EX-10.1 2 nvax-20200930xex10d1.htm EX-10.1

EXHIBIT 10.1

CERTAIN INFORMATION IDENTIFIED WITH [***] HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL AND (ii) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

BASE AGREEMENT

BETWEEN

ADVANCED TECHNOLOGY INTERNATIONAL (ATI)
315 SIGMA DRIVE
SUMMERVILLE, SC 29486

AND

Novavax, Inc.
21 Firstfield Road
Gaithersburg, MD 20878

MEDICAL CBRN DEFENSE CONSORTIUM (MCDC) BASE AGREEMENT NO.: 2020-530

Authority: MCDC Other Transaction Agreement (OTA) No. W15QKN-16-9-1002 and 10 U.S.C. § 2371b, Section 815 of the 2016 National Defense Authorization Act (NDAA), Public Law (P.L.) 114-92.

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This Agreement is entered into between the Advanced Technology International hereinafter referred to as the "Consortium Management Firm (CMF)," and Novavax, Inc ., hereinafter referred to as "Project Agreement Holder." This Agreement constitutes the entire understanding and agreement between the parties with respect to the subject matter hereof and supersedes all prior representations and agreements. It shall not be varied except by an instrument in writing of subsequent dale duly executed by an authorized representative of each of the parties. The validity, construction, scope and performance or this Agreement shall be governed by the laws or the stale of South Carolina, excluding its choice of laws rules .

ADVANCED TECHNOLOGY INTERNATIONAL	**FOR THE PROJECT AGREEMENT HOLDER NOVAVAX, INC.**
/s/ [***]	/s/ John A. Herrmann III
(Signature)	(Signature)
[***], Senior Contracts Manager	John A. Herrmann III, SVP, General Counsel
(Name & Title)	(Name & Title)
June 25, 2020	
(Date)	(Date)

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Article I. SCOPE OF THE AGREEMENT

Section 1.01 Background

The U.S. Army Contracting Command-New Jersey (ACC-NJ) is entering into a Section 815 Prototype Other Transaction Agreement (OTA) with the Medical CBRN Defense Consortium, c/o Advanced Technology International 315 Sigma Drive, Summerville, SC 29486. The Joint Project Manager for Medical Countermeasure Systems (JPM-MCS) through the Joint Program Executive Office for Chemical and Biological Defense (JPEO- CBD) seeks to collaborate with the MCDC to carry out a coordinated research and development program. An OTA is being proposed with the purpose of conducting Research and Development into medical, pharmaceutical, and diagnostic technologies to enhance mission effectiveness of military personnel. The MCDC was formed in response to the Government's expressed interest to engage with an industry consortium comprised of traditional and nontraditional government contractors, small and large businesses, for-profit and not-for-profit entities, academic organizations and their affiliates for the purpose of entering into an OTA for prototype projects.

Under the OTA and associated awards, the Government, along with the non-government members from the MCDC, shall perform coordinated planning and research and development prototype efforts designed to encompass the areas contained within the scope of this OTA as listed in Article I, Section 1.03.

Section 1.02 Definitions

"Academic Research Institution" means accredited institutions (colleges, universities or other educational institutions) of higher learning in the U.S.

"Agreement" refers to the Base Agreement between the Medical CBRN Defense Consortium (MCDC) Consortium Management Firm (CMF) Advanced Technology International (ATI) and the Project Agreement Holder.

"Agreements Officer (AO)" is the U.S. Army Contracting Command – New Jersey's warranted Contracting Officer authorized to sign the final OTA for the Government.

"Agreements Officer Representative (AOR)" is the individual designated by the Government on a per project basis to monitor all technical aspects and assist in agreement administration of the specific project; the AOR shall only assist in agreement administration of the specific project to the extent delegated such administration authority in writing in the AOR delegation letter by the responsible Agreements Officer.

"Basket" is an electronic file containing proposals that have been submitted by MCDC Members in response to Requests for Prototype Proposals (RPP), reviewed by the Government, and favorably evaluated in accordance with the procedures outlined in Section 1.03 of this Article.

"Cash Contribution" means a MCDC member organization's financial resources expended to conduct a project awarded under this Agreement. The cash contribution can be derived from MCDC member organization funds or outside sources or may also come from non-federal contract or grant revenues or from profit or fee on a federal procurement contract. A MCDC member organization's own source of funds may include corporate retained earnings, current or prospective Independent Research and Development (IR&D) funds or any other indirect cost pool allocation. New or concurrent IR&D funds can be utilized as a cash contribution provided those funds identified by the MCDC member organization are to be spent on the conduct of a project's Statement of Work. Prior IR&D will not be considered as part of the MCDC member organization's cash or in kind contributions nor will fee be considered on the Project Awards that include cost sharing. Cash contributions include the funds a MCDC member organization will spend for labor (including benefits and direct overhead), materials, new equipment (prorated if appropriate), subcontractor efforts expended on a project, and restocking the parts and material consumed under a project.

"Consortium Management Firm (CMF)" refers to the organization acting on behalf of the MCDC to execute and administer the efforts under the Other Transaction Agreement for this program as defined in the specific agreement

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entered into between the MCDC and the CMF. The current CMF is Advanced Technology International (ATI). The MCDC reserves the right to replace the CMF at any time.

"Cost Share" means resources expended by the PAH on the proposed project SOW and subject to the direction of the AOR. There are two kinds of cost share: cash contribution and in-kind contribution. Cost Share may only be proposed and collected on cost-reimbursement type agreements.

"Contracting Activity" means an element of an agency designated by the agency head and delegated broad authority regarding acquisition functions. It also means elements or another agency designated by the director of a defense agency which has been delegated contracting authority through its agency charter.

"Date of Completion" is the date on which all work is completed or the date on which the period of performance ends.

"Development" means the systematic use, under whatever name, of scientific and technical knowledge in the design, development, test, or evaluation of an existing or potential new technology, product or service (or of an improvement in an existing technology, product or service) for the purpose of meeting specific performance requirements or objectives. Development includes the research functions of design engineering, prototyping, and engineering testing.

"Effective Date" means the date when this Agreement is signed and executed by the Agreements Officer for the Government.

"Government" means the US Government and its departments and agencies.

"Government Fiscal Year" means the period commencing on October 1 and ending September 30 of the following calendar year.

"In Kind Contribution" means the MCDC member organization's nonfinancial resources expended by the MCDC member organization to conduct a project, such as wear and tear on in-place capital assets like machinery or the prorated value of space used for the conduct of a project, and the reasonable fair market value (appropriately prorated) of equipment, materials, and other property used in the conduct of the project.

"JPM-MCS" means the Joint Project Manager-Medical Countermeasure Systems Office created for the advanced development of medical countermeasures for chemical and biological defense. The JPM-MCS is also the program management office for this overall effort. The JPM-MCS includes an array of stakeholders involved in the development of prototype hardware, software, and system technologies.

"Milestone" means a scheduled event signifying the completion of a major deliverable or a set of related deliverables.

"Medical CBRN Defense Consortium" is the consortium formed by industry in response to the Government's expressed interest to quickly provide the warfighter with safe and effective chemical, biological, radiological, and nuclear countermeasures. The MCDC is comprised of Traditional and Nontraditional Defense Contractors, including small and large (other than small) businesses, for profit, and not for profit entities, and academic research institutions. The MCDC was originally named the National Chemical and Biologic Defense Consortium.

"MCDC Executive Committee" is the Executive Committee, comprised of Traditional and Nontraditional Defense Contractors, including small and large businesses, for profit and not for profit entities, and academic research institutions.

"MCDC Members" means the Nontraditional and Traditional Defense Contractors, including small and large businesses, for profit and not for profit entities, and Academic Research Institutions that are members

in good standing of the MCDC.

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"Nontraditional Defense Contractor" with respect to applicable authority, means an entity that is not currently performing and has not performed, for at least the one-year period preceding the solicitation of sources by the Department of Defense for the procurement or transaction, any contract or subcontract for the Department of Defense that is subject to full coverage under the cost accounting standards prescribed pursuant to section 1502 of title 41 and the regulations implementing such section.

"Other Transaction Agreement (OTA)" refers to the Section 815 Other Transaction Agreement between the Government and the MCDC by its Consortium Management Firm, Advanced Technology International, Agreement No. W15QKN-16-9-1002.

"Other Transactions for Prototype Projects" refers to this type of Other Transaction Agreement (OTA). Section 815 of Public Law 114-92 authorizes the use of OTAs, under the authority of 10 U.S.C. 2371(b), under certain circumstances for prototype projects directly relevant to enhancing the mission effectiveness of military personnel and supporting the 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. This type of OTA is treated by DoD as an acquisition instrument, commonly referred to as an "other transaction" for a prototype project or Section 815 "other transaction".

"Parties" means the Consortium Management Firm, Advanced Technology International, and the Project Agreement Holder where collectively identified and "Party" where each entity is individually identified.

"Payable Milestone" means that once a milestone has been met (see definition of "milestone"), the Government can approve payment to the MCDC of a predetermined dollar amount in relation to performance of a particular project under the Other Transaction Agreement.

"Program Manager" means the Technical Administrator for the Program (located at the JPM-MCS) responsible for Government oversight of the MCDC OTA program.

"Project" refers to the scope of work being completed under a Project Agreement.

"Project Agreement (PA)" means that agreement between the MCDC, by its CMF, and the MCDC member entity whose proposal is evaluated and competitively selected by the Government for funding, establishing the scope of work, terms and conditions for the MCDC member entity performance and payment under the Government funded project. Project Agreements shall comply with all provisions contained within the OTA and any other supporting documents referenced therein. The Project Agreement is initiated by the CMF based on the Technical Direction Letter sent by the Government to the CMF.

"Project Agreement Holder (PAH)" means the MCDC member entity issued a Project Agreement by the CMF.

"Technical Direction Letter (TDL)" is a Government document to be issued to the CMF reflecting the Government's decision to select and fund all or part of a particular proposal submitted by a MCDC member or team of MCDC members through the RPP process conducted under this OTA. The TDL shall establish the scope of work, terms and conditions for performance and payment and include the MCDC member proposal selected for Government funding. Where a specific Government agency laboratory, test facility, center or other location will be used by the MCDC member entity in performance of the Project Agreement, it will be identified and the cost of such use, whether Government-contributed or MCDC member reimbursed, will be identified in the TDL.

"United States Army Contracting Command – New Jersey Contracting Activity" (ACC-NJ) means the contracting activity who is designated as the lead Government organization in charge of executing the Program.

"White Paper" means a document limited to a few pages prepared and submitted by a MCDC member(s) in response to a Government solicitation issued under the terms and conditions of the OTA that briefly describes and summarizes a technology idea or concept for an indicated research area in a Government-specified format. The White Papers are evaluated by the Government to determine whether submission of a full proposal on the summarized concept or idea might be warranted. To the extent that a MCDC member(s) desires to include

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proprietary information in the white paper it shall be identified and marked in accordance with the terms for protection of information under Article VIII. Confidential Information.

Section 1.03 Scope

The Government in conjunction with the MCDC member entities shall perform a coordinated research and development program designed to support the DoD's medical, pharmaceutical, and diagnostic requirements as related to enhancing the mission effectiveness of military personnel. The mission of JPM-MCS is to provide the U.S. military forces and the nation safe, effective, and innovative medical solutions to counter Chemical Biological Radiological and Nuclear (CBRN) threats. Under the OTA and associated Project Agreements, the Government along with the Consortium member entities, shall perform coordinated planning and research and development prototype efforts in support of the JPM-MCS mission through the development of products in three (3) major Medical Countermeasure Systems (MCS) objective areas:

- Detection: Systems and devices to identify CBRN agents and assist in making medical decisions
- Prevention: Prophylaxis, pretreatment, and post-exposure prophylaxis
- Treatment: Therapeutics (post-exposure, post-symptomatic)

The Government will determine which endeavors to pursue and projects to fund. At any time throughout the term of the OTA, the Government may address the needs for the desired MCS objective areas or other related Government needs as they arise. The MCDC and the Government agree that other organizations and agencies within the U.S. Government may participate in the collaborative activities through a Memorandum of Agreement or other such arrangement. It is anticipated that these other organizations may include JPEO-CBD and DTRA.

Request for Prototype Proposal (RPP) Process:

Once the Government identifies a need under one of the MCS objective areas above, the Government will issue a Request for Prototype Proposal (RPP). The RPP will include a Request for White Papers (RWP) and/or a Request for Prototype Proposal (RPP) to the Consortium Management Firm (CMF). Due dates will be indicated for each. The CMF shall in turn issue a similar request to MCDC's member entities, for which the Government will review and evaluate all responses. The Government will be solely responsible for evaluation of the white papers and/or proposal submissions, as applicable. If the RPP includes a RWP, only members submitting white papers will be permitted to submit full proposal submissions. Based on the evaluation of the white papers, the Government will make a recommendation on whether the member should or should not submit a full proposal submission. Any member submitting a white paper, regardless of the Government's recommendation, may submit a proposal.

MCDC member white papers and proposals shall be submitted to the CMF in accordance with the RPP instructions which will include evaluation criteria and a Statement of Work (SOW) template on the due date indicated in the RPP. The CMF will review white paper and proposal submissions for completeness and format compliance. The CMF shall in turn prepare and transmit MCDC's member's white papers and proposals to the Government for evaluation. The Government will be responsible for technical evaluation and selection of the projects from the proposals submitted. The CMF will assess the reasonableness and completeness of the cost estimates and then provide a formal assessment to the Government. The Government Agreement Officer will review this assessment and make the final determination regarding whether the negotiated project cost is fair and reasonable. All Project Agreements will be subject to discussions/negotiations and proposal updates, as appropriate, prior to execution.

Once all steps are complete, the Government will issue a Technical Direction Letter (TDL) to the CMF for the authorization and execution of the selected project to be performed by the selected MCDC's member entity(ies). Once the CMF receives notification of selection of a project for funding via TDL, the CMF will enter into a Project Agreement with the MCDC member.

A modification will be included with the TDL, which will include the funding for the negotiated and agreed-upon project. After receipt of the TDL and review and execution of the funding modification, the CMF shall enter into a Project Agreement (PA) with MCDC member whose project was selected. MCDC CMF shall administer the Government-funded Project Agreements. The Government's designated Agreements Officer Representative (AOR) for the specific project will supervise the technical work performed by MCDC's member entity in execution of the

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PA. The Government reserves the right to revise the terms and conditions of these projects in accordance with Article III, Section 3.04.

Placement in the Electronic "Basket File":

Qualifying proposals, not eligible for current funding, may be entered into an electronic basket and subject to award for up to thirty-six (36) months. The RPP will contain the available ratings and their definitions to be assigned to proposals as a result of the technical evaluation as well as which specific ratings will qualify a proposal for inclusion in the Basket. The Government reserves the right to determine which, if any, proposals are to be selected according to the published criteria.

Once in the Basket, a proposal may be identified for award by the Government based on Government need and availability of funding. The Government reserves the right to 1.) request that the MCDC member who submitted the identified proposal, scale or otherwise adjust the original proposal, and to 2.) fund all or part of the identified proposal. The MCDC member will have an opportunity to update their proposal, as applicable, if selected from the basket. The Government will review any updated information provided by the MCDC member and/or CMF. Upon the Government's decision to fund such a proposal from the Basket, the CMF will receive notification of the award decision through a TDL whereupon the CMF will enter into a Project Agreement with the indicated MCDC member as required.

A selected proposal will reside in the Basket for thirty-six (36) months from the date the corresponding RPP is closed unless funded or the submitting MCDC member requests in writing beforehand to have it removed.

SBIR Phase III Project Requests

It will be incumbent upon the MCDC member, on their own with some general support and guidance from the CMF, to find a Government Technical POC with both (1) available funding and (2) an interest in furthering technology developed under a current or prior SBIR project. Upon doing so, the Government Technical POC will coordinate the feasibility of placing the award under the OTA with the Government AO and OTA Program Manager and the following areas will be considered when making a determination for appropriateness of award under the OTA:

- How the proposed effort derives from, extends, or logically concludes efforts performed under prior SBIR funding agreements;
- How the proposed effort fits within the definition of a prototype effort related to medical, pharmaceutical, and diagnostic technologies to enhance mission effectiveness of military personnel in accordance with the statutory requirement;
- How the proposed effort fits within the overall scope of work and the goals and objectives of the OTA.

Should the Government AO and the OTA Program Manager determine it is appropriate to award the SBIR Phase III under the OTA, the Government AO will send a proposal request to the MCDC member through the CMF, as is standard for any Government request under the OTA. The CMF will provide a cost analysis summary to the Government Agreements Officer (AO) for consideration in the Government's award determination. The Government will evaluate the proposal, conduct any necessary negotiations through the CMF, and make an award determination. If the Government makes the determination to award to the MCDC member, the Government AO will issue a TDL letter to the CMF, resulting in the issuance of a Project Agreement between the CMF and MCDC member.

SBIR Phase III awards under this Agreement shall include the Data Rights provisions and Data Rights granted to the MCDC member contained within Article XI of this Agreement. All administrative, reporting, and other aspects of awards made for SBIR Phase III efforts under this Agreement will be in accordance with the terms and conditions of the OTA. MCDC Members must have been awarded and performed under a

previous SBIR Phase I and/or Phase II contract in order to qualify for SBIR Phase III award under this Agreement.

Section 1.04 Goals/Objectives

The following goals/objectives will be pursued through the execution of the OTA:

- Accelerate the development of mission critical technologies in the areas of concern from applied research into advanced development.
- Deliver therapeutic MCM prototypes targeting viral, bacterial, and biological toxin targets of interest to the DOD. MCM prototypes are drug products that have completed all or part of the activities required to support FDA licensure. This may include meeting warfighter requirements of protection against an aerosolized route of exposure.
- Deliver enabling technologies that will support the development and regulatory review of MCM prototypes. The enabling technologies can include animal models of viral, bacterial or biological toxin disease and pathogenesis (multiple routes of exposure), assays, diagnostic technologies or other platform technologies applicable to development and regulatory review of MCM.
- Develop prototype candidates for the prophylaxis, treatment and diagnosis of Chemical threats. This will include diagnosis of, and prophylaxis and treatment for, exposure to traditional and emerging chemical nerve agent threats, as well as other emerging chemical threat agents other than nerve agents.
- Develop prototype candidates for the prophylaxis, treatment and diagnosis of Radiological and Nuclear threats. This will include prototype candidates for diagnosis of, and prophylaxis and treatment for Acute Radiation Syndrome.
- Develop soldier-carried autoinjector delivery devices for single drug administration. Develop soldier- carried autoinjector delivery devices for administration of two or more drugs.
- [Develop vaccine-manufacturing platforms that offer early stage manufacturing flexibility and diversity using a deep knowledge of protein(s) expression in a biological system that is reproducible and scalable, and preferably with direct FDA experience. The goal is to manufacture and test identified protective molecule(s) and target molecule(s) (along with associated reagents and standards) in multiple scalable, flexible manufacturing platforms encompassing a diverse array of manufacturing systems (e.g., insect, mammalian, live viral, plant, *E.coli*, yeast, etc.) for use in appropriate animal model(s) and in Phase 1 trials.]
- Pharmaceutical development will address the FDA Animal Rule, as appropriate.
- Utilize adjuvants and excipients supporting the ability to develop up to 300,000 equivalent doses within 60 days at clinical quality.
- Support a family of systems diagnostic approach that increases the speed, accuracy, and confidence of agent identification and disease diagnosis. Diagnostic areas include those for organisms that circulate freely and at relatively high numbers at or near the onset of symptoms, organisms that circulate in low numbers early in infection but then integrate with host cells, organisms that have significant genomic diversity from strain to strain, and non-BW agents such as toxins/chemical agents/radiological agents that do not replicate and require low quantities to cause illness.
- Support the Defense Biological Products Assurance Office (formally the Critical Reagents Program), the principal DoD resource of high quality, validated, and standardized biological reference materials, reagents, and assays, as necessary.
- DoD Advanced Development and Manufacturing Capabilities: To facilitate lessons learned and to ensure DoD MCM product development schedules are not impacted, the consortium will consider Advanced Development and Manufacturing (ADM) capability contractors for biologics manufacturing activities for monoclonal antibodies, vaccines, and recombinant proteins may utilize the DoD funded facility.
- Pursue collaborative research with non-traditional technology providers in a manner that enables effective transition of technologies to Government prototyping programs during any phase of life cycle support (affordability, manufacturability, sustainment, etc.).

Section 1.05 Reports

The MCDC member organizations conducting projects in accordance with this Agreement shall maintain records of the activities performed and funding expended under the projects and the results of

any studies analyses, tests, and other investigations conducted. Based on the progress of the funded projects and other information known to the AO or authorized designee, the MCS Program Office shall review the relevant

projects throughout the period to determine if any changes to planning or budget are required. If such a change is expected which will cause a need to modify the OTA, the Technical Direction Letter or an individual Project Agreement may be modified to incorporate such changes. The AO is the only authorized representative of the Government who may make modifications to the OTA. PAHs shall submit the following reports to the CMF who will review and provide one cumulative report detailing status of all funded projects to the MCS Program Office.

a.) Project Agreement Quarterly Report. The report will have two major sections:

(i) Technical Status Report. The technical status report will detail technical progress to date and report on all problems, technical issues or major developments during the reporting period. Each of the topics described below shall be addressed for the effort performed:

(1) A comparison of actual accomplishments with the goals and objectives of the project established for the period.

(2) Reasons why established goals and objectives were not met, if appropriate.

(3) Other pertinent information including, when appropriate, analysis and explanation of cost variances.

(4) A cumulative chronological list of written publications in technical journals. Include those in press as well as manuscripts in preparation and planned for later submission. Indicate likely journals, authors, and titles.

(5) Papers presented at meetings, conferences, seminars, etc.

(ii) Business Status Report. The business status report shall provide summarized details of the resource status of the Project Agreement, including the status of the contributions by all participants. This report will include a quarterly accounting of current expenditures. Any major deviations from the agreed to project plans shall be explained with discussion of proposed actions to address the deviations. The report will also include an accounting of interest earned on Government Funds, if any. It is not expected that any interest will accrue under the Project Agreement(s), as milestone payments will be tracked and adjusted accordingly. In any event, the Government reserves the right to require interest amounts in excess of $250 per year to be remitted to the US Treasury.

b.) Annual Technical Report. Annual technical reports are required for projects whose periods of performance are greater than one year. The PAH's report will provide a concise and factual discussion of the significant accomplishments and progress during the year covered by the report.

c.) Final Technical Report.

(i) Final Technical Report (FTR). A Final Technical Report shall be submitted to the CMF within thirty (30) calendar days of the completion of the Project Agreement. This report will provide a comprehensive, cumulative, and substantive summary of the progress and significant accomplishments achieved during the total period of the effort. Each of the topics described above shall be addressed as appropriate for the effort performed. Upon receipt, the AOR will review and provide any comments within 30 days. If necessary, the PAH will update the FTR within 30 days of receipt of AOR's comments. Once the CMF has informed PAH that the FTR has been approved by the AOR, the PAH shall forward a copy of the FTR to the Defense Technical Information Center, Attn. DTIC-O, 8725 John J. Kingman Road, Suite 0944, Fort Belvoir, VA 22060-6218.

(ii) Format. The cover and title page shall be Standard Form (SF) 298, Report Documentation Page. Item 13 of the form should contain a 100 to 200 word abstract summarizing technical progress

during the reporting period. Style should be third person singular using past tense. Jargon, special symbols or notations, subscripts, mathematical symbols or foreign alphabet letters are not permitted. All pages should be

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prepared for acquisition and distribution by the Defense Technical Information Center (DTIC). All pages should be good quality for copying purposes. The report shall be prepared in accordance with American National Standards Institute (ANSI) document Z39.18-1987, "Scientific and Technical Reports: Organization, Preparation, and Production," which may be obtained from American National Standards Institute Incorporated, 1430 Broadway, New York, NY, 10018. The FTR front page shall be marked in a conspicuous place with a distribution statement to denote the extent of its availability for distribution, release, and disclosure without additional approvals or authorizations.

d.) Final Business Status Report. The final business status report shall provide summarized details of the resource status of the Project Agreement, including the status of the contributions by all participants. This report will include a final accounting of cumulative expenditures. If a project is terminated prior to the end of a quarter or a year and sufficient funding is available, the PAH, through the CMF, must submit a final technical and business status report in the same format as detailed herein.

Note: Deficiencies in regulatory reports must be adequately assessed by the Government, MCDC and the individual performer, or consortium as a whole, to come to resolution.

Article II. TERM

Section 2.01 The Term of this Agreement

The period of performance for this Agreement is from the effective date, which is the date of last signature, to April 7, 2036. If at any time funds expended exceed the amount obligated on a Project Agreement prior to the expiration of the term, the Parties have no obligation to continue performance and may elect to cease their efforts at that point. Provisions of this Agreement, which, by their express terms or by necessary implication, apply for periods of time other than specified in Article II herein, shall be given effect, notwithstanding this Article.

Section 2.02 Termination of this Agreement by Mutual Agreement

Except for the rights and obligations with respect to proprietary information and/or specific intellectual property agreements between or amongst the Government, the CMF and the MCDC member organizations, unless extended by mutual written agreement of the Parties, this Agreement shall automatically terminate by written agreement of the Parties. Unless otherwise directed by the AO through the CMF, individual Project Agreements pursuant to this Agreement shall also terminate upon the termination of this Agreement.

Section 2.03 Termination Provisions

Subject to a reasonable determination that the program, or a project funded under the program, will not produce beneficial results commensurate with the expenditure of resources, the Government may terminate performance of work under this OTA or a specific project, in whole or in part, if the AO determines that a termination is in the Government’s interest. The AO shall terminate by delivering to the MCDC through its CMF a Notice of Termination specifying the extent of termination and the effective date.

After receipt of a Notice of Termination, and except as directed by the CMF, the PAH shall immediately proceed with the following obligations, regardless of any delay in determining or adjusting any amounts due:

(1) Stop work and direct its subawardees to stop work as specified in the notice.

(2) Place no further subagreements or orders (referred to as orders in this clause) for materials, services, or facilities, except as necessary to complete the continued portion of the project.

(3) Terminate all orders to the extent they relate to the work terminated.

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(4) Assign to the Government, as directed by the AO, all right, title, and interest of the PAH under the orders terminated, in which case the Government shall have the right to settle or to pay any termination settlement proposal arising out of those terminations.

(5) With approval or ratification to the extent required by the AO, the CMF may settle all outstanding liabilities and termination settlement proposals arising from the termination of orders; the approval or ratification will be final for purposes of this clause.

(6) Provide CMF, and/or obtain from the subawardees under the terminated portion of the Agreement a transfer of title to the following where applicable and deliver to the Government --

(i) The fabricated or unfabricated parts, work in process, completed work, supplies, and other material produced or acquired for the work terminated; and

(ii) The completed or partially completed plans, drawings, information, and other property that, if the order had been completed, would have been required to be furnished to the Government.

(7) Complete performance of any work not terminated, if applicable.

(8) Take any action that may be necessary, or that the AO may direct through the CMF, for the protection and preservation of the property related to this project that is in the possession of the PAH(s) or any subawardee and in which the Government has or may acquire an interest.

(9) Use commercially reasonable efforts to sell, as directed or authorized by the CMF, any property of the types referred to under Article II. Section 2.03 Termination Provisions, (6)(i) and (ii); provided, however, that the PAH:

(i) is not required to extend credit to any purchaser and

(ii) may arrange for the subawardee who was performing the terminated work to acquire the property under the conditions prescribed by, and at prices approved by, the CMF.

(iii) will in no event be required to continue with such efforts for more than three (3) months after notice by the CMF to sell or disposition such property.

(10) The PAH has no obligation to continue to cost share on the terminated project or terminated portion of the project.

The requirement for at least 1/3 cost share of the total project cost by the PAH is assessed prior to award. In the event that during the course of the performance of the Project Agreement any of the parties to the Project Agreement believe the cost sharing funds available will be insufficient, the PAH shall notify the CMF within twenty-five (25) days of the event that gave rise to the insufficient cost sharing funds. CMF will notify the Government within five (5) days of receiving such notice from the PAH. The Government will determine whether it is in its best interest to either renegotiate the scope and/or terms of the Project Agreement to meet the cost share requirement or terminate the Project Agreement in whole or in part.

The proceeds of any transfer or disposition of project property will be applied to reduce any payments to be made by the Government under that particular project, including credited to the price or cost of the work, or paid in any other manner directed by the CMF.

In the event of a termination of the Project Agreement, the Government shall have patent rights as described in Article X, Patent Rights, and rights in Data as described in Article XI, Data Rights. Failure of the PAH and Government to agree to an equitable adjustment shall be resolved pursuant to Article VII, Disputes.

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Section 2.04 Termination Cost

The CMF will negotiate with the Government and PAH in good faith equitable reimbursement for work performed toward accomplishment of the task or tasks of individual projects. The Government will allow full credit for the Government share of the obligations properly incurred by a PAH prior to termination. Costs incurred by a PAH during a suspension or after termination of a project are not allowable unless the CMF expressly authorizes them in either the notices of suspension, termination, or subsequently. Other PAH's costs incurred during a suspension or after termination which are necessary and not reasonably avoidable are allowable if:

(a) The costs result from obligations which were properly incurred by the PAH before the effective date of the suspension or termination, are not in anticipation of it, and in the case of a termination, are non-cancellable; and

(b) The costs would be allowable if the project was not suspended or the award expired normally at the end of the funding period in which the termination takes effect.

Section 2.05 Close-out Procedure.

If the Government funds an individual Project Agreement and then subsequently terminates the agreement or the requirements of the agreement are met, the following closeout procedures apply:

(a) Definitions.

(i) "Closeout" – the process by which the Government and CMF determine that all applicable administrative actions and all required work have been completed by the PAH.

(ii) "Date of Completion" – the date on which all work is completed or the date on an amendment thereto on which the period of performance ends.

(iii) "Disallowed costs" – those charges that the Government or its representative determines to be unallowable, in accordance with the terms and conditions stated in this Agreement.

(b) Upon request, the Government shall make prompt payments to the PAH through the CMF for allowable reimbursable costs under the MCS Project Agreement being closed out.

(c) The PAH shall immediately refund any balance of unobligated (unencumbered) cash that the CMF has paid and that is not authorized to be retained by the PAH for use in the performance of the Project Agreement.

(d) The CMF shall obtain from the PAH within 90 calendar days after the date of completion of an MCS Project Agreement all financial, performance, and other reports required as a condition of the MCS Project Agreement. The CMF may grant extensions when requested by the PAH.

(e) When authorized, the CMF shall make a settlement for any upward or downward adjustments to the Government's share of costs after these reports are received based on final, actual expenditures in accordance with the Termination Costs provision of the Agreement.

(f) Quick close-out procedures similar to FAR 42.708 shall be followed.

(g) The PAH shall account for any property received from the Government.

Section 2.06 Stop Work

As directed by the AO, the CMF may, at any time, by written order to the PAH, require the PAH to stop all, or any part, of the work called for under this Agreement or any Project Agreement for a period of 90 days after the written order is delivered to the PAH, and for any further period to which the parties may agree. The order shall be specifically identified as a stop-work order issued under this section. Upon receipt of the order, the PAH shall

immediately comply with its terms and take all reasonable steps to minimize the incurrence of costs allocable to the work covered by the order during the period of work stoppage. Within a period of 90 days after a stop-work is delivered to the PAH, or within any extension of that period to which the parties shall have agreed, the CMF shall either:

(a) Cancel the stop-work order; or

(b) Terminate the work covered by the Project Agreement as provided in Article II, Term and Termination.

If a stop work order issued under this clause is canceled, the PAH shall resume work. The CMF shall make an equitable adjustment in the delivery schedule or Project Agreement estimated cost/price, or both, and the Government's share of the Project Agreement shall be modified, in writing, accordingly, if—

(1) The stop-work order results in an increase in the time required for, or in the PAH's cost properly allocable to, the performance of any part of the Project Agreement; and

(2) The PAH asserts its right to the adjustment within 30 days after the end of the period of work stoppage; provided, that, if the Government decides the facts justify the action, the Government through the MCDC CMF may receive and act upon a proposal submitted at any time before final payment under the Project Agreement.

If a stop work order is not canceled and the work covered by the Project Agreement is terminated in accordance with Article II, the MCDC CMF shall work with the PAH to negotiate an equitable reimbursement in accordance with Article II. Section 2.03, Termination Provisions.

Article III. MANAGEMENT OF THE PROJECT

Section 3.01 The Medical CBRN Defense Consortium (MCDC)

The MCDC, as defined in the OTA, was formed to work with the Government and provide input in developing technologies to support the Department of Defense's (DoD) medical, pharmaceutical, and diagnostic requirements as related to enhancing the mission effectiveness of military personnel ultimately resulting in fully executed research and development prototype projects selected by the Government. Every Member in this MCDC is independent of the other, and there is no affiliation between the MCDC members within the definition of 13 C.F.R. 121.103 of the Federal Small Business Regulations and no such affiliation is intended either by the formation or implementation of the MCDC.

As appointed by the MCDC Executive Committee, the CMF has the authority to execute the Other Transaction Agreement (OTA) on behalf of the MCDC and has the responsibility for day to day overall administration of this Agreement, subject to the supervision of the MCDC Executive Committee.

Section 3.02 The following MCDC decisions are subject to the ACC-NJ approval:

1. Changes to the MCDC Articles of Collaboration if such changes substantially alter the relationship of the MCDC and the Government as originally agreed upon when the OTA was executed;
2. Changes to, or elimination of, any ACC-NJ funding allocation to any MCDC Member as technically and/or financially justified.

Section 3.03 Management and Project Structure

Technical and project management of the coordinated research program established under this Agreement shall be accomplished through the management structures and processes detailed in this Article.

The Government competitively selected the MCDC, organized by its Consortium Management Firm Advanced Technology International, a Section 501(c)(3) nonprofit organization. MCDC has entered into an agreement with Advanced Technology International authorizing Advanced Technology International to enter into this OTA as the consortium manager, engage in overall day to day management of the MCDC under the guidance of and as

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designated by the MCDC Executive Committee, including technical, programmatic, reporting, financial, administrative and contractual matters and administer Project Agreements required for performance under this OTA.

As established by funded projects under the OTA, the Government Program Manager shall fully participate in the appropriate program technical meetings held by the MCDC. The AORs and Other Government personnel, as deemed appropriate, also may participate in the technical portion of these meetings.

Section 3.04 Modifications

As a result of scheduled meetings, end of program reviews, or at any time during the term of the OTA, research progress or results may indicate that a change in the OTA's scope, objectives or Term would be beneficial to program objectives. Recommendations for modifications, including justifications to support any changes to the OTA Scope, will be documented in a letter and submitted by the PAH to the CMF, who will then forward it to the Program Manager with a copy to the AO. This documentation letter will detail the technical, chronological, and financial impact of the proposed modification to the OTA. The Program Manager shall be responsible for the review and verification of any recommendations to revise or otherwise modify the OTA Scope or other proposed changes to the terms and conditions of the OTA and subsequently this Agreement.

With regard to projects the Government determines to fund as a result of the RPP process specified in the Agreement Scope, any PAH recommendations for modifications, including justifications to support any changes to the funded projects, will be documented in a letter and submitted by the CMF to the AO with a copy to the Government Agreements Officer Representative designated for the particular project. The AO shall be responsible for review of proposed changes and for all modifications to the terms and conditions of the project awards. The CMF shall modify the Project Agreement(s) in the event of any such modifications or changes to the project.

Management of Projects

(1) Performance of the work on each project is subject to the technical direction of the AOR designated in the Project Agreement. For the purposes of this clause, technical direction includes the following:

    a. Direction to the PAH, which shifts work emphasis between work areas or tasks, requires pursuit of certain lines of inquiry, fills in details or otherwise serves to accomplish the objectives described in the statement of work;
    b. Guidelines to the PAH that assist in the interpretation of drawings, specifications or technical portions of work description.
    c. Review and, where required by the Project Agreement, approval of technical reports, drawings, specifications, or technical information to be delivered by the PAH under the Project Agreement.

    The AOR shall monitor the PAH's performance with respect to compliance with the technical requirements of the Project Agreement.

(2) Technical direction must be within the general scope of work stated in the Project Agreement. Technical direction may not be used to
    a. Assign additional work under the Project Agreement;
    b. Increase or decrease the estimated Project Agreement cost, fee (if any), or the time required for the project performance;
    c. Change any of the terms, conditions or specifications of the Project Agreement; or
    d. Accept non-conforming work.

As such, no verbal or written request, notice, authorization, direction or order received by the PAH shall be binding upon the MCDC, CMF or Government, or serve as the basis for a change in the Project Agreement cost or any other provision of the Project Agreement, unless issued (or confirmed) in writing by the MCDC CMF Contractual Representative designated in the Project Agreement.

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(3) The PAH shall immediately notify the MCDC CMF Contractual Representative whenever a written change notification has been received from anyone other than the MCDC CMF Contractual Representative, which would affect any of the terms, conditions, cost, schedules, etc. of the Project Agreement, and the PAH is to perform no work or make any changes in response to any such notification or make any claim on the MCDC through its CMF or Government, unless the MCDC CMF Contractual Representative directs the PAH, in writing, to implement such change notification.

Article IV. AGREEMENT ADMINISTRATION

Administrative and contractual matters under this Agreement shall be referred to the following representatives of the parties:

MCDC: Advanced Technology International
MCDC Contracts
315 Sigma Drive
Summerville, SC 29486
[***]

Project Agreement Holder: Novavax, Inc.
21 Firstfield Road
Gaithersburg, MD 20878
Attn: John A. Herrmann III, SVP, General Counsel
[***]

Each party may change its representatives named in this Article by written notification to the other parties. Agreements Officer Representative (AOR); AOR will he designated by the Government on a per project basis.

Article V. OBLIGATION AND PAYMENT

Section 5.01 Obligation:

Except as specified in Article VII: Disputes, the CMF's liability to make payments to the PAH is limited only to those funds obligated under the Project Agreement(s). The CMF may incrementally fund the Project Agreement(s). If modification becomes necessary in performance of projects, pursuant to Article V of this Agreement, the CMF and the PAH shall establish and execute a revised Schedule of Payable Milestones consistent with the current Project Agreement.

Section 5.02 Project Payments:

The detailed instructions for project payments will be included in the Technical Direction Letter to be issued by the CMF on a project by project basis.

Section 5.03 Accounting System Requirements:

Prior to the submission of invoices, the PAH shall have and maintain an established accounting system which complies with Generally Accepted Accounting Principles (GAAP) and the requirements of this Agreement. The PAH shall ensure that appropriate arrangements have been made for receiving, distributing and accounting: for Federal funds under this Agreement. Consistent with this stipulation, an acceptable accounting system will be one in which all cash receipts and disbursements arc controlled and documented properly.

Section 5.04 Invoicing Instructions:

Project Payable Milestones: The PAH shall segregate and track all individual project costs separately and shall document the accomplishments of each Payable Milestone under each Project Agreement. A Payable Milestones report shall be detailed on a project basis and submitted with each request to the AOR or designee for approval.

Section 5.04 a. Payment Method Types

Project Agreements will be issued as either a fixed price milestone payment method or a cost reimbursement milestone payment method as described below.

(a) *Fixed Price Milestone Payment Method:* Payments shall be made in accordance with the Payable Milestone Schedule of each Project Agreement, provided the designated AOR has verified compliance with the Statement of Work and accomplishment of the stated effort. The Payable Milestone Schedule may be revised as appropriate and deemed necessary by issuance of a bilateral modification to the Project Agreement. Quarterly reviews by the AOR and the CMF will assess the need for revisions to the Payable Milestone Schedule. An acceptable invoice for adjustable fixed price milestone payments is one that (on the invoice or on the Payable Milestone Report):

(i) contains the date of invoice and the Base Agreement number and Project Agreement number;

(ii) identifies any associated technical milestones and the progress toward completion of each milestone; and

(iii) lists the milestone cost negotiated and contained in each Project Agreement

(b) *Cost Reimbursable Milestone Payment Method (with not to exceed ceiling):* Payment is contingent upon satisfactory progress toward completion of milestones as delineated in Project Agreement. Payment shall be made based on actual costs incurred in completing milestones up to the maximum amount allowable under the applicable Project Agreement, provided the designated AOR has verified compliance with the Statement of Work and accomplishment of the stated effort. Per (ii) below, either a Status Report identifying any associated technical tasks and the progress toward completion of each milestone, a Deliverable Report, or a Milestone Report is required concurrent with the invoice. An acceptable invoice for reimbursable payment is one that (on the invoice or on the attached Status, Deliverable, or Milestone Report in accordance with each Project Task Assignment):

(i) contains the date of invoice and the Base Agreement number and Project Agreement number;

(ii) identifies any associated technical milestones and the progress toward completion of each milestone;

(iii) includes a description of supplies and services, labor costs, subcontractor costs, material costs, travel costs, other direct costs, and extended totals;

(iv) indicates the current period and cumulative man-hours and costs incurred through the period indicated on the invoice; and

(v) contains the following certification statement:

"I certify that the amounts invoiced are for costs incurred in accordance with the agreement, the work reflected has been performed, and prior payment has not been received."

Authorized Signature_____

(c) *Cost Plus Fixed Fee Milestone Payment Method (with not to exceed ceiling):* Payment is contingent

upon satisfactory progress toward completion of milestones as delineated in Project Agreement. Payment shall be made based on actual costs incurred in completing milestones up to the maximum amount allowable under the applicable Project Agreement, provided the designated AOR has verified compliance with the Statement of Work and accomplishment of the stated effort. The PAH will normally fund any costs incurred above this maximum amount. Either a Status Report identifying any associated technical tasks and the progress toward completion of each milestone, a Deliverable Report, or a Milestone Report is required concurrent with the invoice. An acceptable invoice for reimbursable payment is one that (on the invoice or on the attached Status, Deliverable, or Milestone Report in accordance with each Project Agreement):

(i) contains the date of invoice and the Base t Agreement number and Project Agreement number;

(ii) identifies any associated technical milestones and the progress toward completion of each milestone;

(iii) includes a description of supplies and services, labor costs, subcontractor costs, material costs, travel costs, other direct costs, fixed fee and extended totals;

(iv) indicates the current period and cumulative man-hours and costs incurred through the period indicated on the invoice; and

(v) contains the following certification statement:

"I certify that the amounts invoiced are for costs incurred in accordance with the agreement, the work reflected has been performed, and prior payment has not been received."

Authorized Signature_____

(d) *Cost Reimbursable, Cost Sharing Milestone Payment Method (with not to exceed ceiling):* Payment is contingent upon satisfactory progress toward completion of milestones as delineated in Project Agreement and acceptable cost share. Payment shall be made based on actual costs incurred in completing milestones up to the maximum amount allowable under the applicable Project Agreement, provided the designated AOR has verified compliance with the Statement of Work and accomplishment of the stated effort. Per (ii) below, either a Status Report identifying any associated technical tasks and the progress toward completion of each milestone, a Deliverable Report, or a Milestone Report is required concurrent with the invoice. An acceptable invoice for reimbursable payment is one that (on the invoice or on the attached Status, Deliverable, or Milestone Report in accordance with each Project Agreement):

(i) contains the date of invoice and the Base Agreement number and Project Agreement number;

(ii) identifies any associated technical milestones and the progress toward completion of each milestone;

(iii) includes a report of the cost share expended towards the accomplishment of the SOW tasks and/or milestones. This cost share report may be attached to the invoice if contractor practices make inclusion of such information on the invoice itself impractical. If the cost share report is separate from the invoice, it must be signed by an authorized representative. This cost share report must contain a breakout of the cost share by cost element similar to the level of detail required on the invoice and

any in-kind contributions. The preferred method of reporting cost share is to provide an invoice for actual cost incurred with a value for the cost shared amount and the value to be reimbursed by the Government through the CMF;

(iv) includes a description of supplies and services, labor costs, subcontractor costs, material costs, travel costs, other direct costs, and extended totals;

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(v) indicates the current period and cumulative man-hours and costs incurred through the period indicated on the invoice; and

(vi) contains the following certification statement:

"I certify that the amounts invoiced are for costs incurred in accordance with the agreement, the work reflected has been performed, and prior payment has not been received."

Authorized Signature_____

Section 5.04 b. Submission of Invoices

Invoices may be submitted no more frequently than monthly. The PAH shall submit invoices and any necessary supporting documentation via email to [***].

For Cost type Project Agreements, the PAH's final invoice (completion invoice) will be clearly indicated as such and shall indicate the cumulative amounts incurred and billed to completion, and a written certification of the total hours expended. Actual project costs incurred and cost share performance, if applicable, of each project shall be reported and reviewed each quarter.

Section 5.04 c. Payment Terms

Payment terms are NET 30 days after CMF's receipt of an acceptable invoice. An acceptable invoice is one that meets the conditions described in Article V Section 5.04a. Payment Method Types.

Section 5.05 Advance Payments:

On a per project basis, advance payments may be approved by the AO. If the AO has approved advance payments, there will be a requirement to establish a separate interest bearing account. The PAH sets up and maintains funds in a separate interest bearing account unless one of the following applies:

(1) The PAH receives less than $120,000 in Federal awards per year;

(2) The best reasonably available interest bearing account would not expect to earn interest in excess of
$250 per year on such cash advances;

(3) The depository would require an average or minimum balance so high that it would not be feasible within the expected cash resources for the project; or

(4) The advance payments are made one time to reduce financing costs for large up-front expenditures and the fund will not remain in the PAH's account for any significant period of time.

Where a separate interest bearing account is set up, any interest earned should be remitted annually to the CMF. CMF shall forward the funds to the Government as directed by the AO. Interest payments shall be made payable to the U.S. Treasury.

Section 5.06 Limitation of Funds:

Except as set forth in Article VII, the Government's financial liability will not exceed the amount obligated for projects and available for payment.

Section 5.07 Financial Records and Reports:

The PAH shall maintain adequate records to account for Federal funds received under this Agreement and shall maintain adequate records to account for Project Agreement funding provided under this Agreement, should cost sharing procedures be implemented for funding a particular project. PAH's relevant financial records are available and subject to examination or audit on behalf of the ACC-NJ for a period not to exceed five (5) years after final payment of the PAH's project. The AO or designee shall have direct access to sufficient records and information of the PAH to ensure full accountability for all funding under this Agreement. Such audit, examination or access shall be performed during business hours on business days upon prior written notice and shall be subject to the security requirements of the audited party. Any audit required during the course of the program may be conducted by the Government using Government auditors or, at the request of the PAH, by the requesting PAH's external CPA accounting firm at the expense of the requesting PAH.
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Article VI. NONTRADITIONAL DEFENSE/COST SHARING

In accordance with provisions of 10 USC 2371b, Section 815 of the 2016 National Defense Authorization Act, P.L. 114-92, which provides the Department of Defense (DoD) authority to enter into transactions *other than* contracts, grants, or cooperative agreements, the Department of Defense (DoD) has the authority to make awards 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 the improvement of platforms, systems, components, or materials in use by the armed forces. Section 815 revised the definition for the term 'nontraditional defense contractor' as defined in Article I. Section 1.01, Definitions.

Each MCDC Member Organization must meet the definition of a Nontraditional Defense Contractor or have at least one Nontraditional Defense Contractor participating to a significant extent in the performance of an awarded Project Agreement. Examples of what might be considered a significant extent or significant contribution include, but may not be limited to supplying new key technologies or products, accomplishing a significant amount of the effort, or in some other way causing a material reduction in the cost or schedule or increase in the performance.

If significant Nontraditional Defense Contractor participation cannot be fulfilled, the Member Organization must provide at least one third cost share of the value of the Project Agreement awarded to the Member Organization. Proposals that fail to comply with this requirement will not be awarded under the OTA.

Cost Sharing is not required under this Other Transaction Agreement for projects that contain significant nontraditional defense contractor participation. Where both Parties agree, cost sharing may be considered on a per project basis under terms and conditions to be agreed to by the Parties and in accordance with the "Other Transactions" (OT) Guide For Prototype Projects dated January 2001. For traditional Government contractors without a significant nontraditional defense contractor teaming partner, a one third cost share of the project costs is required as described in the "Other Transaction" (OT) Guide For Prototype Projects dated January 2001. For traditional Government contractors with significant nontraditional defense contractor participation, cost sharing is not required for Projects under this OTA.

Throughout the period of performance of any Project Agreement, the Government AO and AOR will actively monitor Nontraditional Defense Contractor participation and/or cost sharing to ensure compliance with this provision in accordance with implementation guidance from HQDA and/or OSD. The PAH will be given the opportunity to become compliant with the guidance should they be found non-compliant. Failure to comply may result in termination.

Article VII. DISPUTES

Section 7.01 General

For the purposes of this Article, "Parties" means the CMF, the PAH and the Government where collectively identified and "Party" where each entity is individually identified. The Parties shall communicate with one another in good faith and in a timely and cooperative manner when raising issues under this Article.

Section 7.02 Dispute Resolution Procedures

Any disagreement, claim or dispute among the Parties concerning questions of fact or law arising from or in connection with this Agreement and whether or not involving an alleged breach of this Agreement, may be raised only under this Article.

Whenever disputes, disagreements, or misunderstandings arise, the Parties shall attempt to resolve the issue(s) involved by discussion and mutual agreement as soon as practicable. In no event shall a dispute, disagreement or misunderstanding which arose more than three (3) months prior to the notification made under this article constitute the basis for relief under this article unless the ACC-NJ, Center Director for Emerging Technologies, in the interest of justice, waives this requirement.

Failing resolution by mutual agreement, the aggrieved Party shall document the dispute, disagreement, or misunderstanding by notifying the other Party in writing documenting the relevant facts, identifying unresolved issues, specifying the clarification or remedy sought, and documenting the rationale as to why the clarification/remedy is appropriate. Within ten (10) working days after providing notice to the other Party, the aggrieved Party may, in writing, request a decision by the ACC-NJ, Center Director for Emerging Technologies. The other Party shall submit a written position on the matter(s) in dispute within thirty (30) calendar days after being notified that a decision has been requested. The ACC-NJ, Center Director for Emerging Technologies, will conduct a review of the matter(s) in dispute and render a decision in writing within thirty (30) calendar days of receipt of such position. Any such decision is final and binding, unless a Party shall, within thirty (30) calendar days request further review as provided by this article.

If requested within thirty (30) calendar days of the ACC-NJ, Center Director for Emerging Technologies' decision, further review will be conducted by the Chair of the MCDC Executive Committee and the ACC-NJ Associate Director. In the event of a decision, or in absence of a decision within sixty (60) calendar days of referral to the Chair of the MCDC Executive Committee and the ACC-NJ, Associate Director (or such other period as agreed to by the parties), either party may pursue any right or remedy provided by law, including but not limited to the right to seek extraordinary relief under Public Law 85-804. Alternatively, the parties may agree to explore and establish an Alternate Disputes Resolution procedure to resolve this dispute.

Section 7.03 Limitation of Liability and Damages

In no event shall the liability of the MCDC PAH or any other entity performing research activities under a Project Agreement exceed the funding such entity has received for their performance of the specific Project Agreement under which the dispute arises.

No Party shall be liable to any other Party for [***], whether arising in contract (including warranty), tort (whether or not arising from the negligence of a Party) or otherwise, except to the extent such damages are caused by a Party's [***]; Notwithstanding the foregoing, claims for contribution toward third-party injury, damage, or loss are not limited, waived, released, or disclaimed.

Article VIII. CONFIDENTIAL INFORMATION

Section 8.01 Definitions

(1) "Disclosing Party" means CMF, MCDC PAHs, or the Government who discloses Confidential Information as contemplated by the subsequent Paragraphs.
(2) "Receiving Party" means CMF, MCDC PAHs, or the Government who receives Confidential Information disclosed by a Disclosing Party.
(3) "Confidential Information" means information and materials of a Disclosing Party which are designated as confidential or as a Trade Secret in writing by such Disclosing Party, whether by letter or by use of an appropriate stamp or legend, prior to or at the same time any such information or materials are disclosed by such Disclosing Party to the Receiving Party. Notwithstanding the foregoing, materials and other information which are orally, visually, or electronically disclosed by a Disclosing Party, or are disclosed in writing without an appropriate letter, stamp, or legend, shall constitute Confidential Information or a Trade Secret if such Disclosing Party, within thirty (30) calendar days after such disclosure, delivers to the Receiving Party a written document or documents describing the material or information and indicating that it is confidential or a Trade Secret, provided that any disclosure of information by the Receiving Party prior to receipt of such notice shall not constitute a breach by the Receiving Party of its obligations under this Paragraph. "Confidential Information" includes any information and materials considered a Trade Secret by the PAH. "Trade Secret" means all forms and types of financial, business, scientific, technical, economic, or engineering or otherwise proprietary information, including, but not limited to, patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing if -

(a) The owner thereof has taken reasonable measures to keep such information secret; and

(b) The information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, the public.

Section 8.02 Exchange of Information:

Neither the Government nor MCDC on behalf of the MCDC member entities or PAHs nor the CMF shall be obligated to transfer Confidential Information independently developed by the Government or the MCDC member entities or PAHs or the CMF absent an express written agreement between the Parties involved in the exchange providing the terms and conditions for such disclosure.

Section 8.03 Authorized Disclosure:

The Receiving Party agrees, to the extent permitted by law, that Confidential Information shall remain the property of the Disclosing Party (no one shall disclose unless they have the right to do so), and that, unless otherwise agreed to by the Disclosing Party, Confidential Information shall not be disclosed, divulged, or otherwise communicated by it to third parties or used by it for any purposes other than in connection with specified project efforts and the licenses granted in Article X, Patent Rights, and Article XI, Data Rights, provided that the duty to protect such "Confidential Information" and "Trade Secrets" shall not extend to materials or information that:

(a) Are received or become available without restriction to the Receiving Party under a proper, separate agreement,

(b) Are not identified with a suitable notice or legend per Article VIII entitled "Confidential Information" herein,

(c) Are lawfully in possession of the Receiving Party without such restriction to the Receiving Party at the time of disclosure thereof as demonstrated by prior written records,

(d) Are or later become part of the public domain through no fault of the Receiving Party,

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(e) Are received by the Receiving Party from a third party having no obligation of confidentiality to the Disclosing Party that made the disclosure,

(f) Are developed independently by the Receiving Party without use of Confidential Information as evidenced by written records,

(g) Are required by law or regulation to be disclosed; provided, however, that the Receiving Party has provided written notice to the Disclosing Party promptly so as to enable such Disclosing Party to seek a protective order or otherwise prevent disclosure of such information.

Section 8.04 Return of Proprietary Information:

Upon the request of the Disclosing Party, the Receiving Party shall promptly return all copies and other tangible manifestations of the Confidential Information disclosed. As used in this section, tangible manifestations include human readable media as well as magnetic and digital storage media.

Section 8.05 Term:

The obligations of the Receiving Party under this Article shall continue for a period of seven (7) years from conveyance of the Confidential Information.

Section 8.06 Flow Down

The PAH shall flow down the requirements of this Article VIII to their respective personnel, member entities, agents, subawardees (including employees) at all levels, receiving such Confidential Information under this OTA.

Article IX. PUBLICATION AND ACADEMIC RIGHTS

Section 9.01 Use of Information.

For the purposes of this Article, “Parties” means the PAH and the Government where collectively identified and “Party” where each entity is individually identified.

Subject to the provisions of Article VIII, Confidential Information, Article IX, Publication and Academic Rights, and Article XI Data Rights, the PAH and the Government shall have the right to publish or otherwise disclose information and/or data developed by the Government and/or the respective MCDC PAH under the Research Project. The PAH and the Government (and its employees) shall include an appropriate acknowledgement of the sponsorship of the Research Projects by the Government and the MCDC PAH in such publication or disclosure. The Parties shall have only the right to use, disclose, and exploit any such data and Confidential Information in accordance with the rights held by them pursuant to this Agreement. Notwithstanding the above, the Parties shall not be deemed authorized by this paragraph, alone, to disclose any Confidential Information of the Government or the PAH.

Section 9.02 Publication or Public Disclosure of Information

(a) Classified Project Agreements

If a release of Confidential Information or Trade Secrets is for a classified Project Agreement, the provisions of the DoD Security Agreement (DD Form 441) and the DoD Contract Security Classification Specification (DD Form 254) apply.

(b) Review or Approval of Technical Information for Public Release.

(1) At least 30 days prior to the scheduled release date PAH shall submit to the CMF a copy of the information to be released. In turn, CMF shall submit to the Government AOR a copy of the information to be released.

The Government AOR is hereby designated as the approval authority for the AO for such releases.

(2) Where the PAH is an Academic Research Institution performing fundamental research on campus. PAH shall provide papers and publications for provision to the CMF for provision to the Government AOR for review and comment 30 days prior to formal paper/publication submission. However, if that Academic Research Institution incorporates into its research results or publications artifacts produced by and provided to these institutions on behalf of other (non-educational institution) MCDC PAHs (or has authors listed on the paper who are not employees or students of the Academic Research Institution) then the procedures in Section 9.02(a) ABOVE must be followed.

(3) Parties to this Agreement are responsible for assuring that an acknowledgment of government support will appear in any publication of any material based on or developed under this OTA, using the following acknowledgement terms:

> "Effort sponsored by the U.S. Government under Other Transaction number W15QKN-16-9-1002 between the MCDC, and the Government**.** The US Government is authorized to reproduce and distribute reprints for Governmental purposes notwithstanding any copyright notation thereon."

(4) Parties to this Agreement are also responsible for assuring that every publication of material based on or developed under this project contains the following disclaimer:

> "The views and conclusions contained herein are those of the authors and should not be interpreted as necessarily representing the official policies or endorsements, either expressed or implied, of the U.S. Government.

The PAH shall flowdown these requirements to its subawardees, at all tiers.

(c) Notices. To avoid disclosure of Confidential Information or Trade Secrets belonging to an MCDC member entity or PAH and/or the Government and the loss of patent rights as a result of premature public disclosure of patentable information, the PAH that is proposing to publish or disclose such information shall provide advance notice to the MCDC, through its CMF, and identify such other parties as may have an interest in such Confidential Information. The CMF shall notify such parties at least thirty (30) calendar days prior to any PAH's submission for publication or disclosure, together with any and all materials intended for publication or disclosure relating to technical reports, data, or information developed by the parties during the term of and pursuant to this Agreement. The Government must notify the MCDC, through its CMF, of any objection to disclosure within this thirty (30) day period, or else the PAH, shall be deemed authorized to make such disclosure.

(d) Filing of Patent Applications. During the course of any such thirty (30) calendar day period, the PAH shall provide notice to the CMF as to whether it desires that a patent application be filed on any invention disclosed in such materials. In the event that a PAH and/or the Government desires that such a patent be filed, the PAH or the Government proposing to publish or disclose such materials agrees to withhold publication and disclosure of such materials until the occurrence of the first of the following:

(1) Filing of a patent application covering such invention, or

(2) Written agreement, from the AO and the CMF (on behalf of the PAH to whom such Confidential Information belong) that no patentable invention is disclosed in such materials.

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(3) Further, during the course of any such 90 calendar day period, the PAH shall notify the AO and the Government, through the CMF, if PAH believes any of its Confidential Information have been included in the proposed publication or disclosure and shall identify the specific Confidential Information or Trade Secrets that need to be removed from such proposed publication. The Government and the CMF on behalf of the PAH proposing the publication or disclosure of such materials agrees to remove from the proposed publication or disclosure all such Confidential Information so identified by the CMF.

Article X. PATENT RIGHTS

Section 10.01 Definitions

“Invention” means any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code.

“Made” when used in relation to any invention means the conception or first actual reduction to practice of such invention.

“Practical application” means to manufacture, in the case of a composition of product; to practice, in the case of a process or method, or to operate, in the case of a machine or system; and in each case, under such conditions as to establish that the invention is capable of being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

“Subject Invention” means any invention of the MCDC’s PAH or its subcontractors of any tier conceived or first actually reduced to practice in the performance of work on a Project Agreement under this Agreement.

"Background Invention" means any invention, or improvement to any invention, other than a Subject Invention, made by a PAH (or their subcontractors of any tier) that was conceived, designed, developed, produced, and/or actually reduced to practice prior to performance of the Agreement or outside the scope of work performed under this Agreement.

Section 10.02 Allocation of Principal Rights

The PAH, or its subcontractor to the extent such is proper assignee of the invention, shall retain the entire right, title, and interest throughout the world to each Subject Invention consistent with the provisions of this Article, Executive Order 12591 and 35 U.S.C § 202. In the event that a PAH consists of more than one entity or person, those entities or persons may allocate such right, title interest between themselves or others as they may agree in writing. With respect to any Subject Invention in which the PAH retains title, the Government shall have a non-exclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the Subject Invention throughout the world. The PAH may elect to provide full or partial rights that it has retained to other parties. The Government shall have the right to use any products or processes used for test and evaluation (including materials for testing or assays) in any other project pursued on behalf of the U.S. Government.

Section 10.03 Invention Disclosure, Election of Title, and Filing of Patent Application

(1) The PAH shall disclose each Subject Invention to the CMF within four (4) months after the inventor discloses it in writing to his company personnel responsible for patent matters. The disclosure to the CMF shall be in the form of a written report and shall identify the Agreement under which the invention was made and the identity of the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention. The disclosure shall also identify any publication, sale, or public use of the invention and whether a manuscript describing the invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure.

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(2) If the PAH determines that it does not intend to retain title to any such invention, the PAH shall notify the CMF, in writing, within nine (9) months of disclosure. However, in any case where publication, sale or public use has initiated the one (1) year statutory period wherein valid patent protection can still be obtained in the United States, the period for such notice may be shortened by the ACC-NJ through CMF to a date that is no more than six (6) months prior to the end of the project.

(3) The PAH shall file its initial patent application on a Subject Invention to which it elects to retain title within one (1) year after election of title or, if earlier, prior to the end of the statutory period wherein valid patent protection can be obtained in the United States after a publication, or sale, or public use. The MCDC PAH may elect to file patent applications in additional countries (including the European Patent Office and the Patent Cooperation Treaty) within either ten (10) months of the corresponding initial patent application or six (6) months from the date permission is granted by the Commissioner of Patents and Trademarks to file foreign patent applications, where such filing has been prohibited by a Secrecy Order.

(4) After considering the position of the CMF on behalf of the PAH, a request for extension of the time for disclosure election, and filing under this Article IX, paragraph C, may be approved by ACC-NJ, which ACC-NJ approval shall not be unreasonably withheld.

Section 10.04 Conditions When the Government May Obtain Title

Upon written request to the CMF, the PAH shall convey to the Government title to any Subject Invention under any of the following conditions:

(1) If the PAH fails to disclose or elects not to retain title to the Subject Invention within the times specified in Section 10.03 of this Article X, Patent Rights; provided, that the Government may only request title within sixty (60) days after learning of the failure of the PAH to disclose or elect within the specified times.

(2) In those countries in which the PAH fails to file patent applications within the times specified in Section 10.03 of this Article X, Patent Rights; provided, that if the PAH has filed a patent application in a country after times specified in Section 10.03 of this Article X, Patent Rights, but prior to its receipt of the written request by the Government through the CMF, the PAH shall continue to retain title in that country; or

(3) In any country in which the PAH decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceedings on, a patent on a Subject Invention.

Section 10.05 Minimum Rights to the MCDC PAH and Protection of the MCDC PAH's Right to File

The Parties agree that:

(1) The PAH shall retain a non-exclusive, royalty-free license throughout the world in each Subject Invention to which the Government obtains title, except if the PAH fails to disclose the invention within the times specified in Section 10.03 of this Article X, Patent Rights. PAH's license extends to the domestic (including Canada) subsidiaries and affiliates, if any, of the PAH within the corporate structure of which the PAH is a party and includes the right to grant licenses of the same scope to the extent that PAH was legally obligated to do so at the time the Project Agreement was funded. The license is transferable only with the approval of the Government, except when transferred to the successor of that part of the business to which the invention pertains. Government approval for license transfer shall not be unreasonably withheld.

(2) The PAH domestic license may be revoked or modified by the Government to the extent necessary to achieve expeditious practical application of the Subject Invention pursuant to an application for an exclusive license submitted consistent with appropriate provisions at 37 CFR Part 404. This license shall not be revoked in that field of use or the geographical areas in which the PAH has achieved practical

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application and continues to make the benefits of the invention reasonably accessible to the public. The license in any foreign country may be revoked or modified at the discretion of the Government to the extent the PAH, its licensees, or the subsidiaries or affiliates have failed to achieve practical application in that foreign country.

(3) Before revocation or modification of the license, the Government shall furnish the CMF, and the CMF shall forward to the PAH, a written notice of the Government's intention to revoke or modify the license, and the PAH shall be allowed thirty (30) calendar days (or such other time as may be authorized for good cause shown) after the notice to show cause why the license should not be revoked or modified.

Section 10.06 Action to Protect the Government's Interest

(1) The PAH shall execute or have executed and promptly deliver to CMF all instruments necessary to (i) establish or confirm the rights the Government has throughout the world in those Subject Inventions to which the PAH elects to retain title, and (ii) convey title to the Government when requested under Section
10.04 of this Article X, Patent Rights, and to enable the Government to obtain patent protection throughout the world in that Subject Invention.

(2) The PAH agrees to require, by written agreement, that its employees working on Project Agreements, other than clerical and non-technical employees, agree to disclose promptly in writing, to personnel identified as responsible for the administration of patent matters and in a format acceptable to the CMF, each Subject Invention made under this Agreement in order that the CMF on behalf of the PAH can comply with disclosure provisions of Section 10.03 of the Article X, Patent Rights, and to execute all papers necessary to file the patent applications on the Subject Invention and to establish the Government's rights in the Subject Invention. The PAH acknowledges and shall instruct its employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) The PAH shall notify the CMF of any decision not to continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceedings on a patent, in any country, not less than thirty (30) days before the expiration of the response period required by the relevant patent office.

(4) The PAH shall include, within the specification of any United States patent application and any patent issuing thereon covering a Subject Invention, the following statement: "This invention was made with U.S. Government support under Agreement No. W15QKN-16-9-1002 awarded by the ACC-NJ to the MCDC. The Government has certain rights in the invention."

Section 10.07 Lower Tier Agreements

The PAH shall include the Article X, Patent Rights, suitably modified to identify the parties, in all lower tier agreements, regardless of tier, for experimental, development, or research work.

Section 10.08 Reporting on Utilization of Subject Inventions

The PAH shall submit, on request during the term of the Project Agreement, periodic reports no more frequently than annually on the utilization of a Subject Invention or on efforts at obtaining such utilization that are being made by the PAH or its licensees or assignees. Such reports shall include information regarding the status of development date of first commercial sale or use, gross royalties received by the PAH, and such other data and information as the agency may reasonably specify. The PAH also agrees to provide additional reports as may be requested by the Government, through CMF, in connection with any march-in proceedings undertaken by the Government in accordance with Section 10.10 of this Article X,

Patent Rights. Consistent with 35 U.S.C. § 205, the Government agrees it shall not disclose such information to persons outside the Government without permission of the MCDC on behalf of the PAHs.

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Section 10.09 Preference for American Industry

Notwithstanding any other provision of the Article X, Patent Rights, the PAH is not to grant to any person the exclusive right to use or sell any Subject Invention in the United States or Canada unless such person agrees that any product embodying the Subject Invention or produced through the use of the Subject Invention shall be manufactured substantially in the United States or Canada. However, in individual cases, the requirements for such an agreement may be waived by the Government upon a showing by the PAH that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that, under the circumstances, domestic manufacture is not commercially feasible.

Section 10.10 March-in Rights

The PAH agrees that, with respect to any Subject Invention in which its PAH has retained title, the Government, through CMF, has the right to require the PAH to obtain and grant a non-exclusive license to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the PAH refuses such a request, the Government has the right to grant such a licensee itself if the Government determines that:

(1) Such action is necessary because the PAH or assignee has not taken effective steps, consistent with the intent of this Agreement, to achieve practical application of the Subject Invention;

(2) Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by the PAH, assignee, or their licensees;

(3) Such action is necessary to meet requirements for public use and such requirements are not reasonably satisfied by the PAH, assignee, or licensees; or

(4) Such action is necessary because the Agreement required by Section 10.09 of this Article X, Patent Rights, has not been obtained or waived or because a licensee who has the exclusive right to use or sell any Subject Invention in the United States is in the breach of such Agreement.

Section 10.11 Opportunity to Cure

Certain provisions of this Article X, Patent Rights, provide that the Government may gain title or license to a Subject Invention by reason of the PAH's action, or failure to act, within the times required by this Article X, Patent Rights. Prior to claiming such rights (including any rights under Article X, Section 10.10 March-In Rights), the Government will give written notice to MCDC, through its CMF, and CMF will convey such written notice to PAH, of the Government's intent, and afford the PAH a reasonable time to cure such action or failure to act. The length of the cure period will depend on the circumstances, but in no event will be more than 60 days. PAH may also use the cure period to show good cause why the claiming of such title or right would be inconsistent with the intent of this Agreement in light of the appropriate timing for introduction of the technology in question, the relative funding and participation of the parties in the development, and other factors.

Section 10.12 Background Information

In no event shall the provisions set forth in this Article X apply to any Background Inventions or Patents. The PAHs or their subcontractors shall retain the entire right, title, and interest throughout the world to each such Inventions and Patents that each party has brought through MCDC to the project issued under this Agreement and the Government shall not have any rights under this Agreement. Projects to be funded under this Agreement will list Background Inventions and Patents anticipated to be used on the project; such listing may be amended by the parties as appropriate to reflect changes in such plans.

Section 10.13 Survival Rights

Provisions of this Article X shall survive termination of this Agreement under Article II.

Notwithstanding the terms of this Article, differing rights in patents may be negotiated among the Parties to each individual project on a case-by-case basis.

Article XI. DATA RIGHTS

This is a Data Rights Clause specifically tailored for this OTA to address respective rights of the Government and MCDC on behalf of its actual or prospective MCDC PAHs to such Data as is owned, developed, to be developed or used by an actual or prospective MCDC member entity or PAH (1) as identified in a MCDC member entity(ies) proposal submitted to the Government through the CMF in response to a competitive Government OTA call for proposals, and (2) when such proposal is selected by the Government for funded performance and the Project Agreement is issued by the CMF to that MCDC member entity for performance of such Government OTA project.

Section 11.01 Definitions

(1) "Commercial Computer Software" as used in the Article is defined in DFARS 252-227-7014(a)(1) (Jun 1995).

(2) "Commercial Computer Software License" means the license terms under which commercial computer software and Data (as defined in this OTA) is sold or offered for sale, lease or license to the general public.

(3) "Computer Data Base" as used in this Agreement, means a collection of data recorded in a form capable of being processed by a computer. The term does not include computer software.

(4) "Computer program" as used in this Agreement means a set of instructions, rules, or routines in a form that is capable of causing a computer to perform a specific operation or series of operations.

(5) "Computer software" as used in this Agreement means computer programs, source code, source code listings, object code listings, design details, algorithms, processes, flow charts, formulae and related material that would enable the software to be reproduced, recreated or recompiled. Computer software does not include computer data bases or computer software documentation.

(6) "Computer software documentation" means owner's manuals, user's manuals, installation instructions, operating instructions, and other similar items, regardless of storage medium, that explain the capabilities of the computer software or provide instructions for using the software.

(7) "Data" as used in this Article of the Agreement, means computer software, computer software documentation, form, fit and function data, and technical data as defined in this Article.

(8) "Form, fit and function data" means technical data that describes the required overall physical, functional and performance characteristics (along with the qualification requirements, if applicable) of an item, component, or process to the extent necessary to permit identification of physically and functionally interchangeable items.

(9) "Government purpose rights" means the rights to use, modify, duplicate or disclose the "Data" licensed with such rights under this OTA within the Government for United States Government purposes only; and to release or disclose data outside the Government to any authorized persons pursuant to an executed non-disclosure agreement for such persons use, modification, or reproduction for United States Government purposes only. United States Government purposes include Foreign Military Sales purposes. Under this Agreement, the period of Government purpose rights shall be no less than ten (10) years and during such time the MCDC member entity or PAH developing or providing such Data to the Government with

government purpose rights shall have the sole and exclusive right to use such Data for commercial purposes. In the event this Data is used to perform another project issued to that MCDC member entity or PAH under this OTA during this ten (10) year period, the period of

government purpose rights shall be extended an additional ten (10) years starting with the date of completion of performance of the additional project.

(10) “Limited rights” as used in this Article is as defined in DFARS 252.227-7013(a)(13) (Nov 1995).

(11) “Restricted rights” as used in this Article is as defined in DFARS 252.227-7014(a)(14) (Jun 1995).

(12) “Specially Negotiated License Rights” are those rights to Data that have been specifically negotiated between the Government and the MCDC on behalf of the member entity or PAH whose proposal is selected by the Government under a call for proposals issued under the OTA.

(13) “Technical data” means recorded information, regardless of the form or method of the recording, of a scientific or technical nature (including computer software documentation). The term does not include computer software or data incidental to contract administration, such as financial and/or management information.

(14) “Unlimited rights” as used in this Article is as defined n DFARS 252.227-7013(a)(16).

Section 11.02 Data Categories

(1) Category A is the Data developed and paid for totally by private funds, or the PAH's (or its subcontractor's) IR&D funds and it is Data to which the PAH (or its subcontractor) retains all rights. Category A Data shall include, but not be limited to,

> (a) Data as defined in this Article and any designs or other material provided by the PAH for a project under this Agreement which was not developed in the performance of work under that project, and for which the PAH retains all rights.
>
> (b) Any initial Data or technical, marketing, or financial Data provided at the onset of the project by any of the MCDC member entities or PAHs. Such Data shall be marked “Category A” and any rights to be provided to the Government for such Data under a specific project shall be as identified in the proposal submitted to the Government and included into the Technical Direction Letter and CMF issued Project Agreements.

(2) Category B is any Data developed under this OTA with mixed funding, i.e. development was accomplished partially with costs charged to a PAH’s indirect cost pools and/or costs not allocated to a PAH’s Project Agreement under this OTA, and partially with Government funding under this OTA. Any Data developed outside of this OTA whether or not developed with any Government funding in whole or in part under a Government agreement, contract or subcontract shall have the rights negotiated under such prior agreement, contract or subcontract; the Government shall get no additional rights in such Data.

(3) Category C is any Data developed exclusively with Government funds under this OTA. Research and Development performed was not accomplished exclusively or partially at private expense. Under this category,

> (a) the Government will have Government Purpose Rights in Data developed exclusively with Government funds under a project funded by the Government under this OTA that is:
>
> > (i) Data pertaining to an item, component, or process which has been or will be developed exclusively with Government funds;
> >
> > (ii) Studies, analyses, test data, or similar data produced for this contract, when the study, analysis, test, or similar work was specified as an element of performance;

(iii) Data created in the performance of the OTA that does not require the development, manufacture, construction, or production of items, components, or processes;

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(iv) Form, fit, and function data;

(v) Data necessary for installation, operation, maintenance, or training purposes (other than detailed manufacturing or process data);

(vi) Corrections or changes to technical data furnished to the Contractor by the Government;

The Government can only order such Data as is developed under the OTA project where the order request is made within one (1) year following OTA project completion. In the event the Government orders such Data, it shall pay the PAH the reasonable costs for all efforts to deliver such requested Data, including but not limited to costs of locating such Data, formatting, reproducing, shipping, and associated administrative costs.

(b) The Government shall have unlimited rights in Data

(i) Otherwise publicly available or that has been released or disclosed by PAH without restrictions on further use, release or disclosure, other than a release or disclosure resulting from the sale, transfer, or other assignment of interest in the Data to another party or the sale or transfer of some or all of a business entity or its assets to another party;

(ii) Data in which the Government has obtained unlimited rights under another Government contract or as a result of negotiations; or

(iii) Data furnished to the Government, under this or any other Government contract or subcontract thereunder, with—

(1) Government Purpose Rights or limited rights and the restrictive condition(s) has/have expired; or

(2) Government purpose rights and the PAH's exclusive right to use such Data for commercial purposes under such contract or subcontract has expired.

(c) However, any Data developed outside of this OTA whether or not developed with any Government funding in whole or in part under a Government agreement, contract or subcontract shall have the rights negotiated under such prior agreement, contract or subcontract; the Government shall get no additional rights in such Data.

(d) Further, the Government's rights to Commercial Computer Software and Data licensed under a Commercial Computer Software License under this OTA, and the treatment of Data relating thereto, shall be as set forth in the Commercial Computer Software License.

(4) The parties to this Agreement understand and agree that the CMF shall require PAHs stamp all documents in accordance with this Article and that the Freedom of Information Act (FOIA) and Trade Secrets Act (TSA) apply to Data.

Section 11.03 Allocation of Principal Rights

(1) The Government shall have no rights to Category A Data.

(2) The Government shall have immediate Government Purpose Rights to Category B or C Data upon delivery or project or Agreement completion (whichever is earlier), except that

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(a) where the PAH whose Data it is, is a small business as defined under the Small Business Innovation research Program (SBIR) under 15 U.S.C. 638, and such data was developed under a project designated by the Government in the RPP as an SBIR program project, such PAH automatically shall be entitled to a delay in the start of the Government Purpose Rights period for at least five (5) years from project completion, or such longer period as may be negotiated among the Government and MCDC on behalf of the PAH, and

(b) The CMF, at the request of small business or an other than small business MCDC member entity or PAH, may request on such member entity's or PAH's behalf a delay of the start of Government Purpose Rights in Category B or C Data for a period not to exceed five (5) years from project or Agreement completion (whichever is earlier). Such requests will only be made in those cases where the CMF has provided information from the affected actual or prospective PAH demonstrating the need for this additional restriction on Government use and shall be submitted to the ACC-NJ AO for approval, which approval shall not be unreasonably withheld. In the event of any dispute regarding approval of this request, the parties agree to treat this as a dispute and shall follow the provisions of Article VII, Disputes.

(c) for Article XI. Section 11.02 3(c) Category C Data, the Government shall have only the rights established under prior agreements.

(d) for Article XI. Section 11.02 3(d) Category C Data, the Government shall only have the rights set forth in the Commercial Computer Software Data license agreement.

(3) Data that will be delivered, furnished, or otherwise provided to the Government as specified in a specific project award funded under this Agreement, in which the Government has previously obtained rights, shall be delivered, furnished, or provided with the pre-existing rights, unless (a) the parties have agreed otherwise, or (b) any restrictions on the Government’s rights to use, modify, reproduce, release, perform, display, or disclose the data have expired or no longer apply.

(4) Each proposal submitted by the MCDC member entities in response to a Government call for proposals under this OTA shall include a list of the Category A, B and C Data to be used or developed under the proposal if selected. Rights in such Data shall be as established under the terms of this Agreement, unless otherwise asserted in the proposal and agreed to by the Government. The Government AO will incorporate the list of Category A, B and C Data and the identified rights therefor in the award document.

Following issuance of a Technical Direction Letter and subsequent CMF issuance of the Project Agreement to the Government selected MCDC member entity (the PAH), the PAH shall update the list to identify any additional, previously unidentified, Data if such Data will be used or generated in the performance of the funded work. Rights in such Data shall be as established under the terms of this Agreement, unless otherwise asserted in a supplemental listing and agreed to by the Government.

Section 11.04 Marking of Data

Except for Data delivered with unlimited rights, Data to be delivered under this Agreement subject to restrictions on use, duplication or disclosure shall be marked with the following legend:

Use, duplication, or disclosure is subject to the restrictions as stated in the Agreement between the U.S. Government and the MCDC, Agreement No. W15QKN-16-9-1002, Project Title and the MCDC Project Agreement with [insert name of company] No. _____.

It is not anticipated that any Category A Data will be delivered to the Government under this Agreement.

In the event commercial computer software and Data is licensed under a commercial computer software license under this OTA, a Special License rights marking legend shall be used as agreed to by the parties.

The Government shall have unlimited rights in all unmarked Data. In the event that a PAH learns of a release to the Government of its unmarked Data that should have contained a restricted legend, the CMF on behalf of the member

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entity or PAH will have the opportunity to cure such omission going forward by providing written notice to the Government AO within three (3) months of the erroneous release.

Section 11.05 Copyright

The PAHs reserve the right to protect by copyright original works developed under this Agreement. All such copyrights will be in the name of the individual PAH. The PAH(s) hereby grant to the U.S. Government a non- exclusive, non-transferable, royalty-free, fully paid-up license to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, for governmental purposes, any copyrighted materials developed under this agreement, and to authorize others to do so.

In the event Data is exchanged with a notice indicating that the Data is protected under copyright as a published, copyrighted work and it is also indicated on the Data that such Data existed prior to, or was produced outside of this Agreement, the Party receiving the Data and others acting on its behalf may reproduce, distribute, and prepare derivative works for the sole purpose of carrying out that Party's responsibilities under this Agreement with the written permission of the Copyright holder.

Copyrighted Data that existed or was produced outside of this Agreement and is unpublished - having only been provided under licensing agreement with restrictions on its use and disclosure - and is provided under this Agreement shall be marked as unpublished copyright in addition to the appropriate license rights legend restricting its use, and treated in accordance with such license rights legend markings restricting its use.

The PAHs are responsible for affixing appropriate markings indicating the rights of the Government on all Data delivered under this Agreement.

The Government agrees not to remove any copyright notices placed on Data and to include such notices on all reproductions of the Data.

Section 11.06 Data First Produced by the Government:

As to Data first produced by the Government in carrying out the Government's responsibilities under this OTA and which Data would embody trade secrets or would comprise commercial or financial information that is privileged or confidential if obtained from the CMF on behalf of any PAH, such Data will, to the extent permitted by law, be appropriately marked with a suitable notice or legend and maintained in confidence by the CMF and any PAH to whom disclosed for three (3) years after the development of the information, with the express understanding that during the aforesaid period such Data may be disclosed and used by the CMF or any PAH, including its respective employees or subcontractors of any tier, (under suitable protective conditions) by or on behalf of the Government for Government purposes only.

Section 11.07 Prior Technology

(1) Government Prior Technology: In the event it is necessary for the Government to furnish the CMF or any MCDC member entity or PAH, including their respective employees or their subcontractors of any tier, with Data which existed prior to, or was produced outside of this Agreement, and such Data is so identified with a suitable notice or legend, the Data will be maintained in confidence and disclosed and used only for the purpose of carrying out their responsibilities under this Agreement. Data protection will include proprietary markings and handling, and the signing of non-disclosure agreements by CMF, PAHs, PAH subcontractors of any tier and their respective employees to whom such Data is provided for use under the OTA. Upon completion of activities under this Agreement, such Data will be disposed of as requested by the Government.

(2) CMF and PAH Prior Technology: In the event it is necessary for the CMF or any PAH to furnish the Government with Data which existed prior to, or was produced outside of this Agreement, and such Data embodies trade secrets or comprises commercial or financial information which is privileged or

confidential, and such Data is so identified with a suitable notice or legend, the Data will be maintained in confidence and disclosed and used by the Government and such Government Contractors or contract employees that the Government may hire on a temporary or periodic basis only for the purpose of carrying out the Government's responsibilities under this

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Agreement. Data protection will include proprietary markings and handling, and the signing of nondisclosure agreements by such Government Contractors or contract employees. Neither the CMF nor any PAH shall be obligated to provide Data that existed prior to, or was developed outside of this Agreement to the Government. Upon completion of activities under this Agreement, such Data will be disposed of as requested by the CMF on behalf of itself or PAHs.

(3) Oral and Visual Information: If information which the PAH (including their subcontractors of any tier and their respective employees) considers to embody trade secrets or to comprise commercial or financial information which is privileged or confidential is expressly disclosed orally or visually directly to the Government and/or CMF, the exchange of such information must be memorialized in tangible, recorded form and marked with a suitable notice or legend, and furnished to the Government and/or CMF within ten (10) calendar days after such oral or visual disclosure, or the Government and/or CMF shall have no duty to limit or restrict, and shall not incur any liability for any disclosure and use of such information. Upon Government and/or CMF request, additional detailed information about the exchange will be provided subject to restrictions on use and disclosure.

(4) Disclaimer of Liability: Notwithstanding the above, neither the Government nor the CMF shall be restricted in, nor incur any liability for, the disclosure and use of:

(a) Data not identified with a suitable notice or legend as set forth in this Article; nor

(b) Information contained in any Data for which disclosure and use is restricted under Article VIII entitled “Confidential Information” above, if such information is or becomes generally known without breach of the above, is properly known to the Government or CMF or is generated by the Government or CMF independent of carrying out responsibilities under this Agreement, is rightfully received from a third party without restriction, or is included in Data which the PAH has furnished, or is required to furnish to the Government or CMF without restriction on disclosure and use.

(5) Marking of Data: Any Data delivered under this Agreement shall be marked with a suitable notice or legend.

Notwithstanding the Paragraphs in this Article, differing rights in Data may be negotiated among the Parties to each individual project on a case-by-case basis.

Section 11.08 Lower Tier Agreements

The PAH shall include this Article, suitably modified to identify the parties, in all subcontracts or lower tier agreements, regardless of tier, or experimental, developmental, or research work.

Section 11.09 Survival Rights

Provisions of this Article shall survive termination of this Agreement under Article II.

Notwithstanding the terms of this in this Article, differing rights in data may be negotiated among the Parties to each individual Technology Project Agreement on a case-by-case basis.

Article XII. EXPORT CONTROL

Export Control

(1) Information subject to Export Control Laws/International Traffic in Arms Regulation (ITAR):

Public Law 90-629, « Arms Export Control Act, » as amended (22 U.S.C. 2751 et. seq.) requires that all unclassified technical data with military application may not be exported lawfully without an approval, authorization, or license under EO 12470 or the Arms Export Control Act and that

such data require an approval, authorization, or license under EO 12470 or the Arms Export Control Act. For purposes of making this determination, the Military Critical Technologies List (MCTL) shall be used as general

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guidance. All documents determined to contain export controlled technical data will be marked with the following notice:

WARNING- this document contains technical data whose export is restricted by the Arms Export Control Act (Title 22, U.S.C., and Sec 2751, et seq.) or the Export Administration Act of 1979, as amended, Title 50, U.S.C., App. 2401 et seq. Violations of these export laws are subject to severe criminal penalties. Disseminate in accordance with provision of DOD Directive 5230.25.

(2) Flowdown.

The PAH shall include this Article, suitably modified, to identify all Parties, in all Project Agreements or lower tier agreements. This Article shall, in turn, be included in all sub-tier subcontracts or other forms of lower tier agreements, regardless of tier.

Article XIII. TITLE AND DISPOSITION OF PROPERTY

Section 13.01 Definitions

In this Article, "property" means any tangible personal property other than property actually consumed during the execution of work under this Agreement.

Section 13.02 Title to Property

No significant items of property are expected to be acquired under this Agreement by the PAH. Title to any item of property valued $10,000.00 or less that is acquired by the PAH pursuant to a Project Agreement with the MCDC, in performance of the project issued to the PAH under this OTA shall vest in the PAH upon acquisition with no further obligation of the Parties unless otherwise determined by the Government AO. Should any item of property with an acquisition value greater than $10,000.00 be required, the PAH through the CMF shall obtain prior written approval of the Government AO. Title to this property shall also vest in the MCDC member entity or PAH upon acquisition. That PAH shall be responsible for the maintenance, repair, protection, and preservation of all such property at its own expense. Property acquired pursuant to this clause shall not be considered as in exchange for services in performance of the project, but shall be considered a Government contribution to the project.

Section 13.03 Government Furnished Property

The Government may provide the PAH Government Furnished Property (GFP) to facilitate the performance of individual projects under this Other Transaction Agreement. Such GFP will be specifically identified to a particular project and incorporated into the applicable Project Agreement. The GFP shall be utilized only for the performance of that individual project unless a specific exception is made in writing by the Agreements Officer.

The PAH shall assume the risk of and be responsible for any loss or destruction of, or damage to, any Government Furnished Property while in its possession or control, with the exception of reasonable wear and tear or reasonable and proper consumption. All property shall be returned at the end of the Project Agreement in as good as condition as when received with the exception of said reasonable wear and tear or in accordance with the provisions of the Project Agreement regarding its use. The PAH shall obtain explicit written authorization for any transfer or disposition of Government Furnished Property.

Article XIV. CIVIL RIGHTS ACT

This Agreement and any resulting Project Agreement is subject to the compliance requirements of Title VI of the Civil Rights Act of 1964 as amended (42 U.S.C. 2000-d) relating to nondiscrimination in Federally

assisted programs. It is the responsibility of each PAH to assure the PAH has signed an Assurance of Compliance with the nondiscriminatory provisions of the Act (Attachment 1).

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Article XV. NO SMALL BUSINESS AFFILIATION

Reserved

Article XVI. ANTITRUST

In the MCDC Articles of Collaboration, members agree to comply with all applicable U.S. laws, including U.S. antitrust laws. The MCDC is recognized under the National Cooperative Research and Production Act of 1993 and the MCDC will be similarly filing under the Act.

Article XVII. SECURITY & OPSEC

All PAH shall comply with DFARS 252.204-7012 (Oct 2016): Safeguarding Covered Defense Information and Cyber Incident Reporting when applicable.

Covered Defense Information (CDI) will be identified at the Project Agreement level. The MCDC Member shall comply with DFARS 252.204-7012 (Oct 2016): Safeguarding Covered Defense Information and Cyber Incident Reporting, which includes implementing on its covered contractor information systems the security requirements specified by DFARS 252.204-7012. Nothing in this paragraph shall be interpreted to foreclose the MCDC Member's right to seek alternate means of complying with the security requirements in National Institute of Standards and Technology (NIST) Special Publication (SP) 800-171 (as contemplated in DFARS 252.204-7008 (Compliance with Safeguarding Covered Defense Information Controls) (Oct 2016) and DFARS 252.204-7012 (Safeguarding Covered Defense Information and Cyber Incident Reporting (Oct 2016)).

Work performed by a PAH under a Project Agreement may involve access to Controlled Unclassified Information (CUI). All Controlled Unclassified Information (CUI) developed under this Agreement will be managed in accordance with DoD Manual 5200.01, Volume 4 dated February 24, 2012. Contractor personnel shall comply with applicable Technology Protection Plans (TPP), Interim Program Protection Plans (IPPP) and/or Program Protection Plans (PPP). If a project involves a Controlled Unclassified Information (CUI) effort, the below listed Department of Defense Directives, Federal Acquisition Regulation (FAR) and the Defense Federal Acquisition Regulation Supplement (DFARS), and ARDEC clauses will be incorporated into the Project Agreements by reference with the same force and effect as if they were given in full text.

(1) Each project Scope of Work will be provided by the Agreements Officer Representative (AOR) to the Joint Project Manager- Medical Countermeasure Systems Office for dissemination to the appropriate Fort Detrick COMSEC officer prior to award for review.
(2) Each project Scope of Work will be subject to Ft. Detrick policy and procedure according to DoD 5220.22- M, (National Industrial Security Program Operating Manual, NISPOM), as deemed applicable and appropriate during the security review process and prior to award. Additional COMSEC requirements may be required at other locations/facilities (based on service/command requirements).
(3) Specific applicable policies, instructions, and regulations will be identified in each project. Throughout the life of the Agreement, if any policy, instruction, or regulation is replaced or superseded, the replacement or superseding version shall apply. The following is a snapshot of key regulatory documents, policies, regulations, etc. that may be applicable at time of project award.
    a) DoDM 5200.01 DoD Information Security Program, 24 Feb 12
    b) DoD 5200.2-R Personnel Security Regulation, Jan 87
    c) DoDD 5220.22 National Industrial Security Program, 28 Feb 06
    d) DoDI 5200.01, Information Security Program and Protection of Sensitive Compartmented Information, 24 Feb 2012
    e) DoD 5400.7-R, DOD Freedom of Information Act, Sept 98
    f) DoDD 2000.12, Antiterrorism Program, 18 Aug 03

g) FAR Clause 4.402, Safeguarding Classified Information Within Industry
h) FAR Clause 52.204-2, Security Requirements, Aug 1996

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(4) For all Project Agreements, the following statement shall be flowed to the MCDC member entities unless otherwise stated within the Project Agreements.

a) Classification guidance for requirement - "The security level for this agreement is UNCLASSIFIED."

(5) Anti-Terrorism Level I Training. This provision is for PAH employees with an area of performance within an Army controlled installation, facility or area. All PAH employees requiring access to Army installations, facilities and controlled access areas shall complete AT Level I awareness training within sixty (60)-calendar- days after project start date or effective date of incorporation of this requirement into the project, whichever is applicable. PAH(s) shall submit certificates of completion for each affected employee and PAH employee, to the AOR or to the Agreements Officer, if an AOR is not assigned, within thirty (30)-calendar-days after completion of training by all employees or personnel. AT level I awareness training is available at the following website: https://atlevel1.dtic.mil/at.

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

(7) Anti-Terrorism Awareness Training for PAH Personnel Traveling Overseas. This standard language text requires U.S.-based PAH employees to make available and to receive Government provided area of responsibility (AOR) specific AT awareness training as directed by AR 525-13. Specific AOR training content is directed by the combatant commander with the unit Anti-terrorism Officer (ATO) being the local point of contact.

(8) iWATCH Training. This standard language is for PAH employees with an area of performance within an Army- controlled installation, facility or area. PAH(s) shall brief all employees on the local iWATCH program (training standards provided by the requiring activity ATO). This local developed training will be used to inform employees of the types of behavior to watch for and instruct employees to report suspicious activity to the AOR. This training shall be completed within sixty (60)-calendar-days of a Project Agreement award and within sixty (60)-calendar- days of new employees' commencing performance with the results reported to the AOR NLT thirty (30)-calendar-days after Project Agreement award.

(9) Impact on PAH performance during increased FPCON during periods of increased threat. During FPCONs Charlie and Delta, services may be discontinued / postponed due to higher threat. Services will resume when FPCON level is reduced to Bravo or lower.

(10) Random Antiterrorism Measures Program (RAMP) participation. PAH personnel working on an installation are subject to participation in Installation RAMP security program (e.g. vehicle searches, wearing of ID badges, etc.).

(11) PAH Employees Who Require Access to Government Information Systems. All PAH employees with access to a government information system must be registered in the ATCTS (Army Training Certification Tracking System) at commencement of services, and must successfully complete the DOD Information Assurance Awareness prior to access to the IS and then annually thereafter.

(12) For projects that Require an OPSEC Standing Operating Procedure/Plan. The PAH shall develop an OPSEC Standard Operating Procedure (SOP)/Plan within ninety (90)-calendar-days of project award to be reviewed and approved by the responsible Government OPSEC officer, per AR 530-1, Operations Security.

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This plan will be submitted by MCDC on behalf of the PAH(s) to the AO for coordination of approvals. This SOP/Plan will include the Government's critical information, why it needs to be protected, where it is located, who is responsible for it and how to protect it. In addition, MCDC shall identify an individual who will be an OPSEC Coordinator. MCDC will ensure this individual becomes OPSEC Level II certified per AR 530-1.

(13) For projects that Require OPSEC Training. Per AR 530-1, Operations Security, new PAH employees assigned by the PAH(s) to perform under a MCDC Project Agreement must complete Level I OPSEC awareness training within thirty (30)-calendar-days of their reporting for duty. All PAH employees performing under an OPSEC-designated project must complete annual Level I OPSEC awareness training. Level I OPSEC awareness training is available at the following website: http://cdsetrain.dtic.mil/opsec/.

(14) For Information assurance (IA)/information technology (IT) training. All PAH employees must complete the DoD IA awareness training before issuance of network access and annually thereafter. All PAH(s) working IA/IT functions must comply with DoD and Army training requirements in DoDD 8570.01, DoD 8570.01-M and AR 25-2 within six (6) months of employment.

(15) For information assurance (IA)/information technology (IT) certification. Per DoD 8570.01-M , DFARS 252.239-7001 and AR 25-2, the PAH employees supporting IA/IT functions shall be appropriately certified upon Project Agreement award. The baseline certification as stipulated in DoD 8570.01-M must be completed upon Project Agreement award.

(16) For PAH personnel authorized to accompany the Force. DFARS Clause 252.225-7040, Contractor Personnel Authorized to Accompany U.S. Armed Forces Deployed Outside the United States. The clause shall be used in projects that authorize PAH personnel to accompany U.S. Armed Forces deployed outside the U.S. in contingency operations; humanitarian or peacekeeping operations; or other military operations or exercises, when designated by the combatant commander. The clause discusses the following AT/OPSEC related topics: required compliance with laws and regulations, pre-deployment requirements, required training (per combatant command guidance) and personnel data required.

(17) For projects requiring Performance or Delivery in a Foreign Country, DFARS Clause 252.225-7043, Antiterrorism/Force Protection for Defense Contractors Outside the U.S. The clause shall be used in projects that require performance or delivery in a foreign country. This clause applies to both contingencies and non-contingency support. The key AT requirement is for non-local national PAH personnel to comply with theater clearance requirements and allows the combatant commander to exercise oversight to ensure the PAH’s compliance with combatant commander and subordinate task force commander policies and directives.

(18) For projects requiring the PAH to obtain U.S. Government Common Access Cards, installation badges, and/or access passes, the PAH shall return all issued U.S. Government Common Access Cards, installation badges, and/or access passes to the AOR when the project is completed or when the PAH employee no longer requires access to the installation or facility.

(19) For projects that require access to Potential Critical Program Information (PCPI) / Critical Program Information (CPI):

a) The PAH shall comply with the associated Interim Program Protection Plan (IPPP) / Program Protection Plan (PPP) / or Technology Protection Plan (TPP). The PAH shall comply with DOD, DA and AMC technology protection requirements in DODI 5200.39, AR 70-1, DA PAM 70-3 and AMC- R-380-13.

(20) Work by the Consortium Management Firm (CMF) and Project Agreement Holder/Consortium Member (PAH) under Project Agreements may involve access to Controlled Unclassified Information (CUI) as well as information classified as "Confidential", "Secret", or "Top Secret". The CMF and the PAH and their employees who work on such Project Agreements shall comply with (1) the Security Agreement (DD Form 441), including the National Industrial Security Program Operation Manual (DOD 5220.22M), (2) any revisions to that manual that may be issued, and (3) the Agreement security classification specification (DD form 254) if included, and all security requirements including but not limited to OPSEC plans and those security requirements specific to the individual projects. During the course of this Agreement the Parties may determine that information developed by the PAH and/or the Government pursuant to this Agreement shall be treated as classified. Such information shall be classified in accordance with DOD 5220.22M.

a) Each project Scope of Work will be provided by the AOR to the AOR's local Security Office prior to award for review. For classified efforts that Security Office will provide the overall Security Classification Specification (DD Form 254). The PAH will be responsible for providing a copy of any Subcontract Security Classification Specification (DD Form 254) to lower tier awards.

b) If a Project Agreement involves a classified effort or a Controlled Unclassified Information (CUI) effort, Department of Defense Directives, Federal Acquisition Regulation (FAR) and the Defense Federal Acquisition Regulation Supplement (DFARS) clauses by reference, and local clauses will be incorporated with the same force and effect as if they were given in full text shall be incorporated into this agreement.

c) Specific applicable policies, instructions, and regulations will be identified in each Project Agreement. Throughout the life of the Project Agreement, if any policy, instruction, or regulation is replaced or superseded, the replacement or superseding version shall apply.

d) Agreement Structure

i) Research and Development under these Project Agreements will be in accordance with the Other Transaction Agreement (OTA) between the United States Army Contracting Command – New Jersey (ACC-NJ) and the MCDC in care of its Consortium Management Firm (CMF), Advanced Technology International (ATI).

ii) Within the Project Agreements, sharing of classified information will be on a need to know basis as directed in required Project Agreements.

iii) Upon Project Agreement completion or termination, the PAH must:

(1) Return ALL classified information received or generated under the Project Agreement;
(2) Destroy all of the classified information; or,
(3) Request retention for a specified period of time Flowdown for OPSEC/Security Requirements:

MCDC shall include the aspects of this Article as they pertain to each project requirement. Each project will include specific OPSEC / Security requirements within each SOW and RPP. The requirements delineated within each project, in turn, shall be included in all sub-tier subcontracts or other forms of lower-tier agreements, regardless of tier.

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Article XVIII. SAFETY

The PAH shall adhere to all local, state, and federal rules and regulations required in maintaining a safe and non- hazardous occupational environment throughout the duration of the project. At a minimum, the PAH shall provide the following reports and materials on an as needed basis:

Accident/Incident Report: The PAH shall report immediately any major accident/incident (including fire) resulting in any one or more of the following: causing one or more fatalities or one or more disabling injuries; damage of Government property exceeding $10,000; affecting program planning or production schedules; degrading the safety of equipment under a project, such as personnel injury or property damage may be involved; identifying a potential hazard requiring corrective action. The PAH shall prepare the report (DI-SAFT-81563) for each incident.

Material Safety Data Sheets (MSDS): The PAH shall prepare and maintain MSDS for all materials used and generated under this Agreement.

Environmental Requirements include the following:

Pollution Prevention: Consideration should be given to alternative materials and processes in order to eliminate, reduce, or minimize hazardous waste being generated. This is to be accomplished while minimizing item cost and risk to item performance.

Environmental Compliance: All activities must be in compliance with Federal, State, and local environmental laws and regulations, Executive orders, treaties, and agreements. The PAH shall evaluate the environmental consequences and identify the specific types and amounts of hazardous waste being generated during the conduct of efforts undertaken under this Agreement.

Hazardous Waste Report: The PAH shall evaluate the environmental consequences and identify the specific types and amounts of hazardous waste being generated during this Agreement. The PAH shall submit a Hazardous Waste Report IAW DI-MGMT-80899.

Disposal Instructions for Residual/Scrap Materials: The PAH shall dispose of all residual and scrap materials generated from this Agreement, including high explosives. The PAH shall specify the anticipated quantities, methods, and disposal costs.

Article XIX. REPRESENTATIONS AND WARRANTIES

Section 19.01 Representations and Warranties of All Parties

Each Party to this Agreement represents and warrants to the other Parties that (1) it is free to enter into this Agreement; (2) in so doing, it will not violate any other agreement to which it is a party; and (3) it has taken all action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement.

Section 19.02 Limitations

Except as expressly provided herein, no party to this Agreement makes any warranty, express or implied, either in fact or by operation of law, by statute or otherwise, relating to (1) any research conducted under this agreement, or
(2) any invention conceived and/or reduced to practice under this agreement, or (3) any other intellectual property developed under this Agreement, and each party to this Agreement specifically disclaims any implied warranty of merchantability or warranty of fitness for a particular purpose.

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Article XX. LIABILITY OF THE PARTIES

Section 20.01 Waiver of Liability

With regard to the activities undertaken pursuant to this Agreement, no Party shall make any claim against the others, employees of the others, the others' related entities (e.g., Government, contractors, subcontractors, etc.), or employees of the others' related entities for any injury to or death of its own employees or employees of its related entities, or for damage to or loss of its own property or that of its related entities, whether such injury, death, damage or loss arises through negligence or otherwise, except in the case of [***].

Section 20.02 Damages

The Parties shall not be liable to each other for [***], whether arising in contract (including warranty), tort (whether or not arising from the negligence of a Party) or otherwise, except to the extent such damages are caused by a Party's [***]; Notwithstanding the foregoing, claims for contribution toward third-party injury, damage, or loss are not limited, waived, released, or disclaimed.

Section 20.03 Extension of Waiver of Liability

The PAH agrees to extend the waiver of liability as set forth above subawardees at any tier under an Project Agreement by requiring them, by contract or otherwise, to agree to waive all claims against the Parties to this Agreement.

Section 20.04 Applicability

Notwithstanding the other provisions of this article, this Waiver of Liability shall not be applicable to:

(1) Claims between the PAH and the CMF regarding a material breach, noncompliance, or nonpayment of funds;
(2) Claims for damage caused by [***]; and
(3) Intellectual property claims.

Section 20.05 Limitation of Liability

In no case shall the CMF, or the PAH's financial liability exceed the amount obligated by the Government or committed as a Cash Contribution or In-kind Contribution by a MCDC member entity under a Project Agreement. Nothing in this Article shall be construed to create the basis of a claim or suit where none would otherwise exist.

Article XXI. GENERAL PROVISIONS

Section 21.01 Fees

The PAH will not be constrained from the payment of an appropriate fee or profit for the effort being conducted on a Project Agreement when cost share is not being contributed. The fees shall be specific to the individual Project Agreements and negotiated on project by project basis.

Section 21.02 Waiver

No waiver of any rights shall be effective unless assented to in writing by the party (Government, MCDC, CMF, or PAH) to be charged, and the waiver of any breach or default shall not constitute a waiver of any other right hereunder or any subsequent breach or default.

Section 21.03 Section Headings

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The headings and subheadings of the sections of this Agreement are intended for convenience of reference only and are not intended to be a part of, or to affect the meaning or interpretation of this Agreement.

Section 21.04 Severability

In the event that any provision of this Agreement becomes or is declared by a court of competent jurisdiction to be illegal, unenforceable or void, this Agreement shall continue in full force and effect without said provision; Provided that no such severability shall be effective if the result of such action materially changes the economic benefit of this Agreement to the Parties.

Section 21.05 Force Majeure

No failure or omission by the CMF or the MCDC PAH in the performance of any obligation of this Agreement shall be deemed a breach of this Agreement or create any liability if the same shall arise from any cause or causes beyond the control of the Parties, including but not limited to, the following: acts of God; Acts or omissions of any Government; Any rules, regulations or orders issued by any Governmental authority or by any officer, department, and agency or instrumentality thereof; fire; storm; flood; earthquake; accident; war; rebellion; insurrection; riot; and invasion and provided that such failure or omission resulting from one of the above causes is cured as soon as is practicable after the occurrence of one or more of the above mentioned causes.

Section 21.06 Regulatory Affairs

Development and production of medical products and processes fall under the purview of the Food and Drug Administration (FDA) and research on these products involving animal or human studies is regulated by other laws, directives, and regulations. Project Awards under this Agreement that involve work in support of or related to FDA regulatory approval will address contingencies for Government access to regulatory rights in the event of product development abandonment or failure. Efforts conducted under this OTA shall be done ethically and in accordance with all applicable laws, directives, and regulations.

The Government shall ensure performance includes regulatory expertise and guidance for candidate medical countermeasure development efforts:

(1) This includes allowing the government to discuss/negotiate in partnership with the consortium how to assume appropriate risk in regulatory strategies. The government will review, negotiate, and come to consensus with the PAH on product-specific risk-based decisions.
(2) PAHs will use all regulatory programs to accelerate the pace of candidate medical countermeasure development, including fast-track status, and as appropriate meeting requirements for priority review vouchers, applying for breakthrough therapy and accelerated approval as appropriate (see FDA Guidance for Industry: Expedited Programs for Serious Conditions – Drugs and Biologics).
(3) PAH will provide FDA submissions to the government such as all documentation requested by FDA and all proposals to FDA.
(4) PAH will allow the government to monitor all FDA communications by listening to teleconferences and attending meetings.
(5) PAH will allow the government to attend regulatory site visits and audits, and actively participate in all third-party audits.
(6) PAH will comply with Quality Assurance according to negotiated standards with the government on reports, material for Interim Fielding Capability (such as Emergency Use Authorization or Expanded Access Protocols), product for trials, prototypes, etc.
(7) PAH will provide strategies to address contingencies that could arise from regulatory directives, and regulatory failures.

Section 21.07 Radioactive Materials

PAH shall ensure compliance with the provisions of Title 10 CFR 21. This regulation establishes procedures and requirements for implementation of Section 206 of the Energy Reorganization Act of 1974.

Section 21.08 Recombinant DNA

PAH shall ensure that all work involving the use of recombinant DNA will be in compliance with guidance provided at the following website: http://www4.od.nih.gov/oba (National Institutes of Health [NIH] Guidelines for Research Involving Recombinant DNA Molecules).

Section 21.09 Required Compliance for Use of Laboratory Animals

Notwithstanding any other provisions contained in this award or incorporated by reference herein, the PAH is expressly forbidden to use or subcontract for the use of laboratory animals in any manner whatsoever without the express written approval of the US Army Medical Research and Materiel Command, Animal Care and Use Office,. The PAH shall receive written approval to begin research under the applicable protocol proposed for a Project Agreement from the US Army Medical Research and Materiel Command, Animal Care and Use Office under separate letter to the PAH and Principal Investigator. A copy of this approval will be provided to the ACC-NJ for the official file. Non-compliance with any provision of this clause may result in the termination of award. Information is provided at the following website http://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.acuro_regulations. The PAH will conduct advanced development/pivotal studies including human safety studies, animal efficacy studies or clinical studies required for approval using validated endpoints, and other studies as deemed necessary by the FDA for licensure of the candidate product in adherence to current Good Laboratory Practice regulations, current Good Clinical Practice regulations, and all other applicable FDA regulations in the conduct of non-clinical and clinical studies as defined by FDA guidance (21 CFR Parts 210-211).

Section 21.10 Required Compliance for Use of Human Subjects

Research under this award involving the use of human subjects may not begin until the U.S. Army Medical Research and Materiel Command's Office of Research Protections, Human Research Protections Office (HRPO) approves the protocol in accordance with 45 CFR Part 46. Written approval to begin research or subcontract for the use of human subjects under the applicable protocol proposed for this award will be issued from the US Army Medical Research and Materiel Command, HRPO, under separate letter to the funded institution and the Principal Investigator. A copy of this approval will be provided to ACC-NJ for the official file. Non-compliance with any provision of this clause may result in withholding of funds and or the termination of the award. Information is provided at the following website: http://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.hrpo.

Section 21.11 Required Compliance for use of Human Anatomical Substances

Research at funded institutions using human anatomical substances may not begin until the U.S. Army Medical Research and Materiel Command's Office of Research Protections, Human Research Protections Office (HRPO) approves the protocol. Written approval to begin research or subcontract for the use of human anatomical substances under the applicable protocol proposed for this award will be issued from the US Army Medical Research and Materiel Command, HRPO, under separate letter to the funded institution and the Principal Investigator. A copy of this approval will be provided to ACC-NJ, from the CMF, for the official file. Non-compliance with any provision of this clause may result in withholding of funds and or the termination of the award. Information is provided at the following web site: http://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.hrpo

Section 21.12 Compliance with current Good Manufacturing Processes (cGMP)

Manufacturing Standards as appropriate for the level of prototype Material used for clinical trials, pivotal non- clinical studies, consistency lots, and other uses as defined in regulatory plans should be compliant with current Good Manufacturing Processes (cGMP) as defined by FDA guidance (21 CFR Parts 210-211). If at any time during the life of the award, the PAH fails to comply with cGMP in the manufacturing, processing and packaging of this product and such failure results in a material adverse effect on the safety, purity or potency of the product (a material failure) as identified by the FDA, the PAH shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure.

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Section 21.13 Registration with Select Agent Program

Where required, consortium members performing studies and tasks using select biological agent or toxins should be registered with the program with the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS) or the Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA), as applicable, before performing work, in accordance with 42 CFR 73. No Government funds can be used for work involving Select Agents, as defined in 42 CFR 73, if the final registration certificate is denied. Listings of select agents and toxins, biologic agents and toxins, and overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program Web site at http://www.cdc.gov/od/sap/.

Section 21.14 Duty-Free Entry

(a) *Definitions.* As used in this clause –

(1) "Component," means any item supplied to the Government as part of an end product or of another component.
(2) "Customs territory of the United States" means the 50 States, the District of Columbia, and Puerto Rico.
(3) "Eligible product" means –
(i) "Designated country end product" as defined in the Trade Agreements clause;
(ii) "Free Trade Agreement country end product" other than a "Bahrainian end product" or a "Moroccan end product" as defined in the Buy American Act – Free Trade Agreements – Balance of Payments Program; or
(iii) "Canadian end product" as defined in Alternate I of the Buy American Act – Free Trade Agreements – Balance of Payments Program.
(4) "Qualifying country" and "qualifying country end product" have the meanings given in the Trade Agreements clause, the Buy American Act and Balance of Payments Program clause, or the Buy American Act—Free Trade Agreements—Balance of Payments Program.

(b) Except as provided in paragraph (i) of this clause, or unless supplies were imported into the customs territory of the United States before the date of a Project Agreement or the applicable subcontract, the price of this Agreement shall not include any amount for duty on-
(1) End items that are eligible products or qualifying country end products;
(2) Components (including, without limitation, raw materials and intermediate assemblies) produced or made in qualifying countries, that are to be incorporated in U.S – made end products to be delivered under an Project Agreement; or
(3) Other supplies for which the PAH estimates that duty will exceed $200 per shipment into the customs territory of the Unites States

(c) The PAH shall –
(1) Claim duty-free entry only for supplies that the PAH intends to deliver to the Government under an Project Agreement, either as end items or components of end items; and
(2) Pay duty on supplies, or any portion thereof, that are diverted to nongovernmental use, other than –
(i) Scrap or salvage; or
(ii) Competitive sale made, directed, or authorized by the Agreements Officer.

(d) Except as the PAH may otherwise agree, the Government will execute duty-free entry certificates and will afford such assistance as appropriate to obtain the duty-free entry of supplies –
(1) For which no duty is included in the Project Agreement price in accordance with paragraph (b) of this clause; and
(2) For which shipping documents bear the notation specified in paragraph (e) of this clause.

(e) For foreign supplies for which the Government will issue duty-free entry certificates in accordance with

this clause, shipping documents submitted to Customs shall –

(1) Consign the shipments to the appropriate –

(i) Military department in care of the PAH, including the PAH's delivery address; or

(ii) Military installation; and

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(2) Include the following information:
(i) Prime Agreement number and, if applicable, delivery order number.
(ii) Number of the subcontract for foreign supplies, if applicable.
(iii) Identification of the carrier.
(iv) (A) For direct shipments to a U.S. military installation, the notation: "UNITED STATES GOVERNMENT DEPARTMENT OF DEFENSE Duty-Free Entry to be claimed pursuant to Section XXII, Chapter 98, Subchapter VIII, Item 9808.00.30 of the Harmonized Tariff Schedule of the United States. Upon arrival of shipment at the appropriate port of entry, District Director of Customs, please release shipment under 19 CFR Part 142 and notify Commander, Defense Contract management Agency (DCMA) New York, ATTN: Customs Team, DCMAE-GNTF, 207 New York Avenue, Staten Island, New York, 10305-5013, for execution of Customs Form 7501, 7501A, or 7506 and any required duty-free entry certificates."
(B) If the shipment will be consigned to other than a military installation, e.g., a domestic contractor's plant, the shipping document notation shall be altered to include the name and address of the contractor, agent, or broker who will notify Commander, DCMA New York, for execution of the duty- free certificate. (If the shipment will be consigned to a contractor's plant and no duty-free entry certificate is required due to a trade agreement, the PAH shall claim duty-free entry under the applicable trade agreement and shall comply with the U.S. Customs Service requirements. No notification to Commander, DCMA New York, is required.)
(v) Gross weight in pounds (if freight is based on space tonnage, state cubic feet in addition to gross shipping weight.)
(vi) Estimated value in U.S. dollars.
(vii) Activity address number of the contract administration office administering the prime contract, e.g., for DCMA Dayton, S3605A.

(f) Preparation of customs forms.
(1)(i) Except for shipments consigned to a military installation, the PAH shall –
(A) Prepare any customs forms required for the entry of foreign supplies into the customs territory of the United States in connection with this Agreement; and
(B) Submit the completed customs forms to the District Director of Customs, with a copy to DCMA NY for execution of any required duty-free entry certificates.
(ii) Shipments consigned directly to a military installation will be released in accordance with sections
10.101 and 10.102 of the U.S. Customs regulations.
(2) For shipments containing both supplies that are to be accorded duty-free entry and supplies that are not, the PAH shall identify on the customs forms those items that are eligible for duty-free entry.

(g) The PAH shall –
(1) Prepare (if the PAH is a foreign supplier), or shall instruct the foreign supplier to prepare, a sufficient number of copies of the bill of lading (or other shipping document) so that at least two of the copies accompanying the shipment will be available for use by the District Director of Customs at the port of entry;
(2) Consign the shipment as specified in paragraph (e) of this clause; and
(3) Mark on the exterior of all packages –
(i) "UNITED STATES GOVERNMENT, DEPARTMENT OF DEFENSE"; and
(ii) The activity address number of the contract administration office administering the prime Agreement.

(h) The PAH through the MCDC CMF shall notify the ACO in writing of any purchase of eligible products of qualifying country supplies to be accorded duty-free entry, that are to be imported into the customs territory of the United States for delivery to the Government or for incorporation in end items to be delivered to the Government. The PAH through the MCDC CMF shall furnish the notice to the ACO immediately upon award to the supplier and shall include in the notice –
(1) The PAH's name, address, and Commercial and Government Entity (CAGE) code;

(2) Prime Agreement number and Project Agreement number;
(3) Total dollar value of the prime Agreement or Project Agreement number;
(4) Date of the last scheduled delivery under the prime Agreement or Project Agreement number;
(5) Foreign supplier's name and address;

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(6) Number of the subcontract for foreign supplies;
(7) Total dollar value of the subcontract for foreign supplies;
(8) Date of the last scheduled delivery under the subcontract for foreign supplies;
(9) List of items purchased;
(10) An agreement that the PAH will pay duty on supplies, or any portion thereof, that are diverted to nongovernmental use other than –
  (i) Scrap of salvage; or
  (ii) Competitive sale made, directed, or authorized by the Agreements Officer;
(11) Country or origin; and
(12) Scheduled delivery date(s).

(i) This clause does not apply to purchases of eligible products or qualifying country supplies in connection with this Agreement if –
  (1) The supplies are identical in nature to supplies purchased by the PAH or any subcontractor in connection with its commercial business; and
  (2) It is not economical or feasible to account for such supplies so as to ensure that the amount of the supplies for which duty-free entry is claimed does not exceed the amount purchased in connection with this Agreement.

(j) The PAH shall –
  (1) Insert the substance of this clause, including this paragraph (j), in all subcontracts for –
    (i) Qualifying country components; or
    (ii) Nonqualifying country components for which the PAH estimates that duty will exceed $200 per unit;
  (2) Require subcontractors to include the number of this Agreement on all shipping documents submitted to Customs for supplies for which duty-free entry is claimed pursuant to this clause; and
  (3) Include in applicable subcontracts –
    (i) The name and address of the ACO for this Agreement;
    (ii) The name, address, and activity address number of the contract administration office specified in this Agreement; and
    (iii) The information required by paragraphs (h)(1), (2), and (3) of this clause.

Section 21.15 Follow-On Production

10 U.S.C. § 2371b, Section 815 authorizes the use of a follow-on production contract (FAR) or transaction (OTA). In order to be eligible for follow-on production, the following criteria is required: (1) the follow-on shall be awarded to the same participants named in the Project Agreement; (2) competitive procedures were used to award the Project Agreement in question; and (3) the Project Agreement was successfully completed. This Agreement was the result of competitive procedures, and competitive procedures are used to award individual projects under this Agreement. The Agreements Officer shall be responsible for documenting whether or not a Project Agreement was successfully completed. Follow-on production efforts shall be strictly limited to the scope of the successfully completed prototype. This Agreement will not be used to award follow-on production efforts; Government customers will be responsible for working with their contracting personnel.

All Project Agreements shall include the following statement:

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

Article XXII. ASSIGNMENT OF AGENCY

Section 22.01 Assignment.

Neither this Agreement nor any rights or obligations of any party hereunder shall be assigned or otherwise transferred by either party without the prior written consent of the other party.

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Article XXIII. ORDER OF PRECEDENCE

In the event of any inconsistency between the general terms of this Agreement, the inconsistency shall be resolved by giving precedence in the following order: (1) the Agreement; (2) Attachments to the Agreement; (3) the Project Agreement documentation (including but not limited to the PAH proposal selected for funding by the Government). In any event, specifically negotiated Project Agreement terms will govern over general terms of this Agreement.

Article XXIV. EXECUTION

This Agreement constitutes the entire Agreement of the Parties and supersedes all prior and contemporaneous agreements, understandings, negotiations and discussions among the Parties, whether oral or written, with respect to the subject matter hereof. This Agreement may be revised only by written consent of the PAH and the CMF Contracting Representative designated in this Agreement.

Attachment I - Assurance of Compliance with Title VI of the Civil Rights Act of 1964

Statement of Assurance of Compliance with
Title VI of the Civil Rights Act of 1964
For MCDC Member Organizations

The Novavax, Inc. hereby agrees that it will comply with the provisions of the Title VI Civil Rights Act of 1964 as amended (42 U.S.C 2000-d) and all requirements imposed pursuant thereto, to the end that, in accordance with Title VI of that Act and the Regulation, no person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination under any MCDC Project for which the MCDC member organization receives Federal financial assistance from the Government.

The MCDC member organization agrees that compliance with this assurance constitutes a condition of continued receipt of Federal financial assistance, and that it is binding upon the MCDC member organization, its successors, transferees and assignees for the period during which such assistance is provided.

The MCDC member organization further recognizes and agrees that the United States shall have the right to seek judicial enforcement of this assurance.

The person or persons whose signature(s) appear(s) below is/are authorized to sign this assurance, and commit the MCDC member organization to the above provisions.

/s/ John A. Herrmann III
John A. Herrmann III, SVP, General Counsel

Novavax, Inc.

Date

Attachment A
Statement of Work
For
Rapid (WF10) Advanced Research & Development to Large Scale Manufacturing of NVX-CoV-2373 as a Vaccine for SARS-CoV-2 Coronavirus

RPP #: 20-11
Project Identifier: MCDC2011-001
Consortium Member: Novavax, Inc.
Title of Proposal: Rapid (WF10) Advanced Research & Development to Large Scale Manufacturing of NVX-CoV-2373 as a Vaccine for SARS-CoV-2 Coronavirus
Requiring Activity: Joint Mission between the Department of Health and Human Services and Department of Defense to Combat COVID-19

1.0 INTRODUCTION, SCOPE, AND OBJECTIVES

1.1 Introduction

To meet the needs of the Coronavirus Disease 2019 (COVID-19) pandemic, the United States Government (USG) is identifying and will support development and at-scale manufacturing of selected vaccine candidates, to ensure timely availability to the US population when needed. This is the primary focus of the mission being executed by the Department of Health and Human Services (HHS) and Department of Defense (DoD), in support of Operation Warp Speed (OWS).

The USG is interested in pursuing prototype vaccines that are in an advanced stage of development, and will support companies that can, in parallel with nonclinical, clinical and regulatory development, rapidly establish the manufacturing capacity required to meet the USG's objective of supplying a safe and effective Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) vaccine to the entire US population. The USG is tasked with marshaling the efforts of the US biotechnology industry to achieve this goal.

1.2 Definition of the Prototype Project

Consistent with USG objectives, the "prototype project" under this agreement is defined as the manufacture and delivery of 100M doses of a SARS-CoV-2 vaccine, NVX-CoV2373, which is suitable for use in humans under a sufficiently informed deployment strategy, and the advanced positioning of a stockpile of critical long lead raw materials for the Matrix-M adjuvant. As such, the "prototype project" will effectively demonstrate Novavax's ability to rapidly stand up large scale manufacturing and seamlessly transition into ongoing production.

The NVX-CoV-2373 vaccine is comprised of the Matrix-M™ adjuvant, and antigen (SARS-CoV-2 spike protein). The vaccine is filled into a multi-dose vial ([***]) and is stored at refrigerated temperature (2-8^{o}C).

Successful development of the prototype will demonstrate Novavax's ability to rapidly stand up large scale manufacturing and seamlessly transition into ongoing production capability, in order to rapidly manufacture to meet surge requirements with little advance notification, and demonstrate capability to stockpile and distribute large quantities of the vaccine to respond when needed, including in order to supply use in clinical studies, under an Emergency Use Authorization (EUA), or pursuant to other clearance from the U.S. Food and Drug Administration (FDA).

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Successful completion of the prototype will require three coordinated and integrated lines of effort:

a) Large scale manufacturing, compliant with 21 CFR Parts 210 and 211, and the Drug Supply Chain Security Act (DSCA), to the extent applicable at the time of manufacturing by statute and FDA interpretive guidance thereof.

b) Parallel nonclinical and clinical studies required to determine if the vaccine is safe and effective.

c) Compliance with all applicable U.S. regulatory requirements.

It is important to note that while results of nonclinical and clinical studies are critical to develop use case scenarios and, in turn, inform the USG's deployment strategy as it relates to product manufactured under this agreement, successful development of the prototype is dependent only on the validity of data from these studies. The degree to which the data are "positive" or "negative" is not a factor in demonstration of the prototype.

1.3 Follow-on Activity

This prototype project includes unpriced options for follow-on production/procurement. During the performance of the prototype, the USG and Novavax will negotiate the scope and price of production/procurement. If the prototype project is successful, the USG may then enter into follow-on production/procurement by executing these options through a separate stand-alone production/procurement agreement, to be negotiated in terms of scope and price as described in the following paragraph.

In accordance with 10.U.S.C. 2371b(f), and upon demonstration of the prototype, or at the accomplishment of particularly favorable or unexpected results that would justify transitioning to production/procurement, EUA, or Biologics License Application (BLA) approved by the FDA, the USG and Novavax may enter into a non-competitive production/procurement follow-on agreement or contract for additional production/procurement, to partially or completely meet the USG objective of supplying a safe and effective SARS-CoV-2 vaccine to vaccinate up to 300M people in the targeted population (≈560M additional doses).

1.4 Scope

Novavax has defined a scope of activities in order to successfully develop the prototype, as defined above. The scope is based on the following assumptions regarding manufacturing and clinical dose:

- Manufacturing Assumptions and Clinical Dose
  - The NVX-CoV-2373 vaccine is comprised of the Matrix-M™ adjuvant, and antigen (SARS-CoV-2 spike protein).
  - A dose range of 5-25 ✪g of antigen is under clinical study. The anticipated dose based on

clinical data obtained to date is [***]µg of antigen with [***]µg of Matrix-M adjuvant.

- For planning purposes, the [***] ([***]µg antigen/dose) has been used and the calculations in this scope of work have been based on this dose.
- The antigen production is the rate-limiting step in vaccine production. The Matrix-M adjuvant will be available prior to antigen production. Dose production has been calculated based on the availability of

antigen. Novavax is planning on a batch-by-batch rapid fill/finish once antigen is manufactured and available.

- The estimated production schedule based on the [***]µg antigen/dose (base case) and [***] µg antigen /dose (anticipated case) is in the table below:

	Estimated Schedule of Cumulative Doses Manufactured by Month				
Dosage	**Oct 2020**	**Nov 2020**	**Dec 2020**	**Jan 2021**	**Feb 2021**
[***] µg/dose (base case)	[***]	[***]	[***]	[***]	[***]**
[***] µg/dose (anticipated case)	[***]	[***]	100,000,000*		

*Actual cumulative projected production at [***] µg/dose is [***] in December 2020. Some doses may be in progress at the end of December 2020.
**Actual cumulative projected production at [***] µg/dose is [***] in February 2021.

The scope includes the following activities:

- o Manufacturing
  - Manufacturing of 100M doses (at [***]µg/dose,[***]) of NVX-CoV-2373 vaccine in 2020 for distribution to the Government upon EUA under section 564 of the Food, Drug, and Cosmetic (FD&C) Act or a biologics licensure granted under Section 351(a) of the Public Health Service Act by the U.S. FDA.
  - Establishment of large-scale current Good Manufacturing Practice (cGMP) manufacturing capacity compliant with 21 CFR Parts 210 and 211, and the DSCA to the extent applicable at the time of manufacturing by statute and FDA interpretive guidance thereof.
  - Comparability among clinical vaccine lots and commercial lots using a comparability protocol linked to the product associated with the Phase 1 clinical study. For adjuvant components, the same raw material lot(s) will be used for the current and new Contract Manufacturing Organization (CMO) processes for the comparability protocol, and the same test lab will be used to ensure only process differences are being evaluated.
  - Validation of manufacturing processes will be performed to cGMP standards.

- o Clinical
  - Phase 3 pivotal clinical trial harmonized with USG clinical strategies.
  - A Phase 3 clinical trial in pediatric populations (<18 years).
  - Phase 2 studies in at-risk subpopulations (co-morbidities, [***], immunocompromised), as well as studies to support manufacturing site comparability.

- o Non-clinical
  -

Studies to support EUA and regulatory approval (BLA).

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- Regulatory
  - EUA submission when data supports it, while maintaining progress toward eventual BLA submission.
  - BLA submission when appropriate.
  - Regulatory support activities (Investigational New Drug (IND) submissions) for manufacturing, clinical, non-clinical studies.
  - Meetings as-needed with regulators.

- Project Management
  - Mandatory reporting requirements, as described in the Base Agreement.
  - Submission of Monthly Progress Reports. Format will be agreed on by the contractor and Agreements Officer's Representative (AOR), and will include both technical and financial status and expenditure forecast.
  - Facilitation of biweekly teleconferences with Novavax and USG Subject Matter Experts.
  - Final prototype project report and applicable patents report(s).
  - Work Breakdown Structure (WBS) and Integrated Master Schedule (IMS).
  - All Regulatory correspondence relevant to the scope of work proposed, including communications with the FDA, and all submissions.

1.4.1 Novavax Project Plan

This is Novavax's plan as of the date of the submission. Novavax desires to move quickly to large scale development as rapidly as possible, in order to meet the objectives of this proposal. As the COVID-19 pandemic is an evolving situation, Novavax may need to adapt its plan in response to FDA guidance, opportunities for manufacturing efficiencies, and clinical trial data.

1.5 Resolution of Conflicting Language

If there is a conflict between the Project Agreement (of which this Statement of Work is part) and the Base Agreement (Medical CBRN Consortium (MCDC) Base Agreement No.: 2020-530), the Project Agreement language will supersede and control the relationship of the parties.

2.0 APPLICABLE REFERENCES

N/A

3.0 REQUIREMENTS

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3.1 Major Task: cGMP Manufacturing of NVX-CoV-2373 compliant with 21 CFR 210 and 211

3.1.1 Subtask: Raw Materials – Obtain Critical Starting Materials for Adjuvant Manufacturing

Sufficient Saponin to manufacture up to 100M vaccine doses will be purchased (Desert King, headquartered in San Diego, CA, facilities in Chile). Long-lead, critical, and limited-supply materials ([***]) will be purchased for the additional 560M vaccine doses to meet the contact requirement, in order to ensure capability to rapidly manufacture to meet surge requirements with little advance notification and demonstrate capability to stockpile and distribute large quantities of the vaccine to respond when needed.

3.1.2 Subtask: Raw Materials – Obtain Critical Starting Materials for Antigen and Fill/Finish Manufacturing

Sufficient materials (vials, stoppers, other consumables) to manufacture up to 100M vaccine doses will be purchased (sources TBD).

3.1.3 Subtask: Raw Materials – [***] Intermediates to Produce Matrix-M Adjuvant Matrix-M Adjuvant a

[***] to supply large-scale manufacturing of vaccine doses will be manufactured at [***]) and PolyPeptide (Torrance, CA & Malmö, Sweden). Technology transfer and start-up of the PolyPeptide facility in Torrance, CA will be completed. Long lead, critical, and limited supply materials will be purchased in order to achieve the goal of large-scale production.

3.1.4 Subtask: Matrix-M Adjuvant Manufacturing to Supply 100M Vaccine Doses

Matrix-M Adjuvant bulk components will be manufactured at ACG Biologics (Seattle, WA) to supply 100M vaccine doses. Technology transfer and start-up of the AGC Bio facility in Seattle will be completed. An analytical comparability manufacturing study and validation studies will be performed as part of the tech transfer to each manufacturing site.

3.1.5 Subtask: Antigen Manufacturing to Supply 100M Vaccine Doses

Antigen will be manufactured at Fuji (2 sites – College Station, TX and Research Triangle Park, NC) to supply 100M vaccine doses. Technology transfer and scale-up activities will be completed. An analytical comparability manufacturing study and validation studies will be performed as part of the tech transfer to each manufacturing site.

3.1.6 Subtask: Fill/Finish of 100M Vaccine Doses

100M doses of finished vaccine in [***] vials will be manufactured at Baxter (Bloomington, IN, USA). This will include secondary packaging. Technology transfer and scale-up activities will be completed. An analytical comparability manufacturing study and validation studies will be performed as part of the tech transfer to each manufacturing site.

3.1.7 Subtask: Shipping and Storage

Novavax assumes that it will maintain a Vendor Managed Inventory (VMI) system for a period of 12 months, with shipments to 10 geographic zones in the USA. Novavax will perform activities to

establish compliance with DSCA to the extent applicable at the time of manufacturing, by statute and FDA interpretive guidance thereof.

3.2 Major Task: Clinical Studies

Novavax will perform these clinical trials and deliver the results in an interim Clinical Study Report (CSR) at the completion of enrollment, and the final CSR when available. These trials will be conducted using a Clinical Research Organization (CRO) that is to be determined.

3.2.1 Subtask: Phase 3 Global Efficacy Study, Adults ≥ 18 and < 75 years

Study: Phase 3 – Global Efficacy Study (to be harmonized with other USG studies), 2019nCoV-301.

Population: Adults ≥ 18 years, inclusive of subjects with more severe co-morbid conditions.

Locations: North America, Europe; may include Africa, Asia, Oceania, South America.

Primary Objectives: Clinical efficacy, safety, immunogenicity.

Design: Randomized, observer-blinded, placebo-controlled.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + Matrix[***] – dose determined by Phase 2 dose confirmation study, Placebo; [***].

Enrollment: TOTAL N: ~30,000 (adjusted for expected endpoint incidence). [***]

3.2.2 Subtask: Phase 2 Efficacy Expansion (US), Adults ≥ 18 and < 75 years

Study: Phase 2 - Part 3 efficacy expansion (US), 2019nCoV-204.

Population: Adults ≥ 18 and < 75 years.

Locations: USA.

Primary Objectives: Clinical efficacy, safety, immunogenicity.

Design: Randomized, observer-blinded, placebo-controlled.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + Matrix-[***]; not greater than [***], [***] to allow for rapid initiation. Placebo. ~0.5 mL dose IM injection, up to 2 doses at Day 0 and Day 21.

Enrollment: TOTAL: N [***]. Adjusted for expected event occurrence. Event driven analysis. Initiation of study gated on completion of Phase 1 study, dose-selection and regulatory approval.

3.2.3 Subtask: Phase 2 Study in Immunocompromised Persons (HIV-positive adult subjects) (Africa)

Study: Phase 2 study in immunocompromised persons (HIV-positive adult subjects) (Africa).

Population: Adults ≥ 18 and < 65 years.

Locations: Republic of South Africa (RSA)

Primary Objectives: Safety, immunogenicity (serum and cellular).

Design: Randomized, observer-blinded, placebo-controlled.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + Matrix-M1; Placebo, 0.5 mL dose IM injection, up to 2 doses at Day 0 and Day 21.

Enrollment: Total N = 2,640 – 2,880 (with n=240 - 480 HIV+); 1:1 Vaccine to placebo. Initiation gated on completion of Phase 1 study, dose selection, and regulatory approval.

3.2.4 Subtask: [***]

Study: [***]

Population: [***]

**Locations: [*****]

**Primary Objectives: [*****]

Design: Randomized, observer-blinded, placebo-controlled.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + Matrix-[***].

Enrollment: [***] Initiation gated on benefit:risk assessment (derived from Task 2.3.1 and/or 2.3.2 and/or other Phase 2 studies) and regulatory approval to conduct studies in this vulnerable population.

3.2.5 Subtask: Phase 2 Manufacturing Site Lot Consistency/Comparability Study (US or other)

Study: Phase 2 manufacturing site lot consistency/comparability study (US or other), 2019nCoV-201.

Population: Adults ≥ 18 to < 50 years.

Locations: USA.

Primary Objectives: Safety, immunogenicity.

Design: Randomized, observer-blinded, placebo-controlled.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + Matrix-[***].

Enrollment: ~600 per cohort, each cohort having 1:1 randomization with Emergent (antigen)/Novavax AB (adjuvant) manufacturing site and new manufacturing sites. Study size may be adjusted to allow non-inferiority testing.

3.2.6 Subtask: Phase 2, Maternal Immunization

Study: Phase 2, maternal immunization, (trial ID TBD).

Population: Adults ≥ 18 to < 40 years.

Locations: Global.

Primary Objectives: Safety, immunogenicity.

Design: Randomized, observer-blinded, placebo-controlled.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + Matrix-M1; Placebo, 0.5 mL dose IM injection, up to 2 doses at Day 0 and Day 22.

Enrollment: Total = 800 mothers + baby. Initiation gated on benefit:risk assessment (derived from Task 2.3.1 and/or 2.3.2 and/or other Phase 2 studies) and regulatory approval to conduct studies in this vulnerable population.

3.2.7 Subtask: Pharmacovigilance; Establishment of Registration Safety Database

A registration safety database will be established to comply with FDA requirements for product safety and licensure.

3.2.8 Subtask: [***]

Study: [***].

Population: [***].

Location: [***].

Primary Objective: [***].

Design: Randomized, observer-blinded, placebo (or active vaccine) control.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + Matrix[***].

Enrollment: TOTAL: N ~12,500 (based on agreed VE, power, and LBCI). [***] Adjusted for expected event occurrence if robust demonstration of clinical efficacy is required by the FDA. Event driven analysis for study termination.

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3.3 Major Task: Non-Clinical Studies

Novavax will perform these non-clinical studies and deliver the results in a study report at completion.

3.3.1 Mouse Study, Immunogenicity

Study 702-100. Immunogenicity [***] in mice for vaccine efficacy profile to comply with FDA guidelines.

3.3.2 Rhesus Study, Immunogenicity

Study 702-099. Immunogenicity/challenge [***] in rhesus monkeys for vaccine efficacy profile to comply with FDA guidelines.

3.3.3 Hamster Study, Immunogenicity

Study 702-102. Immunogenicity/challenge study in hamster [***] for vaccine efficacy profile to comply with FDA guidelines.

3.3.4 Mouse Study, T-Cell Immunogenicity

Study 702-103. T-cell immunogenicity/challenge study in mice [***] for vaccine efficacy profile to comply with FDA guidelines.

3.3.5 Hamster Study, T-Cell Immunogenicity

Study 702-105. Immunogenicity/challenge study in hamster [***] for vaccine efficacy profile to comply with FDA guidelines.

3.3.6 Mouse Study, T-Cell Immunogenicity

Study 702-104. Immunogenicity/challenge study in hamster [***] for vaccine efficacy profile to comply with FDA guidelines.

3.3.7 Non-Clinical Studies: Collaboration with Univ. of Maryland School of Medicine

Three studies to study enhancement/inhibition and neutralization, and virus challenge of vaccinated mice:

1. Validation of Spike nanoparticles in cell inhibition studies: In vitro inhibition studies on cell line permissive to r2019-nCoV, readout TBD.
2. Neutralization studies with virus against bleeds from mice, In vitro microneutralization studies on cell line permissive to r2019-nCoV, TCID50 or fluorescence readout (TBD).
3. Virus challenge of vaccinated mice (mice vaccinated outside and shipped to UM for challenge), Challenge of vaccinated mice (shipped in for infection from Novavax), Lung pathology, Titer, viral Ribonucleic Acid (RNA) quantitation, pathology scoring and reports.

3.3.8 Structural Study of COVID-19 Spike Protein and its Complex with Host Receptor (cooperation with Baylor College of Medicine)

Study to determine the structures of recombinant COVID-19. Spike protein in nanoparticles used in Novavax's human vaccine and in complex with its host receptor ACE2. Will obtain a high-resolution cryoEM structure of full-length COVID-19 Spike protein and a high-resolution cryoEM structure of full-length COVID-19 Spike protein in complex with human receptor ACE2.

3.3.9 Neutralizing Assay Histopathology for On-going [***]

Histopathology readings for current neutralization studies in [***]. This will support the safety profile of the vaccine for FDA approval.

3.3.10 Mouse Study, Immunogenicity [***] Studies

Individual immunogenicity studies [***] in mice for vaccine efficacy profile in different sub-populations to comply with FDA guidelines.

3.4 Major Task: Regulatory Affairs

Novavax will conduct the regulatory activities below, including BLA prep and submission, and provide the meeting minutes and applications to the USG.

3.4.1 Subtask: EUA Submission and Supporting Meetings and Regulatory Filings

An EUA will be submitted to the FDA upon obtaining sufficient clinical data. EUA, FDA meetings to support EUA, submission planning support for the Chemistry, Manufacturing, and Controls (CMC) team, EUA strategy and meeting support, and submission preparation support activities, will all be completed.

3.4.2 Subtask: IND Submission Updates and FDA Meetings

This task will include submissions to the IND and possible FDA meetings that will be required prior to the BLA submission.

3.4.3 Subtask: BLA Submission

A BLA will be submitted to the FDA upon obtaining sufficient clinical data, FDA meetings to support BLA, submission planning support for the CMC team, BLA strategy and meeting support, and submission preparation support activities, will all be completed.

3.5 Major Task: Project Management and Reporting

3.5.1 Subtask: Kick-Off Meeting and Initial Baseline Review of IMS

Novavax shall conduct a Kick-Off Meeting and an initial review with the USG of the IMS, upon initiation of the program.

3.5.2 Subtask: Biweekly Meetings with OWS

Novavax shall submit the agenda in advance. Any technical updates shall be provided in advance for the Government team to review. Minutes shall be submitted after the biweekly meeting to the USG.

3.5.3 Subtask: Written Quarterly Reports

Novavax shall submit quarterly reports to the USG.

3.5.4 Subtask: Written Annual Reports

Novavax shall submit the annual reports to the USG.

3.5.5 Subtask: Written Final Report

Novavax shall submit the final report to the USG.

3.6 Optional Task: Follow-On Production

Follow-on production of finished doses of vaccine up to 560M doses.

4.0 DELIVERABLES

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Del. #	Deliverable Description	Due Date	Milestone Reference	SOW Reference	Government Role	Data Type/Data Rights
	Manufacturing					
4.1	[***]	[***]	5.1	3.1.1	Reviewer	[***]
4.2	[***]	[***]	5.2	3.1.2	Reviewer	[***]
4.3	[***]	[***]	5.3	3.1.3	Reviewer	[***]
4.4	[***]	[***]	5.4	3.1.4	Reviewer	[***]
4.5	[***]	[***]	5.5	3.1.5	Reviewer	[***]
4.6	[***]	[***]	5.6	3.1.6	Reviewer	[***]
4.7	[***]	[***]	5.7	3.1.7	Reviewer	[***]
	Clinical					
4.8	[***]	[***]	5.8	3.2.1	Reviewer	[***]
4.9	[***]	[***]	5.9	3.2.2	Reviewer	[***]
4.10	[***]	[***]	5.10	3.2.3	Reviewer	[***]
4.11	[***]	[***]	5.11	3.2.4	Reviewer	[***]
4.12	[***]	[***]	5.12	3.2.5	Reviewer	[***]
4.13	[***]	[***]	5.13	3.2.6	Reviewer	[***]
4.14	[***]	[***]	5.14	3.2.7	Reviewer	[***]
4.15	[***]	[***]	5.15	3.2.8	Reviewer	[***]
	Non- Clinical					
4.16	[***]	[***]	5.16	3.3.1	Reviewer	[***]
4.17	[***]	[***]	5.17	3.3.2	Reviewer	[***]
4.18	[***]	[***]	5.18	3.3.3	Reviewer	[***]
4.19	[***]	[***]	5.19	3.3.4	Reviewer	[***]
4.20	[***]	[***]	5.20	3.3.5	Reviewer	[***]
4.21	[***]	[***]	5.21	3.3.6	Reviewer	[***]
4.22	[***]	[***]	5.22	3.3.7	Reviewer	[***]
4.23	[***]	[***]	5.23	3.3.8	Reviewer	[***]
4.24	[***]	[***]	5.24	3.3.9	Reviewer	[***]
4.25	[***]	[***]	5.25	3.3.10	Reviewer	[***]
	Regulatory Affairs					
4.26	[***]	[***]	5.26	3.4.1	Reviewer	[***]
4.27	[***]	[***]	5.27	3.4.2	Reviewer	[***]
4.28	[***]	[***]	5.28	3.4.3	Reviewer	[***]
	Project Management					
4.29	[***]	[***]	5.29	3.5.1	Reviewer	[***]
4.30	[***]	[***]	5.30	3.5.2	Reviewer	[***]
4.31	[***]	[***]	5.31	3.5.3	Reviewer	[***]
4.32	[***]	[***]	5.32	3.5.4	Reviewer	[***]
4.33	[***]	[***]	5.33	3.5.4	Reviewer	[***]
4.34	[***]	[***]	5.34	3.5.5	Reviewer	[***]

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Del. #	Deliverable Description	Due Date	Milestone Reference	SOW Reference	Government Role	Data Type/Data Rights
TBD	[***]	[***]	Option 1	3.6	Reviewer	[***]

5.0 MILESTONE PAYMENT SCHEDULE

Milestone #	Milestone Description (Deliverable Reference)	Due Date	Total Program Funds
	Manufacturing		
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
	Clinical		
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
	Non- Clinical		
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
	Regulatory Affairs		[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
	Project Management		[***]
[***]	[***]	[***]	[***]

[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

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Milestone #	Milestone Description (Deliverable Reference)	Due Date	Total Program Funds
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
		Total (Cost Plus Fixed Fee)	**$1,600,434,522**
		Period of Performance (July 6, 2020 – December 31, 2021)	**18 Months (Base)**
		Option 1: Follow-On Production	Cost: [***]

Simplified Table: Estimated Cost by Project Areas

Area	Cost
Manufacturing (100M doses)	$418,151,118
Non-Clinical	$5,092,957
Clinical	$1,158,524,498
Regulatory	$10,362,788
Project Management	$8,303,163
Total Project Cost	**$1,600,434,523**

Simplified Table: Selected Estimated Costs for Key Deliverables*

Area	Milestone/Deliverable	Start	Finish	Cost
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	

* For key deliverables only; does not encompass total project costs.
** Time to obtaining vaccine efficacy data.

6.0 SHIPPING PROVISIONS

The shipment of physical deliverables shall be coordinated with the AOR. Data deliverables shall be provided in accordance with the agreement, and in coordination with the AOR.

7.0 INTELLECTUAL PROPERTY, DATA RIGHTS, AND COPYRIGHTS

7.1 BACKGROUND IP

(a) Ownership. Prior to June 8, 2020, Novavax had funded the development of NVX-CoV2373, and other antecedent vaccine programs relevant to Novavax' proprietary position in the development of NVX-CoV2373, as well as its sf9/baculovirus manufacturing platform, (all

"Background IP") through private funding or in collaboration with a funding partner other than the U.S. Government. Such private and non-governmental funding has continued since June 8, 2020 and is expected to continue during the performance of the Project Agreement. A list of all patents and patent applications included in the Background IP is provided below as Enclosure 4. Background IP also consists of (a) manufacturing know-how, including, without limitation, the NVAX-Cov2373 manufacturing process

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definitions, process development/characterization reports, laboratory scale process procedures, manufacturing records, analytical test methods, product quality target ranges/specifications, quality target product profile, critical quality attributes (collectively "Background Know-How"), (b) data from pre-clinical and clinical research studies, analytical and process development research, and data related to, or generated using, the Background Know-How (collectively, "Background Data"), and (c) proprietary manufacturing materials, including, without limitation, sf9 cell banks (master and working), baculovirus virus stock (master and working), product standards, reference standards, and critical reagents ("Background Materials"). On June 8, 2020, Novavax and the U.S. Department of Defense entered into a Letter Contract for specified U.S.-based clinical and manufacturing development of NVX-CoV2373 which acknowledged Background IP and made no explicit U.S. Government claims to Background IP or subsequent data arising therefrom. The U.S. Government hereby acknowledges such Background IP in full and further acknowledges that it has no ownership rights to Novavax Background IP under this Project Agreement.

(b) Background IP Limited License to Government. Subject to the terms of the Project Agreement, Novavax grants the U.S. Government a nonexclusive, worldwide, nontransferable, non-sublicenseable license to use the Background IP to the limited extent necessary for the U.S. Government to review and use the Deliverables tendered by Novavax under this Agreement identified in Section 4.0 above, and for no other purpose; provided that the U.S. Government agrees that it may not disclose the Background IP to third parties, or allow third parties to have access to, use, practice or have practiced the Background IP, without Novavax's prior written consent. To the extent that a Deliverable with Foreground IP incorporates or uses Background IP, the Deliverable shall be deemed and considered to comprise Background IP and shall be used by the U.S. Government in accordance with this Background IP Limited License.

(c) Background IP License to Novavax. Subject to the terms of the Project Agreement, the U.S. Government grants to Novavax a nonexclusive, worldwide, nontransferable, irrevocable, paid-up license to any intellectual property (including patents and patent applications) to which the U.S. Government has rights thereto, provided that such license is limited to such intellectual property rights necessary to perform Novavax's obligations under the Project Agreement.

7.2 FOREGROUND IP

(a) Ownership. Notwithstanding anything in the Base Agreement to the contrary, Novavax owns all rights, title and interest in and to any development, modification, discovery, invention or improvement, whether or not patentable, conceived, made, reduced to practice, or created in connection with activities funded under the Project Agreement, including, without limitation, all data and inventions, and intellectual property rights in any of the foregoing ("Foreground IP").

(b) Foreground IP Special License. Subject to the terms of the Project Agreement, Novavax grants the U.S. Government a nonexclusive, worldwide, nontransferable, irrevocable, paid-up license to practice or have practiced the Foreground IP for or on behalf of the U.S. Government ("Foreground IP Special License").

8.0 DATA RIGHTS

Article XI, §11.03 of the Base Agreement is hereby amended, consistent with the "Specifically Negotiated License Rights" capability at Article XI, §§11.01(12) and 11.03(4), as follows:

8.1 Data Ownership.

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Novavax owns all rights, title and interest to all Data (as defined in Article XI, Section 11.01(7) of the Base Agreement) generated as a result of the work performed under this Project Agreement, including Subject Data.

8.2 Rights to Data.

(a) Subject Data. Subject to the terms of the Project Agreement, Novavax grants to the U.S. Government a Government purpose rights license to Subject Data that will convert to an unlimited rights license (as the term is defined in Article XI, Section 11.01(14) of the Base Agreement)[1] after three (3) years from the date of delivery. As used herein, "Subject Data" shall mean Technical Data under Article XI, §11.01(13) of the Base Agreement Deliverables that are considered Subject Data are identified in the Deliverable Table set forth in Section 4.0 above.

(b) Transfer of Data. Each party, upon written request to the other party, shall have the right to review and to request delivery of Subject Data, and delivery of such Data shall be made to the requesting party within two weeks of the request, except to the extent that such Data are subject to a claim of confidentiality or privilege by a third party.

(c) Background IP Limited License. To the extent that Subject Data incorporates or uses Background IP, the data shall be deemed and considered to comprise Background IP and shall be used by the U.S. Government in accordance with the Background IP Limited License set forth in Section 7.3 above.

8.3 Background Technical Data Rights Assertions.

Novavax asserts background technical data rights as follows:

The Background Data, as defined in Section 7.1 above, was developed through private funding or in collaboration with a funding partner other than the U.S. Government. Such funding is expected to continue; accordingly, Novavax asserts Background Data as Category A Data pursuant to section 11.02(1) of the Base Agreement and the U.S. Government shall have no rights therein.

9.0 REGULATORY RIGHTS

This agreement includes research with an investigational 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. It is expected that this agreement will result in the FDA authorization, clearance and commercialization of NVX-CoV-2373 as a Vaccine for SARS-CoV-2 Coronavirus (the "Technology"). Novavax is the Sponsor of the Regulatory Application (an investigational new drug application (IND), investigational device exemption (IDE), emergency use authorization (EUA), 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 the FDA) that controls research under this contract. As the Sponsor of the Regulatory Application to the FDA (as the terms "sponsor" 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), Novavax has certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application. This clause protects the return on research and development investment made by the U.S. Government in the event of certain regulatory product development failures related to the Technology.

[1] As used herein, “Government Use” as used “Purpose Rights“ has the meaning set forth in this Section 4.0 means Government purpose rights as defined in the Base Agreement, Article XI, Section 11.01(9).) of the Base Agreement, as modified by Section 8.2(b) below.

Novavax agrees to the following:

a. Communications. Novavax will provide the U.S. Government with all communications and summaries thereof, both formal and informal, to or from FDA regarding the Technology and ensure that the U.S. Government representatives are invited to participate in any formal or informal Sponsor meetings with FDA;

b. Rights of Reference. The U.S. Government is hereby granted a right of reference as that term is defined in 21 C.F.R. § 314.3(b) (or any successor rule or analogous applicable law recognized outside of the U.S.) to any Regulatory Application submitted in support of the statement of work for the Project Agreement. When it desires to exercise this right, the U.S. Government agrees to notify Novavax in writing describing the request along with sufficient details for Novavax to generate a letter of cross-reference for the U.S. Government to file with the appropriate FDA office. The U.S. Government agrees that such letters of cross-reference may contain reporting requirements to enable Novavax to comply with its own pharmacovigilance reporting obligations to the FDA and other regulatory agencies. Nothing in this paragraph reduces the U.S. Government's data rights as articulated in other provisions of the Project Agreement.

c. DoD Medical Product Priority. PL-115-92 allows the DoD to request, and FDA to provide, assistance to expedite development and the FDA's review of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel. Novavax recognizes that only the DoD can utilize PL 115-92. As such, Novavax will work proactively with the DoD to leverage this this law to its maximal potential under this Project Agreement. Novavax shall submit a mutually agreed upon Public Law 115-92 Sponsor Authorization Letter to the U.S. Government within 30 days of award.

10.0 ENSURING SUFFICIENT SUPPLY OF THE PRODUCT

a. In recognition of the Government's significant funding for the development and manufacturing of the product in this Project Agreement and the Government's need to provide sufficient quantities of a safe and effective COVID-19 vaccine to protect the United States population, the Government shall have the remedy described in this section to ensure sufficient supply of the product to meet the needs of the public health or national security. This remedy is not available to the Government unless and until both of the following conditions are met:

i. Novavax gives written notice, required to be submitted to the Government no later than 15 business days, of:

   a. any formal management decision to terminate manufacturing of the NVX-CoV-2373 vaccine prior to delivery of 100 million doses to USG;

   b. any formal management decision to discontinue sale of the NVX-CoV-2373 vaccine to the Government prior to delivery of 100 million doses to USG; or

   c. any filing that anticipates Federal bankruptcy protection; and

ii. Novavax has submitted an Emergency Use Authorization under §564 of the FD&C Act or a biologics license application provisions of §351(a) of the Public Health Service Act (PHSA).

b. If both conditions listed in section (a) occur, Novavax, upon the request of the Government, shall provide the following items necessary for the Government to pursue manufacturing of the NVX-CoV-2373 vaccine with a third party for exclusive sale to the U.S. Government:

i. a writing evidencing a non-exclusive, nontransferable, irrevocable (except for cause), royalty-free paid-up license to practice or have practiced for or on behalf of the U.S. Government any Background IP as defined in clause 7.1 necessary to manufacture or have manufactured the NVX-CoV2373 vaccine;

ii. necessary FDA regulatory filings or authorizations owned or controlled by Novavax related to NVX-Cov2373 and any confirmatory instrument pertaining thereto; and

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

c. This Article shall be incorporated into any contract for follow-on activities for the Government to acquire and use additional doses of the product. Per section 1.3, the estimated quantity for follow-on production/procurement is approximately 560 million doses.

d. This Article will survive the acquisition or merger of the Contractor by or with a third party. This Article will survive the expiration of this agreement.

11. SECURITY

The security classification level for this effort is UNCLASSIFIED.

12.0 MISCELLANEOUS REQUIREMENTS (SAFETY, ENVIRONMENTAL, ETC.)

N/A

13.0 GOVERNMENT FURNISHED PROPERTY/MATERIAL/INFORMATION

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

AOR

NAME: [***]
EMAIL: [***]
PHONE: [***]
AGENCY NAME/DIVISION/SECTION: Joint Program Executive Office, Joint Program Lead-Enabling Biotechnologies

Alternate AOR

NAME: TBD
MAILING ADDRESS:

EMAIL:
PHONE:
AGENCY NAME/DIVISION/SECTION: HHS/ASPR/BARDA

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ENCLOSURE 3: PAYMENT REQUEST INFORMATION

Novavax, Inc. is requesting a payment upon incurring costs, for a total of $[***] to support the development of NVX-CoV2373 as a vaccine for SARS-CoV-2 Coronavirus. The costs, as outlined below, are incorporated into estimates from subcontractors under milestones associated with manufacture. Novavax will work with subcontractors to ensure the appropriate accounting for pre-award costs during subcontract finalization and subsequent billing.

Projected Expenditures

Cost Element	Task/Purpose	Amount
Materials		
Antigen	[***]	[***]
Adjuvant	[***]	[***]
Adjuvant	[***]	[***]
Reservations Fees		
AGC Bio Seattle	[***]	[***]
PolyPeptide	[***]	[***]
Fuji RTP	[***]	[***]
Fuji Texas	[***]	[***]
Acceleration Fee		
Fuji	[***]	[***]
Subtotal		[***]
Indirect + Fee Burden		[***]
Total Requested Amount		[***]

I. Financial Institution Information

Novavax, Inc.
21 Firstfield Road
Gaithersburg, MD 20878

Name of Bank: [***]
Address: [***]
ABA #: [***]

II. Justification for Requesting the Payment

- **Materials Costs: - $[***] Direct Costs**

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Procurement and qualification of critical long lead raw materials needed to produce 100M doses of NVX-CoV-2373 in 2020 and to ensure availability of 100M additional doses of NVX-CoV-2373 in 2021. This also includes materials for the purchase of a stockpile of certain critical long lead raw materials for the Matrix-M Adjuvant, necessary to rapidly initiate large-scale manufacturing without a delay. This will ensure timely availability of the vaccine candidate to the US population when needed, a primary mission of HHS in support of OWS.

- **Reservation and Acceleration Fees: - [***] Direct Costs**

  To quickly address the urgent need presented by the COVID-19 pandemic, Novavax will rely on the reservation of dedicated capacity from manufacturing service provides to be able to produce NVX-CoV-2373. This will ensure timely availability of the vaccine candidate to the US population when needed, a primary mission of HHS in support of OWS.

ENCLOSURE 4: PATENT LISTING

[***]

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