to either add or delete personnel, as appropriate.

Table 2: Key Personnel Summary

(b) (4)				

Appendix D Government Property

Government Property: "Government Property" means any property (i) furnished by the Government and facilitating performance of this Agreement, (ii) acquired by the Awardee under cost reimbursement terms of this Agreement, or (iii) acquired by the Awardee under fixed price terms of this Agreement (FP-GP) if specifically identified in this Government Property Appendix. Except for commercial off the shelf software and licenses thereto, Government Property does not include intellectual property and software. The Government owns and holds title to all Government Property.

The Government shall deliver to the Awardee any Government Property required to be furnished as described in this Agreement together with related data and information needed for its intended use. The delivery and/or performance dates specified in this Agreement are based upon the expectation that the Government-furnished property will be suitable for performance and will be delivered to the Awardee by the dates stated in the Agreement. If not so suitable, the Awardee shall give timely written request to the OTAO who will advise the Awardee on a course of action to remedy the problem.
FPGP includes: [Mark N/A if none]:

Awardee acquired equipment shall be tracked via the USG's GFP spreadsheet.

The Awardee shall have, initiate and maintain a system of internal controls to manage, control, use, preserve, protect, repair, account for and maintain Government Property in its possession and shall initiate and maintain the processes, systems, procedures, records required control and maintain accountability of Government Property. The Awardee shall include this clause in all subcontracts under which Government Property comes into the possession of any subawardee. Unless otherwise provided for in this Agreement or approved by the OTAO, the Awardee shall not: (i) use Government Property for any purpose other than to fulfill the requirements of this Agreement, or (ii) alter the Government Property.
The Awardee shall establish and implement property management plans, systems, and procedures regarding its acquisition of Government Property, its receipt of Government Property, in addition to, the status, dates furnished or acquired, identification, quantity, cost, marking, date placed in service, location, inventory and disposition of Government Property, to include a reporting process for all discrepancies, loss of Government Property, physical inventory results, audits and self-assessments, corrective actions, and other property related reports as directed by the OTAO.
Upon conclusion or termination of the Agreement, the Awardee shall submit a request in writing to the OTAO, for disposition/disposal instructions and shall store Government Property not to exceed 120 days pending receipt of such instructions. Storage shall be at no additional cost to the Government unless otherwise noted in the Agreement. The Government, upon written notice to

the Awardee, may abandon any Government Property in place, at which time all obligations of the Government regarding such Government Property shall cease.

Awardee Liability for Government Property. "Loss of Government Property" means the loss, damage or destruction to Government Property reducing the Government's expected economic benefits of the property and includes loss of accountability but does not include planned and purposeful destructive testing, obsolescence, reasonable wear and tear or manufacturing defects. THE AWARDEE SHALL BE LIABLE FOR LOSS OF GOVERNMENT PROPERTY IN AWARDEE'S POSSESSION, EXCEPT WHEN ANY ONE OF THE FOLLOWING APPLIES:
(I) OTAO GRANTS RELIEF OF RESPONSIBILITY AND LIABILITY FOR LOSS OF THE PARTICULAR GOVERNMENT PROPERTY; (II) GOVERNMENT PROPERTY IS DELIVERED UNDER THE GOVERNMENT'S INSTRUCTIONS; OR (III) GOVERNMENT PROPERTY IS DISPOSED OF IN ACCORDANCE WITH THE GOVERNMENT'S DIRECTIONS.

APPENDIX E PL 115-92 Sponsor Authorization Template

(b) (4)

AWARD/CONTRACT

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)		RATING	PAGE 1 OF PAGES 9
2. CONTRACT (Proc. Inst. Ident.) NO. W911QY2190011	3. EFFECTIVE DATE 04 Dec 2020	4. REQUISITION/PURCHASE REQUEST/PROJECT NO. 0011578602	

5. ISSUED BY W6QK ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	CODE W911QY	6. ADMINISTERED BY (If other than Item 5) W6QK ACC-APG NATICK DIVISION 110 THOMAS JOHNSON DR SUITE #240 FREDERICK MD 21702	CODE W911QY

7. NAME AND ADDRESS OF CONTRACTOR (No., street, city, county, state and zip code) 60 DEGREES PHARMACEUTICALS, LLC 60P 1025 CONNECTICUT AVE NW STE 1000 WASHINGTON DC 20036-5417	8. DELIVERY [ ] FOB ORIGIN [X] OTHER (See below) 9. DISCOUNT FOR PROMPT PAYMENT	
	10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN:	ITEM
CODE 71D06 FACILITY CODE		

11. SHIP TO/MARK FOR CODE See Schedule	12. PAYMENT WILL BE MADE BY CODE HQ0490 DEFENSE FINANCE AND ACCOUNTING SERVICE DFAS-INDY VP GFEBS 8899 E 56TH STREET INDIANAPOLIS IN 46249-3800
13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: [ ] 10 U.S.C. 2304(c)( ) [ ] 41 U.S.C. 253(c)( )	14. ACCOUNTING AND APPROPRIATION DATA See Schedule

15A. ITEM NO.	15B. SUPPLIES/ SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	SEE SCHEDULE				
				15G. TOTAL AMOUNT OF CONTRACT	$4,999,814.00

16. TABLE OF CONTENTS

(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
		PART I - THE SCHEDULE				PART II - CONTRACT CLAUSES	
X	A	SOLICITATION/ CONTRACT FORM	1	X	I	CONTRACT CLAUSES	9
X	B	SUPPLIES OR SERVICES AND PRICES/ COSTS	2			PART III – LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.	
	C	DESCRIPTION/ SPECS/ WORK STATEMENT			J	LIST OF ATTACHMENTS	
	D	PACKAGING AND MARKING				PART IV - REPRESENTATIONS AND INSTRUCTIONS	
X	E	INSPECTION AND ACCEPTANCE	3		K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	
X	F	DELIVERIES OR PERFORMANCE	4				
X	G	CONTRACT ADMINISTRATION DATA	5 - 8		L	INSTRS., CONDS., AND NOTICES TO OFFERORS	
	H	SPECIAL CONTRACT REQUIREMENTS			M	EVALUATION FACTORS FOR AWARD	

CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE

17. [ ] CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)

18. [ ] SEALED-BID AWARD (Contractor is not required to sign this document.)
Your bid on Solicitation Number _____
including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the terms listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract.)

19A. NAME AND TITLE OF SIGNER (Type or print)		20A. NAME OF CONTRACTING OFFICER (b) (6) CONTRACT SPECIALIST TEL: (b) (6) EMAIL: (b) (6)	
19B. NAME OF CONTRACTOR BY _____ (Signature of person authorized to sign)	19C. DATE SIGNED	20B. UNITED STATES OF AMERICA BY (b) (6) (Signature of Contracting Officer)	20C. DATE SIGNED 04-Dec-2020

Section B - Supplies or Services and Prices

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001			Job		$4,999,814.00

Prototype (b) (4)
CPFF
Deliver (b) (4) with an FDA Emergency Use Authorization (EUA) approved as a countermeasure against COVID-19, to include a Phase II clinical trial to assess the safety and efficacy (b) (4) for the treatment of mild to moderate COVID-19 disease, in accordance with the Awardees Statement of Work, Appendix A of the Agreement.
FOB: Destination
PSC CD: AN13

ESTIMATED COST	(b) (4)
FIXED FEE	(b) (4)
TOTAL EST COST + FEE	$4,999,814.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000101					$0.00

Funding
CPFF
PURCHASE REQUEST NUMBER: 0011578602

ESTIMATED COST	$0.00
FIXED FEE	$0.00
TOTAL EST COST + FEE	$0.00

ACRN AA $4,999,814.00
CIN: GFEBS001157860200001

Section E - Inspection and Acceptance

INSPECTION AND ACCEPTANCE TERMS

Supplies/services will be inspected/accepted at:

CLIN	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
0001	Destination	Government	Destination	Government
000101	N/A	N/A	N/A	N/A

Section F - Deliveries or Performance

DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
0001	04-DEC-2021		N/A FOB: Destination	
000101	N/A	N/A	N/A	N/A

Section G - Contract Administration Data

AGREEMENT ADMINISTRATION
A. In no event shall any understanding of agreement, modification, change order, or other matter in deviation from the terms and conditions of this agreement between the contractor and a person other than the Agreement Officer be effective or binding upon the Government. All such actions must be formalized by a proper agreement document
B. The telephone number and e-mail addresss of the Agreement Officer and Agreement Specialist are:
Government Representatives:
Other Transaction Agreements Officer (OTAO)
(b) (6)
ACC-APG-Fort Detrick
110 Thomas Johnson Dr.
Frederick, MD 21702
(b) (6)
(b) (6)
Other Transaction Agreement Specialist (OTAS)
(b) (6)
ACC-APG-Fort Detrick
110 Thomas Johnson Dr.
Frederick, MD 21702
(b) (6)

ACCOUNTING AND APPROPRIATION DATA

AA: 097202020210130000181704464642 55 S.0074658.3.1.2 6100.9000021001
COST CODE: AHPDD
AMOUNT: $4,999,814.00

ACRN	CLIN/SLIN	CIN	AMOUNT
AA	000101	GFEBS001157860200001	$4,999,814.00

CLAUSES INCORPORATED BY FULL TEXT

252.232-7006 WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS (DEC 2018)

(a) Definitions. As used in this clause—

"Department of Defense Activity Address Code (DoDAAC)" is a six position code that uniquely identifies a unit, activity, or organization.

"Document type" means the type of payment request or receiving report available for creation in Wide Area WorkFlow (WAWF).

"Local processing office (LPO)" is the office responsible for payment certification when payment certification is done external to the entitlement system.

"Payment request" and "receiving report" are defined in the clause at 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.

(b) Electronic invoicing. The WAWF system provides the method to electronically process vendor payment requests and receiving reports, as authorized by Defense Federal Acquisition Regulation Supplement (DFARS) 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.

(c) WAWF access. To access WAWF, the Contractor shall—

(1) Have a designated electronic business point of contact in the System for Award Management at https://www.sam.gov; and

(2) Be registered to use WAWF at https://wawf.eb.mil/ following the step-by-step procedures for self-registration available at this web site.

(d) WAWF training. The Contractor should follow the training instructions of the WAWF Web-Based Training Course and use the Practice Training Site before submitting payment requests through WAWF. Both can be accessed by selecting the "Web Based Training" link on the WAWF home page at https://wawf.eb.mil/.

(e) WAWF methods of document submission. Document submissions may be via web entry, Electronic Data Interchange, or File Transfer Protocol.

(f) WAWF payment instructions. The Contractor shall use the following information when submitting payment requests and receiving reports in WAWF for this contract or task or delivery order:

(1) Document type. The Contractor shall submit payment requests using the following document type(s):

(i) For cost-type line items, including labor-hour or time-and-materials, submit a cost voucher.

(ii) For fixed price line items—

(A) That require shipment of a deliverable, submit the invoice and receiving report specified by the Contracting Officer.

_____

(Contracting Officer: Insert applicable invoice and receiving report document type(s) for fixed price line items that require shipment of a deliverable.)

(B) For services that do not require shipment of a deliverable, submit either the Invoice 2in1, which meets the requirements for the invoice and receiving report, or the applicable invoice and receiving report, as specified by the Contracting Officer.

_____Invoice 2in1_____

(Contracting Officer: Insert either "Invoice 2in1" or the applicable invoice and receiving report document type(s) for fixed price line items for services.)

(iii) For customary progress payments based on costs incurred, submit a progress payment request.

(iv) For performance based payments, submit a performance based payment request.

(v) For commercial item financing, submit a commercial item financing request.

(2) Fast Pay requests are only permitted when Federal Acquisition Regulation (FAR) 52.213-1 is included in the contract.

[Note: The Contractor may use a WAWF "combo" document type to create some combinations of invoice and receiving report in one step.]

(3) Document routing. The Contractor shall use the information in the Routing Data Table below only to fill in applicable fields in WAWF when creating payment requests and receiving reports in the system.

Routing Data Table*

Field Name in WAWF	*Data to be entered in WAWF*
Pay Official DoDAAC	HQ0490
Issue By DoDAAC	W911QY
Admin DoDAAC**	W911QY
Inspect By DoDAAC	W56XNH
Ship To Code	W56XNH

(*Contracting Officer: Insert applicable DoDAAC information. If multiple ship to/acceptance locations apply, insert "See Schedule" or "Not applicable.")

(**Contracting Officer: If the contract provides for progress payments or performance-based payments, insert the DoDAAC for the contract administration office assigned the functions under FAR 42.302(a)(13).)

(4) Payment request. The Contractor shall ensure a payment request includes documentation appropriate to the type of payment request in accordance with the payment clause, contract financing clause, or Federal Acquisition Regulation 52.216-7, Allowable Cost and Payment, as applicable.

(5) Receiving report. The Contractor shall ensure a receiving report meets the requirements of DFARS Appendix F.

(g) WAWF point of contact.

(1) The Contractor may obtain clarification regarding invoicing in WAWF from the following contracting activity's WAWF point of contact.

(b) (6)

(2) Contact the WAWF helpdesk at 866-618-5988, if assistance is needed.

(End of clause)

Section I - Contract Clauses

CLAUSES INCORPORATED BY REFERENCE

52.204-25	Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.	AUG 2020

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1 CONTRACT ID CODE	PAGE OF PAGES
	1 | 6

2 AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO	5 PROJECT NO (If applicable)
	26-Feb-2021	SEE SCHEDULE	

6 ISSUED BY	CODE	7 ADMINISTERED BY (If other than item 6)	CODE
W6QK ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	W911QY	W6QK ACC-APG NATICK DIVISION 110 THOMAS JOHNSON DR SUITE #240 FREDERICK MD 21702	W911QY

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		
60 DEGREES PHARMACEUTICALS, LLC 60P 1025 CONNECTICUT AVE NW STE 1000 WASH NGTON DC 20036-5417		9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W911QY2190011
	X	10B. DATED (SEE ITEM 13) 04-Dec-2020
CODE 71D06	FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

See Schedule

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS.
IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

☐ C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

X D. OTHER (Specify type of modification and authority)
In accordance with Article 5 of the Agreement.

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
Modification Control Number: (b) (6)

The purpose of this modification is to incorporate additional cost under CLIN 0001, in the amount of $720,000.00, and additional funding under CLIN 000102, in the amount of $720,000.00. All other terms and conditions remain the same and in full force and effect.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
(b) (6)	TEL: (b) (6) EMAIL: (b) (6)

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
(b) (6) (Signature of pers	2-25-21	BY (b) (6) (S	25 Feb 2021

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text:

P00001

A. The purpose of this modification is as follows:
   1. Incorporate additional funding under subCLIN 000102, ACRN AA, in the amount of $720,000.00.
   2. Incorporate proposal "(b) (4) into the agreement by reference.
   3. Increase the value of CLIN 0001 by $720,000.00, from $4,999,814.00, to $5,719,814.00.
   4. The total funded value of this Agreement is hereby increased by $720,000.00, from $4,999,814.00, to $5,719,814.00.
   5. The total cost of this Agreement is hereby increased by $720,000.00, from $4,999,814.00, to $5,719,814.00.

B. The parties hereby agree that changes effected by this modification constitute both the consideration and the equitable adjustment due under any clause of this agreement resulting from the incorporation of the proposal identified in paragraph A.

C. Articles 3 and 4 are hereby revised to replace the AOR and Primary Project Manager (b) (6) .

D. DFARS Clause 252.232-7006 is hereby revised to change the POC from (b) (6)

E. All other terms and conditions of this Agreement remain the same and in full force and effect.

SECTION A - SOLICITATION/CONTRACT FORM

The total cost of this contract was increased by $720,000.00 from $4,999,814.00 to $5,719,814.00.

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0001

The estimated/max cost has increased by $720,000.00 from $4,475,646.00 to $5,195,646.00.
The total cost of this line item has increased by $720,000.00 from $4,999,814.00 to $5,719,814.00.

SUBCLIN 000102 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000102					$0.00
	FY20 COVID-19 Funding CPFF FY20 COVID-19 Funding PURCHASE REQUEST NUMBER: 0011578602-0001				
				ESTIMATED COST	$0.00
				FIXED FEE	$0.00
				TOTAL EST COST + FEE	$0.00
	ACRN AA CIN: GFEBS001157860200002				$720,000.00

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for SUBCLIN 000102:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by $720,000.00 from $4,999,814.00 to $5,719,814.00.

SUBCLIN 000102:
Funding on SUBCLIN 000102 is initiated as follows:

ACRN: AA

CIN: GFEBS001157860200002

Acctng Data: 097202020210130000181704464642 55 S.0074658.3.1.2 6100.9000021001

Increase: $720,000.00

Total: $720,000.00

Cost Code: AHPDD

The following have been modified:

252.232-7006 WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS (DEC 2018)

(a) Definitions. As used in this clause—

"Department of Defense Activity Address Code (DoDAAC)" is a six position code that uniquely identifies a unit, activity, or organization.

"Document type" means the type of payment request or receiving report available for creation in Wide Area WorkFlow (WAWF).

"Local processing office (LPO)" is the office responsible for payment certification when payment certification is done external to the entitlement system.

"Payment request" and "receiving report" are defined in the clause at 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.

(b) Electronic invoicing. The WAWF system provides the method to electronically process vendor payment requests and receiving reports, as authorized by Defense Federal Acquisition Regulation Supplement (DFARS) 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.

(c) WAWF access. To access WAWF, the Contractor shall—

(1) Have a designated electronic business point of contact in the System for Award Management at https://www.sam.gov; and

(2) Be registered to use WAWF at https://wawf.eb mil/ following the step-by-step procedures for self-registration available at this web site.

(d) WAWF training. The Contractor should follow the training instructions of the WAWF Web-Based Training Course and use the Practice Training Site before submitting payment requests through WAWF. Both can be accessed by selecting the "Web Based Training" link on the WAWF home page at https://wawf.eb mil/.

(e) WAWF methods of document submission. Document submissions may be via web entry, Electronic Data Interchange, or File Transfer Protocol.

(f) WAWF payment instructions. The Contractor shall use the following information when submitting payment requests and receiving reports in WAWF for this contract or task or delivery order:

(1) Document type. The Contractor shall submit payment requests using the following document type(s):

(i) For cost-type line items, including labor-hour or time-and-materials, submit a cost voucher.

(ii) For fixed price line items—

(A) That require shipment of a deliverable, submit the invoice and receiving report specified by the Contracting Officer.

(Contracting Officer: Insert applicable invoice and receiving report document type(s) for fixed price line items that require shipment of a deliverable.)

(B) For services that do not require shipment of a deliverable, submit either the Invoice 2in1, which meets the requirements for the invoice and receiving report, or the applicable invoice and receiving report, as specified by the Contracting Officer.

_____Invoice 2in1_____

(Contracting Officer: Insert either "Invoice 2in1" or the applicable invoice and receiving report document type(s) for fixed price line items for services.)

(iii) For customary progress payments based on costs incurred, submit a progress payment request.

(iv) For performance based payments, submit a performance based payment request.

(v) For commercial item financing, submit a commercial item financing request.

(2) Fast Pay requests are only permitted when Federal Acquisition Regulation (FAR) 52.213-1 is included in the contract.

[Note: The Contractor may use a WAWF "combo" document type to create some combinations of invoice and receiving report in one step.]

(3) Document routing. The Contractor shall use the information in the Routing Data Table below only to fill in applicable fields in WAWF when creating payment requests and receiving reports in the system.

Routing Data Table*

Field Name in WAWF	*Data to be entered in WAWF*
Pay Official DoDAAC	HQ0490
Issue By DoDAAC	W911QY
Admin DoDAAC**	W911QY
Inspect By DoDAAC	W56XNH
Ship To Code	W56XNH

(*Contracting Officer: Insert applicable DoDAAC information. If multiple ship to/acceptance locations apply, insert "See Schedule" or "Not applicable.")

(**Contracting Officer: If the contract provides for progress payments or performance-based payments, insert the DoDAAC for the contract administration office assigned the functions under FAR 42.302(a)(13).)

(4) Payment request. The Contractor shall ensure a payment request includes documentation appropriate to the type of payment request in accordance with the payment clause, contract financing clause, or Federal Acquisition Regulation 52.216-7, Allowable Cost and Payment, as applicable.

(5) Receiving report. The Contractor shall ensure a receiving report meets the requirements of DFARS Appendix F.

(g) WAWF point of contact.

(1) The Contractor may obtain clarification regarding invoicing in WAWF from the following contracting activity's WAWF point of contact.

(b) (6)

(2) Contact the WAWF helpdesk at 866-618-5988, if assistance is needed.

(End of clause)

(End of Summary of Changes)